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Multipolarity, Intellectual Property, and the Internationalization of Public Health Law

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ABSTRACT

This Article critically examines the proliferation of international legal agreements addressing global health threats like the outbreak of infectious diseases, tobacco use and lack of access to affordable medicines. The conventional wisdom behind this trend is that a global normative shift has occurred which has caused states to regard health as "special" and less subject to the normal rules of international law making because health threats endanger all of humanity. This Article challenges that thesis, arguing that at the same time the number and scope of international health law treaties has grown, developed states have subordinated health law to intellectual property protection for patents and trademarks, both of which erect substantial barriers to the objectives of public health law treaties. To the extent international health law has generated meaningful gains for global population health, it has not done so through a normative shift in how diplomacy works, but precisely because of politics as usual. International public health law gains have come largely from the efforts of an emerging group of middle-income, influential states like Brazil, India, Indonesia, South Africa and Thailand who have sufficient weight to force concessions from wealthier states. Using the parallel histories of international intellectual property treaties and global public health law, the Article demonstrates that the normative force of health-based arguments is relatively weak. To the extent public health advocates urge the adoption of more treaties, as they are now poised to do, they must more squarely address the threat posed by international intellectual property protection and make strategic calculations as to the political feasibility of those agreements given the changing distribution of global economic and political power.

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INTRODUCTION

The cause of global health today is arguably the most influential human rights movement ever seen, mobilizing vast flows of direct and indirect aid to the developing world to fight disease and build health care infrastructure; prompting the establishment of international organizations like UNAIDS and the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund); including global health as an agenda priority in major diplomatic summits; and, driving the formation and implementation of international agreements to address global health threats. Champions of this movement claim that the diverse and influential state and non-state actors participating in the development of the global health regime are evidence of its normative, law-making power. Speaking of a range of initiatives undertaken by the World Health Organization, Christopher McDougall, Ross Upshur and Kumanan Wilson wrote that:

> Each . . . also reflects a revolutionary willingness of the international community to accept new forms of supranational authority and to abide by the principle that national sovereignty can in some circumstances be subordinate to public health protection. As such, they are integral parts of the evolution of international health governance towards a global public health security regime.[1]

In 2007, the governments of Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand issued the Oslo Ministerial Declaration declaring that:

> The early 21st century . . . . has seen an unprecedented convergence of global health and foreign policy . . . . Ensuring public health on a global scale is of benefit to all countries. Powerful synergies arise when national interest coincides with the need for concerted regional and global action.[2]

Indeed, the evidence for the normative strength of the global health movement is persuasive. From 1995 to 2010, the value of goods and

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[1] Christopher McDougall, Ross Upshur and Kumanan Wilson , *Emerging Norms for the Control of Emerging Epidemics*, BULLETIN OF THE WORLD HEALTH ORGANIZATION, available at http://www.who.int/bulletin/volumes/86/8/08-051771/en/

[2] Celso Amorim (Brazil); Philippe Douste-Blazy (France); Hasan Wirayuda (Indonesia); Jonas Gahr Støre (Norway); Cheikh Tidiane Gadio (Senegal); Nkosazana Dlamini-Zuma (South Africa); Nitya Pibulsonggram (Thailand), *Oslo Ministerial Declaration—global health: a pressing foreign policy issue of our time* available at http://www.who.int/trade/events/Oslo_Ministerial_Declaration.pdf.

services aimed at improving global health increased at least threefold.[3] Global health was introduced as a priority at the 26th G8 Summit – giving rise to the Global Fund – and has remained on the agenda ever since.[4] Since 2005, states have updated the International Health Regulations to coordinate broader responses to more diseases as well as concluding the first international public health treaty, the Framework Convention for Tobacco Control (FCTC).

Yet that evidence is also deceiving. The 2005 International Health Regulations (IHR), concluded in the wake of outbreaks of diseases largely in developing countries, appeared to falter on the unwillingness of wealthy countries to equitably address vaccine production and distribution. Key provisions of the FCTC have failed in the face of challenges tobacco firms have mounted on the basis of their rights in trademarks and brands. Indeed, formal global health instruments which purportedly capture the health movement's normative force have been systematically undermined by a competing global movement: international intellectual property protection.

Intellectual property rights and public health interventions are in many ways natural antagonists. The exclusive control given pharmaceutical patent holders, while theoretically required to encourage investments in research and development, stands at odds with access to affordable medicines. The goodwill trademark proprietors build through investments in advertising and marketing often trades off with costs imposed upon society through excessive or deceptively-induced consumption.[5] This

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[3] Josh Michaud, *Global Health's Private-Sector Revolution*, WORLD POLITICS REVIEW, 14 Dec. 2010 available at http://www.worldpoliticsreview.com/articles/7328/global-healths-private-sector-revolution

[4] Kurokawa, Kyoshi *et al.*, *Italian G8 Summit: A Critical Juncture for Global Health*, 373 (9663) THE LANCET 526-527 (14 Feb. 2009).

[5] CTRS. FOR DISEASE CONTROL & PREVENTION, REDUCING TOBACCO USE: A REPORT OF THE SURGEON GENERAL 166 (2000), *available at* http://www.cdc.gov/tobacco/data_statistics /sgr/2000/complete_report/pdfs/Chapter5.pdf (describing the various marketing tactics of tobacco companies that have prompted regulatory action); Joe B. Tye, Kenneth E. Warner & Stanton A. Glantz, *Tobacco Advertising and Consumption: Evidence of a Causal Relationship*, 8 J. PUB. HEALTH POL'Y 492, 494–95 (1987) (emphasizing cigarette manufacturers' interest in advertising and promotion to maintain brand); Pinya Silayoi & Mark Speece, *Packaging and Purchase Decisions: An Exploratory Study on the Impact of Involvement and Time Pressure*, 106(8) BRITISH FOOD J. 617 (2004); David A. Marshall, Mark Stuart, & Rick Bell, *Examining the Relationship Between Product Package Colour and Product Selection in Preschoolers*, 17 FOOD QUALITY & PREFERENCE 615, 615 (2006) (noting the importance of color in food choice); Ike-Elechi Ogba & Rebecca Johnson, *How Packaging Affects the Product Preferences of Children and the Buyer Behaviour of Their Parents in the Food Industry*, 11(1) Young Consumers: Insight & Ideas for Responsible Marketers, 77, 79-80 (2010); Aron M. Levin & Irwin P. Levin, *Packaging of Healthy and Unhealthy Food Products for Children and Parents: The Relative Influence of Licensed Characters and Brand Names*, 9(5) J. CONSUMER

antagonism has long played out in the domestic context, where lawmakers conditioned intellectual property rights on their relationship with other national health priorities. India, for example, prohibited pharmaceutical patents for most of its history, a decision driven by the need to facilitate access to affordable medicine for its massive population.[6]

While national politics played the major role in deciding the balance between intellectual property protection and public health priorities, international agreements governing intellectual property and international public health issues tended to acknowledge the threat strong IP protections posed for public health measures. The Paris Convention for the Protection of Industrial Property, for example, allowed states to invalidate or refuse to register trademarks which misled or deceived consumers and left states free to grant compulsory licenses for reasons of public health. In any case, international intellectual property and international public health instruments alike depended on traditional diplomatic compliance mechanisms like good faith fulfillment of obligations, consultations in the

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BEHAVIOUR 393 (2010); Alice Louw & Michelle Kimber, *The Power of Packaging*, The Customer Quality Company, *available at* http://www.tnsglobal.com/_assets/files/The_power_of_packaging.pdf; WHO, Diets, Globalization and Noncommunicable Diseases available at http://whqlibdoc.who.int/publications/9241590416.pdf; Gill Cowburn & Lynn Stockley, *Consumer Understanding and Use of Nutrition Labelling: A Systematic Review*, 8(1) PUB. HEALTH NUTRITION, 21, 21-22 (2005); Carolyn L. Engelhard & Arthur Garson, Jr., *Reducing Obesity: Policy Strategies From the Tobacco Wars* (July 2009) *available at* http://www.urban.org/uploadedpdf/411926_reducing_obesity.pdf.(Governments in the United Kingdom, Australia and New Zealand have found front-of-package, graphic warnings more effectively communicate nutritional information to consumers than nutritional information boxes); Michael Skapinker, *Europe Must Think Again on Food Labels*, FINANCIAL TIMES, June 29, 2010, http://www.ft.com/intl/cms/s/0/3b1e26bc-83af-11df-b6d5-00144feabdc0,s01=1.html ("One report from Australia concluded that the most cost-effective interventions for obesity prevention were a 10% tax on junk food, restricting unhealthy food advertising to children, and the labeling of food packaging with an easier-to-understand traffic-light system); *Cigarette Packaging – What Rights for the Trademark Owner?*, 22 IP in the Media 1-2 (Sept. – Oct. 2010) (discussing plain packaging debate on cigarette packaging) *available at* http://www.completeip.com.au/attachments/File/Issue___22.pdf.

[6] N Nanda and R Lodha, *Access to Essential Medicines and Affordable Drugs: Making Essential Medicines Affordable to the Poor – with Special Reference to India*, 20 WISC. INT'L. L. J. 581 (2002); Vikas Bajaj and Andrew Pollack, *India's Supreme Court to Hear Dispute on Drug Patents*, NY TIMES (Mar. 7, 2012) available at http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all&_r=0

event of a dispute and tit-for-tat sanctions.[7] In short, they were enforced, often weakly, at the state-to-state level.[8]

In the last 30 years, the global movement to elevate the international legal status of intellectual property rights has also achieved substantial gains. Industrialized states successfully tied intellectual property protections they desired to the reductions in tariffs and other barriers to imports of foreign agricultural, clothing and textile goods sought by many developing countries, formalized in the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Thousands of bilateral investment treaties, largely forged between developed states and developing states, included strong protections for intellectual property rights that frequently exceeded those in existing international agreements, even TRIPS, and certainly beyond those typically found in national legislative frameworks.[9]

Yet, unlike the earlier era when IP rights and international public health law were roughly equivalent in their limited influence, the expansion of international public health law has proceeded with its explicit and implicit subordination to IP rights. For example, TRIPS provides a general authorization for parties to "adopt measures necessary to protect public health" but requires that "such measures are consistent with the provisions" of TRIPS.[10]

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[7] Jennifer Prah Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L.J. 423, 438-39 (2008) ("Theoretically, the enforcement model of states' behavior argues that states are rational actors maximizing utility and thus will adhere to or violate treaties depending on a cost-benefit calculation regarding their actions. Under this model and its compliance theory, treaty regimes must have costly enforcement mechanisms to compel compliance.").

[8] Susy Frankel, *WTO Application of the "Customary Rules of Interpretation of Public International Law" to Intellectual Property*, 46 VA. J. INT'L. L. 365, 378 (2006) ("GATT panels did not have any ability to affect intellectual property laws and there was no effective international enforcement of international intellectual property treaties."); J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, 29 INT'L LAWYER 345, 362 (1995) ("In retrospect, the weakness of the international regime governing trademark protection derived only in part from the failure of key developing countries to adhere to the Paris Convention (or to its later versions), and mainly from the lax enforcement of existing norms that state practice tolerated.").

[9] Burton Ong, *The Trademark Law Provisions of Bilateral Free Trade Agreements*, *in* TRADEMARK LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 229, 230 (Graeme B. Dinwoodie & Mark D. Janis eds., 2008) ("Similarly, trademark law provisions which have found their way into bilateral free trade agreements are also intended to fortify and, in most cases, expand the domestic legal framework from which trademark owners derive their exclusive rights.").

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 8, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

The confrontation between the growing strength of international intellectual property law and *national* public health measures is well-documented. Even before TRIPS, IP rights holders successfully used international agreements to thwart domestic public health policies. Contesting Australia's 1992 effort to require tobacco manufacturers to sell cigarettes in plain packaging, British American Tobacco argued before the Australian Senate that such a law would violate both the Paris Convention for the Protection of Industrial Property and the Australian constitution.[11] Persuaded by the tobacco industry, the Australian government rejected the proposed regulations.[12] In 1994, Philip Morris and RJR Reynolds undertook a similarly successful campaign in Canada based in significant part on the intellectual property protection provisions of NAFTA. In 1998, pharmaceutical firms holding the patents to antiretroviral drugs in South Africa brought suit against the government for its efforts to use parallel imports and price controls to expand access to treatment for its exploding HIV/AIDS population.[13] Their suit was based in significant part on the failure of the government's legislative basis for the measures to comply with TRIPS. The firms ultimately relented, although with guarantees by South Africa to respect TRIPS obligations.[14]

The purpose of this Article is to argue that international intellectual property law has not only erected substantial barriers to domestic or national measures taken in the interest of public health, but that intellectual property protections embedded in a wide range of investment, trade and IP treaties have substantially undermined existing and proposed *international* public health law. From vaccine development orchestrated by the WHO acting under the authority of the IHR to the marketing of breastmilk substitutes to pregnant and nursing mothers in developing countries to efforts by national authorities to implement provisions of the FCTC, international intellectual property law has systematically curtailed the intended population health benefits promised by effective implementation of these agreements.

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11. *See* Generic Packaging, Supplementary Submission to Senate Comm.; Submission to the Industry Inquiry from W.D. & H.O. Wills (Aust.) Ltd., The Tobacco Growing and Manufacturing Industries 32 (Jan. 1994) *available at* http://legacy.library.ucsf.edu/tid/kpk33a99/pdf (noting that the proposed packaging regulations "amount to a severe infringement of internationally-registered intellectual property rights").

12. *See* Adam Harvey, *Doctors' Plan to Put Cigarettes in Plain Wrap Fails*, SYDNEY MORNING HERALD, July 24, 1995, at 2 (quoting the spokeswoman for the Ministry of Health as stating that "[u]nfortunately, [the proposal] is just not feasible . . . . We would have to buy the tobacco companies' trademarks, and that would cost us hundreds of millions of dollars").

13 E 't Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines*, 3 CHI. J. INT'L. L. 27-46 (2002).

14 William Fisher & Cyrill Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, Feb. 10, 2005 available at http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf

Indeed, to the extent international public health agreements have influenced the conduct of party states, I argue that they have done so not because of the normative force the global health movement has exercised on foreign policy, but precisely because of politics as usual. The efforts of states like Brazil, India, Indonesia, South Africa, and Thailand in securing affordable access to medicines and vaccines, enforcing international marketing codes, and fending off IP-based challenges to new public health interventions represents one manifestation of a world in which the centers of hard and soft diplomatic power are diffusing from Europe and North America to Africa, Asia and South America.[15] From arms control to climate change, this phenomenon is generally known as "multipolarity", distinguishing the bipolar Cold War rivalry between the U.S. and the U.S.S.R. and harkening back to nineteenth century European politics dominated by Great Powers and characterized by an ultimately unstable balance of power between them.[16]

On the one hand, this trend should encourage international public health law advocates because it increases the likelihood that international public health agreements will achieve at least partial population health gains through unilateral or coordinated action by middle income states. On the other hand, the fact that international public health law is so frail in its confrontation with international IP agreements reveals the weak role norm creation is playing in the context of international public health law. The Article argues that as international public health advocates press for agreements covering a wider range of issues like alcohol control, medical research and innovation and even a comprehensive convention on global health, they must confront obstacles posed by international intellectual property law more squarely than they now do, as well as shape their agenda in light of the shifting alignment of global economic and political power.

Part I of this Article traces the history of international public health law from a loose network of politicized (and subsequently ineffective) international treaties in the late nineteenth century to a comprehensive movement toward a regime of conventions and protocols addressing the prevention and management of health threats that cross international borders. Part II traces the parallel history of international intellectual property protections beginning with the 1883 Paris Convention for the Protection of Industrial Property and growing to include a wide network of bilateral, regional and multilateral investment and trade treaties. In Part

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[15] Gregory Shaffer , Michelle Ratton Sanchez Badin and Barbara Rosenberg, *The Trials of Winning at the WTO: What Lies Behind Brazil's Success*, 41 CORNELL INT'L. L. J. (2008).

[16] Robert Zoellick, "The End of the Third World?" (address to Woodrow Wilson Center for International Scholars, Washington, D.C., April 14, 2010) (defining the new multipolar world); GORDON CRAIG & ALEXANDER GEORGE, FORCE AND STATECRAFT 39 (2010); HENRY KISSINGER, DIPLOMACY 23-24 (1997).

III, I identify episodes beginning in 1994 and concluding in 2012, when these movements collided over a range of international public health law instruments: the 1981 WHO Guidelines on the Marketing of Breastmilk Substitutes, the 2005 International Health Regulations and the 2005 Framework Convention on Tobacco Control. These episodes in turn foreshadow likely conflicts should proposals for a Framework Convention on Alcohol Control or an even wider-reaching Framework Convention on Global Health materialize. These episodes illustrate the weak role of international public health law in shaping states' behavior. In Part IV, I recommend solutions to the current problems including the strengthening of public health exceptions in bilateral investment treaties, the withdrawal of certain dispute resolution procedures across a wide range of treaties, the explicit management of intellectual property rights in future international public health agreements and the crafting of a global public health agenda that focuses on political practicalities available as shifts in global power change the strength and influence of developing states.

I. THE INTERNATIONALIZATION OF PUBLIC HEALTH LAW

The end of the 20th century ushered in the era of global public health. In the "global health revolution,"[17] states have in the last 15 years not only revised and expanded the IHR and established the FCTC, they have re-oriented developing states' public health policy trajectories through their aid programs (like the U.S. President's Emergency Relief for Aids in Africa (PEPFAR)) and the development of health diplomacy. Major non-governmental organizations like the William J. Clinton Foundation (now the Bill, Hillary and Chelsea Clinton Foundation), the Bill and Melinda Gates Foundation and the Bloomberg Family Foundation have also allocated significant and influential parts of their giving to the alleviation of global public health threats ranging from malaria to tobacco use. Other major international legal efforts lie in the wait like the American Public Health Association's call for a Framework Convention on Alcohol Control and even more ambitious proposals like a Framework Convention on Global Health.[18]

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[17] David P. Fidler, *After the Revolution: Global Health Politics in a Time of Economic Crisis and Threatening Future Trends*, 2 GLOBAL HEALTH GOVERNANCE 2-3 available at http://ghgj.org/Fidler_After%20the%20Revolution.pdf; See also Millenium Development Goals, available at http://www.un.org/millenniumgoals/bkgd.shtml ("The eight Millennium Development Goals (MDGs) – which range from halving extreme poverty to halting the spread of HIV/AIDS and providing universal primary education, all by the target date of 2015 – form a blueprint agreed to by all the world's countries and all the world's leading development institutions").

[18] American Public Health Association, *APHA Approves Framework Convention on Alcohol Control*, APHA SECTION NEWS LETTER available at http://www.apha.org/membergroups/newsletters/sectionnewsletters/alcohol/winter07/alcoholcontrol.htm; Lawrence O. Gostin and Eric A. Friedman, *Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL'Y L. & ETHICS 1 (2013). *See also* http://www.jalihealth.org/documents/Manifesto5-11-12.pdf

Theoretically speaking, this revolution represents the growing acknowledgment that economic development depends on a population that enjoys access to a basic level of health care and attention to conditions that accommodate individual and public health, the "right to the highest attainable standard of physical and mental health" under international human rights law.[19] Practically speaking, the growth of international public health law is a response to a globalized world of health threats including disease outbreaks which cross international borders, food security and safety under liberalized investment and trade rules and the worldwide marketing of products like tobacco, alcohol and processed food which pose unique challenges for the management of cancer, diabetes, heart disease, hypertension and strokes.[20] The economic and human cost of these burdens is vast and growing.[21] The emergence of HIV/AIDS in the 1980s as well as increasingly threatening strains of influenza brought into vivid focus the inadequacy of existing international coordinating mechanisms to handle infectious disease including the manufacturing and distribution of medicines and vaccines.[22] Not only did the 1969 International Health Regulations only cover cholera, plague and yellow fever, they lacked meaningful requirements for states to "detect, report, and respond to public health emergencies."[23]

For example, tobacco consumption, the principal preventable threat to individual and public health in both developed and developing countries, annually kills approximately five million people worldwide and is

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[19] International Covenant on Economic, Social and Cultural Rights art. 12(1), Dec. 16, 1966, 993 U.N.T.S. 3. See also Constitution of World Health Organization, [preamble] "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.").

[20] Emily Lee, *The World Health Organization's Global Strategy on Diet, Physical Activity, and Health: Turning Strategy Into Action*, 60 FOOD DRUG L.J. 569, 571 (2005) ("Major noncommunicable diseases (NCDs) (e.g. cardiovascular disease, diabetes, cancers, and obesity-related health conditions) now account for nearly sixty percent of global deaths and almost half (49.5%) of the global burden of disease. Without intervention, NCDs are expected to contribute nearly 75% of all deaths by 2020"); David Byrne, *Is There a Lawyer in the House: the Law of Global Health*, 33 JLME 19 (2005) ("In addition, the indirect costs of ill health, such as reduced productivity, are very high. One recent study has calculated the lifetime cost of cardiovascular disease in Germany. Direct health care costs are estimated at $25 billion; indirect costs in productivity are nearly double at $48 billion . . . Looking to the U.S. . . . one study estimates that the direct and indirect costs of obesity, diabetes, and tobacco each top the $100 billion mark annually.").

[21] *Id.*

[22] David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 JLME 85, 86-87 (2006).

[23] Kumanan Wilson, Barbara von Tigerstrom & Christopher McDougall, *Protecting Global Health Security through the International Health Regulations: Requirements and Challenges*, 179(1) CMAJ 44 (2008) available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2464486/.

expected to kill one billion people in this century if current trends persist.[24] Liberalized trade and investment rules have shifted the massive disease burden from tobacco consumption from developed to developing countries.[25] Indeed, this shift explains in part the origin of the FCTC.[26]

Similarly, the World Health Organization points to processed foods heavily marketed toward children, expanding consumption of fast foods and sugary beverages as important factors in the emerging global obesity epidemic.[27] Obesity levels are rising throughout both developed and developing countries, playing some causative role in heart disease, diabetes, certain cancers, osteoarthritis and strokes.[28] The scope and strength of international instruments targeting these threats has correspondingly expanded.[29]

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[24] THEODORE H. TULCHINSKY & ELENA A. VARAVIKOVA, THE NEW GLOBAL PUBLIC HEALTH 23 (2d ed. 2009); WORLD HEALTH ORG., WHO REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2008: THE MPOWER PACKAGE 7 (2008), *available at* http://www.who.int/tobacco/mpower/mpower report_full_2008.pdf; Allyn L. Taylor, *An International Regulatory Strategy for Global Tobacco Control*, 21 YALE J. INT'L L. 257, 260–61 (1996).

[25] Gro Harlem Brundtland, Burden of Disease and Best Practices: High-Level Roundtable on Tobacco Control and Development Policy (Feb. 3, 2003), *available at* http://www.who.int/dg/speeches/2003/brussels/en/.

[26] Ruger, *supra* note 7, at 436 (2008).

[27] World Health Organization, *Diet, Nutrition and the Prevention of Chronic Diseases: 5.2 Recommendations for Avoiding Excessive Weight Gain and Obesity*, WHO Technical Report Series, No. 916 (TRS 916) 65-66 *available at* http://www.who.int/dietphysicalactivity/publications/trs916/en/gsfao_obesity.pdf. David Fidler, *International Law and Global Public Health*, 48 U. KAN. L. REV. 1, 10 (2000) ("Liberalized trade in certain food products is also thought to contribute to obesity problems in many countries.").

[28]Organization for Economic Cooperation and Development, *Obesity and the Economics of Prevention: Fit Not Fat* (2010) *available at* http://www.oecd.org/dataoecd/21/19/46004918.pdf. For example, obesity cost the Australian Government Aus$58.2 billion in 2008, according to Diabetes Australia, which comprised Aus$8.3 billion of financial costs and Aus$49.9 billion in lost wellbeing. *Editorial: The Day of Diabetes: Coming to a Person Near You*, 376 THE LANCET 1513 (Nov. 6, 2010) *available at* http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673610620120.pdf.

[29] *See generally* David P. Fidler, *The Future of the World Health Organization: What Role for International Law?*, 31 VAND. J. TRANSNAT'L. L. 1079 (1998); Allyn Lise Taylor, *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, 18 AM. J.L. & MED. 301 (1992); Just Balstad Haffield, Harald Siem, and John-Arne Rottingen, *Global Health Governance: Examining the Global Health Arena: Strengths and Weaknesses of a Convention Approach to Global Health Challenges*, 38 J.L. MED. & ETHICS 614, 617 (2010) ("In global health there seems to be a drive towards adopting legally binding instruments, and the examples of recent international regulations are numerous (e.g., 2006 United Nations Convention on Disabilities, 2005 International Health Regulations [IHR], 2003 WHO Framework Convention on Tobacco Control, Medical Research and Development Treaty [current proposal being discussed as a follow up of the Commission on Intellectual Property Rights, Innovation and Public Health] . . .").

This expansion, what I refer to as the *internationalization* of public health law, conceivably includes agreements and political commitments made across several issue-areas.[30] For example, the 1949 Geneva Conventions codified customary rules requiring access of medical personnel to the injured and sick during armed conflicts as well as guaranteeing prisoners of war access to some level of health care. Similarly, arms control treaties like the NPT, the Biological Weapons Convention and the Chemical Weapons Convention are theoretically driven by those weapons' potentially devastating effect on human health and life.[31] The 1978 Alma Ata Declaration and the 1993 Vienna Declaration and Programme of Action marked important turning points in the history of the right to health without formalizing any express commitments by governments.[32] Indeed, judges, scholars, human rights activists and law-makers have never agreed upon the content of the right to the highest attainable standard of health since its codification in international human rights treaties.[33] For purposes of this Article, I limit the internationalization of public health law to international legal regimes designed to address health threats specifically those undertaken by the World Health Organization and its predecessor International Sanitary Conventions.

A. The International Sanitary Conventions

The internationalization of public health law began with an effort to coordinate national efforts to contain disease. In the middle of the

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[30] Ruger, *supra* note 7, at 424 ("In its broadest definition, [global health law] includes all international legal regimes relevant to public health--international environmental law, international humanitarian and human rights law, international trade and labor law, international laws relating to arms control, and so on. Construed more narrowly, it incorporates only those international legal regimes specifically designed to address health threats.").

[31] David Fidler, *The International Legal Implications of "Non-Lethal" Weapons*, 21 MICH. J. INT'L. L. 51 (1999). Yet even in that context, the failure of the Biological Weapons Convention to achieve the same enforcement regime strength as the Chemical Weapons Convention is attributed in significant part to the concerns of biological agent manufacturers that monitoring and site inspections may compromise valuable patents and trade secrets. http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg74704/pdf/CHRG-106hhrg74704.pdf Frank P. Grad, *Public Health Law: Its Form, Function, Future and Ethical Parameters*, 49 INT'L DIG. HEALTH LEGIS. 19, 21 (1998) ("[T]here is no neat package of legislation called 'public health law' but rather a vast array of rules from many difference legal areas."

[32] Sam Halabi, *Participation and the Right to Health: Lessons from Indonesia*, 11 HEALTH AND HUMAN RIGHTS 49 (2009).

[33] Universal Declaration of Human Rights art. 25; ICESCR art. 12; Ruger, *supra* note 7, at 426 ("During this period, appeals to human rights and the right to health in particular have dominated international health discourse, but the human rights movement and the right to health especially have been viewed with considerable skepticism and doubt.").

nineteenth century, states maintained their own standards for inspection and quarantine of foreign goods and peoples which posed public health threats, especially cholera.[34] Between 1851 and 1892, predominantly European powers met in an effort to conclude a list of internationally actionable diseases and the appropriate methods by which their spread might be limited. The health positions taken by participating governments and medical delegates were inevitably politicized as the etiology of each disease (and therefore its containment) necessitated measures that affected the commercial interests of each state.[35] Britain, for example, persistently opposed measures that imposed significant burdens on maritime trade.

Nevertheless, in 1892, the first International Sanitary Convention was concluded which aimed to monitor westbound shipping through the Suez Canal.[36] Between 1893 and 1903, four more international conventions were convened, steadily expanding both diseases deemed appropriate for cooperation and control; international adoption of national policies for surveillance; quarantine of certain items and persons; processes for sterilizing goods suspected of facilitating infection; and, notification requirements for other participants. At the 1903 convention, delegates agreed both on the need to codify in a single instrument the preceding agreements as well as to establish an international health organization.

These objectives of the 1903 ISC continued through the conventions held in 1912, 1926 and 1938. During this time, two international health organizations were established and the 1903 International Sanitary Convention was updated to reflect advances in the control of infectious diseases. At that time, "numerous international legal regimes addressing public health issues arose, particularly treaties dealing with . . . opium and alcohol, occupational hazards, and transboundary pollution." [37] As historians of the ISC conferences observed, over time the agenda of the international meetings moved from coordinating European responses to disease threats originating from Asia to serving as the most important forum for clinical researchers, bacteriologists, physicians and other medical researchers to influence international law and international relations as they affected the spread of disease.

The treaties' stated objectives tended to go unfulfilled. For example, it took seven international conventions meeting between 1851 and 1892 to

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[34] Norman Howard-Jones, THE SCIENTIFIC BACKGROUND OF THE INTERNATIONAL SANITARY CONFERENCES, 1851-1938 9, WHO Geneva (1975).
[35] *Id.*
[36] David . P. Fidler, *The Globalization of Public Health: The First 100 Years of International Health Diplomacy*, 79 BULLETIN OF THE WORLD HEALTH ORGANIZATION 842, 843 (2001).
[37] Ruger, *supra* note 7, at 426 ("In the early part of the twentieth century, international treaties focused on the control of narcotic drugs and ranged from the 1912 International Opium Convention to treaties dealing with trade in alcohol.").

finally generate the International Sanitary Convention of 1892 which was limited to cholera.[38] The fifth International Sanitary Convention succeeded in creating an international health organization but it "had no authority to do field work within a particular country, even at that country's request . . ."[39] In its 2005 revision of the International Health Regulations, the WHO's Intergovernmental Working Group noted that the IHR had been developed "to replace the largely ineffective international sanitary conventions, which were hampered inter alia by a lack of consistency and uniformity in their implementation . . ."[40] The purposes of the conventions became less legal in a strict sense and more technocratic, changes which were to foreshadow the behavior of the World Health Organization upon its establishment in 1948.[41]

B. The World Health Organization

When international law-makers established the World Health Organization (WHO), they intended to give it strong law-making and regulatory authority.[42] Article 19 of the WHO Constitution authorized it to conclude treaties within its broadly worded mandate while Article 21 gave the World Health Assembly the authority to adopt legally binding recommendations in five discrete areas: sanitary and quarantine regulations; nomenclatures on diseases, causes of death, and public health practices; standards for diagnostic procedures for international use; standards for safety, purity, and potency of biological, pharmaceutical, and similar products moving in international commerce; and advertising and labeling of biological, pharmaceutical, and similar products moving in international commerce.[43] Article 22 established the binding legal effect of these regulations unless states opted out of them within the notification

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[38] WHO, Origin and Development of International Health Cooperation 7 (1991) available at http://whqlibdoc.who.int/publications/1991/9290211407_(chp1).pdf

[39] *Id*. at 9.

[40] WHO Intergovernmental Working Group on the Revision of the IHR, Review and Approval of the Proposed Amendments to the International Health Regulations 2 available at http://apps.who.int/gb/ghs/pdf/IHR_IGWG2_ID2-en.pdf. Fidler and Gostin, *supra* note 22, at 92 ("Previous transformations in international law's relationship with public health have, over time, atrophied into insignificance. The history of the old IHR tells just such a story. Further, the new IHR's relevance to some pressing global health problems, such as increasing access to HIV/AIDS treatment in the developing world or stemming the "brain drain" of health workers from developing to developed countries.").

[41] Fidler, *supra* note 27, at 1 (2000) ("In the decades since the Second World War, international activities concerning public health carried out by intergovernmental organizations and nongovernmental organizations made little use of international law.").

[42] George Codding, Jr. *Contributions of the World Health Organization and the International Civil Aviation Organization to the Development of International Law*, 59 PROCEEDINGS OF ASIL 147 (1965).

[43] WHO Constitution Article 19, 21 available at http://www.who.int/governance/eb/who_constitution_en.pdf.

period, an innovation which collapsed the usual drawn-out ratification process historically experienced in the international law-making process. [44]

WHO instead embarked upon several decades of technocratic observation, advising and support.[45] The World Health Assembly updated the International Sanitary Regulations in 1969, but the scope and strength of the IHR were minimal. [46] WHO focused on epidemiological and technocratic expertise, giving itself a central coordinating role between other international and non-governmental organizations and making far more frequent use of its Article 23 recommendation-issuing authority. [47] The World Health Assembly regularly issued resolutions advising governments to undertake a range of measures related to its – highly regarded – epidemiological work but steered almost completely clear of its law-making and regulation-issuing authority.[48]

1. International Code on the Marketing of Breastmilk Substitutes

After the 1969 IHR, WHO aimed at using its Article 21 powers to address child malnutrition in the International Code on the Marketing of Breastmilk Substitutes, although the policy eventually took form as an Article 23 recommendation. In 1974, the World Health Assembly acknowledged the declining rate of mothers exclusively breastfeeding for the first six months of life, the period WHO recommends for both

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[44] WHO Constitution Art. 19, 21, 22.

[45] Fidler and Gostin, *supra* note 22, at 92 ("For decades, WHO has issued recommendations on many public health problems; but the mixed record of state compliance with WHO guidance should temper enthusiasm for the new IHR's recommendation provisions. The political controversies that surrounded WHO's more aggressive actions during SARS may deter WHO from taking similar actions under the new IHR. Laments about the erosion of global and local public health capabilities suggest that WHO's decades-long effort to improve health conditions in developing countries has also met with only qualified success.").

[46] Rebecca Katz & Julie Fischer, *The Revised International Health Regulations: A Framework for Global Pandemic Response*, 3 GLOBAL HEALTH GOVERNANCE, 1, 2 (2010), *available at* http://blogs.shu.edu/ghg/files/2011/11/Katz-and-Fischer_The-Revised-International-Health-Regulations_Spring-2010.pdf.

[47] Ilona Kickbush, Wolfgang Hein and Gaudenz Silberschmidt, *Addressing Global Health Governance Challenges through a new Mechanism: The Proposal for a Committee C of the World Health Assembly*, 38 J.L. MED. & ETHICS 550, 558 (2010) ("As the United Nations technical agency for health, the WHO has been able to benefit from another form of legitimacy based on knowledge, expertise, and evidence. Meanwhile a wide range of expert organizations in the global arena are also able to provide this type of legitimacy – but they do not have the link to formal legal legitimacy, which allows the WHO to be a normative and standard setting organization.").

[48] Fidler, *supra* note 27, at 15 ("This isolation was not accidental but reflected a particular outlook on the formulation and implementation of international public health policy. WHO operated as if it were not subject to the normal dynamics of the anarchical society; rather, it acted as if it were at the center of a transnational Hippocratic society made up of physicians, medical scientists, and public health experts. The nature and dynamics of this transnational Hippocratic society led WHO to approach international public health without a legal strategy.").

maternal and child health.[49] The recommendation is not driven by nutritional variations between breastmilk and infant formula, but by the risks inherent in mixing (especially with contaminated water) and administering formula as well as malnutrition that accompanies improper or imbalanced substitutes. As Ted Kennedy phrased it:

> Can a product which requires clean water, good sanitation, adequate family income and a literate parent to follow printed instructions be properly and safely used in areas where water is contaminated, sewage runs in the street, poverty is severe and illiteracy high?[50]

The evidence is persuasive: 13% of the 10.9 million deaths of children younger than 5 years could be prevented every year if universal protection, promotion and support of breastfeeding were achieved.[51] In addition, breastfeeding plays a role in spacing pregnancies where contraception is unavailable or contraception failures are common. The declining rates of breastfeeding were attributed to food firms' aggressive marketing of infant formula, other milk products, cereals for infants, vegetable mixes, and baby teas and juices, all of which fall under WHO's definition of breastmilk substitutes.[52] These firms' marketing practices either asserted or implied nutritional and other health equivalencies with, or superiority to, exclusive breastfeeding.

Between 1977 and 1979, children's malnutrition became a priority for the World Health Assembly and WHO began working with UNICEF on a framework for "regulating inappropriate sales promotion of infant foods that can be used to replace breast milk".[53] Those discussions revolved around five themes: the encouragement and support of breast-feeding; the promotion and support of appropriate and timely complementary feeding (weaning) practices with the use of local food resources; the strengthening of education, training and information on infant and young child feeding; the promotion of the health and social status of women in relation to infant and young child health and feeding; and the appropriate marketing and distribution of breast-milk substitutes. In 1980, the World Health Assembly endorsed the WHO/UNICEF findings and recommended that "there should be an international code of marketing of infant formula and other products used as breast-milk substitutes". In early 1981, WHO

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[49] See Resolution WHA27.43 (Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II, 4th ed., Geneva, 1981, p.58).
[50] Marketing and Promotion of Infant Formula In the Developing Nations, 1978: Hearings Before the Subcomm. on Health and Scientific Research of the Comm. on Human Resources, 95th Cong., 2d Sess. 1·2 (1978) (statement of Sen. Kennedy).
[51] See HIV, Infant Feeding and the Code 4, available at http://www.ennonline.net/pool/files/ife/hiv,-if-and-code.pdf.
[52] See International Code of Marketing of Breast Milk Substitutes, available at http://www.who.int/nutrition/publications/code_english.pdf
[53] *Id*. at 4 fn. 2.

endorsed a draft of the Code and recommended it to the World Health Assembly which adopted it by an overwhelmingly vote.[54]

The International Code seeks to prevent companies from advertising; implement strict labeling requirements including a proscription on infant images or other pictures which idealize breastmilk substitutes; limit influence on health care workers; and, prohibit distribution of free samples of breast milk substitutes.[55] The International Code, together with subsequent recommendations, is not a binding treaty, but represents an evidence-based minimum standard which informs human rights obligations.[56] Eighty-four states have enacted legislation enacting all or some aspects of the International Code while another 14 have legislation pending.[57] Since the International Code's adoption, food firms have systematically exploited its ambiguities and have directly challenged labeling provisions that diminish intellectual property rights in trademarks and tradenames.[58]

2. International Health Regulations

The 1980s and early 1990s witnessed the emergence of new infectious diseases like HIV as well as the resurgence of older diseases like cholera. In 1995, the World Health Assembly instructed WHO's Director General to revisit the IHR precisely because they neglected "the emergence of new infectious agents" and failed to provide for an adequate response of those that were covered.[59] The World Health Assembly attributed these failures to the erosion of barriers between goods and people.[60] The protracted IHR revision process overlapped with acrimonious negotiations between developing and developed states over the inclusion of intellectual property protections in the global free trade regime.[61] In 2003, the outbreak of

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[54] For the verbatim record of the discussion at the fifteenth plenary meeting, on 21 May 1981, see documentWHA34/1981/REC/2.
[55] *Id.*
[56] See U.N. Committee on the Rights of the Child General Comment No. 15 (2013) on the Right of the Child to the Highest Attainable Standard of Health ¶ 44 (17 Apr. 2013). Generally, WHA recommendations are not binding but they "carry moral or political weight, as they constitute the judgment on a health issue of the collective membership of the highest international body in the field of health." Shubber, S. The International Code, Digest of Health Legislation, Vol. 36, No. 4, 1985, p. 884.
[57] UNICEF, International Code of Marketing of Breast Milk Substitutes available at http://www.unicef.org/nutrition/index_24805.html.
[58] UNICEF, Protecting Breastfeeding in West and Central Africa available at http://www.unicef.org/wcaro/WCARO_Pub_Breastfeeding.pdf
[59] http://www.who.int/ihr/revisionprocess/revision/en/index.html
[60] Katz & Fischer, *supra* note 46 at 2. The threat of the Ebola virus and the emerging HIV/AIDS crisis (among other viruses) were major factors the global community considered when advocating revisions to the existing IHR. *Id*.
[61] David Fidler, *The Revision of the IHR*, ASIL INSIGHTS (April 2004) available at http://www.asil.org/insigh132.cfm

SARS – and the hesitation of the Chinese government to report or contain it – facilitated the 2005 revisions.[62]

The IHR (2005) was revised to encompass the detection and prevention of all infectious diseases.[63] Their scope was expanded "to include any event that would constitute a public health emergency of international concern."[64] "The Regulations now encompass public health risks whatever their origin or source (Article 1.1), including: (1) naturally occurring infectious diseases, whether of known or unknown etiological origin; (2) the potential international spread of non-communicable diseases caused by chemical or radiological agents in products moving in international commerce; and (3) suspected intentional or accidental releases of biological, chemical, or radiological substances."[65] Acknowledging the importance of communication and cooperation to successful detection and prevention of communicable diseases, States Parties are obligated to "develop the means to detect, report, and respond to public health emergencies . . . [and] establish a National IHR Focal Point (NFP)[66] for communication to and from WHO . . ."[67] States Parties must inform WHO within 24 hours of an assessment of any event that could be considered a "public health risk to other States requiring a coordinated international response."[68]

The drafters of the IHR (2005) included important limitations on the measures states could impose when facing a public health "event."[69] These limitations may be categorized in two non-mutually exclusive ways: 1) individual human rights and 2) the harmonization of the IHR with other international agreements. Individual rights, especially those historically characterized as "civil" or "political", often faced curtailment in the name

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[62] Katz and Fischer, *supra* note 46, at 2.
[63] The stated purpose is to "prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." *International Health Regulations (2005)*, WORLD HEALTH ORGANIZATION 1 (2005).
[64] Katz & Fischer, *supra* note 46, at 2.
[65] Fidler and Gostin, *supra* note 22, at 86-87.
[66] The (NFP) is a "national centre, established or designated by each State Party [and] must be accessible at all times for IHR (2005)-related communications with WHO." *International Health Regulations (2005): Toolkit for Implementation in National Legislation*, WORLD HEALTH ORGANIZATION 1, 7 (2009), *available at* http://www.who.int/ihr/NFP_Toolkit.pdf. As of July 2009, ninety nine percent of all States have established an NFP.
[67] Katz & Fischer, *supra* note 46, at 4.
[68] *Id*. at 3. Once an incident has been reported, WHO will then "coordinate communications across nations, provide technical assistance to responding nations, and work with international scientific experts to develop recommendations for mitigating the consequences of the event." *Id*.
[69] Fidler and Gostin, *supra* note 22, at 86-87.

of public health measures. Isolation and quarantine, for example, impose significant restrictions on individual liberty. Under the IHR (2005):

> For a public health measure to restrict a civil and political right lawfully, the measure must (1) respond to a pressing public or social need; (2) pursue a legitimate aim; (3) be proportionate to the legitimate aim; and (4) be no more restrictive than is required to achieve the purpose sought by restricting the right. The rights-restricting measure must also be implemented in a non-discriminatory manner (International Covenant on Civil and Political Rights (ICCPR), Articles 2.1 and 26).[70]

States Parties may implement health measures that achieve the same or greater level of health protection as WHO recommendations but they must be based on scientific principles, available scientific evidence, relevant guidance or advice from WHO, and cannot be more restrictive of international traffic or more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection. [71]

These provisions are explored, *infra*, as dovetailing with health exceptions and rules of interpretation provided in WTO agreements, especially TRIPS. Because the IHR (2005) do not have a strong enforcement mechanism,[72] this ultimately privileges WTO jurisprudence as the benchmark by which public health measures states implement are evaluated.

Indeed, during the IHR negotiation process:

> WHO member states expressed concerns that the expanded scope of the new IHR would bring the Regulations into conflict with other international agencies and treaties that addressed cross-border health risks -- e.g., the International Atomic Energy Agency (nuclear accidents); the World Trade Organization (health measures that restrict international trade); and the Codex Alimentarius Commission (food standards and guidelines to protect consumer health and promote trade in safe products). WHO addressed these concerns by demonstrating that few conflicts existed; amending the negotiating text to remove the small number of possible conflicts; and adding provisions to facilitate

[70] Fidler and Gostin, *supra* note 22, at 92.
[71] World Health Assembly, *Revision of the International Health Regulations*, WHA58.3 (May 23, 2005) (Articles 43.1-43.2).
[72] *Id*. at Article 56. Fidler and Gostin, *supra* note 22, at 90 (acknowledging the lack of an enforcement mechanism).

cooperation and coordination between WHO and other international organizations (e.g., Articles 14, 17(f), 57.1)."[73]

The first meaningful test of the IHR (2005) occurred in the context of the outbreak of the HINI influenza virus in 2009 although the outbreak of avian flu in Indonesia in 2007 also tested the IHR's underlying principles. These episodes demonstrated the confrontation between intellectual property and public health as well as the role middle-income states played in advancing the public health agenda. In 2007, Indonesia refused to share flu samples precisely because of past experiences in which Western firms patented genetic material in order to manufacture unaffordable vaccines.

3. The Framework Convention on Tobacco Control

Parallel to negotiations over the revised IHR, the World Health Organization also oversaw the drafting of its first public health treaty, the Framework Convention on Tobacco Control (FCTC). Just as the surge in old and new infectious agents – tied in a significant way to globalization – prompted calls for an improved set of International Health Regulations, the FCTC represented the culmination of decades of public health measures recommended by the World Health Assembly but persistently undermined by a globally-coordinated effort undertaken by tobacco firms.[74]

In 1995, Canada, Finland, Mexico, and Tanzania supported the idea of an international agreement[75] to regulate tobacco at the World Health Assembly (WHA), which adopted Resolution 48.11, advocating the use of an "international instrument" to curb global tobacco consumption.[76] A detailed outline was delivered to the WHO on July 27, 1995, setting forth options for an international legal strategy for tobacco control and recommending the development and implementation of a WHO framework convention on tobacco control and related protocols to promote global cooperation and national action.[77] In 1998, Member States finally established both a WHO FCTC Working Group to draft core treaty

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[73] *Id*.

[74] Sam Foster Halabi, *The World Health Organization's Framework Convention on Tobacco Control: an Analysis of Guidelines Adopted by the Conference of the Parties*, 39 GA. J. INT'L. & COMP. L. 121, 129-132 (2010).

[75] WHO Director General, *The Feasibility of Developing an International Instrument for Tobacco Control*, EM97/INF.Doc./4 (Nov. 30, 1995).

[76] World Health Assembly, *An International Strategy for Tobacco Control*, EB95.R9, WHA48.11, WHO/PSA/96.6 (May 12, 1995), *available at* http://www.who.int/tobacco/frame work/wha_eb/wha48_11/en.

[77] Ruth Roemer, Allyn Taylor, & Jean Lariviere, *Origins of the WHO Framework Convention on Tobacco Control*, 95(6) AMERICAN J. PUB. HEALTH 936, 937 (June 2005) *available at* http://ajph.aphapublications.org/cgi/reprint/95/6/936.pdf.

elements and an Intergovernmental Negotiating Body to develop the treaty text.[78]

The FCTC was designed as a compromise solution between a purely recommendatory instrument and a binding convention. The FCTC established evidence-based provisions for curbing global tobacco consumption, many of which focused on the advertising, labeling, marketing, packaging and promotion of tobacco products.[79] The convention has been followed by additional action to enhance and clarify the strength and scope of the treaty.[80] The progress of this action, however, has progressed unevenly. The FCTC's Conference of the Parties ("COP") quickly adopted implementing guidelines for some of the treaty's mandates, but struggled to adopt others. A protocol on illicit trade in tobacco products languished for years in the COP. Notwithstanding those efforts, the FCTC was adopted by Member States in 2003 and entered into force on February 27, 2005.[81] One hundred and seventy-seven parties have ratified or acceded to the FCTC as of September 2013.[82]

C. Proposed Conventions

The somewhat disputed success of the International Code, the IHR and the FCTC have led prominent public health scholars and organizations to call for an increase in the number of issue-areas over which national public health measures may be elevated to international fora and to call for a more comprehensive, global approach to international public health challenges.

1. Framework Convention on Alcohol Control

While modest in comparison to tobacco, the disease burden imposed by alcohol consumption is substantial. Alcohol consumption not only results in greater harm to third parties relative to other drugs like cocaine and heroin,[83] but also has substantial deleterious effects on users, such as

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[78] *See Working Group Preceding the Intergovernmental Negotiating Body on the WHO FCTC (1999–2000)*, FCTC: WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, http://www. who.int/fctc/about/pre_neg_working_group/en/index.html (last visited Nov. 20, 2010).

[79] Halabi, *supra* note 74, at 153-164.

[80] *Id*.

[81] *Foreword to* WHO Framework Convention on Tobacco Control, at v, May 21, 2003–June 29, 2004, WHA56.1, 2302 U.N.T.S. 166, 42 I.L.M. 518, *available at* http://www.who. int/tobacco/framework/WHO_FCTC_english.pdf.

[82] http://www.who.int/fctc/signatories_parties/en/index.html

[83] David J. Nutt et. al., *Drug Harms in the UK: A Multicriteria Decision Analysis*, 376 THE LANCET 1558, 1560–61 (2010). Alcohol consumption and its corresponding negative effects are increasing worldwide. *See Alcohol-Related Ills Increasing Worldwide*, U.S. NEWS & WORLD REP. (June 25, 2009), http://health.usnews.com/health-news/family-health/brain-and-behavior/articles/2009/06/25/alcohol-related-ills-

increased risks of cancer and heart disease, traffic accidents, burns, poisonings, and drownings.[84] Additionally, alcohol consumption facilitates risky sexual behavior contributing to the spread of HIV/AIDS and other sexually transmitted diseases.[85]

In 2010, the WHO published a report titled "Global Strategy to Reduce the Harmful Use of Alcohol" (the Report)[86] in which it concluded that "2.5 million people worldwide died of alcohol-related causes in 2004, including 320,000 young people between 15 and 29 years of age[87]." WHO recommended a number of interventions consistent with analogous FCTC mandates including: educating people on the consequences of alcohol abuse; restricting the sale of alcohol to minors; implementing comprehensive marketing restrictions; increasing taxes on alcohol products; and, addressing illicit or informally produced alcohol. The Report is not binding; it merely serves as a guide for member nations when adopting their own alcohol control laws. Organizations like the American Public Health Association[88] and the American Society of Addiction Medicine[89], the World Medical Association as well as leading medical journals advocated an international alcohol control treaty based in significant part on the FCTC and WHO recommendations.[90] Editors of one of these journals, the *Lancet*, has also posed the question as to the desirability of a Framework Convention on Obesity Control based in part on WHO's Global Strategy for Diet, Physical Activity and Health.[91]

2. Framework Convention on Global Health

Without explicitly criticizing the incrementalism inherent in an issue-by-issue approach to international public health law,[92] Lawrence Gostin and his collaborators have endorsed a comprehensive approach to meet the

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increasing-worldwide; Charles D.H. Parry, *Alcohol Problems in Developing Countries: Challenges for the New Millennium*, 2 SUCHTMEDIZIN IN FORSCHUNG UND PRAXIS 216, 217–18 (2000) *available at* http://www.sahealthinfo.org/admodule/Suchtmed.pdf.

[84] WORLD HEALTH ORG., ALCOHOL AND INJURIES: EMERGENCY DEPARTMENT STUDIES IN AN INTERNATIONAL PERSPECTIVE, at iv (2009), *available at* http://www.who.int/substance_abuse/publications/alcohol/en/.

[85] Lori A.J. Scott-Shelden et al., *Alcohol Consumption, Drug Use and Condom Use Among STD Clinic Patients*, 70 J. STUDS. ON ALCOHOL & DRUGS 762, 762–63 (2009).

[86] WHO, Global Strategy to Reduce the Harmful Use of Alcohol 3 (2010) http://www.who.int/substance_abuse/msbalcstragegy.pdf

[87] *Id*. at 5.

[88] APHA, *supra* note 6.

[89] http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2011/12/16/establishment-of-a-framework-convention-on-alcohol-control-and-the-exclusion-of-tobacco-and-alcohol-from-trade-agreements

[90] Allyn L. Taylor & Ibadat S. Dhillon, *An International Legal Strategy for Alcohol Control: Not a Framework Convention – At Least Not Yet*, Addiction, June 20, 2012.

[91] See http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61356-1/fulltext.

[92] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61895-3/fulltext

"basic survival needs" of all humans through a Framework Convention on Global Health.[93] Uniting the broad agreement between governments on a human right to health as well as the health-related aspects of the Millennium Development Goals, Gostin argues that a FCGH would address the substandard living conditions in many developing states.[94] These basic survival needs are sanitation and sewage, pest control, clean air and water, tobacco reduction, diet and nutrition, essential medicines and vaccines, and functioning health systems for the prevention, detection, and mitigation of disease and premature death.[95] The Framework Convention on Global Health would commit states to certain forms of support for these objectives,[96] facilitate cooperation and formation of expert communities addressing them, and impose a range of mechanisms to enforce commitments.[97]

Under the current vision of the agreement, WHO would coordinate states' commitment "to a set of targets, both economic and logistic, and [the dismantling of barriers] to constructive engagement by the private and charitable sectors."[98] In legal terms, a FCGH could "commit states to specific action . . . targeting the unhealthy conditions that combine with poverty to exacerbate and perpetuate inequality."[99]

The FCGH would be implemented in stages through FCTC-like governance structures including a conference of the parties, secretariat, technical advisory body and representative roles for civil society

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[93] A FCGH would "seek innovative solutions for the most pressing health problems facing the world in partnership with non-State actors and civil society, with particular emphasis on the most disadvantaged populations." Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People*, 96 GEO. L.J. 331, 388 (2008).

[94] *See generally* Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health*, GEORGETOWN LAW FACULTY LECTURES (1997), *available* at http://scholarship.law.georgetown.edu/fac_lectures/11/.

[95] Lawrence O. Gostin and Eric A. Friedman, *Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL'Y L. & ETHICS 1 (2013).

[96] Obligations would include: "[i]ncentives, forms of assistance (for example, financial aid, debt relief, technical support, subsidies, tradable credits), and levels of assistance, with differentiated responsibility for developed, developing, and least developed countries." Gostin, *supra* note 93.

[97] Enforcement tools include: "[i]nducements, sanctions, mediation, and dispute resolution." *Id*.

[98] A FCGH would provide several tools to streamline global health policy such as: "global health spending as a portion of GNP, defin[able] areas of cost effective investment to meet basic survival needs, build[ing] sustainable health systems, and creat[ing] incentives for scientific innovation." Gostin, *supra* note 94, at 2.

[99] Scott Buris & Evan D. Anderson, *A Framework Convention on Global Health: Social Justice Lite, or a Light on Social Justice?*, 38 J.L MED. & ETHICS 580, 586 (2010).

groups.[100] Initially, the FCGH would emphasize capacity building,[101] priority setting,[102] engaging stakeholders,[103] activity coordination,[104] and progress evaluation and monitoring.[105]

3. Medical Research and Innovation Treaty

Because of the controversial relationship between intellectual property rights, the changing nature of pharmaceutical financing and innovation and access to medicines in developing countries, the World Health Organization has undertaken a series of studies aimed at addressing the failure of a robust IP-rights protection regime to generate medicines and technologies developing countries need most.[106] The diseases for which treatments are available are too expensive because of patents and trademarks while the diseases for which the market will likely be paltry attract little research and development funding.[107] These efforts are coordinated with the World Trade Organization and the World Intellectual Property Organization as well as major international charities. In 2012, the WHO's Consultative Expert Working Group published *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, in which it called for a binding framework treaty to address innovation and research capacity in

[100] This would facilitate the international community to focus on problems in a "stepwise manner, avoiding potential political bottlenecks over contentious elements." Gostin, *supra* note 93, at 386, 389.

[101] Lawrence O. Gostin and Eric A. Friedman, *Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice*, 13 YALE J. HEALTH POL'Y L. & ETHICS 1, 54-56 (2013).

[102] While well intentioned, many of the charitable donors are simply pouring resources toward health issues that may or may not be the "root" of the problem in a given country. Gostin, *supra* note 93, at 384-385. Because no single entity has the capacity to solve these issues on their own, "consensus building and communal priority setting are sorely needed." *Id*. at 385.

[103] *Id*. at 384. This would enable a wide variety of state and non-state members to pool resources and expertise.

[104] *Id*. As priority setting and engaging stakeholders would essentially bring all players to the same page, activity coordination would harmonize the combined efforts.

[105] *Id*. This would ensure goals being set are met and the promises members make are being kept. *Id*. This is where previous initiatives have failed as there is no effective follow up mechanisms for progress/accountability. *Id*. at 386.

[106] Jack Lerner, *Intellectual Property and Development at WHO and WIPO*, 34 AM J. L. AND MED. 257, 260 (2008).

[107] WHO Consultative Expert Working Group, Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination 1-2 available at http://www.who.int/phi/CEWG_Report_5_April_2012.pdf (discussing progress of CEWG's work). Multiple theories of intellectual property protection might apply to the same good. For example, a pharmaceutical patent might apply to a given compound, while trademark or trade dress protection might apply to the appearance of a given pill. See Jeremy A. Greene, and Aaron S. Kesselheim, *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health*, 365 NEJM 83 (2011).

developing countries and to design a system to promote development of treatments through incentive and other financing mechanisms.[108]

The CEWG's report extensively covered the obstacles strong IP protections pose for addressing medical research and development needs in developing countries. The report squarely addressed existing IP instruments viewing a medical research and innovation "convention not as a replacement for the existing intellectual property rights system but as a supplementary instrument where the current system does not function" and emphasizing the need for research and development breakthroughs to be developed by other researchers.[109] The recommended elements of the proposed treaty suggest the difficulties member states face for attempts to manage IP rights in a health-based treaty. For example, the only element of the proposed treaty which specifically mentions intellectual property reads thusly:

> encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of developing countries, protects public health and promotes access to medicines for all, as well as explore and implement, where appropriate, possible incentive schemes for R&D.

This provision might be read to introduce some modification of the strong IP rights that now characterize multilateral trade as well as bilateral and regional investment treaties. It also obscures underlying disagreement – "managing intellectual property to maximize health-related innovation" might easily accommodate the current views of pharmaceutical patent holders who argue that long periods of exclusive control are precisely the kind of incentive they need to maximize health-related innovation.[110]

D. Public Private Partnerships

It is in the context of the growing ties between the private and public sectors that public health activists, scholars and organizations refer to the growing importance of "governance" in solving public health problems at the international level, a phrase which wraps together individuals, governments, firms, agencies and charities.[111] Indeed, the World Health

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[108] *Id*. The proposed treaty has been variously called the Essential Health and Biomedical R&D treaty, the Medical Research and Development treaty, the Biomedical R&D treaty, etc.

[109] *Id*. at 122, 147

[110] Brian Till, *How Drug Companies Keep Medicine Out of Reach*, THE ATLANTIC, May 15, 2013 available at http://www.theatlantic.com/health/archive/2013/05/how-drug-companies-keep-medicine-out-of-reach/275853/

[111] Kickbush, Hein and Silberschmidt, *supra* note 47, at 559 ("While a government "governs" by using its constitutional powers to pursue specific goals, the term "governance" rather looks at the interactive processes between different actors in the

Organization's Constitution incorporated the role of non-governmental organizations who by 1948 had undertaken significant efforts toward eradicating infectious diseases and caring for injured and sick persons.[112]

The Global Fund for example, is a public-private partnership dedicated to collecting/allocating resources and funds for "a world free from the burden of AIDS, [TB] and malaria."[113] Each needs-based country has control over its own implementation of measures to prevent the spread of these diseases and is provided funding based on the effectiveness of the measures used.[114] Despite pockets of political unpopularity and misuse of money, Global Fund claims to have saved 6.5 million lives since its establishment.[115] Three million people have been provided AIDS treatment, over 7.7 million have been treated for TB, and over 160 million insecticide treated bed nets have been distributed.[116]

Similarly, the Bill and Melinda Gates Foundation together with WHO, UNICEF, the World Bank and major pharmaceutical firms established the Global Alliance for Vaccines and Immunizations (GAVI) which is funded through the International Finance Facility for Immunization (IFFIm), which is itself funded by the governments of Australia, France, Italy, the Netherlands, Norway, South Africa, Spain, Sweden, the United Kingdom.[117] Eligible states determine their immunization needs, apply for funding support and administer approved vaccination programs. Under GAVI's Advance Market Commitment (AMC) program, donors commit funds to guarantee the price of vaccines once they have been developed. In

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absence of a central authority which lead to a specific outcome. It has frequently been associated with "governance without government," a view that is increasingly challenged as the role of states in the global governance system is better understood."). Nan D. Hunter, *Risk Governance and Deliberative Democracy in Health Care*, 97 GEO. L.J. 1, 6 (2008); David Gartner, *Beyond the Monopoly of States*, 32 U. PENN. J. INT'L. L. 595 (2011).

[112] WHO Constitution Articles 69-72.

[113] *Who We Are*, THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA, *available at* http://www.theglobalfund.org/en/about/whoweare/.

[114] *Id*.

[115] John Heilprin, *Fraud Plagues Celebrity-Backed Global Health Fund*, HuffingtonPost.com, *available at* http://www.huffingtonpost.com/2011/01/23/global-health-fund-fraud_n_812801.html ("Global Fund suffered a major setback in early 2011 with serious charges of corruption. A great portion of the money was improperly accounted for by bad book-keeping and forged documents. Donated prescription drugs used to fight the three diseases would wind up on the black market. The countries who were implicated in the corruption scheme lost funding and have been required to return the stolen funds.").

[116] *Id*. A Global Fund spokesperson stated that "[w]ithout a spotlight, without investigations, and without some sort of accountability, it's impossible to root out corruption, [b]ut just simply withdrawing donations, I do believe, would condemn millions of people who are not involved in the corruption to terrible fates." *Id*.

[117] Lisa Clarke, *The Responsibility of International Organizations under International Law for the Acts of Global Health Public Private Partnerships*, 12 CHI. J. INT'L. L. 55 (2011).

exchange, companies promise to provide the vaccines at an affordable price to developing countries.[118]

Global Fund and GAVI represent just two examples of public-private partnerships which number in the hundreds and health-related NGOs which number in the tens of thousands.[119] The participation of major non-governmental organizations in global public health is not new, although the innovations current ones are introducing into administration and management are.[120] In some ways, public-private partnerships are better able to balance IP rights with their public health missions working, as they do, within the strong patent regimes donors generally enjoy.[121] Global Fund and GAVI, for example, are theoretically able to manage a range of supplier behaviors through their contracts.[122]

II. THE EXPANSION OF INTELLECTUAL PROPERTY RIGHTS IN TRADE AND INVESTMENT TREATIES

With the exception of public-private partnerships, the international coordination agreements outlined above are dependent on traditional notions of treaty compliance including reciprocity, transparency, legitimacy, mobilization and vertical integration (i.e. international rules and standards are internalized into national law).[123] There are weak or no

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[118] Susan Sell, *Question for Global Governance in Intellectual Property and Public Health*, 77 TEMPLE L. REV. 363, 371 (2004).

[119] Kickbush, Hein and Silberschmidt, *supra* note 47, at 554 ("The parallels to the dominant position of the Bill & Melinda Gates Foundation today -- who in 2007 spent roughly as much on global health as WHO's budget for that year -- are obvious. They now have a significant impact on setting agendas, shaping global health policies and implementing programs. Their sheer number is staggering: a 2007 estimate of AIDS-related NGOs alone counted more than 60,000. More than 200 public-private partnerships are operating in fields such as developing new medicines for neglected diseases, improving access to medical treatment or pooling resources for specific goals.").

[120] Lawrence Gostin and Allyn Taylor, *Global Health Law: A Definition and Grand Challenges* 1 Public Health Ethics 53, 57 (2008) ("Indeed, a number of modern cutting-edge global health governance initiatives eschew formal international legal regimes, such as the global fund, global health security initiative, international drug purchase facility (UNITAID) and international finance facility for immunization.").

[121] Suppliers include bidders, agents, intermediaries, consultants, contractors, affiliates, employees, subcontractors, and agents. *Sanctions Procedures Relating to the Code of Conduct for Suppliers*, THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA 1, *available at* http://www.theglobalfund.org/en/library/documents/.

[122] *Id*.

[123] Benedict Kingsbury, *The Concept of Compliance as a Function of Competing Conceptions of International Law*, 19 MICH. J. INT'L. L. 345 (1998); Just Balstad Haffield, Harald Siem, and John-Arne Rottingen, *Global Health Governance: Examining the Global Health Arena: Strengths and Weaknesses of a Convention Approach to Global Health Challenges*, 38 J.L. MED. & ETHICS 614, 616 (2010). Abram and Antonia Chayes, THE NEW SOVEREIGNTY: COMPLIANCE WITH INTERNATIONAL REGULATORY AGREEMENTS 135 (1995); Olivier Schachter, *Towards a Theory of International Obligation*, 6 VA. J. INT'L. L. 301 (1968); Francesco Parisi and Nita Ghei, *The Role of Reciprocity in International Law*, 36 CORNELL INT'L. L. J. (2003).

enforcement mechanisms to speak of, the benefits of coordination and mobilization serving as their own justifications. Whatever the strengths of these justifications, they are threatened by a nearly perfectly parallel development in international law: international intellectual property protection. Yet unlike the enforcement mechanisms embedded in international public health law instruments, intellectual property rights holders enjoy, almost uniformly, enforceable rights in these international agreements, even when they conflict with public health measures.

These agreements range from the protections given intellectual property rights holders under regional and multilateral trade treaties to the broad scope of legal protections given both "investors" and "investments" under bilateral investment treaties. The upshot of these parallel, contradictory legal mechanisms is the frustration of global health law objectives like reduced tobacco use, expanded access to vaccines in the event of pandemic or even the mutual trust necessary for international public health treaties to work. The end result is that robust IP protection works in persistent opposition to public health objectives.[124]

A. The 1883 Paris Convention for the Protection of Industrial Property

Contemporaneously with late nineteenth century efforts to establish the first international public health law treaties, a small group of states also sought to protect their citizens' industrial and intellectual properties as they moved across borders.[125] Disparate national patent and trademark regimes meant that rights holders in one state might lose patent or trademark protection in another if they did not simultaneously file for protection in all relevant states.[126] Like public health law, intellectual property law was essentially national in nature though growing international trade mobilized efforts at an international approach to legal barriers for IP. The Paris Convention for the Protection of Industrial Property created a legal union between participating states in which foreign industrial design, patent and trademark applications received the same treatment as national applications; covered intellectual property first protected in one state received priority in other participating states; and,

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[124] Kojo Yelpaala, *Quo Vadis WTO? The Threat of TRIPS and the Biodiversity Convention to Human Health and Food Security*, 30 B.U. INT'L L.J. 55, 85-86 (2012) ("Trade and investment liberalization have produced certain negative externalities in health in developing countries. Trade liberalization has enabled greater availability of highly processed, calorie-rich and nutrient-deprived food in developing countries. Trade liberalization has also opened up the markets of developing countries to other high health-risk products such as tobacco . . . .").

[125] See GHC Bodenhausen, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 9 (1968) (Belgium, Brazil, France, Guatemala, Italy, Netherlands, Portugal, Salvador, Serbia, Spain and Switzerland).

[126] Seth M. Reiss, COMMENTARY ON THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 1 available at http://www.lex-ip.com/Paris.pdf.

codified some common substantive protections.[127] The treaty also specifically addressed forms of unfair competition not related to patents or trademarks, provisions which were subsequently strengthened when the parties revised the treaty in several conferences from 1886 to 1967. Membership in the treaty grew from 11 parties in 1883 to 174 in 2013.

While the treaty never specifically addressed the relationship between international intellectual property protection and public health, it did create exceptions foreshadowing the principal conflicts occurring between 1994 and 2012. Compulsory licenses were always contemplated for public health reasons while the addition of Article 6quinquies(B)(iii) in 1934 allowed the denial of registration or the invalidation of trademarks which might mislead consumers.[128] In short, the Paris Convention, later incorporated into the WTO's TRIPS Agreement, provided broad exceptions for the compulsory licensing of patents related to medicines as well as the prohibition on trademarks that might create false impressions as to products' health-related attributes.[129]

Like public health treaties originating at the same time, the Paris Convention tended to suffer from underenforcement as well as the absence of a specific forum to which an aggrieved IP rights holder might resort. Compliance and complaint were largely diplomatic matters.[130] For example, the international organization created to administer the Paris Convention and, later, the Berne Convention for the Protection of Literary and Artistic Works – the United International Bureaux for the Protection of Intellectual Property (BIRPI – its French acronym[131]) – never enjoyed more than a formal coordinating role and was, strictly speaking, an arm of the Swiss government.[132]

From 1893 to 1967, BIRPI oversaw revisions to the major treaties including the ways in which the agreements would govern new technologies; entry by newly independent former colonies; and, increasing efforts to include substantive law in the treaties.[133] In 1967, the parties

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[127] *Id*.

[128] Paris Convention Art. 5Paris Convention Art. 6 *quinquies(B)(iii)*. Bodenhausen, *supra* note 125, at 70, 116 (1968) ("[Compulsory licenses] may be the case when patents concern vital interests of the country in the fields of military security or public health . . . . The purpose of [Article 6quinquies(B)(iii)] was to enable member States to refuse or invalidate trademarks containing suggestions that the goods concerned possessed non-existing qualities . . .").

[129] John Walker Baxter, John P. Sinnot & William Cotreau, WORLD PATENT LAW AND PRACTICE § 8 (2007) (discussing the local working requirements of section 5A of the Paris Union after TRIPS and laying out approaches used by some countries).

[130] Reichman, *supra* note 8, at 385.

[131] Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle

[132] *Id*.

[133] Christopher May, *The Pre-History and Establishment of WIPO*, 2009 WIPO JOURNAL 16, 20-21 (2009).

agreed to transform BIRPI into an international organization, the World Intellectual Property Organization (WIPO), which operated formally from 1970 and as a specialized agency of the United Nations from 1974. WIPO has largely overseen the growing body of IPR harmonization and substantive law treaties like the Patent Cooperation Treaty, the Trademark Law Treaty and the (slowly forming) Substantive Patent Law Treaty. Indeed, it is funded largley through the fees paid by private users of the treaties it develops.[134] Because WIPO became a specialized agency of the United Nations in the same period that developing and newly independent states were pressing for a New International Economic Order, it never fully served the interests of strong international intellectual property protections. [135]

B. International Trade Law

International intellectual property law became decidedly more influential when it was not only folded in with the international free trade regime, but was equipped with judicial enforcement requirements that gave IP rights holders the capability to enforce those rights in domestic courts and administrative tribunals. Because the Paris Convention and other efforts at international IP protection had failed to satisfy the demands of states with strong IP rights-holding constituencies, individual states had often regulated IP practices through domestic trade statutes.

For example, in the United States, Section 301 of the 1974 Trade Act "authorizes the President to take all appropriate action, including retaliation, to obtain the removal of any act, policy, or practice of a foreign government that violates an international trade agreement or is unjustified, unreasonable, or discriminatory, and that burdens or restricts U.S. commerce." Private IP rights holders were authorized to file 301 petitions, many of which focused on failures to protect IP rights abroad. In 1988, Congress enhanced Section 301 by requiring the Office of the US Trade Representative to compile "Special 301" Reports which identify countries which do not provide "adequate and effective" protection of intellectual property rights or "fair and equitable market access to United States persons that rely upon intellectual property rights".[136] Yet even efforts like these confront diplomatic and political limits. For example, the 2011 Report identified two key US allies, Canada and Israel, as having "serious intellectual property rights deficiencies" yet resolving those deficiencies is likely to be complicated by other diplomatic, commercial and strategic priorities. Therefore, from states with powerful IP rights-holding

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[134] *Id*. at 24.

[135] See John Hughes, *A Short History of "Intellectual Property" in Relation to Copyright*, 33 CARDOZO L. REV. 1293, 1299 (2012).

136.*See, e.g.*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2009 SPECIAL 301 REPORT 3, 8–9, 17, 20, 25, 31 (2009).

constituencies, the desirability of an agreement that gave automatic rights to enforceability was obvious.

1. The WTO

After the failure of the International Trade Organization to obtain US support during the Truman administration, the less centralized General Agreement on Tariffs and Trade (GATT) became the organizing treaty under which states reduced official or governmental barriers to trade. Through eight rounds of negotiations stretching over more than 40 years, trading states gradually lowered tariffs as well as "non-tariff barriers" to trade like customs procedures, import licensing requirements and export subsidies. The so-called Uruguay Round of GATT negotiations commenced in 1986 and lasted through 1994, when the World Trade Organization was established.

The "World Trade Organization" refers to about 60 agreements, several of which affect participating states' ability to establish and regulate their health systems. The Agreement on Technical Barriers to Trade (TBT) governs potentially trade restrictive public health regulations while the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that states pass laws providing intellectual-property rights holders with a number of administrative and judicial protections. The Agreement on Sanitary and Photosanitary Measures (SPS) establishes the principles by which states may regulate food safety. While the WTO agreements provide for relatively circumscribed situations in which public health measures may prevail over liberal trading rules, only other States Parties may avail themselves of the WTO's strong dispute settlement mechanisms. [137]

2. TRIPS

TRIPS is by far the most controversial of the WTO agreements with respect to international public health law.[138] Unlike the general theory of *reducing* barriers to trade which justified GATT, TRIPS was theoretically justified by the need to *increase* legal protections to intellectual property rights holders in order to faciliate expansion of products, processes (and their distinguishing symbols) as well as creative works into new markets.[139]

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[137] Leon Trakman, *The ICSID under Siege*, 45 CORNELL INT'L. L. J. (2012); John D. Blum, *Reshaping the Global legal Structures of public health*, 12 MICH. ST. J. INT'L. L. 207, 218 (2004).
[138] See Yelpaala, *supra* note 124, at 63.
[139] TRIPS art. 16.

> Most economists agree that in most circumstances, eliminating barriers to trade between nations is net welfare increasing for each nation and for the global economy. Indeed, economists argue that a state should adopt open trade policies even if others do not. As Paul Krugman puts it, "[i]f economists ruled the world, there would be no need for a World Trade Organization. The economist's case for free trade is essentially a unilateral case: a country serves its own interests by pursuing free trade regardless of what other countries may do . . ." The issue of the optimal level of intellectual property protection, however, is not so straightforward. Most economists agree that nations should adopt some intellectual property laws, although what the content of these laws should be is a matter of significant disagreement. Intellectual property rules involve distributional issues.[140]

TRIPS grants patent, copyright and trademark holders rights to certain minimal statutory protections as well as resort to administrative and judicial processes to enforce those rights.[141] Member states may pass protections greater than those detailed in TRIPS [142] but additional protections must be extended to nationals of other member states.[143] In addition to substantive provisions, TRIPS also outlines a comprehensive framework for civil adjudication of IP rights.[144] Member States must create private causes of action [145] as well as remedies including injunctions, money damages, and the use of border restrictions.[146] States must also give IP rights holders access to judicial review of all administrative decisions concerning their IP laws.[147]

Prior to the Uruguay Round, the trade liberalization negotiation process had been largely driven by the trade agenda of developed states; agriculture was for the most part excluded and the important bargains

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[140] Rachel Brewster, *The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property*, 12 CHI. J. INT'L. L. 1, 6 (2011).
[141] See generally Nuno Pires De Carvalho, THE TRIPS REGIME OF PATENT RIGHTS (3d ed. 2010) (providing background explanation of the history and economics of patent rights under TRIPS); GLOBAL INTELLECTUAL PROPERTY RIGHTS, KNOWLEDGE, ACCESS AND DEVELOPMENT (Peter Drahos & Ruth Mayne eds., 2002).
[142] TRIPS art. 1(1).
[143] *See id.* at art. 3 (providing the caveat that this provision is subject to any Paris Convention exceptions).
[144] TRIPS art. 41.
[145] Patricia Judd, *Towards a TRIPS Truce*, 32 MICH. J. INT'L. L. 613, 622 (2011).
[146] TRIPS arts. 44–45, 57.
[147] TRIPS, art 61. See also TRIPS, arts 44 (injunctive relief), 45 (damages); 41(4) (requiring that [p]artiesis to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in the Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of the case").

were struck between the industrialized countries.[148] The Uruguay Round, by contrast, involved a greater range of issues many of which were long-standing priorities of developing states. Their interests in lowering barriers to trade in agricultural goods, clothes and textiles resulted in a "grand bargain" in which they agreed to impose strong monopoly protections for copyrights, trademarks, and, most importantly from the North American, Japanese and European perspective, copyrights and patents.[149]

With respect to the relationship between the international public health law movement and the international intellectual property protection movement, the Uruguay Round decidedly subordinated the former to the latter. Developing states won some flexibilities with respect to implementation of TRIPS obligations, including Articles 7 and 8 which respectively emphasized the need for intellectual property rules to allow for development, technology transfer and measures necessary to protect public health and nutrition.[150] Article 8 did not provide a general public health exemption from TRIPS implementation but rather conditioned those measures on TRIPS compliance.[151] Article 31 of TRIPS allows for the nonconsensual authorizations of patents – a provision whose importance was elevated by the Doha Declaration on the TRIPS Agreement and Public Health – but requires that those authorizations be accompanied by appellate access to national courts or "higher administrative authorities."[152]

These protections effectively imparted individually enforceable rights to IP rights holders. Jerome Reichmann detailed how strong these rights may be: "[Developed countries] expect developing countries to implement [their] obligations concerning domestic, judicial and administrative enforcement of foreigners' intellectual property rights, including detailed provisions governing the discovery of evidence, rights to counsel, injunctions, damages and temporary restraining orders. These

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[148] H.E. HaralambidesM. WestenengS. Zou, GATT and its Effects on Shipping and Ports p. 3. Available at http://www.academia.edu/2531450/GATT_and_its_Effect_on_Shipping_and_Ports

[149] Lawrence Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L. L. 1 (2004); Arvind Subramanian, *Patents, Medicines and TRIPS*, available at http://www.imf.org/external/pubs/ft/fandd/2004/03/pdf/subraman.pdf.

[150] A. Blackett, *Whither Social Change? Human Rights, Trade Theory and Treaty Interpretation,* 31 COLUM. HUM. RTS. L. REV. 1 (1999) (suggesting the reliance on Articles 7 and 8 for interpreting issues of human rights).

151.*See, e.g.*, UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT & INT'L CTR. FOR TRADE AND SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 739, 748 (2005), *available at* http://www.iprsonline.org/unctadictsd/docs/6.3TRIPS_COUNCIL_UPDATE.pdf.

[152] TRIPS, Art 41(5); Peter Drahos, *Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach,* 77 TEMPLE LAW REVIEW 401-424 (2004).

provisions mean business."[153] States Parties are not required to allocate more resources toward enforcement of IP rights than "law in general", so many individual IP rights-holders may not see a sufficient payoff to invest resources in pursuing individual civil actions to vindicate property rights. But the economic sectors most closely tied to human health – food, tobacco, alcohol and pharmaceuticals – are precisely those in which IP rights holders are likely to try and preserve substantial investments in advertising, research and development. [154]

3. SPS and TBT Agreements

Relatedly, measures affecting the labeling of food or beverage containers may not only be challenged as they affect trademarks on packaging and labeling, but also as trade restrictive under the SPS and TBT agreements. These agreements do not apply to intellectual property rights per se but may, together with IP rights claims, cumulatively weigh against public health interventions. The SPS Agreement authorizes states to adopt "sanitary and phytosanitary" measures to ensure the safety of food and the prevention of imported pests and diseases, but limits the trade restrictiveness of those measures and encourages the use of internationally accepted standards like those issued by the Codex Alimentarius Commission (Codex).[155] Empowering Codex standards for their WTO relevance has correspondingly pressured decisions toward their free trade compatibility. Emily Lee has detailed this process in the following way:

> The standard-setting process seems to present a unique "democratic" setting in which industry representatives, government officials, and NGOs can negotiate and forge a unified position, but in practice, the distribution of influence is weighted heavily to reflect industry concerns. The composition of national delegations in Codex meetings increasingly reflects the commercial importance of Codex decisions, as does the increasing difficulty in the negotiation of general principles for the elaboration of standards. Proceedings of the Commission often have turned into trade battlegrounds and forums for deregulation

[153] Reichman, *supra* note 8, at 385.

[154] Brewster, *supra* note 140, at 32 ("[T]he civil system might, in practice, be far more important than the administrative or criminal system if foreign rights-holders are willing to bear the costs of detecting and prosecuting intellectual property infringements . . . . In areas such as pharmaceuticals, private suits are cost-effecive because the capacity to reverse engineer and reproduce pharmacueticals is not as widespread. There may be only a few firms in the country.").

[155] Antonia Eliason, *Science Versus Law in WTO Jurisprudence: The (Mis)Interpretation of the Scientific* Process *and the (In)Sufficiency of Scientific Evidence in EC-Biotech*, 41 N.Y.U. J. INT'L L. & POL. 341 (2009).

> where decisions tend to reflect political compromises designed to promote international trade at the expense of human health[156]

European Union officials, for example, argued in 1994 that US nutrition labels restricted trade.[157]

Similarly, the TBT Agreement encourages states to base regulatory measures on international standards when available and appropriate. The easiest way to accomplish this is by adopting an accepted international standard like those issued by the International Standards Organization (ISO). However, the process by which those standards are developed are not only opaque, they are dominated by the industries affected by the standards issued. The tobacco industry, for example, used the ISO standard for low tar labeling as part of its broader effort to convince the public that a "safer" cigarette existed.[158]

4. The Anti-Counterfeiting Trade Agreement and the Trans-Pacific Partnership Agreement

The Anti-Counterfeiting Trade Agreement [159] represents the codification of principles advanced in a number of initiatives undertaken by developed states to enhance protections for intellectual property

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[156] Lee, *supra* note 20, at 595. *See also* Patrick Zylberman, *Making Food Safety an Issue*, 48 MEDICAL HISTORY 1, 25 (2004) ("The SPS Agreement . . . intended that science should play the key role so that food safety could be separated from high foreign policy. Detached from culture, the issue of food protection would thus depend on a single regulator – science, the criterion for evaluating all other standards. This was, of course, either arrant naivete or cynicism.").
Lee, *supra* note 20, at 576 (citing EUROPEAN COMMISSION, 15th ANNUAL REPORT ON UNITED STATES BARRIERS TO TRADE AND INVESTMENT 23 (1999), *available at* http://europa.eu.int/comm/external_relations/us/trade_barriers_report_99/usrbt99.pdf. The report states that U.S. nutrition labeling requirements differ from international labeling standards set by the Codex Alimentarius Commission and present "serious negative consequences on EU-U.S. trade in foodstuffs."). Obijiofor Aginam, *Food Safety, South-North Asymmetries, and the Clash of Regulatory Regimes*, 40 VAND. J. TRANSNAT'L L. 1099, 1100-03 (2007) (discussing the issues of food safety within the context of economic globalization and the regulatory regime of WTO SPS). For a discussion of the interaction between WTO trade rules (GATT XX(d) health exemptions and a review of the SPS process) with other GATT rules and domestic health regulatory regimes, see Catherine Button, THE POWER TO PROTECT: TRADE, HEALTH AND UNCERTAINTY IN THE WTO (2004).

[158] *See generally* Stella A. Bialous and Derek Yach, *Whose Standards Is It Anyway? How the Tobacco Industry Determines the International Organization for Standardization (ISO) Standards for Tobacco and Tobacco Products*, 10 TOBACCO CONTROL 2, 96-104 (June 2001).

[159] Anti-Counterfeiting Trade Agreement § 1, art. 1, *opened for signature* October 1, 2011, available at http://www.ustr.gov/acta.

holders beyond what TRIPS achieved.[160] According to the U.S. Trade Representative, "the goal [of ACTA] is to set a new, higher benchmark for enforcement that countries can join on a voluntary basis . . . ACTA will include commitments in three areas: (1) strengthening international cooperation, (2) improving enforcement practices, and (3) providing a strong legal framework for IPR enforcement."[161] After eleven rounds of negotiations, the final ACTA text was adopted[162] in May 2011.[163]

Originally aiming to combat the counterfeiting of goods and piracy in international markets, ACTA contains increased criminal sanctions for IPRs infringement and stronger border measures[164] to target illegal trafficking in infringing goods through customs processes.[165] ACTA requires, under each Parties' available laws, "enforcement procedures . . . to permit effective action against any act of infringement of [IPRs] covered by [ACTA] . . .."[166] While commentators have detailed criticisms

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[160] Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA*, 64 SMU L. REV. 975, 977-81 (2011) ("Originated more than five years ago, ACTA built on pre-existing anti-piracy and anti-counterfeiting efforts, such as the Global Congress on Combating Counterfeiting and Piracy (Global Congress), Japan's proposal for an anti-counterfeiting treaty, the United States' STOP! (Strategy Targeting Organized Piracy) Initiative, and the European Commission's Strategy for the Enforcement of Intellectual Property Rights in Third Countries (EU IPR Enforcement Strategy . . . In November 2005, Japan officially presented the proposal for an anti-counterfeiting treaty in the Second Global Congress in Lyon, France, an event jointly organized by the International Criminal Police Organization (Interpol), the World Customs Organization (WCO), and the World Intellectual Property Organization (WIPO) in partnership with the International Chamber of Commerce and its new Business Action to Stop Counterfeiting and Piracy (BASCAP) initiative, the International Trademark Association (INTA), and the International Security Management Association").

[161] See Press Release, Office of the U.S. Trade Rep. [USTR], Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes (Oct. 23, 2007), available at http://www.ustr.gov/ambassador-schwab-announces- us-will-seek-new-trade-agreement-fight-fakes.

[162] Eight parties have signed ACTA: Australia, Canada, Japan, Korea, Morocco, New Zealand, Singapore, and the United States. *Anti-Counterfeiting Trade Agreement (ACTA)*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, *available at* http://www.ustr.gov/acta. Mexico, and Switzerland were participants and are supporters, but have yet to sign the agreement. *Id*. The EU signed ACTA on January 26, 2012, but still needs to be signed and ratified by all 27 Member States because ACTA contains "criminal enforcement provisions, an area that is considered 'shared' competence between the EU and its Member States." European Commission, *Fact Sheet*, ACTA-ANTI-COUNTERFEITING TRADE AGREEMENT, (May 4, 2012, 5:00 PM), *available at* http://trade.ec.europa.eu/doclib/docs/2012/january/tradoc_149003.pdf.

[163] http://www.ustr.gov/acta/

[164] *Id*. at §§ 2-3.

[165] Margot Kaminski, *The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement*, 34 YALE J. INT'L L. 247, 250 (2009).

[166] ACTA at art. 6, ¶ 1. ACTA further requires these procedures be "fair and equitable . . . and . . . not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays." *Id*. at ¶ 2.

of those measures specifically (especially border controls), this section will focus on ACTA's civil enforcement provisions.[167]

Under ACTA, "[e]ach party shall make available to [IPRs] holders civil judicial procedures concerning the enforcement of any [IPR] . . ...."[168] Among those procedures are injunctions,[169] damages,[170] other remedies,[171] and the collection and preservation of evidence.[172] These civil enforcement provisions are not limited to first-party infringers. "Each Party shall provide that, in civil judicial proceedings concerning he enforcement of intellectual property rights, its judicial authorities shall have the authority to order against a party to desist from infringement an order to that party or where appropriate to a third party over whom he relevant judicial authority exercises jurisdiction . . . to prevent infringing good from entering the channels of commerce.

ACTA represents a new restructuring of civil enforcement to increase the rights of IP holders, with potentially deleterious effects on access to medicines.[173] For example, because ACTA requires that judicial authorities have the power to issue injunctions against third parties, any intermediary provider of generic medicines to developing countries potentially faces liability under the ACTA regime.[174]

> In the context of access to medicines, the concept "intermediary services" may be quite ominous. Services are obviously provided by ISPs allowing supplier to market medicines online and in the

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[167] *See generally* Eddan Katz & Gwen Hinze, *The Impact of the Anti-Counterfeiting Trade Agreement on the Knowledge Ecomnomy: The Accountability of the Office of the U.S. Trade Representative for the Creation of IP Enforcement Norms Through Executive Trade Agreements*, 35 YALE J. INT'L L. ONLINE 24-25 (2009) (arguing that ACTA is overly broad and needs "increased transparency, accountability mechanisms, and input from civil society . . .").

[168] ACTA at § 2.

[169] *Id*. at art. 8. Parties' competent authorities have the power to order a party to "desist from an infringement . . . and . . . prevent goods that involve the infringement of an [IPR] from entering into the channels of commerce."

[170] *Id*. at art. 9. Each Party must provide its "judicial authorities [the power] to order the infringer . . . to compensate for the injury the [IPR] holder has suffered as a result of the infringement."

[171] *Id*. at art. 10. The "other remedies" provision can basically be summed up as the counterfeit goods, and all materials used in the production of such goods, can be destroyed at the IPR holder's request. Additionally, ACTA authorizes the Party to carry out the disposal/destruction of the goods at the infringer's expense.

[172] *Id*. at art. 11. Each Party must provide the mechanisms, per justified request of the IPR holder, to order the infringer, or alleged infringer, to provide all relevant information relating to the infringement or alleged infringement.

[173] Sean Flynn, *ACTA's Constitutional Problem: the Treaty is Not a Treaty*, 26 AM. U. INT'L. L. REV. 903, 905 (2012).

[174] Cynthia M. Ho, *Global Access to Medicine: the Influence of Competing Patent Perspectives*, 35 FORDHAM INT'L. L.J. 1, 94-95 (2011).

> pharmaceutical context by shipping agents . . . Perhaps more ominously, many others who helped fund or facilitate purchases of generic drugs, as they moved through the stream of international commerce from producer to consumer could face intermediary liability. For example, the Global Fund solicits and funds country-led proposals for funding priority disease prevention, treatment and care.[175]

ACTA compliant laws may enable foreign rights holders to target local industries through threats or use of litigation.[176] The force of the agreement extends beyond its power to shape domestic law as it will inevitably also form the template for future bilateral agreements between ACTA and non-ACTA states.[177] The Trans-Pacific Strategic Economic Partnership Agreement or TPP mimicks many of ACTA's IP provisions, although its conclusion is more distant.[178]

C. Bilateral and Regional Trade and Investment Treaties

More common than broad, multilateral trade instruments like TRIPS and ACTA, bilateral and regional investment and trade agreements contain some of the strongest protections for intellectual property.[179] Bilateral investment and treaties (BITs), for example, take a number of forms and include provisions authorizing IP rights-holders to vindicate claims in national or international courts or dispute resolution fora. Generally, BITs are negotiated between developed states and developing states.[180] BITs contain provisions guaranteeing investors from one state protections for their "investments" in the other state which are often to define IP rights in broad terms. These guarantees may include fair and equitable or non-discriminatory treatment,[181] free transfer of profits and currency, and, in many cases, payment of compensation should a host state adopt measures

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[175] Brook Baker, *ACTA-Risks of Third-Party Enforcement for Access to Medicines*, 26 AM. U. INT'L. L. REV. 579, 588-89 (2011).
[176] Yu, *supra* note 160, at 1024.
[177] *Id*. (referring the "policy laundering" potential of ACTA).
[178] Robert Stumberg, *Safeguards for Tobacco Control: Options for the TPPA*, 39 AM. J. L. & MED. 382 (2013); Jane Kelsey, *The Trans-Pacific Partnership Agreement: A Gold-Plated Gift to the Global Tobacco Industry?* 39 AM. J. L. & MED. 237, 264 (2013) ("At the time of writing, it is unclear if a final deal will be concluded.").
[179] UNITED NATIONS CONFERENCE ON TRADE & DEV. (UNCTAD), INTELLECTUAL PROPERTY PROVISIONS IN INTERNATIONAL INVESTMENT ARRANGEMENTS 5 (2007) ("A sizable proportion of these [investment] treaties include provisions obligating the contracting parties to meet [intellectual-property] standards that are more stringent than the ones found in the TRIPS Agreement.").
[180] *See, e.g.*, Sam Foster Halabi, *Efficient Contracting Between Foreign Investors and Host States: Evidence from Stabilization Clauses* 31 NW. J. INT'L L. & BUS. 261, 263 (2011) (discussing trends in bilateral investment treaty dyads).
[181] Graham Mayeda, *Playing Fair: The Meaning of Fair and Equitable Treatment in Bilateral Investment Treaties*, 41 J. WORLD TRADE 273, 274 (2007).

having the effect of direct or indirect expropriation.[182] The origin and number of BITs in existence is well-documented, although the reasons for their proliferation remain in dispute.[183] At the end of the 1980s, records at the U.N. Conference on Trade and Development showed 385 BITs; a decade later, the number reached 1,857; current estimates show approximately 3,000 BITs in force.[184]

BITs do not, typically, include enumerated rights for contracting states outside their ability to prohibit certain economic activities altogether, exempt certain economic sectors from the treaty's applicability or to take normal regulatory action in the interest of national security, public order, public health or public morality—so-called "non-precluded measures."[185] Contracting states are still potentially obligated to compensate investors for these "regulatory takings." Public health exceptions, for example, are often phrased in vague ways in the preamble, undermining their use as a defense to an investor claim.[186] Most of these treaties provide investors access to one of the major international arbitral tribunals to vindicate rights under a BIT.[187]

These treaties often give much stronger protection, with fewer standard exceptions, to intellectual property rights than international IP agreements, TRIPS or domestic law. For example, the standard Swiss BIT protects as investments "copyrights, industrial property rights (such as patents, utility models, industrial drawings or models, manufacturer's or commercial marks, trade names, indications of provenance or *appellations d'origine contrôlées* (AOC, or "controlled terms of origin"), know-how and clientele" and requires the counterparty to compensate an investor for

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[182] *See, e.g.*, Agreement between the Swiss Confederation and the Oriental Republic of Uruguay concerning the reciprocal promotion and protection of investments, art. 5, Oct. 7, 1988.

[183] *See* Kojo Yelpaala, *Fundamentalism in Public Health and Safety in Bilateral Investment Treaties [Part I]*, 3 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 235, 236, 239 (2008).

[184] U.N. Conf. on Trade and Dev. (UNCTAD), Bilateral Investment Treaties 1959-1999, at 1, U.N. Doc. UNCTAD/ITE/IIA/2 (2000); Jose E. Alvarez, *A Bit on Custom*, 42 N.Y.U. J. INT'L L. & POL. 17, 23 (2009); Robert E. Greig, Claudia Annacker & Roland Ziade, *How Bilateral Investment Treaties Can Protect Foreign Investors in the Arab World or Arab Investors Abroad*, 25 J. INT'L ARB. 257, 259 (2008)

[185] Bill Burke-White & Andreas von Staden, *Investment Protection in Extraordinary Times: The Interpretation and Application of Non-Precluded Measures Provisions in Bilateral Investment Treaties*, 48 VA. J. INT'L L. 307 (2008).

[186] Julien Chaisse, Exploring the Confines of International Investment and Domestic Health Protections—Is a General Exceptions Clause a Forced Perspective, 39 Am. J. L & Med. 332, 341 (2013).

[187] Jason Webb Yackee, *Pacta Sunt Servanda and State Promises to Foreign Investors Before Bilateral Investment Treaties: Myth and Reality*, 32 FORDHAM INT'L L.J. 1550, 1555 (2009). *Contra* Christophe Dugue, *Dispute Resolution in International Project Finance Transactions*, 24 FORDHAM INT'L L.J. 1064, 1072 (2001) (noting that international financiers often prefer English or New York courts).

"measures, [taken] directly or indirectly, of expropriation, nationalization, or any other measure having the same character or same effect."[188] Under the 2012 US Model BIT, an "investment means every asset that an investor owns or controls, directly or indirectly . . . include[ing] . . . intellectual property rights" which are accorded similar rights to arbitration although the U.S. Model BIT creates an explicit nexus between rights to compensation and measures consistent with TRIPS.[189]

Indeed, if TRIPS represented the ceiling of substantive IP rights and accompanying enforcement agreements, the entire debate on the balance between TRIPS and public health might focus on flexibilities available in the language of the agreement.[190] But flexibilities WTO member states might enjoy under TRIPS are narrowed, sometimes drastically, in bilateral investment and trade treaties. For example, the U.S.-Jordan Free Trade Agreement includes limitations on compulsory licenses and parallel imports. The costliest TRIPS-plus terms are those that impose "data exclusivity" separate from patent protection. Under "data exclusivity" regimes, a generic manufacturer is not allowed to use clinical and safety trial data used with the initial drug application, essentially requiring the generics applicant to undertake prohibitively expensive clinical trials and re-imposing the cost to the government or end-user that generics theoretically exist to save.

> These expenditures have required that both public health system and individuals pay higher prices for many new medicines that are needed to treat serious non-communicable diseases (NCDs), such as hypertension, asthma, diabetes, and mental illness. For example, new medicines to treat diabetes and heart disease cost anywhere from two to six times more in Jordan than in Egypt, where there are no TRIPS-plus barriers.[191]

Similar conflicts have arisen over alcohol, food and tobacco regulation. When Uruguay introduced measures restricting the images, colors, words and phrases which could appear on cigarette packages, Phillip Morris International's Swiss subsidiaries challenged the

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[188] See, e.g. Swiss-Uruguay Bilateral Investment Treaty, *supra* note 182.
[189] 2012 U.S. Model Bilateral Investment Treaty available at http://www.ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf
[190] Lee Petherbridge, *Intelligent TRIPS Implementation Strategy for Countries on the Cusp of Development*, 22 U. PA. J. INT'L ECON. L. 1029, 1048 (arguing for the use of interpretative devices).
[191] Oxfam, All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines, Oxfam Briefing Paper, March 2007 available at http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf

constitutionality of the regulations under Uruguayan law.[192] PMI failed in the Uruguay courts before ultimately availing itself of a bilateral investment treaty between Switzerland and Uruguay which not only gave PMI's trademarks much stronger protections than under either international trade or Uruguayan law, but also placed significant limitations on the Uruguayan courts to serve as the final authority on the dispute.[193]

III. CONFRONTATIONS BETWEEN IP RIGHTS AND INTERNATIONAL PUBLIC HEALTH LAW

As international public health law and international intellectual property law have strengthened, so have the conflicts anticipated by each movement's advocates. Between 1994 and 2012, the conflict between international intellectual property rights and international public health law confronted each of the major agreements outlined above and foreshadowed potential agreements under instruments like the Medical Research and Innovation Treaty, the Framework Convention on Alcohol Control and the Framework Convention on Global Health. As the discussion of these episodes shows, international public health law exercised little normative force over strong intellectual property rights. Instead, international public health law norms prevailed most often when sponsored by a strong middle income state like Brazil, India, South Africa or Thailand.[194]

A. Guatemala, Brazil, India, the Philippines and the 1981 WHO Code on the Marketing of Breastmilk Substitutes

Guatemala represents precisely the kind of state for which the 1981 WHO Code on the Marketing of Breastmilk Substitutes was intended.

> In health, the infant mortality rate is 55 per 1,000 live births and the maternal mortality rate is 110 per 100,000 live births. In addition, approximately 16 percent of infants suffer from low birth weight, and approximately 50 percent of all children are malnourished.[195]

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[192] Sam Foster Halabi, *International Trademark Protection and Global Public Health, a Just Compensation Regime for Expropriations and Regulatory Takings*, 61 CATH. U. L. REV. 321, 344 (2012).
[193] *Id*.
[194] See e.g. P Champ and A Attaran, *Patent Rights and Local Working under the WTO Agreement: an Analysis of the US-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365-393 (2002); Daniel Benoliel and Bruno Salama, *Toward an Intellectual Property Bargaining Theory: the Post WTO Era*, 32 U. PA. J. INT'L. L. 265 (2010).
[195] World Bank, Guatemala: An Assessment of Poverty, available at http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTPOVERTY/EXTPA/0,,co

In 1983, Guatemala adopted law 66-83, Law on the Protection of Breastfeeding, which codified many aspects of the WHO International Code, and in 1987, the Ministry of Health implemented the law through Governmental Order No. 847-87. In 1992, Gerber applied to introduce a new "step-by-step" product line in Guatemala and requested that the products be registered with the Food & Drugs Registration and Control Division, an equivalent of the US FDA. The FDRC required that Gerber remove its trademarked infant image, include a notice that "breastmilk is the best for baby" as required under the law and further specify the age of the child for which the products were intended.

Gerber pursued a three-prong strategy in response: asserting the products were "complementary" foods under Guatemalan law and therefore not covered by 66-83 and 841-87; bringing a statutory action under U.S. law to eliminate Guatemala's trading preferences for effectively "nationalizing" its trademark; and, threatening Guatemala's compliance with (still pending) TRIPS provisions. Gerber argued that:

> Article 15 of [TRIPS] states that "The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark" In addition, Article 20 of the proposed agreement provides in relevant part that "The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as . . . use in a special form or use in a manner detrimental to its capability to distinguish the goods . . . .[196]

Applying a strained interpretation of "complementary foods", the Guatemala Supreme Court of Justice determined that 66-83 and 841-87 applied only to locally prepared foods, not to imported goods. Without explicitly acknowledging the role that the trade-based agreements played in their construction of the law, the case "shows . . . that raising the spectre of the new WTO can be an effective pressure tool against small countries that want to implement strong health regulations that may also have negative impacts on commercial interests."[197]
The Pharmaceutical and Health Care Association of the Philippines successfully delayed and then earned relief from comprehensive labeling

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ntentMDK:20207581~menuPK:443285~pagePK:148956~piPK:216618~theSitePK:430367,00.html

[196] Letter from Mario Permuth to Gustavo Hernandez, Ministry of Pub. Health (Feb. 16, 1994) (on file with author) ("The Gerber Executive explained that they will fight with all their strength for the application and enforcement of their industrial property rights in Guatemala and, at this moment, the major damages affecting them derive from the fact that they have not been able to sell the [infant image-labeled] product in Guatemala.").

[197] Barbara Feinig, The Position of the International Code on Babyfood Marketing in the WTO available at http://www.ibfan-alc.org/nuestro_trabajo/archivo/codex/artwemos.pdf

restrictions through similar arguments based in part on the trade restrictive effect of warnings on formula containers.[198]

Brazil, by contrast, fully incorporated the Code into law in 1988, embedded subsequent WHA resolutions into administrative regulations, and authorized third-party monitoring. Breastfeeding rates have risen steadily as a result. [199] Like Guatemala's law, Brazil prohibited infant images on breastmilk substitute packaging. When Gerber entered the Brazilian market, it accepted the prohibition on its infant image. Similarly, in India, where the Infant Milk Substitutes Act adopted a prohibition on images of infants, women, or "phrases designed to increase the saleability of infant milk substitutes or infant food," exclusive breastfeeding at 4-5 months of age is 46%, three times that of the Philippines. [200]

B. Brazil, India, South Africa, Thailand and Access to Medicines

Access to medicines was a principal concern of developing states during the TRIPS negotiations. Many developing states considered the high prices that accompanied patented medicines and their production processes to frustrate their constitutional and international human rights obligations to provide affordable health care to their citizens.

1. Compulsory Licenses and Parallel Imports

In addition to the generally worded provisions in Articles 7 and 8, TRIPS also includes a compulsory license regime under which member states may authorize third-party firms to manufacture patented products or use patented processes.[201] Article 31 obligates states to negotiate with patent holders over the terms of these licenses unless it involved a "case of a national emergency or other circumstances of extreme urgency."[202] TRIPS does not explicitly address parallel import policies, which are used to purchase patented drugs from a third state where a lower price is charged.

Beginning with South Africa's experience with parallel imports in 1997, Brazil, India, South Africa and Thailand have not only led in using these alternatives to expand access to medicines for their own citizens but to obtain collective gains for developing countries generally. The

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[198] Rene Raya, *The Philippine Breastfeeding Struggle Continues*, 371(9615) THE LANCET 794-95 (2008).
[199] See M F Rea,'Rethinking Breastfeeding in Brazil: How we reached 10 months of duration'. *Cadernos de Saude Publica* 2003; 19 suppl.1:37-45, cited in supra n 18
[200] The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution)Act, 1992 as Amended in 2003 (IMS Act) available at http://www.bpni.org/docments/IMS-act.pdf.
[201] Sudhir D. Ahuja, *GATT and TRIPS - The Impact on the Indian Pharmaceutical Industry*, 1994 PAT. WORLD 28, 33 (discussing options faced by negotiators dealing with health needs of member states and thereafter settling for strict safeguards).
[202] TRIPS art. 31.

confrontation between South Africa and Western pharmaceutical firms, paralleled by Brazil's compulsory license regime for AIDS drugs, achieved at least two key victories. First, sponsoring governments withdrew opposition to compulsory licensing for HIV medications. Second, the episodes prompted states to revisit the TRIPS agreement in light of outbreaks and reemergence of infectious diseases with disproportionate effects in developing countries. The 2001 Doha Declaration on the TRIPS Agreement on Public Health emphasized the importance of compulsory licenses for HIV/AIDS, tuberculosis, malaria and other epidemics, as well as affirming the freedom for states to establish their own regimes for parallel imports.[203] The final text was ultimately negotiated between the U.S. and Brazil.[204]

In 2007, Thailand expanded the use of compulsory licenses beyond the communicable diseases specified in Doha, granting a compulsory license for the heart disease medication marketed as Plavix. Thailand also issued compulsory licenses for four cancer drugs, the disease burden of which is heavier than HIV/AIDS.[205] From the Thai government's point of view, cancer "is no less serious than HIV/AIDS . . . ."[206] In 2012, India granted a compulsory license for kidney and liver cancer medications.[207] Indeed, since 1995, "more than half the compulsory licensing episodes occurred in upper middle income countries (including Brazil and Thailand)."[208]

These episodes might be equally construed as protecting powerful domestic industries (India's generics firms)[209] rather than any form of solidarity these states feel with the plight of developing countries facing

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[203] Declaration on the TRIPS Agreement and Public Health (Doha Agreement) available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[204] Fisher & Raglioni, *supra* note 14.
[205] Toni Johnson, *The Debate Over Generic Drug Trade*, COUNCIL ON FOREIGN RELATIONS BACKGROUNDER available at http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055
[206] *Id*.
[207] Vikas Bajaj and Andrew Pollack, *India Orders Bayer to License a Patented Drug*, NY TIMES (Mar. 12, 2012) available at http://www.nytimes.com/2012/03/13/business/global/india-overrules-bayer-allowing-generic-drug.html?_r=0
[208] Read Beall and Randall Kuhn, *Trends in Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis* available at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154
[209] Elliott Hannon, *How an Indian Patent Case Could Shape the Future of Generic Drugs*, TIME, Aug. 12, 2012 available at http://world.time.com/2012/08/21/how-an-indian-patent-case-could-shape-the-future-of-generic-drugs/ ("India's rising global presence is often associated with its booming tech sector. But in many poor countries, India's role is that of a low-cost pharmacy. The country has become a leading supplier of affordable HIV/AIDS and Tuberculosis medications and is the second leading provider of medicines distributed by UNICEF in the developing world.").

large disease burdens.[210] That is the point. It is may not be norm creation or force flowing from the Doha Declaration that has resulted in compulsory license activity, but rather the political and economic strength of the licensing states that has allowed wider access to affordable medicine, even as international intellectual property protections become stronger and more widespread.

2. TRIPS Flexibilities and Model Laws

Compulsory licenses and parallel imports are relatively drastic actions to narrow otherwise strong patent rights. States enjoy a number of other ways in which strong intellectual property rights called for in TRIPS can be diminished. For example, states are under no obligation to allocate greater resources to criminal enforcement of IP rights, leaving IP rights holders the civil justice system to vindicate their rights, although as noted above, this flexibility may not deter patent and trademark holders in the areas most closely related to health.

States are also free to establish their own standards for patentability, including novelty, non-obviousness and utility.[211] For example, India passed a patent protection statute which presumptively meets the minimum requirements of TRIPS, granting 20 year exclusivity, for example, but defining "novelty" and "efficacy" in ways that prevent firms from "evergreening" their patents by filing patent applications with marginally different applications or modalities from the protected patents.[212] Novartis, which had attempted to extend the patent on its cancer treatment drug Gleevec, lost in India's trial courts on even establishing the grounds for a new patent. India's Intellectual Property Appellate Board (which had assumed jurisdiction over patents as a result of TRIPS) determined that it had in fact met the basic requirements of patentability but failed scrutiny under a more specific provision of India's patent act which erected a high barrier for drug efficacy. The Supreme

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[210] *Id*. ("The Indian patent law, however, set the bar much higher than in the U.S. 'India has time and again really expressed a strong preference for public health concerns over private patent rights,' says Shamnad Basheer, a professor of intellectual property law at the National University of Juridical Sciences in Calcutta."). Nunn, A, Da Fonsecab E. Gruskind S, *Changing global essential medicines norms to improve access to AIDS treatment: lessons from Brazil*. GLOBAL PUBLIC HEALTH 2009, 4:131-149. Lee K Chagas LC Novotny TE: *Brazil and the Framework Convention on Tobacco Control: global Health diplomacy as soft power*. PLOS MEDICINE 2010, 7:1-5.

[211] Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 61 (1998) (explaining the technology gap disfavoring the production of biotechnology inventions in developing countries).

[212] UNCTAD, USING INTELLECTUAL PROPERTY RIGHTS TO STIMULATE PHARMACEUTICAL PRODUCTION IN DEVELOPING COUNTRIES: A REFERENCE GUIDE 14 (.2009)

Court of India affirmed the IPAB's decision that the patent failed India's criteria for novelty.[213]

Section 3(d) of India's Patent Act limiting the possibility of evergreening patents is in the process of being replicated in the Philippines while other developing nations are likely to use that section as a model.[214] Brazil's compulsory licensing for AIDS drugs has served as model for other Latin American jurisdictions.[215] In addition, Brazil has brokered collective bargains on behalf of Latin American governments seeking lower prices for medicines.[216]

3. Action at the World Trade Organization

In 2008 and 2009, Dutch customs authorities seized at least 19 shipments of generic drugs transiting through the Netherlands, 16 of which originated in India.[217] Brazil and India initiated proceedings at the World Trade Organization to challenge the Dutch and European laws under which the seizures were authorized. The states secured a promise from the EU in July 2011 to end the seizures, but Dutch authorities seized another 29 cartons of medicine in December 2012 and EU negotiators have balked at specifically addressing the border seizures in ongoing negotiations over an EU-India Free Trade Agreement.[218] While Brazil and Indian complaints are technically in abeyance as long as the EU abides by its agreement, their complaints challenge a wide range of current IP practices in developed states. While larger markets like Brazil, India and Thailand have managed to withstand pressure to include these kinds of provisions in investment and trade agreements, smaller markets, often where the diseases impose higher morbidity and mortality, are buckling.

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[213] *India's Novartis Decision*, NY TIMES, Apr. 4, 2013, available at http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html?_r=0. http://supremecourtofindia.nic.in/outtoday/patent.pdf

[214] Soma Das, *Indian Patent Law will be Emulated by Many Nations: S Chandrasekaran*, THE ECONOMIC TIMES, Apr. 3, 2013 available at http://articles.economictimes.indiatimes.com/2013-04-03/news/38248787_1_glivec-patent-case-patent-office-product-patent

[215] Ellen F.M. 't Hoen, TRIPS, PHARMACEUTICAL PATENTS AND ACCESS TO ESSENTIAL MEDICINES: SEATTLE, DOHA AND BEYOND, 45 available at http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf

[216] Susan Okie, *Fighting HIV—Lessons from Brazil*, 354 NEJM 1977, 1981 (2006).

[217] Monica Steffen Guise Rosina and Lea Shaver, *Why Are Generic Drugs Being Held Up in Transit? Intellectual Property Rights, International Trade, and the Right to Health in Brazil and Beyond*, 40 JLME 197, 201 (2012).

[218] Brook Baker, Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough, PIJIP Research Paper no. 2012-02 American University Washington College of Law, Washington, D.C. available at http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1026&context=research; Jayati Ghose, *India wants EU to stop seizure of generic drugs*, THE FINANCIAL EXPRESS May 3, 2013.

C. Indonesia and the International Health Regulations

The International Health Regulations depend on a number of identification, communication and treatment mechanisms to address potential pandemics. Vaccines, for example, are one of the most important lines of defense against the emergence of pandemics.[219] The development and distribution of vaccines are dependent on patents on "genetic sequences or proteins of the pandemic virus, as well as on novel methods for vaccine production, the actual vaccine," in addition to chemicals which maximize the number of doses available from a given antigen or virus.[220]

Strong patent protections pose at least two related threats to the functionality of the IHR. First, the infrastructure and technology for vaccine development is overwhelmingly located in industrialized, wealthy states.[221] This concentration renders developing states potentially dependent on wealthier states to manufacture and distribute vaccines in sufficient quantities to address their needs in the case of disease outbreaks. Second, the origin of outbreaks, especially influenza, is often in developing states like China, Indonesia and the Middle East. These states must therefore be willing to share disease samples and biological material relevant to risk assessment, risk management, disease research and vaccine development. When firms patent shared samples to produce unaffordable vaccines, the willingness to share is undermined.[222]

In 2006, Indonesia withheld H5N1 avian flu samples from WHO, undermining efforts to monitor and produce vaccines in response to an avian flu outbreak that rapidly spread worldwide.[223] Indonesia asserted

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[219] Eileen Kane, *Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1143 (2009).

[220] Kane, *supra* note 219, at 1158 ("For example, the use of non-viral chemicals that augment the immunogenicity of a vaccine - known as adjuvants - is critical. Such compounds allow a vaccine to include less actual antigen or virus, and thus allow for dose-sparing clinical approaches that maximize the utility of the available viral components. These compounds can be patented in isolation and can also appear in patents that claim a vaccine as a specific combination of antigen and adjuvant.").

[221] *Id*. at 1148 ("A further complication to vaccine production is that only a small group of companies with manufacturing capability exist.").

[222] *Id*. at 1153-55 ("In an effort to document the patent landscape of the field, the WHO has undertaken a project to map where patents have been sought on any of the relevant H5N1 viral materials. This research demonstrates that a small cluster of patent applications have been filed on various sequences and proteins of H5N1 and several patents have been issued, but the report further notes that patent landscaping must continue as the field matures. The sequence of the H5N1 and novel H1N1 influenza viruses have been determined. The WHO provided notice that genetic sequences from one novel H1N1 virus isolate were available on the GISAID database within several days of the first reports of the outbreak . . . Three separate groups of international researchers filed U.S. patent applications on the DNA sequences of the virus.).

[223] David Fidler, Influenza Virus Samples, International Law, and Global Health Diplomacy, 14(1) Emerg Infect Dis. 88-94 (2008).

that its decision was a response to an Australian company's development of a vaccine derived from a virus sample Indonesia provided to WHO.[224] The cycle demonstrated the inequities inherent in the global disease surveillance system established by the IHR:

> Developing countries provided information and virus samples to the WHO-operated system; pharmaceutical companies in industrialized countries then obtained free access to such samples, exploited them, and patented the resulting products, which the developing countries could not afford.[225]

Participation by Indonesia is in many ways crucial to the global surveillance system. As David Fidler noted, "[w]ithout access to Indonesia's influenza strains, global surveillance was jeopardized, as was the refinement of diagnostic reagents and the development of intervention strategies, which depend on the information surveillance provides."

In 2009, the outbreak of H1N1 influenza in Mexico demonstrated not only that the global surveillance system benefited Western pharmaceutical firms, but that in the case of a real pandemic, those firms' sponsoring governments could not be relied upon to equitably share vaccines:

> Canada awarded its vaccine contract to a Canadian company because it feared that foreign governments might restrict exports to Canada because of vaccine shortages within their territories. The Australian government made it clear to the Australian manufacturer CSL that it must fulfill the government's domestic needs before exporting vaccine to the United States. The United States pledged on September 17, 2009, to donate 10% of its vaccine purchases to WHO, but on October 28, US Secretary of Health and Human Services Kathleen Sebelius stated that the United States would not donate H1N1 vaccine as promised until all at risk Americans had access, because production problems had created shortages in the United States.[226]

Despite clear acknowledgment that the 2009 outbreak originated in Mexico and leveled its most significant toll there, Mexico had "a terrifically difficult time getting access to the pandemic vaccine."[227]

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[224] *Id*.
[225] *Id*. at 88.
[226] David P. Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1NI*, 7(5) PLOS MEDICINE 1 (2010) available at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000247.
[227] Richard Knox, *WHO Resolves Impasse Over Sharing of Flu Viruses, Access to Medicines*, NPR Apr. 18, 2011 available at

As a result of these episodes, developing countries led by Indonesia pressed both WHO and developed states to conclude an agreement on equitable access to pandemic vaccines. In 2011, the WHO Open-Ended Working Group of Member States on Pandemic Influenza Preparedness (PIP) finalized an agreement in which developing countries agreed to routinely share mutating flu virus samples in exchange for set-asides of vaccine doses available at reduced or no cost and monetary support commitments from vaccine manufacturers. Even at that, the PIP framework was adopted under WHO's Article 23 recommendatory power, not its Article 19 treaty power nor its Article 21 regulation-issuing authority and the Standard Material Transfer Agreements appended to it are largely deferential to the patent interests of manufacturers.[228]

D. Australia, Uruguay and the FCTC

As with the International Code and the IHR, the WHO's Framework Convention on Tobacco Control engenders confrontations with intellectual property rights, primarily trademarks. At least three of the FCTC tobacco-demand reduction provisions involve or potentially involve conflicts with trademarks, especially on packaging and labeling.[229] Indeed, the visual imagery fundamentally tied to trademarks represents a chief investment by tobacco firms, which use visual and written cues to prompt and manipulate demand for tobacco products.[230] For example, tobacco firms not only introduced "light", "mild" and "ultra-light" in their brands to suggest to consumers that "light" versions of cigarettes were safer, they adapted label and packaging color schemes to convey that message:

> White-and-gold Marlboro Lights will still suggest "lightness" just by the stark contrast to the red, full-strength Marlboros. The powder-blue Camel Lights with their pastel camel will still look milder than the ornery desert-ocher animalon the regular "Filters" pack.[231]

The South American republic of Uruguay implemented a number of FCTC compliant tobacco control measures between 2008 and 2010,

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http://www.npr.org/blogs/health/2011/04/18/135519592/who-resolves-impasse-over-sharing-of-flu-viruses-access-to-vaccines

[228] Sangeeta Shashikant, *Milestone virus/benefit-sharing agreement with shortcomings*, GLOBAL HEALTH WATCH, May 6, 2011 available at www.ghwatch.org/sites/www.ghwatch.org/files/PIP_sangeeta.doc

[229] Framework Convention on Tobacco Control arts. 10, 11, and 13.

[230] E.C. ETZEL ET AL., CONSUMER RESEARCH PROPOSAL: CAMEL FILTER REVISED PACKAGING TEST STUDY 5 (1979), *available at* http://legacy.library.ucsf.edu/tid/qxb79d00; Melanie Wakefield et al., *The Cigarette Pack as Image: New Evidence from Tobacco Industry Documents*, 11 TOBACCO CONTROL i73, i77 (Supp. I 2002).

[231] Geoff Winestock, *"Light" Tobacco Ads Found Deceptive, EU Says'* WALL STREET JOURNAL, (8 November 2000).

including two which addressed the manipulation of packaging and labeling to shape health perceptions of tobacco products. First, the state required that pictorial warnings cover eighty percent of a cigarette pack's surface. Second, the Ministry of Health limited the sale of cigarettes to only one variety per brand, the so-called single presentation requirement.[232] This part of the law prevents a firm from selling multiple varieties of cigarette under a single trademark. For example, Philip Morris International (PMI), whose most important asset is the Marlboro brand, could no longer sell Marlboro "Reds," Marlboro "Greens," and Marlboro "Blues," which leaves "Marlboros" as its only authorized variety (although it owns or licenses other brands in the Uruguayan market).[233] PMI first challenged the regulations in Uruguayan courts, seeking an injunction based in part on Uruguay's revised, TRIPS-compliant trademark law. Unsuccessful in Uruguayan courts, PMI initiated (through entities it controlled) arbitration proceedings under Switzerland's BIT with Uruguay. That treaty included not only broad definitions of "investor" and "investment", it also established narrow and toothless exceptions for public health regulation and required even laws passed with assurance of due process to compensate an investor for an "indirect" expropriation.[234] Despite the regulations falling squarely within the measures recommended by the Framework Convention on Tobacco Control (especially the Article 11 guidelines), the Uruguayan government vacillated on withdrawing or moderating the measures until strong financial and political support emerged from the Bloomberg Family Foundation, the World Health Organization and hundreds of public health NGOs.[235]

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[232] Uru., Ministry of Public Health Ordinance No. 514 (Feb. 14, 2009); Uru., Presidential Decree No. 287/009 (Dec. 2, 2009).

[233] FTR Holding S.A. v. Uruguay, ICSID Case No. APRB/10/17, Feb. 19, 2011, ¶¶ 45, 89 ("As of 31 December 2009, Article 3 of Ordinance 514 has resulted in an approximately 15 per cent decrease in Abal's sales. The hardest hit brand has been 'Marlboro,' of which the discontinued 'Marlboro Gold,' 'Marlboro Blue' and 'Marlboro Green (Fresh Mint)' varieties represent 40.5 per cent of total sales in 2008. . . . It should be noted that Philip Morris affiliates worldwide have invested significant amounts of time and money in developing a revision of the three sub-brands of the Marlboro family. As a result of Ordinance 514, Philip Morris has been prevented from introducing these innovations in Uruguay and accordingly has been deprived of the use of its intellectual property.") available at http://www.smoke-free.ca/eng_home/2010/PMIvsUruguay/PMI-Uruguay%20complaint0001.pdf.

[234] *See* Agreement Between the Swiss Confederation and the Oriental Republic of Uruguay on the Reciprocal Promotion and Protection of Investments, Switz.-Uru., art. 5, Apr. 22, 1991, 575 U.N.T.S. 159, *available at* http://untreaty.un.org/unts/120001_144071/26/2/00021341.pdf.

[235] Beginning in 2005, under the leadership of Tabare Vazquez – an oncologist by training – Uruguay aggressively implemented indoor smoking bans, harsher pack warnings and tax hikes in order to reduce Uruguay's high levels of tobacco consumption and exposure to tobacco smoke. *See*, e.g., Ley Nº 18.256 de 6 de marzo de 2008 & Decreto Nº 284/008 de 9 de junio de 2008. Smoking prevalence and related illnesses declined under the Vazquez regime. *See* A. Blanco-Marquizo, et. al., *Reduction of second hand tobacco smoke in public places following national smoke-free legislation in Uruguay*" 19 TOBACCO CONTROL 231-234 (2010); Press Release, Center for Disease

Even before the FCTC, firms effectively used international trademark law to undermine strong tobacco control measures. In 1992, Australian legislators considered imposing a "plain packaging" regime on cigarettes.[236] This requirement provided that only the manufacturer's name could appear in standardized black font, and that the remainder of the package must remain an entirely uniform color, except for government-mandated health warnings.[237] British American Tobacco argued before the Australian Senate that the Paris Convention for the Protection of Industrial Property and Australian law would require compensation for the value of its cigarette brands.[238] The Australian government rejected the proposed regulations.[239] The Ministry of Health announced that "[u]nfortunately, [the proposal] is just not feasible . . . . We would have to buy the tobacco companies' trademarks, and that would cost us hundreds of millions of dollars."[240] Australia revived its plain packaging plan in 2011 and the government prevailed in the High Court of Australia in 2012. In 2011, PMI initiated arbitration proceedings (again through a wholly owned entity) against Australia under a BIT in effect between it and Hong Kong.[241] Ukraine quickly requested consultations and the establishment of a dispute settlement panel under the auspices of the WTO, attracting the attention of dozens of states interested in whether

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Control, *Statement Regarding First Release of Global Adult Tobacco Survey Results by Uruguay*, (Feb. 9, 2010) http://www.cdc.gov/media/pressrel/2010/s100209.htm (last visited June 27, 2011) ; World Bank, *Uruguay*, 420-421 *available at* http://siteresources.worldbank.org/INTETC/Resources/375990-1112106769274/Uruguay.pdf. PMI's suit coincided with his exit from office, and his successor vacillated between maintaining Uruguay's strong laws and relaxing them in order to placate PMI and avoid costly litigation with substantial risk that an international arbitration panel might issue a large award to PMI. *Gobierno reforzará política anti-tabaco*, EL OBSERVADOR, Sep. 9, 2010, *available at* http://www.observa.com.uy/actualidad/nota.aspx?id=101845 (quoting Foreign Minister Luis Almagro as desiring a settlement with PMI); Gabriel Pereyra, *Mujica se alineó con Vázquez y le dará batalla a Philip Morris*, EL OBSERVADOR, Sep. 8, 2010, (reporting that President Mujica had decided to pursue the case against PMI). The Bloomberg offer of support became public in November, 2010. http://www.nationaljournal.com/bloomberg-supports-uruguay-s-tobacco-fight-20101116

[236] Halabi, *supra* note 191.

[237] GARFIELD MAHOOD, WORLD HEALTH ORG., CANADA'S TOBACCO PACKAGE LABEL OR WARNING SYSTEM: "TELLING THE TRUTH" ABOUT TOBACCO PRODUCT RISKS 7 (2003).

[238] *See* Generic Packaging, Supplementary Submission to Senate Comm., *supra* note 11, at 3.

[239] *See* Adam Harvey, *Doctors' Plan to Put Cigarettes in Plan Wrap Fails*, SYDNEY MORNING HERALD, July 24, 1995, at 2 (quoting the spokeswoman for the Ministry of Health as stating that "[u]nfortunately, [the proposal] is just not feasible . . . . We would have to buy the tobacco companies' trademarks, and that would cost us hundreds of millions of dollars").

[240] *See id.* at 2.

[241] Bloomberg News, *Philip Morris Sues Australia Over Cigarette Packaging*, N.Y. TIMES, June 27, 2011, at B8.

or not Australia's plain packaging regime is consistent with TRIPS, the TBT Agreement, and/or GATT.[242]

E. Thailand and Pictorial Warnings on Alcoholic Beverage Containers

In January 2010, Thailand proposed legislation requiring that graphic warning labels cover thirty percent of the surface of beer, wine, and spirits containers. [243] The subsequent response by international alcoholic beverages firms and their supporting governments foreshadows the similarities likely between strong tobacco packaging and labeling regulations and international intellectual property claims.

> The US representative noted that Clause 3 of the draft regulation precluded US labels from having: "any word or statement that misleads consumers to understand that alcoholic beverages are safe and good for health or contain lower level of harmful substances compared with other alcoholic beverages or contains words or statements that directly or indirectly advertise the alcoholic beverage". . . . . to the extent that a registered trademark contained any such description, this vague provision could result in trademarks being prohibited on alcoholic beverage packaging.[244]

Argentina, Australia, Chile, Mexico, the EU, New Zealand, and Switzerland also raised either intellectual property or trade barrier challenges to the proposed regulations. [245] In his analysis of alcohol manufacturers' participation in trade and investment treaties, Dr. Donald Zeigler observes parallels between the tobacco companies' intellectual property claims and those that alcohol manufacturers advocate in trade and investment instruments.[246]

IV. INTERNATIONAL PUBLIC HEALTH LAW IN A WORLD OF STRONG INTERNATIONAL INTELLECTUAL PROPERTY LAW

It is certainly true that international intellectual property protections do not completely preclude international public health law's potential gains. For example, IP protections pose no obvious barriers to preventing the distribution of free infant formula samples to health care workers nor

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[242] http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds434_e.htm
[243] Patrick Barta & Christina Passariello, *Global Liquor Makers Fight Graphic Labels in Thailand*, WALL ST. J., Sept. 17, 2010, at B1; *see also* Committee on Technical Barriers to Trade, *Notification*, G/TBT/N/THA/332, at 2 (Jan 21, 2010), *available at* http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/tbtn10/THA332.doc.
[244] http://www.smoke-free.ca/trade-and-tobacco/wto-secretariat/TBT50_28mai10.pdf paragraph 10.
[245] Barta & Passariello, *supra* note 241, at B1; *Tobacco and Alcohol Technical Barriers Among Members' Trade Concerns*, WORLD TRADE ORG. (Mar. 24–25, 2010), http://www.wto.org/english/news_e/news10_e/tbt_24mar10_e.htm.
[246] Donald W. Zeigler, *The Alcohol Industry and Trade Agreements: A Preliminary Assessment*, 104 ADDICTION 13, 20–21 (2009).

adopting prohibitions on smoking in public places. Moreover, there are inchoate efforts in discrete areas of international public health law generally unrelated to IP rights, like the international recruitment of health workers.[247] Yet, broadly speaking, the potential gains from existing international public health law instruments and those on the horizon are fundamentally tied to the subordination of the wide powers intellectual property holders now hold. In spite of the episodes described above, the central significance of international intellectual property protection to the development of *international* public health law appears curiously askew of global health advocates' primary agenda.

Article 15 of the Framework Convention on Tobacco Control, for example, calls for the elimination of all forms of illicit trade in tobacco products, of which counterfeit cigarettes are an integral part. When the parties negotiated a separate treaty to give effect to that provision, the Protocol to Eliminate Illicit Trade in Tobacco Products, they agreed in Article 2 that "[n]othing in this Protocol shall affect the rights and obligations of any Party pursuant to any other international convention, treaty or international agreement in force for that Party that it deems to be more conducive to the achievement of the elimination of illicit trade in tobacco products."[248] In short, any agreement which gives strong protection to tobacco trademarks, which are always asserted as a defense against the counterfeit cigarette trade, is fully compatible with the Protocol.[249]

Similarly, at the same time the WHO is attempting to conclude a Medical Research and Innovation Treaty, it is also undertaking greater efforts toward fostering collaboration on counterfeit medicines and devices, i.e., unsafe, unregulated, or fraudulently labeled or represented drugs which pose risks of illness, injury or death to patients. There are of course numerous ways to define "counterfeit" drugs including heavy emphasis on protected trademarks under TRIPS[250] or in connection with their effects on patients, in which IP rights are less implicated.[251] Notwithstanding key policy flexibilities attached to definitional choices, the World Health Assembly has decided to study the public health effects of counterfeit medicines "excluding trade and intellectual property

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[247] WHO Global Code of Practice on the International Recruitment of Health Personnel available at http://www.who.int/hrh/migration/code/practice/en/.
[248] Protocol to Eliminate Illicit Trade in Tobacco Products art. 2(3).
[249] The word "counterfeit" was removed from the Protocol text for this reason, but its absence does not affect the strength of Article 2. Tania Voon, *Growing Conflicts Between Intellectual Property Rights and Health*, 2 EUROPEAN INTELLECTUAL PROPERTY REVIEW (forthcoming 2013).
[250] Gian Luca Burci, *Public Health and "Counterfeit" Medicines: The Role of the World Health Organization* (11 January 2013) 17(2) ASIL INSIGHTS.
[251] Jonathan Liberman, *Combating Counterfeit Medicines and Illicit Trade in Tobacco Products: Minefields in Global Health Governance*, 40 JLME 326, 328-30 (2012).

considerations" which will inevitably influence the outcome of any international agreement on the issue.[252]

Those calling for a Framework Convention on Alcohol Control have argued rather loosely that it should be another version of the FCTC, and have advanced few if any provisions which might address the IP challenges the FCTC has faced. The WHO's Global Strategy to Reduce the Harmful Use of Alcohol acknowledges the role of marketing in influencing consumption but does not address the role of trademarks law in obstructing recommended measures. The Framework Convention on Global Health has gone somewhat further, suggesting that "an FCGH could require states and international organizations to show that loan conditions or trade rules are not detrimental to the public's health."[253] and that "an FCGH could go further by . . . . protecting bilateral and regional trade agreements from provisions that could reduce access to medicine") but still avoids the detailed international IP protections that would jeopardize the FCGH's mission. [254]

A. Rescission of Existing Bilateral, Regional and Multilateral Intellectual Property Agreements

Whatever the promise of health diplomacy, it does not appear that "health" is overcoming the traditional concerns of "diplomacy." Unlikely solutions call for the elimination of international IP agreements altogether. Some, like Kojo Yelpalla would simply throw entire agreements like TRIPS out:

> It is now widely acknowledged by most observers that TRIPS is a serious threat to human health security . . . . Before TRIPS, over forty countries offered no patent protection for pharmaceutical inventions. Such sovereign authority of states has been compromised by TRIPS as part of the WTO system of agreements . . . . This exploitation of the inequalities of bargaining power was undertaken at a time when many developing countries were ill equipped or unprepared to appreciate all the implications of TRIPS. Nor did they fully understand the significance of the converging forces at work. 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, foreign private

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[252] World Health Assembly Resolution 63(10), *Standard/spurious/falsely-labelled/falsified/counterfeit medical products* available at http://apps.who.int/gb/or/e/e_wha63r1.html.
[253] Lawrence O. Gostin, *A Framework Convention on Global Health: Health for All, Justice for All*, 307(19) JAMA 2087-2092 available at http://jama.jamanetwork.com/article.aspx?articleid=1157495.
[254] *Id*.

> interests could subvert the political authority and public interest of the state."[255]

Even scholars less hostile to the underlying purpose of the agreement concede that the built-in flexibilities of TRIPS[256] may not help much against determined IP-rights holders with the heaviest investments in knowledge-intensive processes or assets.[257] Yet it is certainly true that in response to developments in international investment and trade law some states are revising or withdrawing from agreements with strong intellectual property protections.[258]

B. Revision of Existing Bilateral, Regional and Multilateral Intellectual Property Agreements

Other, more pragmatic, solutions require *working within* existing international IP agreement frameworks. Bilateral, regional and international IP treaties, for example, do not need to afford IP holders an entire administrative and judicial framework which may, and often does, exaggerate the benefit those goods offer. Firms, for example, have shown themselves able to punish governments who threaten their intellectual property investments.[259] Other solutions involve explicit limitations on the adjudicatory rights private parties enjoy under bilateral or multilateral instruments.[260] This is, in effect, the aim of the Doha Declaration which emphasizes the rights of governments to facilitate access to medicines for

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[255] Yelpaala, *supra* note 124, at 63.

[256] Yelpaala, *supra* note 124, at 61-64 (citing Carlos M. Correa, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 13-18 (2002) (discussing various available flexibilities for developing countries to exploit in the text of the TRIPS Agreement); Carlos M. Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 22 (2000).

[257] Brewster, *supra* note 140, at 32.

[258] Mercedes Alvaro, *Ecuador Plans to Audit Bilateral Investment Treaties*, WALL STREET JOURNAL, Mar. 11, 2013, available at http://online.wsj.com/article/BT-CO-20130311-708469.html; Investment Treaty News, *South Africa Begins Withdrawing from EU-Member BITs*, Oct. 30, 2012 available at http://www.iisd.org/itn/2012/10/30/news-in-brief-9/

[259] After Thailand issued a compulsory license for Abbott Laboratories' HIV drug Kaletra, Abbott canceled plans to sell seven new medicines in Thailand and threatened to end its drug registration activities altogether. One of these medicines was a heat-stable form of Kaletra that required no refrigeration. See Amy Kazmin and Andrew Jack, *Abbott Pulls HIV Drug in Thai Patents Protest*, FINANCIAL TIMES, Mar. 14, 2007. In Uruguay, Philip Morris International closed a tobacco processing plant in retaliation for the government's anti-tobacco measures. See *Philip Morris Says Closes Plant in Uruguay Amid Lawsuit*, Reuters, Oct. 21, 2011 available at http://www.reuters.com/article/2011/10/22/philipmorris-uruguay-idUSN1E79K1YZ20111022.

[260] Daniela Caruso, *Private Law and State-Making in the Age of Globalization*, 39 N.Y.U. J. INT'L L. & POL. 1 (2006).

their citizens as well as more modern trends in bilateral investment treaties.[261] The United States for example, has determined that investment agreements should not provide foreign investors with greater substantive protections than domestic investors.[262] Australia has recently moved away from investor-state dispute resolution in its investment agreements.[263] Other possibilities include concrete exceptions for public health measures and the exemption of IP and related rights from bilateral agreements.

Another strategy is to explicitly address international intellectual property rights in international public health agreements themselves. WHO Article 19 treaties, like the FCTC and its Illicit Trade Protocol, Article 21 measures like the IHR, and even Article 23 recommendations like the International Code frankly depend on the curtailment or at least contextualization of IP rights to succeed. Ignoring or downplaying the importance of IP rights leaves large gaps in the potential coverage offered by international public health law. To phrase it another way, international public health law to a significant extent *is* intellectual property law. To be sure, IP issues often permeate negotiations over international public health law instruments. Negotiators successfully included "trademark" as a subject of FCTC Article 11's prohibition on misleading descriptors over the objection of states with strong trademark-rights holding constituencies.[264] But the examples described above including the Illicit Trade Protocol, the Framework Convention on Alcohol Control and the Framework Convention on Global Health demonstrate the general reluctance to specifically address management of IP rights as part of broader international public health law initiatives.

This is unsustainable even for public-private partnerships which generally operate well within the boundaries of international intellectual property protection. The Global Fund's activities, for example, may fall afoul of ACTA.[265] The GAVI Alliance's model of Advanced Market Commitment institutionalizes the fundamental difficulty IP rights pose: because the AMC's are so expensive and technically detailed, they both

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[261] Thomas A. Haag, *TRIPS Since Doha: How far Will the WTO Go Toward Modifying the Terms of Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC'Y, 945, 955-66 (2002) (discussing the requirements for triggering the use of Article 31(k)).

[262] Trade Act of 2002, Pub. L. No. 107-210, § 2102(b)(3).

[263] Department of Foreign Affairs and Trade (DFAT). 2011. "Gillard Government Trade Policy Statement: Trading our way to more jobs and prosperity" http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-andprosperity.html#investor-state

[264] Sean D. Murphy, UNITED STATES PRACTICE IN INTERNATIONAL LAW: 2002-2004 147 (2005).

[265] The possibility is not far fetched. One of the generic drugs shipments seized in the Netherlands in 2009 was purchased by UNITAID and moving from India to Nigeria, where none of the drugs were patent protected. Rosina and Shaver, *supra* note 216, at 200-01.

limit the amount of vaccines which can be purchased and threaten to crowd out lower-cost manufacturers.[266]

These strategies do not necessarily need to sharply limit or manage IP rights in the text of agreements. However, they must at least address the fundamental threat that enforceable IP rights in international agreements pose to public health interventions. These threats, of course, vary in their severity. For patents, for example, there is an identifiable point of protection at which original innovation is encouraged and therefore welfare-enhancing. Past that point, the patent monopoly threatens accompanying innovations which may result in higher quality products or processes or means by which those products or processes might be less expensively distributed. For trademarks, especially alcohol, beverage, food and tobacco trademarks, rights-holders spend vast amounts learning which shapes, colors, figures and other visual cues will enhance consumption well beyond any limit set by evidence-based nutrition policy or even the limited purpose trademarks are meant to serve: distinguishing competitors' products or services.[267]

For example, it makes sense to impose upon tobacco manufacturers liability with respect to the costs deceptive trademarks impose on society and the heavy investments they make in shaping the perception of their products' risk. That liability may be imposed without violating trademark protective terms in TRIPS and many bilateral investment treaties. This was originally possible under early versions of Article 19 of the FCTC, although it was eventually given limited scope. The same would be true, to varying extents, for alcohol and food manufacturers. Together, these three industries account for a significant part of the disease burden that international public health law aims to address.

The Medical Research and Innovation Treaty, to date, represents the approach most likely to harmonize international intellectual property law and international public health law in ways respectful of both. The treaty creates a regime under which specific drug and medical device development will occur in a space "where the current [international intellectual property] system does not function." The compromises involved will no doubt disappoint both strong IP-rights advocates and public health advocates, but explicitly balancing the costs and benefits of each in open forum increases the chance that an equitable conclusion will be reached. Indeed, the treaty, once considered dead letter, was revived during the 2013 meeting of the World Health Assembly when the United

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[266] Donald Light, *Saving the Pneumococcal AMC and GAVI*, 7 HUMAN VACCINES 138 (2011) available at http://www.landesbioscience.com/journals/vaccines/News-HV7-2-policy.pdf.
[267] Halabi, *supra* note 191.

States proposed a series of demonstration projects that might bridge the current, deep divides between member states over the treaty's terms.[268]

C. The Role of Multipolarity in Rebalancing International Intellectual Property Protections and International Public Health Law

Addressing intellectual property challenges in public health treaties inevitably means protracted negotiations and perhaps fewer agreements. On the one hand, this might mean resources are allocated to more effective uses. If the allocation of scarce resources requires a choice, advocates for better access to medicines may do better influencing the scope of patentability in statutory regimes than in negotiating a medical research and innovation treaty.[269] On the other hand, the shifting distribution of global political power also increases the opportunities for compromises that may not have existed in 2004 (IHR) or 2005 (FCTC) and certainly did not exist in 1981 (International Code). For example, Brazil and India, which operated largely outside the international trading system in 1981, are now among its most important participants.[270] Their thriving generics industries have encouraged both states to use international intellectual property treaties to loosen the strong protections given patents and trademarks in the medicines context.

Similarly, efforts like a Framework Convention on Alcohol Control face long odds given that the world's largest alcoholic beverage firms have steep roots not only in North America and Europe but also in Australia, Brazil, Mexico and South Africa. Paula O'Brien has pointed out the inconsistency between Australia's aggressive treatment of tobacco trademarks and the protests it has launched against Thailand's efforts to

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[268] Health Action International, *Long Awaited Steps Towards Affordable Access and Needs-Driven Research and Development*, 66th World Health Assembly, 17 June 2013 available at http://haieurope.org/wp-content/uploads/2013/06/HAI-Europe-statement-WHA-66-FINAL.pdf.

[269] See Liberman, *supra* note 250, at 333 (noting Western influence on Kenyan and Ugandan definitions of "counterfeit" which included patented drugs); *Combating Counterfeit Medicines and Illicit Trade in Tobacco Products: Minefields in Global Health Governance*, 40 JLME 326, 328-30 (2012); Gostin and Taylor, *supra* note 120 (noting deficiencies in using international law to address global health issues include "State-centricity in the international legal system; skewed priority setting; flawed implementation and compliance; fragmentation, duplication and lack of coordination).

[270] Lawrence Henry, INDIA'S INTERNATIONAL TRADE POLICY 3 (2008) ("Up until the 1980s, India was not interested in exporting its goods and services abroad and not ready to open its economy to foreign investments."); Eliana Cardoso, A BRIEF HISTORY OF TRADE POLICIES IN BRAZIL: FROM ISI, EXPORT PROMOTION AND IMPORT LIBERALIZATION TO MULTILATERAL AND REGIONAL AGREEMENTS 2 (2009) ("Half a century of trade protectionist policies had resulted in Brazil having less than a 1 percent share in global trade, despite its population representing almost 3 percent of the world's population in 1990. The accumulation of problems from high levels of debt and inefficient state-owned industries induced Brazil to rethink its strategy to a more market-driven and trade oriented approach.") available at http://www.tulane.edu/~dnelson/PEBricsConf/cardoso-trade.pdf.

use the same public health intervention for alcohol disease burden it bears.[271]

It is not only individual states and their relative influence that will bear on the potential success of international public health law in the future.[272] Brazil, India and South Africa also build coalitions and alliances through direct monetary and non-monetary aid.[273] The growing web of economic and political alliances between these and other developing states will expand the possibilities for coalition building in support of certain international instruments but against others.[274]

V. CONCLUSION

Confrontations between expanding intellectual property rights and international public health law are now poised to increase rather than abate as international agreements addressing both proliferate.[275] If the population health gains envisioned by the International Code, the IHR and the FCTC, as well as a Framework Convention on Alcohol Control or a Framework Convention on Global Health are to materialize, their respective advocates must more squarely address the obstacles international property agreements pose for those gains and develop strategies to overcome them or concede their political improbability. These strategies include negotiating concrete public health safe harbors in bilateral investment and trade agreements, modifying dispute resolution mechanisms and conditioning compliance with national law and norms.[276] Other possibilities include ex post strategies which redistribute monopoly gains intellectual property rights holders enjoy. For example, Article 19 of the FCTC might authorize compensation for illness or injury caused by consumption induced by a misleading trademark.[277] The proposed medical research and innovation treaty, for example, places at its core

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[271] Paula O'Brien, *Australia's Double Standard on Thailand's Alcohol Warning Labels*, 32 DRUG AND ALCOHOL REVIEW 5-10 (2013).

[272] Gerald D. Malpass Jr., *Life After the GATT TRIPS Agreement - Has the Competitive Position of the U.S. Changed?* 19 HOUS. J. INT'L L. 207, 226 (1996).

[273] Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 355, 358 (2008).

[274] Susan Okie, Fighting HIV—Lessons from Brazil, 354 NEW ENG. J. MED. 1977, 1981 (2006) (Brazil, Argentina, China, Cuba, Nigeria, Russia, Ukraine, and Thailand are working together to "improve each country's capacity to manufacture medicines, condoms, and laboratory reagents needed to fight AIDS . . . .").

[275] See Voon, *supra* note 247.

[276] Rahim Moloo and Alex Khachaturian, *The Compliance with the Law Requirement in International Investment Law*, 34 FORDHAM INT'L. L.J. 1473 (2011).

[277] This was in part the theory of the U.S. Government in its RICO claim against tobacco firms for "light" and "low" claims. While the trial court approved the government's theory of disgorgement, the federal appellate court ruled the government was not entitled to disgorgement under the relevant statute. U.S. v. Philip Morris et. al., 396 F.3d 1190 (D.C. Cir. 2005).

redistributive defects inherent in strong intellectual property regimes. Despite opposition from states with strong patent right holding constituencies, the proposal is, slowly, moving forward. As or more important, the changing distribution of economic, diplomatic and political power renders a broader range of possibilities for coalition building and influence, especially where Brazil, India and South Africa are key stakeholders.[278]

[278] See, e.g., Carlos M. Correa, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007).