Exploiting Treaty Ambiguity: Public Health Exceptions in the WTO TRIPS Agreement*

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Abstract

Treaty exceptions have long been viewed as essential to the design of international agreements. Yet, agreements also leave "room to maneuver" through the use of constructive ambiguity, that is, by defining treaty terms with deliberately ambiguous words. When are countries more likely to exploit this treaty ambiguity? What does this exploitation look like? We argue that in democratic countries, where states face continued pressures to react to domestic needs, governments are more likely to legislate *unambiguous* circumstances in which they can apply international treaty exceptions. We argue this should be especially true in developing democracies facing external pressure from foreign firms and developed countries to legislate public policy with their external interests in mind. We test our theory in the context of the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and compulsory licensing legislation for HIV/AIDS drugs between 2000 and 2012. We find that when public access to medicines for HIV/AIDS is limited but in high demand, democratic governments are more likely to legislate *explicit* public health protection under TRIPS exceptions, especially in developing countries with high rates of foreign patent ownership. We conclude that such exploitation is most likely when countries seek to prevent precedents by action, or adjudication, that better define constructively ambiguous treaty terms.

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Introduction

In May of 2000, the United States filed consultations with the World Trade Organization (WTO) Dispute Settlement Body (DSB) against two countries in Latin America: Argentina on June 6th (DS196, *Argentina – Certain Measures on the Protection of Patents and Test Data*) and Brazil on June 8th (DS199, *Brazil – Patent Protection*). At the center of the trade disputes were domestic laws both adopted in 1996, one year after the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into force. For Argentina, DS196 largely targeted Law No. 24,481 (as amended by Law 24,572) on Patents and Utility Models, and in Brazil, DS199 focused on Law No. 9,279 on Industrial Property. Both of these laws allowed their respective governments to use patents without authorization from their owners under special circumstances, a practice legally known as compulsory licensing. At that time, the United States asserted that the laws violated Articles 27 and 28 of TRIPS, where WTO members agreed to confer exclusive rights to patent owners. However, TRIPS offered rights to ratifying countries to engage in compulsory licensing under Article 8.2, which states that "appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders."[1] Ultimately, all parties reached mutually agreeable solutions before the DSB issued a formal ruling. However, the ways in which Argentina and Brazil defended their patent laws' compliance with TRIPS were different.[2]

The TRIPS agreement represents a prime example of an international agreement with embedded exceptions, leaving states "room to maneuver" on domestic public policy demands (Hellwig, 2015). Existing international relations scholarship has stressed that treaty exceptions, in the form of "escape clauses", allow states to commit to deeper treaty commitments by defining specific circumstances under which governments can break treaty terms (Rosendorff and Milner, 2001; Koremenos, 2005; Pelc, 2016). However, in this instance, Argentina and Brazil did not

[1]The text of the TRIPS agreement can be accessed at `https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm`.

[2]More information about their mutual agreements can be found in the WTO documents database for both Argentina (WT/DS196/4) and Brazil (WT/DS199/4).

rely on Article 8 as a whole to exempt their domestic intellectual property rights (IPR) laws. Instead, they exploited ambiguity in the treaty terms themselves, enabling both countries to take advantage of the fact that TRIPS did not define "appropriate measures" or what constituted "abuse" of intellectual property rights (IPR) under Article 8.

The patent laws in Argentina stated that any "anti-competitive" practice could be construed as "an abuse of a dominant position"[3] while "non-exploitation of the object of the patent" could also be considered as an "abuse of economic power" under patent laws in Brazil. Because of the ambiguity in Article 8, domestic translations into policy were left to each member state's discretion. Although Article 30 of TRIPS requires that "such exceptions do not unreasonably conflict with a normal exploitation of the patent", for compulsory licensing legislation, in particular, no consensus had been reached either on what "unreasonable conflict" entailed, leading states to provide different conditions for compulsory licensing within their jurisdiction.

Why did Argentina and Brazil interpret the TRIPS exceptions allowing for compulsory licensing differently? Existing research on the design of international law in international relations has argued that countries rely on treaty exceptions more when they impose costs (often in the form of information provision) on countries that use them, making their use more credible to other treaty members (Pelc, 2016). However, the manipulation of ambiguous treaty terms differs: there are no costs to member states like Brazil and Argentina relying on these interpretations. Instead, we argue that countries have adopted domestic laws that *unambiguously* define treaty terms to meet the preferences of their respective domestic audiences, especially when public interest needs are high. They do this while simultaneously avoiding the creation of specific definitions applied to all member states internationally. By avoiding the creation of legal precedent in WTO disputes, or narrowed definitions by treaty amendment, developing countries maintain "room to maneuver" and sustain constructive ambiguity in the original agreement, even if doing so is read as noncompliance by other treaty members.

[3]The exact legal texts are available at the WIPO database for both Argentina and Brazil. Ultimately, the United States and Argentina agreed not to take the mere existence of anti-competitive practices as an illegal trade practice.

We evaluate this argument in the context of IPR law and the HIV/AIDs epidemic between 2000 and 2012 when HIV/AIDS cases were disproportionately concentrated in developing and least-developed countries. We hypothesize that countries with lower public access to medicines for HIV/AIDS are more likely to have governments use compulsory licensing to satisfy their domestic interests. As illustrated by the WTO disputes against Argentina and Brazil, we also conjecture that developing WTO members are more likely to specifically argue in their domestic laws that officials can regulate anti-competitive practices by patent holders through the issuance of compulsory licenses. We argue this should be especially the case when local pharmaceutical producers also have limited access to patented drugs within the region, or the patents depend on each other, allowing patent owners other means to exercise their market power.

To assess our claims, we construct various indicators of domestic access to HIV/AIDS medicines between 2000 and 2012. We primarily rely on the private Cortellis Competitive Intelligence database, which allows us to measure the degree of domestic firm patent ownership on HIV/AIDS-related pharmaceuticals. We regress these measures against a novel measure of domestic IPR laws, and the conditions under which compulsory licenses can be granted, using data from the World Intellectual Property Organization (WIPO) Lex Database. After controlling for other institutional features that can filter domestic political interests, such as the regime type, we find that states whose citizens have more limited access to HIV/AIDS medications are more likely to add "public interest" as an excuse for compulsory licensing during the initial legislation of TRIPS. We also find that developing countries states are more likely to make anti-trust concerns as a rationale for compulsory licensing when more patented medicines are inactive in their domestic markets, and the drugs also require other patents for treatment.

Our findings contribute to two main branches of literature in international political economy (IPE): the rational design of international trade agreements and the politics of international dispute settlement. Early studies on the design of international agreements successfully demonstrate why treaty depth and flexibility often go hand in hand when the trade agreements are

designed (Rosendorff, 2005; Kucik and Reinhardt, 2008; Johns, 2014). More recent studies reveal how domestic political interests provide a link between the two. When international agreements create winners and losers, escape clauses allow states to engage in policies that alleviate distributional consequences (Kucik, 2012; Baccini, Dür, and Elsig, 2015; Bearce, Eldredge, and Jolliff, 2016). We extend the literature on treaty flexibility by highlighting the most general of treaty exceptions in action: constructive ambiguity. We further show how domestic preferences impact how states exploit treaty ambiguity, particularly during public health crises.

Previous research on treaty ambiguity and dispute settlement presumes that tensions between treaty depth (wanting to make more consequential commitments) and treaty flexibility (the need for public policy to address the distributional consequences from such commitments) "is further exacerbated in the case of politically charged issues like health and safety standards, intellectual property protection, or domestic regulation"(Pelc and Busch, 2019, 474). Such studies have argued that the WTO DSB can persuade members and their domestic audiences through the use of affective words in panel reports. What has not been shown yet, however, is whether this persuasion by international tribunals actually assuages negative emotions among domestic audiences toward globalization. Our results fill this void in the literature by showing how *steadfast* the vested interests of domestic audiences can be in such issue areas, especially where WTO adjudication has been limited. We also demonstrate how WTO members have exploited the "room to maneuver" in TRIPS exceptions. We argue that the constructive ambiguity in the treaty has been left vague *by design* in order to accommodate different interests between countries, with active efforts to prevent panel rulings on the topic as a result.

In the next section, we provide a brief overview of constructive ambiguity in international law, and the TRIPS agreement and compulsory licensing in particular. Following that, we introduce our core arguments for the exploitation of treaty ambiguity, the observable implications of our theory, and our empirical strategy for hypothesis testing. Lastly, we present our results and conclude with suggestions for future research.

Designing ambiguous trade agreements

Existing scholarship on the rational design of institutions in IPE has largely characterized treaties in terms of their "depth" and "flexibility." Treaty depth has been defined as those agreements with both increased scope (the number of topics covered) and degree (more stringent and encompassing commitments) (Downs, Rocke, and Barsoom, 1996; Dür, Baccini, and Elsig, 2014). In the context of agreements fostering economic integration between countries, the trade regime has been defined as more "rigid" as a result(Rosendorff, 2005; Johns, 2014). By contrast, treaty flexibility captures all treaty aspects allowing each party to temporarily suspend their obligations under the agreement in the form of escape clauses and exceptions. (Baccini, Dür, and Elsig, 2015; Rosendorff and Milner, 2001).

Studies on the "depth-flexibility" trade-off in international agreements has found that deeper treaties are more likely to have additional flexibility measures, particularly if there is domestic uncertainty over the capacity of states to maintain compliance with treaty terms in the long run(Kucik and Reinhardt, 2008; Baccini, Dür, and Elsig, 2015). The extent to which treaty depth and flexibility vary across international trade agreements depends on the distributional consequences of those treaties (Kucik, 2012) as well as how domestic political institutions aggregate their trade policy preferences (Baccini and Urpelainen, 2014; Baccini, Dür, and Elsig, 2015). Bearce, Eldredge, and Jolliff (2016) have also shown how change in the international trade regime depends on how restrictive the conditions for treaty "escape" are.

Other scholars have also highlighted a broader form of treaty flexibility in the form of "constructive ambiguity," defined as "the deliberate use of ambiguous language in a sensitive issue area to advance a negotiation" (Konken, 2022). A clever play on words, or the use of open-ended terms, is often deployed by treaty negotiations to loosen firm commitments. By doing so, parties to an agreement can leave a negotiation with different interpretations of a specific commitment, reconciling what would otherwise be irreconcilable preferences (Conti, 2008; Koremenos, 2013). Also referred to as "equivocality" by scholars of international negotiation, treaty language of this

kind allows parties to "pretend to agree even where they disagree" (Iklé, 1967, 15). Historical accounts of the founding of the General Agreement on Tariffs and Trade (GATT), in particular, have noted how preliminary drafts of the 1942 Mutual Aid Agreement between the United States and the United Kingdom failed to "specify the precise terms (under) consideration," while "governments clung to different interpretations of what had been agreed to" (Irwin, Mavroidis, and Sykes, 2008, 21).

While treaty flexibility is often measured by a count of the number of specified escape clauses in an agreement, constructive ambiguity is inherently contextual and based on the specific words used to define the commitments, and even exceptions, themselves. In constructing the continent of international law (COIL) data set, Koremenos (2016, 160-161) defined treaty precision as the "exactness or vagueness of its prescribed, proscribed, and authorized behaviours" while simultaneously noting that there was no agreed-upon way of measuring constructive ambiguity in the field. Extant studies have widely adopted a dictionary approach to measuring treaty ambiguity, where a bag of words representing positive or negative sentiments (Pelc and Busch, 2019) or having more precise meanings (Gastinger and Schmidtke, 2022) are used as a reference point to check how they are distributed across an agreement.

Constructive ambiguity clearly exists and is consequential, yet scholarly efforts have remained limited with regard to measuring the degree of ambiguity in specific treaty terms, particularly in a way that takes into consideration the context. There also remains limited research on how states specifically engage with treaty ambiguity after the agreement has been ratified. While constructive ambiguity is recognized as a means to preserve conflicting policy preferences, whether those conflicting preferences are ultimately realized is unclear. We build on this scholarship by developing a theory of when and how countries are more likely to exploit treaty ambiguity in the context of the international trade regime.

Theory: exploiting treaty ambiguity

A substantial body of literature on international trade law highlights the role of adjudication and legal precedents, wherein states have turned to international dispute settlement mechanisms to determine the meaning of treaty commitments (Bhala, 1999; Pelc, 2014). When multilateral negotiations in the WTO became deadlocked in 2001, scholars noted that member states, including the United States, *de facto* delegated treaty interpretation to the WTO DSB (Goldstein and Steinberg, 2008). Countries learned the benefits of WTO adjudication through participation, enabling states to manage domestic political issues more efficiently (Davis and Bermeo, 2009; Davis, 2012). How far states pursued trade disputes depended on the values of precedents created in each step, which in turn depended on who participated in a dispute and how far the precedent could diffuse to other member states (Busch and Reinhardt, 2006; Busch and Pelc, 2010; Pelc, 2014; Johns and Pelc, 2014, 2016, 2018). Wüthrich and Elsig (2021) have recently shown that states' experience in WTO litigation indeed affects how preferential trade agreements are designed thereafter. However, the ability of the WTO DSB to adjudicate cases, or offer interpretations of ambiguous treaty terms in panel reports, is dependent on states bringing disputes to the institution and not settling the matter before a report is circulated to members. On sensitive topics, such as the TRIPS agreement, disputes have not progressed to panel reports (Pauwelyn, 2010). Given the WTO DSB is not adjudicating meaning on many constructively ambiguous terms, how then can states "persuade their domestic audiences of the legitimacy of compliance"? (Pelc and Busch, 2019).

Countries can exploit ambiguous treaty terms under international trade law by applying *unambiguous* domestic laws, thereby preserving their preferred interpretation of a treaty and maintaining compliance internationally. Absent adjudication, treaty amendments or mutual understandings, the constructive ambiguity embedded in the international agreement also persists. By ratifying more explicit domestic laws on international treaty commitments, states are also better able to satisfy the preferences of their particular domestic audiences. In this regard,

constructive ambiguity functions exactly like a traditional escape clause, however, unlike escape clause use that imposes costs on the user through contingency or compensation, the exploitation of ambiguous treaty terms signals to other member states compliant noncompliance(Pelc, 2016).

Under what conditions are states more likely to exploit treaty ambiguity in this way? For countries ratifying new international commitments that impose foreseeable limitations on their right to regulate domestic policy issues, state autonomy can be preserved by ratifying domestic legislation that more precisely defines when states can break treaty terms. This is especially likely for democratic countries, where leaders are highly responsive to their constituents to stay in power. For developing countries, the desire to maintain state autonomy over domestic regulation and public policy is faced with additional challenges from powerful countries and multinational corporations (MNCs). Noncompliance with treaties signed with advanced developed democracies like the United States can carry high costs in the form of disputes or retaliation. In such situations, more developed, advanced economies stand to benefit from their increased wealth, and, thereby legal capacity (Bown, 2010).[4] For policies that disproportionately affect multinational corporations (MNCs), there is the added risk that escape clause use may be challenged via trade or investment dispute settlement procedures by a specific firm. Such was the case with Phillip Morris International pursuing disputes against Uruguay and Australia when they introduced plain packaging laws to reduce cigarette purchases (Hartmann, 2017).

For developing countries with open economies, MNCs can exert disproportionate power over policy-making simply by threatening disputes that create liabilities for policymakers (Moehlecke, 2020). In instances where MNC or external influence may specifically challenge treaty noncompliance because public policy may threaten their interests, exploiting constructive ambiguity offers developing democracies the best of both worlds: it offers means to appease domestic audiences while offering a valid interpretation of international commitments. Should disputes occur, however, it would be against the interest of both the developing and developed countries for a panel

[4]While the WTO established the Advisory Center on WTO Law wherein low legal capacity countries can receive assistance preparing disputes, scholarship still acknowledges the gap between developed and developing country participation in the WTO DSB. See Bown and McCulloch (2010).

ruling to be issued: doing so threatens to offer precision to treaty terms that, if fully defined, would not be mutually accepted. Given developed democracies also seek to ratify their preferred interpretation of ambiguous treaty terms, disputes will likely be limited in nature.

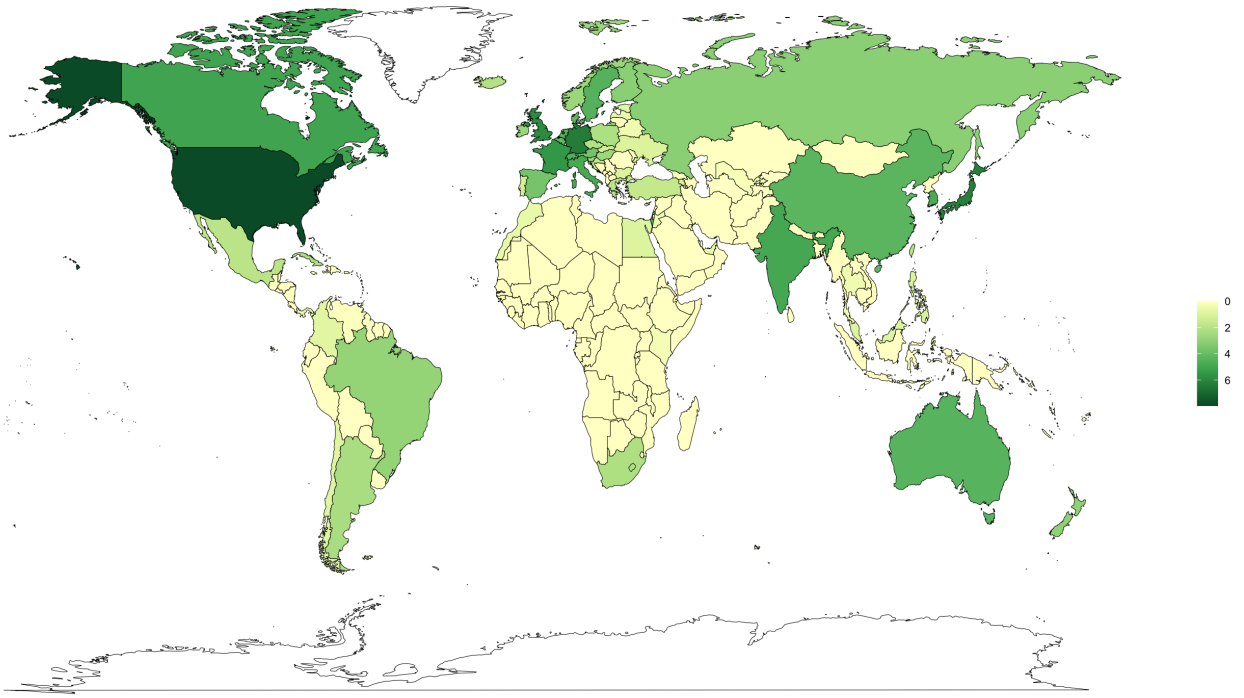
These theoretical developments offer us two theoretical claims, and two scope conditions. First, democracies are more likely to domestically ratify precise interpretations of ambiguous international treaty terms, enabling them to respond to domestic preferences. Second, developing democracies are especially likely to ratify these precise interpretations when developed countries and MNCs have vested interests in their domestic market. We expect such state actions to be possible only when constructive ambiguity exists in treaty terms, and when negotiations or adjudication are not viewed as a preferred means to define treaty terms.

Domestic Interests in Patented Medicines for HIV/AIDS and the WTO TRIPS Agreement

To test how our theoretical expectations are borne out empirically, we assess the exploitation of constructive ambiguity in the WTO TRIPS agreement in the context of the HIV/AIDS epidemic between 2000 and 2012. We do so because of the high degree of constructive ambiguity in the TRIPS agreement, and urgent public access needs for newly patented medicines during the epidemic. Upon signing TRIPS in 1995, many developing countries committed to establishing the necessary domestic offices and laws to honour patent protections within their national boundaries for the first time. In doing so, countries such as Thailand, India and Brazil rapidly saw pharmaceutical corporations requesting patent protections for newly developed anti-retroviral therapies (ARTs), evidenced in 1. We assess whether and how countries exploited ambiguity in the TRIPS agreement to respond to domestic pressures for access to generic patents.

In 1994, over 100 countries signed the TRIPS Agreement as part of the Uruguay Round negotiations that saw the General Agreement on Tariffs and Trade (GATT) evolve into the WTO on January 1st, 1995. Like other multilateral trade agreements administered by the WTO, the

Figure 1: **International Patent Application of Medicines : A61K (log, PCT, 2002)**

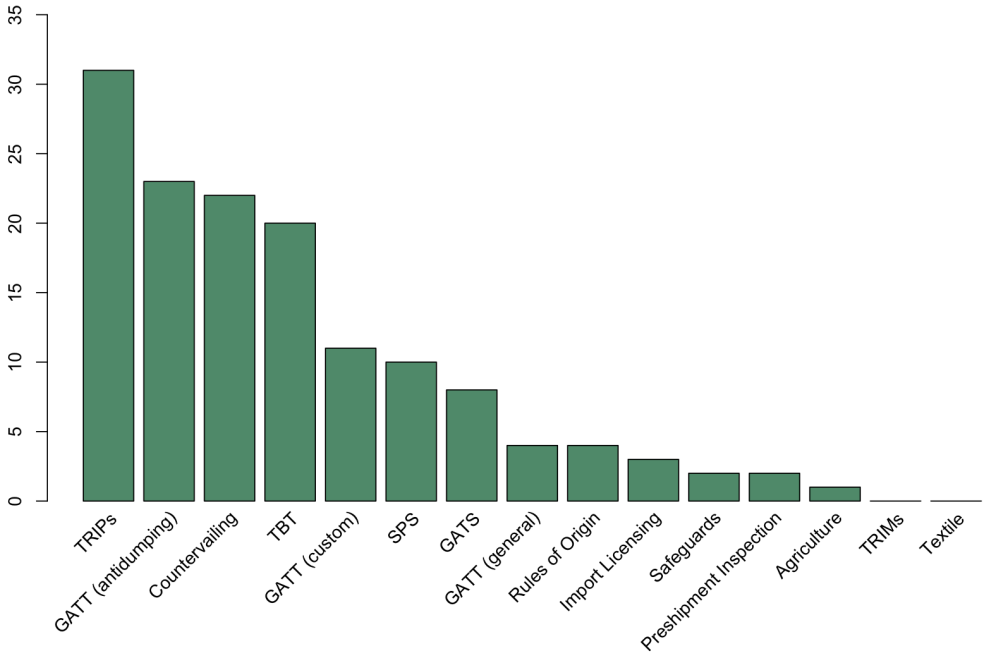


TRIPS agreement can be understood through the lens of depth and flexibility.[5] TRIPS required signatories to extend the term of protection for patents and copyrights up to twenty and fifty years, respectively. Since most patents for modern technologies were owned by multinational companies from the Global North at the end of the 20th century, however, the standards were certainly more than minimal in the eyes of developing and least developed countries (LDCs). As most parties negotiating the TRIPS agreement had competing interests over the scope and definition of intellectual property rights (IPR), negotiators leaned into the use of constructive ambiguity to come to an agreement. Excluding IPR from the Uruguay Round negotiations was non-negotiable. Negotiating parties also agreed to staggered deadlines for TRIPS ratification.

The high degree of constructive ambiguity in TRIPS relative to other WTO agreements is evident in Figure 2. TRIPS relies frequently on open-ended legal terms, such as 'reasonable' or

[5]For other theoretical perspectives on TRIPS, such as those of constructivist, see Sell (1995) and Sell (2003). For more comprehensive overview of TRIPS and TRIPS flexibilities, see Deere (2009) and Syam (2022).

Figure 2: **The number of word 'reasonabl' appearing in WTO trade agreements**



'abuse', which offer "some scope for interpretation and 'reading between the lines' when it comes to implementation" (Deere, 2009). Given this high degree of ambiguity in the TRIPS agreement, it is a most likely case where states have the opportunity to exploit treaty terms.

Yet, in the same period that TRIPS was ratified, many of the countries negotiating in the Uruguay round faced immense public pressure to provide free access to life-saving ART patents to foster access to generic medicines. HIV more frequently affected the poorest and most marginalized groups in society. The cost of ARTs on an annual basis often exceeded the lifetime incomes of the infected. The situation was a catch-22: forcing pharmaceutical companies to provide access to generics would break newly signed commitments under TRIPS and potentially harm critical research and development into essential medicines, but not doing so would leave millions of people worldwide to die simply because they were poor.

Existing research on the politics of public health and TRIPS provides ample evidence on how limited access was to patented drugs for HIV/AIDS in developing countries and LDCs in the early 2000s (Hoen, 2002; Abbott, 2002, 2005; Abbott and Reichman, 2007). In 2000,

only 1 in 1000 people living with HIV in Africa had access to ARTs (Ho, 2011). At the time, azidothymidine (also referred to as retrovir, zidovudine or AZT) and Lamivudine (commonly referred to as 3TC) had only been available since 1986 and 1995 respectively, yet they were the most commonly prescribed ARTs. In early 2001 the cost for both ranged between $10,000 and $15,000 US dollars a year depending on the required dose (Boseley, 2001). At a cost of $7.30 a dose in some countries, general publics the world over began to question the source of the pricing problem (Boseley, 2001).[6] In doing so, many countries turned to TRIPS and the patent protections it provided to pharmaceutical companies developing new drugs.

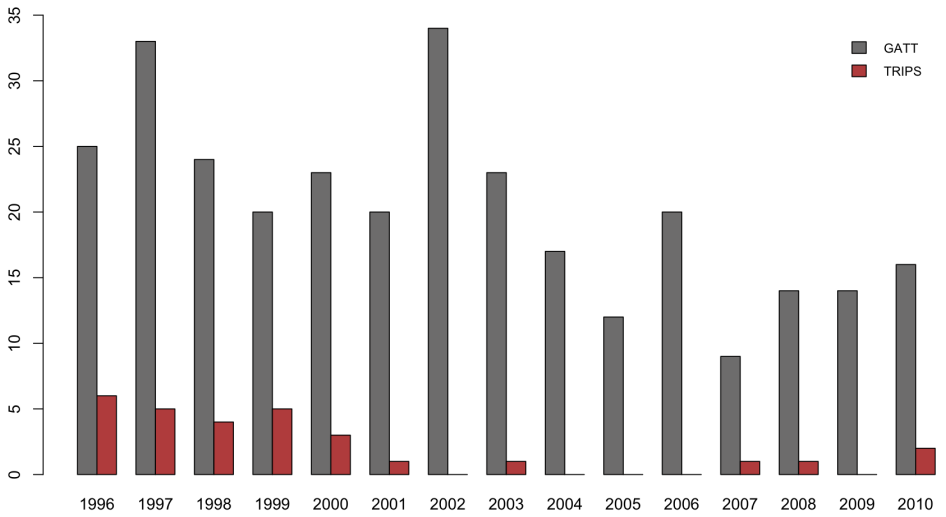
The conflict of interest between drug recipients and MNCs culminated in American trade disputes with Argentina and Brazil in 2001 and Thailand from 2006 to 2009, when major drug companies, including Abbott Laboratory from the United States, faced political protests created by some non-governmental organizations (NGOs) and civil society in Latin America. In all three countries, governments had tried to meet public demand for ARTs by issuing compulsory licenses on many HIV/AIDS drug patents.[7] As Figure 3 shows, however, actions regarding the interpretation of patent protections under TRIPS were not filed with the WTO DSB after 2001, and the three disputes settled before rulings could be issued. This resulted from Bill Clinton issuing a moratorium on American-led disputes against compulsory licensing policies for HIV/AIDS drugs, and WTO member states signing the Doha Declaration on TRIPS and Public Health that year, avoiding the need for a panel report's interpretation.

As to why the US trade disputes on compulsory licensing by other developing countries and LDCs were filed, we argue that the conflicts were rooted deeply in how nations had taken advantage of constructive ambiguity in TRIPS exceptions domestically. Specifically, TRIPS required all member states to develop policies for non-voluntary licenses and contingency plans

[6]The International Medical Products Price Guide notes that in 2001, a combined 3TC/AZT dose cost roughly $7.31 US despite costing roughly $0.30 to produce. In 2003 this would drop to an estimated 0.77 price for buyers. See more at `http://mshpriceguide.org/en/single-drug-information/?DMFId=457&searchYear=2001`.

[7]After the trade disputes on compulsory licensing, a number of transnational initiatives, both inter-governmental and non-governmental, were established to enhance access to patented medicines for HIV/AIDS but without excessive reliance on compulsory licensing, including the Global Fund and the Medicines Patent Pool (Hoen et al., 2011; Kapstein and Busby, 2013)

Figure 3: **The number of complaints filed to the DSB : GATT 1994 vs. TRIPS**

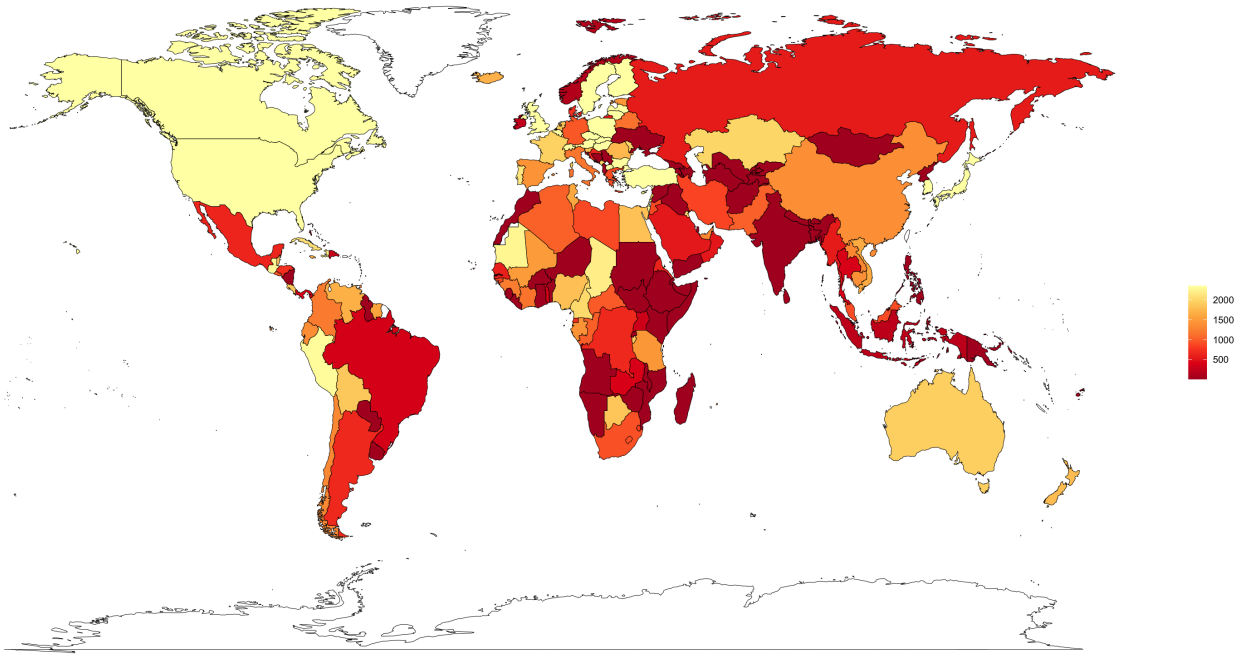


for their issuance domestically or reform pre-existing laws to be compatible with such provisions. What drove lawmakers in some nations to pass new laws on compulsory licensing faster than legislators in other countries? 4 shows that Argentina, Brazil, and Thailand were among the top few countries whose public access to ART drugs was more limited than others in their continents. Therefore, we expect that domestic demand for increased access to such medicines was also the highest in these countries, creating pressures on lawmakers to make compulsory licensing legally available earlier in their jurisdictions.

We specifically consider the different circumstances under which compulsory licensing may be used in each country as a proxy for whether and how much each member state exploits constructive ambiguity in TRIPS. TRIPS Article 30, the agreement's general exception, states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Figure 4: **Reported Number of People Receiving ARTs (in hundreds, 2002)**



However, what constitutes "legitimate interests" is left completely undefined. Such constructive ambiguity in Article 30, and others, allows member states to provide different circumstances under which patents can be used without permission from their original owners. In doing so, they can exploit treaty terms for strategic reasons.

Given the opportunity to exploit ambiguity in TRIPS, when are countries more likely to do so? Given our theory of treaty exploitation, we hypothesize that the more limited public access to patented drugs for HIV/AIDS is in a country, the earlier WTO member states will reform their patent laws to allow a compulsory license to be specifically issued for the benefit of the general public.

However, 4 also shows other nations whose public access to HIV/AIDS drugs was even more limited worse than Argentina, Brazil, and South Africa but didn't experience trade disputes or compulsory licensing concerns with the United States. As theorized, this is most likely due to the extent to which politicians needed to respond to the needs of their public varies across political

institutions (De Mesquita et al., 2005), whose mechanisms are applied to compulsory licensing and public health regulation as well (Park, 2022). For this reason, we also condition our claim on how political institutions affect the aggregation of public policy preferences.

Hypothesis 1 *Conditional on political regime type (democracy), the more limited public access to medicines, the more likely states are to enact laws on compulsory licensing early to meet domestic interests.*

To what degree are countries more likely to exploit constructive ambiguity in TRIPS? As theorized, we hypothesize that states whose economies are more vulnerable to the exercise of market power by patent owners of HIV/AIDS drugs are more likely to set anti-trust cases as a ground for compulsory licenses. Extant studies point out that brand-name drug producers often exercise their power over generics producers, using their exclusive rights over patents, and some governments introduce their anti-competitive practice as a source of threat to public health (Correa, 2002; Shadlen, 2007; Bond and Saggi, 2014, 2020). This is primarily so because incumbent firms can charge high licensing fees to other firms and also refuse to share their patented products with other producers. In doing so, firms can delay the prompt supply of essential drugs. As mentioned, such practices were a concern during the early 2000s with ART drugs (Sell and Prakash, 2004; Elbe, 2006).

The working requirements in Argentina and Brazil in 2001 are just a few examples of how developing nations and LDCs shield their domestic market from the right holders' exercise of market power. Another notable case is India's compulsory licensing over Bayer AG, a German multinational pharmaceutical company, in 2012 and how it provoked a series of trade talks between India and the US. Similar to other LDCs as of 1995, the transition period for TRIPS ratification was extended to 2005 for India, at which time producing generic drugs already became a major part of Indian pharmaceutical industry (Chaudhuri, Goldberg, and Jia, 2006) and the debate over whether India's issuance of compulsory license was appropriate went intense at the national level. At the pinnacle of the trade dispute, Anand Sharma, Commerce Minister of India,

defended the government's stance on the dispute by stating that "we are committed to protect Indian generics and also to ensure that the Indian pharmaceutical industry continues to produce new molecules, new versions, and a new generation of medicines both for HIV/AIDS and other endemic diseases like tuberculosis (TB), malaria and other life-threatening diseases."[8]

Hypothesis 2 *The smaller the number of patents working in a domestic economy, the more likely states are to enact laws on compulsory licensing early to regulate non-working patents.*

Other than non-working patents as a target of compulsory licensing for regulation, we also focus on how each country allows infringement of patents that cannot be separated in their operation, wherein patent owners have more leeway to exercise their market power to their customers or licensees. As is often the case for the major diseases targeted by global health initiatives, a collection of therapies is often prescribed by doctors for their treatment, such as Highly Active Anti-retroviral Therapy (HAART) for HIV/AIDS, whose medicinal products were invented and owned by a handful of companies after the disease was first discovered in 1981 (Gottlieb et al., 1981) and its therapeutics were proposed in 1986 (Fischl et al., 1987). Since then, states like India have made supplies of these drugs more competitive in their economies by forbidding exclusivity to secondary inventions unless "they result in the enhancement of the known efficacy".[9]

Hypothesis 3 *The more concentrated foreign patent ownership is in a country, the more likely the country will explicitly legislate compulsory licensing to regulate dependent patents.*

Data Collection

The main empirical challenge for the study of constructive ambiguity is how to measure the unmeasurable: the strategic use of ambiguous words that can be interpreted in multiple ways. In

[8] "Govt not lax on pharma policy" (November 23th, 2013)
[9] Section 3(d), the Patent (Amendments) Act of 2005 in India (WIPO Lex Database)

this respect, extant studies on constructive ambiguity in international agreements widely adopt a so-called "dictionary" approach to measurement, where a bag of words representing positive or negative sentiments (Pelc and Busch, 2019) or having more or less precise meanings Gastinger and Schmidtke (2022) are used as a reference point to check how they are distributed across a set of documents. In such papers, scholars examine how ambivalent words are employed by international courts or treaties to cope with politically sensitive issues, such as the persuasion of the domestic audience standing against economic integration or the mitigation of power asymmetry among signatory states. Other scholarship has also addressed similar research questions, such as how vague words are used by the Supreme Courts to circumvent contestable legal outcomes (Owens and Wedeking, 2011; Owens, Wedeking, and Wohlfarth, 2013; Corley and Wedeking, 2014). For this reason, these other disciplines have also adopted a similar methodological approach for their research.

In this paper, we also adopt a quantitative empirical approach to test our hypotheses. However, unlike existing studies, we evaluate how ambiguous treaty terms are translated uniquely in each jurisdiction *after* the treaty has been signed and ratified. Therefore, instead of using a dictionary approach, we measure how exactly ambiguous words stated in TRIPS, such as "the legitimate interests" in Article 31 or "the abuse of intellectual property rights by right holders" in Article 8 of TRIPS for compulsory licensing, are realized in national laws differently, sometimes as 'public interest in the access to medicines and at other times as 'anti-competitive practices by right holders'. To better explain state preferences on constructive ambiguity, we evaluate how interpretations of the same treaty terms vary in a multi-dimensional space.

Dependent Variable: Exploitation of Constructive Ambiguity

For our dependent variables, we use the WIPO Lex Database to trace all legislative activities ratifying among WTO member countries from 2000 to 2012. In so doing, we measure whether each country puts forward different conditions for compulsory licensing within its jurisdiction

(provisions are often titled "non-voluntary licensing"). Based on our hypotheses, we check if compulsory licenses can be issued (1) for the benefit of public, (2) to regulate non-working patents, or (3) to prohibit the application of dependent patents. The specific conditions under which compulsory licensing can be granted are collected by the Committee on Development and Intellectual Property (CDIP) in the World Intellectual Property Organization (WIPO). Using this meta-dataset, we create three indicators, each of which represents whether each condition for compulsory licensing is stated under each national IPR law.

Independent Variables: Democracy, Demand, & MNC Presence

Given our central independent variable is the presence of democratically elected leaders, we rely on two measures of democratic institutions. Following the current standard in the field, we code where countries are democratic or not using the Polity IV measure. However, we primarily rely on the Boix-Miller-Rosato (BMR) dichotomous democracy score, updated through 2012 (Boix, Miller, and Rosato, 2013).

To measure the existence of high demand for public action, we use various indicators to check precisely how limited public access to HIV/AIDS medicines was in each country between 2000 and 2012. For instance, despite its communicable attribute as a disease, notice that not all populations within a country are infected by HIV/AIDS in each year, and only HIV/AIDS patients require access to ART drugs. How much these patients have access to ARTs is more likely to represent the domestic audience whose political demands politicians need to care about. Among these sub-populations, we measure the percentage of people who have access HIV/AIDS therapies, whose information we gather from the World Health Organization's (WHO) Global Health Observatory database.

To test the second and third hypotheses on the presence of foreign MNC interests, we use a privately owned database, the Cortellis Competitive Intelligence™, and measure how multinational pharmaceutical companies exercised their property rights over HIV/AIDS medicines

between 2000 and 2012. Specifically, for non-working patents, we check the number of patented drugs for HIV/AIDS whose term of protection did not expire in each year under study. For each of these medicines whose sales remained exclusive, we identify the nationality of each pharmaceutical company that invented the drug. Using this index, we operationalize how dependent each country in our data-set is on supplies of these drugs by multinational pharmaceuticals; the smaller the value, the more susceptible each market is to the exercise of market power by these drug companies and likely to regulate non-working patents.

Level	Title	Description
Section	A	Human Necessities
Class	A61	Medical or Veterinary Science; Hygiene
Subclass	A61K	Preparations for Medical, Dental, or Toilet Purposes
Group	A61K 39	Medical Preparations containing Antigens or Antibodies
Subgroup	A61K 39/21	Retroviridae (e.g. equine infectious anemia virus)

Table 1: **An Example of Patent Classification for HIV/AIDS Medicines (IPC)**

For the third hypothesis, we identify the concentration of ownership of HIV/AIDS medicines, which rely on each other for effective medical treatment, by measuring how the medicinal products are classified under the international patent system. Every patent belongs to a certain class or group under the International Patent Classification (IPC) system, which was established by the Strasbourg Agreement in 1971 and administered by the WIPO for international patent applications. By examining how each patented medicine for HIV/AIDS is classified under IPC, we measure how many distinct patent varieties each company owns for HIV/AIDS treatment.

Similar to the previous exercise, we then check the nationality of each of the drug companies and aggregate this information to the national level, then divide it by the number of companies who own the patents. This normalization step is essential as the size of ownership of unique patent varieties may also increase at a country level when more multinational pharmaceuticals share the same origin or head-quarter location.

Control Variables

To tease out the effects of domestic political factors, we also add other international or non-political determinants that also drive the same policy outcome. It is widely known that other transnational initiatives have been created since HIV/AIDS epidemic in the early 2000s "to accelerate access to care and treatment for HIV infection and AIDS in less develop countries" (Cochrane, 2000), such as the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Global Fund, the Medicines Patent Pool and the President's Emergency Plan for AIDS Relief (PEPFAR) (Hoen et al., 2011; Kapstein and Busby, 2013). Also, states can introduce new drugs and supply them to their citizens in a timely manner to various degrees depending on state capacity for pharmaceutical production. Such capabilities are often contingent on their economic fundamentals. These variables include but are not limited to population size, GDP per capita, and expenditure on research and development (R&D), all of which we add as control variables to our estimations.

Test Results

The test results using the Cox Proportional Hazards model with time-dependent co-variates are summarized in the following tables. Notice that positive coefficients in survival analysis imply that the event hazard would increase. This is interpreted as the amount of time it takes for each state to legislate new IPR laws for compulsory licensing. Our hypotheses expect the time to legislate to decrease as our independent variables of interest increase in value.

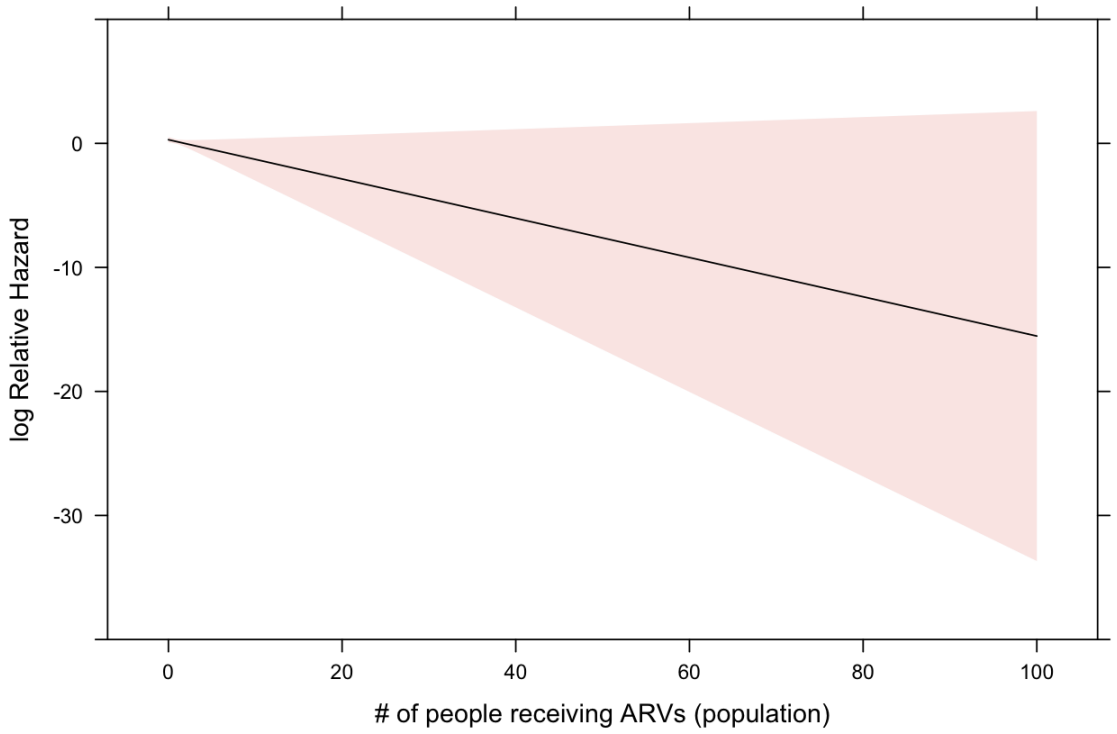
Table 2 summarizes the results of testing our 1st hypothesis, whose interaction terms lend support to our main argument. That is, the more limited public access to HIV/AIDS medicines between 2000 and 2012, the more likely it is that democratic governments will legislate compulsory licensing in for precise public health reasons earlier than non-democracies, ceteris paribus. The effects grow when a group of people who are in dire need of the medicines, such as preg-

Table 2: Hypothesis 1

	Legislation of CL (Public Interests)			
	(1)	(2)	(3)	(4)
HIV therapies (all, % of HIV infection)	−0.003***			
× Democracy (polity)	(0.0005)			
HIV therapies (all, % of HIV infection)		−0.020***		
× Democracy (BMR)		(0.007)		
HIV therapies (all, % of population)			−0.343***	
× Democracy (BMR)			(0.118)	
HIV anti-transmission (women, % of population)				−8.474***
× Democracy (BMR)				(3.051)
HIV therapies (all, % of HIV infection)	0.015***	0.019***		
	(0.005)	(0.007)		
HIV therapies (all, % of population)			0.183**	
			(0.091)	
HIV anti-transmission (women, % of population)				1.060
				(1.315)
Democracy (polity)	0.154***			
	(0.018)			
Democracy (BMR)		1.227***	1.146***	1.462***
		(0.180)	(0.153)	(0.314)
Population (log)	0.335***	0.165	0.131	−0.213
	(0.121)	(0.115)	(0.114)	(0.224)
GDP per capita (log)	−0.234	−0.390*	−0.341	−1.456***
	(0.250)	(0.237)	(0.234)	(0.504)
Health expenditure (log)	0.224	0.274	0.250	0.754*
	(0.198)	(0.195)	(0.186)	(0.391)
Trade (imports, log)	−0.176	−0.044	−0.004	0.442*
	(0.137)	(0.130)	(0.129)	(0.262)
FDI (net inflow, % of GDP)	−0.003	−0.005	−0.008	0.013
	(0.009)	(0.009)	(0.009)	(0.019)
R&D expenditure (log)	0.035	−0.182	−0.361	0.640
	(0.267)	(0.252)	(0.251)	(0.545)
HIV/AIDS medical control	0.002	0.002	0.001	−0.007
	(0.002)	(0.002)	(0.003)	(0.006)
HIV/AIDS social mitigation	−0.360**	−0.377**	−0.297**	−0.023
	(0.146)	(0.148)	(0.140)	(0.298)
People living with HIV (in millions)	−0.438***	−0.239*	−0.165	0.311
	(0.151)	(0.140)	(0.138)	(0.612)
Observations	682	692	693	138

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

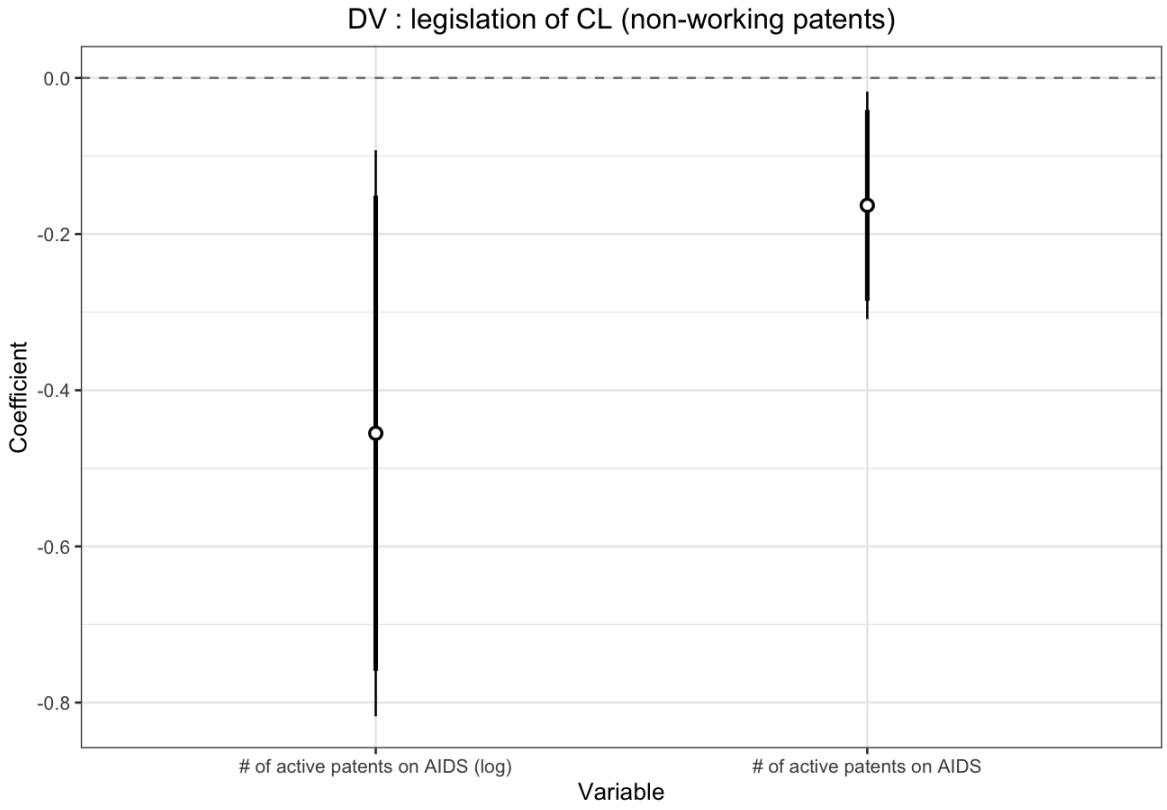
Figure 5: Increasing likelihood of democracies explicitly legislating compulsory licensing as the number of people receiving anti-retroviral therapies increases



nant women, have limited access to HIV/AIDS drugs. Also, it should be noted how domestic political regimes condition the effects. For instance, (1) shows that when a government is democratic (0.154), limited access to medicines (0.003) is more likely to prompt earlier legislation of compulsory licensing explicitly for public health protection ($0.154 - (-0.003) = 0.157$). This is primarily so because both lawmakers and the executive in democracies are exposed to more political pressure from their public citizens than in autocracies. As a result, they seek earlier legislation of TRIPS laws in specific terms to maximize their capacity to respond, and increase their chance of political survival (Park, 2022). Our results hold for different proxies of political regime type (Marshall, Jaggers, and Gurr, 2002; Boix, Miller, and Rosato, 2013). These effects are visualized in Figure 5.

The results described in Table 3 support our 2nd hypothesis: states that rely on foreign

Figure 6: Effect of foreign MNC concentration in market (by number of active patents) on likelihood of treaty exploitation (explicit legislation of compulsory licensing)



pharmaceutical companies for their supplies of AIDS drugs are more likely to specify non-working patents as a rationale for their execution of compulsory licensing. This is visualized in Figure 6. To partial out the effects of public interests on compulsory licensing legislation, notice that we add an interaction term between public access to the drugs, `Access to HIV therapies`, and political regime type, `Democracy`. The results still remain consistent with our 1st hypothesis. We also take the log transformation of patented medicines for HIV/AIDS active in each year, as such medicines were invented and owned by only a handful of multinational pharmaceutical companies over the world. Even when accounting for this concentrated ownership, our results still hold. For the remaining control variables, states who allocate fewer government expenses on healthcare are also more likely to enact explicit compulsory licensing laws earlier than those that spend more money on public health protection.

Table 3: Hypothesis 2

height	Legislation of CL (Non-working Patents)		
	(1)	(2)	(3)
Number of active patents for HIV		−0.163**	
		(0.074)	
log(Number of active patents for HIV + 1)			−0.455**
			(0.185)
Access to HIV therapies (% of population, total)	−0.139**	−0.140**	−0.141**
× Democracy (BMR)	(0.055)	(0.055)	(0.055)
Access to HIV therapies (% of population, total)	0.120*	0.110*	0.107*
	(0.061)	(0.062)	(0.063)
Democracy (BMR)	0.341***	0.363***	0.372***
	(0.131)	(0.131)	(0.131)
Population (log)	0.043	0.071	0.079
	(0.103)	(0.102)	(0.102)
GDP per capita (log)	0.390*	0.372*	0.370*
	(0.206)	(0.209)	(0.210)
Health expenditure (log)	−0.303*	−0.284*	−0.279*
	(0.165)	(0.166)	(0.166)
Trade (imports, log)	−0.016	−0.023	−0.025
	(0.116)	(0.114)	(0.114)
FDI (net inflow, % of GDP)	−0.009	−0.009	−0.008
	(0.008)	(0.008)	(0.008)
R&D expenditure (log)	−0.236	−0.021	0.005
	(0.230)	(0.245)	(0.246)
HIV/AIDS medical control	0.002	0.003	0.003
	(0.002)	(0.002)	(0.002)
HIV/AIDS social mitigation	−0.044	−0.058	−0.062
	(0.073)	(0.073)	(0.073)
People living with HIV (in millions)	0.068	0.072	0.086
	(0.110)	(0.108)	(0.107)
Observations	693	693	693

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

Table 4 also demonstrates how the concentration of power by a handful of pharmaceutical companies leads to more prompt and explicit regulation of monopolistic practices by using compulsory licensing. In this exercise, our model captures the remaining variation in the legislation of compulsory licensing among countries, mostly those from the North who could supply patented medicines for HIV/AIDS more easily than those from the South. This is primarily so because the number of distinct patent classification codes, which we use as a proxy for the concentration of patent ownership, can only be defined over AIDS drugs whose patents are active in a given year. Therefore, the results should be read as follows: while some states can produce AIDS drugs by themselves easily, they still have incentives to regulate the exercise of power by pharmaceuticals if these firms own the majority of patents for HIV/AIDS.

Robustness Checks

In the appendix, we conduct additional analyses to check whether the main results still remain valid after we (1) manipulate our dependent and independent variables in a non-trivial way, (2) add more control variables that are deemed important, and (3) correct for the selection bias. For instance, by only looking at a group of industrialized states for the 3rd hypothesis, whose number is smaller than 100 in a 12-year longitudinal study, we leave the remaining variation among developing countries and LDCs unexplained, whose sample size takes up most of the population. Hypothesis testing without accounting for the sub-samples is also problematic from a theoretical standpoint, because weak countries are more susceptible to the exercise of market power by multinational pharmaceuticals than strong nations are, especially when most of the patents are owned by these large companies. This implies that our model still does not capture most of the variation, if not the coefficients are biased. We overcome this challenge by using a Heckman selection model where we consider how the large firms select into self-regulation in global market, and find that the same results still hold.

Table 4: Hypothesis 3

	Legislation of CL (Dependent Patents)			
	(1)	(2)	(3)	(4)
Number of unique IPC on active patents		0.886***	0.841**	1.337**
		(0.329)	(0.359)	(0.654)
Number of active patents on HIV			−0.017	
			(0.066)	
Access to HIV therapies (% of living with HIV, total)				0.118
				(0.155)
Democracy (polity)	0.015	22.343**	21.754**	13.557
	(0.011)	(9.073)	(9.210)	(29.546)
Population (log)	0.176	−1.530	−1.510	0.366
	(0.111)	(0.972)	(0.981)	(2.956)
GDP per capita (log)	0.341	−0.159	−0.065	−3.243
	(0.231)	(4.582)	(4.572)	(13.679)
Health expenditure (log)	−0.125	−6.074	−5.950	−2.650
	(0.181)	(4.290)	(4.280)	(16.759)
Trade (imports, log)	−0.097	1.006	1.004	−0.723
	(0.127)	(1.062)	(1.066)	(3.074)
FDI (net inflow, % of GDP)	−0.026**	−0.050	−0.049	−0.032
	(0.011)	(0.040)	(0.040)	(0.051)
R&D expenditure (log)	−0.622**	6.356***	6.246***	7.671
	(0.243)	(1.835)	(1.871)	(7.288)
HIV/AIDS medical control	−0.0001	0.0004	0.0004	−0.001
	(0.001)	(0.010)	(0.010)	(0.013)
HIV/AIDS social mitigation	0.016	−0.305	−0.310	−0.433
	(0.069)	(0.392)	(0.393)	(0.459)
People living with HIV (in millions)	0.096	1.684	1.744	0.194
	(0.113)	(2.200)	(2.206)	(6.814)
Observations	716	93	93	61

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

Conclusion

Constructive ambiguity has long been viewed as a central element of the design of international agreements (). Despite being a long-recognized element of treaties, studies of agreement flexibility have largely focused on the design and use of specific escape clauses. We present a novel argument of when and how countries are more likely to exploit treaty ambiguity as a form of flexibility. States possess contradictory preferences on key issues in international agreements, yet often include provisions on these topics in new treaties. When states cannot tolerate negotiation failure, constructive ambiguity allows states to simultaneously agree to treaty terms while signing onto an agreement that can be interpreted by both parties in different ways. Signatories can then ratify such treaty terms domestically in ways that meet their policy preferences while remaining in compliance with broad treaty terms.

This exploitation facilitates democratic responsiveness in the face of crises, while also giving states the capacity to retain domestic policy autonomy. We argue that democratic countries are more likely to exploit treaty ambiguity than autocracies. For developing democratic countries with higher degrees of foreign MNC presence, this is especially so. As a result, our paper presents evidence of ways in which developing countries have committed to globalization without entirely yielding domestic policy autonomy to developed countries or foreign MNCs. In the case of intellectual property rights and the HIV/AIDS crisis, constructive ambiguity in TRIPS provided rapid means for countries with high need for generic ART drugs to gain access to essential medicines.

Our paper makes an additional empirical contribution by studying treaty exploitation in context. Instead of relying on generic dictionary-based measures of treaty ambiguity, we rely on measures of how exactly different countries interpreted the same treaty terms. By studying the different ways countries exploit constructive ambiguity over when states can engage in compulsory licensing under TRIPS, we are able to offer a more direct operationalization of our core concepts: constructive ambiguity and treaty exploitation.

However, constructive ambiguity is no panacea for retaining domestic policy autonomy when committing to free trade or other liberal economic policies. Compulsory licensing laws have remained contentious and subject to negotiation, litigation and policy debate. Most of the policies ratified for compulsory licensing in the period of study were specific to the HIV/AIDS crisis, preventing state action on drugs for other communicable diseases - including patents for COVID-19 vaccines. The 2001 Doha Declaration on Public Health was also specific to the HIV/AIDS epidemic. Specificity in domestic policy in this context allowed states to perceive the need as legitimate and limited, but at the cost of preventing broad responsiveness to public health emergencies. In situations where access to essential medicines is a matter of life or death, the requirement for explicit legislation for each crisis can cost lives.

Our paper also highlights that for treaty terms that highly rely on constructive ambiguity, adjudication is especially rare to prevent the narrowing of such terms. Yet how the politics of constructive ambiguity relate to increasing or declining support for global governance is an open question. Populist backlash movements to international organizations, such as the withdrawal of the United Kingdom from the European Union (or "Brexit"), claim they want to reclaim domestic policy autonomy from international institutions and bureaucrats. Declining constructive ambiguity through more precise interpretations (via amendment/negotiation) or adjudication may be one reason why this is the case. For disputes that do reach adjudication, panellists are faced with deciding which countries' interpretation is correct or rendering their own view. In the latter context, the WTO DSB found itself increasingly accused of judicial activism, which saw the United States withdraw support for the appellate body as a result ().

Future work would do well to evaluate whether state support for the WTO DSB or other institutions with similar authority such as the ECJ, waned in response to judicial activism on particularly ambiguous treaty terms, where states have the most significant interests in ensuring their preferred interpretation stands. Alternatively, it may be the case that panellists were more likely to engage in judicial economy (refraining from issuing rulings or interpretations). Instead,

other transnational actors, such as the WTO secretariat and the TRIPS Council chairs, may be responsible for standardizing states' exploitation of ambiguity. Recent findings suggest that this may well be the case (Pauwelyn and Pelc, 2022). We suggest more work be done on how different actors employ effective language to persuade other member states, and their domestic audiences, of treaty compliance.

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