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Project - <u>Enforcement of intellectual property rights of drugs: the European Union vs. Brazil,</u> By Elize Massard da Fonseca Phd.

Introduction

Intellectual property (IP) of drugs is a controversial topic within public health. IP rights allows the pharmaceutical research industry to obtain the monopoly, during a certain timespan, over production and commercialization of medications developed in their researches. If on the one hand, the governments must ensure this monopoly in order to encourage research and development within the sector, on the other hand, it must provide these medications at an affordable price for the population. During the 1990s, developed and developing countries discussed the content of this regulation and when it should be applied. Currently, the debate is focused on how to enforce intellectual property rights. The present study demonstrates the influence of the pharmaceutical industry in intellectual property rules in the European Union and the tensions that emerge when the EU attempts to export this preference to other contexts. The key message of this chapter is that international transportation of medicines has become a problem of global health governance. Brazil leads a group of 16 countries that oppose to the EU regulations.

Main findings

(1) The actions to apply IP norms range from alerts on counterfeit products sold on the internet to more controversial measures, such as strict customs rules, in order to control the transit of drugs through European ports and airports. Should the EU countries adopt different norms to resolve this issue, they could produce different public health protection patterns and encourage counterfeiters to act in countries with more lenient norms.

(2) In 2008, the European Commission (EC) founded a program to control the entrance and transit of counterfeit drugs within the block (Medi-fake), when over 23 million drugs were confiscated. Sequentially, resolutions were produced which allowed for the drug industry to denounce loads in transit to Europe to the customs authorities if there was any suspicion of breaking IP regulation (Resolution 1383/2003). This collaboration resulted in 18 thousand inspections in 2010 and raised harsh criticism towards public officials acting in favor of private companies. In 2008 a public consultation in order to clarify Resolution 1823 had 123 participants, 100 of them being from the drug industry and who supported the maintenance of the norm in its current terms. Moreover, it was observed that the EC has exported this model of enforcement of IP rights by means of clauses contained in bilateral trade agreements with developing countries.

(3) A large portion of the apprehensions referred to medications originating from India in transit through the European territory and bound to Latin America. Legitimate drugs, produced by generic drug industries, were seized several times. This led to a debate, headed by Brazil, between developing countries and international organizations (such as Doctors Without Borders) over the content of the European regulation. It was argued that according to the World Trade Organization (WTO) counterfeiting refers to the violation of the brand name while low quality medications, according to the WHO, may cause severe adverse effects. The lack of clarity in the definition of the terms could limit the legal generic drug commerce and harm the access to medication in developing countries. The Brazilian and Indian diplomacy presented criticism towards the European decisions for the WHO and the WTO. Furthermore, they argued that customs authorities have no adequate training for verifying patent validity and medication quality.

(4) There are two theoretical implications in this debate. First of all there is the definition of public interest. Both coalitions express concern towards the safety of patients and public health. Defining the EU preference as a mere echo of the demands of the drug industry (which would be obstructing the access to generic drugs) ignores an important contribution of the block to encourage the development of medical technologies and their strict regulation on local pharmaceutical industries, both in the name of public interest. That is to say, actors may have multiple, controversial and fluid interests instead of static ones. These preferences may be modified in answer to the evolution of interactions with the government and among the groups themselves. Secondly, it refers to the strategy of taking the public debate to the more favorable institutional arena (venue-shopping). Since the agenda for IP execution has been defined as city -safety and competitiveness, then customs control seems to be the most adequate sphere. On the other hand, the coalition of developing countries and NGOs has criticized the changing of the arena from commerce (WTO) to customs authorities, considering the latter would lack the legitimacy and necessary expertise to decide over IP.

Political implications

Within the EU, the present study observed that drug industries have had larger participation in the political process regarding IP execution than civil society. The EU should be more effective in answering to the preferences of the NGOs and their demands should be cautiously introduced in the IP execution actions. Future studies should understand the reason as to why these groups have not been active in such discussions and that this absence leads to social and political inequalities. Moreover, several departments and agencies have been held responsible for the execution of IP rights. This fragmentation of the decision -making/authority process presents a challenge for the regulators. A more pluralist strategy towards these issues could promote more effective collaborations, aimed to improve public health and avoiding arbitrary partnerships. Finally, there is evidence that Brazil intends to sign a bilateral trade agreement with the EU. Therefore, it is necessary to monitor how local actors will react to this issue as their preferences and incentives might differ from the Ministry of Foreign Affairs.

Methodology

For the qualitative research, 57 interviews were carried out with decision makers in Brussels, pharmaceutical industries, government representatives and groups of patients, between the years of 2009 and 2010. European Union documents were also analyzed (referring to the international drug trade norms, official resolutions and newspaper articles) between the years of 1990 and 2010. In order to guarantee methodological rigor, this research adopted the following actions:
(i) For the theoretical and methodological guideline there are several studies in international law regarding the execution of IP norms within the EU. These are important in order to understand why and how actors behave within institutional boundaries. The present research intended to answer such questions.
(ii) Studies on interest groups usually deduce the actors' preferences a priori. The present study aimed to investigate the participants' revealed preferences in the process of execution of IP rules within the EU, the places where such demands are expressed and the possible reactions to them.
(iii) The present study used several information sources and attempted to explore both sides of the debate (EU and developing countries/NGOs).

Bibliography

Fonseca, E.M. 2012. Intellectual property enforcement in the EU. In Greer, S. and Kruzer, P. (Org.) *European Union Public Health Policy: regional and global.* London: Routledge