FROM TRIPS-PLUS TO RIGHTS-PLUS? EXPLORING RIGHT TO HEALTH IMPACT ASSESSMENT OF TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS THROUGH THE THAI EXPERIENCE

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ABSTRACT

Current international trade rules such as the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) may restrict domestic policy options to increase access to affordable medicines. This impact is amplified in bilateral and regional free trade agreements containing stronger "TRIPS-Plus" intellectual property rights. These rules may run counter to the human rights imperative to increase access to affordable medicines, with deleterious impacts on individual and population health. This paper explores the feasibility of implementing an impact assessment tool drawn from the international human right to health to measure and remediate these impacts. It explores the potential utility of this tool against the backdrop of law, theory and politics

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relevant to global pharmaceutical access, focusing on relevant policy experience in Thailand.

KEYWORDS: *TRIPS, TRIPS-Plus, right to health, right to health impact assessment tool, RTHIA, Thai-U.S. FTA negotiation, National Human Rights Commission of Thailand*

I. INTRODUCTION

Since 1995, 153 member states of the World Trade Organization [hereinafter WTO] have become bound by the organization's subsidiary Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPS], which requires countries to protect pharmaceutical patents with strictly circumscribed and enforced 20 year terms.[1] At the same time, many countries have become additionally bound under bilateral or regional free trade agreements [hereinafter FTAs] that require significantly stronger "TRIPS-plus" intellectual property rights. The threatened impact of these rights is to exacerbate existing gaps in access to essential and other medicines in low and middle income countries [hereinafter LMIC]. These duties appear to stand in direct contravention of the duties that most governments hold to realize the right to the highest attainable standard of physical and mental health (the right to health), including by assuring access to affordable medicines.[2] Yet most policy makers do not consider their right to health duties when negotiating or implementing TRIPS or TRIPS-plus intellectual property rights. This lacuna suggests the need to assure consideration of human rights duties by policy-makers when it comes to negotiating and implementing trade-related policy and practice.

This paper will explore a policy tool drawn from the right to health in international law to assess the impact of trade-related intellectual property rights on access to affordable medicines in LMIC. This is the right to health impact assessment tool [hereinafter RTHIA], a pragmatic mechanism to enable social actors and policy makers to gather evidence about the impact of pharmaceutical patents on drug prices and accessibility, and accordingly to propose changes to law, policy and programs to prevent or mitigate any such impacts. In doing so, it enables actors to mitigate any restrictive effects of intellectual property rights on access to medicines, realize the human right to affordable medicines, and potentially even challenge the deeper priorities that permit commercial interests to routinely restrict even the most essential health needs in LMIC.

These lofty aspirations must raise immediate questions about the feasibility of such a tool to achieve these goals, particularly given powerful countervailing economic and political interests. The inherent power differentials at stake may make it tremendously difficult for a policy maker

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 28.1.a and b, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

[2] International Covenant on Economic, Social, and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESR]; Constitution of the World Health Organization Preamble, June 22, 1946.

in a low income country to refuse these rights, irrespective of the strength of evidence adduced by an RTHIA. Similarly, it is questionable whether an RTHIA could effectively remediate the restrictive impact of trade-related intellectual property rights given their global influence on the production and movement of generic drugs. These dilemmas outline key questions regarding the implementation of an RTHIA, including the kinds of countries, actors, methods and approaches best suited to ensuring effective uptake and implementation. Relevant insights can be gleaned from country experiences, particularly a human rights impact assessment conducted in 2006 in Thailand of stringent intellectual property rights being negotiated in an FTA with the United States (the U.S.). The following paper explores the Thai experience through a review of relevant political and academic literature and interviews with key informants in civil society, government and academia.[3] The structure of the article is as follows, first, the article contextualizes the need for this tool in relation to global access to medicines and trade-related intellectual property rights. Second, it explores the legal and theoretical framework behind the tool and the methodology itself. Third, the article describes the Thai human rights impact assessment of the U.S. FTA. It closes with thoughts about the implications of the Thai experience for implementing an RTHIA more generally.

II. ACCESS TO MEDICINES AND TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS

As of 2004, two billion people — one third of the global population — lack regular access to essential medicines.[4] This figure rises to half the population in the poorest parts of Asia and Africa.[5] While access to medicines is determined by several factors, such as rational use, adequate infrastructure, and sustainable financing,[6] drug pricing can have a disproportionate impact on access. A 2011 World Health Organization [hereinafter WHO] Report confirms that high medicines prices and low affordability remain key impediments to access in many LMIC.[7] The outcome is that many patients have to choose between purchasing drugs in the private sector at prices they cannot afford at the risk of becoming impoverished, or foregoing treatment in totality for life threatening and

[3] Five interviews were conducted by telephone and Skype between March and May 2011, only two interviewees consented to being identified.
[4] World Health Organization [WHO], *WHO Medicines Strategy: Countries at the Core 2004-2007*, at 3, WHO/EDM/2004.5 (2004).
[5] *Id.*
[6] *Id.* at 24.
[7] Alexandra Cameron et al., *The World Medicines Situation 2011: Medicine Prices, Availability and Affordability*, at 2, WHO/EMP/MIE/2011.2.1 (2011).

painful health conditions.[8] Drug prices are primarily determined by patents, and since 1995, any country acceding to the WTO must protect these internationally under TRIPS, which requires WTO members to provide 20 year exclusive protection to pharmaceutical patents.[9] TRIPS harmonized international legal standards in relation to intellectual property rights and patents for the first time, inducing many countries (such as India) which previously had not patented drug products to do so and requiring others to increase extant levels of patent protection.[10] TRIPS excludes states from either making or importing cheaper drugs unless they use limited exceptions called TRIPS flexibilities, which enable policy-makers to access cheaper drugs when necessitated by public health needs. These flexibilities include practices such as parallel imports (whereby countries import cheaper patented medicines) and compulsory licensing (whereby countries manufacture or import generics under strict conditions).[11] However it is a tremendous misnomer to call a provision like compulsory licensing a flexibility, since there is nothing flexible about the rules or the environment in which countries seek to implement them. For example, the compulsory license rule is highly complex and circumscribed, permitting use only if the drug in question will be used for public non-commercial use, national emergency or extreme urgency. Yet none of these key terms are defined, and the consequent vagueness means that countries issuing compulsory license under almost any circumstances are likely to attract real or threatened trade sanctions or litigation or drug removals by companies.

The implementation of TRIPS in countries which have not previously protected pharmaceutical patents significantly increases drug prices. For example, in Malaysia between 1999 and 2005, drug prices rose by 28% on average per year once patents were introduced.[12] As TRIPS is implemented it will eventually phase out generic manufacture of patented medicines in totality unless it is done under compulsory licensing, resulting in TRIPS flexibilities becoming the sole mechanism whereby governments can access more affordable versions of patented medicines. At the same time even stricter intellectual property rights in regional and bilateral FTAs place further restrictions on the use of TRIPS flexibilities. These "TRIPS-plus rules" exceed the standards in that agreement, extending monopoly

[8] *Id.* at 6; Laurens M. Niens et al., *Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-country Comparison of the Affordability of Medicines in the Developing World*, 7(8) PLOS MED. 1, 6 (2010).
[9] TRIPS, art. 33.
[10] Sandra Bartelt, *Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6(2) J. WORLD INTELL. PROP. 283, 285 (2003).
[11] TRIPS, arts. 6 & 31.
[12] Richard D. Smith et al., *Trade, TRIPS and Pharmaceuticals*, 373(9664) THE LANCET 684, 689 (2009).

pricing and limiting market entry for generics including by restricting the grounds on which compulsory license can be issued.[13] The U.S. is by far the primary initiator of bilateral and regional trade agreements, signing bilateral trade agreements with 42 countries between 1986 and 2000.[14] It has also negotiated regional trade agreements affecting approximately 50 countries, including the Andean FTA, Free Trade Agreement of the Americans and the Central American FTA.[15] Additional FTAs are being signed and/or negotiated between multiple LMIC and the European Union [hereinafter EU] or the European Free Trade Association [hereinafter EFTA].[16] TRIPS-plus intellectual property rights have expanded well beyond FTA in a range of other bilateral agreements, including the proposed Anti-Counterfeiting Trade Agreement [hereinafter ACTA] which defines generic medicines as counterfeit or pirated goods in its efforts to create an institutional mechanism to challenge their movement,[17] and the Trans-Pacific Partnership between Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the U.S. and Vietnam.

Efforts to advance restrictive intellectual property rights of this nature continue despite the 2001 WTO Doha Declaration, which explicitly endorses the right of WTO members to protect public health and promote access to medicines for all, and to use TRIPS flexibilities to the full, including compulsory licences.[18] While the Doha Declaration sought to confirm that compulsory licenses could be used legitimately for epidemics like HIV/AIDS, tuberculosis and malaria,[19] in practice pharmaceutical companies and their host governments have tried to limit the use of the

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[13] Lisa Forman, *Trading Health for Profit: Bilateral and Regional Free Trade Agreements Affecting Domestic Property Rules on Intellectual Property Rules on Pharmaceuticals*, *in* THE POWER OF PILLS: SOCIAL, ETHICAL, AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING 190, 193-94 (Jillian C. Cohen et al. eds., 2006).

[14] Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting* 50-51 (Commission on Intellectual Property Rights, Study Paper No. 8, 2002).

[15] *Id.*

[16] Carlos M. Correa, *Intellectual Property Rights and Inequalities in Health Outcomes* 24 (WHO Commission on Social Determinants of Health, Globalization and Health Knowledge Network, Research Paper No. 8, 2008).

[17] ACTA was proposed by Japan and the United States in 2006, joined by Canada, the European Union and Switzerland from 2006-07, with Australia, Mexico, Morocco, New Zealand, the Republic of Korea and Singapore joining the official negotiations in June 2008.

[18] WTO, Declaration on the TRIPS Agreement and Public Health, ¶ 4, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration]. Paragraph 4 states:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

[19] *Id.* ¶ 5.c.

compulsory licenses to these three diseases and only to the incidence of these diseases in Sub-Saharan Africa.[20] The outcome is that compulsory licenses for AIDS drugs outside of Africa or for health needs beyond HIV and AIDS continue to be attacked as impermissible breaches of TRIPS rights, threats to the medical innovation system, and outright theft and piracy. The net impact is to maintain high drug prices, restrict access to generics and sustain and even exacerbate the drug gap at great human cost.

III. THE LEGAL AND THEORETICAL FRAMEWORK FOR AN RTHIA METHODOLOGY

This outcome threatens the realization of a range of human rights primarily the right to health protected extensively in international law, including the International Covenant on Economic, Social and Cultural Rights [hereinafter ICESCR].[21] The right to health in the ICESCR has been authoritatively interpreted by the United Nations Committee on Economic, Social and Cultural Rights [hereinafter CESCR] to impose a state duty to provide universal access to essential medicines as a core and hence prioritized duty under this right.[22] Implicit within CESCR's interpretation of this right is that it also imposes a general state duty to ensure access to affordable, available and safe drugs.[23] CESCR has further interpreted a state's minimum core duty to extend to preventing unreasonably high costs for essential medicines.[24] These duties appear to be in conflict not simply with the TRIPS imperative to provide 20-year exclusive protection to pharmaceutical patents, but also with the legal, political and economic strictures on using TRIPS flexibilities to assure broader access. Conflicts

[20] The corporate and trade actions described in this paper against Thailand's use of compulsory licenses for HIV/AIDS and cancer drugs provide a case in point. *See also* the unchallenged growth of compulsory licensing in multiple African countries after 2002, discussed in James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents* (Knowledge Ecology International, Research Note 2007:2, Mar. 8, 2007, revised May 6, 2007), *available at* http://www.k eionline.org/misc-docs/recent_cls.pdf.

[21] ICESR, *supra* note 2. *See also* Universal Declaration of Human Rights, G.A. Res. 217A, at 71, U.N. GAOR, 3d Sess. 1st plen. mtg., U.N. Doc. A/810 (Dec. 10, 1948); International Convention on the Rights of the Child, art. 24.1, Nov. 20, 1989, U.K.T.S. 1992 No. 44, 28 I.L.M. 1448 (1989); International Convention on the Elimination of Racial Discrimination, art. 5.e.iv, Dec. 21, 1965, 660 U.N.T.S. 195, 5 I.L.M. 352 (1966); Convention on the Elimination of All Forms of Discrimination Against Women, arts. 11.1. f & 12, Dec. 18, 1979, U.K.T.S. 1989 No. 2, 19 I.L.M. 33 (1980); Convention on the Rights of Persons with Disabilities, G.A. Res. 61/106 (Jan. 24, 2007).

[22] U.N. Econ. & Soc. Council [ECOSOC], Comm. on Econ., Soc. & Cultral Rights [CESCR], *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 43.d, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

[23] *Id.* ¶ 12.

[24] ECOSOC, CESCR, *General Comment 17 (2005): The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He or She Is the Author (Art. 15, ¶ 1(c), of the Covenant)*, ¶ 35, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006).

between these duties also raise pragmatic concerns, since policy-makers are not required to consider potential health impacts when negotiating or implementing trade and intellectual property rights.

Accordingly, there has been a growing call within the human rights community for policy makers to take the right to health into account when entering trade agreements, including by assessing the impact of trade agreements through the lens of the right to health. For example, several treaty monitoring committees at the United Nations have cautioned states about the potential adverse effects of trade agreements on access to affordable medicines and called on countries to conduct assessments of the effect of international trade rules on the right to health.[25] In 2006, Paul Hunt, the first United Nations Special Rapporteur on the right to health, recommended that urgent attention be given to developing a methodology for RTHIA assessments of trade rules.[26] At the same time, there has been a significant growth in methodologies and scholarship exploring human rights impact assessments related to health[27] and the impact of TRIPS and FTA on access to medicines.[28] This legal and political backdrop has provided the framework for the development of an RTHIA of trade-related intellectual property rights.

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[25] *See, e.g.*, ECOSOC, CESCR, *Concluding Observations of the Committee on Economic, Social and Cultural Rights: Ecuador*, ¶ 55, E/C.12/1/Add.100 (June 7, 2004); ECOSOC, CESCR, *Concluding Observations of the Committee on Economic, Social and Cultural Rights: Morocco*, ¶ 56, E/C.12/MAR/CO/3 (Sept. 4, 2006); ECOSOC, CESCR, *Concluding Observations for Costa Rica*, ¶¶ 27 & 48, U.N Doc. E/C.12/CRI/CO/4 (Jan. 4, 2008); U.N. Comm. on the Rights of the Child [CRC], *Consideration of Reports Submitted by States Parties under Article 44 of the Convention - Concluding Observations: El Salvador*, ¶ 48, CRC/C/15/Add.232 (June 4, 2004).

[26] ECOSOC, Comm. on Human Rights [CHR], *Economic, Social and Cultural Rights: The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health – Addendum: Mission to the World Trade Organization*, ¶ 74, U.N. Doc. E/CN.4/2004/49/Add.1 (Mar. 1, 2004) (*prepared by* Paul Hunt).

[27] For example, WHO & U.N. Educ., Sci. & Cultural Org. [UNESCO], *Health and Human Rights Working Paper Series No 6: Impact Assessments, Poverty and Human Rights: A Case Study Using the Right to the Highest Attainable Standard of Health* (May 31, 2006) (*prepared by* Paul Hunt & Gillian MacNaughton); *see generally* Humanist Committee on Human Rights, Health Rights of Women Assessment, Humanistisch Overleg Mensenrechten, Utrecht (2006), http://www.humanrightsimpact.org/fileadmin/hria_resources/HeRWAI_Training/HeRWAI_engels_2010.pdf.

[28] *See generally* Chuan-feng Wu, *Raising the Right to Health Concerns within the Framework of International Intellectual Property Law*, 5(1) ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141, 153-61 (2010); SIMON WALKER, THE FUTURE OF HUMAN RIGHTS IMPACT ASSESSMENTS OF TRADE AGREEMENTS (2009); Ellen Shaffer & Joseph Brenner, *A Trade Agreement's Impact on Access to Generic Drugs*, 28(5) HEALTH AFF. 957, 957 (2009); IFARMA, IMPACT OF THE EU-ANDEAN TRADE AGREEMENT ON ACCESS TO MEDICINES IN PERU (2009), *available at* http://www.haiweb.org/11112009/ReportIFARMAImpactStudyPeru(EN).pdf; Thomas Faunce et al., *Assessing the Impact of the Australia-United States Free Trade Agreement on Australian and Global Medicines Policy*, 1(15) GLOBALIZATION & HEALTH 1, 1 (2005); Nusaraporn Kessomboon et al., *Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-U.S. FTA*, 41(3) SE. ASIAN J. TROPICAL MED. & PUB. HEALTH 667, 667 (2010); Joan Rovira et al., *Guide to the IPRIA (Intellectual Property Rights Impact Aggregate) Model* (2009), *available at* http://ictsd.org/downloads/2010/03/guide-to-the-ipria-model.pdf.

The tool's methodology and approach is best understood through theories of rights as drivers of social change, particularly constructivist theories of socially-driven normative diffusion. These latter theories suggest similar processes whereby norms are advanced by norm entrepreneurs and transnational networks, leading to the emergence of new rules and their internalization as they are adopted as collective understandings.[29] In the Finnemore and Sikkink approach, transnational networks and social actors reframe how issues are viewed, pushing new normative frames into acceptance until "a critical mass of relevant state actors adopt [it]" and the norm starts to cascade into more general acceptance.[30] This cascade continues until the norms "acquire a taken for granted quality and are no longer a matter of broad public debate," and states (and other actors) begin to act in general compliance with the normative prescriptions initially sought by actors.[31]

This theoretical framework sees the RTHIA tool potentially playing a more subterranean normative role by diffusing and internalizing new human rights norms around medicines, so that policy makers are forced to consider their right to health duties when dealing with intellectual property rights. This process may act as a trigger for social and policy learning around the health impacts of intellectual property rights.[32] The aspiration of conducting these kinds of iterative exercises is that they would contribute towards reconfiguring prevailing norms that deprioritize health as a matter of course to competing commercial interests. Certainly the Thai experience appears to animate this possibility, given the parallel emergence of an explicit political focus on social and policy learning as a critical component of policy-making related to health.

The tool will therefore operate on a range of levels, namely by enabling social actors and policy makers to gather evidence about the impact of trade related intellectual property rights on drug prices and access. Once gathered, this evidence may substantiate changes to law, policy and programs to prevent or mitigate this impact, including expanded use of TRIPS flexibilities, changes in the formulation and implementation of trade-related intellectual property rights, altered FTA negotiations and mitigation measures such as increased health expenditure or drug

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[29] Harold Hongju Koh, *Why Do Nations Obey International Law?*, 106(8) YALE L.J. 2599, 2645-59 (1997); Martha Finnemore & Kathryn Sikkink, *International Norm Dynamics and Political Change*, 52(4) INT'L ORG. 887, 895-905 (1998); Thomas Risse & Kathryn Sikkink, *The Socialization of International Human Rights Norms into Domestic Practices: Introduction*, *in* THE POWER OF HUMAN RIGHTS: INTERNATIONAL NORMS AND DOMESTIC CHANGE 1, 5-6 (Thomas Risse et al. eds., 1999).

[30] Finnemore & Sikkink, *supra* note 29, at 895.

[31] *Id.*

[32] Andrew T.F. Lang, *The Role of the Human Rights Movement in Trade Policy-Making: Human Rights as a Trigger for Policy Learning*, 5 N.Z. J. PUB. INT'L L. 77, 95-101 (2007); Wu, *supra* note 28, at 168.

reimbursement schemes. The right to health component of the RTHIA is intended not simply to add moral weight to the necessity of such measures, but to emphasize the legal responsibility that states have to ensure the affordability of medicines or ensure broader access. At the same time conducting these kinds of assessments is intended to constitute a form of education for key stakeholders about trade-related intellectual property rights and the right to health, mainstreaming right to health concerns into trade policies so that policy makers making trade-related decisions may be more respectful of their health implications. The tool may also enable affected communities to voice concerns and thereby influence policy formulation, as well as enable the building of networks and coalitions between social actors, policy makers and international actors that will collectively work to assure that affordable medicines are more broadly accessible within countries.

IV. THAILAND'S HUMAN RIGHTS IMPACT ASSESSMENT OF THE U.S. FTA

The feasibility of these aspirations is partially illustrated in the human rights impact assessment conducted by the National Human Rights Commission of Thailand [hereinafter NHRCT] of an FTA being negotiated with the U.S. in the mid 2000's. This exercise was the first time that a rights-based impact assessment of trade-related intellectual property rights was carried out by a low or middle income country, so the motivations for the report, its methodology and outcomes hold important lessons for taking the tool forward, particularly given Thailand's key role globally in access to medicines debates.

The NHRCT report responded to the initiation in 2004 by Thaksin Shinawatra, then the Prime Minister of Thailand, of negotiations with the George Bush-led U.S. government to conclude a free trade agreement between the two countries. The agreement would have allowed expanded trade of Thai agricultural and industrial products to the U.S. (Thailand's second largest export market),[33] in exchange for broad liberalization in a range of areas including intellectual property rights. The agreement went through six rounds of negotiations between 2004 and 2006, and was part of Shinawatra's broader policy approach of negotiating FTA as a centre piece of economic policy, which saw agreements negotiated with China, India, Bahrain, Australia, Peru, New Zealand, Japan and the European Free Trade Association.[34]

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[33] RAYMOND J. AHEARN & WAYNE M. MORRISON, US-THAILAND FREE TRADE AGREEMENT NEGOTIATIONS, CRS Report for Congress, Order Code RL32314, at 5 (2004).

[34] Pajnapa Peamsilpakulchorn, *The Domestic Politics of Thailand's Bilateral Free Trade Agreement Policy*, 2(1) INT'L PUB. POL'Y REV. 64, 79-80 (2006); AD HOC COORDINATING SUB-

The NHRCT report was produced in 2006, two years after negotiations had initiated, motivated in large part because the Commission had received a complaint from a national advocacy coalition called FTA Watch, alleging that the FTA breached national and international human rights.[35] FTA Watch was formed in 2003 in response to Shinawatra's policies, as a coalition of NGOs, academics and people living with HIV.[36] FTA Watch conducted research on the potential impacts of FTA on human rights and development, and broadly disseminated their findings through media, public presentations and publications (including two books in Thai and one English translated version).[37] The central tenet of the coalition's advocacy was that detailed studies should be conducted of the effects of FTA,[38] including in relation to access to medicines and right to health,[39] and that intellectual property rights not be included in the Thai-U.S. FTA. The coalition made significant use of human rights norms and actors in its strategies, submitting petitions to a range of domestic institutions, including the Thai Ombudsman, the Thai Senate's Foreign Affairs Commission, the Socio-Economic Advisory Board and the NHRCT,[40] as well as to international human rights actors such as the U.N. Special Rapporteur on the Right to Health[41] and the U.N. Human Rights Committee.[42]

FTA Watch's complaint to the NHRCT argued that the Thai-U.S. FTA negotiations posed a serious risk to Thai society and required the NHRCT

COMMITTEE TO REVIEW AND EXAMINE THE ESTABLISHMENT OF THAILAND-UNITED STATES FREE TRADE AREA, AD HOC SUB-COMMITTEE TO REVIEW AND EXAMINE THE ESTABLISHMENT OF THE THAILAND-UNITED STATES FREE TRADE AREA WITH RESPECT TO AGRICULTURE, ENVIRONMENT AND INTELLECTUAL PROPERTY, AND AD HOC SUB-COMMITTEE TO REVIEW AND EXAMINE THE ESTABLISHMENT OF THE THAILAND-UNITED STATES FREE TRADE AREA WITH RESPECT TO SERVICES AND INVESTMENT, REPORT ON RESULTS OF EXAMINATION OF HUMAN RIGHTS VIOLATIONS 5 (2006) [hereinafter NHRCT].

[35] Skype interview with Buntoon Sathasiroj, Advisor to NHRCT and taskforce working group member on HRIA (Mar. 8, 2011); Skype interview with anonymous civil society representative (May 10, 2011).

[36] The coalition included the Thai National Human Rights Commission, Médecins Sans Frontières, FTA-Watch, Drug Study Group, Assembly of the Poor and Focus on the Global South. South-North Development Monitor [hereinafter SUNS], *Thai NGOs Appeal to UN on FTA's Effect on Health* (June 22, 2005), http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CGUQFjAA&url=http%3A%2F%2Fwww.twnside.org.sg%2Ftitle2%2FFTAs%2FIntellectual_Property%2FIP_and_Access_to_Medicines%2FThaiNGOsAppealToUNOnFTAsEffectOnHealth.doc&ei=WjgiUJP_A6nwmAXVyICgCA&usg=AFQjCNH8Jp8WMLCfx8Q5jWuEzaa_z29SOQ&sig2=OnDmXAIj_MJdVYgJg0K5Xg.

[37] JAKKRIT KUANPOTH ET AL., FREE TRADE AGREEMENTS: IMPACT IN THAILAND 5 (2005).

[38] Niramon Yuwanaboon, *The People's Movement Against the Thai-U.S. Free Trade Agreement (FTA) Negotiations*, *in* FREE TRADE AGREEMENTS: IMPACT IN THAILAND, *supra* note 37, at 175, 192.

[39] SUNS, *supra* note 36.

[40] Skype interview with anonymous civil society representative (May 10, 2011).

[41] SUNS, *supra* note 36.

[42] FTA-Watch Thailand, *Thailand's Free Trade Agreements and Human Rights Obligations, Submission to the 84th Session of the U.N. Human Rights Committee* (Mar., 2005).

to request information under the constitutional right to information on the potential impact of the FTA in order to protect Thai society.[43] While FTA Watch's complaint was key in motivating the institution to initiate a human rights impact assessment of the Thai-U.S. FTA, internal participants viewed two additional factors as equally influential: firstly, the fact that Professor Saneh Jamerik, the Commission Chair, held a "broad view" that human rights included not only political rights, but also social rights to development, a decent environment and to access medicines.[44] Secondly, that the Commission was responsive to considerable concern amongst Thai civil society and the public about the Shinawatra's government's concurrent FTA negotiations with a range of countries,[45] compounded by the Commission's inability to get information about the negotiations from the government.[46]

As a result, in 2006 the NHRCT conducted an assessment of the human rights impact of the Thai-U.S. FTA on agriculture, environment, intellectual property, services and investment. Given the secrecy of negotiations, the report was based on a leaked text of the intellectual property chapter and the texts of previously concluded FTA.[47] The NHRCT relied on its legal authority to examine potential violations of human rights under the 1997 Thai Constitution and the 1999 National Human Rights Commission Act.[48] The Commission argued that these provisions authorized its report given that the agreement's topics were "related to national interests and the livelihood of every fabric of Thai society,"[49] and raised concerns about impacts on a range of human rights including rights to access drugs and public health services (as well as development, socio-economic and cultural rights, community rights, right to access resource bases).[50]

The approach followed by the report team was to gather information from key negotiators on demands and assessment of impacts,[51] review documents and explanations from government agencies, and conduct analytical studies by three sub-committees on the expected impacts of the

[43] Skype interview with anonymous civil society representative (May 10, 2011).
[44] Skype interview with Buntoon Sathasiroj, *supra* note 35.
[45] *Id.*; Skype interview with anonymous civil society representative (May 10, 2011).
[46] Skype interview with anonymous civil society representative (May 10, 2011).
[47] Sanya Smith & Kuala Lumpur, *Thai Human Rights Commission Attacks FTA with U.S.*, THIRD WORLD NETWORK (Jan. 24, 2007), http://www.twnside.org.sg/title2/twninfo492.htm.
[48] The report relied on section 56 of the Constitution of the Kingdom of Thailand 1997, which requires impact assessments to be conducted of the environmental impacts of policies and projects. It also relied on the National Human Rights Commission Act B.E. 2542 (1999), which gives the Commission the power to examine acts which violate human rights and propose remedial measures (section 200.1).
[49] NHRCT, *supra* note 34, at 2.
[50] *Id.* at 3.
[51] *Id.* at 4.

FTA on the specified areas. The Commission did not specify which methodologies the sub-committees should use in completing their reports, beyond requiring them to use academic methodologies.[52] As a result, the methodologies used by the sub-committees varied, with for instance, the committee conducting the environmental impact assessment using the European Union's Trade Sustainability Impact Assessment model, and the committee conducting the intellectual property rights assessment using aspects of an economic modelling method developed by Joan Rovira (albeit without the public scoping component that is often key to health and human rights impact assessments).[53] The team conducting the intellectual property rights impact assessment was comprised of academics from Chulangkorn University and Khon Kaen University, a representative from the Government Pharmaceutical Organization [hereinafter GPO], and a member from the Thai Association of Generic Drug Companies.[54]

The section on intellectual property rights articulated its approach as being based on human rights in the 1997 Thai Constitution and the Universal Declaration on Human Rights, as well as data from the Negotiation Team and research by NHRCT Sub-Committees. The authors of the report presented their analysis in three sections exploring Thai intellectual property protection, conducting a comparative analysis of Thailand's compliance with TRIPS, and analyzing the agreement's impact on both people's right to access medicines and on national drug security.

In overviewing Thai intellectual property law, the report outlines a long history of U.S. pressures around intellectual property rights, which saw Thailand increasing its level of intellectual property protection to full compliance with U.S. demands by the early 2000's. In 1979, Thailand introduced a Patent Act that excluded drugs and pharmaceutical products from patent protection, providing legal protection only to drug production processes and providing 15 year patent terms.[55] Claims by the U.S. pharmaceutical industry that it had lost USD 165 million in export revenues to Thailand because of weak patent protection for pharmaceuticals prompted U.S. trade attention.[56] In 1985 the U.S. initiated negotiations on a bilateral Generalized System of Preferences, offering preferential duty-free market entry to Thailand if it granted patents on pharmaceutical products and extended patent terms to 20 years.[57] While these pressures sparked tremendous national protests against the potential increase to drug prices, by 1992 a second Amendment to the Patent Act had been passed, giving

[52] Skype interview with Buntoon Sathasiroj, *supra* note 35.
[53] *Id.*; Skype interview with anonymous civil society representative (Apr. 13, 2011).
[54] Skype interview with anonymous civil society representative (Apr. 13, 2011).
[55] NHRCT, *supra* note 34, at 15.
[56] Jiraporn Limpananont, *Impact of U.S.-Thailand FTA in Access to Medicines in Thailand*, *in* FREE TRADE AGREEMENTS: IMPACT IN THAILAND, *supra* note 37, at 57.
[57] NHRCT, *supra* note 34, at 15.

protection to drugs and pharmaceutical products and extending patent terms to 20 years. Despite this outcome, the civil society campaigns were successful in ensuring that the amendment permitted compulsory licensing and parallel imports.[58] Additional protections were later implemented that extended patent protection including by giving pipeline protection to drugs patented in foreign countries in 1994, and introducing a 2002 Trade Secret Act that protected test data.[59]

The NHRCT report found that Thailand had been in compliance with TRIPS since 1992, and turned to analyze in some detail the U.S. demands in the FTA regarding intellectual property rights, concluding that these rights would effectively expand market monopolies via the patent regime.[60] The report turned to assess the impact of these expanded monopolies on drug access and expenditure, drawing data from existing scholarship which compared the price of generic and branded drugs in Thailand, and estimated the price increases ensured by from extended patent terms. The first of these studies found that branded antiretroviral drugs in Thailand were two to ten times more expensive than generics, with generic medicines costing 40 to 448 Baht ($1.30-15) versus 252 to 791 Baht ($8.50-26.45) for branded drugs.[61] The study further found that branded drugs cost approximately 1.5 to 4.7 times the daily minimum wage of 170 Baht per day ($5.60).[62]

The intellectual property rights section also explored a study estimating drug costs if patent terms or market monopoly was extended from one to ten years. The study found that a one year patent extension would increase drug costs per item ten-fold, from 4.29 to 43.95 Baht ($0.14-1.46 per item), while a ten year extension would increase drug prices six-fold, from 181.10 to 1,116.16 Baht ($6-37).[63] The study estimated that since around 60 new drugs were registered per year, a one year extension would increase overall drug spending ten-fold, from 257.24 to 2,636.78 million Baht ($8-88 million). A ten year extension would increase spending six-fold, from 33,466.69 to 216,464.53 million Baht ($1.1-7.2 billion).[64] The report

[58] Suwit Wibulpolprasert, *Globalization and Access to Essential Drug: Case Study from Thailand*, http://www.haiweb.org/campaign/novseminar/suwit1.html (last visited Aug. 22, 2012).
[59] In 1994, a Safety Monitoring Programme (SMP) was launched giving pipeline protection to drugs patented in foreign countries during the period from 1986 to 1991. In 2002 the Trade Secret Act was passed, which required any applicant to manufacture, import or export drugs to submit scientific data, and indicated that if the data was considered a trade secret resulting from a discovery or invention, the agency had the duty to supervise and maintain such trade secret from unauthorized disclosure and unfair exploitation for commercial gains. NHRCT, *supra* note 34, at 17.
[60] NHRCT, *supra* note 34, at 21.
[61] All USD figures are according to 2011 currency rates, not 2006.
[62] NHRCT, *supra* note 34, at 21.
[63] *Id.* at 22.
[64] *Id.* at 22-23.

concluded that the impact would be that drug costs would be too expensive or beyond people's purchasing power, and that the estimated increase required (over 100 billion Baht/3.3 billion USD) exceeded the annual health budget and would "undermine any earnest attempt to manage the health system in Thailand, particularly the health insurance scheme."[65]

The report assessed the potential impact of an FTA on Thailand's domestic pharmaceutical industry, consisting of 200 domestic "downstream" factories conducting R&D. The report noted that none of these domestic factories had been granted national patents, including the Government Pharmaceutical Organization [hereinafter GPO] that had developed its own antiretroviral drug. The report pointed out that 98% of national patents were filed first in foreign countries, with most R&D not done in Thailand. Moreover it intimated that not all of these patent applications were legitimate, given two successful court challenges brought by NGOs against the novelty of such applications. The report found that if introduced the FTA would decrease the number of domestic pharmaceutical plants, obstruct R&D of local industry, and allow multinationals with greater R&D capacities and funds to monopolize the Thai market.

Based on the analytical report, the NHRCT sub-committees made a range of recommendations, including delaying the negotiations to study sectors affected by the FTA, and allowing experts to review the treaties instead of leaving it to government alone.[66] The NHRCT's proposals regarding intellectual property were that "intellectual property protection relating to drugs and public health services should not be considered in the bilateral trade negotiations."[67] The report argued that if the demands impacted on health, access to drugs and public health services, they should be rejected since according to the principle of human rights and the Thai Constitution, every person has fundamental rights to good health.[68] It suggested that experiences from Singapore and Chile showed that FTA tend to reinforce market monopolies in pharmaceuticals and increase drug prices and that local drug industries did not have the capacity to compete with transnational drug companies.[69]

Opinions by NHRCT sub-committees were appended to the report, indicating that the report's finding are based on the 1997 Thai Constitution, the International Covenant on Civil and Political Rights [hereinafter ICCPR] and the ICESCR. The addendum excerpted relevant rights from each law, including the Thai Constitution's extensive rights requiring public

[65] *Id.* at 22.
[66] *Id.* at 56.
[67] *Id.* at 58.
[68] *Id.*
[69] *Id.*

participation in policies that could impact health or environment, and the state duty to study and evaluate the impact of any project or activity that may seriously affect the environment prior to its operation.[70] The articles excerpted from key international human rights treaties included rights to self-determination in both the ICCPR and ICESCR (article 1 respectively) and the right to work and enjoy benefits of scientific progress in ICESCR (articles 6.1 and 15).

V. LESSONS FROM THAILAND

It cannot be known whether the Thai government would have taken any account of the report, as shortly thereafter Shinawatra was deposed in a military coup and the FTA negotiations were indefinitely suspended. A final report was never issued.[71] Nonetheless there are several aspects to the NHRCT report and subsequent Thai law and policy that offer guidance regarding the feasibility of implementing an RTHIA, and the actors, institutions and legal frameworks that may facilitate same.

Civil society played a key role in triggering the report, including through formally petitioning the NHRCT. This impact suggests that the tool should not be targeted to policy makers alone, particularly given the political sensitivities associated with trade negotiations and the intellectual property rights arena in particular. The strong influence of civil society in the NHRCT report is also apparent in its findings, which largely reflect the pre-existing positions taken by FTA Watch and other NGOs advocating for the excision of intellectual property rights from FTA. While this outcome certainly illustrates the strength of civil society, the suggestion of bias is also a weakness of the report. A potential bias is intimated in some of the strong language employed in the report. For example, the authors assert that the U.S. demands on intellectual property rights

> clearly reflect the greed on part of pharmaceutical corporations expressed through the strong position taken by the U.S. negotiation team, which tried in every possible ways to gain the most from it. It was an obvious attempt to gain double or overlapping benefits, but still the U.S. agenda was to monopolize the pharmaceutical market and procedures of treatment, being one of the four basic needs for human existence or survival.[72]

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[70] Ratthamnūnhængrāt`ānāčhakrathai [Constitution] §§ 56, 59, 76 & 79 (Thail.).

[71] Although the Commission presented the draft report at a public seminar in January 2007 titled "Free Trade Agreements: Impact on Human rights," along with several UN agencies and 150 human rights experts, policy-makers and NGO leaders. *See* Smith & Lumpur, *supra* note 47.

[72] NHRCT, *supra* note 34, at 18.

As Harrison and Goller suggest, this kind of language suggests reliance "on pre-existing ideological positions rather than robust methodological frameworks," which may weaken the perceived legitimacy, independence or influence of the report unless they are strongly linked to human rights standards and an evidence base.[73]

It is also notable that the report was carried out by the National Human Rights Commission of Thailand, an independent quasi-governmental human rights institution that not only had the authority to investigate human rights violations and propose remedies, but also to summon negotiators and government agencies to provide information about negotiations and advise how they had evaluated human rights impacts in their negotiations. This latter inquiry is a directly normative instruction, articulating to negotiators the necessity of carrying out such assessments. This is an authority that civil society actors implementing an RTHIA could not approximate, suggesting that human rights commissions or analogous quasi-governmental bodies may be the particularly suitable institutions for implementation.

The existence of the NHRCT is itself significant, speaking to the strength of the national human rights culture. This inference is supported by Thailand's strong legal framework on the right to health, both in the National Constitution and subsidiary legislation, and in its ratification of human rights treaties that contain this right. These legal frameworks provided strong enabling factors for the enactment of the report.

The report methodology offers less guidance as a model for an RTHIA given the limitations of its rights components. Although the report is articulated as a human rights impact assessment, it does not adopt a systematic human rights methodology. Instead the intellectual property rights section uses economic analysis of the impact of intellectual property rights on drug prices without explicit reference to human rights rights or impacts. While the authors conclude that this will lead to expensive drugs beyond purchasing power, they do not reach these conclusions through a right to health analysis, but rather presume that a human rights violation will occur because of likely price increases.[74] Absent is an explicit assessment of how these intellectual property rights could have impacted on codified and binding right to health obligations regarding medicines.[75] Similarly, the report's conclusions about violations are not related back to the rights in question or are only done at a very high level of generality.

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[73] James Harrison & Alessa Goller, *Trade and Human Rights: What Does "Impact Assessment" Have to Offer?*, 8(4) HUM. RTS. L. REV. 587, 608 (2008).
[74] *Id.* at 605.
[75] *Id.* at 607-08.

Thus while reference is made to rights at several points in the report, they are not integrated into the analytical components.[76]

The report is particularly uneven in how it relates to the right to health. While several parts refer to the right to health and the more specific right to access medicines, the report's core conclusion that intellectual property demands should be rejected is premised on the rationale that health is a fundamental human right and a right under the Thai constitution.[77] Yet there is no explicit reference in the report itself or the appended human rights texts to article 12 of ICESCR which contains the international right to health which Thailand has ratified.[78] Nor is there any reference to the analytical framework regarding state duties regarding medicines developed by the CESCR, nor strangely to section 52 of the Thai Constitution which entrenches the right to receive standard public health service and indigent right to receive free medical treatment from state public health centres.

While the report had no formal uptake in Thai policy, the exercise and associated civil society advocacy appear to have had discernible social, political and legal impacts. Firstly, the exercise appears to have seeded similar practices, with impact assessments published by domestic academics of the public health impacts of the Thai-U.S. FTA.[79] Civil society also used the report as an educational tool, submitting the report and a corresponding "pocket-book" to broader networks of academics and civil society to enable learning about TRIPS-plus intellectual property rights and their impact on access to medicines, and explaining technical terms like data exclusivity or linkages between the registration process and the patent filing office. In addition, a range of workshops were conducted with civil society to increase understanding about the TRIPS-plus aspects of the FTA, and the impacts shown in the study.[80] For example, NHRCT ran a large public seminar with the United Nations Development Program [hereinafter UNDP] to publicize the report to stakeholders, including the Thai government negotiation team, the public and the mass media.[81] Moreover the report was published in the mass media, and FTA Watch used the report in subsequent events as a tool for scrutinizing and monitoring government's FTA negotiations.[82] Internal participants surmised that the report and its use influenced government efforts to

[76] *Id.* at 605.
[77] NHRCT, *supra* note 34, at 58.
[78] Office of the United Nations High Commissioner for Human Rights, *Status of Ratifications of the Principal International Human Rights Treaties – As of 16 June 2006*, 10 (2006), *available at* http://www2.ohchr.org/english/bodies/docs/RatificationStatus.pdf.
[79] *See generally* Kessomboon et al., *supra* note 28; Chutima Akaleephant et al., *Extension of Market Exclusivity and Its Impact on the Accessibility to Essential Medicines, and Drug Expense in Thailand: Analysis of the Effect of TRIPS-Plus Proposal*, 91(2) HEALTH POL'Y 174 (2009).
[80] Skype interviews with anonymous civil society representative (Apr. 13, 2011 & May 22, 2011).
[81] Skype interview with Buntoon Sathasiroj, *supra* note 35.
[82] *Id.*

improve the transparency of the negotiating process and to involve stakeholders in doing so.[83] The report was also seen to have raised awareness for negotiators in the trade ministry and commerce ministry, and to have it made very difficult for government to argue that prospective FTA had only positive impacts.[84]

The report appears to have influenced subsequent Thai law and policy, with health impact assessment becoming strongly entrenched within law and policy, drawing from the constitutional requirement that environmental impact assessments be conducted before potentially harmful projects are implemented.[85] This constitutional provision motivated the 2007 enactment of a National Health Act to entrench health impact assessment into national policy, which gives individuals and groups the right to request and participate in assessments of health impact resulting from public policy, and creating a National Health Commission to prescribe rules and procedure on health impacts of public policies.[86] In 2010, the Commission issued rules and procedures for health impact assessments of public policies, requiring mandatory health impact assessment for a range of policies, including free trade agreements.[87] This insertion suggests the success of advocacy to ensure that FTA not be conducted without impact assessment on health (if not human rights). Certainly civil society representatives viewed the NHRCT report and civil society action as influential in convincing the post-coup Parliamentary drafting counsel to insert article 190 into the Constitution which prescribes the parliamentary procedure for entering into an international agreement like FTA.[88] Similarly, a government group was influenced into doing their own study on the FTA, with funding from the Department of Trade Negotiation.

It is notable that the National Health Commission defines health impact assessment throughout these rules as "a joint learning process of society." This idea of participatory health impact assessment as a learning process appears to have emerged from a political move towards national health system reform in 2000, which advocated broad civic involvement in health, articulated as the catchy idea of "all for health" to achieve health for all and which defined health systems to encompass a range of factors that influence health.[89] The ideas of health in all policies and of civic participation in reform allied strongly to a highly influential theory

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[83] *Id.*

[84] Skype interview with anonymous civil society representative (May 10, 2011).

[85] Ratthamnūnhængrāt`ānāčhakrathai [Constitution] § 56 (Thail.).

[86] National Health Act, §§ 11 & 25.3 (Thail.).

[87] NAT'L HEALTH COMM. OFFICE THAIL., THAILAND'S RULES AND PROCEDURES FOR THE HEALTH IMPACT ASSESSMENT OF PUBLIC POLICIES (2010).

[88] Skype interview with anonymous civil society representative (May 10, 2011).

[89] Wiput Phoolcharoen et al., *Development of Health Impact Assessment in Thailand: Recent Experiences and Challenges*, 81(6) BULL. WORLD HEALTH ORG. 465, 465 (2003).

articulated by Prawase Wasi, a Thai academic and key participant in health reform process, known as the triangle that moves the mountains. The triangle describes an approach to dealing with large and ostensibly unmovable problems (the "mountains") through a three pronged approach that creates relevant knowledge through research, informs social movement or social learning, and engages political involvement.[90] Wasi argues that knowledge creation through research must interact with social movement to assure social learning, to strengthen the movements and empower the public and ultimately to engage politicians with authority over the use of state resources and law promulgation.[91] This idea is cited across the scholarship and policy documents in this area and by several interviewees, and appears to have been highly influential in the methods used by civil society groups and the policy approaches of the health ministry including in the 2007 and 2008 compulsory licenses.

While we cannot know if the report would have influenced Thai negotiations in the FTA given the coup, the government's use of compulsory licenses for HIV/AIDS, heart disease and cancer drugs was in direct contravention of the kinds of TRIPS-plus intellectual property rights being negotiated in the FTA. The TRIPS-plus versions of compulsory licensing at stake in the Thai-U.S. FTA negotiations would not only have precluded compulsory licensing on non-AIDS drugs, but also would likely not have permitted AIDS in Thailand to be seen as legitimately founding a licence. Certainly the furore which greeted these licenses suggests the accuracy of this reading. Moreover the issuing of these licenses suggests that policy makers, at least in the Ministry of Health, were somewhat in sympathy with civil society advocacy and the sentiments in the report.[92]

In 2007, the government issued compulsory licences on two antiretroviral drugs (Efavirenz, marketed as Stocrin, and Lopinavir+Ritonavir, marketed as Kaletra), and a heart disease drug (Clopidogrel, marketed as Plavix). In 2008, the government issued compulsory licenses on four anti-cancer drugs (Docetexel, marketed as Taxotere, Letrozole marketed as Femara, Erlotinib marketed as Tarceva, and Imatinib, marketed as Glivec). A White Paper issued in 2007 by the Thai Ministry of Public Health and National Health Security Office directly addressed the government rationale for the licenses, which it argued lay in government's mandate to achieve universal access to essential medicine for

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[90] *See generally* Prawase Wasi, *"Triangle that Moves the Mountain" and Health Systems Reform Movement in Thailand*, 4(2) HUM. RESOURCES HEALTH DEV. J. 106 (2000).
[91] *Id.* at 106.
[92] This sentiment is somewhat apparent in VICHAI CHOKEVIVAT, THAI MINISTRY OF PUBLIC HEALTH & THE NATIONAL HEALTH SECURITY OFFICE, FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED DRUGS IN THAILAND: DOCUMENT TO SUPPORT STRENGTHENING OF SOCIAL WISDOM ON THE ISSUE OF DRUG PATENT (2007).

all including antiretroviral therapies for all.[93] Yet the public health insurance schemes could not afford to fulfil this mandate, despite significant increases to the health budget.[94] The White Paper argued that the licenses complied with national and international intellectual property law which did not limit government use of patents to only emergency or extreme urgency situations or only to antiretroviral therapies,[95] and that these were "clear evidence of the government's commitment to put the right to life above the trade interest."[96]

It is notable that the White Paper makes explicit reference to the idea of social learning and the triangle that moves mountains. The document is sub-titled "a document to strengthen social wisdom on drug patents," and calls the licenses themselves a form of social movement aimed at improving access to essential medicines and people's health.[97] It explicitly refers to the triangle that moves the mountain, arguing that "[i]t is the educated and motivated society that will push for and support the political commitment to bring real and sustainable success to any social reform movement."[98] In this light, the Minister argued that the White Paper was not only aimed at answering questions around the compulsory licensing, but was intended to act as "a tool to inform and educate the Thai and Global Society as a whole, on the issue of pharmaceutical patent and the public health."[99]

Despite the Doha Declaration's assertion that countries are free to use TRIPS flexibilities to the full to promote access to medicines and to determine the grounds on which to use compulsory licenses,[100] Thailand's compulsory licenses attracted very broad condemnation from companies, their host governments and corporate allies.[101] The 2007 USTR Special 301

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[93] *Id.* at 1-2.
[94] *Id.* at 2.
[95] *Id.* at 3-4.
[96] *Id.* at 4.
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] Doha Declaration, ¶¶ 4 & 5.b.
[101] Peter Mandelson, EU Trade Commissioner, argued that the government's systematic recourse to compulsory licenses were "an easy excuse for governments not to set up health reimbursement mechanisms or negotiate lower prices with manufacturers," and would "eventually be detrimental to the innovation and the development of new medicines." Letter from Peter Mandelson to ITC (2008), *cited in* Sean Flynn, *Timeline for US-Thailand Compulsory License Dispute* 18-19 (Program on Information Justice and Intellectual Property, 2009). A U.S. based NGO called U.S.A. for Innovation whose executive director also ran public relations campaigns for Abbott and Merck, launched an extensive advertising campaign against the licenses, putting adverts in two Bangkok newspapers, the Wall Street Journal and Washington times which accused Thailand of theft and piracy, of being part of an "axis of IP evil" along with China and India, and of self-serving protection of domestic pharmaceutical industries rather than public health needs. *See* SRIPEN TANTIVESS ET AL., INTRODUCING GOVERNMENT USE OF PATENTS ON ESSENTIAL MEDICINES IN THAILAND, 2006-2007: POLICY ANALYSIS WITH KEY LESSONS LEARNED AND RECOMMENDATIONS

Report elevated Thailand to the priority watch list, a move which precedes formal trade sanctions, arguing that this status related to the government's issuing of compulsory licenses, which the USTR argued was an indication of "a weakening of respect for patents."[102] Thailand has remained on every report since, albeit that it has never been subjected to trade sanctions. Abbott Laboratories, the patent holder on Kaletra, withdrew all of its new products from Thailand, including drugs for HIV, rheumatoid arthritis, kidney disease, heart disease and high blood pressure, and respiratory infections.[103] It also threatened not to register any of its new medicines in Thailand in the future because "Thailand has chosen to break patents on numerous medicines, ignoring the patent system."[104] Even the World Health Organization [hereinafter WHO] noted concern over the compulsory licenses, with Margaret Chan, then the new Director General, urging the Thai government to first negotiate with pharmaceutical companies before issuing compulsory licenses (a step not required in TRIPS for public non-commercial use), and encouraging the Health Ministry to improve its relationship with the drug industry in order to "strike the right balance" in access to medicines.[105] It is notable however that none of these complaints ever amounted to trade sanctions or a complaint lodged with the TRIPS Council. As the Thai Minister of Public Health at the time of the licenses later argued, the disputes were likely intentionally left controversial to discourage low and middle-income countries from using TRIPS flexibilities for public-health purposes.[106]

Given drug access problems in Thailand and other LMIC, the impact of the compulsory license on drug pricing and availability are worth noting. By June 2008, the government had imported generic Efavirenz, Lopinavir and Clopidogrel from three Indian manufacturers (Ranbaxy, Matrix and Cadila), with significant increases in the volume of these drugs being provided through the three major publicly subsidized health benefit plans.[107] Access to these medicines increased significantly, with people taking Efavirenz growing from 5,000 to 20,000 by September 2008, and people taking Lopinavir-Ritonavir growing from under 300 to 3,000.[108] Moreover, prices of all three of these drugs reduced globally,[109] which each

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109 (2008); Robert Weissman, *Ken Adelman's (New) Lies*, HUFFPOST (May 7, 2007, 2:11 PM), http://www.huffingtonpost.com/robert-weissman/ken-adelmans-new-lies_b_47864.html.

[102] OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 27 (2007).

[103] TANTIVESS ET AL., *supra* note 101, at 103.

[104] Thomas Fuller, *Thailand Takes on Drug Industry, and May Be Winning*, N.Y. TIMES, Apr. 11, 2007.

[105] TANTIVESS ET AL., *supra* note 101, at 73.

[106] Mongkol Na Songkhla, *Health before Profits? Learning from Thailand's Experience*, 373 THE LANCET 441, 442 (2009).

[107] TANTIVESS ET AL., *supra* note 101, at 120-24.

[108] Songkhla, *supra* note 106, at 442.

[109] TANTIVESS ET AL., *supra* note 101, at 125.

of the companies holding patents offering significant price reductions even before the compulsory licenses were issued (although generic drugs for some versions remained cheaper than the patented product). [110]

The licenses have therefore contributed significantly to increasing access to affordable drugs in the public sector, serving important health and human rights objectives and illustrating the feasible use of a key policy approach that remains contested irrespective of the gains made at Doha, not just by the USTR, pharmaceutical companies and their allies, but arguably even by the WHO. This continued contestation suggests that global policy and politics around medicines are still significantly imbalanced in favour of intellectual property rights and trading interests as against health.

VI. CONCLUSION

The Thai experience suggests that RTHIA may offer a feasible mechanism for migrating health and human rights concerns in the trade and intellectual property arena. Certainly the feasibility of an RTHIA is facilitated by the broad adoption of health impact assessments globally as well as growing efforts to assure that trade-related intellectual property rights are assessed according to their health impacts. Moreover, the apparent influence of the NHRCT Report on subsequent Thai law and policy appear to suggest that an RTHIA is not simply a technical exercise in information gathering, but a more normative exercise that may advance broader acceptance of access to medicines as a human rights claim. This outcome may ultimately assure greater recognition of the right to health among policy makers and social and even corporate actors, leading to more general compliance with this right in policy and law, and even cultural shifts towards human rights compliance amongst diverse actors in this arena. In this light rights-based advocacy, evidence and strategies (including RTHIA) remain potentially influential mechanisms for advancing state capacity to realize the right to affordable medicines and assure that trade mechanisms do not negatively impact on health.

[110] *Id.* at 119.

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