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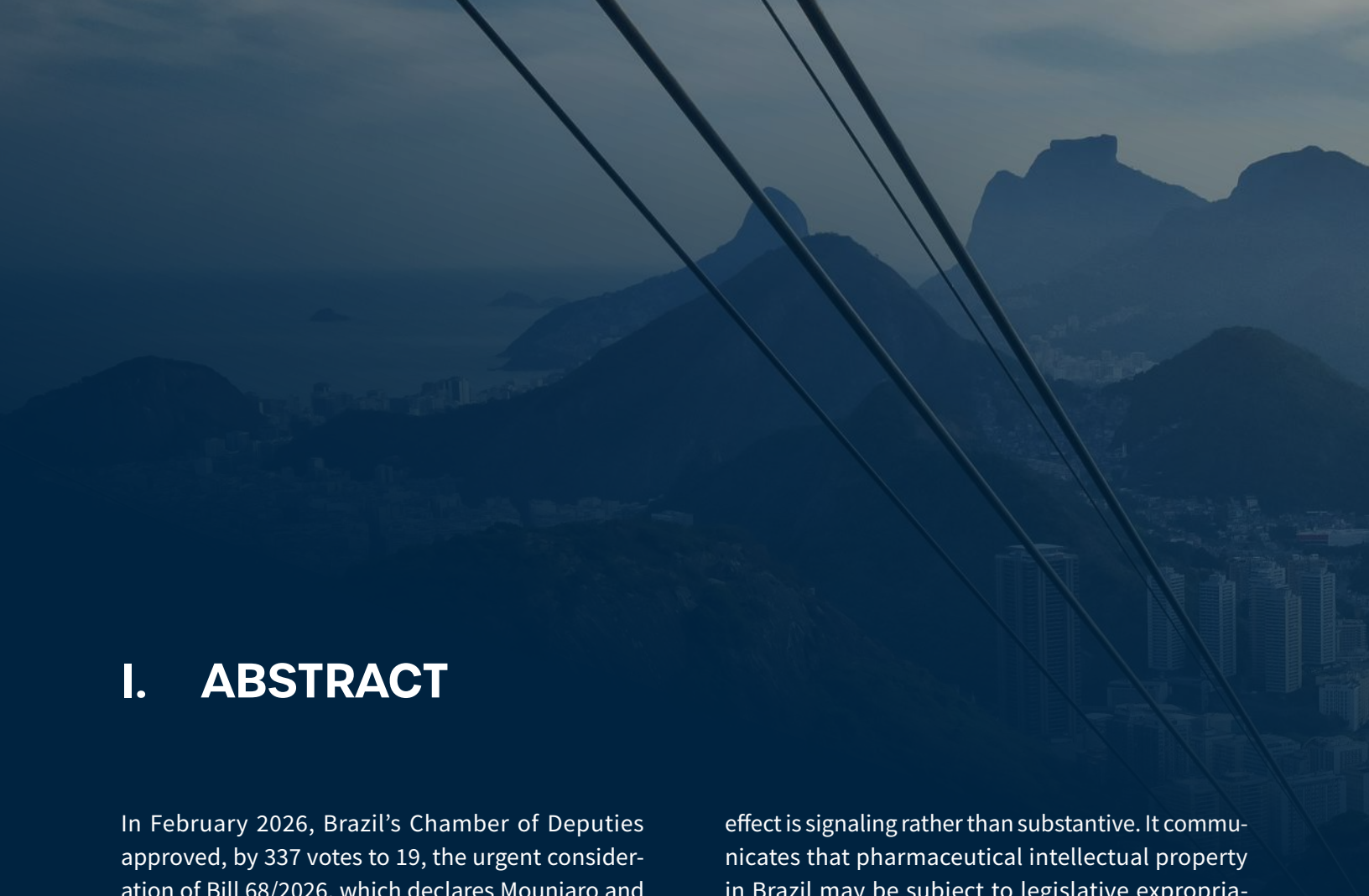
INTERNATIONAL PROPERTY RIGHTS INDEX 2026

COMPULSORY LICENSING AND INTELLECTUAL PROPERTY RIGHTS IN BRAZIL: THE CASE OF MOUNJARO (TIRZEPATIDE) AND BILL 68/2026

CASE STUDY

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I. ABSTRACT

In February 2026, Brazil's Chamber of Deputies approved, by 337 votes to 19, the urgent consideration of Bill 68/2026, which declares Mounjaro and Zepbound, tirzepatide-based medicines manufactured by Eli Lilly, to be of public interest, opening the path to compulsory licensing of these patents. This case study argues that the bill, although presented as a public health measure against obesity and type 2 diabetes, errs both in its legal diagnosis and in its proposed remedy. PL 68/2026 attempts to perform, through ordinary legislation, an act that the Industrial Property Law (Law 9,279/1996) and the TRIPS Agreement expressly reserve to the Executive Branch: the declaration of public interest that precedes a compulsory license. No ministry requested the measure, and Eli Lilly, the patent holder, was not heard during the legislative process. The study further contends that even if the bill is approved and signed into law, it is unlikely to lower prices in the short term, given that tirzepatide is a complex molecule, and Brazil currently lacks the manufacturing capacity to produce it at scale. The episode's most probable effect is signaling rather than substantive. It communicates that pharmaceutical intellectual property in Brazil may be subject to legislative expropriation whenever a medicine becomes simultaneously popular and expensive. That signal carries a measurable institutional cost — Brazil's Intellectual Property Rights subindex in the International Property Rights Index (IPRI) already stands at 4.988, below the global average, in 58th place among 126 countries. The paper concludes with policy recommendations as alternatives to legislative expropriation.

Case study style/approach: Academic and advocacy policy paper

Keywords: compulsory licensing; intellectual property rights; pharmaceutical patents; property rights index; Brazil



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II. INTRODUCTION

On February 9, 2026, Brazil's Chamber of Deputies approved a request for urgent consideration of Bill 68/2026 by a wide margin: 337 votes in favor and only 19 against. The bill, authored by Deputies Antonio Brito (PSD-BA) and Mário Heringer (PDT-MG), declares Mounjaro and Zepbound, both built on tirzepatide, the active ingredient developed by the American pharmaceutical company Eli Lilly, to be of public interest under Article 71 of Brazil's Industrial Property Law. In practice, the measure opens the path to compulsory licensing of these patents, a mechanism the press has simplified as "patent-breaking."

The choice of these two medicines is not incidental. Mounjaro was approved by ANVISA in 2023 for the treatment of type 2 diabetes mellitus and had its approved use expanded in June 2025 to cover obesity and overweight conditions with comorbidities. Tirzepatide acts simultaneously on two hormone receptors, GLP-1 and GIP, which partly explains its superior efficacy relative to older drugs such as semaglutide. The political problem stems from price; the drug is administered through an injection pen which can cost between R$1,400 and nearly R$4,000 depending on the dose. This creates a burden for the average patient and for Brazil's public health system (SUS), which faces growing pressure to incorporate this class of treatment.

The case is relevant to IPRI readers for two mutually reinforcing reasons. The first is that it tests, in a middle-income country such as Brazil, the real limits of compulsory licensing as a public health instrument. The country does not benefit from the TRIPS



exemptions granted to least-developed nations, yet it also lacks the industrial capacity of a pharmaceutical powerhouse capable of substituting a patented biologic overnight. The second is broader — the episode illustrates how the popularity of a single medicine can, on its own, mobilize nearly the entire political spectrum against a property right, regardless of whether the correct legal procedure is observed.

This case study seeks to answer three research questions. First, does PL 68/2026 meet the legal requirements, domestic and international, for compulsory licensing? Second, assuming the bill is passed and signed into law, would it in fact expand access to tirzepatide in the short to medium term? Third, what does the episode reveal about the intellectual property environment in Brazil as measured by the IPRI?

The paper proceeds as follows. Section II situates the case within the relevant literature on compulsory licensing. Section III presents data and methodology. Section IV provides the discussion and analysis of the case. Section V summarizes the three central problems identified. Section VI offers policy recommendations and conclusions.

III. BODY

A. Situating the Case in the Literature

The tension between pharmaceutical patent protection and access to medicines dates back to the adoption of the TRIPS Agreement in 1994, which established a global minimum standard of intellectual property protection, including a 20-year term for pharmaceutical patents, while authorizing member states to resort to compulsory licensing under specific conditions set out in Articles 27, 31, and 31bis.

The literature on the subject is extensive. Correa (2002) documented the flexibilities TRIPS grants to developing countries. Hoen and colleagues (2011) catalogued compulsory licensing episodes on a global scale, predominantly in the HIV/AIDS field. The 2001 Doha Declaration explicitly recognized each country's right to define what constitutes a national emergency for compulsory licensing purposes. In Brazil, these flexibilities were incorporated through Law 9,279/1996 (the Industrial Property Law, or LPI) and later expanded by Law 14,200/2021.

A point frequently overlooked in Brazil's political debate, yet well established in the literature, is that compulsory licensing produces better outcomes when the country imposing it already possesses the technical capacity to replicate the product. Abbott and Reichman (2007) insist on this. It is precisely here that the tirzepatide case becomes complicated. It is a molecule that is difficult to synthesize, closer to a biologic, and no Brazilian manufacturer has thus far demonstrated the capacity to produce it at commercial scale.

On the property rights side, the IPRI itself provides consistent evidence that strong intellectual property protection correlates with greater innovation and stronger economic performance. The 2025 edition records a very strong correlation with the Global Knowledge Index (0.92) and the Artificial Intelligence (AI) Preparedness Index (0.93). Brazil scores 4.988 on the Intellectual Property (IP) subindex, ranking 58th out of 126 countries, below the global average of 5.13. Episodes such as PL 68/2026 tend to push that figure lower still.

Brazil has faced a comparable situation before. In 2007, the Lula government issued a compulsory license for Efavirenz, an antiretroviral manufactured by Merck, citing the cost of HIV/AIDS treatment for SUS. It is worth noting that Brazil did not manufacture Efavirenz domestically but imported it from India. Even Brazil's sole precedent for pharmaceutical compulsory licensing, therefore, did not resolve the manufacturing capacity problem on its own; it merely substituted a patented supplier with a generic foreign one. For tirzepatide, that Indian shortcut likely does not yet exist.

B. Relevance of the Case

PL 68/2026 is significant for more than one reason, and not merely because of the medicine itself. First, the bill attempts to use ordinary legislation to perform an act that both the LPI and TRIPS reserve to the Executive Branch. It was introduced on February 2nd, and reached the floor only one week later, on February 9th, without passing through any thematic committee capable of assessing its technical soundness. This procedural feature is not a minor detail; as argued below, it constitutes the core of the problem.

Second, the case fits a recurring global pattern — the popularity of so-called injectable weight-loss pens has generated political pressure for access solutions that are not always well designed. It bears noting that, also in February 2026, the United States government, under the Trump administration, had separately negotiated with Eli Lilly a voluntary price reduction of up to 85% for tirzepatide, evidence that at least one negotiated path, without expropriation, has already produced results.

Third, PL 68/2026 arises amid pre-existing legal instability. The Supreme Federal Court's 2021 decision in ADI 5529 invalidated the automatic extension of patent terms whenever INPI, Brazil's patent office, took excessive time to examine an application, a decision that affected multiple pharmaceutical patents simultaneously. Adding legislative uncertainty to an environment already marked by judicial volatility hardly constitutes a sound institutional strategy.

C. Data and Methodology

This study employs a qualitative, documentary, and legal methodology, combining legal analysis, policy analysis, and institutional assessment. Primary sources include the text of PL 68/2026, the congressional record of the urgency vote, Law 9,279/1996 and Law 14,200/2021, the TRIPS Agreement, the Doha Declaration, ANVISA's regulatory record on tirzepatide, Eli Lilly's official statements, and Brazil's country profile data from the 2025 IPRI.

Secondary sources comprise peer-reviewed literature on compulsory licensing, analyses from law firms specializing in intellectual property, and public statements from industry associations, chiefly Interfarma. The temporal scope extends from 2007, the Efavirenz episode, to 2026, with Brazil as the primary focus and comparative references to other countries where relevant.

No econometric approach is adopted, given the inherent limitations of predicting counterfactual investment flows. The analysis instead relies on the correlation methodology already established by the IPRI, between property rights protection and innovation indicators, to situate the likely implications of the episode, without claiming a numerical precision the available data cannot support.

D. Discussion and Analysis of the Case

PL 68/2026 declares Mounjaro and Zepbound "of public interest" for purposes of Article 71 of the LPI, as amended by Law 14,200/2021. Article 71 itself, however, establishes without ambiguity that this declaration is made by presidential decree, an act of the Executive Branch, not the Legislature. This is the first and most fundamental defect of the bill — it seeks to accomplish through Congress what the law reserves to the Executive.

The objection extends beyond the formal plane. The Ministry of Health issued no recommendation in favor of the measure, and Eli Lilly, the patent holder, was neither notified nor heard during the legislative process, a direct violation of Article 73 of the LPI, which requires the patent holder's participation prior to the grant of any compulsory license. Eli Lilly recorded this point in an official statement, noting that the Brazilian legal framework requires compulsory licensing to be exceptional, technically justified, and initiated by the Executive Branch, and that neither the Ministry of Health nor the company had been involved in the process. The statement also highlights a point central to the analysis — a compulsory license does not guarantee access. The safe manufacture of a biologically complex medicine requires technical expertise, infrastructure, additional regulatory approvals, and time — elements absent from the legislative text.

At the international level, the problem recurs. Article 31 of TRIPS requires prior negotiation with the patent holder (barring a declared national emergency), adequate remuneration, and the non-exclusive character of the license. A bill that declares public interest without an administrative process or prior negotiation fails to meet these requirements. Should Brazil pass and implement the measure as drafted, Eli Lilly would have solid grounds to bring the case before the World Trade Organization.

Regarding substantive access, a significant gap emerges between the bill's political narrative and industrial reality. Tirzepatide is a complex molecule, close to a biologic, and no Brazilian manufacturer currently demonstrates the capacity to produce it at scale. The domestic generics industry, although robust with small, traditional molecules, has limited experience with complex peptides of this kind. Even if a license were granted immediately, ANVISA approval for the generic or biosimilar version would still be pending; which, under current regulatory timelines, would require years rather than months.

The comparison with the Efavirenz precedent is instructive but cuts against the bill's supporters — Brazil did not manufacture Efavirenz domestically in 2007, having instead imported it from India. In the case of tirzepatide, there is no indication that the Indian generics industry currently possesses a commercial-scale biosimilar ready for production. The practical access benefit of a compulsory license, in the near to medium term, therefore, remains uncertain.

The IPRI allows these conclusions to be situated within a broader perspective. Brazil's IP subindex score of 4.988, already below the global average of 5.13, chiefly reflects weaknesses in the perception of intellectual property protection (4.644), even though formal patent protection scores somewhat more favorably (5.717). The PL 68/2026 episode, regardless of its final legislative outcome, feeds precisely this perception of institutional fragility, an effect that will not register immediately in the Index score but functions as a leading indicator of future deterioration.

Within Congress, the only political force that consistently opposed the urgency vote was the Novo party, whose Deputy Adriana Ventura (Novo-SP) characterized the proposal as "a direct violation of intellectual

property rights." The remaining opposition parties allowed their members to vote freely, which produced the 337-to-19 outcome. In an election year, faced with a popular and expensive medicine, voting against the bill carried significant political and electoral cost for any lawmaker.

Outside Congress, opposition also surfaced. On the same day the urgency regime was approved, the Frente Parlamentar pelo Livre Mercado, at the time an institutional partner of Instituto Livre Mercado, issued a statement describing itself as "firmly opposed" to the measure on the grounds that the proposal weakens intellectual property protection guaranteed under Article 5, items XXII and XXIX, of the Federal Constitution, and that it creates legal uncertainty for pharmaceutical research and development (R&D) investment. Instituto Livre Mercado, a pro-market advocacy organization with an established presence in Brasília, took the same position in its institutional and media communications. It characterized PL 68/2026 as a dangerous precedent of legislative expropriation of intellectual property rights, one capable of deterring pharmaceutical investment in Brazil without delivering, in practice, the access gains promised to the population.

E. Three Central Problems

The preceding analysis highlights three central problems.

First: procedural legality. Using ordinary legislation to perform what the law reserves to executive discretion constitutes a significant institutional anomaly, not a mere technicality to be corrected later. Legislative compulsory licensing, as a legal category, does not exist in Brazilian intellectual property law, and its creation would require broad legislative reform, including amending the LPI itself. As drafted, PL 68/2026 would in practice depend on executive implementation to produce any genuine legal effect, meaning that its current value is predominantly political rather than legal.

Second: access effectiveness. Even if approved and implemented, the bill would face substantial obstacles — the absence of domestic manufacturing capacity, the absence of a rapid regulatory pathway for biosimilars, and the absence of an identified generic manufacturer both willing and able to produce at scale — to lowering tirzepatide prices in Brazil within a short timeframe. The more reliable path to access, already underway, is the natural expiration of semaglutide patents (Ozempic, Wegovy), which should introduce genuine competition into the GLP-1 class without requiring expropriation.

Third: the investment climate. Interfarma has stated plainly that compulsory licensing should constitute an absolute exception, and that not even during the COVID-19 pandemic did any country resort to this instrument for vaccines. PL 68/2026 arises in a non-emergency context, without endorsement from the Ministry of Health, for a condition, obesity, that, however serious, does not fit the national-emergency standard contemplated by TRIPS and the LPI. The risk is positioning Brazil as a jurisdiction in which pharmaceutical intellectual property may be expropriated whenever a medicine becomes excessively popular.

IV. POLICY RECOMMENDATIONS AND CONCLUSIONS

The analysis developed in this case study demonstrates that PL 68/2026 is legally fragile, has limited practical effect on access, and is counterproductive for the investment climate. On this basis, the following policy recommendations are proposed.

First, it is recommended that the National Congress reject PL 68/2026 in its current form, on procedural grounds. The declaration of public interest for compulsory licensing purposes is a competence of the Executive Branch, not the Legislature. Should Congress consider that access to tirzepatide warrants intervention, the appropriate path is to press the Ministry of Health to initiate the administrative procedure provided for under Article 71 of the LPI, with notification to and good-faith negotiation with Eli Lilly.

Second, it is recommended that the Brazilian government prioritize negotiated price agreements as an alternative to compulsory licensing. The American example is illustrative; the agreement reached by the Trump administration with Eli Lilly in 2025 produced a price reduction of up to 85% for tirzepatide without any patent expropriation. SUS has a track record of successful price negotiation with patent-holding companies; this mechanism should be activated before resorting to legislative shortcuts.

Third, in the medium term, the more solid strategy for expanding access to GLP-1 class medicines consists of accelerating the regulatory pathway for biosimilars. It is recommended that ANVISA develop a dedicated, more expedited procedure for generics and biosimilars of complex peptides without compromising safety standards. Through this path, access gains would arise from market competition driven by the regular expiration of patents rather than from expropriation.

Finally, the most structural recommendation: Brazil should cease treating its IPRI Intellectual Property Rights subindex, 4.988, below the global average, with perception scores in decline, as a secondary statistical detail. PL 68/2026 does not constitute an isolated event but forms part of a pattern that includes ADI 5529, the ongoing semaglutide patent litigation, and recurring legislative proposals targeting pharmaceutical intellectual property. To attract genuine pharmaceutical research investment, an affirmative IP-strengthening agenda is recommended: greater capacity at INPI to reduce the patent examination backlog, greater predictability in pharmaceutical patent terms, and effective enforcement mechanisms, measures to be adopted alongside, not in place of, legitimate health access policies.

The Mounjaro case illustrates a central proposition of the IPRI framework; property rights and access to innovation are not on opposite sides of the same equation. Countries with stronger intellectual property protection attract greater pharmaceutical R&D investment, develop more capable domestic generics industries, and ultimately achieve better long-term access outcomes. PL 68/2026, in seeking a shortcut through expropriation, risks precisely the environment that makes it possible for future generations of treatments to reach Brazil at all.



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VII. APPENDICES

Appendix A – Brazil's IPRI Subindex Scores (2025)

Table A.1 summarizes Brazil's performance across the three IPRI components and their subcomponents, as reported in the 2025 International Property Rights Index.

TABLE A.1 – BRAZIL'S 2025 IPRI COUNTRY PROFILE

OVERALL IPRI SCORE	GLOBAL RANK	REGIONAL RANK
4.984	58th	6th (Latin America and the Caribbean)

Overall IPRI score: 4.984 | Global rank: 58th | Regional rank: 6th (Latin America and the Caribbean)

Legal and Political Environment (LP): 4.497

- Judicial Independence: 5.175
- Rule of Law: 4.382
- Political Stability: 4.438
- Control of Corruption: 3.993

Physical Property Rights (PPR): 5.468

- Perception of Property Rights Protection: 6.667
- Registering Property: 3.539
- Ease of Access to Loans: 6.200

Intellectual Property Rights (IPR): 4.988 (down 0.044 from the prior year)

- Perception of Intellectual Property Protection: 4.644
- Patent Protection: 5.717
- Copyright Protection: 3.757
- Trademark Protection: 5.834

Source: Property Rights Alliance, 2025 International Property Rights Index, https://internationalpropertyrightsindex.org/country/brazil



Appendix B – Legislative Timeline

TABLE B.1 – KEY DATES IN THE PL 68/2026 LEGISLATIVE PROCESS

FEBRUARY 2, 2026	PL 68/2026 filed by Deputies Antonio Brito (PSD-BA) and Mário Heringer (PDT-MG)
FEBRUARY 9, 2026	Chamber of Deputies approves urgent consideration by 337 votes to 19
AS OF JUNE 2026	the bill remains “ready for the floor,” awaiting scheduling by the Chamber president

Note: besides the Novo party, the Frente Parlamentar pelo Livre Mercado, at the time an institutional partner of Instituto Livre Mercado, publicly opposed the urgency of PL 68/2026 in a press statement issued on February 9, 2026.



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