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Research Paper

Reflections of the transnational capitalist class on the global health: The case of India

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Abstract

Objectives This study aims to explore the transformations in the relation of global health and capitalism during the last three decades and its reflections on the nature of power relations between the state, local and transnational capital in the Indian pharmaceutical industry.

Methods In this study, the effects of the developments in the international political economy after TRIPS (Trade-Related Aspects of Intellectual Property Rights) in the global pharmaceutical sector and in the Indian local sector are examined within the framework of the International Relations discipline. In this sense, a historical review of the Global Patent Regime has been made and a literature review has been conducted on the global pharmaceutical industry, drug patents and post-TRIPS agreements. Qualitative research method is used in the study in which the literature review is evaluated in an empirical and theoretical framework.

Key findings The Global Patent Regime has been constructed for the interests of the transnational capitalist hegemon and in this sense has increased inequality in the global health. However, when the changes created by the global economy in the pharmaceutical sector, cooperation between the Southern countries and state policies are analysed, it is seen that a struggle area has been formed. This struggle adds value to global health in terms of access to medicine.

Conclusions In transnational capitalism, the emergence of the state in strategic sectors such as the pharmaceutical sector in India indicates a new political and economic power.

Keywords: drug patents; pharma sector; global health; India

Background

The World Trade Organization (WTO) stated that the Global Patent Regime is for the benefit of underdeveloped and developing countries, that strong intellectual property and patent protection will improve innovation, transfer technology and knowledge, and thus contribute to the development of new medicines.^[1] It was stated that governments should participate in regulatory standards to be able to circulate medical goods and services and to establish their own pharmaceutical markets to cope with emerging epidemics. On the other hand, with the Regime, public health policies have been emptied to reduce costs in the public sector and pressure has been

put on the developing and underdeveloped countries to maintain free trade and privatizations. However, the multinational companies dominating the pharmaceutical sector have weakened the institutional capacities of developing and underdeveloped countries participating in the Regime and made their interventions difficult in the field of health.^[2] So, the Global Patent Regime has reinforced the inequality between the developed and developing countries and further weakened health protection systems in developing countries. And, it was emphasized the difficulty of implementing an ambivalent policy that promotes the protection of public health interests of citizens while promoting local innovation and promoting foreign

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investment in a competitive market environment. In other words, there is a significant tension between the aim of compensating the investments of the global pharmaceutical industry and the control of the healthcare costs of the states. Therefore, the global health field has become controversial since it was included in international trade in the 1980s. For example, the proliferation of HIV/AIDS infections and unaffordable prices for patented HIV/AIDS drugs have caused criticism and resistance to the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights)1 within the global civil society. Civil society organizations argued that by establishing a link between the TRIPS and the HIV/AIDS crisis, strong patent protection increased drug prices that prevent poor people in developing countries from accessing these drugs, and presented it as a health and human rights issue. Towards the end of the 1990s, international non-governmental organizations increased the intensity of their opposition to the TRIPS Agreement and advocated compulsory licence use in developing countries. Leading NGOs, including Medecins Sans Frontieres (MSF), OXFAM, Health Action International (HAI), ACT UP and the Consumer Technology Project (CPTECH), launched an effective protest movement about the rights of access to health and access to medicine in developing and less developed countries. Also, the NGO-led Access Campaign raised significant normative changes related to intellectual property rights on public health.[3] In March 1999, HAI organized The Conference on Increasing Access to Essential Drugs in a Globalized Economy for better understanding of effective use of flexibilities such as compulsory licencing in developing countries.

Thus, in light of these criticisms, the Doha Declaration (2001) was adopted to facilitate the development and access to the pharmaceutical industry in the underdeveloped and developing countries. It redefines the mechanisms that governments can use in the context of TRIPS to achieve public health goals.[4] Although the Doha Declaration does not impede the TRIPS Agreement in legal terms, and the protection of patent rights continues to stand out from public health, it also provided a basis for legitimacy on the right to access to medicine. Moreover, to prevent breaks in the application of the Patent Regime, the European Union (EU) and the USA have entered into bilateral and regional trade agreements for free trade and economic partnerships called TRIPS Plus Agreements since the 2000s. [5] Although free trade agreements are bilateral or regional, they can have a multilateral impact. Because these agreements provide for protection beyond the international patent standards introduced by the Regime in the manner that provisions limiting the compulsory licence and parallel import practices, provisions on the extension of patent periods and the extension of the patent subject. Especially the data exclusivity provisions in free trade agreements are attempts to undermine the generic pharma sector in developing countries. These provisions require generic drug companies to produce their own safety and efficacy findings in the generic drug²

- TRIPS (Trade-Related Aspects of Intellectual Property Rights), which was accepted in addition to the founding agreement of the WTO during the Uruguay Round negotiations between 1986 and 1994, was added to the international trade system in 1995 as an agreement regulating trade-related intellectual property rights. TRIPS is the most comprehensive internationally accepted agreement in the field of intellectual property. The significance of the agreement is that it is broader in terms of scope and sanctions.
- A generic drug has the same active pharmaceutical ingredient (API) as the original (patented drug), but it may differ in some characteristics such as the manufacturing process, formulation, excipients, colour, taste and packaging.

approval process, rather than using the clinical trial test data. Thus, they serve to strengthen the monopolistic position of transnational pharma companies by preventing generic competition.

In this context, countries such as China, India, Brazil, South Africa and Thailand pursue resistance policies and establish cooperation to overcome health problems. These countries make bilateral and multilateral regional agreements for the generic production of high-cost drugs. Domestic pharmaceutical companies are limited in number, most of them focused on chemical production and domestic production of active pharmaceutical ingredients, creating institutions such as Health Minister's Institution and created their obligations in the field of health. [6] Especially, special vaccine and drug manufacturers in India, facilitate access to generic drugs in developing countries. At the same time, biomedical research centres, R&D programmes and medical education established by the government provide direct observation of diseases and research of treatments. Another example is the partnership between Lupin Company in India and Farmanguinhos and the Brazilian Ministry of Health for technology transfer to facilitate the local production of tuberculosis medicine. Especially generic production of antiretroviral drugs and sharing of healthcare services are important for access to drug and primary health care in these countries.

Objective

The aim of this study is to interpret the effects of the international economic-political system on the global pharmaceutical industry and its effects on global health in theoretical perspective. Another aim is to examine the local reflections of the transformation in the global pharmaceutical industry. The Indian pharmaceutical market is studied empirically as a case study to see the local-level results of the theoretical analysis.

Method

In this study, the transformation in the pharmaceutical industry and its effects on developing countries, after the adoption of the TRIPS Agreement, are discussed within the framework of International Relations theories. The theory that can best explain the effects of the Global Patent Regime, which is part of the 21st-century international economic-political system, in the pharmaceutical industry is William Robinson's transnational capitalist class thesis. In this context, the developments explained by the transnational capitalist class thesis are confirmed through the India case study. The interaction of the Indian pharmaceutical capital with foreign capital and the role of the state in the development of the local pharmaceutical sector are empirically examined and the literature on the pharmaceutical industry is reviewed. India presents a unique example which indicates the transformations in the relations of global health and capitalism during the last three decades and its reflections on the power relations between the state, local and transnational capital.

Results

Theoretical overview

William I. Robinson argues that understanding the current dynamics of the global system requires a broader approach that allows innovation to grasp new transnational processes within the global society at the beginning of the 21st century. Therefore, he analyses the globalization of capital relations within a historical framework. He claims that with globalization there is a new class fraction or alliance between national and transnational class fractions. The

globalization of production – the internal and external expansion of capitalism – forms the material basis of this new transnational class formation. In this sense, transnationalization is a process that occurs when national capitals are combined with other internationalizing national capitals by crossing borders and penetrating each other, and today's hegemony is the transnational capitalist class.

The transnational capitalist class fraction

Robinson expresses the reflection of the above mentioned new sovereignty as follows: We cannot simply speak of the hegemony of a state. Hegemony; it is applied by social groups, classes or class fractions, by a particular social design of these fractions. A country cannot be a 'hegemon'. A social group that applies hegemony through a state can be hegemonic. The transnational capitalist class means that managers of transnational companies; 'Globalizing bureaucrats, politicians and professionals' and 'consumerist elites' in the media and trade sector.^[7] The reflection of this in the field of health is that decisions – decisions about the public health and who is worth living – are determined and controlled by the transnational capitalist class at the global level.

Key indicators in the rise of the transnational capitalist class are the expanding strategic alliances of multinational companies, the expansion of these companies and economic arrangements such as cross-border mergers and acquisitions, foreign direct investments, subcontracting and licence agreements. With these regulations, while local companies lose their nationality, they become a part of a complex network that integrates vertically and horizontally.

It is considered that the power of transnational class formation in developing countries is relatively weak, so that the national bourgeois can still control the state and organize effective political projects. However, at the end of the 20th century and the beginning of the 21st century, with the crises that damaged the global economy, from Mexico to Asia, from Russia to Brazil, it is seen that the local capitalists of the affected countries began to integrate with transnational capital. This situation raises the question of the role of the state in certain strategic sectors.

The reflections of the transnational capitalist system to the pharmaceutical industry

Drug patents as the mechanism of transnational capitalist class

The patent rights inherently restrict access to pharmaceutical products due to their exclusive properties. To make it clear, in the case of pharmaceuticals, there are two main types of patents: product patents and process patents. Both patents provide exclusive rights to produce, market and licence patented drug for certain time periods (20 years) and allow the innovators to earn more much than the costs in R&D activity for pharmaceutical innovations. This was the main reason that today's developed countries have been keeping pharmaceutical products out of patentability for a certain time period. For example, in the Paris Convention that is the first international agreement on the protection of industrial property, there were no restrictions on the health policies of the countries. The contracting countries were free to exclude all areas of technology or certain products or processes from patentability. The contract also left the authority to decide on its own patentability criteria and also left the authority to decide that a patent cannot work locally to issue a compulsory licence. The TRIPS Agreement has brought a number of important changes in the field of patent law. First of all, it brought the obligation to make patents available in all areas of technology and for both products and processes. One of the areas included in the patent law is pharmaceutical products that are strategically

important for transnational corporations. For the research-intensive transnationals, which lead the global pharmaceutical industry, patent protection is the most important mechanism through which they protect the monopoly power. Because, transnationals profit from monopolization, and if they invest under low intellectual property protection, as there will be losses rather than economic gain in the event that patents and copyrights are violated. That's why they put pressure on stronger intellectual property protection in the 1980s.

The incorporation of drug patents into the trade was accomplished in 1995 with the signing of the TRIPS which made patent protection on drugs mandatory for all countries. The Agreement in question is a reflection of the new type of sovereignty emerging in the international system. To make it clear, the most important reason for drug patents to be included in the trade is the decline in American production competition in the 1980s. The efforts of pressure groups to establish a Global Patent Regime in Uruguay Round, such as the Pharmaceutical Manufacturers Association and the Intellectual Property Committee that are formed to protect their profits of multinational companies in the pharmaceutical sector in developed countries. The fact that intellectual and industrial rights are one of the most important economic factors determining the exports of developed countries such as the USA, European countries and Japan necessitated the inclusion of underdeveloped and developing countries in the Regime. So, both coercive power and consent instruments were used for the adoption of the TRIPS Agreement. US economic sanctions and threats against countries that do not enforce the Regime, [8] prevention being a member of the WTO of the states that do not accept the TRIPS Agreement, in other words, sanctions such as 'exclusion from the global market' are the 'hard power' of transnational capitalist hegemon and push the underdeveloped and developing countries through the acceptance of Regime. This means that although the agreement of 1995 was realized between states as political actors, the transnational capitalist power played the key role in the background of this process.

Transnational capitalist hegemon does not only use the 'hard power', but also needs the 'soft power' to embrace anti-TRIPS resistance policies implemented by the multitude through free choices because in the transnational capitalist system, every nation-state seems to have the right to freely choose its own policies. So, by adopting resistance policies, it makes an anti-hegemonic movement and revolution against him impossible. This means that when the countries criticize the TRIPS Agreement, it seems as if their justified demands are being taken into account in the international system. However transnational hegemonic power wants to neutralize everything that could threaten its hegemony. Therefore, it produces differentiated plural strategies and techniques in which actors in the international system are constantly supervised and managed. The sovereign seeks to embrace revolutionary ideas and deflect them. The Doha Declaration is an example of soft power that was adopted to facilitate the development and access to the pharmaceutical industry in the underdeveloped and developing countries. It redefines the mechanisms that governments can use in the context of TRIPS to achieve public health goals.

In this case, can a line of struggle be established in the pharmaceutical sector against the transnational capitalist hegemony? If so, would the cooperation of the Southern countries in the sector represent a counter-hegemonic movement? Or does the existing system necessitate the integration of national capitals with transnational capital?

Analysis of the pharmaceutical industry

When the pharmaceutical sectors in developing countries are analysed, mergers and acquisitions can be seen between transnational companies and local companies since the 2000s. The main reason for

the cooperation between growing national capitals and transnational capitalist class in the 21st century is the crisis in pharma sector. As mentioned above, pharmaceutical companies generally profit from drugs with high sales margins, both the expiration of the patents on these drugs and the obstruction in innovation caused a crisis. After the crisis, more than 25 000 people were laid off in 10 large companies. [9] In 2010, the profits of large companies, including Merck, Bristol Myers and GlaxoSmithKline, fell sharply; China, India, Brazil, Russia, South Korea, has experienced a growth in the markets of developing countries such as Mexico and Turkey. After the crisis, compared with Western European, US and Japanese markets, we can see that local pharmaceutical markets in the developing countries contribute to more than half of the global pharmaceutical market. [10]

The boom in generic markets and R&D activity has led multinational companies to local companies in large developing countries, especially India, Brazil and China, to both embark on generic production and reduce innovation costs. In the developing countries, an increase has occurred in the number of patents and patented drug production of local companies in the 2000s and exports to the central countries have increased. However, large pharmaceutical companies in the developed countries have also started to produce generic drugs. Public and private insurance companies in both the EU and the USA also encourage the use of less costly generic brands to reduce healthcare costs. It is noteworthy that generic drugs constitute 80% of the US market, which has 40% of the world pharmaceutical market. As a result, we can say that the difference between large companies and local companies has blurred in the 21st century. Especially in China and India, mergers between multinational companies and local firms, and outsourcing in the R&D activity in these countries have caused interaction between state-nation capital and transnational capital.

The reflections of transnational capitalist system in India

Since the pharmaceutical sector in India was seen as one of the strategic areas, it was protected by the state before 1980 whereas the protection policy was abolished after 1980. It is stated that the main reason for this policy change is the economic crisis it experienced and joined the free market as a result of the IMF's imposition.[11] In this context, India has been articulated to the global production chain again as a result of its membership in the WTO and its commitment to TRIPS. As part of the Washington Consensus, it changed the economic policies towards liberalization. Government policies have undergone significant changes in the pharmaceutical industry. Price controls were lifted and foreign direct investments were allowed. The changes in industrial policy in 1991 paved the way for the first wave of mergers and acquisitions in India that are abolition of some restrictive articles of Monopolies and Restrictive Trade Practices, Reforms in Foreign Exchange Regulation Act (1993), enacting of Foreign Exchange Management Act (2000). Some authors point out that the integration of transnational capital and local capital in the capitalist system may seem to be in the interest of developing countries in the short run, but in the long run, if there is any conflict between foreign and national capital, developing countries may be at a disadvantage as the state cannot protect local capital in the country.[12] However, on the contrary, it is seen that the Indian pharmaceutical industry has grown and developed after joining the global market. Because while foreign capital has been included in the Indian pharmaceutical industry since the 2000s, the Indian government has taken various steps to protect local capital. For example, the 2002 Competition Policy Act was created and the Indian

Competition Commission was set up to lift forces that reduce competition. [13] This commission aimed to control anti-competitive activity that could lead to market domination violations such as cartel formation and consolidation through mergers and acquisitions. That is the policy implemented by the state to restrict the presence of foreign capital in the sector.

Since the mid-2000s, as in other developing countries, even more than ever, cooperation between global and Indian firms has been formed. Thus, while foreign firms benefited from the traditional knowledge and resources in the Indian sector, Indian firms such as Cipla, Wockhardt, Piramal Healthcare and Orchid provided information on quality and production standards and techniques as well as entering North American and Western European markets as part of their research projects.^[112]

Indian firms have evolved, with increased government support, both by participating in R&D activity and by participating in research partnerships with transnational companies. Accordingly, the Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilizers, the Government of India has established the Pharmaceutical Bureau, a body of technical experts that will act as a single-point interface for problems with the pharmaceutical and medical devices industry.^[14] In this context, the central government works in coordination with the state governments and supports domestic and foreign investments in the Indian pharmaceutical market. For example, the Department of Pharmaceuticals has projected to originate a venture capital fund of US\$149.11 million to support start-ups in the investigation and improvement in the pharmaceutical and biotech industry.[15] In other words, in the transnationalized capitalist system, the state itself is an actor that accelerates, manages and controls the development of the pharma sector and the companies. Thus, the state tries to maximize profit by acting like a company in line with global dynamics. In this sense, it is a functional actor for capital accumulation.

However, India is separated from other developing countries by using the flexibilities of TRIPS Agreement and contributing to the right to access the drug. For example, according to the article 70/3, TRIPS Agreement, if there is a public issue before 1 January 1995, there is no obligation for the WTO member country to provide patent protection on the product or idea on the subject. Based on the Article in question, after 1995, patents of Novartis cancer drug Imatinib mesylate and Gilead's HIV/AIDS drug Tenofovir disoproxil fumarate were rejected by the Indian Patent Office and the Supreme Court. Because the basic components of these two drugs, namely originally patentable inventions, were discovered before 1995 by Indian Company, Mesylate (a special beta crystal form) and Disoproxil fumarate (a kind of salt) and produced by Indian generic companies. Cancer drug Erlotinib (Tarceva) production is also protected based on the same article of TRIPS.[16] Apart from that, another TRIPS flexibility used in accessing the drug is compulsory licences. The first example of the compulsory licence in India is carried out about the production of cancer drug Sorafenib by the Indian company Natco Pharma, which was patented by Bayer in 2012 and also produced by Nexavar. Another example is Gilead's licencing to leading Indian companies such as Cipla, Hetero Labs, Ranbaxy, Sequent Scientific for the generic production of Harvoni and Sovaldi medicines used for hepatitis C treatment. Considering that there are 30 million patients with hepatitis C in India, it turns out that Gilead has received a serious profit share on the royalty³ it received on every sale. Moreover, India develops parallel imports with underdeveloped and

This means profiting from patent licencing.

developing countries, enabling the lower and middle class to meet their pharmaceutical needs.

The Indian pharmaceutical market has several unique features. First, the country's strength in the branded generic drug market is its greatest strength. Second, the industry has many local players creating their own niche through early investments and new formulation development capabilities. Six domestic firms, Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs, have the UN-backed Pharmaceutical Patent Pool to produce anti-AIDS drugs for more than 112 countries in emerging markets. [17] Healthy competition in the market and generic production have made drug prices of Indian manufacturers extremely low compared with global prices. Although India ranks tenth globally in terms of pharmaceutical production value, it ranks third in production volumes. Thus, new network relationships were established and Indian companies began exporting to Asian, African and Latin American markets as it facilitates access to pharmaceutical and healthcare services. [18]

Conclusion

The Global Patent Regime has been constructed for the interests of the transnational capitalist hegemon and in this sense has increased inequality in the global health. However, when the changes created by the global economy in the pharmaceutical sector, cooperation between the Southern countries and state policies are analysed, it is seen that a struggle area has been formed. This struggle adds value to global health in terms of access to medicine.

In the transnational capitalism, the emergence of the state in strategic sectors such as the pharmaceutical sector in India indicates a new political and economic power. As seen in the case of India, state activity is a new strategy to maintain both to make profit in accordance with the current transnational stage of the capitalist system and to control political development and increase its power in the system.

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Author Contributions

In this study, the pharmaceutical industry was examined within the framework of the International Relations discipline. In this regard, two remarkable were made to the literature in this study. Firstly, a macro level analysis was made by analyzing the impact of capitalism on global health through the pharmaceutical industry. Secondly, a micro-level analysis was conducted that analyzed the local reflections of the relationship between capitalism and the pharmaceutical sector.

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Conflict of Interest

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