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

## *Abstract*

Just a few years following the coming into force of the World Trade Organization (WTO) and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreements, the risks they posed to human health and food security became self-evident. This problem has been acknowledged by the WTO in the Doha Declaration, by other United Nations Organs and commentators. Joined at the hip the WTO and TRIPS system, as implemented, seems to have aggravated the severe and debilitating disease burden and food insecurity of many of its member developing countries that existed prior to TRIPS. Although the WTO and its Council on 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 to the protection of foreign intellectual property rights. The risks to health and food security appear to have their nesting conditions and roots deep in some structural flaws of the WTO and TRIPS as a system. The marriage of two complex international systems demanded the prior investigation of two critical questions. First, whether under international law there is a fundamental right of states to trade. Second, whether an idea however formed

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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 advancement of human society across regions, and its link to human health and food security, we argue that the WTO and TRIPS should be delinked and TRIPS reconstructed as a separate system. A reconstruction of TRIPS would give the global community the opportunity to adopt a more balanced system with greater sensitivity to the evident cultural diversity, and the needs of all countries in achieving economic development, health and food security taking into account the history of ideas in the evolution of humanity as a species.

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## I. INTRODUCTION

The global community of sovereign states achieved what appeared to be a milestone in the organization of a world trading system in 1994.<sup>1</sup> This was the 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.<sup>2</sup> It was the realization of long standing aspirations for an idealized overarching international trading system inspired by the inhumanity to humanity manifested in two successive world wars in the last century. Even before the Second World came to an end, diplomats, economists, policy makers and others in the United States devoted serious attention to constructing a new post war international order to confront the root causes of war.<sup>3</sup> Widespread protectionism and beggar thy neighbor trade policies were generally believed to be significant contributing factors to the Second World War.<sup>4</sup> The solution, the policy makers thought, lay in the establishment of a comprehensive and coherent international free and non-discriminatory trade system which found expression in the establishment of the International Trade Organization (ITO), sometimes referred as the Havana Charter.<sup>5</sup> Free and non-discriminatory trade found a steady and strong champion in the Secretary of State of the U.S. Cordell Hull who believed that the peace and security of the world hinged on the success of that system.<sup>6</sup> Unfortunately, the ITO suffered a frustrating post-

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<sup>1</sup> **MARRAKESH DECLARATION OF 15 APRIL 1994**, Ministers representing 124 Governments and the European Communities participating in the Uruguay Round of Multilateral Trade Negotiations, on the occasion of the final session of the Trade Negotiations Committee at Ministerial level held at Marrakesh, Morocco from 12 to 15 April 1994, adopted the establishment of the World Trade Organization (hereinafter, MARRAKESH DECLARATION, 1994)

<sup>2</sup> Document coming into force

<sup>3</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* (Holly Sklar, ed. 1980) at 135, 136-139 ( hereinafter, Shoup & Minter, *Shaping a New World Order*) (discussing how "The War and Peace Studies Project" initiated by a few key members of the Council on Foreign Council Relations in the U.S. constructed the framework for the post war new order including the U.N. and all its institutions); for a history of the ITO and the Havana Charter, see, KENNETH W. DAM, *THE GATT: LAW AND INTERNATIONAL ECONOMIC ORGANIZATION* (1970)(hereinafter DAM, *THE GATT*) at 12 (explaining the role of the Secretary of State Hull in framing the U.S. postwar trade and economic policies).

<sup>4</sup> JOHN H. JACKSON, *LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS* (West Publishing, Co. 1977, at 396-401)(hereinafter, JACKSON, *INTERNATIONAL ECONOMIC RELATIONS*)( discussing the history of the General Agreement on Tariffs and Trade (GATT) and how the concrete obligations enshrined in was to eliminate beggar thy neighbor trade policies invoke before the war); EDITH T. PENROSE, *THE ECONOMICS OF INTERNATIONAL PATENT SYSTEM*, 151,(1951)( Hereinafter, PENROSE, *INTERNATIONAL PATENT SYSTEM*)(discussing the nature of beggar they neighbor trade policies under in the patent context).

<sup>5</sup> For a discussion of the history of the International Trade Organization (ITO) sometimes referred to as the Havana Charter, see JACKSON, *INTERNATIONAL ECONOMIC RELATIONS*, *id.* at 396-399; for a history of the ITO and the Havana Charter, see, DAM, *THE GATT*, *supra* note 3, at 10-16 (discussing the goals of U.S. postwar trade policies).

<sup>6</sup> The Council on Foreign Relations with the support of Hull Secretary of State as a member of War

war defeat at the hands of U.S. Congress.<sup>7</sup> A less grandiose organization, The General Agreement on Trade and Tariffs (GATT) with a limited focus on negotiated tariff reductions, was established.<sup>8</sup>

In the WTO, the hopes for a comprehensive world trading regime were finally realized half a century later and after decades of rounds of negotiations. But the crowning achievement of the WTO might have been the broadening of its scope and its centralizing usurpation of power in matters tangentially related to trade.<sup>9</sup> It visited a power deficit not only on well established international organizations with mandates going back to the League of Nations but also on sovereign member states.<sup>10</sup> Such a concentration of power in a single United Nations (U.N.) organ is widely inconsistent with the original organizing framework for the distribution of power among the U.N. subsidiary and

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Council explored thoroughly the central role of trade as part of a general framework of larger ideals freedom, equality, prosperity and peace as the construct for a post war new order. *See*, Shoup & Minter, *Shaping a New World Order*, *supra* note 3 at 144-146; DAM, THE GATT, *supra* note 3, at 12-16 (providing the reasons for the failure of Congress to adopt the GATT were multiples, in footnote 10 quoting descriptions of the ITO as “a wretched compromise...it merely 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...*Fortune’s* concluding appraisal of the (Charter: a meaningless document with everybody’s name on it”).

<sup>7</sup> *See*, Hearings on Trade Agreements Act and the Proposed ITO Before the House Ways and Means Committee., 80<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1947); Hearings on Proposed ITO Before the Senate Committee, 80<sup>th</sup> Cong. 1<sup>st</sup> Sess., (1947); for discussion *see*, JACKSON, INTERNATIONAL ECONOMIC RELATIONS, *supra* note 4 at 397; W. Diebold, *The End of the I.T.O.*, (Essays in International Finance No. 16) Princeton University (1952).

<sup>8</sup> According Jackson, the GATT was not contemplated to be a separate organization but part of the broader concept of trade under the ITO, JACKSON, INTERNATIONAL ECONOMIC RELATIONS, *id.* at 397; The GATT was implemented through a Protocol of Provisional Application to the General Agreement on Tariff and Trade, October, 30, 1947, 61 Stat. pts 5, 5, TIAS No. 1700, n55 UNTS 308; cited, at 398; DAM, THE GATT, *supra* note 3, at 14 (stating that by 1950, the ITO was dead).

<sup>9</sup> The central focus of the GATT was trade although as an exception some measures might be taken to address intellectual property issues as distortions but within the GATT framework, Article XX(d) provided this remedy. Broadening the mandate of the GATT into areas tangentially related to trade presented a problem that had to be over by the United States pushing for the link between trade and the protection of intellectual property rights, *See*, Michael Gadbaw and Rosemary E. Gwynn, *Intellectual Property Rights in the New GATT Rounds*, in INTELLECTUAL PROPERTY RIGHTS, GLOBAL CONSENSUS, GLOBAL CONFLICT, (Michael Gadbaw and Timothy J. Richards Ed, (1988)( GLOBAL CONSENSUS, GLOBAL CONFLICT ) (hereinafter Gadbaw & Gwynn, *Intellectual Property Rights*) at 43-45(explaining that the U. S. rationalization that the distortion had to be addressed at its source).

<sup>10</sup> MARRAKESH DECLARATION, 1994 *supra* note 1; the agreement expressed concern and demanded cooperation between the WTO, the Bank for Development and Reconstruction (The World Bank) and the International Monetary Fund (IMF) although no mention was made of other organs such as United Nations Conference on Trade and Development (UNCTAD) and other organs with a trade agenda as part of their mission. However, Article 63(2) of the United Nations Charter the Economic and Social Council (ECOSOC) has the responsibility of coordination the activities of the specialized agencies for achieving the economic, social and cultural goals of the Charter. For a discussion and commentary on the United Nations Charter, *see*, LELAND M. GOODRICH, EDWARD HAMBRO and ANNE PATRICIA SIMONS, CHARTER OF THE UNITED NATIONS: COMMENTARY AND DOCUMENTS (3d and Revised Ed. 1969) (hereinafter, GOODRICH, HAMBRO & SIMONS, CHARTER OF THE UNITED NATIONS) at 419-426.

specialized organs, current liberal creed of good governance which calls for democracy and the decentralization of political power.<sup>11</sup> It is also inconsistent with the prevalent orthodoxy of market based liberalization of economic policies and the promotion of free trade and investments.<sup>12</sup> For, the mandate of the WTO was expanded beyond traditional trade areas captured in the GATT into other areas especially intellectual property rights, previous the domain of the World Intellectual Property Organization (WIPO).<sup>13</sup> This expansion of the scope and jurisdiction of the WTO has serious implications on the effective functions of the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and other organs concerned with the human condition and development mandated by Article 55 of the U.N. Charter.<sup>14</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>15</sup> The view was maintained, and

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<sup>11</sup> For a discussion of the various U.N. Specialized Agencies such as the International Labor Organization (ILO), the Food and Agriculture Organization (FAO), the World Health Organization (WHO), Economic and Social Council (ECOSOC), the United Nations Development Program (UNDP) and many others established as part of the United Nations system, see, JACKSON, INTERNATIONAL ECONOMIC RELATIONS, *supra*, note 4 at 377-383.

<sup>12</sup> The term Washington Consensus is a term attributed to John Williamson, Senior Fellow, Institute for International Economics in describing the prescription of the Washington establishment for the economic transformation of Latin America. See, John Williamson, *The Washington Consensus as Policy Prescription for Development*, (A lecture in the series "Practitioners of Development" delivered at the World Bank on January 13, 2004); (providing ten policy prescriptions based substantially on market principles, privatization, liberalization of trade and investment etc.) However, see, Moisés Naím, *Washington Consensus or Washington Confusion*, FOREIGN POLICY, SPRING 2000 87 (pointing out there is hardly any consensus in the so-called prescriptions of the Washington Consensus).

<sup>13</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 WTO. Furthermore, the Agreement Between the World Intellectual Property Organization and the World Trade Organization of December 22, 1995), Official English title. Entry into force: January 1, 1996. Source: Communication from the International Bureau of WIPO and the WTO Secretariat, Article 2 (2) gives WTO members and WTO Secretariat free access WIPO data and Article 3 (a), (b), and (c) further give the Council for TRIPS, the WTO Secretariat full access to WIPO collection of laws, and regulations. These changes leave WIPO in a subservient position. The question has been raised whether this is good. Prior to the adoption of TRIPS as part of the WTO a symposium was organized to discuss the merits of GATT or WIPO as the new way for organizing intellectual property protection. See, GATT or WIPO? NEW WAYS IN INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY, (IIC Studies in Industrial Property and Copyright Law Vol. II, Friedrich Karl Beier and Gerhard Schricker (ed. 1989) (discussing the various positions on the question from the U.S., European Union and industry perspectives).

<sup>14</sup> Inter alia, Article 55 of the U.N. Charter stated: 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; (b) solutions of international economic, social, health and related problems, and international cultural and educational cooperation....These provisions read with Article 63(2) leaves one wondering how the WTO fits into this scheme of mandates to the specialized agencies. For a commentary on Article 55, see, GOODRICH, HAMBRO & SIMONS, CHARTER OF THE UNITED NATIONS, *supra* note 10 at 371-380.

<sup>15</sup> The pro-monopoly threat created by TRIPS can best be understood from the foreword by Professor

wrongly so, that international trade is so inextricably linked to the protection of ideas in the form of intellectual property rights that the right to trade must, of necessity, be conditioned on the protection of ideas by member states.<sup>16</sup> Under the leadership of the TRIAD (U.S., EU and Japan)<sup>17</sup> and against the vociferous objections of many developing countries<sup>18</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>19</sup> Under this unprecedented new world trading regime, TRIPS imposed certain minimum levels of mandatory intellectual property protection on WTO member states.<sup>20</sup> Never before in the history of the world was such a marriage between the right to trade and the protection of something as ephemeral as the origins of an idea conceived 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 protection of ideas. Contracting states retained their unfettered

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Fritz Machlup to Edith Penrose' book on *The Economics of the International Patent System* in which he argued that Penrose views were not out of line with the Second Interim Report of the Swan Committee which declared "that it 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." PENROSE, *INTERNATIONAL PATENT SYSTEM*, *supra* note 4 at ix.

<sup>16</sup> Gadbar & Gwynn, *Intellectual Property Protection*, *supra* note 9 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>17</sup> Peter Drahos, *Negotiating Intellectual Property Rights: Between Coercion and Dialogue*, in *GLOBAL INTELLECTUAL PROPERTY RIGHTS, KNOWLEDGE, ACCESS AND DEVELOPMENT* (Peter Drahos and Ruth Mayne ed. 2002)(hereinafter, Drahos, *Negotiating Intellectual Property Rights*) at 167-168( 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 along the way).

<sup>18</sup> Drahos, *Negotiating Intellectual Property Rights id.* for a discussion of the opposition of the developing countries who reacted angrily that they had been left out of the process (at 167); prominent among the countries opposing TRIPS were, India, Brazil, Argentina, Cuba, Egypt, Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia, (at 170) and many countries did not even participate (at 167).

<sup>19</sup> The General Agreement on Tariffs and Trade Uruguay Round, AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) APRIL 15, 1994, 1994 WL 1711191(TRTY)

Drahos, *Negotiating Intellectual Property Rights*, *supra* note 17 at 170 (given the opposition from Brazil, India, Nigeria and others, questioned 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). Gadbar & Gwynn, *Intellectual Property Rights* , *supra* note 9 at 40 (explaining the approach as driven by the perception that WIPO and UNCTAD were institutions through which developing countries blocked attempts to broaden the intellectual property regime, neutralization of the developing countries seemed essential to the outcome of the negotiations or coercion); EDWARD SLAVKO YAMBRUSIC, *TRADE BASED APPROACHES TO THE PROTECTION OF INTELLECTUAL PROPERTY* (1992) at 7-25 (explaining the different perceptions of intellectual property of developing and newly industrialized countries and its role in international trade).

<sup>20</sup> While Article 28 Of TRIPS provides the usual substantive rights for patent protection Article 33 mandates a minimum duration of 20 years.

sovereignty in their fundamental policy domain particularly with respect to public health, safety and security.<sup>21</sup> Before TRIPS, over 40 countries offered no patent protection for pharmaceutical inventions.<sup>22</sup> Such sovereign authority of states has been seriously compromised by TRIPS as part of the WTO system of agreements. The serious implications of the loss of sovereignty over significant policy issues deserve some explanation. Following the collapse of the New International Economic Order (NIEO) in the 1980s, a severe global recession and the debilitating Third World debt crisis of the same decade, developing countries suffered the consequences of serious vulnerability dependence and a resulting diminished bargaining power.<sup>23</sup> The TRIAD seized the moment and exploited the bargaining power asymmetry thus presented. Other international economic events of that era further weakened the leverage of developing

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<sup>21</sup> The limitations imposed on member states by the Paris Union were on 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, March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, in INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY (2d ed, Marshall A. Leaffer, ed 1997) See, FROM GATT TO TRIPS—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, (IIC Studies, Studies in Industrial Property and Copyright Right Law Vol. 8) Frieddrich-Karl Beier and Gerhard Schricker (Eds 1996)(hereinafter, Beier & Schricker, FROM GATT TO TRIPS ) at 171 (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 uses); PENROSE, INTERNATIONAL PATENT SYSTEM, *supra* note 4 at 62-63, 78 (discussing the retention of sovereignty over patent abuse and compulsory licensing to address domestic technology needs).

<sup>22</sup> WHO & WTO, *WTO Agreements & Public Health, A Joint Study by the WHO and the WTO Secretariat*, (2002)(hereinafter, WHO & WTO, *Agreements & Public Health* ) at 42.

<sup>23</sup> The literature on the New International Economic Order is extensive. For an insightful review of that literature from the different ideological camps, see, Robert W. Cox, *Ideologies and the New International Economic Order: Reflections on Some Recent Literature*, 32 INTERNATIONAL ORGANIZATION 257 (1979) AT 258-2266 (discussing the definition of the new international economic order and offering 5 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, *THE END OF WORLD ORDER* (1983) at 110 (discussing the perceived role of geopolitics rather than juridical arrangements sought to be achieved by the U.S.); THE NEW INTERNATIONAL ECONOMIC ORDER: NORTH-SOUTH DEBATE (Jagdish N. Bhagwati ed.)(hereinafter, Bhagwati, *THE NIEO NORTH-SOUTH DEBATE*)(a symposium in which the establishment view point was vigorously expressed); MAHBUB UL HAQ , *THE POVERTY CURTAIN: CHOICES FOR THE THIRD WORLD* (1976) at ix, 142 (presenting a Third World view point 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); Julius Nyerere, *Unity for a New Order*, in *DIALOGUE FOR A NEW ORDER* (Khadija Haq (ed 1980) at 3 (arguing that the Third World needs one voice); NORTH-SOUTH A PROGRAMME FOR SURVIVAL (Report of the Independent Commission on International Development Issues (The Willy Brandt Report (1980) at 13 (arguing human being 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 the poor));ROBERT L. ROTHSTEIN, *GLOBAL BARGAINING UNCTAD AND THE QUEST FOR A NEW INTERNATIONAL ECONOMIC ORDER* (1979) at 15, 25-27 (arguing that the Third World countries were demanding more than a seat at the table but concluded that debates and search for a NIEO had reached a stalemate making progress difficult).



countries. The decade of the 1980s also witnessed the global proliferation of product 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. Tremendous pressure group politics exerted by private interests in the U.S. compelled U.S. trade negotiators to exploit the glaring bargaining power disparities enjoyed by the TRIAD.<sup>25</sup> This exploitation of the bargaining power disequilibrium was undertaken at a time when many developing countries were ill-equipped or unprepared to appreciate the full implications of TRIPS.<sup>26</sup> Nor did they fully understand the significance of the converging forces at work.<sup>27</sup> In riding the tidal 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 the political authority and public interest of the state could be subverted by foreign private interests.<sup>28</sup>

The linkage of intellectual property protection and international trade was then part of a gathering storm of the hegemonic powers brewing over the years. Frustrated for almost a century 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. Under the unanimity requirements of the Paris Union for modifications, reform of the patent system to increase protection and address concerns with compulsory licensing was virtually impossible. Nor could developed countries compel their co-equal weaker sovereign 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 and thoroughly drench the world with an increasingly aggressive, acquisitive and permanent international intellectual property regime oblivious to the needs of large portions of humanity. Just a few years earlier, the Convention on Biological Diversity (Biodiversity Convention) had

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<sup>24</sup> Janet H. MacLaughlin, Timothy J. Richards, and Leigh A. Kenny, *The Economic Significance of Piracy*, in Gadbar and Richards Ed, (hereinafter, *Economic Significance of Piracy*) at 89, 96-97 (explaining and estimating the cost of piracy and counterfeiting in the U.S in the millions of dollars).

<sup>25</sup> Gadbar & Gwynn, *Intellectual Property Protection*, *supra* note 9, 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 concluded that the linkage between TRIPS and GATT was predominantly driven by the private sector).

<sup>26</sup> Drahos, *Negotiating Intellectual Property Rights*, *supra* note 17, at 167 (discussion the relative unpreparedness of the developing countries and the fact that many did not even participate in the negotiations or what he termed coercion; Gadbar & Richards, GLOBAL CONSENSUS, GLOBAL CONFLICT) *supra* note 9(presents contributions by other contributors explaining the pressure put on those countries considered as obstacles to the U.S. objectives, e.g. Brazil at 149, India, at 186, South Korea 272 ); Conference in Thailand on Access to pharmaceuticals..Speech by incoming head of WTO

<sup>27</sup> Drahos, *Negotiating Intellectual Property Rights*, *supra* note 17, at 169 (asserting that indeed all states were ignorant of the likely effects of TRIPS other than the gains the U.S. would make).

<sup>28</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, *supra* note 9, at 224 (question claims that the WTO and TRIPS would a negative impact on the public interest and global welfare and claiming that the alternatives to TRIPS could more harmful).

already laid the foundations for TRIPS. Adopted in 1992, the Biodiversity Convention simultaneously created access to biodiversity resources and also mandated the protection of biotechnology inventions derived from those resources.<sup>29</sup>

The combined effect of TRIPS and the Biodiversity Convention is the stacking impact of two reinforcing global asymmetries: the digital or technology divide and the biodiversity resource concentration. The digital divide which favors developed countries guarantees the location in developed countries of substantial numbers of inventive activities and patents of great utility to developing countries. On the other hand, the biodiversity resources concentration which favors substantially developing countries does not necessarily translate into ownership of biotechnology inventions. While the access provisions of the Biodiversity Convention provides for access to those resources only those with the technological capabilities can meaningfully exploit them 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 under the mechanism of the WTO poses a serious threat to human health security. The fears of those who protested against wrapping up the right to trade with the mantle of intellectual property rights have been more than borne out to be legitimate. For barely half a decade after the WTO came into force, the threat posed by TRIPS as constructed and implemented to human health and food security was widely recognized not only by the WTO but also by other international organizations.<sup>30</sup> There is also a large body of

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<sup>29</sup> Convention on Biological Diversity, (with Annexes) concluded at Rio de Janeiro, June 5, 1992, [31 I.L.M. 822, 832](#) (1992). Article 16, (5) states that Contracting Parties recognize that intellectual property rights may have an influence on the implementation of the Convention and then mandates that they cooperate for the protection of intellectual property protection consistent with national legislation and international law which would include TRIPS.

<sup>30</sup> WTO, *Doha Declaration on TRIPS Agreement and Public Health*, (2001) (Ministerial Conference, Fourth Session, Doha, 9-14 November 2001) WT/MIN(01)/DEC/W/2, 14 November 2001 (hereinafter WTO, *Doha Declaration on TRIPS*). 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 state taking measures to address this problem. However, the Doha Declaration sought to provide solutions within the flexibilities within TRIPS as long as their use was consistent with TRIPS. See, FAO, *The State of Food Insecurity in the World* (2008), at 2 (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) high food prices share much of the blame; (3) the poorest, landless and female-headed households are the hardest hit; (4) initial government policy measures have limited effect; (5) high 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. The FAO states that it strongly believes in renewed investment in agriculture focusing on small holder farmers and rural development and food technology, and concludes that it is unacceptable that 862 million people are still hungry., at 43-44; OECD, *OED-FAO Agricultural Outlook* (2009) at 4 (projecting long term global food production needs to increase more than 40% by 2030 and 70% by 2050; Julian M. Alston, Philip G. Pardey, and Johannes Roseboom, *Financing Agricultural Research: International Investment Patterns and Policy Perspectives*, 26 WORLD DEV. 1057, at 1063 (arguing that public R&D expenditures in agriculture is a complex picture; Agricultural R&D in developed countries doubled between 1985 and 1991 from \$7.3

growing expository and critical literature focusing on various aspects of WTO and TRIPS including public health.<sup>31</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. These studies are mostly concerned with content and textualism rather than structure and contextualism. Little, if any, 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 organs have focused on finding solutions to the public health needs of countries within the “so-called” built-in flexibilities of TRIPS.<sup>32</sup> Focused on textual analysis, most of these studies are concerned

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billion to \$15 billion while developing countries are lagging behind; Julian M. Alston, Jason M. Beddow, Philip G. Pardey, *Agricultural Research, Productivity, and Food Prices in the Long Run*, 325 SCIENCE 1209 (2009) at 1210 (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 trend appears universal globally).

<sup>31</sup> The interested reader may examine the following: CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007)( hereinafter, CORREA, COMMENTARY ON THE TRIPS AGREEMENT)(providing a thorough analysis of the different intellectual property subject areas covered by TRIPS) ; NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, (3d. 2010)(hereinafter, DE CARVALHO, TRIPS PAENT RIGHTS)(devoted totally to the patent aspects of TRIPS with background explanation of history and the economics of patents); Beier & Schriker, FROM GATT TO TRIPS, *supra* note 21, at 20(providing a general and EU perspective on the provisions of TRIPS); INTELLECTUAL PROPERTY RIGHTS, KNOWLEDGE, ACCESS AND DEVELOPMENT (Drahos and Mayne( Ed 2002.)(hereinafter Drahos & Mayne, GLOBAL INTELLECTUAL PROPERTY RIGHTS)(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 patents and industrial property recognized in contracting states; L. Petherbridge, *Intelligent TRIPS Implementation Strategy for Countries on the Cusp of Development*, 22 U. PEN. J. INT’L ECON LAW 1029, at 1048( arguing for the use of interpretative devices); Daniel Gervais, *Traditional Knowledge: A Challenge to the International Property System*, in (INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY, VOL 7 (H. Hansen ed. 2002); G.D. Malpass Jr. *Life after the GATT TRIPS Agreement—Has the Competitive Position of the U.S. Changed?* 19 HOUSTON J. INT’L L. 207, 226 (1996); JOHN WALKER BAXRWE, JOHN P. SINNOT & WILLIAM COTREAU, WORLD PATENT LAW AND PRACTICE (2007) at 8-3(discussing the local working requirements of section 5A of the Paris Union after TRIPS; at 8-7 approaches used by some countries); Kevin W. McCabe, *The January 1999 Review of Article 27 if the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELLECTUAL PROPERTY LAW, 41, 61(explaining the technology gap disfavoring the production of biotechnology inventions in developing countries); T. A. Haaq, *TRIPS Since Doha: How far Will the WTO go toward Modifying the Terms of Compulsory Licensing?* 84 J. PAT. & TRADEMARK OFF. SOCIETY, 945, 955- 966) (2002)(discussing the requirements for triggering the use of Article 31(k)); A. Blackett, *Whither Social Change? Human Rights, Trade Theory and Treaty Interpretation*, 31 COLUMBIA HUMAN RIGHTS LAW REVIEW..(1999)( suggesting the reliance on Articles 7 and 8 for interpreting issues of human rights); S. D. Ahuja, *GATT and TRIPS—The Impact on the Indian Pharmaceutical Industry*, 1994 PATENT WORLD 28 (discussing the options faced by the negotiators in dealing with health needs of member states settling for strict safeguards).

<sup>32</sup> Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, (WHO, 2002)(hereinafter, Correa, *Implications of Doha Declaration*) at 13-18 (discussing various available flexibilities within the context of the text for exploiting the TRIPS Agreement by developing countries); *integrating Public Health Concerns into Patent Legislation in Developing Countries*, (Geneva, South Center), at 22; *Pro-competitive Measures under TRIPS to Promote Technology Diffusion in Developing Countries*, in Drahos & Mayne, GLOBAL INTELLECTUAL PROPERTY RIGHTS, *supra* note

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>33</sup> Other studies are directed at supply and access to medicine at affordable prices.<sup>34</sup> Economists, using simulation models have started to study the impact of TRIPS on the welfare of consumers in the pharmaceutical industries in developing countries. These studies confirm that TRIPS has a significant negative impact on domestic prices of pharmaceutical products and health services in developing countries.<sup>35</sup> There are also insightful contributions on trade and health issues within the context of Sanitary and Phyto-sanitary Measures (SPS).<sup>36</sup>

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31(hereinafter, Correa, *Pro-competitive Measures under TRIPS*) 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)

<sup>33</sup> CORREA, COMMENTARY ON THE TRIPS AGREEMENT, *supra* note 31, at 22 (discussing in several pages the nature and scope of the substantive legal obligations under of TRIPS); DE CARVALHO, TRIPS PATENT RIGHTS, *supra* note 31, at 1-22 (in an introductory note explanation of the structure of the legal rights under patents and in TRIPS).

<sup>34</sup> Richard D. Smith, Carlos Correa, Cecilia Oh, *Trade, TRIPS, and Pharmaceuticals*, [www.thelancet.com](http://www.thelancet.com) Vol 373, February 21, (2009)(hereinafter Smith, Correa & Oh, *TRIPS and Pharmaceuticals*) p.685-688 (discussing the issues of patents trade and pharmaceutical); WHO *The Public and Private Circuits for the Distribution of Drugs in the Chilean Health System*, (Health Economics and Drugs DAP Series No 2, WHO/D/AP/96.1 (1996) at 9, 23-41 (a study inspired and support by the collaboration between UNICEF and WHO addressing the 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 LAW AND DEVELOPMENT REVIEW 325 (2010)(examining the legal tactics and marketing behavior of multinationals with respect to access to pharmaceuticals in India argues 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 that topic, *see*, COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE, *Framework Study on Food Security and Access and Benefits-Sharing for Genetic Resources for Food and Agriculture*, (FAO, Background Study Paper No. 42, 2009) at 7-10 (accessing national genetic benefit sharing laws and making suggestions on modifications and standardizations of the law and procedures); FAO, *Food Insecurity in the World. 2008*, 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, and sending the following 6 key messages: world hunger is increasing, high food prices share much of the blame, the poorest, landless and female-headed households are the hardest hit, initial governmental policy response have had limited effect, high food prices are also an opportunity, and a comprehensive twin-track approach is required).

<sup>35</sup> Shubham Chaudhuri, Pinelopi K. Golberg, and Panle Jia, *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India*, 96 AMERICAN ECONOMIC REVIEW 1477 (2006) <http://www.jstor.org/stable/30034983>, accessed: 24/09/2009) at 1480-1481 (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, also finding that in the absence of any price regulation, the price patented products would rise between 100 percent and 400 percent; with price regulation the profits of foreign producer would be at its pre-TRIPS level: \$19.6 million as opposed to \$53 million per year without price regulation.)

<sup>36</sup>Obijiofor Aginam, *Food Safety, South-North Asymmetries, and the Clash of Regulatory Regimes*, 40 VAND. J. TRANSNAT'L L. 1099 (2007) at 1100-1102, 1103(discussion the issues of food safety within the context of economic globalization and the regulatory regime of the WTO Agreement on Sanitary and Phyto-Sanitary Measures (SPS)); For a discussion of the interaction between WTO trade rules, (GATT XX

Exploring the textual content of the WTO and TRIPS for meaningful solutions to the health challenges they pose to humanity presupposes a substantive problem which can be solved within the text of TRIPS. The returns on such an approach are of marginal utility. The structural problems of TRIPS cannot be solved through 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 the root causes which are substantially structural, aggravated by a web of interwoven substantive provisions. Given the gravity of the 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 threat presented by TRIPS to human health and food security with emphasis on the evidence on health security. 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. One of the sources of the structural defects of TRIPS is found in the operating premises upon which it was constructed. Part IV is devoted to challenging 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 to 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. The interplay between the structure and substance of TRIPS on the risk to human health and food security is explored in Part V. History provides numerous examples of transcendent idealism in the establishment of new world orders. Part VI argues that the structural and substantive risks posed by TRIPS were substantially due to the failure of the framers to draw upon the rich lessons of history. Given these challenges, the conclusion returns to central question posed: *Quo vadis WTO?* What is the road ahead for the WTO and TRIPS? It offers suggestions and solutions which confront directly the root causes not the symptoms of the risks of TRIPS to human health and food security.

## **II THREAT TO HUMAN HEALTH AND FOOD SECURITY**

Barely half a decade after the WTO came into force, the threat posed by TRIPS as constructed and implemented to human health was widely acknowledged not only by the

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(d) health exemption 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).

WTO and its organs but also by other international organizations and commentators.<sup>37</sup> In paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 2001, the Fourth WTO Ministerial Conference acknowledged the problem and instructed the WTO Council for TRIPS to address the public health issues of developing countries.<sup>38</sup> More specifically it instructed the WTO Council on TRIPS to address the pharmaceutical needs of countries lacking or with insufficient manufacturing capacities.<sup>39</sup> In response to this mandate, the General Council of WTO issued a Decision on August 30, 2003 outlining the implementation of Paragraph 6 of the Doha Declaration.<sup>40</sup> Against the background of an increasing international debate over the relationship between TRIPS, the protection of intellectual property and public health, the World Health Organization (WHO) decided to establish an independent Commission on Public Health (WHO Commission on Public Health) to study this important issue.<sup>41</sup> To facilitate carrying out its mandate, the WHO Commission commissioned 22 separate studies on different and broader aspects of the subject. Almost contemporaneously, the WHO and the WTO undertook a joint study on the WTO Agreements & Public Health in 2002.<sup>42</sup> In the midst of all these, several other studies were conducted either independently or under the auspices of the WTO or WHO on the question of the public health implications of TRIPS.<sup>43</sup>

Concerned about not only the public health implications of TRIPS but also the broader implications of its structural and substantive mandate on economic development, some countries have essentially demanded a reopening of the Agreement for de novo negotiations.<sup>44</sup> The catalogue of legitimate issues raised poses a burning question about how responsive TRIPS was 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 taken into account in the initial structuring of the TRIPS. Certainly, the action

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<sup>37</sup> WTO, WHO, *Macroeconomics and Health: Investing in Health for Economic Development*, (2001),

<sup>38</sup> WTO, *Doha Declaration*), *supra* note 30.

<sup>39</sup> WTO *id*

<sup>40</sup> WTO, *Doha Declaration*), *supra* note 30 (General Council Decision)

<sup>41</sup> WORLD HEALTH ORGANIZATION, *Public Health: Innovation and Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, (2006). (hereinafter, WHO, *Commission on Public Health*)

<sup>42</sup> World Health Organization and World Trade Organization. *WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat*, (2002)(hereinafter, WHO & WTO, *WTO Agreements & Public Health*)(discussing the nature of the disease burden the attempt in TRIPS to strike a balance between intellectual property protection and access to medicine, medical technology and need for cooperation between WHO and WTO on matters of health).

<sup>43</sup> WHO, *Commission on Public*, *supra* note 41, provides an extensive list of numerous studies by the WHO, other U.N. Organs and other entities and institutions addressing the nature of the disease burden and possible global responses. The interested reader may review the lists provided in each chapter of that study.

<sup>44</sup> DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* (Sweet & Maxwell 3d ed. (2008)(hereinafter, GERVAIS, *TRIPS DRAFTING HISTORY AND ANALYSIS*) at 60-61(discussing the position of several developing countries and in particular calling for amending Article 31 and viewed as reopening the Agreement).

by the WTO Council on TRIPS was an explicit admission of the deficiencies of TRIPS. An explicit or implicit call for revisiting TRIPS by developing countries merely reinforces its inadequacies which are not simply substantive but also structural.

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

The nature and scope of the threat posed by TRIPS is better understood by examining the nature of the disease burden and food insecurity in developing countries. Such understanding can best be achieved by reviewing studies directed at this threat. Distilled from these studies are certain basic health challenges faced by developing countries under TRIPS. A useful starting point is the report of the WHO Commission on Public Health.

The WHO Commission on Public Health Report provides a highly 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>45</sup> Viewed from the perspective of the incidence of disease and mortality rates, this population bears a substantial burden of the neglected diseases or the 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 children are stillborn and over 10 million children die before their fifth birthday.<sup>46</sup> The density of malaria cases in developing countries is relatively substantial. Although malaria account for only 3% of the disease burden worldwide about 90% of malaria cases are in developing countries.<sup>47</sup> In comparison with other diseases, malaria is the greatest disease of public health concern. Its victims are mostly children and pregnant women. According to reports, over 58% of all malaria cases are found in the poorest countries of the world which constitute about 20% of the world's population.<sup>48</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 their impact. Lamenting the lack of incentives for R&D in these diseases, Rachel Glennester and Michael Kremer pointed out that malaria, tuberculosis and an African strain of HIV/AIDS alone kill more people than all the wars in the past 50 years.<sup>49</sup> Together they claim 5 million lives each year mostly in developing countries and particularly sub Saharan Africa. Of the 2.3 million deaths attributable to HIV/AIDS, about 70% is in sub Saharan Africa.<sup>50</sup>

The WHO Commission on Public Health report, like others studies, identifies three

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<sup>45</sup> WHO, *Commission on Public Health*, *supra* note 41, at 2.

<sup>46</sup> *Id.* at 4.

<sup>47</sup> *Id.* at 6 (explaining that Africa is home to 90% of the malaria burden and over a majority of the malaria related deaths).

<sup>48</sup> *Id.* at 4; UNICEF, *The State of World's Children, Maternal and New Born* (2009) at 2,6 (arguing that 1500 women die from complications of childbirth mostly in Asia and Africa accounting for over 95% of such deaths each year).

<sup>49</sup> Rachel Glennester and Michael Kremer, *A Better Way to Spur Medical Research and Development*, REGULATIONS, 34(hereinafter, Glennester & Kremer, *Medical Research and Development*), at 36.

<sup>50</sup> *Id.* Explaining the death rates due to tropical and infectious diseases; malaria 1.1 million a year mostly children and pregnant women, tuberculosis, 1.9 million a year.

different types of diseases in the world. Type I diseases are communicable (measles, hepatitis B) and non-communicable diseases (diabetes, cardiovascular diseases).<sup>51</sup> Type I diseases 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 tends to depend 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. Unfortunately, although vaccines for non-communicable Type I diseases are available they are inaccessible to poor countries because of cost.<sup>52</sup>

Type II diseases are also incident in both rich and poor countries although they afflict disproportionately the population of poor countries. For instance, over 90% of the incidence of HIV/AIDS and tuberculosis is in poor countries.<sup>53</sup> However, Type III diseases are either substantially or exclusively found in developing countries. Type III diseases which include the African river blindness (onchocerciasis) and sleeping sickness (trypanosomiasis) receive little or no R&D attention;<sup>54</sup> the point of concern by Glennester and Kremer.<sup>55</sup> Neither public nor private expenditures on health research in developed countries are directed at these diseases. Unfortunately, developing countries face the compounding factor of Type I diseases taking on increasingly the characteristics of Type II diseases. This means they suffer a double burden but the afflicted will not receive adequate treatment.

One of the negative externalities of globalization is the changing patterns in nutrition and food habits in developing countries. People in poor countries are increasingly shifting their nutrition and eating habits towards those of their counterparts in developed countries. It is a cultural shift with significant implications on the redistribution of the global disease burden. This cultural shift has resulted in an increase in the incidence of non-communicable chronic diseases such as diabetes and stroke in developing countries. In addition to the traditional infectious tropical diseases, people in remote African villages are now confronted with the challenges posed by such diseases for which there are no names in local languages. This comes at a time when chronic diseases account for about 60% of all deaths worldwide but about 80% of these deaths occur in developing countries.<sup>56</sup> 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 concentrated in the hands global agro-business MNEs.

The astonishing nature of these statistics should have engaged the undivided attention of the world community. However, the response of the global community as

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<sup>51</sup> WHO, *Commission on Public Health*, *supra* note 41, at 13.

<sup>52</sup> WHO, *Commission on Public Health*, *supra* note 41, at 13.

<sup>53</sup> *Id.* at 13

<sup>54</sup> *Id.* at 13

<sup>55</sup> Glennester & Kremer, *Medical Research and Development*, *supra* note 49.

<sup>56</sup> Global Forum for Health Research, *Monitoring Financial Flows for Health Research 2008: Prioritizing Research for Health Equity* (2008) (hereinafter, Global Forum, *Monitoring Financial Flows* 2008) at p. xvii



demonstrated by health research expenditures directed at diseases of the poor is by all measures disappointing. In the first 10/90 Report on Health Research by the Global Forum for Health Research the disequilibrium in health research expenditures were captured.<sup>57</sup> According to this report, developed countries have been mostly concerned with addressing their fundamental health needs. In 1986 when global investment in health research stood at about \$30 billion, only \$1.6 billion or about 5% of that amount as devoted to problems of developing countries.<sup>58</sup> Just six years later, in 1992 the estimates 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>59</sup> Further estimates by Harvard in 1992 and 1995 which found a similar imbalance of 5-10% led to the conclusion that there was generally 10/90 imbalance in global health expenditures. That is, of the billions of dollars spent each year on health research only 10% is devoted to the needs of the developing countries and 90% to those of developed countries.<sup>60</sup> The regions of the world with over 80% of the world population and the greatest disease burden receive little health research funding.

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

The discussion of the apparent inequity or imbalance in the health research expenditures by high income countries (HIC) is better framed within the context of the financial flows in health research expenditures worldwide. An investigation of this question by the Global Forum for Health Research confirms that the higher the income of a country the more it is likely to investment in health research.<sup>61</sup> In 2005 high income countries (HIC) accounted for a substantial (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 public and private sectors in HIC and LMIC worldwide.<sup>62</sup>

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<sup>57</sup>Global Forum for Health Research, *The 10/90 Report on Health Research*, (1999)(hereinafter, Global Forum, *The 10/90 Report 1999*) at 16

<sup>58</sup> *Id.* at 69

<sup>59</sup> *Id.* at 69

<sup>60</sup> *Id.* at 69

<sup>61</sup> Global Forum, *Monitoring Financial Flows*, *supra* note 56, at 25-30)

<sup>62</sup> *Id.* at 28

**Table 1**

Estimated global total investments 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(a)                                     | 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 (b),</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(c )                                    | 71.0         | 44         | 53.2         | 42         | 44.1         | 42         | 35.0        | 41         |
| Foreign pharmaceuticals (c )                                    | 8.7          | 5          | 6.1          | 5          | 5.8          | 5          | 5.0         | 6          |
| Private not-for-profit (d)                                      | 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 (e)</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 ODA (f)                             | 0.6          | 0.4        | 0.4          | 0.3        | 0.4          | 0.4        | 0.4         | 0.5        |
| 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> |

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

(a) 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.

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

(c) 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.

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

(e) 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.

(f) 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. What is significant here is the substantial public sector investment in health. Although TRIPS is designed to protect private intellectual property rights public expenditures in developed countries for the generation of innovation is substantial. HIC

dominated the investment scene with \$155.2 billion as compared with \$5.1 billion in LMIC. The concentration is even more startling when a global comparison of these expenditures is made. According the Global Forum for Health Research, the U.S. dominated the picture accounting for about 50% of all investments leaving far behind other members of the TRIAD such as Japan (10%) and the rest. The only developing countries in the distant horizon were China and Taiwan with only 1% combined.<sup>63</sup> But the disequilibrium also exists in the private profits motivated health research as captured in Table 2 below.<sup>64</sup>

**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>  |

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

As is apparent in Table 2, the U.S. private sector dominated private sector investments in health research with about 50% of such investments followed in the distance by Japan with 13.1%, Germany 6.9% and the rest of HIC. Only two developing countries, China and India register investments of this type with less than 1% each. Furthermore, the geographic distribution of investments by pharmaceutical member companies in 2006 puts U.S. companies clearly in a dominant position with 79.3% while the remainder is scattered across the globe with less than 2% in any country.<sup>65</sup> The picture painted by these statistics is hardly appealing to developing countries in terms of their ability to finance health research.

Certain patterns seem to emerge from this brief survey. The distribution of disease burden during the negotiations and after the implementation of TRIPS has remained stubbornly skewed against developing countries. Health research expenditures aimed at the disease burden of the world have also remained significantly directed at the needs of

<sup>63</sup> *Id.* at 29

<sup>64</sup> *Id.* at 40

<sup>65</sup> *Id.* at 47

developed countries. In view the pattern of concentration in these expenditures, innovation and product development will continue to display a substantial imbalance against the interest of developing countries. Studies by FAO confirm a similar disequilibrium in food security R&D in agriculture.<sup>66</sup> The structure and substance of TRIPS accentuate rather than correct the disequilibrium.

These imbalances may be shocking but hardly surprising. They capture perceptions of the responsibility of states 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 legislative provisions in some countries.<sup>67</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. It defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.<sup>68</sup> It goes further to state that

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<sup>66</sup>The nature of the food insecurity of developing countries is best captured in the following study by the Food and Agriculture Organization of the United Nations: FAO, *The State of Food Insecurity in the World* (2008). The report presented a summary of six key points: 1. World hunger is increasing, about 923 million people were hungry in 2007; 2 Food prices share much of the blame contributing to about 75 million more people to the list; 3, The poorest, landless and female-headed households are the hardest hit; 4. Initial government response has limited effect; 5, high food prices are also an opportunity in the long run for agriculture; 6, A comprehensive twin-track approach is required: a combination of efforts by governments, the UN, non-governmental organizations, civil society and the private sector. at 2. According to this report only 7 countries (India, China, The Democratic Republic of the Congo, Bangladesh, Indonesia, Pakistan and Ethiopia) account for 65% or 823 million of the undernourished between 2003 and 2005, at 12; part of the problem is food production, at 44; Carlos M. Correa, *Access to Plant Genetic Resources and Intellectual Property Rights* COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE (1999) at 6-7 (explaining that although biotechnology patents issued between 1990 and 1995 was about 25,000 they constituted only 1% of all patents and were highly concentrated in the U.S.(35.4%) Japan (34.9%) and Europe (29.4%); China (1.1%) Republic of Korea 0.7%), and the most active applicants for plant patents are multinational companies from developed countries); Walter Smolders, *Commercial Practice in the Use of Plant Genetic Resources for Food and Agriculture*, COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE ACTING AS INTERIM COMMITTEE FOR THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (FAO) Background Study Paper No. 27 From limited data, the report argued that there is a growing consolidation of global seed companies and the top 10 agro-business global enterprises are located in developed countries and that seed companies are increasingly doing less or no basic research.<sup>10</sup> 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>67</sup> Yelapaala, *Fundamentalism in Public Health and Safety II*, *supra* note.. at 474-479.(discussion the constitutional protections to health provided by some countries); CONSTITUTION; WHO, *Commission on Public Health*, *supra* note..at 9-10

<sup>68</sup> **CONSTITUTION OF THE WORLD HEALTH ORGANIZATION (WHO CONSTITUTION)**

THE STATES Parties to this Constitution declare, in conformity with the

“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>69</sup> Article 12.1 of the International Covenant on Economic Social and Cultural Rights also recognizes “the right of everyone to the enjoyment of the highest attainable of physical and mental health.”<sup>70</sup> As appropriately pointed out by the WHO Commission on Public Health, these obligations of the state are not simply utopian. They constitute both moral and legal imperatives.<sup>71</sup> The question of interest 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 rights in 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 whether a state can legally abrogate its responsibility to protect the human rights of its citizens by treaty for private gain.<sup>72</sup>

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Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

*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.*

The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.

The achievement of any State in the promotion and protection of health

is of value to all. (The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (*Off. Rec. Wld Hlth Org.*, 2, 100), and entered into force on 7 April 1948. Amendments adopted by the Twenty-sixth, Twenty-ninth, Thirty-ninth and Fifty-first World Health Assemblies (resolutions WHA26.37, WHA29.38, WHA39.6 and WHA51.23) came into force on 3 February 1977, 20 January 1984, 11 July 1994 and 15 September 2005 respectively and are incorporated in the present text. WHO, *Commission on Public Health*, *supra* note..at 9

<sup>69</sup> WHO, *CONSTITUTION*, *id.*

<sup>70</sup> International Covenant on Civil and Political Rights, Dec. 16, 1966, S. Exec. Doc. E, 95-2, 999 U.N.T.S. 171, 6 I.L.M. 368 (1967) [hereinafter ICCPR]; International Covenant on Economic, Social, and Cultural Rights, Dec. 16, 1966, S. Exec. Doc. D, 95-2, 993 U.N.T.S. 3, 6 I.L.M. 360 (1967);, *see* Yelapaala, *Fundamentalism in Public Health and Safety in Bilateral Investment Treaties* [ Part II], 3 ASIAN JOURNAL OF WTO & INTERNATIONAL HEALTH LAW AND POLICY, 235 (2008)(hereinafter, Yelapaala, *Fundamentalism in Public Health and Safety II*) at 484-492 (arguing that the right to health is governed by international law under conventions and under *jus cogens*)...

<sup>71</sup> WHO, *Commission on Public Health*, *supra* note 41, at 8-10.

<sup>72</sup> Kojo Yelapaala, *Fundamentalism in Public Health and Safety in Bilateral Investment Treaties*, [Part I] 3 ASIAN JOURNAL OF WTO & INTERNATIONAL HEALTH LAW AND POLICY, 235 (2008)(hereinafter, Yelapaala, *Fundamentalism in Public Health and Safety I*) 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.)

### ***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 the inception of GATT to its transformation into a system of Agreements under the WTO, free trade has always been *purposive*; the achievement of social and economic advancement of the world, something larger than free trade itself. The free trade ideal first captured in the 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 tradable goods and services.<sup>73</sup> Thus the WTO and its system of agreements are not concerned with achieving free trade per se but rather facilitating the social and economic development of its member states. However, a major component of 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 a shifting disease burden and limitations on their health policy choices. The cost and benefits of trade liberalization are hardly equitably distributed as the gulf between the health impact and expectations of high income and low income countries is huge. Again, the complexity of these topics deserve more time and space than is available here. We 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 1960s focused on factor accumulation, physical capital, labor supply and infrastructural investments. Under these theories health was a mere consequence but not an engine of development. Modern development theories now recognize the central role of human capital in development in which health is an engine not a consequence of development.<sup>74</sup> Indeed, health is both a cause and a consequence of development.<sup>75</sup> It is argued that the returns on health research investments are often substantially higher than those in conventional infrastructural investments.<sup>76</sup> Health affects education, skills acquisition, labor productivity and economic development.<sup>77</sup> The evidence from the East Asia miracles suggests that economic growth, rising per capital income and meaningful

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<sup>73</sup> This is what the WTO preamble in part states: “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.”

<sup>74</sup> Global Forum for Health Research, *The 10/90 Report on Health Research, 2003-2004* (2004)(hereinafter, Global Forum, *The 10/90/ Report 2003-2004*) at 30.

<sup>75</sup> David E Bloom and David Canning, *Commentary: The Preston Curve 30 Years On: Still Sparking Fires*, 36 INTERNATIONAL JOURNAL OF EPIDEMIOLOGY 498 (2007)(hereinafter, Bloom & Canning *The Preston Curve 30 Years On*), at 499.

<sup>76</sup> Global Forum, *The 10/90/ Report 2003-2004 supra* note 74, at 30.

<sup>77</sup> Bloom & Canning, *The Preston Curve 30 Years On, supra* note 75, at 499.

international trade require high labor productivity of high quality and low cost manufactured exports.<sup>78</sup> But these are linked to a healthy labor force. The sources of growth and development included 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>79</sup> If the goals of the WTO include social and economic development through trade the logical pro-trade and pro-development policies of WTO would have been to foster sound member state health policies, easy access to health related technologies, and the availability of affordable pharmaceutical products worldwide. The limitations imposed by TRIPS on member states even within its so-called flexibilities seem to be contradictory to the very ideals preached by the WTO.

The relationship between TRIPS, health and economic development is however a complex and controversial one. 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 capital income and life expectancy. In 1975 Samuel Preston in a seminal paper argued that there was a complex but concave or non-linear positive relationship between per capita income and life expectancy between and within countries.<sup>80</sup> Put differently, among the poorest countries, longevity and increases in average income tend to be strongly associated but the relationship weakens and even flattens out among the richest countries.<sup>81</sup> Beyond a certain point, 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>82</sup> The suggested sensitivity of longevity to variations in average income

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<sup>78</sup> The literature on the East Miracles is voluminous; the following provides a window into the explanations for the miracle and review of the literature, See Kojo Yelapaala, *Rethinking the Foreign Direct Investment Process and Incentives in Post Conflict Transition Countries*, 30 NORTHWESTERN J. INT'L LAW & BUSINESS 23 (2010) at 53-54 ( discussing the reasons for the East Asian Miracles and the role of the developmental state); John Page, *The East Asian Miracle: Four Lessons for Development Policy*, in NBER MACROECONOMICS ANNUAL 1994, at 219 (Stanley J. Fischer, & Julio J. Rotemberg, eds., 1994); Dani Rodrik, *Getting Interventions Right: How South Korea and Taiwan Grew Rich*, ECON. POL'Y, Apr. 1995 (explaining the complexities of the policy mix used by South Korea and Taiwan for achieving development and riches); 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 relying heavily on international trade); 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);.

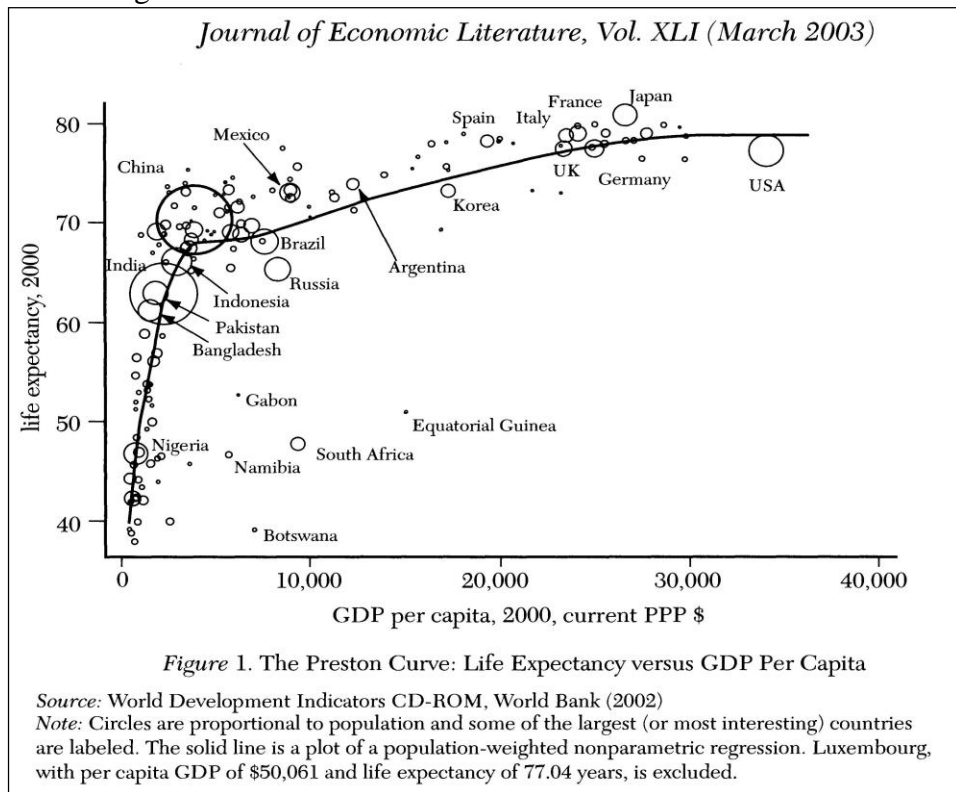
<sup>79</sup> Bloom & Canning, *The Preston Curve 30 Years On*, *supra* note 75, at 499

<sup>80</sup> Samuel H. Preston, *The Changing Relation Between Mortality and Level of Economic Development*, 29 POPULATION STUDIES 231 (1975). The Preston Curve had has been the subject of much recent discussion on among organizations concerned with the global health crisis and health research. See, Global Forum, *Monitoring Financial Flows 2008*, *supra* note 56, at 8 (discussing the complexity of the Preston Curve in life expectancy across countries); Global Forum, *Monitoring Financial Flows 2009: Behind the Global Numbers* (2009)(hereinafter Global Forum, *Monitoring Financial Flows*) at 3-4 ( discussing the Preston Curve and life expectancy in the 20<sup>th</sup> century); Global Forum, *The 10/90 Report 1999*, *supra* note 57, at 76, 85 (discussing differences in life expectancy and poverty between countries).

<sup>81</sup> Global Forum, *Monitoring Financial Flows 2008*, *id.* Global Forum, *Monitoring Financial Flows 2009*, *id.*

<sup>82</sup> Chantal Blouin, Mickey Chopra, Ralph van der Hoeven, *Trade and Social Determinants of Health*, [www.thelancet.com](http://www.thelancet.com) vol 373 February 7 2009 p. 502-607, at 502.

depicted in the Preston Curve has recently been investigated by Angus Deaton<sup>83</sup> and is captured in Figure 1 below.



It is apparent from this figure that countries at the lower levels of the wealth ladder can dramatically improve the life expectancy of their populations by increasing average wealth. For instance, increasing average income by less than \$10,000 has 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 is however more complex than is immediately apparent in the Preston Curve. Variables other than income or wealth affect health and longevity of a population. For while countries such as China and others in the Mediterranean region have low average income they nevertheless enjoy long life expectancy; suggesting that factors such as diet, nutrition, clean water, sanitation and preventive public health policies contribute to higher levels of longevity in those countries.<sup>84</sup>

<sup>83</sup> Angus Deaton, *Health, Inequality, and Economic Development*, 41 J. ECON. LITERATURE 113, 116 (2003) (arguing that in conclusion that 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) at 15. But note that redistribution from rich countries through trade could have a positive impact on the health citizens of poor countries; trade can result in wealth transfer from high income counties to low income countries but a healthy work force in both, particularly in low income countries would essential to trade.

<sup>84</sup> WHO, *Commission on Public Health*, *supra* note 41, at 2-3 (the Commission pointed that income and health are not necessary related.); Bloom & Canning, *The Preston Curve 30 Years On*, *supra* note 75, at



The connection between the Preston Curve indicia of longevity and TRIPS is therefore neither direct nor obvious. Indeed, the association we seek to make here is not between income and health but rather between income and the capacity of a state to address its fundamental health needs. Such a connection can be made through the following 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 ill-equipped financially to address their health services and research needs adequately. Third, as indicated by the health financial flows, there appears to be a direct relationship between the wealth of a country and its health research expenditures aimed at addressing its fundamental health needs. Public and private health research expenditures are predominantly carried out in rich developed countries to handle their health needs.<sup>85</sup> On the average, about only 10% of these expenditures are directed at the needs of developing countries although their disease burden and mortality rates are substantially greater.<sup>86</sup>

The Preston Curve seems to provide another angle of view of 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 raising wealth, poor countries can substantially improve the health and longevity of their populations through health research expenditures, public health policies and economic development. 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 rather 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 these hold 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, the WHO and many commentators.<sup>87</sup>

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<sup>85</sup> *The 10/90 Report 1999*, *supra* note 57, at 45 (arguing that most of about 95% of the R&D resources are devoted to issues relevant only to the needs of a minority of the world's population, 5%); Global Forum, *Monitoring Financial Flows 2008*, *supra* note 56, at 25-27 (confirming the devotion of the expenditures on health research mostly for developed countries); Global Forum, *The 10/90 Report on Health Research 2003-2004*, (2004) at 118-119 (explaining the small percentage of research resources devoted to the needs of developing countries).

<sup>86</sup> *The 10/90 Report 1999 id.* 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 by both private public sectors, only 10% was devoted to the health problems of 90% of the world's population).

<sup>87</sup> WTO, *Doha Declaration on TRIPS*, *supra* note 30. Smith, Correa, Oh, *TRIPS, and Pharmaceuticals* *supra* note 34, at 686.

Beyond the issues of macroeconomics and health, the health burdens of TRIPS within the WTO system on developing countries seem imbedded in the concept of free trade advocated by the WTO. The liberalization of trade and investments within a shrinking economic geography of the current system of globalization appears to have unforeseen negative consequences on public health in developing countries.<sup>88</sup> Trade and investment liberalization has 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. Trade liberalization has also opened up the markets of developing countries to other high health risk products such as tobacco. These food exports from global agro-business MNEs are not necessarily what developing countries need. As consumption of these products has increased so has the associated disease burden of non-communicable diseases such as diabetes, obesity, strokes and other chronic diseases previously unknown in those countries. Thus, trade liberalization has not only changed the nature of the disease burden in developing countries but has also imposed greater restrictions on them under TRIPS to address these new diseases. Yet, TRIPS appears to offer no direct channels to countries to deal with them except under its so-called system of flexibilities.<sup>89</sup> As noted above, the inadequacy of the internal solutions of TRIPS has prompted the General Council of WTO to issue the Doha Declaration only a few years after the implementation of TRIPS. The problems created by TRIPS are essentially structural although aggravated by its substantive provisions. Structural problems cannot easily or adequately be resolved by analysis of the substantive provisions.

However, even as the markets for food and tobacco products are liberalized the markets for the pharmaceutical products and health technology to deal with the negative externalities of liberalization are hardly liberalized under TRIPS. Patent holders can engage in various marketing practices which are tantamount to market partitioning and patent abuses but face little if any challenges from weak and poor governments. Burdensome patent abuse procedures under TRIPS create incentives for global pharmaceutical and agro-business MNEs to register patents in foreign countries for the sole purpose of blocking third party imports. The burdens of the patent abuse procedures but ensure that only rich countries with the capacity can use them effectively.<sup>90</sup>

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<sup>88</sup> Smith, Correa, Oh, *TRIPS and Pharmaceuticals*, *supra* note 34, at 684.

<sup>89</sup> Correa, *Pro-competitive Measures Under TRIPS*, *supra* note 32, 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 32, at 13-17 (suggesting different ways in which the flexibilities within TRIPS could be exploited); WHO, *Commission on Public Health*, *supra* note 41, at 22, 126 (commenting on the flexibilities available within TRIPS); Smith, Correa, Oh, *TRIPS and Pharmaceuticals*, *supra* note, 34, at 690 (suggesting measures within the flexibilities of TRIPS that could be adopted and implemented by developing countries.)

<sup>90</sup> The patent abuse solutions in TRIPS 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. For commentary on these provisions *see*, GERVAIS, *TRIPS DRAFTING HISTORY AND ANALYSIS* *supra* note 44, at 384-402 (discussion and commentary on the patent abuse provisions in TRIPS).

Moreover, global food and supermarket MNEs enjoy a liberalized investment regime under which they can freely establish their marketing subsidiaries in developing countries. The MNEs and their affiliates also enjoy and exploit significant information asymmetry to market health risk products to unsuspecting consumers in developing countries without adequate warning. In doing so, they magnify the public health and food risks and impose on governments a regulatory burden which cannot easily be borne by poor countries.

### **Summary**

In summary, TRIPS seems to impede the achievement of the free trade goals of the WTO. 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 can address the health and food needs of their workers and the general population. This is not just a matter of economics but more so a question of ensuring the enjoyment of human rights. Unfortunately, what the WTO seems to give with one hand it takes away with the other under TRIPS.

### **III. THE RESPONSE OF TRIPS**

The WHO Commission on Public Health confronted the issue of the response of TRIPS to the public health needs of developing countries with what it described as a paradox or fundamental dilemma.<sup>91</sup> The world now has at its disposal incredible human technological capabilities which could be used to confront human misery and the disease burden of developing countries. Yet there is a mismatch between that capacity and its utilization for actual problem solving.<sup>92</sup> The tremendous technological advances of the world are locked up in the hands of a few private interests and monopoly rent seeking global oligopolies with little or no desire to tackle the health needs of the poor and the vulnerable. The intellectual property regime mandated by TRIPS substantially reinforces the profit motive within an oligopolistic market structure and denies any effective response by states in the public interest. Profit is not a dirty word nor is the pursuit of it undesirable. It is failure of the global community of states to separate clearly the public and political responsibilities of the state from those of private interests which are the focus of markets.

The central theme in the explanation of this mismatch of capabilities and their use is the incentive theory of innovation.<sup>93</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

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of these provisions); Beier & Schriker, FROM GATT TO TRIPS, *supra* note 21, at 208-210 (discussing the procedures and burden of proof by states for patent abuse responses).

<sup>91</sup> WHO, *Commission on Public Health*, *supra* note 41, at 1

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 19-22 (discussing the function of incentives in innovation and patent protection)

private enterprises or the absence of lucrative markets but rather to the non-existent or weak intellectual property protection in developing countries. To them, guaranteeing minimum intellectual property rights protection in WTO member states will act as a catalyst for innovation, the transfer of technology and the development of pharmaceutical products.<sup>94</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. However, precisely because of its *ex facie* appealing nature it has been suggested that TRIPS tried to strike a balance between the incentive to innovate and access to technology and products.<sup>95</sup> However, such a balance is hardly achieved at least in the case of developing countries.

If the assumption behind the balance sought was that intellectual property protection would encourage inventive activities in the health needs of developing countries, that has proved to be disappointing if not perhaps based on false hope.<sup>96</sup> Years after the implementation of TRIPS, the hoped for benefits in developing countries are still to be realized even as the system is visiting tremendous burdens on them.<sup>97</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>98</sup> A recent empirical study of the impact of TRIPS on the price of drugs and the economic welfare in India after the implementation of TRIPS 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 from 100% to 400% but also that the welfare loss would be more significant than estimated by other studies.<sup>99</sup> As is 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

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<sup>94</sup> WHO & WTO, *Agreements & Public Health*, *supra* note 22, at 12 (claiming that TRIPS is seeking a balance between incentives and access to future inventions, new drugs and affordable access to existing drugs.); Article 7 of TRIPS captures this balance by stating as one of its objectives the achievement of a balance between rights and obligations to ensure the transfer and diffusion of technological innovations...); WHO, *Commission on Public Health*, *supra* note 41.

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 66, (explaining that several years after TRIPS there have been no expected acceleration in the products reaching patients as predicted in 1995.)

<sup>97</sup> *id.* at..22, 83 explaining that for diseases of the poor are irrelevant to patents and developing countries with little technological and innovative capacity are bearing the cost of implementing TRIPS).

<sup>98</sup> Allan V. Deardoff, *Welfare Effects of Global Patent Protection*, 59 *ECONOMICA* 35 (1992); Judith C. Chin and Gene M. Grossman, *Intellectual Property and North-South Trade*, in *THE POLITICAL ECONOMY OF INTERNATIONAL TRADE: ESSAYS IN HONOR OF ROBERT E. BALDWIN* ed. Ronald W. Jones and Anne O. Krueger 90 Cambridge MA: Basil Blackwell (1990); Ishac and Dani Rodrik, *Patents, Appropriate Technology, and North-South Trade*, 30 *JOURNAL OF INTERNATIONAL ECONOMICS* 27 (1991); Gene M. Grossman and Edwin L. c. Lai, *International Protection of Intellectual Property*, 94 *AMERICAN ECONOMIC REVIEW* 1635 (2004); Elhanan Helpman, *Innovation, Imitation, and Intellectual Property Rights*, 61 *ECONOMICA* 1247 (1993); Jean O. Lanjouw and Iain M. Cockburn, *New Pills for Poor People? An Empirical Evidence after GATT* 29 *WORLD DEVELOPMENT* 265 (2001)

<sup>99</sup> Shubham Chaudhuri, Pinelopi K. Goldberg and Panie Jia, *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India*, 96 *AMERICAN ECONOMIC REVIEW* 1477, 1481, 1507(2006).

transfer and pharmaceutical products been realized. But 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 benefits. It is hardly surprising that the WHO Commission on Public Health questioned the validity of the incentive theory in developing countries.<sup>100</sup>

Any doubts about the weakness of the incentive theory as applied to developing countries can best be addressed by examining the 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 by products.<sup>101</sup> Estimates of the industry for 2006 hold that pharmaceuticals alone account for about 55% of health related trade.<sup>102</sup> The industry is highly concentrated in the TRIAD which accounted for about 75% of the market share. According Kyle, the U.S. is the largest market with \$97 billion followed by five of the largest European markets with \$51 billion.<sup>103</sup> The geographic distribution is best captured by Table 4 below which describes the country of origin, global sales and R&D expenditure of the top 10 pharmaceutical MNEs.

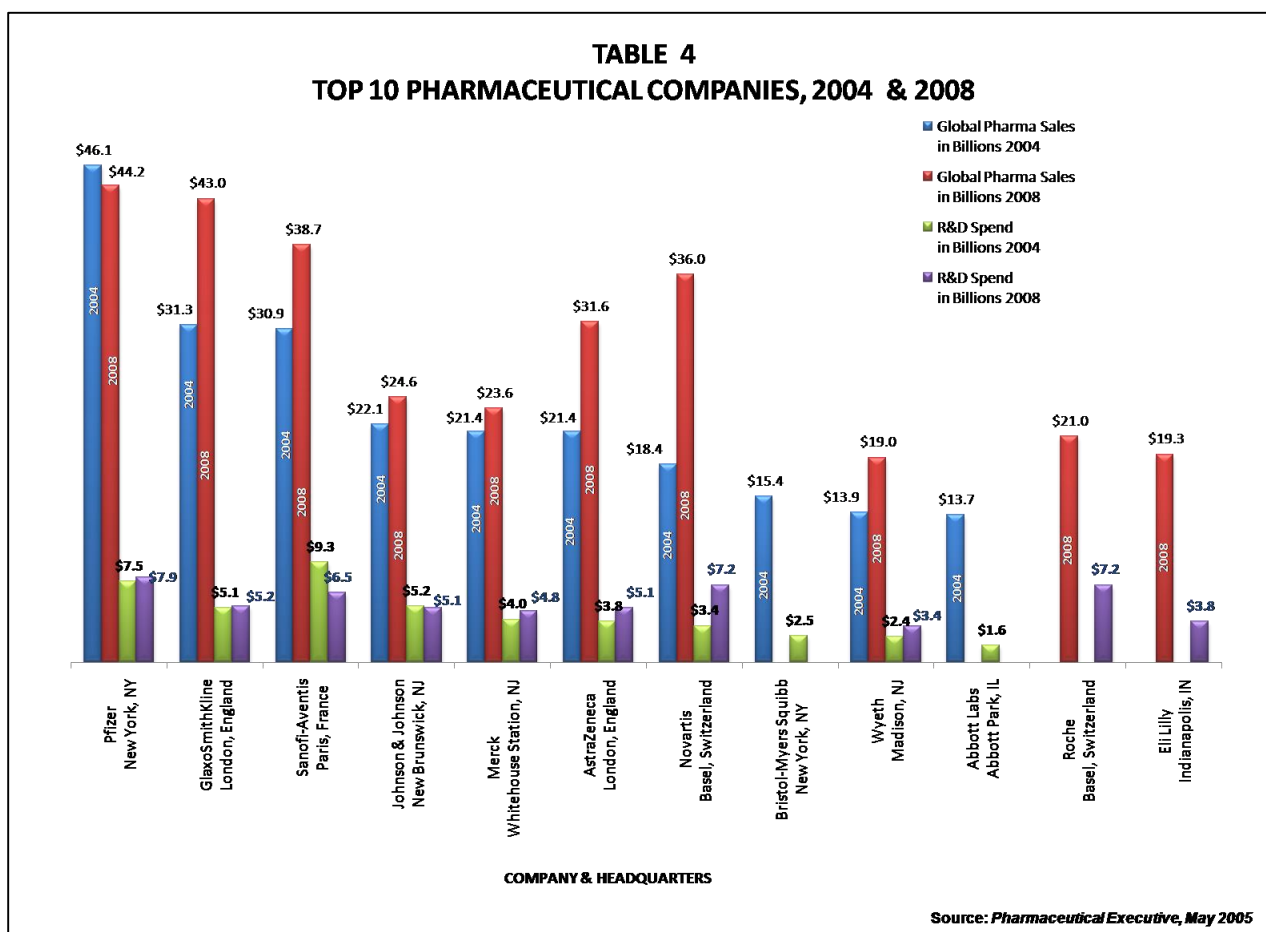
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<sup>100</sup> WHO, *Commission on Public Health*, *supra* note 41, at 20 (explaining that the necessary conditions for the incentive theory to work such as mature industries, capital and inventive capacity are generally absent in developing countries).

<sup>101</sup> Margaret K. Kyle, *The Role of Firm Characteristics in Pharmaceutical Product Launches*, 37 THE RAND JOURNAL OF ECONOMICS 602 (2006) at 604.

<sup>102</sup> *Id*

<sup>103</sup> *Id.*



It is apparent from Table 4 that the U.S. has the highest concentration, accounting for seven of the top ten MNEs. According to estimates by Smith, Correa and Oh, the top 10 pharmaceutical MNEs account for about 50% of the global markets and North America, Europe, Japan and Latin America count for about 85% of sales.<sup>104</sup> As is apparent from Table 4, although the global sales are measured in the tens of billions in U. S. dollars only small fractions of MNE resources are devoted to R&D. However not apparent in this picture are the results of R&D efforts and research in diseases of poverty.<sup>105</sup> Although global health R&D increased in the decades of the 1990s there was nevertheless a fall in innovative productivity and the number of new drugs introduced.<sup>106</sup> Moreover, very little of the 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 malaria to be a burning 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 of that

<sup>104</sup> Smith, Correa & Oh, *TRIPS and Pharmaceutical*, supra note 34.

<sup>105</sup> WHO *Commission on Public Health*, supra note 41, at 83;

<sup>106</sup> WHO *Commission on Public Health*, supra, note 41, at 66

amount was directed at malaria research.<sup>107</sup> Indeed, the WHO Commission for Public Health reported that only three of the MNEs in the top 10 (GlaxoSmithKline, AstraZeneca and Novartis) were involved in any R&D in diseases of poverty.<sup>108</sup>

What is apparent from this discussion is 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 Donald Kennedy, between 1975 and 1999 there were 1233 new drugs marketed. Of this number only 13 were for diseases of poverty.<sup>109</sup> Even more startling is the finding that most of these drugs were not the product of deliberate R&D directly related to diseases in developing countries but a by-product of some other activity.<sup>110</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 declarations 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 innovations, TRIPS cannot deliver for developing countries on the objectives stated in Article 7. The benevolence of private profit seeking MNEs cannot be the basis upon which human rights to health can be responded to by the global community of nations.

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 economic geography of the world for the highest return on investments. Such conduct is consistent with prevalent corporate strategic directives which call for focusing on high per capita income markets. This is best illustrated in Table 5 below which describes the top 10 selling pharmaceutical drugs in the world in 2004 and 2008.

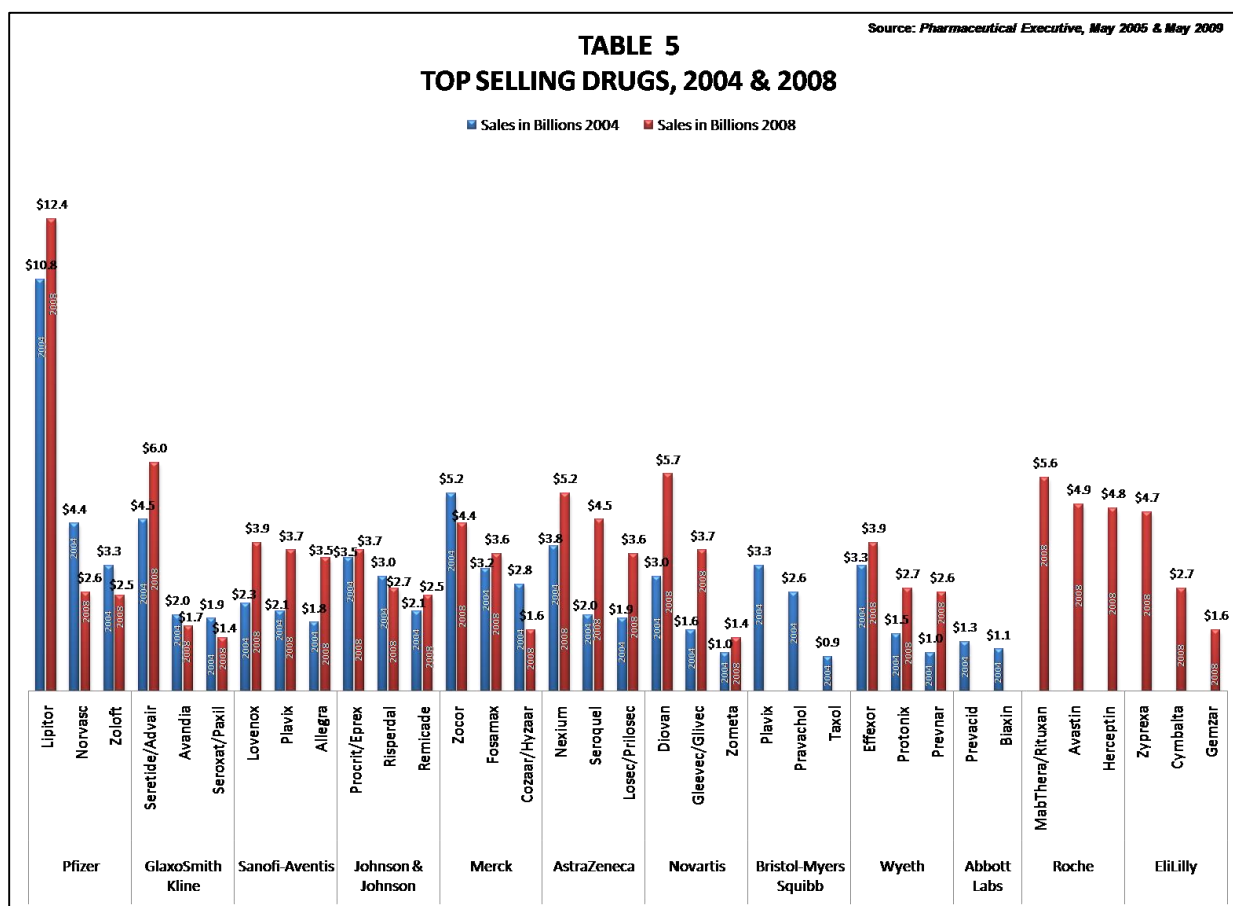
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<sup>107</sup> Remigius N. Nwabueze, *What Can Genomics and Health Biotechnology Do for Developing Countries?*, 15 ALB L J SCI & TECH 369, 387 (2005)(hereinafter, Nwabueze, *Genomics and Health Biotechnology*).

<sup>108</sup> WHO Commission on Public Health *supra* note 41, at 70.

<sup>109</sup> See, Donald Kennedy, *Drug Discovery* 303 SCIENCE 1729 (2004), at 1729

<sup>110</sup> Nwabueze, *Genomics and Health Biotechnology*, *supra* note 107, at 388 (explaining that only 4 drugs came out of new R&D, 9 were improvements on old drugs and 7 came from military and veterinary research.)



A few pertinent observations ought to be made from Table 5. The top 10 drugs are manufactured by the leading pharmaceutical MNEs. Not captured in this table is a similar concentration in therapeutic classes of drugs also aimed at the needs of developed countries.<sup>111</sup> The top therapeutic drug marketed in the U.S. included anti-psychotics, lipid regulators, proton pump inhibitors, seizure disorders and anti depressants.<sup>112</sup> Not surprisingly the best selling drugs in Table 5 are high-value drug aimed at diseases in

<sup>111</sup>The *Pharmaceutical Executive*, May 2009 listed an estimate of the 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 disorders \$11.3 billion, Anti-dpressants \$9.6 billion, Angiotensin II antognists \$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.

<sup>112</sup> See, WIPO, Total Number of Patent Families by Country of Origin (1990-2006) This list clearly illustrates the divide between patents held by developed countries in comparison with those held by developing countries. In 1990 455204 patents were held by OECD countries compared with 9664 for developing countries. In 2006 the gap remained and even widened; OECD 609863 ptents, developing countries, 119686 patents. Reports of by WIPO of patent applications by field of application including medical technology, food and agriculture, biotechnology confirmed the concentration in developed countries such as the the U.S., Japan, Germany, United Kingdom etc. see, WIPO, Patent Application by Field of Technology and Country of Origin 2002-2006.



developed countries. They provide treatment for types I diseases, including disorders involving the nervous system and lifestyle diseases. None of these drugs is aimed at diseases prevalent in developing countries. The target markets are the high per capita income regions such as the U.S. and Europe. 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 to them 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 drugs producers in the world. After TRIPS the Indian producers no longer have the freedom to use their capacity to reverse engineer and manufacture off-patent generics. In fact, TRIPS has imposed two related restrictions on the supply of generics by countries with the capacity to produce them. First, TRIPS and TRIPS PLUS agreements provide plausible legal roadblocks to the manufacture of off-patent generics. The substantive rights mandated under Article 28 of TRIPS pose a legal impediment as do TRIPS PLUS agreements which 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>113</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. These terms and others in the 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>114</sup> Bilateral unilateralism permits powerful states such as the U.S. to limit the opportunities for off-patent generics production. The opportunities for controlling production and flow of generics extend to global pharmaceutical MNEs. Through the strategic use of mergers and acquisitions pharmaceutical MNEs may takeover successful generic drugs manufacturers in developing countries to limit or redirect the production and marketing of generics to more profitable affluent markets. The acquisition of the Indian generic manufacturer Ranbaxy by the Japanese MNE certainly provides the latter with several strategic rent seeking options.<sup>115</sup>

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<sup>113</sup> Chutima Alkalephan et al, 91 HEALTH POLICY 174 (2009) at 175 (explaining how TRIPS-PLUS extends the obligations of states and limits rights in 10 most crucial TRIPS\_PLUS provision generally found in such as agreements: (1) protection for test data exclusivity; (2) linkages between drug registration and patents; (3) patent compensation for granting delay; (4) patent term compensation for delay of marketing; (5) strengthening intellectual protection enforcement; (6) compulsory licensing restrictions to national emergency for public non-commercial use; (7) parallel import limitations through contracts with patent holders; (8) prohibition of the revocation of patent on public interest grounds; (9) patentability of new uses of products; and (10) patentability of animals and plants (natural sources of medicines).

<sup>114</sup> Yelapaala, *Fundamentalism in Public Health and Safety I*, *supra* note 72, at 249

<sup>115</sup> WHO *Commission on Public Health* *supra* note 41, at 84-85( reporting that Ranbaxy planned to increase its share of revenue in the developed world from 20% in 2000 to 70% in 200; the fact that Ranbaxy was collaborating with Medicines for Malaria Ventures might be negatively affected by an acquisition in its interest in Type II and Type III diseases)

### ***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 structure and operating objectives and principles 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 Charter of the United Nations with 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 seen by Lord Halifax of the United Kingdom, the United Nations Charter preferred to lay down purposes and principles which gave “freedom to accommodate actions to circumstances which no one today can foresee.”<sup>116</sup> In his words, the hope was to create “an organic body which will have within itself the seeds of a vigorous life, and so may grow into the great society of nations which, throughout the centuries, men and women have dreamed, and which in our own times, please God, may bring healing and hope to a wounded world.”<sup>117</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 agreement 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>118</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>119</sup> These declared objectives and principles of TRIPS have been essentially undermined by the structural organizing scheme of TRIPS which does not permit structural changes but 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 debilitating crisis in the U.S. financial markets has raised legitimate questions about placing unrestrained faith in the self-regulating powers of markets.<sup>120</sup> The

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<sup>116</sup> GOODRICH, HAMBRO, & SIMONS, CHARTER OF THE UNITED NATIONS, *supra* note 10, at 24.

<sup>117</sup> *Id.*

<sup>118</sup> Article 7 of TRIPS states that the protection of intellectual property rights *should contribute to the promotion of technological innovation and the transfer and dissemination of technology...* (emphasis added).

<sup>119</sup> Article 8 (1) of TRIPS authorizes member states in their implementation of TRIPS through their laws and regulations to adopt measures necessary to protect public health and nutrition and to promote the public interest. *provided they are consistent with the provisions of this Agreement.*” (emphasis added).

<sup>120</sup> In a fascinating and accessible read Michael P Malloy provides a lucid biographical analysis of the U.S. mortgage crises and the meltdown process. *See*. MICHAEL P. MALLOY, ANATOMY OF A MELTDOWN: A

responsibility of the state to achieve the lofty 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 has several strengths and responsibilities; one of them is not the obligatory pursuit of the public good as its primary goal. Yet, TRIPS seems to assume that private profit making entities would allocate their R&D resources to the study of all diseases with significant public health implications particularly in developing countries. Notwithstanding the evidence of the substantial public expenditures in health research by developed countries, market principles seem to dictate the structure and substance of TRIPS on this question. Moreover, the explicit assumption in Article 7 that technological innovations would be shared as a result of TRIPS has proved to be a distant *fading* hope. The benefits sharing provisions of the Biodiversity Convention reinforce this conclusion.<sup>121</sup>

Second, TRIPS exhibits unfortunate blind spots and contradictions in its philosophical belief in the organizing and self correcting powers of markets in matters of such global social, cultural and political complexity as sovereignty over health policy. Paradoxically, TRIPS relies substantially on private enterprises to address the health needs of developing countries through innovation but failed to take into account the role of profitable markets in innovation. 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 variants of the incentive theory such as the transaction function, the disclosure and the signaling function all seem to hinge on the profitability of innovations.<sup>122</sup> Poor developing countries with low purchasing power do not provide the type of markets that would spur R&D and innovation for their diseases. 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

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DUAL FINANCIAL BIOGRAPHY OF THE MORTGAGE CRISIS (2010) at 7 (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).

<sup>121</sup> Article 15 (7) Of the Biodiversity Convention requires Contracting Parties to take legislative, administrative or policy measures ..in accordance with Article 16 and 19 and where necessary..Articles 20 and 21 for 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. Such sharing shall be on mutually agreed upon terms. Article 16 as whole continues to cover the benefits sharing but appears more targeted at achieving conservation and sustainable use of biological resources. 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>122</sup> WHO *Commission on Public Health* *supra* note 41, at 19-21 ( explaining the transaction function as necessary condition for markets of certain specialized technologies, the disclosure function allows the disclosure of technology which would otherwise be kept as trade secrets and the signaling function relates to the ability of patentees to raise capital because of their innovative capabilities). .

enforceable intellectual property protection system and trade is the incentive theory of innovation. TRIPS, similar to the intellectual property regimes of developed countries, start from the premise that the protection of intellectual property rights would be a catalyst for innovation particularly in the area of health products and technology for all. 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, it 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>123</sup> TRIPs did not arrive in 15<sup>th</sup> century Venice or 19<sup>th</sup> century Europe when the global diffusion and accessibility of information was much more limited. In a world of shrinking information and ideas gap, structural and substantive flexibility in TRIPS should have been achieved. 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 indispensable 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>124</sup> In his view, as human beings evolved beyond the hunting and gathering stage to food production the conditions were created for specialization and innovation.<sup>125</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 link between creativity and exclusive rights in ideas.<sup>126</sup> Moreover, any familiarity with the history of metallurgy, alchemy and other tremendous inventive activities in archaic societies should lead one to question the necessary link between

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<sup>123</sup>For an instructive discussion of 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* (2006)(hereinafter, ANDREASEN, *CREATIVE BRAIN*) at 127-135 (discussing the raw gift of genius or creativity, the type of environment that fosters creativity and the plasticity of the human brain).

<sup>124</sup> JARED DIAMOND, *GUNS, GERMS, AND STEEL*, (1997)(hereinafter, DIAMOND, *GUNS, GERMS*) at 83

<sup>125</sup> *Id.* at..

<sup>126</sup> ANDREASEN, *CREATIVE BRAIN*, *id.* at 146 (explaining the neuroscience of the plasticity of the brain as marvelously responsive, adaptable, generally changing in response to the demands and pressures of the environment it encounters; neuroscience makes us aware of the complexity of the brain and our ability to remake the brain through who we are, our actions, awareness, reactions, perceptions, postures and posture every minute of the day and so on); apparently the brain is a self-organizing organism, totally flexible and does not seem to understand exclusivity or monopoly of ideas and experience.

protection of intellectual property rights and the incentive to innovate.<sup>127</sup> Time and space considerations do not permit the type of analysis this topic deserves here. Suffice it to mention that the inventiveness and creativity of our ancient ancestors in Egypt, China, Persia, India, the Mayans, Greece, Rome and Benin in Nigeria, just to mention a few, achieved unparalleled levels of success without an intellectual property regime.<sup>128</sup> After the initial limited appearance of the patent system in Venice about between 1474 and 1550,<sup>129</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>130</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 commonweal.<sup>131</sup> How then could the framers of TRIPS have missed this rich history which demonstrates the need to subjugate private interest for the common good? Or, being conscious of that history, they unfortunately chose the wrong instrument as a remedy.

#### 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 the issue of whether under international law there is a fundamental right of sovereign states to trade. The second relates to the 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. We shall examine them separately and briefly below.

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<sup>127</sup> The history of alchemy across cultures and over time is shrouded with the spiritual relationship between artisan, the supernatural natural and nature in which human 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*, (1962)(hereinafter, ELIADE, *FORGE AND CRUCIBLE*.) at 50 -52 (explaining that gold is the only legitimate child Nature desires and the alchemist only accelerates that process as supported by ancient Chinese text of 122 B.C.; the h\Huai-nan-tsu; and 53 a chapter devoted to explaining spiritual dimensions of metallurgy and alchemy from ancient China, Africa, Europe and other regions of the world).

<sup>128</sup> DIAMOND, *GUNS, GERMS*, *supra* note 125, in chapter 12 at 215 (where Diamond alludes to this phenomenon in his discussion of the origins of writing).

<sup>129</sup> PENROSE, *INTERNATIONAL PATENT SYSTEM* *supra* note 4, at 2.

<sup>130</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 industrialist, manufacturers and engineers pushing for better patent protection, noting in particular that the conflict in Germany was intense).

<sup>131</sup> *Id.* at 4-6 (arguing that under the Elizabethan patent system there 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).

### ***The Fundamental Rights under International Law of States to Trade***

The question of whether under international law there is a fundamental right of states to trade is of great importance in international trade jurisprudence. In negotiating for the inclusion of TRIPS the U.S. tactically avoided this question.<sup>132</sup> Nevertheless, the answer to this question should have been a prerequisite to and informed the structure and substantive operating provisions of TRIPS particularly in matters relating to human health and food security. For, 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 some reasonable or rational basis for modifications. If so, under what circumstance might trade involving them be interfered with? Claims that Article 30 of TRIPS offers an escape valve for WTO member states appears to be only a feeble response to the requirements of such a fundamental right.<sup>133</sup> Under the EU Treaty the right to trade is so firmly established that intellectual property rights are conditioned by the free movement of goods and services provisions.<sup>134</sup> The same cannot be said of TRIPS provisions. Under TRIPS the protection of intellectual property rights is firmly established. Article 30 is but a limited qualification of that 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. It is the subject of a separate endeavor. 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 the FAO and the WHO. Moreover, human exchange in goods and services seem to be as old as organized society. 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 are examples of this phenomenon.<sup>135</sup>

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<sup>132</sup> Gadbar & Gwynn, *Intellectual Property Rights*, *supra* note 9, at 41-44.

<sup>133</sup> GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS *supra* note 44, at 379-383( commenting on Article 30).

<sup>134</sup> Treaty Establishing the European Economic Community (EEC), March 25, 1957, 298 UNTS 11, 4 Eur. Y. B. 412, (Treaty of Rome) as amended Treaties Establishing the European Communities (EC Off'l Pub. Office, 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. A long line of European Court of Justice jurisprudence has emerged from an interpretation of these provisions within the context the free movement principles.

<sup>135</sup> For a discussion of the problems faced European countries in using the old trade routes to the Far East, *see*, DIFFIE and GEORGE D. WINIUS, FOUNDATIONS OF THE PORTUGUESE EMPIRE 1415-1580 (1977)(hereinafter, DIFFIE & WINIUS FOUNDATIONS OF THE PORTUGUESE EMPIRE) at 195-209 (discussion the problems posed by the Muslims to East-West trade and the national determination to address the problem which affected not just Spain and Portugal but also Venice and other Italian city States); F. AGBODEKA THE RISE OF THE NATION STATE, A HISTORY OF WEST AFRICAN PEOPLES 1800-1964, (1965)(hereinafter,

The right and expectations of nations to engage in international trade triggered political conflict and serious diplomatic exchange and protests following the Papal Bulls of the 15<sup>th</sup> century which granted exclusive trading rights to specific Christian nations of Europe such as Spain and Portugal,<sup>136</sup> latter followed by the partition of Africa in the Berlin Conference of 1883/1884.<sup>137</sup> The struggle among nations over the right to trade in goods and services seems to have been one of the root causes of the Second World War.<sup>138</sup> The negotiations leading to the ITO and the formation of the GATT were a direct

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ABODEKA, RISE OF THE NATION STATE) 5-6 (describing briefly the trans-Saharan trade in gold); Nehemia Levtzion, *The Early States of the Western Sudan*, in HISTORY OF WEST AFRICA VOLUME ONE (2d edition, J.F. A. Ajayi and Micahel Crowder ed. 1976) at 114-118 (explaining the rise and fame of ancient Ghana reaching as far as Baghdad and the rise of the trans-Saharan trade with the introduction of the camel; with the Arab conquest of the region with arrival of Islam accelerated the trans-Saharan trade); For a description of the *kula* see BRANISLAW MALINOWSKI, ARGONAUTS OF WESTERN PACIFIC (1922) at 83 (in a chapter describing in detail the essentials of the *kula*); Kojo Yelapaala, *Legal Consciousness and Contractual Obligations* 39 MCGEORGE L. REV. 193 (2008) at 236-241 (discussing the nature of contractual obligations from the perspective of anthropology).

<sup>136</sup> By the Papal Bull of June 18, 1455, *Dum Diversa*, Pope Nicolas V gave the Kings of Spain and 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, as well as their kingdoms, duchies, counties, principalities, and other property..and to reduce their persons into perpetual slavery, This was followed and reiterated by the bull *Esti Cuncti* of 1456 by Pope Calixtus III and others in particular the papal bull of May 4, 1493, *Inter Caetera*, Pope Alexander VI, a citizen of Valencia, which among other things following the discoveries of Columbus gave the King Ferdinand and Queen Isabella of Castille, Leon, Aragon, Sicily and Granada and their successors exclusive right to lands discovered and to be discovered under the penalty of excommunication of any violators. The bull contained very language against violators promising the incurring of the wrath of Almighty God and the blessed apostles Peter and Paul. For a discussion of the papal bulls see, HENRY HARRISSE, DISCOVERY OF NORTH AMERICA, CRITICAL, DOCUMENTARY, AND HISTORIC INVESTIGATION (1892) at 55-56 (explaining the diplomatic maneuvering between Portugal and Spain that followed because of vagueness in the bull). Apparently there were two papal bulls *Inter Caetera*, the first issued on 3 May, 1493 containing the statement “no rights conferred on any Christian Prince is hereby understood as withdrawn or to be withdrawn” the ambiguity in this statement led to the second on 4 May, 1493 worded differently by Pope Alexander VI. See, DIFFIE & WINIUS FOUNDATIONS OF THE PORTUGUESE EMPIRE, *supra* note 136, at 173-174 (explaining that the second bull made a fundamental change in the division of territories between Portugal and Spain. It set a line one hundred leagues west of either the Azores or Cape VERDE Islands, thus imposing a limitation on Spain not in either of the other bulls leading to negotiations and the Treaty of Tordesillas, June 7, 1494.) However, the part of the driving force behind the papal bulls was the rivalry and warfare over trade between Portugal, and Italian cities and Pope Nicolas V and advances made by the Turks.) at 108; for further discussion of the role of the papal bulls and Portuguese and Spanish explorations along the West Coast of Africa see, JOHN DOS PASSOS, THE PORTUGAL STORY: THREE CENTURIES OF EXPLORATION AND DISCOVERY (1969) at 162 (arguing Pope Alexander issued three successive papal bulls each setting narrower limits to Portuguese claims to return a favor owed to the Spanish King and Queen for supporting his elevation to the papacy), and at 172 (Kin John of Portugal after the Treaty of Tordesillas 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).

<sup>137</sup> For a discussion of the partition of Africa see, ABODEKA, RISE OF THE NATION *supra* note 136, at 71-74 (explaining the rivalry between European powers, King Leopold, Germany, France Britain which took place not only in Europe but also on the Continent precipitated the Berlin Conference for the partition of Africa).

<sup>138</sup> JACKSON, INTERNATIONAL ECONOMIC RELATIONS, *supra* note 4, at 396 (explaining that one aspect

response to the need to reaffirm this right in very concrete terms. 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. It did so without sufficient consideration and safeguards for the type of trade involved nor the type of intellectual property to be protected. It is well established that certain fundamental rights protected under domestic constitutions and international conventions involve trade. 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 several working groups.<sup>139</sup> Even then the adherence to 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>140</sup> The same fear of loss of sovereignty led to the disapproval of the Havana Charter by the U.S. Congress.<sup>141</sup> If the preservation of sovereignty was so important to the U.S. why was it not extended to all 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>142</sup> Such a distortion seems to have been the purpose of Article XX (d) of the GATT. Similarly, Chile argued for a bifurcation of the process in which any corrections of the Paris Union and the Berne Convention should remain in the domain of WIPO.<sup>143</sup> Other developing countries, concerned about over protection and denial of access to technology argued for an approach generally referred to as Paris-Plus and Berne-Plus.<sup>144</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 were the restrictions imposed on trade in essential products and technology pertaining to health and food challenged on that basis.

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of American policy recognized the role international economic relations as a cause of World War II and wanted to prevent the reoccurrence of these events); DAM, THE GATT, *supra* note 3, at 12 (In footnote 5 quoting a statement of the philosophy of Secretary of State Hull on the essential relationship between war and peace and non-discriminatory free trade: I have never faltered, and I will never falter, in my belief that enduring peace and welfare of nations are indissolubly with friendliness, fairness, equality and the maximum practicable degree of freedom in international trade” citing *Economic Barriers to Peace* ( New York: Woodrow Wilson Foundation, 1937 at p. 14). .

<sup>139</sup> GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS , *supra* note 44, at 12 (stating that there were 14 separate negotiating groups established including a group on TRIPS)..

<sup>140</sup> *Id.* at 4.

<sup>141</sup> DAM, THE GATT, *supra* note 3, at 14 ( rejection by the U.S. Congress of the Havana Charter).

<sup>142</sup> GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS ,*supra* note 44, at 14-19.

<sup>143</sup> *Id.* at 17.

<sup>144</sup> *Id.* at 4



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

The second fundamental question which also seems to have escaped the explicit examination of the framers of TRIPS is perhaps, even more troublesome. It concerns the origins of ideas. Implicit in the structure and operating premises 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>145</sup> The debates and submissions by countries leading up to the adoption of TRIPS suggest that there was significant subconscious and justifiable unease about the implications of these operating premises upon which international trade henceforth would be hinged.<sup>146</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>147</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 trade distortion or produce the least but necessary distortion.<sup>148</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>149</sup> Even then

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<sup>145</sup> Gadbar & Gwynn, *Intellectual Property Rights*, *supra* note 9.

<sup>146</sup> *see*, GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS, *supra* note, 44, at 16-19 (Submissions by groups of developing countries suggest at least a subconscious awareness of this problem).

<sup>147</sup> Article 64 of TRIPS incorporates the GATT dispute settlement provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied to TRIPS. For a commentary *see*, GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS, *supra* note 44, at 506-515.

<sup>148</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 to the point of divergence; he suggests a hierarchy of policy choices from the first-best to the second best and so on. *See*, W. M. CORDEN TRADE POLICY AND ECONOMIC WELFARE, (1974)(hereinafter, CORDEN, TRADE POLICY) at 28. In a discussion of whether tariffs constitute the first-best policy for income redistribution he argues that tariffs might fit this model, the use of income taxes on subsidies might best suit income redistribution for social welfare purposes, at 109. The argument is that tariffs for income redistribution does not get to the source of the problem but would distort trade.

<sup>149</sup> ACG on its Home page provides the following summary of counterfeiting in an article, *Statistics on Counterfeiting and Piracy*, the estimated cost of counterfeits to the U.S. by the U.S. Trade Commission in 1982 was \$5.5 billion, just two years later in 1984 the International Anti-Counterfeiting Coalition estimated

that evidence clearly indicates that counterfeit goods originate from very few countries and constitute but a very small fraction of global trade.<sup>150</sup> In a more sophisticated analysis the OECD reported that counterfeit products could have been about \$200 billion in 2005 but estimated the growth rates of intangible products between 2000 and 2005 to be 1.85% and 1.95% of world trade.<sup>151</sup> The estimates by type of product have a similar characteristic. All these estimates constitute but a small percentage of the estimated \$12.178 trillion of global merchandise trade in 2009<sup>152</sup> To impose such a rigid system on all countries for the relatively minor sins of a few seems to violate all principles of equity and fairness. Poor countries without the capacity for counterfeiting are called upon to

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the value of counterfeits sold at \$60 billion, in 1986 the estimates stood at \$62 billion and by 1994 it reached \$200 billion; 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 this estimated was not based on accurate statistics to support this perception but concluded that these figures are now accepted, OECD, *The Economic Impact of Counterfeiting*, (1998)(hereinafter, OECD, *Impact of Counterfeiting*) at 23; for the origins of counterfeit goods the study identified 10 countries none of which falls into the world's poorest countries, at 18- 21; Gadbar & Richards, *Introduction*, in GADBAR & RICHARDS, INTELLECTUAL PROPERTY RIGHTS, *supra* note 9, at 12, 23 (estimating the value of pirated products generally and by country of origin for 1986 to be in millions of dollars; Jane H. Maclaughlin, Timothy J. Richards, and Leigh A. Kenny, *The Economics of Piracy*, in GADBAR & RICHARDS, INTELLECTUAL PROPERTY RIGHTS, *supra* note 9, at 89 & 94-98 (indicating the levels of piracy in 1982 in various industries to be in low millions of dollars from a few countries); OECD, *The Economic Impact of Counterfeiting*, (1998) at 10 ( estimating the sales of pirated products in the music industry in 1996 from a few priority countries also in the millions of dollars; the report also examined the sales levels for other industries); PRODUCT COUNTERFEITING: HOW FAKES ARE UNDERMINING U.S. JOBS, INNOVATION AND CONSUMER SAFETY, (HEARING BEFORE THE SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION OF THE COMMITTEE ON ENERGY AND COMMERCE, HOUSE OF REPRESENTATIVES, ONE HUNDRED NINTH CONGRESS FIRST SESSION, (JUNE, 25, 2005, No. 109-26, U.S. GOVERNMENT PRINTING OFFICE WASHINGTON: 2005)(hereinafter, SUBCOMMITTEE ON COMMERCE HEARINGS, 2005) at 2 (estimating the increase of in the value of pirated products from \$5.5 billion to \$600 billion between 1982 and 2005).

<sup>150</sup> See, Maclaughlin, Richards, and Kenny, *The Economics of Piracy*, *id* at 89 at 94-98 (indicating the levels of piracy in 1982 in various industries to be from a few countries); OECD, *The Economic Impact of Counterfeiting*, *id* at 10 ( estimating the sales of pirated products in the music industry in 1996 from a few priority countries); SUBCOMMITTEE ON COMMERCE HEARINGS, 2005 *id* at 2 (reporting that over 60% of the goods seized by the U.S. Customs originated from China); ASIAN BUSINESS COUNCIL, *Intellectual Property Rights: A Survey of Major Issues*, (A Report for the Asian Business Council by Minxin Pei, Carnegie Endowment for International Peace, September 2005) at 2 ( identified 8 countries: China, Russia, Brazil, Mexico, Italy, South Korea, Canada and India as countries placed on the U.S. Special 301 priority list for pirated copyright materials); however WHO estimated that 10% of all pharmaceuticals sold worldwide are counterfeited, in some developing countries counterfeit pharmaceuticals account for over 60% of all drugs sold) *id*.

<sup>151</sup> OECD, MAGNITUDE OF COUNTERFEITING AND PIRACY OF INTANGIBLE PRODUCTS: AN UPDATE, (November 2009)

<sup>152</sup> WTO, World Trade Developments, International Trade Statistics, 2010, at 10, Table 1.4; The insignificance of counterfeiting in global trade goes back to the decades of the 1980s when the debate over linkage intellectual protection to international trade to curb counterfeiting had just started. In 1983 world merchandise trade stood at almost two trillion (\$1, 882); in 1993 it was \$ 3,786, in 2003, it stood at \$7,689 and in 2009, at \$12,421. at 12, Table 1.7.

answer for the deeds of a few for the benefits of yet another few.<sup>153</sup> The fact that the U.S. and Japan supported by the EU 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>154</sup> Moreover, the EU stated what appears to have been the real reason for TRIPS a position held by the U.S.: to help technologically advanced states maintain their technological competitive edge.<sup>155</sup> Certainly, technological competitiveness has but an indirect impact on trade and hardly offers the first best solution to the free flow of goods and services sought to be addressed by TRIPS. 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>156</sup>

In any case, the very notion of attaching a national identity or territorial origins to something as ephemeral as an idea however expressed 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>157</sup> To assign an unmistakable national origin to ideas is such a bold assumption, explicit or

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<sup>153</sup> *Supra* notes.... confirm the small number of countries involved in counterfeiting

<sup>154</sup> THE ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA)—SUMMARY OF KEY ELEMENTS UNDER DISCUSSION, November 6, 20009(outlining the purpose of ACTA, its initiating members and basic structure); THE ANTI-COUNTERFEITING AGREEMENT, 3 December 2010, Open for signature by participating member and other WTO members from March 31, 2010 to March 31, 2013 and will come into force This Agreement shall enter 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..

<sup>155</sup> EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR TRADE; INTELLECUAL, at 1 <http://ec.eu/trade/creating-opportunities/trade-topics/intellectual-property/> visited 12/7/2010. PRODUCT COUNTERFEITING: HOW FAKES ARE UNDERMINING U.S. JOBS, INNOVATION, AND CONSUMER SAFETY, HEARING, Before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce House of Representatives, One Hundred Ninth Congress, first Session, June 25, 2005, Serial No. 109-206, (hereinafter U.S. PRODUCT COUNTERFEITING HEARING 2005) Hon. Cliff Stearns, Chair (presiding) opened the hearing by outlining the disturbing nature of counterfeiting and what at stake for the U.S. economy and consumer. In his opening remarks said: “My concern today is about how fakes are robbing our U.S. companies of hard earned intellectual property and ingenuity that they own and need to compete globally.” at 2, his language appeared even stronger as to the purpose behind the anti-counterfeiting measures of the U.S. He said: As I said at last week’s hearing...Intellectual Property Rights (IPR) are critical to the U.S. economy and its engine of innovation. The fortress around our ingenuity, technological leadership, and creativity is the rule of law. As we will hear today, it is time to ensure that our laws are as robust as they can be, they 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.” at 4; Gadbar & Richards, *Intellectual Property supra* note 9, at 41 (arguing that the purpose of introducing intellectual property rights in the GATT negotiations was to maintain U.S. competitive advantage).

<sup>156</sup> ACTA AGREEMENT, 3 December 2010 (the preamble recognizes the health issues in TRIPS in the following words.....

<sup>157</sup> DIAMOND, GUNS, GERMS *supra* note 125, at 254, 259-261; ELIADE, FORGE AND CRUCIBLE, *supra* note 126( the lesson of this work is the simultaneous, sequential and multi cultural and geographically dispersed the phenomenon of metallurgy in history).

implicit, staring into the glaring eyes of doubt. The moral from the Ghanaian Akan Ananse origin myth teaches us that knowledge or ideas are in the air we breathe from the moment of birth.<sup>158</sup> Ideas are therefore highly diffusible, floating in the air, as it were, in the winds and no respecters of territorial boundaries and national political demarcations. They can be exploited simultaneously by every one without depletion; the prototypical public good that does not suffer from an over use or contagion.<sup>159</sup> Moreover, studies of the evolution of human creativity demonstrate that some of the most famous inventions which have changed the technological landscape of the world were the result of borrowing and sharing of ideas across cultures and nations.<sup>160</sup> Throughout history, technological giants such as James Watt and Thomas Edison stood on the shoulders of others without regard to geography, culture or nationality.<sup>161</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>162</sup> How then can one with any degree of certainty assign 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 or worldwide web which has created a single and simultaneous information system through which ideas float across territorial boundaries with little or no restrictions.

A powerful insight captured in the famous Arrow's paradox is the fleeting and intractable nature of this phenomenon of ideas however expressed.<sup>163</sup> There is little

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<sup>158</sup> According to a well known Akan of Ghana 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 them in a gourd which 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 on the ground and the knowledge in it evaporated into the air we breathe from the moment we are born. 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 one thing less susceptible than all others of exclusive property, it is the action of thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself;" See, *The Writings of Thomas Jefferson*. Edited by Andrew A. Lipscomb and Albert Ellery Bergh, 20 Vols. Washington: Jefferson Memorial Library Association, 1095; provided in The Founder's Constitution, Volume 3, Article 1, Section 8. Document 12, [http://press-pubs.uchicago.edu/founders/documents/a\\_1\\_8\\_8s\\_12.html](http://press-pubs.uchicago.edu/founders/documents/a_1_8_8s_12.html), The University of Chicago Press (1987). ,

<sup>159</sup> See, ANTHONY B. ATKINSON, JOSEPH E. STIGLITZ, LECTURES ON PUBLIC ECONOMICS (1980) at 482-486 provide an extensive discussion of public goods. They 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); or national defence." at 484.

<sup>160</sup> DIAMOND, GUNS, GERMS, *supra* note 125, at 242-245.

<sup>161</sup> *Id.* at 242-245.

<sup>162</sup> *Id.* at 125-128.

<sup>163</sup> The nature of the general market failure of information markets and the difficulty transacting business in them has been the subject of investigation by economists. For example, see KENNETH S.

debate, if any, over these characteristics of ideas. The implicit assumption of national origin of ideas upon which TRIPS was constructed therefore appears flawed. Indeed, one can argue that linking the right to engage in international trade to the protection of foreign origin ideas is not only unprecedented in human history but perhaps also of doubtful legality and certainly bad global trade policy; particularly when it comes without sufficient safeguards for trade in the essentials to life and living. 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 the country of origin of the constituent ideas synthesized or crystallized? Take for an example, a French scientist who has been studying the DNA structures and biochemical composition of prostitutes in three African countries resistant to HIV/AIDS on vacation in Yosemite in the U.S. Watching the sun rise over the waterfall of the Dome he was suddenly inspired to pull together all the scientific and chemical pieces for an effective AIDS vaccine on a napkin. What would be the national origin of that breakthrough, the U.S., the African countries where he was researching or France his country of nationality? The answer to this question is neither obvious nor suggest itself. It is therefore hardly surprising the U.S. suggestion of the country of first to invent was rejected during the TRIPS negotiations.<sup>164</sup> Moreover, under TRIPS countries and indigenous cultures with useful traditional knowledge or ideas but without the 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 yet another complex system of international trade. The magnitude of that error is glaring given the explicit EU and U.S. goal of maintaining the technology gap<sup>165</sup> between the haves and the have-nots which virtually guarantees 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>166</sup> The concentration of power in the WTO is widely inconsistent with current global good governance modalities which call for checks and balances on the exercise of power. This is more so when intellectual property rights are not directly trade related but affect the health, safety and food needs of humanity.

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

As demonstrated in the proceeding section, the quality of the structure and substance

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ARROW, *ESSAYS IN THE THEORY OF RISK BEARING*, 150-156 (1971). (The author discussed the peculiar attributes of information markets that make them susceptible to imperfections and the difficulties of adopting appropriate pricing policies for contracts involving information). MARK CASSON, *ALTERNATIVES TO THE MULTINATIONAL ENTERPRISE* 36-38 (1979) [hereinafter *ALTERNATIVES TO MULTINATIONALS*] (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).

<sup>164</sup> *see*, GERVAIS, *TRIPS DRAFTING HISTORY AND ANALYSIS*, *supra* note 44, at 338.

<sup>165</sup> *See*, EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR TRADE; *INTELLECUAL* *supra* note 156; U.S. PRODUCT COUNTERFEITING HEARING 2005, *supra* note 156.

<sup>166</sup> GERVAIS, *TRIPS DRAFTING HISTORY AND ANALYSIS*, *supra* note 44, at 17.

of a complex international agreement depends in large measure on its operating premises and assumptions. The substantive provisions of TRIPS have been the subject of extensive literature and for that reason shall not detain us here. The goal of this section is to explore briefly how the structural defects of TRIPS interplay with its substantive provisions to magnify the risks to human health and food security.

Standardized structures in agreements are often simultaneously 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 which determines access to and enjoyment of substantive rights. Rigid and unfriendly procedural hurdles may render otherwise meaningful substantive rights inaccessible to the most needy. The so-called TRIPS flexibilities may well fall into this category. Inflexible structural and substantive provisions make agreements less easily responsive to future unfolding 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 a 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 were left as sovereign political choices reflective of each nation's values, needs and the protection of the public interest. Almost with a single stroke, TRIPS has changed the landscape in all these areas.

### **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 it is new, involves an inventive step and is capable of industrial application.<sup>167</sup>

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<sup>167</sup> see, GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS, *supra* note 44, at 343-345( discussing the complexity of the concept “*ordre public*” as used in Article 27 of TRIPS. It does not equate with the English term “public policy” it seems to conform more to the French term “*bonnes mœurs*”); Rainer Moufang, *The Concept of “Ordre Public” and Morality*, in PATENT LAW, ETHIC AND BIOTECHNOLOGY (Geertrui Van Overwalle (ed. 1998) at 69; Kojo Yelapaala, *Owning the Secrets of Life: Biotechnology and Property Rights Revisited*, 32 MCGEORGE L. REV. 111,(2000)(hereinafter, Yelapaala. *Owning the Secrets of Life*)at 200-210 (discussing the concept of public policy under U.S. patent system and suggesting ways to address patentability of biotechnological inventions under a revised patent regime).

These technical 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 the invention or the type of technology.<sup>168</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>169</sup> Article 39 protection extends to pharmaceutical data thereby denying access to generic drug manufacturers to such data and delaying the introduction of generics.

The prescription of a mandatory regime of the subject matter of 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>170</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 of a “harmless” exploitable invention with the purpose of making it widely available on public health and food security grounds. However, we have argued elsewhere that certain subject matters or inventions may be of such significant utility to humanity with respect to life and living to justify exclusion from patentability.<sup>171</sup> Patentability is denied not because they pose a threat to humanity but rather precisely because they are essential to maintaining health or sustaining life. A state may reasonably conclude that in the public interest such inventions should not be patentable so that they can be exploitable by any and all for the public good.<sup>172</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 sought to be addressed by WTO General Council Declaration might have been eliminated. Any risks associated with the retention of sovereignty by WTO members in this area could have been addressed with certain checks and balances. Unfortunately, absent a complete overhaul, the door to such a solution appears permanently shut under the current TRIPS regime.

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<sup>168</sup>The primary provisions in TRIPS dealing directly with the issue of discrimination are Articles 3 (National Treatment) and Article 4 (the Most Favored Nation Treatment). 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. 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 the latter does not. See, GERVAIS, DRAFTING HISTORY AND ANALYSIS, *supra* note 44 at 357-359.

<sup>169</sup> See, TRIPS, Article 39, dealing with the protection of undisclosed information.

<sup>170</sup> Article 27 (2) providing for an exemptions of patentable subject matter including *ordre public*. Yelapaala, *Owning the Secrets of Life* *supra* note 168, at 200-210, proposing Norm 3 for framing an extensive discussion of public policy as larger concept than is provided for in Article 27(2) of TRIPS).

<sup>171</sup> Yelapaala, *Owning the Secrets of Life* *id.* at 196 (suggesting three norms for governing patentability; Norm 2 states: that which can be owned may nevertheless not patentable. By it a deliberate policy choice may be made to put certain useful patentable inventions in the public domain to achieve some public policy objectives).

<sup>172</sup> *Id*

Second, the loss of sovereignty over the subject matter of patents is also significant in the context of 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 the patent regime.<sup>173</sup> Indeed, pharmaceutical inventions were not patentable in Italy until 1978<sup>174</sup>. The evidence does not show that innovation came to a halt. The pharmaceutical industry has always been a highly concentrated and resilient oligopoly with significant technical and financial entry barriers providing them with a protective shield.<sup>175</sup> They hardly needed the doubly fortified shield of Zeus provided by TRIPS. Moreover, the subject of what constitutes property is imbued with such deep and cultural sensibilities demanding some room for variation across cultures. Relative to the whole world, the EU is a small geographic and less diverse cultural 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>176</sup> Besides, as discussed above,

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<sup>173</sup> WHO & WTO, *WTO Agreements & Public Health*, *supra*, note 22, at 42.

<sup>174</sup> In *Merck & Co Inc v Stephar BV and Stephanus Exler* case 187/80 (1981) involved 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 the question of patentee in the Netherlands could rely on national patent legislation and Article 36 to prevent the importation by a third of pharmaceutical it manufactured under its patent and distributed in Italy where pharmaceutical patents were prohibited by Italian statute. The Court in reciting the facts described the context of the Italian law in the following passage: “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 Costituzionale (Constitutional Court) delivered on 20 March 1978 - prohibited the grant of patents for drugs and their manufacturing processes.” Par 2.

<sup>175</sup> See, Peter Drahos and John Braithwaite, *Intellectual Property, Corporate Strategy, Globalization: TRIPS in Context*, 20 WIS. INT’L L. J. 451 (2001-2002) at 463-467 (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 from cases the abuse of dominant position cases in the EU and the monopolization cases in the U.S.. For the EU See, *Europemballage and Continental Can v Commission* [1973] E.C.R. 215 where the Commission described the hallmarks of dominant position in the following words: “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.” This was endorsed by the Court. at 257. Although this case did not involve pharmaceuticals it was followed in *Hoffman-La Roche v Commission*, case 85/76 [1979] E.C.R. 467 at case dealing with the distribution of pharmaceutical products. See also *United Brands Company v Commission*, Case 27/76 [1978] E.C.R. 207 where the court followed the same line of reasoning involving the distribution of bananas. For an example of U.S. monopolization cases see, *United States v United Shoe Machinery Corp.* 110 F. Supp. 295 (D. Mass. 1953), *Affirmed per Curiam*, 347 U.S. 521 (1954) *Machines ... where the U.S. Supreme Court discussed monopoly power by looking not only at market share but also at the financial and other resources United Machinery commanded as a corporation.*

<sup>176</sup> Article 222 of Treaty of Rome Article stated as follows: “This Treaty shall in no way prejudice the



Article 36 of the same treaty which recognized the protection of industrial and commercial property rights has been interpreted as being subservient to the free movement provisions of the treaty.<sup>177</sup> The Paris Union did not see it fit to impose a mandatory system of rights in patents on its members. It is hard to find any compelling justifications for a delivered mandatory system of rights in TRIPS given the complexity and importance of the subject to economic development. Assuming a compelling justification for such a standardized and universal system, would prudence not have counseled for an exception in areas of such importance to humanity as public health and food security? Apparently, the light of wisdom shone on a different subject: and in its shadow, the subjugation of the public interest to that of foreign private interests received greater attention.

### **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>178</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 nationality provisions of the Paris Union prohibits nationality based discrimination.<sup>179</sup> However, for the first time, Article 4 introduces the most favored nation (MFN) treatment generally used in international trade agreements into an international intellectual property protection agreement.<sup>180</sup> This is unprecedented and carries with it serious implications.

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rules in Member States governing the system of property ownership.” See also Beier & Schrickter, ... at 170-175

<sup>177</sup> In Case 15/74 *Centrafarm BV and Adriaan De Peijper v Sterling Drugs Inc.* [1974] E.C.R. 117, the European Court of Justice interpreted the scope of Article 36 as applied to patents to be limited to the specific subject matter of patents, which is which is the guarantee to the patent to use the invention to manufacture the industrial products and put them into circulation either directly or through a licensee for the first time, Par 8-9. As the Court reasoned to hold otherwise would permit the patentee to partition markets and undermine one of the fundamental principles of the Treaty of creating a single market through the free movement of goods. For a discussion of this ingenious interpretation of Article 36, see, DERRICK WYATT and ALLAN DASHWOOD, *EUROPEAN COMMUNITY LAW*, (3<sup>rd</sup> Ed. 1993) at 576.

<sup>178</sup> Article 28 (1) confers exclusive rights where the subject a product, the right to prevent third parties without the owner’s permission from making, using, offering for sale, selling, or importing for these purposes. In the case of process patents Article 28 (2) provides similar rights.

<sup>179</sup> Article 3 mandates the national treatment formerly part of the Paris Union.

<sup>180</sup> In an unprecedented move, Article 4 introduced the Most Favored Nation (MFN) treatment in TRIPS by providing that “with regard to the protection of intellectual property, *any advantage, favor, privilege or immunity granted by a Member to the nationals of any other country* shall be accorded immediately and unconditionally to the nationals of all other Members” emphasis added). Reactions to the MFN have been varied; GERVAIS, *THE TRIPS AGREEMENT*, *supra* note 44, at 189 (argues that it was a novelty with limited initial impact because of the exemptions provided within Article 4); CORREA, *COMMENTARY ON THE TRIPS AGREEMENT*, *supra* note 31, at 66 (puts it rather mildly by arguing that the principle was absent from pre-TRIPS conventions); DE CARVALHO, *TRIPS PATENT RIGHTS*, *supra* note 31, at 161 (arguing

Besides, paradoxically, even under a system of standardized rights, TRIPS managed to retain the old territorial independence of patents issued by member states.<sup>181</sup> Moreover, the mandatory rights conferred by TRIPS are considered minimum rights. The skeptics may ask why these rights and obligations? Certainly, beyond the mandated minimum protection, member states may independently grant more rights and protections. Combined together these provisions provide a gaping loophole for expanding rights beyond the minimum through bilateral arrangements now expressed in what is generally called TRIPS Plus agreements often detrimental to the public health and food security of developing countries caught in such schemes.<sup>182</sup> The introduction of the MNF and retention of the 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 that long standing objective in TRIPS.<sup>183</sup> With the MNF and territorial independence of patents powerful countries can now use bilateral trade agreements to impose greater intellectual property protections on weaker states for the benefit of other WTO members.

Thus, while the WTO may be criticized for allowing a loophole in TRIPS which could facilitate discriminatory treatment it seems the loophole was a strategic ploy for the general expansion of intellectual property rights. Exploiting this loophole, economically and politically powerful states such as the U.S. and the EU have embarked on negotiating TRIPS PLUS bilateral agreements with various developing countries in which intellectual

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that although the MNF principle appears to be the natural expansions of the GATT into other areas, the reason behind Article 4 was to address the practice of grants of advantages and privileges by states in bilateral agreements not prohibited by the Paris Union.).

<sup>181</sup> Although TRIPS determines the subject matter of the patent, the nature of the rights granted, and the duration of those rights, patents are still to be issued and governed by local law which must conform to the terms of TRIPS. Thus the patents remain territorially independent under TRIPS and combined with the MNF may pose serious risks. *See*, DE CARVALHO, TRIPS PATENT RIGHTS, *supra* note 31, at 163 (arguing that the use of language in Article referring to any advantage, favor, privilege ..granted to the national of any other country expands the scope of intellectual property rights in agreements bilateral agreements between WTO members and non member states.; but *see*, CORREA, COMMENTARY ON THE TRIPS AGREEMENT, *supra* note 31, at 66 (arguing that the impact

<sup>182</sup> *See*, GRAIN in cooperation with SANFEC, “TRIPS-plus” Through The Back Door: How Bilateral Treaties Impose Much Stronger Rules For IPRs On Life Than The WTO (July 2001), available at [http://www.grain.org/briefings\\_files/trips-plus-en.pdf](http://www.grain.org/briefings_files/trips-plus-en.pdf) (last visited 6 July 2009). GRAIN in collaboration with Dr. Silvia Rodriguez Cervantes, *FTAs: Trading Away Traditional Knowledge: Traditional Knowledge in Increasingly Popping Up in Bilateral and Regional Free Trade Agreements. What’s Going On?* (March 2006), available at [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, Quaker United Nations Office (QUNO), Geneva, Quaker International Affairs Programme (QIAP), Ottawa and International Centre for Trade and Sustainable Development (ICTSD), Geneva, p.4 (2003), available at <http://www.quno.org/geneva/pdf/economic/Issues/FTAs-TRIPS-plus-English.pdf> ); CORREA, COMMENTARY ON THE TRIPS AGREEMENT, *supra* note 31, at 69 (admitting the troublesome impact of FTAs by the U.S., the EU and Japan under the MNF, nevertheless argues that the impact of the MFN would be limited by the scope of coverage of the TRIPS Agreement.)

<sup>183</sup> Article 4 of TRIPS mandating the MFN treatment together the fact the TRIPS protections are minimum open the door for reciprocity under TRIPS-PLUS agreements.

property rights have been expanded beyond the TRIPS minimum.<sup>184</sup> Characteristically developing countries tend to suffer a relative bargaining power deficit. The process and its results, driven by bargaining power asymmetries, has been described elsewhere as bilateral/unilateralism.<sup>185</sup> Put differently, although these agreements came clothed as bilateral they were essentially unilateral in the sense that TRIPS PLUS agreements are uneven in the rights and obligations of parties. Reciprocity has been resisted for about a century because of its invidious implications for weak states in any global system.<sup>186</sup> 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 patent protection which have a negative impact on their health security. The same pattern of bilateral/unilateralism has been unfolding in the thousands of bilateral investment treaties.<sup>187</sup>

The risk to health security created in these agreements has wider implications for those countries and ultimately for patent rights under TRIPS. Although Article 4 provides some exceptions they are less beneficial to developing countries.<sup>188</sup> But, under the MNF provision of TRIPS it is doubtful whether developing countries which have agreed to expanded 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 the open gates as free riders, even when the privileges and advantages are extended to non-WTO member states. One may therefore again argue that the guarantee of minimum rights under TRIPS followed by the MNF clause was a deliberate strategy for expanding intellectual property rights without any safeguards for human health and food security. States with the relative bargaining power can systemically expand the international intellectual property regime by selectively negotiating TRIPS PLUS agreements with many important developing countries which are governed by the MNF. One only has to examine the working of the MNF provisions in BITs to appreciate this

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<sup>184</sup> Some differences exist between U.S. and EU TRIPS\_PLUS agreements; See Carlos M. Correa, *Internationalization of The Patent System and New Technology*, 20 Wis. Int'l L.J. 523, 528-531 (2002). 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, 242-257 (2007).

<sup>185</sup> Yelapaala, *Fundamentalism in Public Health and Safety I*, *supra* note 72, at 249 (discussing the concept of bilateral unilateralism as the use of bilateral negotiations to achieve the same level of investment protection could have unilaterally imposed, the results are generally lopsided, hardly equal or reciprocal in actual fact)

<sup>186</sup> PENROSE, INTERNATIONAL PATENT SYSTEM, *Supra* note 4, at 64-66 (explaining that reciprocity was rejected 1880; however the U.S. mounted the only serious but unsuccessful push for reciprocity particularly between 1897 and 1900; it was feared that reciprocity would undermine the very foundation of the Paris Union and it into a series of bilateral agreements).

<sup>187</sup> Yelapaala, *Fundamentalism in Public Health and Safety I*, *supra* note 72, at 237-240 (discussing the proliferation of BITS; in 1999 there were about 1,857 BITS by 2008 there were over 2,500 in number).

<sup>188</sup> Article 4 of TRIPS offer the following four exceptions: (a) advantages etc derived 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, etc, and (d) derived from international agreements relating to intellectual property in existence prior to the entry into force of the WTO if notified to the TRIPS Council)

point.<sup>189</sup>

It would therefore appear that countries which lost the battles for expanding intellectual property rights under the Paris Union seized upon the opportunity presented in the WTO and TRIPs to achieve what was not possible under the Paris Union. If their goal was to maintain the digital divide to ensure their global technological advantage and competitiveness the strategy worked but at the expense the weak and vulnerable 80% of the world's population with the greatest exposure to the neglected diseases and hunger. If, as we have argued, 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 goals of the UN Charter provide opportunities for undermining those goals and fundamental rights?

### **Risk of Patent Abuse under TRIPs**

One of the themes that dominated the history and deliberations of the Paris Union right from the beginning and beyond was the threat of patent abuse presented by the new international patent regime. Starting with the Vienna Conference of 1873 which set into motion the deliberations leading to the Paris Union in 1883 and a ratified convention in 1884 the dominant subject was the threat of patent abuse.<sup>190</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>191</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 that patents would be registered with no intent to use but purely as

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<sup>189</sup> For a discussion of MFN clauses in BITS see, Jarod Wong, *The Application of Most-Favored-Nation Clauses to Dispute Resolution Provisions in Bilateral Investment Treaties*, 3 ASIAN JOURNAL WTO & INTERNATIONAL HEALTH LAW AND POLICY 171 (2008) at 173 (arguing that although the use of the MFN clauses in BITS have 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, case célèbre of the risks posed to sovereign policy choices under BITS is the Argentine financial crisis in the last weeks of 2001. In response to the financial, economic and political crisis that followed the government took corrective measures that visited cost on local and foreign investors interests. Over 40 investment arbitration disputes were filed against Argentina by foreign investors and questions were raised about treating interpretation of BITS provisions when a state is faced with crippling economic crisis of widespread impact. For a discussion of the constraints faced by the state see, William W. Burke-White, *The Argentine Financial Crisis: State Liability Under BITS and the Legitimacy of the ICSID System*, 3 ASIAN JOURNAL WTO & INTERNATIONAL HEALTH LAW AND POLICY 199 (2008) at 205 (arguing that “the Argentine other issues of treaty interpretation that sought to handcuff the government of Argentina in its necessary response to an

<sup>190</sup> PENROSE, INTERNATIONAL PATENT SYSTEM *supra* note 4, at 178-180 (after an extensive discussion, concluded that the abuse of patent monopoly provisions had a turbulent history because they directly impinged on the interest of less industrialized states and their national economies and the interests of individual patent holders).

<sup>191</sup> *Id.* at 47( after a vigorous the Resolution was accepted against the objections of the U.S. and not to come up again for the next 50 years by a vote of 42/7).

instruments for monopolistic practices and market reservation.<sup>192</sup> Patents would prevent local exploitation and imports which would be detrimental to the development of local industry and leave the fate of the country in the hands of foreign patentees.<sup>193</sup> Such an outcome was unacceptable to many countries including those which had no patent systems and those which subscribed to international free trade.<sup>194</sup>

Three potential solutions were debated throughout the history of Paris Union. One solution was to give states the right to revoke patents for non-working. The second, 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>195</sup> A state could legislatively revoke a patent for non-working if compulsory licensing proved to be an inadequate response. The power to revoke was substantially left to the state. Between 1897 and 1934, the U.S. tried unsuccessfully to eliminate this provision because any modifications required unanimity.<sup>196</sup> In fact, in 1925 Japan, Yugoslavia and Poland blocked another U.S. attempt on the grounds that it would be detrimental to the growth of industry.<sup>197</sup> Professor Penrose after an exhaustive examination of this subject concluded that “in 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>198</sup> Professor Penrose remarks proved to be prophetic since the search for a solution to the patent abuse problem remained a thorny issue until its resolution in TRIPS in 1994.<sup>199</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 suffering from economic and technological gap increased significantly since the era of decolonization. Besides, absent in the calculus that shaped the Paris Union are the current pressing health and food security problems confronted by many of the members of the WTO and TRIPS. The logic which led to the preservation of the right of patent revocation or compulsory licensing as a sanction for

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<sup>192</sup> *Id* at 47

<sup>193</sup> *Id* at 80 (explaining that the interests of states would be hurt with the abolition of compulsory working; Japan, Yugoslavia & Poland blocked U.S. for that reason).

<sup>194</sup> *Id* at 15-16 (Switzerland and the Netherlands had no patent system at the time).

<sup>195</sup> For a discussion of conditions imposed by Article 5A of the Paris Union on compulsory licensing, see, Beier & Schriker, FROM GATT TO TRIPS, *supra* note 21, at 173.

<sup>196</sup> See, PENROSE, INTERNATIONAL PATENT SYSTEM *supra* note 4, at 81-86 (The attempts of the U.S. to repeal the revocation of patents for non-working goes back to 1880 but the effort was redoubled but unsuccessful on many occasions between 1897 and 1934), the provisions in Article 5(A) were finalized in 1962.

<sup>197</sup> *Id* at 84

<sup>198</sup> *Id* at 86.

<sup>199</sup> See, TRIPS, Article 31( providing for compulsory licensing under numerous conditions).

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 which affected the outcome.

The resolution of the controversy over patent abuse which came in two forms was naturally affected by the 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 was subjected to judicial review.<sup>200</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 and the resolution of that issue may be complex and protracted. Besides, as one commentator has remarked, the judicial review process could lead to a stalemate.<sup>201</sup> This could have severe consequences during times of public health emergencies if the review process is protracted due to a challenge by the patentee or becomes indeterminate. TRIPS does not appear to assign the appropriate qualitative value to the public interest in times of emergency.

The second, compulsory licensing as a sanction for non-working was addressed in Article 31 of TRIPS. Dubbed as the 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>202</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 when the need is immediate and serious.<sup>203</sup> The further condition that compulsory licensing can only be used to supply domestic market needs until such needs are resolved it is virtually meaningless for many developing countries with small domestic markets and weak purchasing power.<sup>204</sup> Basic economic theories teach us that economies of scale have a significant impact on efficient, low cost

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<sup>200</sup> Article 32 of TRIPS states rather simply, “An opportunity for judicial review of any decision to forfeit a patent shall be available.”

<sup>201</sup> GERVAIS, TRIPS DRAFTING HISTORY AND ANALYSIS, *supra* note 44, at 402.

<sup>202</sup> Article 31 of TRIPS offers 12 conditions for the use of compulsory licensing. Read together these conditions do not make compulsory licensing easy for states. Add Article 31 conditions and requirements; *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*, University of Buenos Aires, April 2004, Essential Drugs and Medicines Policy. This document was produced by the Drug Action Programme of the Department of Essential Drugs and Medicines Policy. Ordering code: WHO/EDM/PAR/2004.4, available on the Internet at: <http://www.who.int/medicines/>, at 15-26 (discussing the conditions for the use of compulsory licensing under Paragraph 6 of the Doha Declaration).

<sup>203</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.” This places the burden on the state seeking to rely on Article 31 and makes it difficult in determining reasonable commercial terms when the market for information are notoriously imperfect and often unique.

<sup>204</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.”

production, low prices and consequently affordable pharmaceutical prices. These are 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 plight of small countries and markets.<sup>205</sup> The exemption to Article 31 (f) provided 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>206</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 to join forces in the use of compulsory licensing to take advantage of the economies of scale to confront their needs.

As it stands, only more advanced developing countries with the requisite domestic markets, technical capacity and the resources to tackle the conditions imposed by Article 31 can employ compulsory licensing. One wonders how Article 31 addresses the needs of several developing countries with limited territorial markets and technical capacity but face most of the global disease burden and food insecurity. Although the General Council Declaration recognizes this problem it hardly provides a meaningful solution. The problem is structural and the various measures suggested do not confront the structural impediments. Of course, Article 31 resolved decades of frustrating attempts by the U.S. to eliminate the sanction-based use of compulsory licensing. When the Paris Union was initially ratified there were only 10 contracting states several of them with colonies or colonial aspirations.<sup>207</sup> Even when the number of countries increased, our knowledge of disease and food security problems of the world was limited in comparison to what it is today. With the knowledge that over 80% of the world's population faces critical health and similar food insecurity how could the drafters of TRIPS justify Article 31? The justification might have been the evidence of poor governance and mistrust of the

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<sup>205</sup> The goal of the exemption canvassed is similar to those that inspired the exemptions to the GATT obligations. Article II of the GATT, the Most Favored Nation (MFN) Clause is one the most fundamental obligations of the 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 custom union would eliminate trade barriers between the members of the custom union thereby moving them toward further trade liberalization. For an explanation of the MFN clause and custom union under GATT *see*, JACKSON, INTERNATIONAL ECONOMIC RELATIONS, *supra* note 4, Chap 9, 515& 560. One of the earliest economist who addressed the trade creation and diversion impact of custom unions was Viner; J. VINER, THE CUSTOM UNION ISSUE (1950). 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 ONTEGRATION, THEORY AND PRACTICE POLICY (1990) at 9 (arguing that economic integration is not an objective in and by itself but to serve higher purposes: to raise the economic prosperity for all co-operating units among others).

<sup>206</sup> Correa , *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, *supra* note 203.

<sup>207</sup> PENROSE, INTERNATIONAL PATENT SYSTEM *supra* note 4, at 57 ( the original signatories of Paris Union were Belgium, Portugal, France, Guatemala, Italy, Netherlands, San Salvador, Serbia, Spain and ,Switzerland,another 29 countries joined later). Several of early members were colonial or aspiring colonial powers.)

exercise of power by states. But, the abuse of power by states is hardly a new phenomenon nor is it limited to weak and small countries. 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 public interest of society based on some criteria of reasonableness. Article 31, is essentially a meaningless provision for most countries and appears blind to the wealth of information of the health and food needs of the most needy population groups of the world. Some commentators have suggested that developing countries should more effectively exploit the internal flexibilities of TRIPS to address their pharmaceutical and health needs.<sup>208</sup> Unfortunately, most of the countries in need lack the technical, legal and economic resources to examine and exploit the flexibilities which are nested and buried in a structural maze. Instead of confronting the issue from the point of view of flexibilities, we should admit that 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. We have argued that one of the major sources of the threat of TRIPS to human health and food security is the linkage between trade and intellectual property protection 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 peace time, about a decade after the collapse of the attempt by developing countries to establish a New International Economic Order some higher human ideal needed to be the guiding light. Unfortunately, the circumstances invited the exploitation of the significant asymmetrical distribution of economic, technological and political power between the North and the South and a higher human ideal seemed elusive.<sup>209</sup> The WTO itself derived its moral and human aspirations from the GATT, a product of the post war mentality sharply focused on an international free trade regime as a 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 history of wars.

Wars tend to have a sobering and introspective awakening of the transcendent but often latent idealism in humanity. From the carnage and violence of warfare humanity often arise the hope for, and faith in, a transcendent path forward for the benefit not just of the victors but also of humanity in general. This is neither the time nor the place to

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<sup>208</sup> Correa , *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, *supra* note 203.

<sup>209</sup> Drahos, *Negotiating Intellectual Property Rights*, *supra* note 17, at 172-173 (suggesting that TRIPS was negotiated under coercion).



examine this statement against the history of all regions and cultures of the world. A brief examination of Western Europe shall suffice to make the point.

Although we could go further back let us start with the improbably defeat of the Roman army by Constantine in 312 AD.<sup>210</sup> After that battle the unification of the Western and Eastern Roman Empires was achieved and Constantine stood as the sole temporal and military power. 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>211</sup> The outcome of this union was the eventual creation of the Holy Roman Empire. Supposedly, the most powerful general was not concerned about himself but rather about advancing the goals of God's universal moral order for humanity. Henceforth, the sword would be lifted in defense of this universal moral order.<sup>212</sup> Indeed, Constantine's first decree was to prohibit religious persecution.<sup>213</sup> But, the new order under the Holy Roman Empire was an unstable one 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 Pope and eventually 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 society.

The Peace of Augsburg of 1555 essentially formalized the declining influence of the Holy Roman Empire with the doctrine of *cuius regio eius religio*.<sup>214</sup> The higher ideal captured here was the principle of religious sovereignty of states.<sup>215</sup> Unfortunately

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<sup>210</sup> After successive victories against very powerful foes including his own father, the former Emperor Maximian and the greatest Emperor of his time Diocletian, Maxentius the Emperor of Rome looked invincible particularly with a heavily armored cavalry called *katafractoi*. After an initial setback from a surprise attack by the forces of Maxentius, Constantine and his army charged across the Milvian Bridge and in the slaughter of the enemy forces the Emperor himself drowned. For an interesting account of Constantine's victory, see, W. H. CROCKER III, TRIUMPH, THE POWER AND GLORY OF THE CATHOLIC CHURCH: A 2000 YEAR HISTORY, 1-5 (2001)(hereinafter, CROCKER, TRIUMPH).

<sup>211</sup> *Id.* at 55 (discussing the Council at Nicea called by Constantine in 325 AD at which a definitive summary of Christian belief was formulated; at 59 ( explaining the creation of the Christian Empire by Constantine). that the best form of rule was when cross,

<sup>212</sup> *Id.* 59 (the view was that the best form rule was when cross, sword, crozier and scepter worked in union and establishing the divine right of kings as guardians of the Christian faith).

<sup>213</sup> *Id.* at 4 ( religious freedom was given by the Edith of Milan).

<sup>214</sup> The Peace of Augsburg promulgated on September 25, 1555, by the Diet of the Holy Roman Empire, assembled earlier that year at Augsburg was the first permanent legal basis for the existence of Lutheranism as well as Catholicism in Germany. Against the wishes of The Holy Roman Emperor, Charles V of Spain but with his brother Ferdinand I (future Emperor) the Diet "determined 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..in each of the territories of the empire, only one church was to e recognize, the religion of the ruler's choice being thus made obligatory for his subjects." It appeared that the Peace of Augsburg helped to maintain peace for at least 50 years. <http://www.britannica.com/EBchecked/topic/42767/Peace-of-Augsburg?sections=42767mai> Last visited 1/8/2011.

<sup>215</sup> See, Ali A. Mazrui, *Panel Discussion*, in THE NEW INTERNATIONAL ECONOMIC ORDER: THE NORTH-

religion and other political objectives continued to be the source of conflict leading to 30 years of warfare ending in the Peace of Westphalia in 1648 which reaffirmed the principles captured in the Peace of Augsburg.<sup>216</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 the avaricious appetite of empire builders and their supporters of powerful economic interest groups. The struggle for establishing and sustaining higher human ideals found further expression centuries later in the Peace of Versailles following the First World War which, among other things, sought to provide protection for human health and food security in the establishment of WHO and FAO.<sup>217</sup>

The focus on human health and food security reemerged as two important elements in a network of international institutions established by the allied powers following the end of the Second World War.<sup>218</sup> Even before the war ended and particularly in the last days of the war, the allied powers under the leadership of the U.S. were already reflecting on the root causes of the two successful wars that had taken such a heavy toll on humanity.<sup>219</sup> They were determined to construct a new comprehensive international

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SOUTH DEBATE 371 (Jagdish N. Bhagwati, ed. 1977) at 373 (arguing that the Peace of Augsburg was basically a doctrine of religious sovereignty, one that prohibited the interference by one Prince in the religious affairs of another. However the general point Professor Mazrui tried to convey was the New Orders were part of the history of the world and the Peace of Augsburg was one of them).

<sup>216</sup> The Peace of Westphalia, was negotiated from 1644 in the Westphalian towns of Munster and Osnabruck and was concluded on October 24, 1648 after the Spanish-Dutch Treaty signed on January 30, 1648. One of the important settlements 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 Catholic, Lutheran and Calvinist; but also important the recognition 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 shadow of power. The central authority of the empire was not only replaced by that of 300 Princes but also involved the loss of vast amounts of territory. <http://www.britannica.com/EBchecked/topic/641170/Peace-of-Westphalia/7889/TheDecisions?anchor=ref164494&sections=641170main>, Last visited 1/8/2011; S. Crocker provides an excellent account of the Thirty Years War leading up to the Treaty of Westphalia in 1648, CROCKER, TRIUMPH, *supra* note 211, at 297-302).

<sup>217</sup> Abdullah El Erian, *The Legal Organization of International Society*, in MANUAL OF PUBLIC INTERNATIONAL LAW, (Max Sorensen ed 1968) (hereinafter, SORENSON, MANUAL OF PUBLIC INTERNATIONAL LAW) at 60-65 (discussing the establishment of the League of Nations and various international organizations such as the FAO and WHO following the end of the First World War).

<sup>218</sup> Several United Nations Subsidiary and specialized agencies were established; for a discussion of context and reasons for these agencies including the WHO and the FAO, *see*, Max Sorensen, *Institutionalized International Cooperation in Economic, Social and Cultural Fields*, in SORENSON, MANUAL OF PUBLIC INTERNATIONAL LAW, *id.* at 605 (explaining the structure and purpose of the economic and social relations established under the UN Charter under the direction of ECOSOC and the focus among others on establishing WHO & FAO); GOODRICH, HAMBRO & SIMONS, CHARTER OF THE UNITED NATIONS, *supra* note 10, at 385 (discussing the establishment of the Food and Agriculture Organization of the United Nations, approved by General Assembly, December 14, 1946 (U.N. Doc. A/78, Sept. 30, 1946; 1 UNTS, 208-31) and at 386, discussing the approval of the World Health Organization, on April 7, 1948 (UN DOC. E/155; ECOSOC/3D Sess/1946; 14 UNTS, 185-285).

<sup>219</sup> Shoup & Minter, *Shaping a New World Order*, *supra* note 3; DAM, THE GATT, *supra* note 3.

system that would constrain aggression but more importantly appeal to the deeper and humane side 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, health and food security was called for.<sup>220</sup> These were the guiding principles upon which the Charter of the United Nations and its numerous autonomous but interdependent organs including the WHO and the FAO were established.<sup>221</sup> To further the economic development and trade objectives, the Bretton Woods system and the GATT were also established.<sup>222</sup> It was evident that trade required economic development and the capacity to trade. The establishment of the Bank for Reconstruction and Development and the International Monetary System were to address the development and monetary systems essential for trade.<sup>223</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 evolution of the WTO and the threat it poses to human health and food security in TRIPS.

The natural question begging for an answer is what are the ideals of the WTO and TRIPS conjoined as a single system? Ideals are aspirational, always unfolding and demanding adjustments, sometimes major and often incremental and marginal. Health, food security technology are some of the most important engines of 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 many countries? The centralization of power in the WTO in areas tangential to international trade but important to access to technology threatens and interferes with the effective and smooth functioning of other semi-autonomous United Nations organs such as the WHO and the FAO. Perhaps unintended, the centralization of

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<sup>220</sup> Article 55 of the U.N. Charter stated “With a view to creating of conditions of stability and wellbeing 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, an observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.” The question is whether the combined effects of the WTO and TRIPS advance these principles. For a discussion of Article 55 *see*, GOODRICH, HAMBRO & SIMONS, CHARTER OF THE UNITED NATIONS, *supra* note 10, at 371-380.

<sup>221</sup> *See supra* note 219.

<sup>222</sup> *See*, , Gerald M. Meier, *The Bretton Woods Agreement—25 Years After*, 23 STANFORD L. REV. 245 (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 the GATT originated under the authority of ECOSOC.

<sup>223</sup> *See*, Bank for Reconstruction and Development Articles of Agreement which constitute Annex B of the Bretton Woods Final Act, came into force Dec 3, 1945; International Monetary Fund, Annex A of the Final Act of the United Nations Monetary and Financial Conference of Breton Woods held July 1-22, 1944, the Agreement came into force , Dec 27, 1945. For a discussion of the IMF, *see*, Joseph Gold, *The International Monetary Fund in International Law: An Introduction*, IMF PAMPHLET SERIES NO. 4 (1965) at 8 (describing the structure and governance of the IMF).

power in the WTO in these areas has created a hierarchy in the U.N. organs with the WTO at the top of the pyramid and the WIPO expressly sidelined.<sup>224</sup>

One wonders whether the ideal of free trade, the initial mission of the 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 its creativity and free floating of ideas. It is a necessity not an ideal. Access to air, light, food and health are an integral part of that existence and complex system deserving of its own independent consideration and not part of another complex system of trade.<sup>225</sup> Historically, the technology gap has always explained differences in economic and military powers of states.<sup>226</sup> Constructing an artificial regime of monopoly and exclusive rights in some technological ideas however expressed, even if necessary, reinforces the gap and should not be part of the free trade ideal under GATT sought to be refined under the WTO. Monopoly and exclusive rights in ideas essential to life and living are distinguishable from inventions of robotic machines and industrial systems for the manufacture of ordinary goods.<sup>227</sup> Conditioning the right to trade in all goods irrespective of their nature and importance to life and living 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.

## VI. QUO VADIS WTO?

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<sup>224</sup> See, Agreement Between the World Intellectual Property Organization and the World Trade Organization (of December 22 1995) Entry into force: January 1, 1996. Source, Communication from the International Bureau of WIPO and the WTO Secretariat. Article 2 of this Agreement leaves little doubt as to the dominant role of the WTO in the carrying out of the obligations under TRIPS and mandates cooperation from WIPO when requested and accessibility to WIPO Databases.

<sup>225</sup> Drahos argued that differences in intellectual property protection leads to trade distortion and sought to justify the existence of TRIPS on that account; see, Drahos, *Negotiating Intellectual Property Rights*, *supra* note..at 177. It should however be noted most trade theorists would argue that any such trade distortion should be addressed when it occurs and be targeted at the source of the distortion. See, CORDEN, *TRADE POLICY*, *supra* note 149; but see Robert M. Sherwood, *Why a Uniform Intellectual Property System Makes Sense for the World*, in *GOBALDIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY* (Mitchel B. Wallerstein, Mary Ellen Mogee, Roberta A. Schoen eds. 1993)(seeking to stimulate discussion on what the global intellectual property system is and what the costs and benefits including the ethics of the system might be).

<sup>226</sup> Celso Cintra Mori, *Informatics in Brazil*, in *LICENSING AGREEMENTS: PATENTS, KNOW-HOW, TRADE SECRETS AND SOFTWARE*, (Kojo Yelapaala, Donald R. Worley, Dennis Campbell ed. 1988); at 350-355 ( in providing the background to the Brazilian policies and law on informatics, argued that technological development such new navigation techniques, know-how and the technological innovation behind the industrial revolution played and continues to play a role in differences in level of development and global competitiveness).

<sup>227</sup> Yelapaala, *Owning the Secrets of Life*, *supra* note 168, at 186-188 (arguing the current U.S. patent system designed originally for mechanical devices was out of sync with the current biotechnological and scientific world and needed reform.).

We have argued that the root causes of the risk posed by TRIPS to human health and food security are 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 an unprecedented 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 however expressed 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 rights. If, these structural problems exist what should be the road ahead for the WTO and TRIPS in response to the acknowledged problems. Put more directly, *quo vadis WTO?* We have argued that reliance on the substantive revisions of TRIPS would have marginal transformative effects on its structural root causes. Perhaps, the starting point in confronting the solution is to pay attention to the wisdom in the African proverb stated at the heading 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 incredible disease burden and food insecurity faced by many developing countries and the response by the WTO is no more than attacking the shadow of the problem. It is in the spirit of this proverb that we make below several suggestions which go to the root structural problems of TRIPS as part of the WTO system of Agreements.

The first and logical response to the question of the future direction of the WTO should address the linkage between TRIPS and the WTO. Not only should the WTO and TRIPS be delinked but also TRIPS should be dismantled and reconstructed to address its larger shortcomings. The right to health is not only a human right recognized under certain multilateral instruments but also a constitutional right in some countries.<sup>228</sup> The obligation of states to advance human rights is therefore both a moral and positive legal imperative under international law and some municipal legal systems.

No country should be deprived of the right to protect the health and food security of its citizens under any international instrument that unreasonably limits its sovereign right 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 risks of abuse. The solution to such a risk is not the suppression of sovereignty but its reasonable regulation. The reinstatement of sovereign authority in this area would empower states to confront their public health needs, disease burden and food security subject to the usual limitations under international and municipal law. This is more so when the imposition of a new delivered international order of intellectual property rights is a replication of a system constructed upon 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 WTO General Council irrelevant.

Disparities in economic development, technological and industrial capacity of states have had a consistent and persistent pattern in human history. A rational international trading system and its implementation should not systematically consign a large number

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<sup>228</sup> Yelpaala, *Fundamentalism in Public Health and Safety II*, *supra* note 70, at 474-479.

of states to the back waters of under development by elevating private rights of foreign patentees to the detriment of the development objectives and fundamental public interest of the state. The so-called built-in flexibilities of TRIPS are inadequate and misleading in that they are inaccessible to the most needy states. At best, they merely pay lip service to the ideals of free trade and the advancement of humanity. To advance the core ideals in the mission of the U.N. Charter, the WTO must unambiguously dismantle TRIPS in the interest of humanity and in particular, the fundamental needs of developing countries.

Second, 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 the human species. From the beginning of time, ideas have always been fluid and ephemeral, having the qualities of the air and light we enjoy. Unimpeded access to ideas played a critical role in the advancement of human society. Some ideas emerged simultaneously in different parts of the world others were borrowed and transformed to suit local needs. The building blocks of the modern technological society were built by many ancient civilizations and cultures which also borrowed from others over time. To ascribe a national or territorial origins to *all* ideas however expressed or manifested suggests a serious misunderstanding of the history of the human creative and innovative process. 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 separate process. The round of negotiations undertaken by the TRIAD for a new anti-counterfeiting agreement to maintain their technological competitiveness merely confirms the conclusion that the key reasons for the marriage between the WTO and TRIPS were self-serving to the dominant few and flawed.

Third, the world now faces a delivered moral imperative of democratization of human political governance institutions and the liberalization of trade and investment policies by states. 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 with an expanded scope 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 the 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 that are not directly related but complicate the effectiveness of other U.N. organs should be immediately delinked.

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 these fundamental needs. In the short term, in addition to 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 their fundamental health and food security needs. Public/Private productive joint ventures between countries with insufficient markets and purchasing power would address the cost and profitability constraints they face. This policy would permit coordination between middle income countries with better capacity

such as Brazil, China and India with those without the capacity to address the issues of generic drugs, affordable pharmaceutical products as soon as possible.

In the long term developing countries must confront the issue of the digital divide and the disequilibrium in health and food R&D. The primary responsibility of developed countries is toward their own citizens. In the foreseeable future, the current disequilibrium in health research expenditures favoring developed countries should be expected. 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 of health and food research aimed at their fundamental needs. The real question would be what modalities and business models would be most effective within or outside TRIPS,

In thinking about the fundamental health and food technology needs of developing countries two points should be kept in mind. Developing countries as a group control over 90% of the biodiversity resources now sought to be exploited by global pharmaceutical and agro-business MNEs largely for purposes other than the needs of developing countries. Second, under the U.N. General Assembly Resolution 1803 (XVII) of 1963 developing countries continue to have permanent sovereignty over their biodiversity resources even under 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 public/private corporate regional and sub regional R&D entities in which foreign research institutions can play a secondary and supporting role. The governments of developing countries should provide the appropriate funding for these research entities as pure and simple investors similar to the funding of Airbus by European governments. However, the mission and vision of the R&D entities must be directed concretely at confronting the fundamental health and food security needs of developing countries,

In short, in the long run developing countries must take their destiny into their own hands in a variety of areas particularly in bridging the technology gap which is contributing to their various vulnerabilities in health, food and trade. No reliance on the benevolence of global MNEs or their home governments to share their technical innovations can be stable or reliable. Colorful dreams, visionary conferences and eloquent speeches will not suffice. ***Critical and concrete policy measures and actions must be taken today to intercept the future.*** Short of this, the struggle for recalibrating the global economic relations of the decade of 1970s and 1980s to achieve the lofty goals of a more equitable distribution of the benefits of the global economic progress will be recurrent and similar to playing broken record.