The Politics of Compulsory Licensing : Electoral Accountability and Regulatory Threat

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Abstract

A burgeoning literature on private regulation focuses on the initiatives set forth by private actors, leaving unexplained how political institution that they belong to shapes their strategic choice. I argue that whether the public, activists and the like, put pressure on the government for regulation renders government regulation more threatening to firms, leading to more private regulation. Using game theory, I show how democratic states signal their willingness to secure public access to medicines, where both legislators and the executive are put under domestic political pressure. To test its empirical implication, I construct a new dataset on compulsory licensing and examine when pharmaceuticals reach licensing agreements against HIV/AIDS. I find that multinational pharmaceuticals license the drugs more voluntarily when democracies enact laws on compulsory licensing. I also find that democracies enact the laws earlier than autocracies as lawmakers meet the demands of the public by holding the executive accountable for limited access to patented drugs. The results illustrate when "political consumerism" breaks down and delineate conditions under which politicians reflect on voter preferences.

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1 Introduction

On December, 2003, the GlaxoSmithKline and the Boehringer Ingelheim, both British and German multinational pharmaceutical companies, decided to license some of patented drugs for HIV/AIDS, known as anti-retrovirals (ARV), to generics companies in South Africa. In 2002, the brand-name drug producers were initially criticized by activist groups in the region, the Treatment Action Campaign and the Generic Anti-retroviral Procurement Project, for charging excessive prices over their ARVs in South Africa. Later on October, 2003, the South African Competition Commission concluded that petitions for compulsory licensing by these advocacy groups had legitimate grounds, and the big pharmaceuticals thereafter decided to voluntarily license their ARVs to local firms in the region before they are forced to do so by the courts or agency (Hassim, Heywood, and Berger, 2007). At the end, the drug price fell more than 50%[1].

In 2006 and 2007, similar trade disputes on HIV/AIDS therapy took place between two US brand-name pharmaceuticals, the Merck and the Abbott Laboratory, and other activist groups in Thailand, including the Thai Network of People living with HIV/AIDS. Despite years of negotiation to bring down the drug prices without issuing compulsory licenses[2], however, the Thailand Competition Commission eventually forced licensing on their products, Efavirenz on November, 2006, and Kaletra on January, 2007 (Ho, 2011). What's interesting about the story in Thailand is that when other transnational advocacy groups, including the AIDS Coalition to Unleash Power (ACT UP) in Paris, supported the movement in Thailand and thereby created an even greater amount of pressure against the Abbott, the company put up with its initial offer and refused to lower its drug prices further during negotiation.

Where does this discrepancy in the dispute resolution stem from? In this paper, I argue that difference in the regime between South Africa and Thailand led to different policy outcome. In

[1] "Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others. (UNCTAD Case Law Database - Intellectual Property and Public Health)", "South African HIV/AIDS groups threaten Boehringer Ingelheim with court action (The Pharma Letter, 2003)."

[2] For more detailed timeline, check "Timeline for US-Thailand Compulsory License Dispute" (The American University Program on Information Justice and Intellectual Property, 2009).

specific, when host governments are democratic, I argue that pharmaceutical companies take a threat to impose compulsory license on their patents more credible, due to domestic political pressure that the executive is put under and how it attempts to meet the demands to win the (re)election. Similarly, legislators in democracies would also respond to the public needs more promptly by making such provision legally available because lawmakers also care about their own (re)election and try to maximize their chance of winning. It is electoral accountability as a domestic political constraint, therefore, that makes the threat of government intervention in democracies more threatening to producers in economic markets than under non-democracies.

Going back to the previous cases, it turns out that Thailand had a coup d'etat in 2006 and its elected prime minister Thaksin Shinawatra was replaced during the trade dispute with US multinationals, making its political regime extremely unstable since then. On the other hand, after Apartheid legislation was repealed in 1991 and Nelson Mandela was elected from the first general election in 1994, South Africa made it clear in its constitution that "the state has a duty to take steps to put in place a legal framework that facilitates access to health care services", and introduced a competition law in 1998 where the Competition Commission was created for the first time. Although compulsory licensing was available in the Patents Act 57 of 1978, legal practitioners find it difficult for NGOs to verify "abuses" of patents in the courts without resorting to agencies monitoring anti-competitive practices in their market (Hassim, Heywood, and Berger, 2007). Indeed, the exercise of power by the South African Competition Commission in 2003 added more credibility to the movements at that time, resolving the conflicts between pharmaceutical companies and activist groups in public access to medicines more peacefully.

Contributions made in this paper can be summarized in two folds. First, although there has been a growing number of research on private regulation in political science across issue areas, ranging from the environmental regulation (Potoski and Prakash, 2005; Prakash and Potoski, 2006*a*) to labor rights and other safety standards in workplace (Greenhill, Mosley, and Prakash, 2009; Malesky and Mosley, 2018; Ahlquist and Mosley, 2021), no research has yet shown how

political regimes could also alter the landscape of private regulation. This is most likely due to the nature of these topics, making it theoretically challenging to distinguish the liberal values that their voluntary programs inherit from domestic political system. In this paper, I overcome the challenges by looking at voluntary decisions made by pharmaceuticals as the liberal values are less intrinsic in public health, compared to other public policy domains. As suggested clearly by the outbreak of COVID-19, dictators and other leaders in authoritarian regimes, such as China and North Korea, closed their border as early as democratic leaders did, out of fear that the infectious disease may endanger the lives of the elites as well as the mass public upon which they thrive. I take this not as an exceptional case of COVID-19, but rather as a general social phenomenon that is common across political systems in the domain of public health.

In so doing, I also address an overlooked problem in the literature on public versus private regulation, endogeneity between the two regulatory frameworks, and conceptualize regulatory threat rigorously, using game theory. Existing findings suggest that firms' voluntary efforts to regulate their behavior affect the policy making process preemptively (Malhotra, Monin, and Tomz, 2019), when Werner (2012) shows how public and private policy makings are interrelated and firms also engage in self-regulation as a response to potential government intervention or social movements by activist groups. This leaves an important theoretical puzzle of which form of regulation then precedes the other and when, calling for our conceptual understanding of what "regulatory pressure" means and under what conditions it operates. While the findings on firms' socio-political environments are well-established (Maxwell, Lyon, and Hackett, 2000; Baron, 2003; Baron and Diermeier, 2007; Vogel, 2005, 2007, 2008; Werner, 2015; McDonnell and Werner, 2016) and the existence of domestic political pressure and its effect on regulation are shown in other institutional setting (Berliner and Prakash, 2014; Berliner et al., 2015), no theoretical framework has been established yet for regime types. Using a signaling game, I show when regulatory threat becomes credible under different levels of domestic political constraint, where legislators reform existing regulatory policies and the executive implements a new one.

To test the empirical implications of my theory, I probe when states enact patent laws on compulsory licensing and also examine when multinational pharmaceuticals voluntarily license their patented drugs. In doing so, I pick one of the most detrimental diseases that brought up public health crisis around the globe in the early 2000s, HIV/AIDS, for the following two main reasons. First, a body of literature on the politics of public health shows how HIV/AIDS crisis fundamentally transformed the way global pharmaceutical market operates (Sell and Prakash, 2004; Elbe, 2006; Ho, 2011; Kapstein and Busby, 2013), making it more qualified to test how political mechanism this paper highlights operates in our real world, while other diseases may also be driven by other economic and physiological factors significantly. Since the early 2000's, there has also been a rise in transnational approaches to increasing public access to medicines for HIV/AIDS, such as the WTO Doha Declaration and the UN AIDS summit, which allow us to isolate domestic politics from other alternative mechanisms in international politics, such as the pressure created by INGOs, for empirical analysis.

I find empirical regularities that are consistent with the theory. In specific, democracies are found to enact patent laws on compulsory licensing earlier than autocracies, and multinational pharmaceutical companies are more likely to reach licensing agreements on patented drugs for HIV/AIDS when compulsory licensing is legally available in democracies. Lastly, I find that democracies are less likely to execute compulsory licensing on HIV/AIDS drugs when multinational pharmaceuticals license more of their medicines to local drug producers in the regions, which remain significant after I use other proxies of regime type and correct the selection bias.

The remainder of this paper proceeds as follows. First, I explain why compulsory license is designed as such. After a comprehensive overview of literature on the forms of regulation and compulsory licensing, I develop a theory, derive some testable hypotheses from it, and describe my empirical strategy, including my data collection process. Lastly, I summarize the results of my empirical analysis and robustness check, discuss about the limit of their implications, and highlight other directions for future research.

2 Patented Drugs: Compulsory or Voluntary Licensing?

Why does the government grant patents to inventors and what are the owners able to do with their patents? On the basis of some criteria for examination, such as novelty and industrial applicability, new inventions are patented by patent offices to reward the inventors' effort to develop new technologies. Once granted patents, the inventors then own the rights to exclude others to use their assets and claim the ownership in case of infringement for a finite duration, whose privatization and under-utilization of scientific knowledge often beget social inefficiency, widely known as "the tragedy of the anti-commons" (Heller, 1998; Buchanan and Yoon, 2000).

How does the government control concentration of market power or scientific knowledge in their economy, due in part to the patent system? To balance the trade-off between the cost of social welfare losses in the present and the benefit of encouraging investments to develop new technologies in the future, every patent office mandates patent applicants to disclose scientific information about their new inventions in a timely manner so that others can reallocate their resources efficiently to develop new technologies or challenge the novelty. Also, if the officials find that existing patents stifle market competition too much, due to their interdependent use in industrial application[3], or pose existential threat to the citizens by charging too high prices, which is often the case for patented drugs, the agencies can force the owners to license their patents without asking for their permission, known as *compulsory licensing*. While compulsory licensing is indeed a form of patent infringement, governments have widely acknowledged its inevitable uses since the Doha Declaration on the TRIPS Agreement and Public Health was adopted by WTO member states in 2001.

When it comes to patent protection in general, a body of research in social sciences finds that states have asymmetric incentives to enforce patent protection. For instance, McCalman (2001), Grossman and Lai (2004) and Chaudhuri, Goldberg, and Jia (2006) find that the costs

[3]This is known as a patent thicket in the literature. For more information, check Shapiro (2000); Lerner and Tirole (2004).

of protection outweigh its benefits among less developed nations who lack innovative capacity, wherein nations from the South reform their patent systems only if there are greater spillover effects of FDI or technology transfer (Helpman, 1993; Branstetter, 2006; Branstetter, Fisman, and Foley, 2006). The patent system remains politically contentious among industrialized countries as well; it incurs an amount of costs in settling the disputes between the owners and users of patents within each country and regulating those who do not exercise the patents as intended, known as Non-Practicing Entities (NPE) or Patent Troll (Bessen and Meurer, 2009; Bessen, Ford, and Meurer, 2011; Bessen and Meurer, 2013).

To this end, the scholarly works identify conditions under which the government executes compulsory licensing and research its effect on social welfare. The less developed, for instance, are found to force licensing more collectively and frequently to boost their innovative capacity while minimizing its backlash to FDI (Bird and Cahoy, 2008), whose success in leveling the playing field in the world economy is thus often viewed as their victory over powerful nations in international politics (Abbott, 2005; Abbott and Reichman, 2007). Other studies find that compulsory licensing over foreign-owned inventions indeed boosts domestic innovation (Moser and Voena, 2012), although it can bring unintended consequences of delays in public access to patented items under certain economic conditions (Bond and Saggi, 2014, 2017, 2020).

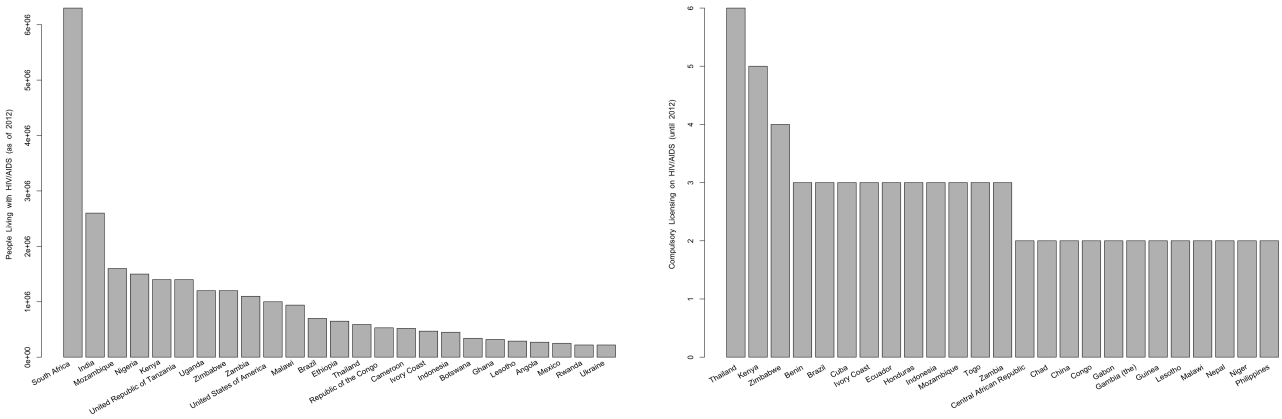


Figure 1: **The Number of People living with HIV and Compulsory Licensing on HIV**

3 Democracy and Regulatory Threat in Public Health

What's critically missing at the intersection of compulsory license and the politics of regulation is that no research program accounts for (1) voters as a beneficiary of government regulation, (2) firms' strategic incentives to comply with government regulation, and (3) domestic political constraints that lawmakers and government officials are subject to, simultaneously. In specific, the aforementioned studies on compulsory licensing in economics and law do not consider how consumers' lack of access to patented drugs, including those of essential medicines, feeds back into the policy making process and how it determines the status quo at the end. On the other hand, while current research in the politics of regulation recognizes the significance of public interests in this process and highlights interactions between the public and private actors, or "political consumerism", but without considering domestic pressure the policy makers receive, under-estimating the effects on their decision making (Druckman, Valdes et al., 2019). Nor does a broader literature on health policy and democracy explain how political systems alter the incentives of health care providers, either (Lake and Baum, 2001; Franco, Álvarez-Dardet, and Ruiz, 2004; Besley and Kudamatsu, 2006; Bhalotra and Clots-Figueras, 2014).

Figure 1 illustrates a gap between what we can derive from the extant theories and what we observe empirically. As of 2012, Thailand is not among the top 10 who suffer mostly from HIV/AIDS pandemics. Nonetheless, it is the one who has executed compulsory licensing most frequently against HIV/AIDS globally as of 2012. When activist groups against HIV/AIDS in Thailand were able to garner support from other NGOs as well, then why was their organized interest not enough to bring more peaceful concession from pharmaceuticals? Why has South Africa never issued compulsory license on pharmaceuticals, despite the fact that it suffered the most from HIV/AIDS? I argue that these puzzles cannot be solved clearly without a holistic approach to domestic politics.

3.1 A Political Theory of Compulsory Licensing

In this section, I introduce a game-theoretic model to delineate conditions under which private actors, such as patent holders in pharmaceutical industry, self-regulate their behaviors. In so doing, I refer to the models of coercive diplomacy in international relations (Schultz, 1998; Kurizaki, 2007; Kurizaki and Whang, 2015) as the way voters and domestic parties render the leader's use of force threatening during international crisis resembles the nature of conflicts between the public and drug companies and how legislators and government officials mediate their relationship during public health crisis (Sell and Prakash, 2004; Elbe, 2006; Ho, 2011; Kapstein and Busby, 2013).

Among the key assumptions is that pharmaceutical companies are subject to what I call *targeted interventions* by the government. Although this assumption sounds counter-intuitive at a glance as there are actually multiple companies who produce medicines in practice, it in fact reflects the very exclusive and proprietary nature of patent system where the government confers power to those who introduce new technologies to society as a reward, selectively. As illustrated in the beginning, however, it is also this endowment of power by the government that calls for more social responsibility and makes individual pharmaceutical more vulnerable to government intervention, which I operationalize in the model. The other assumptions and primitives are discussed in detail as follows, where I parameterize domestic political pressure, assuming that public recipients of patented medicines would want the drugs at a lower price while pharmaceuticals would always favor much higher prices over their exports.

Players, Pay-offs, and Informational Structure

A canonical signaling game with domestic political constraints is described in Figure 2. In this game, three players bargain over the uses of patented drug, whose profit margin is normalized into 1 and distributed to these players differentially at each terminal node. If foreign company F who owns the patent chooses to license the drug before regulator G in country H forces to do

so, then the value is transferred to country H and regulator G shares the profit with a group of legislators L. The ratio of political contributions made by L and G to the outcome is $r : 1 - r$ with $0 < r < 1$. If firm F voluntarily license the product, then there is no extra cost that the outcome entails. But if foreign firm F was compelled to license the patent, then L and G commonly suffer from political cost c_H, which follows uniform distribution with 0 and $\overline{c}_H$ as its lower and upper bounds and is unknown to F. The political cost c_H represents the negative effects of compulsory licensing on the image of country H in the world economy. Similarly, if foreign firm F waits until compulsory licensing is executed, then its pursuit of profit margin at the cost of others, such as limited access to medicines among the public during public health crises, incurs reputational damage c_F to F, which independently follows uniform distribution with 0 and $\overline{c}_F$ as its lower and upper bounds and is not known to L and G. The probability distributions of c_H and c_F, however, are common knowledge to all players in this game.

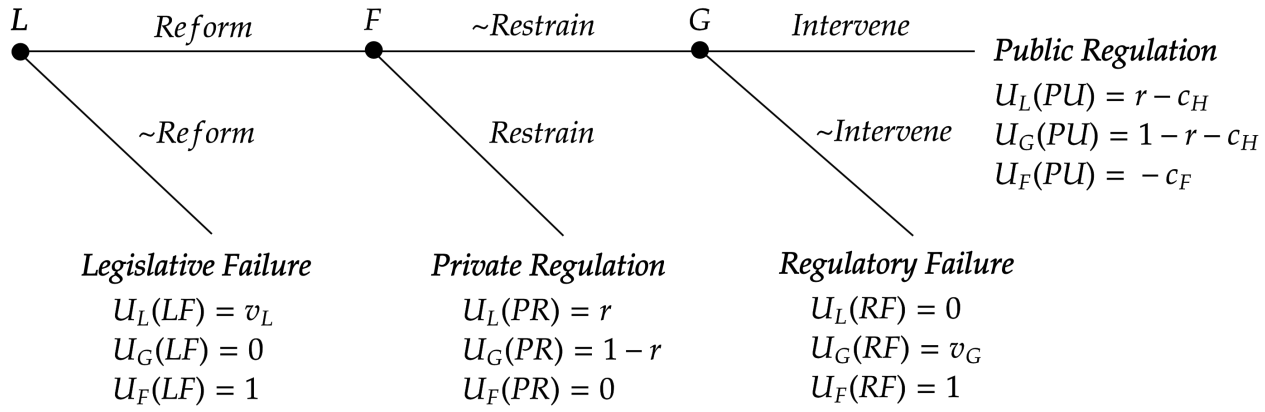


Figure 2: **A Signaling Game with Domestic Political Constraints**

Sequence of Decision Making

The game starts by a group of legislators L in host country H making a policy proposal that allows official G to force licensing out of foreign pharmaceutical F whose exercise of the right to supply patented drug exclusively can impose threat to public health in H. If politicians L

fail to reform the patent law, then their legislative failure is punished by the drug recipients in their districts through v_L and the game ends. On the other hand, if the reform is made successfully, then foreign company F decides whether it keeps producing the drug by itself or lets other pharmaceuticals use its patent to produce the same drugs at a lower price. When the patent owner F decides to share its drug voluntarily with other drug companies, its profit margin diminishes to 0 for the price competition that follows, and the game ends without any political actors in country H paying some political costs. If foreign firm F chooses to maintain its market power by refusing to share its patented drug with other pharmaceuticals, however, then regulator G decides whether it forces the owner F to license its drug at a lower price. If regulator G chooses not to intervene during public health crises, then its policy choice confronts a backlash from the drug recipients among the public, realized under v_G, and the game ends. But if regulator G intervenes and issues compulsory licensing over foreign firm F's drug, then firm F loses its market share by 1 in country H and pays extra domestic political cost of c_F, while policy makers L and regulator G in country H also suffer from international political cost of c_H upon compulsory licensing being executed against foreign investors.

Equilibrium

In the appendix, I show that there exist Perfect Bayesian Equilibria (PBE) in this game, where we end up having either pooling, separating or semi-separating equilibrium, depending on the values of parameters (r, v_L, v_G), but not more than one at the same time. The semi-separating equilibrium is illustrated in Figure 3 in which I use notations α, β and γ to indicate cut-point strategies of G, F and L, respectively. Based on sequential rationality and belief updating criteria of PBE, the cut-points can be written as a function of our parameters, which I express using asterisks. In the semi-separating case, the extent to which foreign firm F perceives regulator G's threat to issue compulsory licenses on its drug credible is characterized by $\gamma^* = \gamma(r, v_G; \beta)$, where β represents F's perception of L's willingness to enact laws on compulsory licensing.

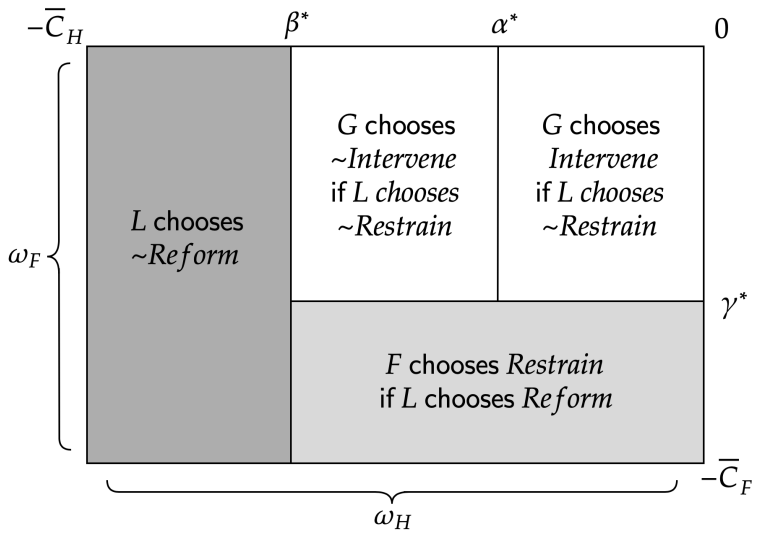


Figure 3: **Perfect Bayesian Equilibrium (PBE) : the Semi-separating Equilibrium**

Proposition 1. *When $r \geq v_L$ and $1-r \geq v_G$, there exists a unique Perfect Bayesian Equilibrium (PBE) to the signaling game with the following cut-point strategies and beliefs. For $\omega_H \equiv -c_H$ and $\omega_F \equiv -c_F$, L chooses Reform if $\omega_H \geq \beta^*$. If L chooses Reform, then F chooses ~Restrain if $\omega_F \geq \gamma^*$, where F's belief that G will choose Intervene is equal to μ^*. If F chooses ~Restrain, then G chooses Intervene if $\omega_H \geq \alpha^* = r + v_G - 1$.*

Corollary 1. *When $\alpha^* \leq \beta$ and $r = v_L$, we have the following separating equilibria.*

$$\beta^* \geq r + v_G - 1, \quad \gamma^* = 0, \quad \mu^* = 1$$

Corollary 2. *When $\alpha^* > \beta > -\overline{c}_H$, we have the following semi-separating equilibrium.*

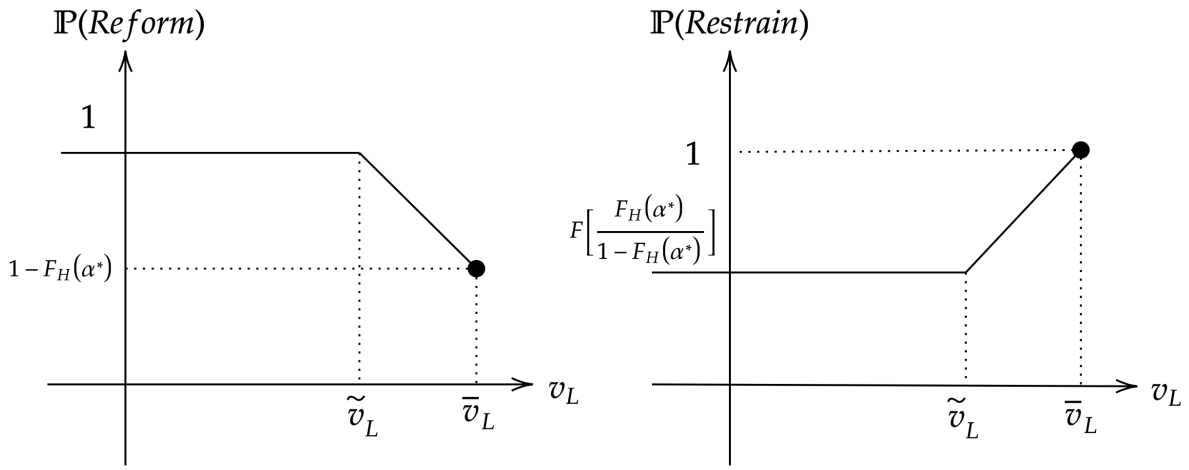
$$\beta^* = F_H^{-1}\left[\left\{1 - F_H(\alpha^*)\right\} \cdot F_F^{-1}\left(\frac{v_L}{r}\right) + F_H(\alpha^*)\right], \quad \gamma^* = \frac{F_H(\beta^*) - F_H(\alpha^*)}{1 - F_H(\alpha^*)}, \quad \mu^* = \frac{1 - F_H(\alpha^*)}{1 - F_H(\beta^*)}$$

Corollary 3. *When $\alpha^* > -\overline{c}_H \geq \beta$, we have the following pooling equilibria.*

$$\beta^* \leq -\overline{c}_H, \quad \gamma^* = \frac{-F_H(\alpha^*)}{1 - F_H(\alpha^*)}, \quad \mu^* = 1 - F_H(\alpha^*)$$

Comparative Statics

The comparative statics analyses are summarized in figure 4, describing how the equilibrium changes when the parameters representing domestic political constraints of legislators L and government official G, v_L and v_G, vary. Three important things to notice about the parametric assumptions stand out. First, the conditions under which PBE exists, $r \geq v_L$ and $1 - r \geq v_G$, illustrate how legislators and the executive respond to the public demand for easier access to medicines *proactively*. That is, it is when the policy makers appreciate their political gains in case of success in regulatory threat, r and $1 - r$, more than their pay-offs in case of the failure, v_L and v_G, that regulatory pressure operates. Next, what makes it credible as a threat depends on attractiveness of the alternatives. If a group of legislators, for instance, forgo their benefit of not being responsive to the needs of their constituents, v_L, regulatory threat becomes more credible as the opportunity cost v_L of reforming the existing policies gets larger. Lastly, when government officials suffer more from being irresponsible for the pandemic, in which case v_G decreases, regulator G is more likely to issue compulsory licenses, and this scenario makes it more profitable for foreign firm F to self-regulate their behavior beforehand.



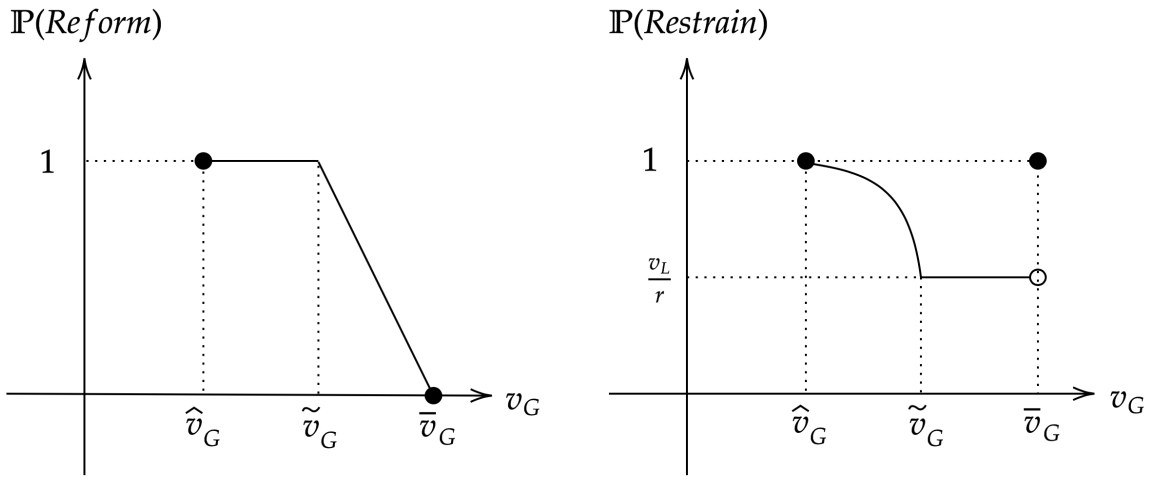


Figure 4: **Comparative Statics : under Greater Public Pressure for Regulation** (v_G)

3.2 Testable Implications

What predictions made in the theoretical model suggest is that the greater domestic political pressure the public can impose directly upon government officials in case of regulatory failure, the more likely it is that (1) foreign firms would license patented drugs voluntarily and (2) legislators would also make coercive policy instruments legally available in their jurisdiction, such as compulsory licensing, whose uses to meet the objectives remain at regulators' disposal. It also follows from the two hypotheses that (3) democratic governments under such domestic political pressure would in fact issue compulsory licenses less often, due to the self-regulation.

What are the means by which public citizens exert direct influence over government officials and legislators? What are the rules for aggregating public preferences on regulatory policies, and how do they affect the way the common interests are represented? A broader literature in international relations commonly points to voting rights and elections as a mediator of the outcome, both economic (Milner, 1997; Mansfield, Milner, and Rosendorff, 2000, 2002; Milner and Kubota, 2005) and military (Fearon, 1994, 1995; Schultz, 1998, 2001), in a number of ways, and it is these features that mark democracy as a distinctive domestic political institution.

How public interests are represented in democracies also helps us better understand why we get regulatory threat working under some policy domains of regulation, but not in the other. Various instruments are available to the public outside of elections, who can still carry their interests without voting, such as boycotting and buycotting for the environmental regulation, and which means are more effective depends on non-institutional factors as well, ranging from the coordination problem between activist groups to the power of public citizens as consumers in economic markets. For public health and drug regulation, however, these non-institutional mechanisms are less likely to be applicable as the general public as consumers must put their own lives at risk in case of boycotting patented medicines that have no substitutes, while for some infectious diseases that can easily transmit to others, like AIDS, collective action problem is less likely to hinder creation of social movements for preserving access to their therapies.

Hypothesis 1. *Laws on compulsory licensing are passed earlier in democracy.*

Hypothesis 2. *Foreign pharmaceuticals license patented drugs more voluntarily when democracies enact laws on compulsory licensing.*

Hypothesis 3. *Compulsory licensing is executed less frequently in democracy.*

4 Empirical Analysis

To test the hypotheses, for dependent variables, first we need congressional archives that fully record how patent laws of each nation have changed until recent years or when its legislature passed the laws. As the previous South African case suggests, this is largely so because some states had put in place compulsory licensing under their patent laws before the World Trade Organization (WTO) embraced compulsory licensing under the multilateral trade agreement on intellectual property (TRIPS) in 1995 and re-emphasized its availability under the Doha Declaration on TRIPS and public health in 2001. For other remaining response variables, one also needs to measure licensing agreements signed each year between pharmaceuticals around

the globe on each disease, or HIV/AIDS in this case, whose information is usually kept highly private. Compulsory licenses have also been issued by each country on various diseases other than HIV/AIDS over the years, such as Tuberculosis, which must be differentiated. Lastly, we need empirical models for hypothesis testing, whose choice must be guided by one's theoretical inquiries and underpinnings.

4.1 Data Collection

To overcome these challenges, I've gathered some information from scratch and constructed a new dataset, while I also referred to other databases available on the websites and combined them together to test the hypotheses. At the end, the final panel dataset has country-year as a unit of analysis, which contains more than 160 countries from 2000 to 2012, including their legislation of compulsory licensing, its issuance on HIV/AIDS over the years, and the number of licensing agreements on HIV/AIDS patents and drugs, signed between domestic and foreign pharmaceuticals and effective in each year.

Legislation of Compulsory Licensing

For each country's legislative activities regarding compulsory licensing, I checked the years in which compulsory licensing was enacted for the first time and the latest date of its amendment from the database[4] administered the World Intellectual Property Organization (WIPO). For ambiguous terminologies used to describe compulsory licensing in TRIPS, such as "reasonable commercial terms" under article 31, the WIPO also provides a summary of how each state has come up with different conditions under which its government can issue compulsory licenses. The contingency plans include whether compulsory licenses can be issued "over non-working patents", "to correct patent abuses", or "for public interest", which differ across jurisdictions and are considered later in the appendix.

[4] The WIPO Lex Database

Execution of Compulsory Licensing on HIV/AIDS

Whether each state has used compulsory licensing in regulatory practice and, if so, when and over which disease have been collected by a group of researchers and lawyers, called Medicines & Law Policy[5]. The center refers to various sources of information to identify each incident of compulsory licensing, including academic journals, media platforms, and technical reports published by governmental agencies. Also, the database contains more detailed information about which pharmaceutical companies were involved, how much were the royalty rates, etc., and the latest information on compulsory licensing over COVID-19 vaccines are also available on the website.

Voluntary Licensing Agreements on HIV/AIDS

Lastly, I use a licensed database to identify all licensing agreements signed between pharmaceuticals between 2000 and 2012. The original database managed by Clarivate™, the Cortellis Competitive Intelligence™[6], spans more than 80000 deals reached between more than 200,000 pharmaceuticals around the globe over a million of patented drugs, granted since 1980 up to date. For each year and country, I select licensing agreements that are signed between domestic and foreign pharmaceuticals as a part of HIV/AIDS therapies, and drop the ones already expired. Firms sign licensing agreements for different purposes, from asset divestment to commercialization and litigation settlement, all of which I subset in my empirical analyses.

Control Variables

It should be noted that each state's legislature also pass the laws for non-political reasons, based on its economic and physiological backgrounds, while multinational pharmaceuticals can also license their patented drugs for purely commercial purposes. It is widely recognized, for instance, that less developed nations usually have a higher infection rate of HIV/AIDS, either

[5] Medicines & Law Policy
[6] The Cortellis Competitive Intelligence™

for their lack of public awareness of or access to contraception, or because their economy as a whole lacks innovative capacity or R&D infrastructures to develop new medicines. To control for such alternative mechanisms that can also drive the same policy outcome, I add a battery of control variables[7] which are widely adopted in the literature, such as the number of people living with HIV/AIDS, GDP, population, and R&D expenditure to name a few.

In addition, I include external supports provided by inter-governmental organizations (IGO) as control variables to take into account other transnational activities that also enhance public access to drugs for HIV/AIDS, such as the initiatives set forth by the UN General Assembly Declaration of Commitment to HIV/AIDS and the Joint Programme on HIV/AIDS (UNAIDS) as well as those guidelines provided by the World Health Organization (WHO). In so doing, I also add the amount of financial resource each country receives from other international non-governmental organizations (INGO) and individual donors as a part of foreign aids as well, including the Global Fund, whose donations make HIV/AIDS therapies more easily accessible.

4.2 Model Specification

For hypothesis testing, I employ different methods, based on how each theoretical prediction could be borne out in our data. In the 1st hypothesis, for example, I use the Cox Proportional Hazards model, instead of logistic regression, as we only observe each legislature pass the law within the timeline of our data (2000-2012) but no laws on compulsory license are abrogated once they become available in each legal system. On the contrary, because compulsory licenses are issued once in a while in practice and lasts for a finite duration, I use logistic regression to test the third hypothesis. Since the number of licensing agreements on HIV/AIDS that are signed between pharmaceuticals and remain effective in each year ranges between 0 and more than 1000, I use linear regression to test the second hypothesis, instead of Poisson regression.

[7]These datasets come from Singer et al. (1972), Barbieri, Keshk, and Pollins (2009), and Pevehouse et al. (2020), while other demographic and physiological datasets are gathered from the Creditor Reporting System (CRS) database provided by OECD, World Development Indicators (WDI) administered by the World Bank, the Global Health Expenditure Database (GHED) managed by the WHO, and the Global Fund website.

In specific, to test whether democracies enact the laws on compulsory licenses earlier than autocracies, I use the Cox Proportional Hazard model as follows, where the proxies of regime type and all other control covariates are *time-dependent* (Cox, 1972; Fisher, Lin et al., 1999). Unlike other models of survival data analysis, including Exponential and Weibull regressions, the Cox model adopts no parametric assumption over the baseline hazard rate $\lambda_0(t)$, allowing for more flexible adaptation[8]. Because our independent variable, political regime type, varies significantly over time and is available in various sources (Marshall, Jaggers, and Gurr, 2002; Cheibub, Gandhi, and Vreeland, 2010; Boix, Miller, and Rosato, 2013; Coppedge et al., 2018) and so does our control variables, it is essential to model the Cox model, using time-varying covariates $X_i(t)$. Since there are no recurrent events taking place throughout the entire period in our panel dataset in which no state repeals compulsory licensing provisions but only enacts the laws, it is also unlikely that the events are correlated within each jurisdiction in our model (Therneau, Crowson, and Atkinson, 2017).

$$\lambda\big(t, X_i(t)\big) = \lambda_0(t) \cdot \exp\Big[X_i(t)^\top \beta\Big] \tag{1}$$

For the remaining hypotheses, I also include country- and year-fixed effects to account for unobservable heterogeneity at each state and year level. For the major independent variables, the proxies for democracy, much of their variation rises across each country and year, and the Hausman tests also confirm this modeling, whose p-values are all smaller than 0.001.

4.3 Results

The results of hypothesis testing are summarized in the following tables, all of which undergird the presumptions derived from the theory. With regard to the first hypothesis that represents legislative outcome in the equilibrium, Table 1 shows that democracies are likely to enact laws on compulsory licensing faster than autocracies, where lawmakers are more easily exposed to

[8]For more information on how the hazard rate has been modeled in political science research, check King et al. (1990), Londregan and Poole (1990), and Warwick and Easton (1992).

domestic political demand among their constituents and thus are more likely to be responsive to the needs for their own political survival. The domestic origin of rule-making remains valid and is statistically more significant than other diplomatic channels by which each country can also alleviate the concern, such as external medical treatments and social campaigns provided by IGOs and INGOs (`HIV/AIDS medical control` and `HIV/AIDS social mitigation`), and the results stay the same when different proxies for democracy are used (`Democracy (polity)` and `Democracy (BMR)`). It should be noted that nations who spend less money in developing new technologies or medicines are more likely to rely other policy instruments, such as compulsory licensing, to boost their innovative capabilities, consistent with Moser and Voena (2012).

	Legislation of Compulsory Licensing		
	(1)	(2)	(3)
Democracy (polity)		0.033***	
		(0.010)	
Democracy (BMR)			0.388***
			(0.115)
Population (log)	−0.085	−0.040	−0.072
	(0.089)	(0.093)	(0.092)
GDP per capita (log)	−0.163	0.101	0.013
	(0.176)	(0.198)	(0.186)
Health expenditure (log)	0.091	−0.153	−0.100
	(0.137)	(0.154)	(0.148)
Trade (imports, log)	0.153	0.101	0.138
	(0.102)	(0.109)	(0.105)
FDI (net inflow, % of GDP)	−0.008	−0.007	−0.007
	(0.008)	(0.008)	(0.008)
R&D expenditure (log)	−0.430**	−0.396*	−0.403**
	(0.204)	(0.211)	(0.203)
HIV/AIDS medical control	0.001	0.002	0.001
	(0.001)	(0.001)	(0.001)
HIV/AIDS social mitigation	−0.042	−0.028	−0.029
	(0.067)	(0.069)	(0.069)
People living with HIV (in millions)	0.037	−0.030	−0.020
	(0.101)	(0.110)	(0.110)
Observations	731	716	726

Note: Robust standard errors are shown in parentheses. *p<0.1; **p<0.05; ***p<0.01

Table 1: **The Effects of Regime Type on Legislation of Compulsory License**

Once it becomes legitimate for government officials to issue compulsory licenses under various circumstances, when do pharmaceutical companies voluntarily license their patents, especially those invented as a part of ARV therapies? Table 2 reveals that it is when democracies enact laws on compulsory license that multinational pharmaceuticals sign more licensing agreements on the drugs with their domestic counterpart. The baseline model under column (1) of table 2, for instance, suggests that, conditional on compulsory licensing being legally available in host countries (`CL legislation` = 1), foreign drug companies are more likely to reach agreements when host countries are more democratic (-0.006 + 0.008 = 0.002). Such interpretation of the interaction effects holds valid when other proxies of regime type are used in column (2) and the results also remain consistent when samples of contracts that are signed only for licensing patented drugs on HIV/AIDS are used in column (3) and (4) for hypothesis testing.

For other control variables, the negative coefficients of `GDP per capita` and `Trade` and the positive sign of `HIV/AIDS medical control` indicate that foreign pharmaceuticals' voluntary licensing activities are mostly concentrated around poor countries, whose economies are more closed to the world economy and thus need to rely more on non-market-based solutions to deal with HIV/AIDS epidemics, such as other external financial supports from IGOs and INGOs. The negative association between the number of licensing agreements on HIV/AIDS and `People living with HIV` reflect profit-maximizing behavior of firms who would prefer their dominant positions in economic markets, unless they are threatened by the government to behave in a socially responsible manner.

Once democracies enact the laws sooner than non-democracies for regulation and foreign pharmaceuticals are thereby pushed by the government to self-control their market strategies, table 3 demonstrates that democracies indeed use their regulatory authority less frequently to increase public access to patented medicines against HIV/AIDS. Similar to the previous two hypotheses, the results are reaffirmed as we start using other proxies for democracy. For the remaining variables, the positive coefficients of `Health expenditure` imply that once nations

reach the point at which their concern about HIV/AIDS pandemics cannot be easily resolved, then the government employs as many policy instruments as possible, whose expenses are no longer substitutable nor mutually exclusive.

	Log(Licensing Agreements on HIV/AIDS + 1)			
	All		Patents and Drugs	
	(1)	(2)	(3)	(4)
Democracy (polity) × CL legislation	0.008***		0.008***	
	(0.002)		(0.002)	
Democracy (BMR) × CL legislation		0.360***		0.359***
		(0.061)		(0.063)
Democracy (polity)	−0.006***		−0.006***	
	(0.002)		(0.002)	
Democracy (BMR)		−0.350***		−0.344***
		(0.084)		(0.087)
CL legislation	0.101***	−0.119**	0.096**	−0.123**
	(0.038)	(0.055)	(0.039)	(0.056)
GDP per capita (log)	−0.189*	−0.219**	−0.190*	−0.221**
	(0.106)	(0.103)	(0.108)	(0.106)
Population (log)	0.050	0.246	−0.008	0.184
	(0.287)	(0.285)	(0.294)	(0.293)
Health expenditure (log)	0.043	0.114	0.044	0.116
	(0.097)	(0.094)	(0.099)	(0.097)
Trade (imports, log)	−0.142**	−0.119**	−0.156***	−0.133**
	(0.058)	(0.057)	(0.059)	(0.058)
FDI (net inflow, % of GDP)	0.003	0.002	0.004**	0.003*
	(0.002)	(0.002)	(0.002)	(0.002)
R&D expenditure (log)	0.003	0.035	−0.024	0.008
	(0.125)	(0.123)	(0.128)	(0.126)
HIV/AIDS medical control	0.004***	0.004***	0.004***	0.004***
	(0.0003)	(0.0003)	(0.0003)	(0.0003)
HIV/AIDS social mitigation	0.002	−0.003	−0.001	−0.006
	(0.015)	(0.015)	(0.015)	(0.015)
People living with HIV (in millions)	−0.920***	−0.897***	−0.920***	−0.898***
	(0.093)	(0.091)	(0.095)	(0.094)
Observations	716	726	716	726
Year FE	YES	YES	YES	YES
Country FE	YES	YES	YES	YES
Adjusted R^2	0.222	0.244	0.209	0.229

Note: Robust standard errors are shown in parentheses. *p<0.1; **p<0.05; ***p<0.01

Table 2: **The Interaction Effects of Regime Type on Voluntarily License**

	Execution of Compulsory Licensing (HIV/AIDS)		
	(1)	(2)	(3)
Democracy (polity)		−1.211**	
		(0.608)	
Democracy (BMR)			−7.697***
			(2.738)
GDP per capita (log)	−9.212	−11.702	−13.826*
	(6.321)	(7.528)	(7.253)
Population (log)	−9.207	2.545	−3.501
	(17.999)	(25.931)	(28.174)
Health expenditure (log)	11.523**	15.814**	16.457***
	(5.781)	(6.486)	(6.231)
Trade (imports, log)	0.016	1.706	2.825
	(3.991)	(4.655)	(4.989)
FDI (net inflow, % of GDP)	−0.216	−0.169	−0.222
	(0.176)	(0.185)	(0.184)
R&D expenditure (log)	0.822	−4.848	1.145
	(6.691)	(8.178)	(7.826)
HIV/AIDS medical control	−0.016	−0.025	−0.034
	(0.020)	(0.022)	(0.024)
HIV/AIDS social mitigation	0.287	0.500	0.506
	(0.395)	(0.407)	(0.421)
People living with HIV (in millions)	−3.805	−3.451	−3.944
	(4.145)	(4.864)	(4.936)
Observations	167	167	167
Year FE	YES	YES	YES
Country FE	YES	YES	YES
Log Likelihood	-42.932	-36.621	-36.817

Note: Robust standard errors are shown in parentheses. *p<0.1; **p<0.05; ***p<0.01

Table 3: **The Effects of Regime Type on Execution of Compulsory License**

4.4 Robustness Check

Apparently, the above results do not provide us with conclusive evidence about the theory for several reasons. Most importantly, while the theory suggests that lawmakers in democracy are less struck by collective action problems when they make the rules for public health, it is not clear whether the aggregate measures of regime type employed earlier capture or represent the mechanism this paper highlights. Indeed, others have shown that "existing measures of political

regimes are significantly different in terms of both their theoretical grounding and operationalization and, for this reason, should not be treated as interchangeable" (Cheibub, Gandhi, and Vreeland, 2010), and democracies do vary significantly within themselves, depending on which institutional aspects one focuses on in terms of aggregating preferences. As long as compulsory licensing is concerned, legal scholars have also found that the provision serves other purposes, depending on who uses it, which is why the World Trade Organization (WTO) has employed ambiguous terms in its draft of the TRIPS agreement, such as "reasonable", to accommodate different interests among its member states in intellectual property protection. Therefore, the mere fact that each country has introduced some laws on compulsory licensing should not be taken as a whole or at face value, but instead one should have a grasp of the context within which legislators bring such provision into their legal system.

In this paper, I conduct robustness checks in response to these concerns, one relating to our independent variable and the other corresponding to our dependent variables. With respect to the first hypothesis, the theory points out the interaction between lawmakers and government officials as a major source of regulatory threat, where the former reform existing policies and the latter implements the new one. In particular, the game was structured in a way that both political actors are better off if firms opt to self-regulate, whereas how much legislators and the executive are worse-off when drug companies choose not to depends on the magnitude of their own constraints, v_L and v_G. In the equilibrium, then the reason why legislative outcomes are also conditional on domestic political pressure imposed only upon regulators was that, having known the situation the authorities will be facing, lawmakers take advantage of their position as the first-mover and strategically decide whether they change the policies in the first place.

What the interdependence between legislators and the executive in policy making process suggests in practice is *checks and balances*, or the separation of power between two branches, where government officials are obligated by constitution to protect public health and legislators hold the executive accountable for its emergency, making potential uses of compulsory license

more likely in democracies. Thus, the theory suggests that legislation of compulsory licensing be taken as an indication of lawmakers' willingness to use their power to achieve the desired outcome and thereby raise the chances of their own political survivals. Table 4 demonstrates how the underlying motives of legislators drive their legislative activities, using several indices that are available in the Varieties of Democracy (V-Dem) project. `Democracy (congressional hearing)`, for instance, represents "the power of summons through which the head of state or head of government could be forced to explain its policies or testify", and other proxies also capture legislative and other bodies' actions against the executive's unconstitutional activities.

	Legislation of Compulsory Licensing		
	(1)	(2)	(3)
Democracy (congressional hearing)	0.113***		
	(0.042)		
Democracy (legislative investigation)		0.164***	
		(0.040)	
Democracy (executive oversight)			0.222***
			(0.044)
Population (log)	−0.070	−0.071	−0.083
	(0.091)	(0.091)	(0.092)
GDP per capita (log)	0.020	0.024	0.023
	(0.189)	(0.185)	(0.186)
Health expenditure (log)	−0.085	−0.102	−0.138
	(0.151)	(0.145)	(0.147)
Trade (imports, log)	0.127	0.122	0.135
	(0.104)	(0.105)	(0.105)
FDI (net inflow, % of GDP)	−0.007	−0.008	−0.010
	(0.008)	(0.008)	(0.008)
R&D expenditure (log)	−0.454**	−0.596***	−0.596***
	(0.203)	(0.207)	(0.204)
HIV/AIDS medical control	0.001	0.001	0.001
	(0.001)	(0.001)	(0.001)
HIV/AIDS social mitigation	−0.038	−0.034	−0.035
	(0.067)	(0.066)	(0.067)
People living with HIV (in millions)	0.018	0.036	0.002
	(0.101)	(0.099)	(0.100)
Observations	725	728	728

Note: Robust standard errors are shown in parentheses. *p<0.1; **p<0.05; ***p<0.01

Table 4: **The Effects of Legislative Constraints on Legislation of Compulsory License**

	Log(Licensing Agreements on HIV/AIDS + 1)	
	All	Patents and Drugs
Democracy (DD) × CL legislation	0.279***	0.271***
	(0.071)	(0.074)
Democracy (DD)	−0.254**	−0.243**
	(0.104)	(0.108)
CL legislation	−0.060	−0.066
	(0.061)	(0.064)
GDP per capita (log)	−0.121	−0.134
	(0.134)	(0.140)
Population (log)	−0.065	−0.128
	(0.468)	(0.487)
Health expenditure (log)	0.054	0.085
	(0.115)	(0.120)
Trade (imports, log)	−0.145*	−0.190**
	(0.082)	(0.085)
FDI (net inflow, % of GDP)	0.002	0.004**
	(0.002)	(0.002)
R&D expenditure (log)	0.119	0.073
	(0.209)	(0.218)
HIV/AIDS medical control	0.003***	0.004***
	(0.001)	(0.001)
HIV/AIDS social mitigation	0.034*	0.022
	(0.020)	(0.021)
People living with HIV (in millions)	−0.948***	−0.862***
	(0.155)	(0.162)
Observations	498	498
Year FE	YES	YES
Country FE	YES	YES
Adjusted R^2	0.087	0.053

Note: Robust standard errors are shown in parentheses. *p<0.1; **p<0.05; ***p<0.01

Table 5: **The Interaction Effects of Electoral Turnovers on Voluntary License**

Following the same chain of reasoning, what lower values of v_G represent for the executive is the chance of government officials being contested by legislature and other political actors. Despite other means by which the stakeholders of public health can challenge the executive, election is by default one of the major tools of influence by which the head of government can be punished and what the authorities mostly suffer from. As issuance of compulsory licenses is one of the available options that the officials can choose from in order to avoid the worst

scenario, whether incumbent can be removed by elections, either by their populace or political parties, should be the driving force above any other institutional features of democracy. This characteristic has been translated into a binary indicator by Cheibub, Gandhi, and Vreeland (2010) that spans 199 countries between 1946 and 2008. Once our panel data is truncated and merged into the Democracy and Dictatorship (DD) dataset, table 5 shows that the results still hold the same. Given that host governments incorporate compulsory licensing into their patent laws (`CL legislation` = 1), foreign pharmaceuticals sign more licensing agreements when an elected official holds the cabinet in destination countries and the rules of electoral competition remain consistent throughout the years (-0.254 + 0.279 = 0.025).

In the appendix, I run additional robustness analyses on our dependent variable, where I categorize each legislation of compulsory license into several classes whose terms and conditions are stated differently. Once the WTO left much room for maneuver by using ambiguous terms, its members have adopted different criteria on which they can invoke compulsory license, some of which reflect more of public interests than private interests. I run the same analyses to test the first and second hypotheses, and find that the results are statistically significant but only for those relating to public interests. In so doing, I also add more control variables, such as inter-state disputes each country is involved in and its other physiological conditions that are relevant for HIV/AIDS, and find that the results stay robust to alternative explanations.

Last but not least, to close the gap between my theory and empirical analysis, I run the Heckman selection model to correct endogeneity bias due in part to selection process between private and public regulation, and find that the results for the third hypothesis still hold the same. In particular, in the selection stage, I find that democracies are more likely to have at least one patented drug for HIV/AIDS voluntarily licensed by multinational pharmaceuticals, wherein democracies indeed have less incentive to issue compulsory licenses on these drugs in the following stage or the outcome equation.

5 Conclusion

This paper complements existing literature on the politics of regulation by introducing a scope condition under which private regulation prevails: political regime type. In so doing, I look at a regulation policy in public health, compulsory license, as its policy domain is most neutral under ideological spectrum, and find that democracies use compulsory licenses less often than non-democracies. As for why, I argue that pharmaceutical companies select into self-regulation more when they export patented drugs to democracies, because otherwise these exporters are more likely to be forced by importing states to merchandise their products at a cheaper price, due to domestic political pressure created upon the products of high salience at destination. I formalize my argument, using game theory, and test its empirical implications on a particular disease, HIV/AIDS, whose epidemic in the early 2000's allows me to control alternative explanations.

The findings of this study open new avenues for future research. To begin with, behavioral aspects of social movements that create domestic political pressure for government regulation are under-theorized. Under what domestic conditions can regulatory threat also break down in democracy, and what determines multinational pharmaceuticals' perception of government intervention to protect public health (Weeks, 2008; Tomz and Weeks, 2013)? Do the general public evaluate legislation and execution of compulsory licensing in the same way as activists do, and how do politicians garner support from the audience for their legislative activities for non-communicable diseases (Kertzer and Brutger, 2016; Brutger and Kertzer, 2018); do public interests still matter in this case?

When it comes to intellectual property and public health, the findings also suggest there is asymmetry between countries in terms of their cost and benefit of using compulsory license for regulation. Then, how are international systems or organizations established in such a way that nations can restore their balance of gains from trade? Can this issue be fully resolved by IGOs even if the strong can exert power over their governance and the issue at hand can be

politicized? If not, then what are the roles of INGOs and other transnational public-private partnership (PPP), such as the Medicine Patent Pool (MPP)? When such institutions do not provide any certificate and drug companies thus cannot brand themselves as a member of the 'club' (Potoski and Prakash, 2005; Prakash and Potoski, 2006*b*), why do some pharmaceuticals commit themselves to the initiatives while others don't, and to what extent are their business activities driven by their normative concern vs. material interests (Sell and Prakash, 2004)?

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