

**11th Annual International Conference on Politics & International Affairs and
Annual International Forum on Policy and Decision Making**

17-20 June 2013,

Athens, Greece

Amending the TRIPS Agreement: Hegemonic Struggle of Social Forces

With the Doha Ministerial Declaration on the TRIPs Agreement and Public Health adopted in November 2001, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was amended to facilitate trade in generic versions of patented medicines. Based on a neo-Gramscian theoretical framework, this paper examines this change in the key provisions of the TRIPS Agreement, which became more socially responsive to health concerns of developing countries. Using the qualitative instruments of discourse analysis and examining hegemonic struggle of opposing social forces, this paper attributes this outcome to the strategy of *trasformismo* used by market-oriented social forces to legitimize the policies of the WTO and prevent popular political mobilization against the market-driven TRIPS Agreement. It argues that non-governmental organizations (NGOs) such as *Medecins Sans Frontieres* worked as a counter-hegemonic force that effectively campaigned for facilitating the legal access of least developed countries to generic drugs. However, flexibilities introduced by the Doha Declaration can be seen more as a strategy of *trasformismo* used by market-oriented social forces to absorb counter-hegemonic ideas than the counter-hegemonic groups, successful incorporation of the right to protect public health into the TRIPS Agreement.

Keywords: TRIPS, social forces, hegemony, counter-hegemony, *trasformismo*

With the establishment of the World Trade Organization (WTO) in 1994, the mandate of the multilateral trade regime has been expanded to new areas such as services, investment measures, and intellectual property rights. The TRIPS Agreement created a market-based system for the commercial use of technological products, knowledge, ideas, and artistic works by broadening the scope for protection to all fields of technology including food and medicine, extending the terms of protection to 20 years, restricting the scope of compulsory licensing', and requiring domestic intellectual property (IP) enforcement mechanisms. in the field of pharmaceuticals, with stronger IP rights protection, TRIPS created a global IP regime that protect patent-holding pharmaceutical companies from unauthorized use of their invention. The penetration of market norms to the intellectual property regime fuelled political conflicts between a broad set of actors within civil society. For critics, TRIPS symbolized a trade system that created a barrier for the access of affordable essential drugs in developing countries. Particularly, the required reform of patent and health care regimes in line with TRIPS Agreement led to a growing concern over putting commercial interests before health and other social concerns in many developing countries (Wallace and Woodall 2004; May 2002:98-101).

Nevertheless, in November 2001, six years after its entry into force, with the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, the TRIPS Agreement was amended to facilitate trade in generic versions of patented medicines. With the flexibility introduced for the implementation of the TRIPS Agreement, developing countries were given greater policy space to issue compulsory licenses for public health reasons and patent-holding pharmaceutical companies began to make their medicines accessible in least developed countries. What made market-oriented intellectual property rights (IPR) regime introduced by the TRIPS Agreement more inclusive and responsive to social concerns constitutes the puzzle of this paper.

The reasons for that transformation have been located in a range of factors, ranging from the changes in the global distribution of power, to the competition between research and development-based pharmaceutical companies and a rapidly developing generic industries (Roemer-Mahler 2012), and also to the role played by civil society actors such as Health Action International, Medecins Sans Frontieres and Third World Network (t Hoen 2009; Sen and Prakash 2004; Drezner 2007). From a neo-Gramscian perspective, however, this paper aims to illustrate how changes in global intellectual property regime are best explained by looking at the hegemonic struggle of opposing social forces in a changing world economy and global order.

Two opposing social groups are involved in the confrontation over the neoliberal globalization process, with each representing distinctly alternative views towards the global economy. On the one hand, market-oriented transnational social forces favor the elimination of any constraints or obstacles to the liberalization of capital and trade markets. On the other hand, counter-hegemonic groups feel marginalized by increased economic globalization and thus perceive such an elimination of barriers as detrimental to social justice (Butko 2006:86). To demonstrate the hegemonic struggle of these opposing social forces, the paper examined how a coalition of transnational corporations (TNes) embedded in global production and finance networks tried to expand neo-liberal market rules and promoted the idea of creating a market-based system of intellectual property rights under the WTO. At the same time, it examined how those market-oriented social forces were challenged by civil society actors that resisted the TRIPS legal framework by producing counter arguments to de-legitimize the market-oriented intellectual property rights regime.

On one hand, transnational pharmaceutical corporations objected to the use of flexibilities permitted under the TRIPS Agreement such as compulsory licensing and parallel importing; instead claimed that patents were instrumental to protect and encourage innovation and to facilitate further research and development (PhRMA 2003). On the other hand, the opponents pursued a sustained campaign to ensure the primacy of public health over intellectual property rights and demanded access to affordable medicines for all (Hannah 2008: 179). Under the slogan of "another world is possible", the counter-hegemonic groups demanded a reform of the intellectual property rights regime so that the values of democracy, economic justice, and human rights take precedence over market values (Moon 2010).

To resist reform demands, however, market-oriented social forces employed the strategy of *trasformismo*, which is a strategic tool of coopting the counter-hegemonic movement's principles into the hegemonic groups' own rhetoric (Gramsci 1971). At the heart of this concept of *trasformismo* is the assertion that it absorbs potentially counter-hegemonic ideas and makes these ideas consistent with the hegemonic doctrine (Gramsci 1971). With the discourse of 'free and fair' trade and the flexibility introduced for the implementation of the TRIPS Agreement, market-oriented social forces have engaged in *trasformismo* by embracing the language of counter-hegemonic groups and depicting themselves as the champions of global justice (Patterson 2006: 170).

The paper uses the qualitative instruments of discourse analysis and looks into the participation of social forces in the process of making the TRIPS Agreement more socially-responsive or more market-oriented through their agenda-setting activities. The analysis of the role of social forces in the transformation of the trade regime is conducted through tracking the consensus-making processes of opposing social forces by disseminating certain ideas. The TNC strategies were processed to identify whether TNCs disseminated their ideas through building discursive coalitions with other companies, and if they endeavored to educate policy-makers and negotiators. The same research process was applied to analyze the influence of counter-hegemonic groups such as MSF, OXFAM, and Health Action International in raising awareness about the negative social consequences of the TRIPS Agreement. The analysis of these ideational inputs were carried out through an examination of how certain problems were defined and solutions were framed and by interpreting which sets of ideas were dominant in a specific time.

Explaining the Transformation of the TRIPS Agreement as a Function of Hegemonic Struggle of Social Forces

Neo-Gramscian approaches consider international regimes or institutions as intersubjective entities but they emphasize their embeddedness in the material and ideational world. Therefore, questions such as why market-oriented intellectual property rules appeared on the global political agenda at a specific point in time, in the 1980s and why a specific policy alternative appeared on the agenda in the early 2000s will be dealt with more accurately from this perspective. Based upon an intersubjective ontology and historicist epistemology, Neo-Gramscian scholars do not take institutions and social power-relations for granted, but puts them into question by dealing with their origins and how and whether they might be changing (Cox 1981:89). Historical change is understood as a reciprocal relationship between social forces and historical structures.

Historical structures are socially constructed inter-subjective frameworks for action that involve the interaction among ideas, material capabilities, and institutions (Cox 1996b: 149). Based on this interaction, structures that are formed by collective human activity over time, in turn shape the thoughts and actions of agents by imposing pressures and constraints

(Cox 1995:33). These pressures do not, however, determine actions in any direct or mechanical way since it is agents that intersubjectively decide whether to adjust or resist structural constraints. Thus, structure can be thought as both determined by and determining the agency (Bieler 2006:123). Such dialectical or reciprocal relations between structure and agents overcome the understanding of structural change resulting solely from external pressure. Instead of attributing a causal role to external factors, the method of historical structures help to identify which social forces and what particular objectives lie behind change (Bieler 2006: 123; van Apeldoorn 2002:2). It particularly avoids reductionism by putting emphasis on the open-ended struggle among various social forces over the realization of change (Gill 1993).

In line with an emphasis on the interaction between structure and agency, neo-Gramscian approaches focus on social forces as the most important collective actors. These social forces include those that identify their interests with the globalization of production and capital such as the top owners and key executives of transnational corporations (TNCs) and private financial institutions who manage transnational capital; international financial institutions (IFIs) such as the IMF and the World Bank; leading politicians and globalizing bureaucrats inside the state structure, particularly those who work for state agencies that are in close contact with the global economy; media corporations, and organic intellectuals (Cox 1987; Sklair 2001; Robinson 2001; Gill 2003). These transnational social forces that became the bases of power within and across states (Cox 1987:4) favor the logic of market supremacy and act as key actors of shaping the ideological framework of the world order and associated international regimes (Overbeek 2004: 1 18; Bieler and Morton 2001 :212).

Particularly, TNCs are regarded as forces that produce policy formulas and promote them to the states through building coalitions within and across borders with business, government and civil society actors. They contribute to the formation of transnational compromises regarding the requirements of global economy and ultimately generate a dominant global discourse, designed to inform public policy-making throughout the world (Baker 1999:81; Carroll and Carson 2006:53-58; Cox 2006:41). To gain the consent of subordinate actors, their strategies include alliance building through production and dissemination of certain ideas that are presented as serving the needs and interests of societal actors (Cox 1987; Gill 2003).

The neo-Gramscian perspective analyzes the consensus formation process of social forces through the concept of hegemony. Based on Gramsci's work (1971), it can be understood as the dominance of a certain way of life and thought that is diffused throughout society by the ruling groups and classes to pursue their interests in such a way that they are seen by ruled groups and classes as common or general interests (Gramsci, 1971: 160- 1 61, 182; Cox, 1996a:133; Morton, 2007:113). It thus refers to a relation between social forces, in which one group takes a leading role in gaining the active consent of other classes and groups through moral and intellectual leadership (Gramsci, 1971). This process also requires sacrifices from immediate interests, and engagement with other groups in the form of

alliances (Gramsci 1971: 11 9-20; 238-9). Building hegemony is a long-run process that entails strategic planning and intellectual efforts to create consensus among wider society.

The power-based perspectives fail to consider this consensus formation process of social forces. Thus, in their analysis, the process by which certain ideas were diffused, accepted, and adopted by policymakers and various social groups remains largely unexplored. The role of ideas is crucial in the organization of hegemony since they play an important role in shaping political struggles and outcomes. In a hegemonic struggle, several ideas confront each other until one of them tends to prevail; and the prevailing ideas contribute to the establishment of intellectual and moral unity and thus facilitate the dominant group's enforcing hegemony over subordinate ones (Gramsci, 1971:181-182).

Nevertheless, what is crucial in the concept of hegemony is that in any order, hegemony is not a one-and-for-all achievement and being a dynamic process, hegemonic production is never complete (Gramsci, 1971). This open-ended and conflict-ridden nature of hegemony implies that it is a process in which there are always counter-hegemonic forces that resist the dominant system and do not give their consent and the possibility always exists for the formation of social struggles. Different social forces may struggle for hegemony by developing counter-hegemonic policy formulas and engage in a long-run struggle within the civil society, which Gramsci (1971: 110- 111) calls a "war of position".

Since Seattle protests of the WTO, demonstrations by counter-hegemonic forces have become a common feature of intergovernmental meetings, ranging from concerns over environmental degradation, the social justice of economic policies, women rights, human rights, and the use of military force (Rupert, 2005). De Sousa Santos (2005:29) defines the current form of counter-hegemonic groups as the vast set of networks, organizations, and movements that struggle against social exclusion and propose alternative conceptions of world order.

Market-oriented social forces, however, try to pacify and divide counter-hegemonic movements through the concept of *trasformismo*. *Trasformismo* is a policy to legitimize the hegemonic structures of power through cooptation of counter-hegemonic ideas into elite rhetoric (Patterson, 2006:35). It reflects the desire to absorb potentially counter-hegemonic ideas and makes these ideas consistent with the hegemonic doctrine. It is designed to secure public legitimacy and to pacify political opponents by bringing them into political institutions, but preventing these opponents from actually changing policies (Patterson, 2006: 17).

Based upon these insights, it can be argued that the attempt of further deepening the WTO with the TRIPS Agreement reflected an attempt of transnational social forces to lock in new market disciplines on states in the area of intellectual property rights. Nevertheless, the contestation of neoliberal hegemony, institutions and policies by a large set of civil society actors, the so called counter-hegemonic forces called into question the material power and ideas of the hegemonic groups. These counter-hegemonic forces were instrumental in amending the contested articles of the TRIPS Agreement in a way to facilitate trade in generic versions of patented medicines. However, such flexibilities introduced by the Doha Declaration can be seen more as a strategy of *trasformismo* used by the hegemonic political

elites to legitimize the TRIPS Agreement and make it more sustainable by deflecting criticisms over its negative social consequences.

The following section will outline major strategies and agenda-setting activities of TNCs to build consensus for a market-based intellectual property rights regime as of the 1980s.

Transnational Social Forces and the Creation of the Market-Based TRIPS Agreement
Intellectual property rights (IPR) protection was not part of the trade agenda and policy making before the 1970s. This situation changed when a coalition of US-based TNCs representing copyrights, patents, and trademarks interests mobilized in the mid-1970s and conducted a campaign for enhancing international IPR protection (Sell and Prakash 2004). Building a policy network, supporting new academic research, and utilizing the media, they engaged in an encompassing agenda-setting initiative. In their public speeches, contacts with policy-makers and in their media appearances, they highlighted intellectual property as a trade related issue (Sell 2003). In order to establish this new pattern of thinking and to disseminate their case within civil society, they promoted IPR as a major source of wealth, competitiveness, and employment for the United States and other advanced economies (Sell and Prakash 2004).

In neo-Gramscian terms, the hegemonic social forces in the world trade regime were determined to strengthen their domination and their advantages through strong IPR protection. To this end, to mobilize other business executives and government officials in the US and abroad around their objective, CEOs from twelve major US-based TNCs in pharmaceuticals (Bristol Myers, Johnson and Johnson, Merck and Pfizer), chemicals (DuPont and Monsanto), media (CBS), IT (HP and IBM) and other technology intensive industries (GE and General Motors) established the Intellectual Property Coalition (IPC) in March 1986 (Sell 2003; Moon 2010:62). The TNCs aimed at establishing a hegemonic mental framework that gradually changed the intersubjective meanings of trade and protectionism within the core capitalist nations (Altay 2011: 118). Thus, members of the IPC cooperated their industry counterparts in Europe (UNICE) and Japan (Japan Federation of Economic Organizations) to build a transnational private sector consensus for a market-based IPR protection (Sell 2003; Moon 2010).

This transnational coalition lobbied their governments to establish multilateral IPR protection standards in Uruguay Round. Given their financial resources and collective action capability and their expertise on intellectual property, they played a central role in determining the negotiating positions of their respective governments (Sell 2003; Sell and Prakash 2004; t'Hoen 2009). They also shaped the intellectual content of the TRIPS agreement by preparing in 1988 the Basic Framework of GATT Provisions on Intellectual Property that calls minimum standards for copyrights, patents, trademarks; enforcement, and a dispute settlement mechanism (Sell and Prakash 2004). The Basic Framework was presented to the GATT

Secretariat as representing the coordinated views of the US, European and Japanese business communities (Matthews 2002:9).

The new way of thinking concerning intellectual property rights as a trade issue was shared by a larger set of actors in the OECD region by the mid-1980s. Nevertheless, despite the business-government coalition for IPRs in the OECD countries, intergovernmental negotiations on IP during the Uruguay Round went through a highly contested process between developing and developed countries. Since benefits were largely expected to flow to the developed countries that predominantly own technological capacity and IP-rights holders, developing countries reacted against the inclusion of IPRs within the GATT framework. India and Brazil in particular raised serious objections against extending patent protection to inventions related to public health and food (Singh 2006:61-3). To convince developing countries, developed countries argued that providing greater IP protection would result in increased foreign direct investment and facilitate technology transfer (Maskus 1999).

To achieve consensus around their preferences, powerful actors such as the US and EU attempted to coerce weaker states through the use of trade and other sanctions. Through coercive means such as using the US Section 301 trade act" as a tool for unilateral pressure on states, the US tried to get the consent of the opposing states to the TRIPS Agreement (Draho 2003). For instance, after Uruguay Round started, the US Pharmaceutical Research and Manufacturers Association (PhRMA) filed a complaint at United States Trade Representative (USTR) against Brazil in 1987 for not providing pharmaceutical product patents. After Brazil refused to change its laws, the US placed 100% retaliatory tariffs equaling \$39 million on Brazilian exports ((Draho and Braithwaite 2002 cited Moon 2010:65).

The US also revoked \$500 million worth of generalized system of preferences (GSP) for Mexico, after it refused to grant pharmaceutical product patents in a 1987 section 301 case. Upon the complaint of PhRMA on Thailand's insufficient protection to American IP-rights holders, the US revoked GSP preferences and denied duty-free status for \$165 million of Thai imports (Moon 2010: 100). In 1989, the US included India on the Special 301 Priority Watch List, downgraded India to the more serious status of Priority Foreign Country in 1991, and raised tariffs on \$80 million worth of Indian exports (Moon 2010: 129).

The direct association of stronger IP protection with unilateral US trade preferences urged some developing countries to change their behavior in accordance with market-based intellectual property rules. For instance, Thailand adopted key changes in its patent law in 1992. It granted patents for food and medicines, extended patent terms from 15 to 20 years, and brought stricter conditions for compulsory licenses (Moon 2010). Other developing countries also reversed their objections to the TRIPS in the Uruguay Round after being suppressed by developed countries through a combination of concessions on textiles and agriculture and threats of trade sanctions (Sell and Prakash 2004).

When TRIPS agreement was finally incorporated to the WTO Treaty in 1994, Jacques Gorlin, the advisor to the IPC expressed his satisfaction with the agreement by stating that IPC got 95% of what it wanted (Patterson, 2006). In a speech to the US Council for International Business, Emeritus Edmund I. Pratt, the Chairman of Pfizer similarly said that,

"The current GA TT victory, which established provisions for intellectual property protection, resulted in part from the hard-fought efforts of the US government and US business, including Pfizer, over the past three decades. We've been in from the beginning, taking a leadership role" (Pratt 1995 cited Patterson 2006: 119).

Although the market-driven TRIPS Agreement served the interests of hegemonic social forces, the protection and enforcement of intellectual property rights in the field of pharmaceuticals had negative social effects in terms of access to medicines by developing and least developed countries. Particularly, the proliferation of HIV/AIDS infections and unaffordable prices for patented HIV/AIDS drugs led to a growing concern over putting commercial interests before health and other social concerns. The penetration of market norms to the intellectual property regime fuelled counter-hegemonic struggle of a broad set of actors within civil society.

Counter-Hegemonic Struggle of Social Forces

Following the entry into force of the TRIPS Agreement in 1995, the US, EU and their pharmaceutical industries began to put pressure on developing countries for respecting intellectual property rights (Sell and Prakash 2004; Moon 2010). The South African government that had the world's highest number of people living with HIV, allowed compulsory licenses and parallel imports by passing the Medicines and Related Substances Control Amendment Act in 1997 in order to improve access to affordable HIV/AIDS drugs. Despite the presence of flexibilities in the TRIPS Agreement to allow governments to take measures to protect public health, the South African government faced a strong opposition from transnational pharmaceutical companies, the US government and the EU. They exerted diplomatic, economic and legal pressure on South Africa to modify the provisions of the Act.

By arguing that the Amendment Act violated the TRIPS Agreement regarding the issue of compulsory licensing and parallel imports, the Pharmaceutical Manufacturers' Association of South Africa and several international pharmaceutical companies launched a case against the South African government in February 1998 (Hannah 2008:156). Although this act did not pose an immediate threat to their sales in Africa, pharmaceutical companies challenged the South African Act due to its potential to serve as a model for other countries that would follow the same path to reduce drug prices by granting compulsory licensing.

In line with corporate interests, the US agencies, including the USTR, Department of Commerce, the Office of the Vice President raised the issue of repealing the Act with South

African officials (Hannah 2008). By invoking the Section 301 of the Trade Act, the USTR placed South Africa on its Watch List, and threatened trade sanctions if South Africa failed to repeal the Amendment Act. With the letter sent by the Vice- President of the European Commission to the Vice-President of South Africa, the European Union also challenged South Africa's Amendment Act by arguing that its implementation would negatively affect the interest of the European pharmaceutical industry ('t Hoen 2002).

Pharmaceutical companies and developed countries showed a similar reaction when Brazil enacted the Industrial Property Law in 1996. The law required patent holders to produce their product in Brazil within three years of patenting and allowed for compulsory licensing if a patent was not worked in Brazil for three consecutive years. It also allowed for parallel importing if patent holders produced their product elsewhere. Pharmaceutical company, Merck, which was a key supplier of antiretroviral AIDS drugs in Brazil claimed that importing its drugs to Brazil should have the same effect of working the patent, thus urged that the use of compulsory licensing should not be allowed. Pharmaceutical Research and Manufacturers of America asked the USTR to challenge Brazil's law at the WTO (Leon 2010:59). In 2000, the US filed a case against Brazil by arguing that art.68 of the Law, with regard to compulsory licensing violated the TRIPS Agreement and discriminated against US patent holders (WTO 2000).

The aggressive stance taken by the pharmaceutical sector, the US and the EU against South Africa and Brazil coupled with the raging AIDS crisis in Africa contributed to the mobilization of a coalition of AIDS activists, public health advocates and developing countries into action. Leading NGOs, including Medecins Sans Frontieres (MSF), Health Action International (HAi), OXFAM, ACT UP, and the Consumer Project on Technology (CPTECH) launched an influential campaign aimed at ensuring that the TRIPS Agreement did not interfere with poor peoples' access to essential medicines (Hannah 2008). The South African-based NGO Treatment Action Campaign (TAC) founded in December 1998 managed to mobilize thousands of activists in defense of the South African Medicines Act (Moon 2010:112). In early 1999, the Global Access Project Health (GAP), a US-based NGO, joined in the campaigning efforts for global access to medicines and to oppose the policies advocated by pharmaceutical companies and the US government (Moon 2010).

Although industrialized countries and pharmaceutical sector tried to frame IP standards as an economic and trade issue, these civil society groups presented it as a health and human rights issue (Forman 2007). Establishing a link between TRIPS and the AIDS crisis, they argued that strict patent protection increases drug prices which prevent the access of poor people in developing countries to these drugs. For them, the market-oriented implementation of TRIPS would affect local manufacturing capacity of developing countries negatively (Hannah 2008:158). They also provided research that effectively undermined pharmaceutical TNCs' argument that high prices for medicines will result in greater R&D for disease treatments.

In 1999, international civil society organizations increased the intensity of their opposition to TRIPS Agreement and advocated the use of compulsory licensing in developing

countries. The NGO-led Access Campaign increased awareness of the potential impact of IPR on public health. To increase understanding among developing country government officials of the flexibilities available in TRIPS such as compulsory licensing, MSF, CPTech, and Health Action International organized the Conference on Increasing Access to Essential Drugs in a Globalised Economy in March 1999. The Amsterdam Declaration issued at this conference highlighted that TRIPS would be interpreted and applied in a manner sensitive to public health (Moon 2010:140).

In its Briefing Paper, Oxfam (2001 :4) pointed out that pharmaceutical companies face a major reputation risk if they do not promote access to life-saving drugs in the developing world. Oxfam (2001: 17) particularly praised Brazil for its efforts in reducing drug prices by relying on locally manufactured generics and imported drugs in order to fight HIV/AIDS. On 12 February 2001, Oxfam joined Medecins sans Frontieres, Act-Up and other NGOs in the global access campaign to increase the pressure on pharmaceutical companies to reduce their prices of AIDS-drugs in developing countries (Fraundorfer 2012).

By 1999-2000, networks between actors, ranging from UN bodies, developing country governments such as Thailand, South Africa, and Brazil, and civil society group began to emerge. These actors put forward normative claims that IP rules should not undermine social concerns such as public health, development, and human rights. UNDP Human Development Reports (1999, 2000, 2001) carried sections on TRIPS and its potential negative effects on developing countries. On the eve of the Seattle Ministerial in 1999, the UN Committee on Economic, Social and Cultural Rights issued a statement to the WTO highlighting its concerns regarding the negative consequences of TRIPS particularly on food security, bio-safety, and access to health care (Moon 2010:138).

The UN Commission on Human Rights Resolution 2001133, "Access to medication in the context of pandemics such as HIV/AIDS" adopted on 23 April 2001, and the UN Sub-Commission on Human Rights Resolution 200017, "Intellectual Property Rights and Human Rights", adopted on 14 June 2001 expressed concern regarding restrictions on access to patented medicines (Fraundorfer 2012). In a report issued on 27 June 2001, the UN Commission on Human Rights emphasized the primacy of human rights over trade and intellectual property, and supported developing countries' use of TRIPS flexibilities to improve access to essential medicines as a human right obligation (Forman, 2007). Moreover, addressing the fact that less than four percent of those in need of AIDS treatment had access to lifesaving drugs in 2001, WHO (2002) also strengthened the access to medicines as a human right issue. Adopting the '3x5' program, WHO undertook to provide three million people in developing countries with antiretroviral treatment by 2005.

Counter-hegemonic groups promoted the reports issued by these UN bodies and attempted to problematize market-oriented IP rules by using the political legitimacy of the UN. The increasing global awareness on the access to medicines as a human right issue brought negative publicity on the drug companies and put a lot of pressure on American and European governments to consider their moral obligations. Faced with the strong pressure of counter-

hegemonic groups, transnational networks of state elites and corporate interests adopted a policy of *trasformismo* by absorbing the language and demands of the protesters into their rhetoric. Many of the policy demands of the counter-hegemonic groups such as fair trade, global justice, labor and human rights, enhanced transparency and democracy within international organization, and sustainable development were embedded in press releases and the political rhetoric of the market-oriented social forces (Patterson 2006).

For instance, the WTO began to depict itself as an institution embracing sustainable development, engaging with NGOs, and promoting the interest of the poorest countries through the Doha Development Round. In the lead up to the Doha Ministerial Conference, Michael Moore (2001), the then Director General of the WTO, declared the Doha Round to be solely concerned with the needs of the developing world. He emphasized that a strong predictable and rule-based multilateral trading system would be in the interest of all countries, particularly developing countries (Patterson 2006).

Declaring that the WTO had to embrace environmental concerns, public inclusiveness and transparency in order to remain legitimate, the US also embarked on a significant policy shift on IP and medicines. On 1 December 1999, World Aids Day, Bill Clinton announced the US commitment to make sure that US intellectual property policy is flexible enough to respond to legitimate public health crises (Moon 2010:142). In May 2000, Clinton formalized the policy shift he had announced in Seattle by issuing the Executive Order 13155. Accordingly, the US undertook not to seek the revision of any intellectual property law or policy of a beneficiary if it promotes access to AIDS drugs and provides adequate intellectual property protection consistent with TRIPS (Moon 2010: 142-3).

EU policymakers responded positively to demands by NGOs for improved transparency and public accountability and opportunities for participation in the external trade policymaking process. A mechanism was introduced to engage in Civil Society Dialogues and informal meetings with NGOs. By gaining a formal voice in policymaking, NGOs had the opportunity to disseminate information and generate public awareness about the links between stringent IPR enforcement and access to medicines (Hannah 2008). Moreover, with an emphasis on the pursuit of economic growth, employment and poverty reduction, the European Commission acknowledged that the Doha Development Agenda not only would improve conditions for worldwide trade; it would also generate the most benefits for the development of developing countries (Patterson 2006:212).

As counter-hegemonic groups began to frame the IP regime as a social and public health issue, the pharmaceutical TNCs began to explore measures to make AIDS drugs more accessible in less developed countries (Moon 2010:98). TNCs like Merck announced a \$100 million AIDS initiative in Botswana in July 2000. Boehringer announced a five-year donation of nevirapine to prevent mother-to-child transmission of AIDS (Moon 2010). In March 2000, ACT-UP, Health GAP, and MSF launched a campaign to push Pfizer to reduce the price of fluconazole or issue voluntary licenses to permit generic importation in developing countries. Within a month, Pfizer announced that it would donate fluconazole to South Africa (Moon

2010:145). Moreover, pharmaceutical TNCs withdrew their lawsuit against South Africa in March 2001. The US government also announced in July 2001 that it would withdraw its complaint against Brazil (SeII 2003: 1 58).

Such strategy of *trasformismo* adopted to mitigate the counter-hegemonic struggle of civil society actors was instrumental in the renegotiation of the contested articles of the TRIPS agreement and the adoption of new concessions that would facilitate access to pharmaceuticals in lower income countries through the Doha Ministerial Conference on TRIPS Agreement and Public Health.

The Strategy of *Trasformismo* and a Socially Responsive TRIP S Agreement

In April 2001, on behalf of the African Group, Zimbabwe asked the WTO TRIPS Council to hold a special session on intellectual property and access to medicines. In the session held in June 2001, Brazil submitted a document stressing the necessity of prioritizing human rights and public health rather than the protection of patent rights (Fraundorfer 2012).iii No resolution was reached at the June meeting and members met again in July and September to continue negotiations. Developing countries insisted for broadening the concept of public health beyond AIDS drugs alone, clarifying the right to use TRIPS flexibilities such as compulsory licensing without threat from industrialized countries.

In the run-up to the Doha Ministerial Conference in 2001, TNCs in developed world continued to pressure their respective governments in terms of further strengthening the rules in international trade in such areas as competition, investment, trade facilitation, and government procurement, the so-called Singapore issues (Deutsch 2001:35-36). TNCs strategically argued that the implementation of stronger rules in these areas would fasten the transnational economic activities, and that, in turn, would directly contribute to the well being of economies of developed and developing countries (Boyd 2002: 97-100). However, developing countries and civil society actors strongly opposed to negotiate the Singapore issues without solving the existing problems in the world trade system.

Developed countries understood that progress in the context of a new round of multilateral trade negotiations could not proceed until the negative effects of TRIPS Agreement were addressed. NGOs' active interest and involvement in the WTO agenda pushed negotiating governments and business groups to adjust their strategies by taking into account NGO inputs, reactions, and actions (Altay 2011 :306). After intense negotiations, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health on 14 November 2001.

The Declaration (WTO 2001 :Para.4) emphasized that the TRIPS Agreement should not prevent WTO Members from taking measures to protect public health and to promote access

to medicines for all. Declaration clarified that all WTO member states have the right to grant compulsory licenses under any conditions they deem appropriate (WTO 2001:Para.5). Members also had the right to determine what constitutes a national emergency or other circumstances of extreme urgency, including those relating to AIDS, tuberculosis, malaria, and other epidemics (WTO 2001:Para.5). The Declaration also extended the deadline for LDC members to enforce pharmaceutical related patents from 2006 to 2016 (WTO 2001 :Para. 7). Moreover, in August 2003, the WTO General Council released a temporary solution, which would enable countries with limited or no manufacturing capacity to import generic drugs from other countries in case of a national emergency. With the annex introduced to the Protocol Amending the TRIPS Agreement on 6 December 2005, the General Council agreed to make this change permanent (WTO 2005).

The Doha Declaration's emphasis on the "right to protect public health" and "access to medicines for all" reflects the extent to which counter-hegemonic groups, discourses were embedded within the Declaration. These measures can be understood as part of a wider effort of hegemonic social forces to legitimize the TRIPS Agreement and make it more sustainable by deflecting criticisms over its negative social consequences. Rather than marking a fundamental reorientation of the international IPR regime, the Doha Declaration was a political compromise designed to highlight already existing flexibilities in the system and to accelerate ongoing WTO negotiations in other areas.

After the Declaration, it became clear that transnational social forces' position on TRIPS and Access to Medicines had not undergone a major substantive or normative change. Reviewing the lobbying record of the transnational pharmaceutical companies and their influence over US government policy, OXFAM (2002a:2) indicates that the number of complaints against developing countries relating to patents and medicines made by the pharmaceutical companies to the US government has not fallen; nor has the number of complaints which the US government responded to. In its complaint to the USTR in May 2002, the Pharmaceutical Research and Manufacturers of America cited 41 countries for insufficient patent protection for medicines. Many of these countries were generic-producing countries, such as India, Brazil, Argentina, and Egypt, but also other countries with limited capacity such as Vietnam and Bolivia (Oxfam 2002a:7). The US government included 66 per cent of the countries recommended by PhRMA in its 2002 Special 301 report.

Discontent with the level of protection pharmaceutical patents would have by the TRIPS Agreement, developed countries pushed for concessions on IP through bilateral and regional free trade agreements (FTAs). The United States has tried to impose more stringent intellectual property rights known as TRIPS-Plus provisions in FTAs negotiated with countries as diverse as Vietnam, Jordan, Singapore, Chile, Morocco, Australia, El Salvador, Guatemala, Honduras, Nicaragua, Costa Rica, the Dominican Republic, Columbia, Ecuador, Peru, Thailand, Panama, Oman, Republic of Korea, and the United Arab Emirates (Sell 2011:452; Baird 2013). Provisions, including rigid data exclusivity policies, limitations on

compulsory licensing and parallel importation, and extensions for patent terms attached to FTAs (Sell 2011 :453) suggest that the promises and assurances made by the Doha Declaration would be baseless in practice.

US FTAs with Morocco and Singapore for instance require each country to grant patent holders the right to block parallel imports (Ho 2007). The US-Australia FTA prohibits parallel importation where the patent holder has indicated that a product is solely meant for sale within a specified country (Baird 2013). In the FTAs it concluded with Panama, Peru, Morocco, and Chile, the US requires the same level of protection foreseen in its own patent law for the data exclusivity (Baird 2013). The TRIPS-Plus data exclusivity provisions in US FTAs effectively empower patent holders to extend monopolistic control of pharmaceuticals by obstructing generic competition as they require generic pharmaceutical producers to generate their own clinical trial test data, rather than rely on safety and efficacy findings of the patent holders in the generic drug approval process (Sell 2011).

Moreover, TRIPS-Plus provisions embedded in US FTAs with Australia, Singapore and Vietnam require that compulsory licensing can only be granted in emergency situations, as an anti-trust remedy, or for public noncommercial use (Baird 2013). FTAs also permit challenges to compulsory licenses on the grounds that a license was not warranted under the specific circumstances and compulsory licenses require reasonable and entire remuneration for patent owners as opposed to adequate remuneration required by the TRIPS Agreement (Roffe and Spennemann 2006).

In addition to pushing for TRIPS-plus provisions in FTAs, the US encouraged developing and least-developed countries for undertaking political, economic and legal reforms, including intellectual property rights through its aid and trade privileges policy. In 2002, in exchange for duty-free and quota-free access of their products to the US market, Kenya and Uganda introduced and amended their intellectual property law to restrict parallel imports and compulsory licensing (Oxfam 2002b).

Developed countries and multinational pharmaceutical companies also reacted against developing countries' TRIPS-compliant attempt to issue compulsory licenses. For instance, when in late 2006 and early 2007, Thailand issued compulsory licenses for two antiretroviral drugs used in the HIV/AIDS treatment, and one for a drug used to treat cardiovascular diseases, the Thai government received sharp criticism for issuing these compulsory licenses (Reichman and Abbott 2007:956). The Pharmaceutical Research and Manufacturers' Association (PhRMA), which represented multinational firms in Thailand, criticized the government for not having consulted sufficiently with the patent holders. The pharmaceutical industry accused Thailand of violating the spirit of the WTO by arguing that compulsory

licenses should be used for national emergencies like AIDS or other epidemic infectious diseases not for chronic ones such as cancer or cardiovascular diseases (Fuller 2007). Upon Thailand's issuance of a compulsory license for antiretroviral drug, Kaletra, the US drug company, Abbott, retaliated against the Thai government by withdrawing the supply of seven medicines from the Thai Market (Moon 2010:225).

By accusing Thailand of weakening respect for patents, the USTR elevated Thailand from "Watch List" to "Priority Watch List" in its 2007 Special Report. The European Commission also publicly questioned the use of compulsory licenses by the Thai government. The Trade Commissioner, Peter Mandelson, sent a letter to the Thai government indicating that, "Neither the TRIPS Agreement nor the Doha Declaration appear to justify a systemic policy of applying compulsory licenses wherever medicines exceed certain prices (Moon 2010:228). For Mandelson, "other means should be explored to increase access to essential medicines among the Thai people before resorting to such exceptional measures" (Hannah 2008:224).

Despite the Doha Declaration's explicit recognition that countries had the freedom to determine the grounds for compulsory licensing, these reactions illustrated the ongoing hegemonic struggle against implementing IP laws in a manner sensitive to public health. The outcome of this struggle will determine whether the TRIPS Agreement will become more flexible or more market-oriented in the future.

Conclusion

The paper has examined why and how TRIPS Agreement was amended to facilitate trade in generic versions of patented medicines. Rather than attributing this outcome to the states' relative position in the international system, this paper has addressed the intellectual and moral leadership of opposing social forces embedded within a broader historical structure. From a neo-Gramscian framework, it has demonstrated that changes in global intellectual property regime are best explained by looking at the hegemonic struggle of opposing social forces over the nature of global IP regime. It analyzed how those market-driven social forces have expanded neo-liberal market rules and practices in global IP regime through the TRIPS Agreement. It also examined how those fractions embedded in global production and finance networks were challenged by counter-hegemonic groups that demanded a new global IP regime responsive to democratic norms and social justice.

The paper has argued that TRIPS Agreement created a barrier for the access of affordable essential drugs in developing and least developed countries. In the early 2000s, however, a

powerful shift occurred in the policies of developed countries and pharmaceutical TNCs in favor of more flexible IP rules. The role of counter-hegemonic forces in pursuing access to medicines campaign was instrumental in this change in the attitude of market-oriented social forces.

Counter-hegemonic forces comprised of a network of transnational NGOs such as MSF, Health Action International, Oxfam, and CP Tech that forced the TRIPS Agreement onto the international trade agenda for revision by emphasizing the trade-off between patent protection for pharmaceuticals and high drug prices. Acting as moral agents capable of setting the trade agenda, counter-hegemonic forces managed to restrict the room for maneuver for the transnational corporations (TNCs) in pursuing corporate interests through trade policies. They put pressure on pharmaceutical TNCs to make their medicines broadly available in the developing world whether through donations, price reductions, voluntary licenses or declarations they would not enforce their patents in certain countries (Moon 2010: 71). Supporting developing countries' issuing of compulsory licenses they also influenced state preferences in the interpretation of IP rules.

Due to the emergence of NGOs engaged in a hegemonic struggle to establish a new global IP regime responsive to democratic norms and social justice, hegemonic social forces attempted to co-opt and absorb forces of civil society who resisted or rejected the main tenets of the TRIPS Agreement. They engaged in a strategy of *transformismo* and attempted to absorb opposing groups by creating interactive platforms for consultation with civil society organizations working on a range of issues including public health. In an effort to reproduce and legitimize the market-oriented IP regime, they also adjusted their strategies by taking into account NGO inputs, reactions, and actions. Counter-hegemonic groups' emphasis on the "right to protect public health", "access to medicines for all" and "ensuring the implementation of TRIPS flexibilities" have been embedded within the Doha Declaration on TRIPS Agreement and Public Health.

The Doha Declaration has enabled WTO member states to implement IP laws in a manner sensitive to public health and development goals. States could issue compulsory licenses as a useful tool to reduce drug prices and to legitimize generic production. However, pharmaceutical companies and developed countries like the US and the EU attempted to prevent countries from doing so either through the discourse of a positive relation between strong IP protection and economic growth, foreign investment, and innovation or through coercive bilateral mechanisms. TRIPS flexibilities have been eroded by the widespread use of TRIPS-plus provisions in US negotiated bilateral trade deals, aid and trade privileges programs. These provisions would eliminate many of the TRIPS flexibilities that the Doha Declaration sought to protect.

By investigating why and how particular social forces promoted or challenged the adoption of specific policy choices such as more stringent IP protection, the paper has addressed the issue of the role of agency, ideas, and discourse in regime transformation. It has emphasized that ideas used to legitimize particular policies and discourse that helps to transmit ideas and create an opening to policy change serve as a necessary condition in the organization of hegemony. It highlighted that opposing social forces attempted to achieve their policy objectives by altering actors' perceptions of the policy problem and by influencing their preferences through certain discourses. Discursively, both sides attempted to re-frame IPR rules: Those seeking tighter IPR rules attempted to reframe IP enforcement as an economic and trade-related issue and promoted the idea that strong intellectual property rights protection provided greater economic prosperity for all. Those seeking more flexible IP rules attempted to re-frame IP rights as an issue of human rights. The transformation of the global IPR regime has thus been a dynamic and evolving outcome of a contested political economy rather than a smooth one.

This finding of the paper contributes to the debate on the resistance to neoliberal hegemony. The existence of social forces, which may support and legitimize or equally challenge existing power relations, lead to an understanding of regime transformation as a politically open and contested process. Although hegemony ensures the prevailing power relations and hardens the emergence of challenging alternatives, there is always the possibility of the emergence of counter-hegemonic initiatives through a concrete program of action. The paper has shown that there has been a resistance movement against market-oriented TRIPS Agreement coming from civil society organizations. However, the paper has also shown that advocates of more stringent IPR rules attempted to counterbalance the efforts of those that asked for more flexible rules. The global IP regime is likely to remain highly contested with the economic and social stakes rising for both IPR rights-holders and end-users.

Notes

i Suspending patent rights without the permission of the patent holder is called a compulsory license. Article 31 of the TRIPS Agreement allows member states the flexibility to disregard the commitment to protect a patent right and issue compulsory license when the patent constitutes a significant barrier in responding to a national emergency. The Doha Declaration clarified the circumstances under which compulsory licenses could be invoked and specified that HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national

emergency.

ii Section 301 of the US Trade Act adopted in 1974 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, or discriminatory, and that burdens or restricts US commerce. Section 301 cases can be self-initiated by the United States Trade Representative (USTR) or as the result of a petition filed by a firm or industry group.

iii This document on TRIPS and Public Health (IP/C/W/296) had been supported by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (Fraundorfer 2012).

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