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The WTO's compulsory licencing of patented pharmaceuticals: implementation challenges

SUMMARY

The focus of the research is the topic of compulsory licencing, the right under the Agreement on Trade-Related Aspects of Intellectual Property Rights for countries to use patented medicines without the patent holder's consent as a form of relief (flexibilities) for developing countries. The research aims to assess whether the application of compulsory licencing has fulfilled its primary goals and purpose. The research problem is the inconsistency between the compulsory licencing application in practice and the original purpose. It is reflected in the mass use of this right by countries with higher incomes and, secondly, in the symbolic presence of contagious diseases. That was investigated using the Generalized Linear Model. The results confirmed that the actual situation of public health and the income level of beneficiaries had been marginalised as grounds for exercising compulsory licencing. The arbitrary application of compulsory licencing has led to the situation that the poorest countries, with the most significant health crises, remain in the background of this World Trade Organisation mechanism.

Keywords: WTO, compulsory licencing, TRIPS flexibilities, developing countries, intellectual property rights, pharmaceuticals.

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STO prinudno licenciranje patentiranih farmaceutskih proizvoda: izazovi implementacije

SAŽETAK

U fokusu istraživanja je tema prinudnog licenciranja, prava iz Sporazuma o trgovinskim aspektima prava intelektualne svojine, da zemlje koriste patentirane lekove bez saglasnosti nosioca patenta, kao vid olakšice (fleksibilnosti) za zemlje u razvoju. Istraživanje ima za cilj da proceni da li je primena prinudnog licenciranja ispunila svoje primarne ciljeve i svrhu. Istraživački problem je nedoslednost između primene prinudnog licenciranja u praksi i prvobitne namene. Ono se ogleda u masovnom korišćenju ovog prava od strane zemalja sa višim prihodima, i drugo, u simboličnom prisustvu zaraznih bolesti. Istraživanje je obavljeno korišćenjem generalizovanog linearnog modela. Rezultati su potvrdili da su stvarno stanje javnog zdravlja i nivo prihoda korisnika marginalizovani kao osnova za sprovođenje prinudnog licenciranja. Proizvoljna primena prinudnog licenciranja dovela je do toga da najsiromašnije zemlje, sa najkritičnijom zdravstvenom situacijom, ostaju ukraćene za korišćenje ovog mehanizma Svetske trgovinske organizacije.

Ključne reči: STO, obavezno licenciranje, TRIPS fleksibilnosti, zemlje u razvoju, prava intelektualne svojine, farmaceutski proizvodi.

Introduction

In the last decades of the 20th century, the World Trade Organisation (WTO) has made significant efforts to establish a globally recognised system of protection and enforcement of intellectual property rights. As a result of these multilateral initiatives and activities, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed in 1994 and entered into force on January 1, 2005.[4]

One of the fundamental backbones of disagreement among WTO members was the protection of intellectual property in the field of pharmaceuticals. The majority of the world's population has always been unable to afford the most effective medicines and pharmaceuticals, and the TRIPS rules made them even more unaffordable for developing countries. In the late 1990s, this problem made developing countries propose certain flexibilities (exceptions) in the TRIPS Agreement. Partly due to the inability to protect intellectual property rights in international trade and partly due

[4] WTO, "Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement')", Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994.

to humanitarian impetus, the WTO adopted several flexibilities in applying TRIPS to pharmaceutical patents in 2001 under the Doha Declaration.

The most common explanations for TRIPS flexibilities in the literature are "to ensure access to medicines for all"; "to make it easier for economically weaker WTO members to access affordable generic drugs manufactured in other countries"; or "to mitigate the negative externalities of diminished medicines access from cross-country harmonisation of patent protection"; and so on.[5]

There are four different types of concessions for the use of protected and registered patents in the pharmaceutical industry: a) compulsory licencing; b) the Least Developed Country transition provisions (LDCs); c) patent exceptions; and (d) parallel imports. This study focuses on compulsory licencing (CL) as the most commonly used TRIPS flexibility, in addition to the great challenges that arise in its application. In short, CL is a right granted by a state authority to use a patent without the patent holder's consent. CL was conceived to handle health crises, which the WTO would keep under control with strict standards. In contrast, CL has reached enormous proportions.

The research aims to assess whether the implementation of compulsory licencing met the primary goals and purposes that made the WTO adopt this type of flexibility. The justification and purposefulness of the application of CL in this study are assessed qualitatively and quantitatively, seeking answers to the following research questions:

1. Are the rights to CL most often used by developing countries, for which all TRIPS flexibilities were initially intended?
2. Is it used only in situations of a public health crisis?

The first section of the article analyses the main challenges of compulsory licencing–inconsistency between the application of CL in practice and its original purpose. In two separate parts of this section, two problem indicators were analysed. The first relates to the CL mechanism itself and some provisions of Article 31, which do not support developing countries. Second, a preliminary review of the TRIPS database indicated the absence of a health crisis as a ground for CL implementation. Based on the explained problems, two primary hypotheses are formed: the first is that CL is not suitable for developing countries, and the second is that the application of CL is inconsistent with the real presence of the public health situation.

[5] FM't Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V. Hogerzeil, "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016", *Bulletin of the World Health Organization*, Vol. 96, No. 3, 2018, 185–193, DOI: 10.2471/BLT.17.199364; Sanja Jelisavac Trošić, Dragoljub Todić & Milorad Stamenović, *Svetska trgovinska organizacija, životna sredina i sistem zdravstvene zaštite*, Institut za međunarodnu politiku i privredu, Beograd, 2018; Ebenezer K. Tetteh, "Pharmaceutical innovation, fair following and the constrained value of TRIPS flexibilities", *The Journal of World Intellectual Property*, Vol. 14, No. 2, 2011, 202, DOI: https://doi.org/10.1111/j.1747-1796.2010.00415.x.

These hypotheses are tested empirically in the second chapter using a Generalized Linear Model (GLM). The main factors included in research questions are income level and public health crises, as well as health expenditure and governments' efficiency. These four characteristics of countries are set as variables in the empirical model. Quantitative research aims to assess the intensity and direction of the impact of these critical factors on the application of CL.

The third chapter is a discussion of the results obtained. It observes whether the empirical model has proven two initial hypotheses about the inappropriate use of this instrument.

Challenges of compulsory licencing in TRIPS flexibilities

In practice, TRIPS flexibilities were not used as expected. Out of the total of 158 signatories to the TRIPS Agreement, only 82 countries claimed this right from the entry into force of the TRIPS Agreement from 1995 to 2021.

The distribution of requests by regions of the world is expected to follow their level of development. Africa had the most significant number of requests for TRIPS flexibilities (73), followed by Asia and Latin America. However, the number of requests from Europe is not small, as many as 16.[6]

Most of the requests, as many as 110, have been submitted for pharmaceuticals treating HIV/AIDS, including antiretroviral therapy, as they are considered costly treatments. Most HIV/AIDS-related requests (72) were under compulsory licencing.[7] The second-largest group of diseases is connected with chronic non-inflammable diseases—cancer treatments (14). Analysis shows that the preferred flexibility option is connected with the compulsory licence for that type of medicine.

The effects of applying TRIPS flexibilities were primarily assessed positively by the authors, who study these mechanisms collectively. They usually focus on the general idea of access to lower-priced generic medicines without noticing any adverse effects or inadequate implementation.[8] Some of them point to the need for its more comprehensive application to all

[6] Medicines Law & Policy, "The TRIPS Flexibilities Database", http://tripsflexibilities.medicineslawandpolicy.org, 14/09/2022.

[7] Ibid.

[8] Jilian Clare Cohen-Kohler, Jillian Clare, Lisa Forman & Nathaniel Lipkus, "Addressing legal and political barriers to global pharmaceutical access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards", *Health Economics, Policy and Law*, Vol. 3, No. 3, 2008, 229256; Dianne Nicol & Olasupo Owoeye, "Using TRIPS flexibilities to facilitate access to medicines", *Bulletin of the World Health Organization*, Vol. 91, 2013, 533–539; FM't Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V. Hogerzeil, "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016".

diseases, while others cite some internal constraints to implement TRIPS flexibilities and suggest a regional approach as a way to overcome them.[9]

Among TRIPS flexibilities, compulsory licencing is the most commonly used. Contrary to widespread support for TRIPS flexibilities in general, almost all authors researching compulsory licencing evaluate its application as controversial or even harmful. At the heart of most criticisms are the risks of overuse of CL, discouraging investment in innovation in the pharmaceutical industry, decomposing the R&D structure in pharmaceuticals, and leaving only the generic drug market.[10] The possibility of slowing down innovation in pharmaceuticals is not the focus of this research, but it is essential to keep in mind this negative aspect as well.

In addition to criticisms for the risk of reduced innovation, many authors point to controversial and unjustified applications of CL. These articles mainly related to case studies in certain countries or even individual cases and gave plenty of cases of unjustified use of CL. Zolotaryova cites the example of Brazil, where the government has repeatedly used CL as a threat "in order to have stronger bargaining power in their negotiations with pharmaceutical companies".[11] Many articles refer to the Thai government's decision to carry out extensive, multiple compulsory licencing of cancer and heart disease drugs (not included in Article 31). The Thai government excessively used CL as many as 11 times in 2006–2012 (some of them were justified by the real HIV epidemic, but most were not), which has led to much domestic and international controversy. Some authors criticised the government for its decisions, which led to compensation, political conflicts, international pressures, etc.[12] Others praised the exceptional results in cancer treatment, not denying that the whole process was inconsistent with

[9] Kevin Outterson, "Should access to medicines and TRIPS flexibilities be limited to specific diseases?", *American journal of law & medicine*, Vol. 34, No. 2-3, 2008, 279–30; Bryan Mercurio, "TRIPS-plus provisions in FTAs: recent trends", in: *Regional Trade Agreements and The WTO Legal System*, Lorand Bartels & Federico Ortino, (eds.), 2006, Oxford, Oxford University Press, 215–237.

[10] Pier DeRoo, "Public non-commercial use compulsory licensing for pharmaceutical drugs in government health care programs", *Mich. J. Int'l L.* Vol. 32, No. 2, 2011, 347; Daniel D. Kim, "Voluntary licensing of pharmaceuticals: The strategy against compulsory licensing", *Am. U. Intell. Prop. Brief*, Vol. 8, 2016, 63; Tsai-Yu Lin, "Compulsory License for Access to Medicines, Expropriation and Investor-State Arbitration under Bilateral Investment Agreements: Are There Issues beyond the Trips Agreement?", *IIC-International Review of Intellectual Property and Competition Law*, Vol. 40, 2009 123–246; K. D. Raju, "Compulsory v voluntary licensing: A legitimate way to enhance access to essential medicines in developing countries", *Journal of Intellectual Property Rights*, Vol. 22, No. 1, 2017, 23–31.

[11] Vera Zolotaryova, "Are we there yet? Taking TRIPS to Brazil and expanding access to HIV/AIDS medication", *Brook. J. Int'l L*, Vol. 33, No, 3. 2007, 1099.

[12] Richard A. Epstein & F. Scott Kieff, "Questioning the frequency and wisdom of compulsory licensing for pharmaceutical patents", *The University of Chicago Law Review*, Vol. 71, 2011, 71–93.

regulations.[13] As De Roo noticed, "there is a fine line dividing when the practice of issuing compulsory licences is proper and when it will cause disastrous results".[14]

The basis for such an arbitrary interpretation is mainly found in the provisions of Article 31 itself, in which cases the application of CL is justified:

a) When reasonable commercial negotiations have failed;
b) When the compulsory licence is for "public non-commercial use," a condition that is not defined;
c) When a national emergency or other circumstance of extreme urgency has arisen, with the additional explanation that "each Member *has the right to determine what constitutes a national emergency* or other circumstance of extreme urgency".[15]

The first provision left plenty of room for applying CL based on the balance of power between pharmaceutical lobbies and authorities in a particular country rather than the health system's needs. The second and third gave legitimacy to any government to issue compulsory licencing at any time and for any purpose.

Based on the above provisions of the Declaration (2001), the CL justification problem is divided into two segments. The first problem, questioning its justification, is that CL is less used by underdeveloped countries than developed ones; and second, CL is often not justified by a health crisis, nor is the disease cited as the basis for CL contagious. These are two critical research problems, which are further analysed. Separate hypotheses about them were adopted and then subjected to statistical evaluation.

Income level, health expenditure, and compulsory licencing

The frequent application of CL by high-income countries is entirely in line with the content of Article 31. What is this about?

The pharmaceutical companies with the most advanced R&D sectors and the highest innovations are primarily from the most developed countries. In order to distribute benefits more equitably, Article 31 provided flexibility for

[13] Suwit Wibulpolprasert, Vichai Chokevivat, Cecilia Oh & Inthira Yamabhai, "Government use licenses in Thailand: The power of evidence, civil movement and political leadership", *Globalization and Health*, Vol. 7, No. 32, 2011, 1–8; Inthira Yamabhai, Adun Mohara, Sripen Tantivess, Kakanang Chaisiri & Yot Teerawattananon, "Government use licenses in Thailand: an assessment of the health and economic impacts", *Globalization and Health*, Vol. 7, No. 32, 2011, 1–12.

[14] Pier DeRoo, "Public non-commercial use compulsory licensing for pharmaceutical drugs in government health care programs".

[15] WTO, "Declaration on the TRIPS agreement and public health", 5b, 20 November 2001, WT/MIN(01)/DEC/2.

developing countries. CL was used to produce generic drugs, for which the patent belongs to companies from developed countries in the territory of developing countries. But many LDCs could not produce generic medicines of sufficient quality, so they imported generic drugs from other less developed countries with production capacity and that could provide an acceptable price based on CL. The provision of the 2001 Declaration, Article 31(f), stated that CL should be used predominantly for domestic use, virtually closing the possibility of using the benefits of CL for the LDCs that do not have a pharmaceutical industry.

The provision on the use of CL for the domestic market in a few years has led to the demands from high-income countries reaching a larger share in the total CL than the middle and least developed countries. There is a relatively large number of requirements for CL in countries with the most developed pharmaceutical industries: the US, the UK, Israel, Italy (three times each), Switzerland, and Norway.

All this is an indicator for the following hypothesis:

H1: *A country's low income does not increase the likelihood that its government will apply compulsory licencing to pharmaceutical patents.*

Public health crisis and measuring the justification of compulsory licencing

The direct result of the provision that each WTO member "has the right to determine what constitutes a national emergency" are numerous examples of the use of CL for HIV by countries with 0.1–0.3% of registered infected populations (Korea, which is not in any database for AIDS data, then Romania, Pakistan, Mongolia, with less than 500 patients, etc.).

Another, though not very different, problem relates to the use of CL for medicines for diseases not listed in the TRIPS Agreement or Declaration. In the Declaration, public health crises are defined as those "related to HIV/AIDS, tuberculosis, malaria, and other epidemics that can represent a national emergency or other circumstances of extreme urgency." Apart from African countries, with a consistently high number of people living with HIV, there are not many examples of the use of CL for health crises. The use of CL for cancer drugs, as the most common of the "unrecognised" bases for CL, is widespread. In addition, there are numerous examples of CL requirements for cardiovascular diseases (Thailand), rheumatoid arthritis (Ecuador twice), kidney transplantation (Ecuador), diabetes (India), bacterial infection, migraine and prostatic hyperplasia (Italy), cystic fibrosis (the UK), even opioid overdose (the US, pending), etc.[16]

[16] Medicines Law & Policy, "The TRIPS Flexibilities Database".

This preliminary review serves as an indicator for the next hypothesis.

H2: Public health crises do not increase the likelihood of applying compulsory licencing to pharmaceutical patents.

Empirical Model

Data and variables

The data included in the empirical model refer to all 158 TRIPS flexibility cases for which 82 countries applied. Most of the required data were collected from the TRIPS Flexibilities Database and include the type of flexibility, the country that used it, the year in which it was realised, and the disease that is the reason for flexibility.

The TRIPS flexibility types (Paragraph 7, Article 30, Article 31, and Article 31bis) are set as dependent variables in the model. As the goal is to estimate the factors that affect only the request for CL, in the model with the binary dependent variable, CL has a value of 1. In contrast, other types of flexibilities have a value of 0. Their presence is, however, statistically necessary for model construction.

The model includes four independent variables, two of which are categorical (income level and public health crisis) and two quantitative (Government Effectiveness and Health Expenditure).

1. Income level in this model is not a numerical but a categorical variable. Although there are numerous and common ways to present revenues numerically (GDP, GDP *per capita*, GNI, etc.), the numerical indicator is not suitable for this research. A statistical link between a country's economic strength and the use of any health assistance mechanism is expected, but this link is not expected to be linear. Therefore, it is assumed that the statistical significance of belonging to a particular income group is greater than the monetary value of income. More importantly, since flexibilities are realised in different years (there are no time series in the model), incomes from different years for different countries must not be related to the same model. The income level variable refers to the classification of the United Nations according to the GNI per capita criteria.[17] The variable includes the following categories: High-Income (HI); Upper Middle-Income (UMI); Lower Middle-Income (LMI); and Low-Income countries (LI).
2. Due to the overuse of CL, the justification for a public health crisis (PHC) was assessed in each case of its application. This categorical variable is

[17] UNAIDS, "Countries", https://www.unaids.org/en/regionscountries/countries, 22/08/2023.

represented in the model by the binary principle: by 0 when the data show that the disease listed in the Declaration is not prevalent; by 1 when a public health crisis is an objective situation. The following are combined to assess the justification: a) the mentioned definition of PHC in the Declaration that "HIV/AIDS, tuberculosis, malaria, and other epidemics can represent a national emergency or other circumstances of extreme urgency," and b) the TRIPS Flexibilities Database.[18] On this basis, to build an empirical model, CL related to all forms of influenza (H1N1 influenza, COVID-19, and avian flu), anthrax, and SARS, and all applications marked with "all diseases", were rated with 1. On the other hand, the cases of cancer, migraine, rheumatoid arthritis, and kidney transplantation are marked with zero since they do not meet any criteria for a public health crisis defined in the Declaration.

A particular challenge for model construction is evaluating the justification of CL in HIV cases. This is the most common ground for applying CL in a number of cases in countries with a negligible number of patients. The margin of 0.5% infected with HIV/AIDS was determined arbitrarily. This is the lowest margin determined by reviewing epidemic status data in general. A larger (probably more realistic) margin would further emphasise the unfoundedness of many CL cases. All cases of CL related to HIV are shown at zero in countries with less than 0.5%. The number of infected is given in the WHO and UNAIDS databases.[19] The classification of the parameters obtained in this way shows that the number of unjustified uses of CL is higher than justified (67 versus 42).

3. The variable Health Expenditure (HE) implies per capita data, expressed in thousands of US dollars, in the year in which the CL was applied, according to the World Bank indicators database.[20] This is one of the primary indicators of the observed countries investing in healthcare and can indicate the government's need to implement CL.
4. In addition to low income and a lower level of investment in the health system, most LDCs have poor implementation of procedures and regulations. The ability to manage is one of the critical factors in the functioning of any system, including public health. Therefore, another variable is considered: Government Effectiveness. According to the World Bank, this composite indicator includes the quality of public and civil services, policy formulation and implementation quality, the credibility of the government's commitment to such policies, and more.[21]

[18] Medicines Law & Policy, "The TRIPS Flexibilities Database".

[19] WHO, "The number of people living with HIV", https://apps.who.int/gho/data/view.main.22100?lang=en 18/03/2023; UNAIDS, "Countries".

[20] World Bank, "Current health expenditure per capita (current US$)", https://data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD, 29/04/2023.

This is a potentially critical factor in developing healthcare institutions (including the health emergency preparedness level). No hypothesis has been created for this variable, not even an assumption, because the effectiveness of government can be seen as a willingness to manage the health system without flexibilities successfully, but it can also be seen as efficiency in using all available support mechanisms, thus compulsory licensing. The estimation of this variable relies entirely on the empirical model.

The time frame for the collected data refers to the entire period from the introduction of TRIPS flexibilities in 2001 to the latest available data for 2020. All data are harmonised with the year when certain flexibility for the pharmaceutical product has been approved.

Method and research design

Assessing the effects of these variables (countries' characteristics) on the use of CL rights requires constructing an empirical model. The data were structured into a country-by-year-level panel. Regarding the choice of model, this research has special requirements. The dependent variable is binary, while some independent variables are categorical and others are quantitative. Most empirical models imply only quantitative variables (multiple regression and its variants) or refer only to categorical variables (Probit analysis, Logistic regression).

Only some types of Generalized Linear Models (GLM), in particular the standard General Linear Model and Poisson regression, meet all the criteria of this research:

a) They may include categorical or quantitative, fixed or random, crossed or nested variables in the same model.[22] In this case, the possibility of simultaneously including quantitative and categorical variables is very important. Most of the variables in this research could not be presented quantitatively, and those that could (such as income) were categorised into groups.

b) Despite the word linear, these models do not assume a linear relationship between dependent and independent variables. This is crucial because this dependent variable cannot be normally distributed with a constant variance;

c) GLM estimates the probability (maximum likelihood estimation (MLE) instead of ordinary least square (OLS) that a country with specific

[21] World Bank, "Worldwide Governance Indicators", https://info.worldbank.org/governance/wgi/, 14/05/2023.

[22] Alan Agresti, *Foundations of linear and generalized linear models*, John Wiley & Sons, Hoboken, New Jersey, 2015.

characteristics will apply for CL. The probability is significant for this type of research because the goal is not to determine all the factors that affect the application of CL, but "What is the effect of specific factors on the application of CL?"

d) The great advantage of the GLM, although it does not assume a linear relationship between dependent and independent variables, is that it allows "the linear model to be related to the response variable…"[23]

The assumption of GLM is the availability of observations on a set of independent "response variables" Y_1…, Y_n, whose expectations $\mu_1,\ldots\mu_n$ are related to the "explanatory variables" of $x_{1,\ldots,}\ x_k$ through the model ${}_jx_{ij}$

$$g(\mu_i)=\alpha+\beta_1x_{i1}+\beta_2x_{i2}+\cdots+\beta_kx_{ik} \qquad (1)$$

The function $g(\mu_i)$, assumed to be known, is referred to as the "link function" and is one of the most important generalizations of the classical "general linear model" (McCullagh, Nelder 1989). $\beta_1, \ldots, \beta_k$ are unknown parameters, and $x_{i1},\ldots x_{ik}$ are the values of the explanatory variables for the ith response.

In this research, the GLM took the following form:

$$CL = \alpha + \beta1\,(Income\ level) + \beta2(Public\ health\ crisis) + \beta3(Health\ Expenditure) + \beta4(Government\ Effectiveness) \qquad (2)$$

Disaggregating groups of factors into independent variables produced the following model:

$$CL = \alpha + (\beta1*HI + \beta2*UMI + \beta3*LMI + \beta4*LI) + (\beta5*PHC0 + \beta6*PHC1) + (\beta7*HE) + (\beta8*GE) \qquad (3)$$

The GLM was applied using Statgraphics 18 software, which, in contrast to commonly used software, includes the natural GLM's advantage of separate parameter estimation for each category in categorical variables.

Results and discussion

Table 1 summarises the results of fitting a general linear statistical model relating compulsory licencing to four predictive factors. Since the P-value in the first ANOVA table for CL is less than 0.01, there is a statistically significant relationship between CL and the predictor variables at the 99.0% confidence level.

[23] Zhao Yangchang, "Regression", in: *R and Data Mining*, Zhao Yangchang (ed.), Academic Press, 2013, DOI: https://doi.org/10.1016/B978-0-12-396963-7.00005-2, 45.

Table 1. Analysis of Variance (ANOVA) for GLM

Source	Sum of Squares	Mean Square	F-Ratio	P-Value
Model	34.3253	5.72088	8.70	0.0000
Residual	99.3456	0.657918		
Total (Corr.)	133.671			
R^2	31.679%			
R^2 (adjusted)	30.726%			
Standard Error	0.8107			
Mean absolute error	0.6363			

Source: authors

As one of the creators of GLM, McCullagh explains its multiplicative effects resulting from "independence in cross-classified data".[24] That means that the result is not one parameter per variable but a separate parameter for each category. The results are shown in Table 2.

The confidence interval for the coefficients in the model is 99.0%. The ANOVA of coefficients, which was included in the model, showed the high statistical significance of each of the factors at the 99.0% confidence level. The exception is Health Expenditure, which is statistically significant at the 90.0% confidence level (P-value = 0.07).

The variance inflation factors (VIF) are also included to measure the extent to which the predictor variables are correlated amongst themselves (similar to the multicollinearity test in other models). VIF's above 10, of which there are 0, are usually considered to indicate serious multicollinearity, which can significantly increase the estimation error of the model coefficients. According to the results, the model variables are not correlated with each other.

[24] Peter McCullagh & John A. Nelder, *Generalized linear models*, 2nd edition, Chapman and Hall, London, 1989, DOI: http://dx.doi.org/10.1007/978-1-4899-3242-6.

Table 2. Coefficient estimates for Compulsory Licencing

Variables	Parameter	Estimate	F-Ratio	V.I.F.
CONSTANT		1.8106 (0.1603)		
Public health crisis	PHC 0	0.2313*** (0.0761)	8.52	1.3632
	PHC 1	-0.2313*** (0.0761)		1.3632
Income level	HI	0.5216*** (0.1689)	10.93	2.5261
	UMI	-0.0191*** (0.1452)		2.8271
	LMI	0.1570*** (0.1134)		1.7524
	LI	-0.6595*** (0.1248)		2.1027
Health expenditure	HE	0.0163* (0.0137)	0.46	1.0637
Government efficiency	GE	-0.0084*** (0.0033)	6.38	1.6557

*** $p<0.01$; ** $p<0.05$; * $p<0.10$; Standard error in parenthesis.

Source: authors

The obtained parameters for the binary variable PHC confirm the hypothesis that the public health crisis has no impact on the likelihood that the government will apply CL to pharmaceutical patents. PHC1, which indicates the presence of a situation defined by the WHO as urgent, has a negative sign (-0.23). In contrast, the parameter for the absence of an emergency for the disease underlying CL (PHC0) has a positive sign. The statistical significance for this variable is 99% (p-value<0.01). Although the epidemiological situation in many countries was the primary impetus for adopting the Declaration on TRIPS flexibilities, in practice, the state of public health is completely marginalised as a prerequisite for CL in pharmaceuticals.

Concerning the income level of countries exercising compulsory licencing rights, the results support the initial hypothesis that low income does not increase the likelihood that their governments will use CL. Similar to previous findings, the parameters have the opposite sign of the initial intentions of the WTO. For example, model variables show that LI and UMI countries are less likely to apply for CL than HI countries. In contrast, the TRIPS database used shows that LI and especially UMI countries use CL in greater numbers than HI category countries. To reiterate, this is not a simple statistical probability based on the distribution within the realised CLs. The empirical model gives a probability assessment within a framework that

includes all factors. Other listed independent variables are considered, but most importantly, the model includes zero as a dependent variable when the country uses some other TRIPS flexibility. The UMI and LI countries have a negative sign of the parameter because they probably find more convenient mechanisms than CL to supply themselves with affordable medicine (Paragraph 7, for example).

Given the high degree of statistical reliability and relatively high parameters, it can be argued that the application of compulsory licencing within TRIPS flexibilities is not in line with the initial idea of supporting the health systems of developing countries.

The parameters for the UMI and LMI categories are slightly below and above zero. No hypothesis has been set for these two income categories. However, the data show the same tendency as in previous results: both groups of middle-income countries are more likely to apply CL than low-income countries.

In addition to confirming key hypotheses, the research results provide additional information on the impact of health expenditure and government efficiency on the probability of compulsory licensing. These variables were not included in the research question but served as a supplement to the broader picture of the factors that define governments' compulsory licencing decisions. Although without a significant impact, both variables showed statistical significance.

Conclusion

This article has deeply analysed the compulsory licencing of pharmaceutical patents as the most commonly used and controversial type of exception in protecting intellectual property rights. An analysis of the content of the final version of Article 31 has shown that instead of establishing strict protection measures, the WTO left plenty of room for arbitrary interpretation of situations when the use of this right is justified. A review of CL implementation by countries and diseases and a review of articles investigating individual cases of its application have shown that these opportunities are used very often.

Based on these indicators, two hypotheses have been made: neither low income nor a health crisis affects the likelihood that the government will apply compulsory licencing.

They were estimated statistically by designing an empirical model. The general linear model (GLM) method was applied, which estimates the probability (MLE) that a country with specific characteristics uses the right of CL. The model included four independent variables: Income level, Public Health Crisis, Government Effectiveness and Health Expenditure. Since GLM can evaluate separate parameters for each category in categorical

variables, the probability of CL being implemented by high-, middle-, and low-income countries was separately assessed, as was the probability of CL being used by countries with and without a health crisis.

The results (with a statistical probability of 99%) confirmed the assumption that the real situation of public health and the income level of beneficiaries have been completely marginalised as a basis for exercising the right to compulsory licencing.

In terms of the impact of the income group on the choice of CL as a means of purchasing cheaper medicines, the model parameters showed that CL is most suitable for high-income countries. This is not because they use this opportunity more often than other groups, but because middle- and less-developed countries are more likely to opt for other types of TRIPS flexibilities (paragraph 7, for example). Empirical research has confirmed the hypothesis that income level is not an essential factor in the use of CL and the preliminary general assumption that CL is not particularly useful for countries whose health systems need the most help.

The state of public health as a basis for CL is a simple but more severe problem than the previous one. Countries with a stable state of public health are more likely to implement CL than those amid a health crisis. This is the result of an empirical model and a simple statistical distribution, which shows that the number of unjustified uses of CL is about 50% higher than the number of justified cases. This does not indicate a choice of other flexibilities but a direct disregard for the rules of the TRIPS Declaration.

The conclusion that emerges is not so much about the harmfulness of arbitrary application of CL but about the fact that the poorest countries, at the same time with the most significant health crisis, remain in the background of the whole mechanism of compulsory licencing in pharmaceuticals.

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