CROSS-SECTIONAL ANALYSIS OF THE COUNTRIES AND CORRESPONDING TRIPS FLEXIBILITIES FOR PHARMACEUTICALS

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ABSTRACT

The TRIPS Agreement enabled countries to use flexibilities to make exceptions to patent rights. The governments can make limited exceptions to patent rights, provided certain conditions are met. The paper examines the use of TRIPS flexibilities to facilitate access to medicines. The right to health and access to medicines for all is imperative. However, the developing nations with the greatest pharmaceutical need also have the least access to them. This paper is intended to draw valuable lessons from the cases of states that have applied for TRIPS flexibility for pharmaceutical patents by analyzing them according to the region, type of flexibility, type of disease, GDP per capita, health expenditure, and government effectiveness. Among the 82 countries covered by the analysis, it was noted that the highest number of applications came from the region of Africa, while the most widely used flexibility was Article 31. Analysis per medical indication shows that HIV/AIDS has the highest number of applications, followed by cancer, while most requests were made under Article 31, followed by Part 7. The explanation is that the diversification of approach to flexibilities is independent of the country's wealth. Our study provides evidence of a correlation between the mean values of Government Effectiveness indicators for countries requesting flexibilities through Part 7 and compulsory licensing. However, a significant difference in GDP per capita values was noted for countries that have applied for Part 7 flexibility. We explained this by type of disease and costs of treatment in applications. The findings suggest that more WTO member states should be encouraged to request flexibilities through TRIPS Agreement and that cross-sectional factors must be considered in further research to define how countries can best use the flexibilities.

Keywords: *TRIPS flexibilities, pharmaceuticals, public health, developing countries, LDCs, patent protection, WTO, GDP*

1. INTRODUCTION

To a great extent, the prices make pharmaceuticals unaffordable for millions across the globe. [1] The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) is the minimum global legal standard for pharmaceutical patents. TRIPS Agreement recognizes a need for flexibility, which allows countries to mitigate the impact of patents due to the high price of patented medicines, epidemics, high mortality, etc. Unfortunately, most countries have yet to make use of it. The use of TRIPS flexibilities for pharmaceuticals can be achieved through Article 30 (Patent exceptions), Article 31 (Compulsory licensing and non-commercial public use), Article 31bis (lack of manufacturing capacities) and Part 7 of TRIPS Agreement (the Least Developed Country transition provisions). According to Article 30, countries may provide exceptions to patent rights under the condition that: 1) the exception is limited, 2) it must not 'unreasonably conflict with a normal exploitation of the patent', and 3) it must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.

Each country, World Trade Organization (WTO) member, has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. [2] The right to include in their patent legislation a provision for use without authorization of the patent holder is stipulated by Article 31 of TRIPS. Article 31, "Compulsory licensing", lists minimum standards that must be included in implementing legislation. This is the crucial TRIPS flexibility. The amendments of the TRIPS Agreement, through the Protocol of Dec. 6 2005, that entered into force on Jan. 23 2017, inserted a new Article 31bis into the Agreement. The primary purpose of the amendment is to waive the domestic supply requirement under Article 31(f). In addition, article 31-bis allows a country to grant a compulsory license to import a particular drug and to export a generic drug to a country that has issued a compulsory license. This way, countries that lack manufacturing capacities can obtain cheaper generic drugs. For the Least-Developed Country Members, there was a transitional period of 10 years in which they were not obliged to apply most provisions of the TRIPS Agreement to enable them to create a sound and viable technological base. This period was extended to Jan. 1 2016, in the case of pharmaceutical patents, under the Doha Declaration on TRIPS. Public Health ("WTO Members must indefinitely extend the exemption for LDCs from the application of TRIPS provisions in the case of pharmaceutical products."). [3] This is because LDCs have low GDP rates as well as low GDP/pc and therefore have a lower level of investment in the health system and prevention of health emergencies. In addition, most LDCs need a better implementation of procedures and regulations and more vital institutions, contributing to their greater need to use flexibility through Part 7. Given the specific needs and requirements of LDCs, and their economic, financial and administrative constraints, the use of flexibility can facilitate the creation of a sustainable technological base in these countries. In addition, amendments to the TRIPS agreement, unanimously adopted by WTO members in 2005, entered into force only in 2017, when two-thirds of member countries finally deposited their signatures. Thus, a WTO agreement was amended. For the first time since this organization's establishment protocol that changes TRIPS is a permanent mechanism to make it easier for economically weaker WTO members to access affordable generic drugs manufactured in other countries. [4] The TRIPS Agreement also allows WTO members to ensure that life-saving drugs are available and affordable for their citizens. In cases where patented drugs have been unaffordable or not widely available, governments may use WTO-compliant compulsory licensing procedures. An additional possibility within the scope of WTO rules is the voluntary licensing of patents and the pooling of intellectual property for various drugs or medical technologies.

2. LITERATURE REVIEW

More than ten years ago, research showed that developing countries are not making full use of flexibilities built into TRIPS to overcome patent barriers, such as compulsory licenses and parallel imports (Smith et al., 2009). [5] But, the newer study (Hoen et al., 2018) found that countries made extensive use of TRIPS flexibilities between 2001 and 2016. [6] In the case of a low or even a medium-income country in which disease affects millions of poor people, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market. [7] The problem of how to mitigate the impact of pharmaceutical patents on the delivery of essential medicines to the world's poor is far from being resolved (Nicol& Owoeye, 2013). [8] Several attempts have been made to limit TRIPS flexibilities to particular diseases, namely AIDS, tuberculosis and malaria, or more generally to infectious public health emergencies (Outterson, 2008). [9] On the other hand, there are also calls for fresh attempts to enact workable legislation that fits within the prescribed requirements of international law without going beyond them (Nicol & Owoeye, 2013). [10] The trend in modern Free Trade Agreements (FTAs) is the introduction of TRIPS-Plus Provisions, which, especially in cases of new obligations in the field of public health-related IPRs, go well beyond the TRIPS minimum

standards and can cause increased costs and disable access-to-medicines to lower-income countries and individuals. [11] There is no easy or low-cost set of policy choices for low-income nations to follow because even a policy choice of accepting bilateral trade deals may damage the collective bargaining leverage of all low-income countries. [12] So reforming the TRIPS regime in pharmaceutical protection may be the only long-term solution for the underdeveloped. Some of the exciting findings suggest that higher patent protection in China compared to India generates negative impacts on the pharmaceutical industries; thus, governments should utilize TRIPS flexibilities and other regimes like price control to offset the anticompetitive effect in designing patent policies. [13] There is also a study that explores the role of South-South regional approaches in overcoming the constraints that they face in implementing the TRIPS flexibilities effectively at the national level for public health purposes. [14] Given this, we aimed to empirically investigate the particularities of the cases per requested flexibility type and the cross-sectional characteristics of the observed countries applying for flexibilities.

3. METHODOLOGY

This research is based on cross-sectional analysis and analysis of the characteristics of countries applying for TRIPS flexibilities for pharmaceuticals. The observed flexibilities refer primarily to different concessions in using protected and registered patents in the pharmaceutical industry. The preparation of data for analysis in this paper required a study of literature reflected in many published papers, books, electronic materials and databases. Also, this paper builds on the previous work of researchers in interpreting and analyzing the work of the WTO related to allowing flexibility for pharmaceutical products. In addition to data analysis and synthesis, datasets have been formed that represent the basis for statistical analysis. For quantitative data analysis, the "R" programming language was used. The theoretical framework is constructed based on literature and the research question: *"How the characteristics of the flexibility type in requested cases and the cross-sectional characteristics of the observed countries connects to applying for flexibilities?"* Based on this research question, we have formed a model as presented below.

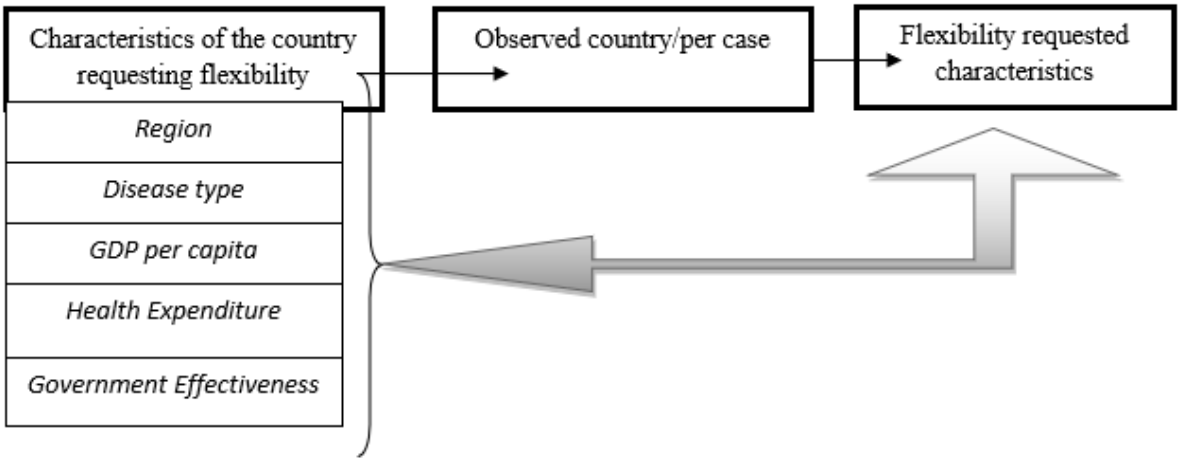

Figure 1: Model of the presented research

3.1. Dataset and analysis

The research framework is represented by countries that have applied for the use of flexibility in the use of pharmaceutical patents (drugs) due to various reasons (drug deficit, high incidence/mortality rate, epidemics, and the poverty rate of the country seeking flexibility). Data collection was gathered for quantitative analysis, as well as constructed from the

databases: Medicines Law and Policy, World Bank, World Health Organization and available literature. [15] The data collected are based on observed cases from 82 countries that have applied for TRIPS flexibility (in a total of 159 cases). World regions group countries according to the World Bank classification: Europe, Africa, Central Asia, North America, Asia & Pacific and Latin America. The time frame for the collected data ranges from 2000-2019 for the entire Dataset (e.g. in 2000, it was applied by Israel as the first case used in the research, while in 2019, it was applied by Kazakhstan, Switzerland and the United Kingdom). In addition, the Dataset also collected data for the type of flexibility applied for by the states on the following legal grounds: Article 30 (Patent exceptions), Article 31 (Compulsory licensing and non-commercial public use), Article 31bis (Lack of manufacturing capacities) and Part 7 of TRIPS Agreement (the Least Developed Country transition provisions). These data include time components relating to when flexibility has been requested, approved or planned for approval for granting access to medicines for public health reasons. Also, data were collected and analyzed for the types of diseases for which the observed state requested a specific type of flexibility. Therefore, data were collected for applications by disease type within the following categories: HIV/AIDS, Avian fly, Bacterial infection, cancer, cardiovascular disease, Covid 19, cystic fibrosis, H1N1 Influenza, HCV, Kidney transplants, Leprosy, tuberculosis, Migraine, Opioid overdose, Prostatic hyperplasia, Rheumatoid Arthritis, Spinal muscular atrophy and type II Diabetes. This paper collected but did not analyze data related to the requested drug. In addition, data were collected for *Gross Domestic Product (GDP) per capita, Current Health Expenditure as % Gross Domestic Product (GDP) and Government Effectiveness* indicator for all of the observed countries. The data are harmonized with the year when the observed state requested certain flexibility for the pharmaceutical product, and thus, a systematization was done for each state and each request. In order to define the variables used in this research, we are providing the definition and the reason for using mentioned variables. According to the definition, Gross Domestic Product (GDP) per capita is the most used economic indicator for assessing comparative analysis of economic performance among countries (in statistical analysis, this indicator is marked as "GDPc"). [16] We also collected data for the *Current Health Expenditure as % of Gross Domestic Product (GDP)*, which represents an essential indicator of the observed countries' investment in healthcare (in the statistical analysis this indicator is marked as "HE"). This indicator shows the total financing of the health system of the observed country concerning the Gross Domestic Product. Of course, the health system can be financed in different ways (e.g. NGO, out-of-pocket, government, etc.), but we wanted to show the total costs concerning the GDP rate to understand the relationship between the economy and investment in the health system. This is especially important regarding TRIPS flexibility requirements arising from specific problems connected with the health system. Another factor that we considered important for the analysis is *Government Effectiveness* (in the statistical analysis, this indicator is marked as "Gov"). [17] This indicator contributes to research when it comes to government-related aspects. Namely, the indicator is prepared by collecting data from numerous sources and qualitative and quantitative assessments. It collects and describes the quality (perceptions of the government's effectiveness), making them available as a numerical value on the universal scale. We considered using this indicator and added it to the list of other factors (related to healthcare and flexibilities) because we wanted to cross-check mutual correlation and the potential impact of this umbrella indicator. Also, there is no evident impact of this umbrella indicator on the statistical analysis as the umbrella indicator shows the perception of the relevant groups on the aspects of interest for this research. This indicator is shown in values from -2.5 (weak) to 2.5 (strong) for the work of the government on the mentioned issues. We believe that such an indicator showing the degree of democracy in the process of adopting new laws and regulations, as well as the implementation of initiatives proposed by the civil sector, also demonstrates the degree of development of

society and its willingness to respond to challenges promptly (including health system challenges). In some cases, this might also lead to public health emergencies and the development of healthcare institutions (including health emergency preparedness level).

4. RESULTS

Out of 139 states signatories to the TRIPS Agreement, 82 sought certain flexibility about pharmaceutical products regarding patent rights. When we observed the number of applications by region, it turned out that 16 requests were forwarded from the region of Europe, 73 from Africa (mainly Sub-Saharan region); in Central Asia, there were 11, North America - 5, Asia & Pacific – 27, and Latin America - 27 (Figure 2). Subsequently, we analyzed according to the type of flexibility requested, resulting in the following: Article 30 - 3 requests; Article 31 - 108 requests; Article 31bis - 1 requests; Part 7 -46 requests; parallel import - 1 request (Figure 3).

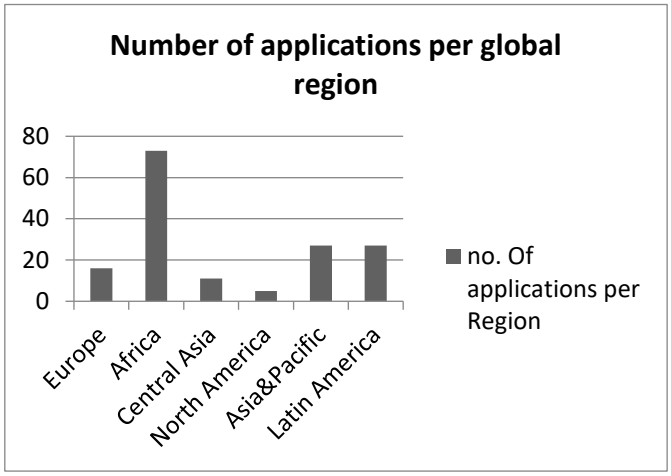

Figure 2: number of applications for flexibilities by region

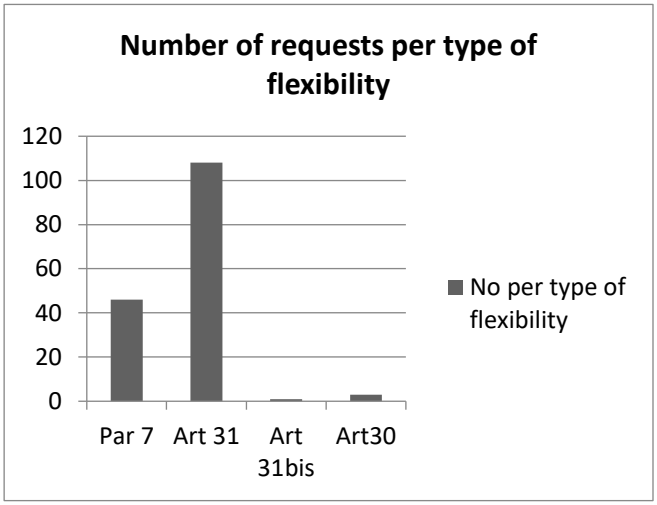

Figure 3: number of requests for flexibilities per type of request

After conducting statistical analysis per medical indication and disease, we established the following results: HIV/AIDS – 110; Anthrax – 2; Avian fly -2; Bacterial infection – 1; Cancer – 14; cardiovascular disease – 1; Covid19 -1; Cystic fibrosis – 1; H1N1 Influenza – 1; HCV – 5; Kidney transplants – 1; Leprosy, tuberculosis – 1; Migraine – 1; Opioid overdose- 1; Prostatic hyperplasia – 1; Rheumatoid Arthritis -2; Spinal muscular atrophy – 1; type II Diabetes – 1; ALL – 12 (Figure 4).

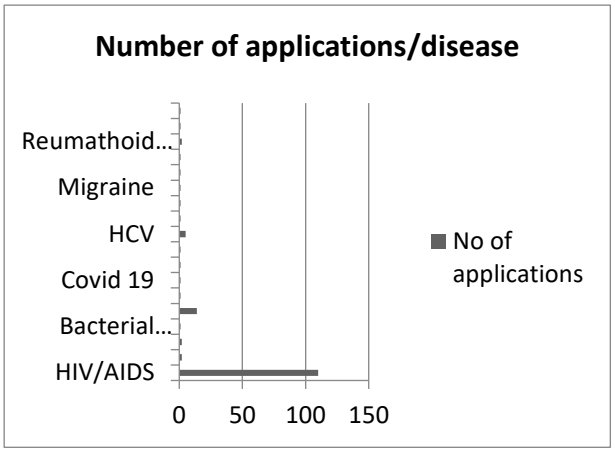

Figure 4: number of applications per disease for requested flexibilities

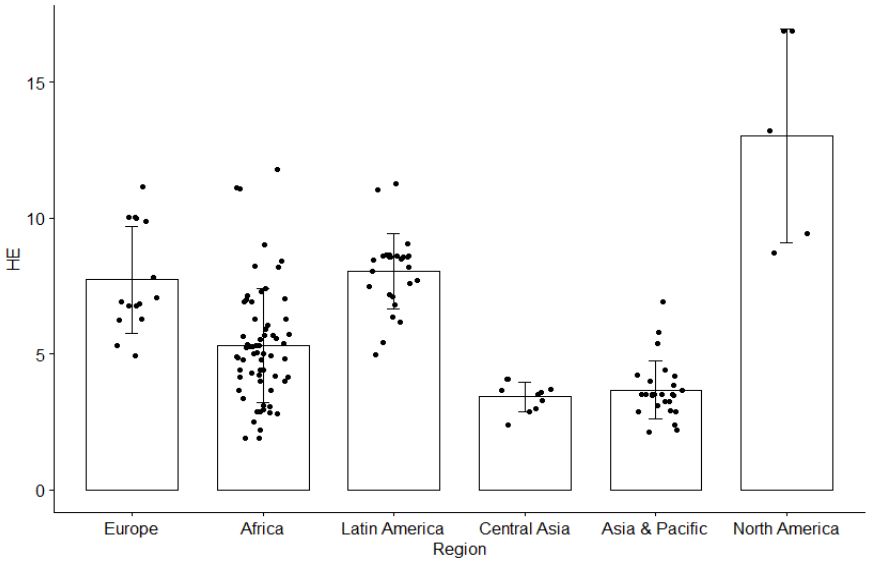

Figure 5: mean SD analysis of countries per region and Heath Expenditure (total)

In the further course of the analysis, we wanted to show the mean values for the observed variables (total) in order to compare them with sectional analysis data later:

mean(Gov)	mean(GDPc)	mean(HE)	range(HE)	range(GDPc)	range(Gov)
-0.312517	6803.782	5.902721	1.9 -16.9	139 -81485	-1.76- 1.92

Table 1: mean values per variable (total)

Also, we have analyzed covariance among observed data, and the results show the expected relationship according to theory. Therefore, we had a positive relationship among observed variables in all cases, indicating positive covariance.

cov(HE, GDPc)	cov(HE,Gov)	cov(GDPc,Gov)	cor(HE,Gov)
20689.17	0.765137	7996.638	0.3386453

Table 2: Covariance results of observed variables

Also, we were interested to understand the impact of different diseases on a country level prompting TRIPS flexibility requests. Most requests have been submitted for pharmaceuticals treating HIV/AIDS, including antiretroviral therapy, as they are considered costly treatments.

We have counted the following types of treatments for HIV/AIDS: EFV/FTC/TDF, 3TC/AZT/EFV. Most HIV/AIDS-related requests (72) were by Article 31 flexibility (Compulsory licensing), while Part 7 was referred to by 32 requests, in addition to 3 requests in line with Article 30. This demonstrates that not all low-income countries are prone to apply for flexibility through Part 7, although it was intended as the Least Developed Country transitional provision. The second largest group of diseases is connected with chronicle non-inflammable diseases – cancer treatments. Within this group, we have noted the following products: Imipenem/Cilastatin, Imatinib, Gemcitabine, Sunitinib, Sorafenib Tosylate, Dasatinib, Imatinib, Pertuzumab, Letrozole, Trastuzumab-Emtansine, Clopidogrel, LPV/r, Lumacaftor-ivacaftor. Analysis shows that the preferred flexibility option is connected with a compulsory license for those drugs. The following Table 3 shows other diseases per flexibility type.

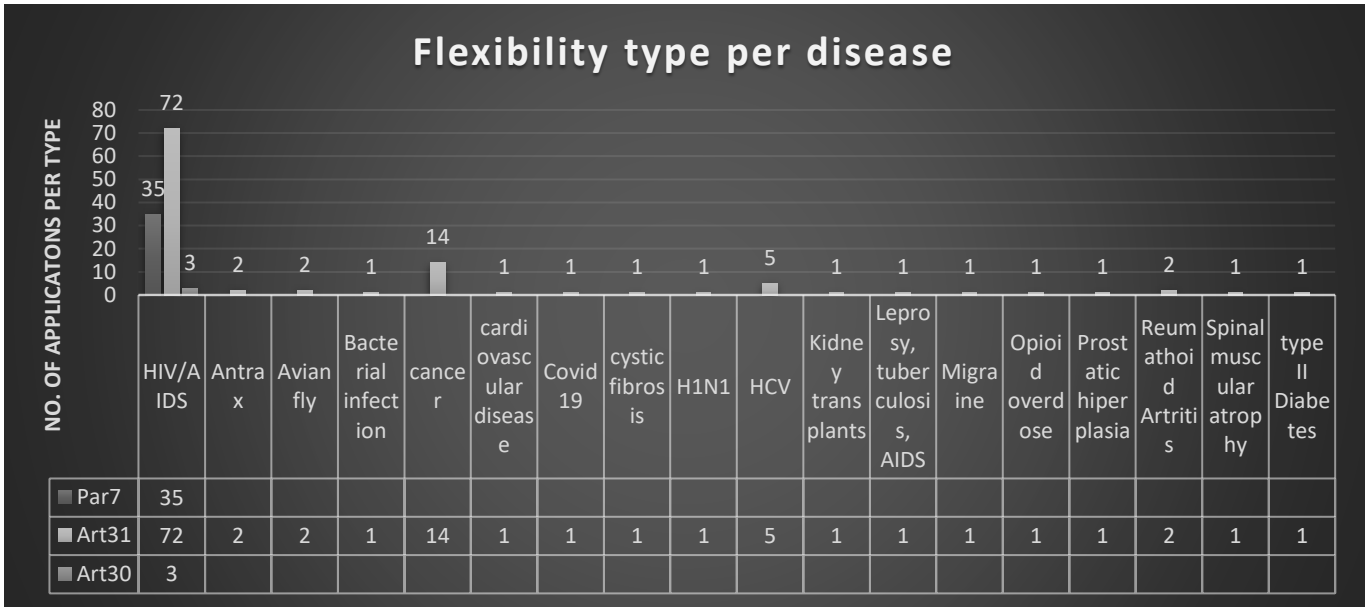

Table 3: Flexibility type per disease

In the following step, we were interested in analyzing the mean and standard deviation in the type-oriented flexibility data required to analyze and present the characteristics of the cross-sectional factors and possible correlations. The Dataset used contains 44 state cases with indicators "Gov ", "GDPc, "HE "per type of flexibility, based on Part 7 flexibility. Also, 101 state cases and cross-sectional context were used for flexibility requirements based on Compulsory licensing (including Article 31bis flexibility). The results of the mean and standard deviation analysis according to the type of flexibility required are as follows:

Mean and Standard deviation per observed variables	**Part 7**	**Compulsory Licensing (article 31 and 31bis (lack of manufacturing capacities))**
Mean (HE)	5.65	6.07
SD (HE)	2.19	2.98
Mean (GDPc)	709.5	9422
SD (GDPc)	536.18	15367
Mean (Gov)	-0.87	-0.9
SD (Gov)	0.44	0.84

Table 4: Statistic analysis of mean and standard deviation of cross-sectional indicators per flexibility type

The results indicate a significant difference in mean values between the two experimental groups. We were interested in showing the influence of various cross-sectional factors that can theoretically describe the general socio-economic and state investment in the health system and the development of institutions, their political independence in terms of decision making and others. Comparing the sample of 44 cases with flexibility requested through Part 7, concerning 101 cases in the second group (compulsory licensing), it became evident that the mean value of the indicator "Gov "- is approximately the same. This is interesting given the difference between predominantly developing countries applying through Part 7 flexibility and the significant covariance between the "GDPc "and "Gov "variables. However, in contrast to the observed factor "Gov ", the "GDPc "indicator differs significantly; in the first group, it is only 709.5, while in the second group, it is 9422. This is explained by the type of disease that caused the health crisis in developed and underdeveloped countries, but also with the required treatment used for a particular disease where correlation is also established. As a result, investments in the health system are at approximately the same level, indicating that international standards recommendations are observed in terms of the level of gross domestic product spent on the health sector. On the other hand, considering the difference in levels of GDP per capita, it shows a clear disproportion between the number of nominal amounts that finance the health system.

5. CONCLUSION

This study analyzes 82 countries, grouped by world regions, which have applied for TRIPS flexibility for pharmaceutical patents in the 2000–2019-time frame. In the quantitative analysis, we used the data for the type of flexibility applied, types of diseases, GDP/pc, current health expenditures, and government effectiveness. Following analysis of the applicant countries, we noted that the highest number of applications came from the region of Africa (predominantly Sub-Saharan Africa) (73), followed by Latin America (27), Asia and Pacific (27), Europe (16), Central Asia (11) and North America (5). Furthermore, the most widely accessed flexibility was through Article 31 (108 requests), followed by Part 7 (46), Article 30 (3), Article 31 (bis) (1), and parallel import (1). Conducted analysis per medical indication shows that HIV/AIDS has the highest number of applications (110), followed by cancer (14) and others (please refer to section Results). After that, we analyzed requests concerning HIV/AIDS in terms of flexibility, and it showed that most of the requests had been made under Article 31 (72), followed by Part 7 (32). We explain this result as a diversification of approach to flexibilities that is not necessarily dependent on the country's wealth status (i.e., Part 7 was initiated as the Least Developed Country transitional provisions). The second largest group of requested flexibilities for cancer treatment analysis shows the dominance of compulsory licensing. Our study provides evidence of the correlation between the mean values of the Government Effectiveness indicator for countries that requested flexibilities through Part 7 and Compulsory licensing. However, a significant difference in GDP per capita values was noted for countries that applied for Part 7 flexibility (LDCs). We explained this by type of disease and costs of treatment in applications. Also, in the same analysis, we confirmed that all countries had a similar percentage of GDP investments in healthcare, from which we can conclude that countries applying for flexibilities consistently follow international guidelines and country-level implementation (considering high GDP level differences among countries). All the above-mentioned findings suggest that several countries requesting flexibilities through TRIPS Agreement show historical growth in international engagement through available procedures, which might benefit those countries and encourage other WTO member states to apply for the flexibilities when needed. Also, it was noted that those countries observe international standards in healthcare investment per GDP and Government Effectiveness. The mean value for Government Effectiveness for all countries was -0.3 (range -1.76-1.92), while the mean Health Expenditure per percentage of GDP was 5.9 (range 1.9-16.9).

On the other hand, the GDP per capita mean was 6803 with high dispersion in rage from 139-81485. In addition, it was shown that Government Effectiveness has approximately the same value in cases of countries that applied for Part 7, compared to the compulsory licensing. Finally, the type of flexibility might be highly connected to specific diseases and medical treatments. The findings suggest that more and more WTO member states are encouraged to request flexibilities through TRIPS Agreement and that cross-sectional factors must be considered in further research to define a better approach so that the countries can take full advantage of the flexibilities. Although African countries are most interested in flexibility, high-income countries from Europe and North America are also interested. Furthermore, procedures and flexibility options should be more accessible to countries with competent advisories due to the procedural complexity, bearing in mind that the type of disease and medical treatment necessary play a vital role in countries' approach to flexibility.

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