



**ACKNOWLEDGING THE FLEXIBILITIES OF THE  
TRIPS AGREEMENT: ENSURING THE RIGHT TO  
ACCESS TO MEDICINES OR A STRATEGY OF PASSIVE  
REVOLUTION?**

**TİCARETLE BAĞLANTILI FİKRİ MÜLKİYET  
ANLAŞMASI ESNEKLİKLERİNİN TEYİT EDİLMESİ:  
İLAÇLARA ERİŞİM HAKKININ GARANTİ ALTINA  
ALINMASI MI, PASİF DEVRİM STRATEJİSİ Mİ?**

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**ABSTRACT**

**The Doha Ministerial Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health adopted in November 2001 clarified the right to use the TRIPS flexibilities to promote public health. Examining the hegemonic struggle of opposing social forces from a neo-Gramscian perspective, the paper attributes this outcome to the strategy of trasformismo used by market-oriented social forces to legitimize the policies of the World Trade Organization (WTO) and prevent resistance against the market-driven TRIPS Agreement. It argues that although non-governmental organizations (NGOs) such as Medecins Sans Frontieres, Third World Network, and Oxfam worked as a counter-hegemonic force to ensure the access of least developed countries to generic versions of patented drugs, flexibilities confirmed by the Doha Declaration can be seen more as a strategy of trasformismo to absorb counter-hegemonic ideas than the counter-hegemonic groups'**

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\* Makale Geliş Tarihi: 01.12.2017  
Makale Kabul Tarihi: 08.03.2018

successful incorporation of the right to ensure public health into the TRIPS Agreement.

**Keywords:** TRIPS, Hegemony, Counter-Hegemony, Passive Revolution, Trasformismo.

## ÖZ

Kasım 2001 yılında kabul edilen Ticaretle Bağlantılı Fikri Mülkiyet Anlaşması (TRIPS) ve Halk Sağlığı Konusundaki Doha Deklarasyonu, TRIPS esnekliklerinin kamu sağlığının garanti altına alınması amacıyla kullanılması hakkını teyit etmiştir. Karşıt sosyal gruplar arasındaki hegemonya mücadelesini Neo-Gramşiyen perspektiften inceleyen bu çalışma, söz konusu değişikliği, piyasa odaklı toplumsal güçlerin Dünya Ticaret Örgütü (DTÖ) politikalarını meşrulaştırmak ve TRIPS Anlaşması'na karşı direnişi önlemek amacıyla kullandığı trasformismo stratejisi ile açıklamaktadır. Sınır Tanımayan Doktorlar, Üçüncü Dünya Ağı ve Oxfam gibi sivil toplum kuruluşları (STK), az gelişmiş ülkelerin jenerik ilaçlara yasal erişimlerini kolaylaştırmak için hegemonya karşıtı bir mücadele sürdürmüştür. Ancak, çalışma, Doha Deklarasyonu ile getirilen esnekliklerin, hegemonya karşıtı grupların ilaçlara erişim hakkını TRIPS Anlaşmasına dahil ettirmesinden çok, piyasa odaklı sosyal güçlerin hegemonya karşıtı fikirleri absorbe etmek için kullandıkları bir trasformismo stratejisinin bir sonucu olduğunu ileri sürmüştür.

**Anahtar Kelimeler:** TRIPS, Hegemonya, Karşı-Hegemonya, Pasif Devrim, Trasformismo.

## INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) broadened the scope for protection to all fields of technology including food and medicine. In the field of pharmaceuticals, with stronger intellectual property rights protection, TRIPS created a global intellectual property regime that protects patent-holding pharmaceutical companies from unauthorized use of their invention. The penetration of market norms to the intellectual property regime began to be criticized by various actors within civil society. Particularly, the required reform of patent and health care regimes in line with TRIPS

Agreement led to a growing concern over privileging corporate interests at the expense of health and other social concerns in many developing countries (May, 2002: 98-101). For critics, TRIPS symbolized a trade system that prevented least developed countries to have access to affordable life-saving drugs. Nevertheless, in November 2001, six years after its entry into force, the Doha Ministerial Declaration on the TRIPs Agreement and Public Health acknowledged existing TRIPS flexibilities that facilitate trade in generic versions of patented medicines in public emergencies. With the flexibilities confirmed, developing countries were given greater policy space to issue compulsory licenses for public health reasons and patent-holding pharmaceutical companies began to sell their products in reasonable prices to least developed countries.

What made market-oriented intellectual property rights (IPRs) introduced by the TRIPS Agreement more inclusive and responsive to social concerns constitutes the research question of this paper. This question has been explained through factors ranging from the changes in the global distribution of power, to the competition between research and development-based pharmaceutical companies and rapidly developing generic industries (Roemer-Mahler, 2013), and also to the successful role played by civil society actors such as Oxfam International, Medecins Sans Frontieres, Health Action International, and Third World Network ('t Hoen, 2009; Sell and Prakash, 2004; Drezner, 2007). Based on the premises of the neo-Gramscian approach, however, the paper aims to demonstrate how the confirmation of the existing TRIPS flexibilities are best explained by scrutinizing the hegemonic struggle of opposing social forces in a changing world economy and global order.

Analysing the data from primary sources, such as reports, bulletins, and press releases produced both by the pro-TRIPS and anti-TRIPS groups, the paper traced the processes in which opposing social forces struggled to make the TRIPS Agreement more socially responsive or more market-oriented through their agenda-setting activities by disseminating certain ideas. Transnational pharmaceutical corporations objected to the use of flexibilities foreseen in the TRIPS Agreement, including compulsory licensing and parallel importing; instead emphasized the crucial role played by patents in protecting and encouraging further research and innovation (PhRMA, 2003). To delegitimize this hegemonic discourse that dominated the intellectual property rights regime since the 1980s, the opponents pursued a sustained campaign to ensure the primacy of public health over intellectual property rights and demanded access to medicines for all at reasonable prices (Hannah, 2008: 179). Resistant groups, including MSF, OXFAM, and Health Action International, tried to raise awareness about the negative effects of the TRIPS Agreement on public health and sustainable development. Under the slogan of 'another world is possible', the counter-hegemonic groups demanded a reform of the intellectual property

rights regime in line with the values of human rights and social and economic justice rather than market values (Moon, 2010).

When the counter-hegemonic struggle of the NGOs destabilized pro-patent and anti-generics hegemonic discourses, market-oriented social forces led by transnational pharmaceutical corporations attempted to resist NGOs by employing 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). The key aspect of the concept of the *trasformismo* is that it absorbs potential contentious ideas and adjusts them in accordance with the hegemonic ideology (Gramsci, 1971). Market-oriented social forces engaged in *trasformismo* by embracing the language of counter-hegemonic groups. They accordingly emphasized free and fair trade, expressed their commitment to respect the flexibilities of the TRIPS Agreement, and depicted themselves as responding to the right to live concerns of resistance groups (Patterson, 2006: 170). However, they indeed kept their market-oriented position on intellectual property rights and by relying on bilateral and regional free-trade agreements on TRIPS known as TRIPS-Plus they sought to undermine the Doha Declaration's acknowledgment of the right to use TRIPS flexibilities.

The paper is composed of four parts. The first part deals with major Gramscian concepts, including hegemony, counter-hegemony, passive revolution, and *trasformismo*, which were successfully elaborated by neo-Gramscian scholars to explain the current world economic order. The second part examines how a coalition of transnational corporations (TNCs) 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 regime under the WTO. The third part highlights how those market-oriented social forces were challenged by civil society actors that resisted the TRIPS Agreement by generating counter arguments to delegitimize the market-oriented intellectual property rights regime. The fourth part analyzes how market-oriented groups attempted to pacify and neutralize counter-hegemonic groups by pursuing the strategy of *trasformismo*.

## 1. THE MAIN PREMISES OF THE NEO-GRAMSCIAN APPROACH

Examining the origin of the world order and social power relations embedded within that order, the Neo-Gramscian perspective examines the emergence of institutions and regimes as part of the material and ideational world (Cox, 1981: 89). Based on the interaction between structure and agency, it focuses on social forces as crucial actors that shape the world economic order and the associated international regimes (Overbeek, 2004: 118; Bieler and Morton, 2001: 212; Cox, 1987: 4). It examines how a network of market-

oriented social forces, particularly TNCs, the International Monetary Fund (IMF), the World Bank, and the World Trade Organization engage in consensus and coalition building with governmental and civil society actors to set up world economic rules (Sklair, 2001; Baker, 1999). The neo-Gramscian perspective analyzes this consensus formation process through the Gramscian concept of hegemony that entails strategic planning and intellectual efforts to create common sense among wider society. The concept of hegemony reflects the way ruling groups manage to convince subordinate groups to accept their own interests, norms, values as universal and part of the collective national-popular will (Gramsci, 1971: 181-182).

While attempting to universalize their interests and priorities, the ruling groups at the same time sacrifice their short-term interests for ensuring the representation of the needs and interests of subordinate groups. Although ruling groups extend some concessions to reproduce and sustain the consent of the dominated groups, hegemony is an unsteady process in which the latter can challenge the ideological and moral leadership of the former (Gramsci, 1971). This vulnerability to resistance that might emerge within civil society implies the potential for the formation of counter-hegemonic groups that challenge the dominant political-economic order. These dialectical concepts of hegemony and counter-hegemony are crucial to comprehend not only how the current neoliberal world order have been created but also how that order has been challenged by various resistance groups within global civil society. 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.

Gramsci (1971) argues that in case of a friction in hegemony, ideas that used to be treated as natural and unquestionable can be challenged. For Gramsci (1971: 59, 119-120), in such a moment of a hegemonic crisis, ruling groups try to recapture the broken consensus by incorporating the demands and needs of subordinate groups through the strategy of passive revolution. The concept of passive revolution reflects an attempt of the ruling groups to pre-empt resistance groups from challenging the capitalist order, without resorting to violence, but ensuring that subordinated groups remain excluded from the policy-making process (Moore, 2007:47; Morton, 2003). Passive revolution relies on a process of top-down restructuring political-economic order in a way that the expectations and the interests of subordinate groups would be responded, while keeping the soul of capitalist social relations intact (Morton, 2003: 632).

Gramsci argues that for conducting passive revolution, the ruling groups resort to the strategy of *trasformismo* to pacify internal contradictions by

neutralizing and assimilating counter-hegemonic movements that propose alternative conceptions of world order (Cox, 1983: 130-131). *Trasformismo* is a tool used by the ruling groups to increase legitimacy for the established power structures by harmonizing potentially counter-hegemonic groups and their alternative ideas with their own accumulation strategies (Cox, 1983: 166-167; Patterson, 2006: 35). *Trasformismo* is thus designed for creating an opportunity space for resistance groups to express themselves in policy-formulating processes and coopting their discourse into elite rhetoric but ensuring that these groups cannot actually take part in the decision-making process (Patterson, 2006:17; Moore, 2007: 14). Alternative ideas of the subordinate groups, including sustainable development, the right to live, and respect for the environment, may be reflected in the official documents of the ruling groups, but the essence of the neoliberal accumulation strategy does not change (Patterson, 2006). In other words, the ruling groups try to restore their leadership position by generating legitimacy and consent for their strategies without formulating policies that would benefit the subordinate groups in any meaningful way.

Based upon these insights, 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 (Gill, 2000). Nevertheless, this attempt of hegemonic groups to spread new market norms that would have detrimental social and economic consequences for poorer states began to be contested by a diverse set of actors within global civil society. Counter-hegemonic forces engaged in resisting the destructive consequences of the neoliberal order by raising awareness over issues, including human rights and the social, economic, and environmental justice (Rupert, 2005; De Sousa Santos, 2005: 29). These counter-hegemonic forces played an important role in the acknowledgment of TRIPS flexibilities to facilitate trade in generic versions of patented medicines. However, such flexibilities confirmed by the Doha Declaration can be seen more as a strategy of *trasformismo* used by the hegemonic political elites to legitimize the TRIPS Agreement by pacifying 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.

## **2. TRANSNATIONAL SOCIAL FORCES AND THE CREATION OF THE MARKET-BASED TRIPS AGREEMENT**

A coalition of American TNCs representing copyrights, patents, and trademarks interests mobilized in the mid-1970s and conducted a campaign for enhancing international intellectual property rights protection (Sell and Prakash, 2004). By engaging in an encompassing agenda-setting initiative, they highlighted intellectual property (IP) as a trade related issue (Sell, 2003). In order

to generate consent for their position within civil society, they promoted IP rights as generating wealth, competitiveness, and employment for all (Sell and Prakash, 2004). In order to mobilize the political and economic elite worldwide around their objective, twelve major American TNCs in pharmaceuticals (Bristol Myers, Johnson and Johnson, Merck and Pfizer), chemicals (DuPont and Monsanto), media (CBS), information technology (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). 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 intellectual property rights protection (Sell, 2003; Moon, 2010).

This transnational coalition lobbied their governments to establish multilateral intellectual property protection standards in the 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, and a dispute settlement mechanism (Sell and Prakash, 2004). They submitted the Basic Framework to the GATT Secretariat as representing the consensus of the American, European, and Japanese capital groups on intellectual property rights (Matthews, 2002: 9).

The new way of thinking concerning intellectual property rights as a trade issue was acknowledged by the Organization for Economic Cooperation and Development (OECD) by the mid-1980s. Nevertheless, despite the support for intellectual property rights in the OECD countries, intergovernmental negotiations on the issue 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 intellectual property rights 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: 61-63). To convince developing countries, developed countries argued that providing greater IP protection would encourage higher foreign direct investment and facilitate technology transfer (Maskus, 1999).

From a Gramscian perspective, the concept of hegemony reflects a synthesis of consent and coercion (Gramsci, 1971). Accordingly, to achieve

consensus around their preferences, powerful actors such as the United States (US) and the European Union (EU) attempted to convince less developed countries by threatening them with trade 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 (Drahos, 2003). For instance, in 1987, the US Pharmaceutical Research and Manufacturers Association (PhRMA) put pressure on the United States Trade Representative (USTR) for taking action against Brazil for its failure to provide pharmaceutical product patents. After Brazil refused to change its laws, the US placed 100% retaliatory tariffs equaling \$39 million on Brazilian exports (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 (Watal, 2001: 24). Upon the complaint of PhRMA on Thailand's insufficient protection to American intellectual property 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).

In order not be subject to trade sanctions of developed countries, some developing countries undertook 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 the terms of patents 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 the TRIPS agreement was finally incorporated to the WTO Treaty in 1994, Jacque 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 his speech delivered at the US Council for International Business, Edmund Pratt, the then Chairman of Pfizer, similarly said that:

The current GATT 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 (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 less developed countries. Particularly, the proliferation of HIV/AIDS infections and unaffordable prices for patented HIV/AIDS drugs led to a growing concern over health and other social concerns. The penetration of market norms to the intellectual property regime fueled resistance within the global civil society against the TRIPS Agreement.

### **3. COUNTER-HEGEMONIC STRUGGLE OF SOCIAL FORCES TO ENSURE ACCESS TO MEDICINES**

After the TRIPS Agreement came into force in 1995, the US, the EU and their pharmaceutical companies 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 figures for HIV infection, allowed in 1997 compulsory licenses and parallel imports by passing the Amendment Act of Medicines and Related Substances Control in order to make HIV/AIDS medicines more accessible. Although the TRIPS Agreement provided flexibilities for governments to ensure public health, the South African government faced a strong opposition from transnational pharmaceutical companies, the US and the EU.

Claiming that South Africa 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 sued 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). The USTR placed South Africa on its Special 301 Watch List, and made it clear that South Africa would face trade sanctions if it did not repeal the Amendment Act. With the letter sent by the European Commission to the South Africa, the European Union also challenged South Africa's Amendment Act by arguing that the Act would harm European pharmaceutical interests ('t Hoen, 2002).

Another country that was challenged for allowing compulsory licensing and parallel importing of patented medicines was Brazil. The Pharmaceutical Research and Manufacturers of America asserted that the art.68 of the Brazilian

government's 1996 Industrial Property Law that allowed compulsory licensing and parallel importing of patented medicines violated the TRIPS Agreement and discriminated against US patent holders (Leon, 2010:59). Upon these claims, the US brought a case against Brazil at the World Trade Organization in 2000 (WTO, 2000). Due to the diplomatic, economic and legal pressure exerted by the pharmaceutical sector, the US and the EU against South Africa and Brazil coupled with the raging AIDS crisis in Africa, a network of global civil society actors mobilized against the TRIPS Agreement. Prominent NGOs, including Medecins Sans Frontieres (MSF), Health Action International (HAI), OXFAM, ACT UP, and the Consumer Project on Technology (CPTECH) launched an influential protest movement to ensure that poor people can have better access to life-saving drugs (Hannah, 2008). The South African-based NGO Treatment Action Campaign (TAC) managed to mobilize thousands of activists in defense of the Amendment Act passed by the South African government (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). By the late 1990s, international civil society organizations increased the intensity of their opposition to TRIPS Agreement and advocated the use of compulsory licensing in developing states.

The NGO-led Access Campaign increased awareness of the potential impact of intellectual property rights 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 Globalized Economy in March 1999. The Amsterdam Declaration issued at this conference highlighted the need to make TRIPS responsive to public health concerns (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'. It (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 United Nations (UN) bodies, developing country governments such as Thailand, South Africa, and Brazil, and civil society groups 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. United Nations Development Program (UNDP) Human Development Reports (1999, 2000, 2001) carried sections on TRIPS and its potential negative effects on developing states. Just before the Seattle Ministerial Conference in 1999, the Economic, Social and Cultural Rights Committee of the UN highlighted its concerns regarding restrictions on access to patented medicines as well as the negative effects of TRIPS on food security and bio-safety (Moon, 2010: 138).

In a report issued on 27 June 2001, the UN Human Rights Commission 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 life-saving drugs in 2001, the World Health Organization (WHO) also strengthened the access to medicines as a human right issue (WHO, 2002). Adopting the '3x5' program, WHO undertook to ensure that three million AIDS patients have the necessary antiretroviral treatment by 2005.

By increasing global awareness on the access to medicines as a human right issue and putting pressure on American and European governments and pharmaceutical companies to consider their moral obligations, the transnational network of NGOs pursued a counter-hegemonic struggle against the market-oriented implementation of the TRIPS Agreement. As part of their counter-hegemonic strategy, NGOs promoted the reports issued by the UN bodies and attempted to problematize market-oriented IP rules by using the political legitimacy of the UN. 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.

#### **4. THE STRATEGY OF TRASFORMISMO AND THE ACKNOWLEDGMENT OF TRIPS FLEXIBILITIES**

Under the strategy of the *trasformismo*, many of the policy demands of the counter-hegemonic groups such as fair trade, environmental justice, human rights, transparent decision-making within international organizations, and

sustainable development were embedded in the 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 developmental concerns of less developed countries through the Doha Development Round. The then Director General of the WTO, Michael Moore promoted the Doha Round as serving the interest of all countries, particularly developing countries (Patterson, 2006).

Emphasizing the need for increasing the legitimacy of the WTO by taking into consideration the environmental and social consequences of trade relations and increasing NGO access to the WTO decision-making process, the US also embarked on a significant policy shift on intellectual property rights and medicines. On 1 December 1999, World Aids Day, Bill Clinton announced the US commitment for following a flexible IP policy to respond to 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 challenge the measures of developing countries that promote access to AIDS drugs within the framework of the flexibilities introduced under the TRIPS Agreement (Moon, 2010: 142-3).

The EU policymakers decided to engage in a broader dialogue with NGOs for ensuring transparency and opened a space for them to participate to the policymaking process on trade issues. A mechanism was introduced to engage in Civil Society Dialogues and informal meetings with NGOs. 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 respond to the development concerns of developing states (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 necessary drugs 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 prize 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 cases against South Africa in March 2001. The US government also announced in July 2001 that it would withdraw its case against Brazil (Sell, 2003: 158). 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 at the Doha Ministerial Conference on TRIPS Agreement and Public Health.

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). 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 developed states. To restore the much-debated legitimacy of the WTO and accelerate trade negotiations in other market-oriented issue areas, including services, competition, and investment, developed countries agreed to compromise with the demands of the developing countries on the TRIPS issue. Accordingly, the Doha Declaration on the TRIPS Agreement and Public Health was adopted on 14 November 2001.

The Declaration (WTO, 2001: para.4) emphasized that the TRIPS Agreement should not prevent member states from taking measures to protect public health and to promote access to medicines for all. Declaration clarified the right of states to allow 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 that used to be heavily criticized for its detrimental effects on public health. It acknowledged already existing flexibilities of the TRIPS agreement without fundamentally changing the multilateral IP regime. Transnational social forces kept their market-oriented position on intellectual property rights. Reviewing the pressure of transnational pharmaceutical

companies on the US government for shaping IP policy in line with market norms, OXFAM (2002a: 2) indicates that pharmaceutical companies kept on challenging developing countries' use of flexibilities of the TRIPS Agreement. In its complaint to the USTR in May 2002, the Pharmaceutical Research and Manufacturers of America listed more than forty states that failed to provide sufficient protection for patented medicines. These countries included India, Brazil, and Argentina that had generic drugs industries as well as those countries like Vietnam and Bolivia that had limited potential for generic production of medicines (Oxfam, 2002a: 7). In 2002, the US government put more than half of the countries recommended by PhRMA in its Special 301 report.

As part of their strategy of *trasformismo*, developed countries presented themselves as respecting the flexibilities of TRIPS at the multilateral level, but discontent with the level of protection pharmaceutical patents would have by the TRIPS Agreement, they pushed for concessions on IP through bilateral and regional free trade agreements (FTAs) at the bilateral level. The United States tried to impose more stringent intellectual property rights known as TRIPS-Plus provisions in FTAs negotiated with countries as diverse as Singapore, Morocco, Australia, Honduras, Thailand, Nicaragua, Costa Rica, the Dominican Republic, Columbia, Chile, Peru, Panama, Oman, Republic of Korea, and the United Arab Emirates (Sell, 2011: 452; Baird, 2013). Provisions, including limitations on compulsory licensing and parallel importation, and extensions for patent terms attached to FTAs suggest that the promises and assurances made by the Doha Declaration would be baseless in practice.

In the FTAs the US concluded with Morocco and Singapore, these countries agreed to extend patent holders the right to block parallel imports (Ho, 2007). In the FTA concluded between the US and Australia, parallel imports were banned in case the patent holder made it clear that a product would only be sold within a particular state (Baird, 2013). In the FTAs it concluded with Panama, Peru, Morocco, and Chile, the US required the same level of protection foreseen in its own patent law for the data exclusivity (Baird, 2013). The data exclusivity provisions embedded into the FTAs concluded by the US require generic pharmaceutical companies to produce their own safety and efficacy findings rather than use the clinical trial test data of the patent holders in the generic drug approval process (Sell, 2011). They thus serve as strengthening the monopolistic position of pharmaceutical companies by preventing generic competition.

It should be noted that although FTAs are bilateral or regional in nature, as shown by OXFAM (2007) in the case of FTA concluded between the US and Jordan, they may have multilateral effect. In its report, OXFAM (2007) emphasized that developing countries must change their national intellectual

property laws to fully implement TRIPS-plus rules. This enables other countries' companies to benefit from the new national legislation on the IP rights. Accordingly, it was not just American companies, but European Union and Swiss drug companies as well that benefited from the data exclusivity condition of the US-Jordan FTA (OXFAM, 2007). In addition to pushing for TRIPS-plus provisions in the 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).

Developing countries' TRIPS-compliant attempt to issue compulsory licenses was also challenged by pharmaceutical companies. 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 was heavily criticized for issuing these compulsory licenses (Reichman and Abbott, 2007: 956). The Pharmaceutical Research and Manufacturers Association (PreMA), 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 then 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 had to 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 intellectual property laws in a manner sensitive to public health.

## 5. CONCLUSION

The paper has examined why and how the flexibilities foreseen in the TRIPS Agreement were confirmed by the Doha Declaration to make it more sensitive to public health concerns. This paper has explained the acknowledgement of TRIPS flexibilities as a function of the strategy of *trasformismo* used by market-oriented actors to legitimize the TRIPS Agreement that was challenged by transnational NGOs, including MSF, Health Action International, Oxfam, and CPTech that demanded respect for TRIPS flexibilities. The paper has indicated that faced with such a challenge, hegemonic social forces attempted to co-opt, absorb and pacify forces of civil society who resisted or rejected the main tenets of the TRIPS Agreement. They engaged in a strategy of *trasformismo* and attempted to neutralize 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 sensitivities and suggestions. 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.

From a neo-Gramscian framework, the paper 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 has analyzed how those market-driven social forces have exerted new market discipline in global IP regime through the TRIPS Agreement. It has also examined how these market-oriented social forces were challenged by counter-hegemonic groups that demanded respect for the TRIPS flexibilities. It accordingly has acknowledged the moral leadership exerted by counter-hegemonic NGOs to put pressure on pharmaceutical TNCs to make their medicines broadly available in the developing world. Arguing that the TRIPS Agreement created a barrier for the access of affordable essential drugs in developing and least developed countries, these NGOs pursued a counter-hegemonic struggle to shift the policies of developed countries and pharmaceutical TNCs in favor of more flexible IP rules. By emphasizing the trade-off between patent protection for pharmaceuticals and high drug prices, they played an active role in forcing the TRIPS Agreement onto the international trade agenda for the clarification of its flexibilities.

However, an important finding of the paper has demonstrated that although the Doha Declaration has enabled WTO member states to implement IP laws in a manner sensitive to public health and development goals, 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. Based on the strategy of *traformismo*, they have presented themselves as respecting the flexibilities of TRIPS Agreement at the multilateral level while simultaneously concluding TRIPS-plus agreements with developing countries at the bilateral level. Although, the Doha Declaration acknowledged that states could issue compulsory licenses as a useful tool to reduce drug prices and to legitimize generic production, such 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 tracing the processes in which opposing social forces promoted or challenged the adoption of specific policy choices such as more stringent IP protection, the paper has dealt with the role of agency and their ideas in regime transformation. It has emphasized that ideas used to legitimize particular policies and facilitate policy change were crucial in the organization of hegemony. It has highlighted that contentious social forces attempted to achieve their policy objectives by changing the way actors perceive and define a particular policy problem and by influencing their preferences through certain ideas. Discursively, both sides have attempted to re-frame IP rules: Those seeking tighter IP 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. On the other hand, those seeking more flexible IP rules attempted to re-frame IP rights as an issue of human rights. To pacify and neutralize the latter group that challenged the dominance of the strong patent protection regime, the former has adopted the strategy of *trasformismo* and struggled for absorbing counter-hegemonic ideas. The paper has thus shown how the transformation of the global IP regime has thus been realized within a contested global political economy.

This finding regarding the global IP regimes contributes to the literature on the contested nature of the neoliberal economic order. The dynamic concept of hegemony implies that although the ruling elites attempt to sustain the prevalent power relations by generating consent for their policies, counter-hegemonic groups may always emerge to challenge the former's legitimacy by formulating alternative ideas. The paper has shown that there has been a resistance movement against market-oriented TRIPS Agreement coming from civil society organizations. However, it has also demonstrated that the advocates of more stringent IP rules attempted to counterbalance the efforts of those that asked for more flexible rules through the strategy of *trasformismo*. The global IP regime

remains highly contested with the economic and social stakes rising for both IP rights-holders and end-users.

## BIBLIOGRAPHY

Baird, Sean (2013), “Magic and Hope: Relaxing Trips-Plus Provisions to Promote Access to Affordable Pharmaceuticals”, *Boston College Journal of Law and Social Justice*, 33 (1): 107-145.

Baker, Andrew (1999), “Nebuleuse and the Internationalization of the State in the UK?”, *Review of International Political Economy*, 6 (1): 79-100.

Bieler, Andreas and Adam David Morton (Eds.) (2001), *Social Forces in the Making of the New Europe: The Restructuring of European Social Relations in the Global Political Economy* (London: Palgrave).

Cox, Robert W. (1981), “Social Forces, States and World Orders”, *Millennium: Journal of International Studies*, 10 (2): 126-55.

Cox, Robert W. (1983), “Gramsci, Hegemony and International Relations: An Essay in Method”, *Millennium: Journal of International Studies*, 12 (2): 162-175.

Cox, Robert W. (1987), *Production, Power, and World Order. Social Forces in the Making of History* (New York: Columbia University Press).

De Sousa Santos, Boaventura (2005), “Beyond Neoliberal Governance: The World Social Forum as Subaltern Cosmopolitan Politics and Legality”, De Sousa Santos, Boaventura and Cesar A. RodriguezGaravito (Eds.), *Law and Globalization from Below: Towards a Cosmopolitan Legality* (Cambridge: Cambridge University Press): 29-63.

Drahos, Peter (2003), “When the Weak Bargain with the Strong: Negotiations in the World Trade Organization”, *International Negotiation*, 8 (1): 79-109.

Drezner, Daniel W. (2007), *All Politics is Global: Explaining International Regulatory Regimes* (Princeton: Princeton University Press).

Forman, Lisa (2007), “A Transformative Power? The Role of the Human Right to Medicines in Accessing AIDS Medicines-International Human Rights Law, TRIPS and the South African Experience”, Unpublished PhD Thesis, (Canada: University of Toronto).

Fraudorfer, Markus (2012), "The US vs. Brazil in the WTO Trade Dispute of 200 I-Patent Rights vs. Human Rights", Paper presented to the Annual Convention of the International Political Science Association, Madrid, 8-12 July.

Fuller, Thomas (2007), "Thailand Takes on Drug Industry, and May Be Winning", New York Times, 11 April, <http://nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html> (21.05.2017).

Gill, Stephen (2000), "The Post-Modern Prince", *Millenium: Journal of International Studies*, 29 (1): 131-141.

Gramsci, Antonio (1971), *Selections from the Prison Notebooks of Antonio Gramsci* (London: Lawrence and Wishart).

Hannah, Erin N. (2008), "Contesting Cosmopolitan Europe: A Study of Non-Governmental Organizations in the European Union's External Trade Policymaking Process", Unpublished PhD Thesis, (Canada: University of Toronto).

Ho, Cynthia M. (2007), "A New World Order for Addressing Patent Rights and Public Health", *Chicago-Kent Law Review*, 82: 1470-1515, <https://pdfs.semanticscholar.org/3c31/f06fa5cefe0b4166c473560a719450abcb54.pdf> (12.04.2017).

Leon, Diane (2010), "Intellectual Property Rights and the Campaign For access to Essential Medicines: the Advocacy Role Assumed by Medecins Sans Frontieres", Unpublished PhD Thesis, (Canada: Brock University).

Maskus, Keith E. (1999), "The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer", *Duke Journal of Comparative and International Law*, 9 (1): 109-161.

Matthews, Duncan (2002), "Trade-Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?", CSGR Working Paper, No. 99/02.

May, Christopher (2002), *A Global Political Economy of Intellectual Property Rights: The New Enclosures?* (London: Routledge).

Moon, Suerie (2010), "Embedding Neoliberalism: Global Health and the Evolution of the Global Intellectual Property Regime", Unpublished PhD Thesis, (USA: Harvard University).

Moore, Phoebe V. (2007), *Globalization and Labor Struggle in Asia. A Neo-Gramscian Critique of South Korea's Political Economy* (London: Tauris).

Morton, Adam David (2003), "Structural Change and Neoliberalism in Mexico: 'Passive Revolution' in the Global Political Economy", *Third World Quarterly*, 24 (4): 631-653.

Overbeek, Henk (2004), "Transnational Class Formation and Concepts of Control: Towards a Genealogy of the Amsterdam Project in International Political Economy", *Journal of International Relations and Development*, 7 (2): 113-141.

Oxfam (2001), *Patent Injustice: How World Trade Rules Threaten the Health of the Poor* (Oxford: Oxfam), <https://community.oecd.org/docs/DOC-33052> (10.10.2016).

Oxfam (2002a), "US Bullying on Drug Patents: One Year After Doha", Oxfam Briefing Paper, 33, <http://policy-practice.oxfam.org.uk/publications/us-bullying-on-drug-patents-one-year-after-doha-115060> (10.10.2016).

Oxfam (2002b), "Generic Competition, Price and Access to Medicines: the Case of Antiretrovirals in Uganda", Oxfam Briefing Paper, 26, <http://policy-practice.oxfam.org.uk/publications/generic-competition-price-and-access-to-medicines-the-case-of-antiretrovirals-i-114502> (10.10.2016).

Oxfam (2007), "All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines", Briefing Paper, <https://policy-practice.oxfam.org.uk/publications/all-costs-no-benefits-how-trips-plus-intellectual-property-rules-in-the-us-jord-114080> (21.11.2016).

Patterson, W. Bill (2006), "Altering the World Order: The Alter-Globalization Movement and the World Trade Organization", Unpublished PhD Thesis, (Scotland: University of Stirling).

PhRMA (2003), *Pharmaceutical Industry Profile* (Washington, DC: PhRMA).

Reichman, Jerome H. and Frederick M. Abbott (2007), "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions", *Journal of International Economic Law*, 10: 921-987.

Roemer-Mahler, Anne (2013), "Business Conflict and Global Politics: The Pharmaceutical Industry and the Global Protection of Intellectual Property Rights", *Review of International Political Economy*, 20 (1): 121-152.

Rupert, Mark (2005), "In the Belly of the Beast: Resisting Globalisation and War in a NeoImperial Moment", Eschle, Catherine and Bice Manguashca (Eds.), *Critical Theories, International Relations and Anti-Globalisation Movement: The Politics of Resistance* (Abingdon: Routledge): 36-52.

Sell, Susan K. (2003), *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press).

Sell, Susan K. (2011), "TRIPS was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP", *Journal of Intellectual Property Law*, 18 (2): 447-478.

Sell, Susan K. and Aseem Prakash (2004), "Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights", *International Studies Quarterly*, 48 (1): 143-175.

Singh, J.P. (2006), "The Evolution of National Interests: New Issues and North-South Negotiations During the Uruguay Round", Odell, John S. (Ed.), *Negotiating Trade: Developing Countries in the WTO and NAFTA* (Cambridge: Cambridge University Press): 41-85.

Sklair, Leslie (2001), *The Transnational Capitalist Class* (Oxford: Blackwell).

't Hoen, Ellen (2002), "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: a Long Way from Seattle to Doha", *Chicago Journal of International Law*, 3 (1): 27-50.

't Hoen, Ellen (2009), *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPs and Public Health* (Diemen: AMB Press).

United Nations Development Program (UNDP) (1999), *Human Development Report 1999* (Oxford: Oxford University Press), [http://hdr.undp.org/en/media/HDR\\_1999\\_EN.pdf](http://hdr.undp.org/en/media/HDR_1999_EN.pdf) (18.02.2016).

United Nations Development Program (UNDP) (2000), *Human Development Report 2000: Human Rights and Human Development* (Oxford: Oxford University Press), [http://hdr.undp.org/sites/default/files/reports/261/hdr\\_2000\\_en.pdf](http://hdr.undp.org/sites/default/files/reports/261/hdr_2000_en.pdf) (18.02.2016).

United Nations Development Program (UNDP) (2001), *Human Development Report 2001: Making New Technologies Work for Human Development* (Oxford: Oxford University Press), <http://hdr.undp.org/en/media/completenew1.pdf> (18.02.2016).

Watal, Jayashree (2001), *Intellectual Property Rights in the WTO and Developing Countries* (London: Kluwer Law International).

World Health Organization (WHO) (2002), *Accelerating Access Initiative: Widening Access to Care and Support for People Living with HIV/AIDS*, [http://www.who.int/hiv/pub/prev\\_care/en/isbn9241210125.pdf](http://www.who.int/hiv/pub/prev_care/en/isbn9241210125.pdf) (15.11.2006).

WTO (2000), Dispute Settlement: DS199, Brazil-Measures Affecting Patent Protection, [https://wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds199\\_e.htm](https://wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm) (22.01.2016).

WTO (2001), Declaration on the TRIPS Agreement and Public Health, [https://wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm) (27.01.2016).

WTO (2005), Amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/wt1641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wt1641_e.htm) (12.02.2016).