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When Patent Territoriality Meets Integrated Border Economies: Lessons from the Tirzepatide Market between Brazil and Paraguay

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Abstract

International patent law allocates exclusive rights through national legal orders, while regional integration increasingly organizes trade, mobility, and consumption across those same borders. This article asks whether territorial patent systems can adequately govern pharmaceutical innovation in economically integrated border regions where neighboring States maintain autonomous patent and pharmaceutical-regulatory institutions. It argues that territoriality remains legally coherent but becomes analytically incomplete when the relevant pharmaceutical market is functionally integrated across jurisdictions. The Brazil-Paraguay border and the market for tirzepatide-based products serve as a critical case. Eli Lilly's tirzepatide patent was not extended to Paraguay—an absence reported by the Paraguayan pharmaceutical-industry chamber and consistent with the absence of any indexed Paraguayan member of the relevant patent family, though not independently confirmed against the national register—in a State that remains outside the Patent Cooperation Treaty, while at least five Paraguayan manufacturers obtained sanitary registration from Paraguay's health authority to market tirzepatide-based products domestically; several of these products were later prohibited from entering Brazil for lack of Brazilian registration, not for patent infringement. The case is not treated as an inquiry into the validity of a particular patent claim or the safety of a particular product batch. Instead, it exposes the interaction among territorially allocated patent rights, nationally administered marketing authorization, cross-border consumer mobility, and uneven enforcement capacity. Drawing on international patent law, legal geography, comparative institutional analysis, and regional-integration theory—including a contrast with the

more centralized intellectual property regime of the Andean Community—the article develops the concept of institutional mismatch: a condition in which patent law and border markets remain internally coherent but operate according to different spatial logics. The mismatch does not justify abandoning territoriality, creating supranational patent rights, or displacing the problem onto private ordering. It does, however, require scholars and policymakers to distinguish the territorial unit of legal authority from the functional unit of market analysis.

Keywords

Patent Territoriality, Pharmaceutical Regulation, Integrated Border Economies, Brazil, Paraguay, Tirzepatide, MERCOSUR, Andean Community, Legal Geography, Institutional Mismatch, Private Ordering

1. Introduction

Patent law and economic integration organize space differently. A patent derives its legal force from a particular sovereign order: it is applied for, examined, granted, limited, and enforced under the law of a State or, where a regional arrangement exists, under authority expressly delegated by participating States. Markets do not necessarily respect the same cartography. Transport infrastructure, price differentials, consumer mobility, digital advertising, medical demand, and commercial networks may cause a border region to function as a single economic environment even when the legal institutions governing the relevant products remain separate. The coexistence of these two spatial arrangements is especially visible in pharmaceutical markets, where patent rights intersect with marketing authorization, prescription rules, customs controls, public-health oversight, and highly mobile demand.

International intellectual property scholarship has long explained the territorial character of patent rights. The Paris Convention preserved the independence of patents obtained for the same invention in different countries (WIPO, n.d.-a), while the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established minimum standards without converting national patents into a single transnational entitlement (WTO, n.d.). The Patent Cooperation Treaty simplified international filing but did not create a worldwide patent. Territoriality is therefore not a historical residue that survived by accident. It is a deliberate architecture for allocating legal authority among sovereign legal orders (Bodenhausen, 1968; Correa, 2007; Dinwoodie & Dreyfuss, 2012).

Regional-integration scholarship begins from a different institutional problem. It asks why States remove barriers to trade, coordinate policy, establish common institutions, and permit economic activity to become increasingly interdependent (Keohane & Nye, 1977; Mattli, 1999). In border regions, integration is not merely expressed through treaty commitments. It is lived through recurrent movement:

consumers compare prices across jurisdictions, suppliers adapt to cross-border demand, and goods pass through formal and informal channels that are often more economically significant than the national categories through which lawyers initially describe them. MERCOSUR illustrates this duality. It promotes a common market project while retaining an intergovernmental structure and extensive national autonomy in patent administration and pharmaceutical regulation.

The tension considered here arises because these literatures generally employ different units of analysis. Patent law begins with the jurisdiction. Regional integration begins with the relationship among jurisdictions and the economic space produced by that relationship. Each approach is coherent on its own terms. Yet neither, standing alone, fully explains how a patented pharmaceutical product operates in a border economy whose commercial organization extends across national territory while the relevant rights, approvals, and enforcement powers remain nationally allocated.

This article asks: can territorial patent systems adequately govern pharmaceutical innovation in economically integrated border regions where neighboring States adopt materially different institutional approaches to patent protection and pharmaceutical regulation? The answer advanced here is qualified. Territorial patent systems remain capable of performing the legal task for which they were designed: allocating exclusive rights, defining their scope, and assigning authority for their enforcement. Their legal coherence does not guarantee that the State remains the only satisfactory unit for analyzing the market in which patented products circulate. In integrated border economies, the relevant economic environment may be transboundary even though every decisive legal competence remains territorial.

The central hypothesis is that economically integrated border regions reveal an institutional mismatch between territorially allocated patent authority and functionally integrated pharmaceutical markets. The term mismatch is not used to imply invalidity, dysfunction, or institutional failure. Patent systems and border markets may each operate coherently while producing friction at the point of interaction. Patent law answers where legal authority exists. The integrated market answers how products, consumers, information, and commercial incentives are organized in practice. The two answers need not coincide.

The market for tirzepatide-based products along the Brazil-Paraguay border provides a critical case through which this mismatch becomes observable. Tirzepatide is a dual GIP and GLP-1 receptor agonist used in the treatment of type 2 diabetes and, under approved indications, obesity. Brazil's National Health Surveillance Agency (ANVISA) approved Mounjaro, held by Eli Lilly do Brasil, as a new medicine in September 2023 (Conselho Federal de Farmácia, 2023) and later extended its approved indications to weight management (Estado de Minas, 2025). Eli Lilly's corresponding patent protection was not extended to Paraguay: according to the Paraguayan Chamber of the Pharmaceutical-Chemical Industry (Cifarma), no Paraguayan patent application was filed for tirzepatide, leaving the

compound unprotected under Paraguayan law notwithstanding the Brazilian patent (La Nación, 2026). At least five Paraguayan laboratories, including Laboratorio de Productos Éticos, subsequently obtained sanitary registration from Paraguay's health authority (DINAVISA) to manufacture and market tirzepatide-based products domestically. In November 2025, ANVISA prohibited the importation, distribution, and use in Brazil of five such products by name—T.G. 5, Lipoless, Lipoless Éticos, Tirzazep Royal Pharmaceuticals, and T.G. Indufar—expressly on the ground that they lacked Brazilian sanitary registration, not on any finding of patent infringement (ANVISA, 2025b). These events demonstrate that pharmaceutical circulation cannot be understood through patent doctrine alone, nor reduced to sanitary regulation. The market forms at the intersection of exclusive rights, authorization regimes, enforcement, scarcity, pricing, and mobility.

Tirzepatide is therefore not the substantive object of the research. It is a methodological instrument. Critical-case analysis is useful where a particular setting makes a broader mechanism unusually visible (Flyvbjerg, 2006). The case concentrates several institutional variables: a high-value pharmaceutical product; strong consumer demand; a border economy with established commercial mobility; autonomous patent offices and health regulators; and the movement of products from one regulatory space into another. The purpose is not to decide the validity or scope of any individual patent, authenticate any particular product, or quantify illicit trade. It is to identify what the interaction reveals about territoriality as an institutional design.

Methodologically, the article combines doctrinal legal analysis with comparative institutional analysis and qualitative documentary research. It examines the Paris Convention, TRIPS, the Patent Cooperation Treaty, MERCOSUR's and the Andean Community's founding and secondary instruments, Brazilian and Paraguayan patent legislation, the Brazilian private-law framework bearing on the border market—its rules on contractual effects, competition, consumer protection, and conflict of laws—and official materials issued by patent and health authorities, supplemented by contemporaneous press reporting and industry-association statements concerning the Paraguayan market. This last category of source deserves a methodological caveat: the claim that Eli Lilly did not seek patent protection for tirzepatide in Paraguay rests on a public statement by the president of Cifarma, the Paraguayan pharmaceutical-industry chamber, rather than on an independent search of DINAPI's patent register conducted by the authors. The statement is consistent with Paraguay's continued position outside the Patent Cooperation Treaty, discussed in Section 2.2. That coincidence is treated below as a plausible institutional incentive bearing on filing decisions, not as a demonstrated explanation of this one, since no applicant-level evidence of the filing decision is publicly available. Even so, the broader argument does not depend on the precise scope of that single patent family. The structural point is more general: patent status and regulatory authorization are independently determined within each jurisdiction, while the border market connects the consequences of those determi-

nations.

Because a substantial part of the factual record consists of official notices, industry statements, and press reports rather than adjudicated findings, the documentary analysis followed an explicit source-selection protocol. Sources were collected for the period running from ANVISA's approval of Mounjaro in September 2023 to April 2026, in Portuguese, Spanish, and English, and were ranked in four tiers of evidentiary weight. The first tier comprises binding legal instruments and formal administrative acts—treaties, statutes, regulations, and the published decisions and technical notes of ANVISA, DINAVISA, INPI, and DINAPI—which are treated as authoritative as to their own content and legal effect. The second comprises non-binding official communications, such as agency press releases and institutional web pages, which are treated as reliable evidence of the agency's own position and of the existence of the underlying act, but not as independent proof of contested facts. The third comprises statements by market participants and their representative associations, including Cifarma and Eli Lilly. These are treated as party statements: probative of what the declarant asserts and of the declarant's interest in asserting it, but not, without corroboration, of the fact asserted. The fourth comprises press reporting, admitted only for facts of a kind a reporter can directly observe or verify—retail prices, product presentations, patient practices at a specified crossing, the occurrence of a seizure or a theft—and preferred where the same fact was reported by at least two outlets under separate ownership, or where the report reproduces a first- or second-tier document.

Conflicts among sources were resolved by tier. Where a formal administrative act and a press account diverge, the act controls and the divergence is recorded rather than harmonized. Where two accounts of comparable authority conflict and neither can be preferred on documentary grounds, the article states the conflict and declines to resolve it. Where a fact rests on a single third-tier source that no first- or second-tier document corroborates—as is the case for the assertion that no Paraguayan patent application was filed for tirzepatide—the dependency is marked expressly at each point of use and the analytical weight placed on the fact is confined accordingly, a discipline applied in Sections 1, 2.2, 4.1, and 5. Sources that could not be retrieved in full text, or whose authorship or date could not be established, were excluded.

The assertion that tirzepatide is unprotected in Paraguay was also subjected to an independent documentary check, whose method and limits are stated here so that it can be replicated. The relevant patent family was first identified from the originator's own filings: the priority application US 62/101,559 of 9 January 2015; the international application PCT/US2016/012124, published on 14 July 2016 as WO 2016/111971 A1 under the title "GIP and GLP-1 co-agonist compounds"; the United States patent US 9,474,780 B2, granted on 25 October 2016; the European patent EP 3 242 887 B1; and the Brazilian national-phase filing BR 11 2017 010596-9, granted as BR 112017010596 B1, whose anticipated term runs to 5 January 2036. These documents share the DOCDB simple-family identifier 55315708, which was

used as the retrieval key.

Searches were run on 08/12/2026 against Espacenet and its Latin American interface LATIPAT, against PATENTSCOPE, and against the Google Patents family view, combining the family identifier with the free-text terms "tirzepatide", "tirzepatida", "LY3298176", "GIP and GLP-1 co-agonist", and "coagonista"; with the applicant name "Eli Lilly"; and with the classification symbols C07K 14/605 and A61K 38/26, filtering results by the country code PY. No Paraguayan member of the family was retrieved. Two qualifications must accompany that negative result. First, it is a finding about database coverage as much as about the register: Paraguayan patent data are not comprehensively indexed in the international collections consulted, and the authoritative record remains DINAPI's own register and its Patent Bulletins, which are published as sequential documents rather than exposed through a keyword-searchable public interface; a conclusive answer therefore requires either a formal search request addressed to DINAPI or a document-by-document review of the Bulletins. Second, the absence of a family member is evidence that no application deriving from the same priority was filed, not proof that no application naming tirzepatide was ever filed in Paraguay by any applicant. What the check establishes is therefore convergence rather than proof: the industry association's public statement, the absence of an indexed Paraguayan member of the family, and Paraguay's position outside the Patent Cooperation Treaty all point in the same direction, and the argument developed below is calibrated to that level of confidence.

The argument proceeds in three stages. Section 2 reconstructs patent territoriality as a deliberate allocation of legal authority rather than a defect to be corrected by economic integration. Section 3 examines the Brazil-Paraguay border as an integrated economic space governed by institutionally autonomous legal orders. Section 4 uses tirzepatide as a critical case to show how territorially allocated rights and approvals interact with a market organized across the border. Section 4 also asks whether private ordering—the contractual instruments through which patent holders organize territorial exclusivity—can compensate for what territorial patent law leaves uncovered, and finds that it reproduces the same mismatch rather than curing it. The conclusion argues that the territorial State remains the indispensable unit of legal authority but should not be treated as the exclusive unit of market analysis.

2. Patent Territoriality as an Institutional Design

2.1. Territoriality and the Independence of National Patents

Territoriality is often described as a limitation on intellectual property rights, but that description can obscure its institutional function. A patent does not simply stop at the border because international law failed to complete the task of harmonization. It stops because the entitlement is constituted by a legal order whose authority is territorially bounded. The relevant State determines patentability, examination, grant, exceptions, remedies, and public-interest limitations. Territori-

ality therefore combines two propositions: the legal effects of a patent are limited to the jurisdiction that recognizes it, and equivalent inventions may receive different legal treatment in different jurisdictions.

The Paris Convention gave this structure an explicit doctrinal form. Article 4bis states that patents applied for in the countries of the Union by nationals of those countries are independent of patents obtained for the same invention in other countries (Paris Convention for the Protection of Industrial Property, 1883). Independence means that the grant, refusal, revocation, lapse, or duration of one national patent does not automatically determine the fate of another. The rule protects national competence while allowing applicants to pursue protection across multiple legal orders. As Bodenhausen's authoritative guide explains, the provision prevents the legal history of one patent from mechanically controlling another member of the international family (Bodenhausen, 1968).

This independence is compatible with international cooperation. The priority system created by the Paris Convention permits an applicant to rely on an earlier filing date when seeking protection abroad, but priority does not merge the resulting rights. It facilitates coordinated entry into national systems. The distinction matters: international patent law reduces procedural fragmentation while preserving legal plurality. A common filing chronology does not produce a common entitlement.

The territorial model also distributes political responsibility. Patent protection involves choices about the relationship between innovation incentives, competition, access, industrial policy, and public health. Assigning those choices to national institutions permits variation within the minimum limits established by international law. The resulting differences may create costs, but they also reflect the continuing legitimacy of domestic lawmaking. A territorial patent is thus both a private right and an institutional decision about the conditions under which exclusivity will be recognized in a particular political community.

2.2. Harmonization without Supranationalization

TRIPS substantially increased the degree of harmonization in international intellectual property law. It required World Trade Organization members to comply with minimum standards concerning patentable subject matter, rights conferred, term, exceptions, compulsory licensing, enforcement, and dispute settlement. It also incorporated core provisions of the Paris Convention. Yet the agreement did not create a unitary patent title or a centralized patent administration. Article 1.1 permits members to determine the appropriate method of implementing the agreement within their own legal systems and practices (TRIPS Agreement, 1994). Harmonization therefore operates through internationally binding obligations implemented by territorially competent authorities.

This structure reflects a compromise between common standards and institutional diversity. TRIPS narrows the range of permissible national choices but does not erase national patent law. Patent applications remain subject to domestic or

regionally delegated examination; infringement remains a matter for competent courts and authorities; and exceptions remain embedded in national legal orders, even when their compatibility with TRIPS may be reviewed internationally. Correa's commentary demonstrates that the agreement's substantive convergence coexists with meaningful implementation choices, particularly in areas affecting pharmaceuticals and public health (Correa, 2007).

The Patent Cooperation Treaty follows the same logic at the procedural level. It allows applicants to file an international application, obtain an international search and, where requested, a preliminary examination. The national or regional phase nevertheless remains decisive. The PCT does not grant an international patent (Patent Cooperation Treaty, 1970). It postpones and coordinates the applicant's interaction with multiple offices. Procedural integration is used to manage territorial rights, not to replace them.

Paraguay illustrates the practical stakes of this procedural architecture. Unlike most Latin American States, Paraguay has not acceded to the Patent Cooperation Treaty; accession remains under evaluation by national authorities (Abente Stewart, n.d.). An applicant seeking protection in Paraguay must therefore rely on the Paris Convention's twelve-month priority period for a direct national filing, rather than the thirty-month window the PCT affords applicants who file nationally after an international phase. This asymmetry increases the cost and the urgency of a Paraguay-specific filing decision relative to jurisdictions where the PCT is available, and it supplies a structural, non-conspiratorial explanation for why some pharmaceutical patent holders decline to seek Paraguayan protection: the absence of a right in Paraguay may reflect a rational allocation of filing resources under a demanding procedural calendar rather than a substantive gap in Paraguayan patentability standards. Territoriality, in other words, is shaped not only by where an applicant may file but by how burdensome filing is procedurally—a point the tirzepatide case will make concrete in Section 4.

That explanation is offered as an institutional incentive rather than as a demonstrated cause, and the distinction matters. Establishing causation would require applicant-level evidence—internal filing criteria, market-size thresholds, or a statement by the applicant explaining the decision—none of which is publicly available for this patent family. Two features of the documentary record counsel against treating the procedural asymmetry as sufficient on its own. First, the indexed family described in Section 1 contains no member in Chile either, although Chile has been a Patent Cooperation Treaty contracting State since 2009 (WIPO, n.d.-b); the availability of the international route is therefore not by itself determinative of where an applicant files. Second, the burden of a direct Paris-route filing, while real, is modest relative to the commercial stakes of a product of this value, which suggests that expected market size, enforcement conditions, and portfolio-level cost allocation operate alongside—and possibly ahead of—the procedural calendar. The claim advanced here is accordingly the weaker one: Paraguay's non-membership of the PCT raises the cost and compresses the timetable

of a Paraguay-specific filing decision, and so plausibly contributes to selective non-filing, without having been shown to explain it.

Dinwoodie and Dreyfuss describe the international intellectual property regime as resilient partly because it accommodates national variation within an increasingly dense network of international rules (Dinwoodie & Dreyfuss, 2012). That resilience should not be confused with uniformity. The system's operation depends on a layered allocation of authority: international agreements define obligations; domestic institutions constitute and enforce rights; and regional institutions may coordinate or partially centralize functions where States have consented to do so. In the absence of such delegation, economic integration alone does not transfer patent competence.

MERCOSUR's intergovernmental design is not the only model available for regional economic integration involving pharmaceutical patents. The Andean Community offers an instructive counterpoint. Decision 486 of the Andean Community Commission establishes a Common Regime on Industrial Property that applies directly and uniformly in Bolivia, Colombia, Ecuador, and Peru, superseding inconsistent national law without requiring domestic transposition (Andean Community, 2000). The regime is enforced in part by the Andean Tribunal of Justice, which by the late 2000s had issued more than fourteen hundred rulings on intellectual property matters and had measurably shaped how national patent offices apply the common standard (Helfer, Alter, & Guerzovich, 2009). Alter and Helfer's subsequent study describes the Tribunal as effective specifically within this intellectual property domain, even though the broader Andean integration project has not replicated the European Union's deeper political and judicial centralization (Alter & Helfer, 2017). The comparison is useful precisely because it shows that harmonization without supranationalization, as described above for TRIPS and the PCT, is a choice rather than a necessity: regional blocs can adopt directly applicable, centrally adjudicated patent law when their member States consent to it. MERCOSUR has not made that choice. Its member States, including Brazil and Paraguay, retain full national competence over patent examination, grant, and enforcement, coordinated only through the general commitments of the Treaty of Asunción and the Protocol of Ouro Preto. The institutional mismatch this article identifies is therefore not an inevitable feature of regional economic integration as such. It is a contingent feature of the particular institutional choice MERCOSUR has made, one that a differently designed regional bloc could in principle narrow, though not eliminate, since even the Andean Tribunal's harmonized patent standard leaves marketing authorization, customs enforcement, and pricing outside its jurisdiction.

The political-science literature on international intellectual property governance frames this choice in comparable terms. Helfer's account of regime shifting describes how States dissatisfied with outcomes in one international forum relocate their intellectual-property agenda to others, producing a layered and only partly coherent regime rather than a single hierarchy (Helfer, 2004, 2009). The

access-to-medicines literature records how that layering was tested in the pharmaceutical field, where the flexibility available to States under TRIPS proved to depend heavily on national administrative capacity and political choice rather than on the text alone (Hoen, Berger, Calmy, & Moon, 2011). Regional governance in South America shows the same pattern from below: Riggirozzi's study of health diplomacy documents genuine regional coordination on health that nonetheless stops short of transferring decision-making competence away from national authorities (Riggirozzi, 2014). The Andean and MERCOSUR trajectories are best read against that background—as institutional choices about where competence should sit, made and revisable by States, rather than as stages in a single convergence.

For present purposes, the crucial result is that international patent law harmonizes legal standards more readily than it harmonizes market conditions. Two neighboring States may both comply with TRIPS while producing different practical outcomes because their patent offices, courts, health regulators, customs authorities, administrative capacities, and market structures differ. Such differences do not necessarily indicate noncompliance. They are a foreseeable consequence of harmonization without supranationalization.

2.3. Legal Coherence and Institutional Performance

A distinction between legal coherence and institutional performance clarifies the argument. A legal arrangement is coherent when its rules, competencies, and consequences can be understood within the architecture that created them. Patent territoriality satisfies this criterion. It identifies the authority that grants the right, the territory in which the right has effect, and the institutions competent to enforce it. A Brazilian patent does not purport to govern Paraguay, and a Paraguayan decision does not purport to determine the validity of a Brazilian patent. The system supplies a clear jurisdictional answer.

Institutional performance asks a different question: how does that arrangement operate when it interacts with other institutions and with the social environment? A territorially coherent patent system may encounter a market in which consumers and products cross borders frequently. In that setting, the patent's territorial limits remain legally clear, but the economic consequences of national divergence are transmitted through the integrated market. A difference in price, authorization, enforcement, or availability in one jurisdiction may influence demand and circulation in the neighboring jurisdiction.

The distinction prevents two analytical errors. The first is to infer from cross-border circulation that territoriality has failed. The movement of goods beyond the territory in which a right is recognized may create infringement, customs, exhaustion, or regulatory questions, but it does not make the territorial rule incoherent. The second error is to assume that because territoriality remains coherent, national analysis is sufficient to explain the market. Legal validity and explanatory sufficiency are not the same thing.

The institutional mismatch identified in this article arises at this second level. It describes the interaction between a territorially allocated legal competence and a functionally integrated economic environment. The mismatch is relational. It cannot be located exclusively in Brazilian law, Paraguayan law, or MERCOSUR law because it emerges from the way their separate institutions operate within a connected border market. Nor is it resolved simply by proving that each State has complied with its international obligations. Compliance may coexist with cross-border effects that no single institution was designed to manage comprehensively.

This conceptualization preserves the normative value of territoriality while opening a broader field of analysis. It directs attention toward institutional interfaces: the point at which patent decisions interact with pharmaceutical authorization; the point at which lawful availability in one market generates demand from another; the point at which customs and health surveillance encounter products produced, labeled, or sold under foreign rules; and the point at which regional integration increases mobility without integrating every legal function.

2.4. Institutional Mismatch and Legal Geography

The distinction between legal coherence and institutional performance developed above intersects with a body of scholarship this article has not yet engaged: legal geography. Since the 1990s, legal geographers have argued that law is not merely applied within space but is constitutive of it—that jurisdiction, property, and territory are produced through the same practices that produce social space (Blomley, 1994). Blomley, Delaney, and Ford's edited reader consolidated this claim into a research program examining how legal categories such as the border, the jurisdiction, and the market are themselves spatial artifacts rather than neutral containers for legal rules (Blomley, Delaney, & Ford, 2001). Delaney's concept of the nomosphere extends the argument further, describing the cultural-material environment produced by the reciprocal entanglement of legal signification and lived space, in which ordinary commercial practices—a purchase, a border crossing, a delivery—simultaneously enact and are shaped by legal categories (Delaney, 2010). Braverman, Blomley, Delaney, and Kedar's later collection extends this program to biotechnology, borders, and infrastructure, domains structurally similar to the pharmaceutical border market examined here (Braverman, Blomley, Delaney, & Kedar, 2014).

This literature anticipates, in a different idiom, the argument that territorial legal categories can be coherent while failing to describe the space in which they operate. It would therefore be a mistake to present institutional mismatch as a wholly new discovery. What legal geography contributes is a claim about how law and space are mutually constitutive; what this article adds is a narrower, institutionally specific claim about administrative competence—namely, that patent offices, health regulators, and customs authorities each observe only the portion of an integrated market that falls within their territorial mandate, and that no institution among them is positioned to observe the connected whole. The legal-geog-

raphy literature is generally more concerned with how law produces spatial meaning—for instance, how a border comes to be experienced as a legal fact—than with the narrower administrative question of which agency has jurisdiction to act on a cross-border commercial pattern once it is observed. Institutional mismatch, as used here, borrows the former literature's premise that territorial categories are not self-evidently adequate descriptions of economic space, while directing that premise toward a more applied question: which institutions, if any, are capable of managing the interfaces among territorially bounded regimes. The tirzepatide case in Section 4 is offered in that applied register.

3. Integrated Border Economies and the Brazil-Paraguay Context

3.1. Integration as a Functional Economic Relationship

The Treaty of Asunción established MERCOSUR with the objective of creating a common market based on the free movement of goods, services, and factors of production, a common external tariff, coordination of macroeconomic and sectoral policies, and the harmonization of legislation in relevant areas (MERCOSUR, 1991). The Protocol of Ouro Preto later supplied a definitive institutional structure and international legal personality (MERCOSUR, 1994). These instruments express an integration project, but they do not establish a federal or fully supranational order. MERCOSUR's principal decision-making bodies remain intergovernmental, and implementation frequently depends on domestic legal and administrative processes.

This institutional design produces a familiar feature of regional integration: economic relationships may deepen more quickly or more extensively than legal centralization. Mattli argues that integration responds to demand for reduced transaction costs and to the supply of regional governance, but the institutional form varies according to political conditions (Mattli, 1999). MERCOSUR lowers and coordinates barriers while preserving national competence across many regulatory fields. Its border regions therefore combine intensified economic interdependence with persistent jurisdictional separation.

The Brazil-Paraguay border is an especially revealing environment. Ciudad del Este and Foz do Iguaçu are not merely adjacent municipalities located on opposite sides of an international line. They form part of a broader cross-border commercial system shaped by daily mobility, tourism, retail specialization, logistics, currency and tax differentials, and the social networks of the Triple Frontier. The Friendship Bridge is simultaneously a border checkpoint and an artery of an integrated urban economy. Formal legal categories remain national; commercial behavior is routinely transboundary.

Keohane and Nye's concept of complex interdependence is useful here because it shifts attention from isolated sovereign units to multiple channels of interaction and reciprocal effects (Keohane & Nye, 1977). Border markets do not eliminate State authority. They multiply the pathways through which decisions in one juris-

diction affect actors in another. A regulatory approval, shortage, price change, enforcement operation, or advertising trend on one side of the border may rapidly alter conduct on the other.

The term integrated border economy is used here in a functional rather than constitutional sense. It does not imply the disappearance of customs, perfect freedom of movement, or uniform law. It identifies an economic space in which cross-border interaction is sufficiently recurrent and organized that analyzing each side as a self-contained national market omits a material part of the commercial reality. Integration is therefore a matter of patterned interdependence, not legal fusion.

3.2. Autonomous Patent and Pharmaceutical Institutions

Against this integrated economic background, patent and pharmaceutical institutions remain national. In Brazil, the National Institute of Industrial Property (INPI) administers patents under Law No. 9279 of 1996 (Brazil, 1996). In Paraguay, the National Directorate of Intellectual Property (DINAPI) performs the corresponding function under Law No. 1630 of 2000, as amended (Paraguay, 2000). Each office applies its own procedures and national law within the constraints of international commitments. A patent application concerning the same molecule may therefore have a distinct procedural history, claim scope, status, or enforceability in each country.

Paraguay's continued position outside the Patent Cooperation Treaty is one further expression of this institutional autonomy, discussed in Section 2.2: the procedural route by which a foreign applicant secures protection differs from one side of the border to the other, independently of the underlying patentability standards each office applies.

Pharmaceutical regulation is institutionally separate from patent administration. ANVISA evaluates the quality, safety, and efficacy of medicines for the Brazilian market under Brazil's health-surveillance framework. Paraguay's National Directorate of Health Surveillance (DINAVISA) performs comparable regulatory functions within its jurisdiction. Marketing authorization does not itself confer a patent, and a patent does not itself authorize commercial sale. The two regimes protect different public interests through different legal tests.

The distinction is elementary but indispensable in cross-border disputes. A product may be unpatented yet unregistered; patented yet authorized to a licensee; authorized in one country and unregistered in another; genuine but unlawfully imported; or falsified regardless of patent status. The legal analysis therefore requires a matrix rather than a single binary classification. Patent law, health regulation, customs law, consumer protection, and criminal law may attach different consequences to the same physical item.

National autonomy also extends to enforcement capacity and regulatory practice. Offices differ in resources, inspection priorities, judicial speed, border-control strategies, and access to information. These differences can produce uneven practical conditions even where the written law is broadly aligned. International

minimum standards do not equalize institutional capacity, and regional trade integration may make the consequences of those differences more visible by connecting the affected markets.

The Brazil-Paraguay setting therefore contains an asymmetry between the density of economic interaction and the allocation of regulatory authority. Consumers can cross the border more easily than a patent right or marketing authorization can. A medicine lawfully registered in one State does not acquire authorization in the other by virtue of physical proximity or regional integration. Likewise, the absence, expiration, limitation, or non-enforcement of a patent in one jurisdiction does not alter the territorial effect of a patent recognized in the neighboring jurisdiction.

3.3. Pharmaceutical Circulation across the Border

Pharmaceutical markets intensify this asymmetry because demand is shaped by health needs, perceived urgency, scarcity, and substantial price differences. Consumers may be less willing to treat the national market as exclusive when a desired medicine appears available nearby. Social media and messaging platforms further detach information from territory: advertisements, testimonials, price lists, and informal recommendations circulate before regulators can establish the origin or status of the products being offered.

This pattern is not peculiar to the Brazil-Paraguay border, and a body of peer-reviewed scholarship on cross-border pharmaceutical purchasing allows it to be stated with more precision. Studies of the United States-Mexico border have documented sustained purchasing of medicines across the line, driven by price, by the absence of insurance coverage, and by more permissive dispensing practice on the cheaper side, with a substantial share of purchases made without a prescription (Rivera, Ortiz, & Cardenas, 2009; Essigmann et al., 2022). Within MERCOSUR, Giovanella and colleagues surveyed municipal health secretaries in sixty-nine Brazilian border localities and found routine, structurally embedded demand crossing the border in both directions, largely unrecorded by the national information systems that each State uses to plan its own provision (Giovanella, Guimaraes, Nogueira, Lobato, & Damacena, 2007). The European experience of parallel trade in medicines points the same way from the supply side: price differentials between adjacent regulated markets are durable and are systematically exploited by intermediaries even where patent and marketing-authorization rules are harmonized and the internal market is legally unified (Kanavos & Costa-Font, 2005). What the tirzepatide case adds to this literature is not the discovery of cross-border purchasing but a setting in which the divergence has a patent dimension as well as a price dimension.

The physical movement of a pharmaceutical product across the border transforms its legal characterization. A product sold under Paraguayan rules enters a different legal environment when brought into Brazil. Brazilian patent rights, import controls, personal-use exceptions, prescription requirements, and ANVISA

registration rules may become relevant. The product does not carry the law of the place of purchase with it. At the same time, the commercial incentive that generated the transaction may have arisen from the integrated market rather than from either national market considered separately.

This intuition has a precise basis in the conflict of laws. Brazilian private international law, codified in the Law of Introduction to the Norms of Brazilian Law (Decree-Law No. 4657 of 1942, the LINDB) (Brazil, 1942), determines the law governing an obligation by the place where it is constituted through its Article 9 and asserts Brazilian jurisdiction where the obligation is to be performed in Brazil through its Article 12. A purchase concluded in Paraguay may thus be governed, as a contract, by Paraguayan law. But the rules that matter most at the border are not dispositive contract rules; they are mandatory norms of public order—patent territoriality, marketing authorization, import control—which apply as *lex fori* regardless of the law attached to the underlying transaction. The conflict-of-laws rule allocates the private contract; it does not displace the territorial competence of the importing State over patents and public health. This is the doctrinal reason the product does not carry the law of its place of purchase with it: the private transaction and the public regime answer to different, and independently determined, choice-of-law logics.

This explains why border circulation should not be described only as leakage from one jurisdiction into another. Leakage suggests a primary, self-contained market from which goods escape. In an integrated border economy, cross-border demand may be constitutive of the market itself. Suppliers may anticipate foreign consumers; consumers may treat the neighboring jurisdiction as part of their ordinary choice set; transport services may be organized around purchasing trips; and digital commerce may connect buyers and sellers without regard to the regulatory boundary that ultimately determines legality.

None of this eliminates the importance of enforcement. On the contrary, it makes enforcement more complex. Customs and health authorities must distinguish personal importation from commercial distribution, genuine products from falsified products, registered products from unregistered products, and patent-related conduct from public-health violations. The same package may trigger several legal regimes, each with a different evidentiary basis and institutional owner.

The border economy thus operates as an interface among legal systems. Its significance lies not in being outside the law, but in being governed by several territorial legal orders whose effects converge in a single commercial environment. This convergence prepares the ground for the tirzepatide case.

4. Tirzepatide as a Critical Case

4.1. Why Tirzepatide Makes the Institutional Relationship Visible

A critical case is valuable not because it is statistically representative, but because it makes a mechanism particularly clear (Flyvbjerg, 2006). Tirzepatide has this quality, and recent regulatory and commercial developments along the Brazil-Par-

aguay border make the mechanism observable in unusually concrete terms rather than only in principle.

ANVISA approved Mounjaro, containing tirzepatide, as a new medicine in September 2023 for adults with type 2 diabetes, and later extended the indication to weight management for adults with obesity or overweight with comorbidities; commercial sale in Brazil began in May 2025 (ANVISA, 2023; Conselho Federal de Farmácia, 2025). The Brazilian registration identifies Eli Lilly do Brasil as the holder. Meanwhile, at least five Paraguayan laboratories—among them Laboratorio de Productos Éticos, manufacturer of the product marketed as Lipoless—obtained sanitary registration from DINAVISA to produce and sell tirzepatide-based injectable products in Paraguay (Eticos Paraguay, n.d.). According to the president of Cifarma, the Paraguayan pharmaceutical-industry chamber, this is possible because Eli Lilly did not file a Paraguayan patent application for tirzepatide, and under Paraguayan law a patent can exist only where an application was filed (La Nación, 2026). Consistent with this account, and as discussed in Section 2.2, Paraguay's continued position outside the Patent Cooperation Treaty makes selective non-filing in smaller markets a foreseeable outcome of ordinary filing economics rather than a gap in Paraguayan patent law itself.

Two methodological qualifications attach to that account. The documentary family check described in Section 1 neither confirms nor contradicts it from the register itself: it establishes only that no Paraguayan member of the relevant patent family—identified through the priority application US 62/101,559, the international application WO 2016/111971 A1, and the Brazilian national-phase grant BR 112017010596 B1, all sharing the simple-family identifier 55315708—is indexed in the international collections consulted. And, consistent with the reframing offered in Section 2.2, Paraguay's position outside the Patent Cooperation Treaty is treated here as an institutional incentive that plausibly bears on filing decisions, not as a demonstrated explanation of this one.

Two distinct categories of tirzepatide-related product circulation must be kept separate, and the border market contains documented examples of each. The first is the genuine, DINAVISA-registered Paraguayan product: Lipoless and comparable products are lawfully manufactured and sold in Paraguay under Paraguayan sanitary and, in the qualified sense above, patent law, but lack ANVISA registration and therefore cannot lawfully be sold in Brazil (ANVISA, 2025a). In November 2025, ANVISA prohibited the importation, distribution, advertising, and use of five such products by name—T.G. 5, Lipoless, Lipoless Éticos, Tirzazep Royal Pharmaceuticals, and T.G. Indufar—expressly for lack of Brazilian sanitary registration (ANVISA, 2025b). The measure did not allege patent infringement, trademark counterfeiting, or that the products were adulterated; the products' legal defect in Brazil is regulatory, not proprietary. The second category is the counterfeit product: in 2026, Eli Lilly do Brasil itself identified falsified batches bearing the Mounjaro trademark, with lot numbers and serial numbers inconsistent with genuine production, leading ANVISA to order seizures in February and July 2026

(ANVISA, 2026a, 2026b). These products are not manufactured by a licensed Paraguayan competitor; they misappropriate Eli Lilly's mark and packaging, and they raise trademark and consumer-protection questions that are analytically distinct from the Lipoless-type case. Collapsing the two categories, as informal reporting on the border market sometimes does, would obscure exactly the institutional distinctions this article aims to clarify: one category tests the limits of territorial patent and registration law operating as designed; the other is a conventional case of product counterfeiting that territorial law is well equipped to condemn in either jurisdiction.

On the counterfeit axis, a further body of Brazilian law is engaged that the registration cases do not touch. The Consumer Defense Code (Law No. 8078 of 1990) (Brazil, 1990) imposes strict liability along the supply chain for harm caused by defective products, distinguishing liability for a product defect that endangers the consumer, through its Article 12, from liability for a quality defect, through its Article 18. Falsified Mounjaro, bearing lot and serial numbers inconsistent with genuine production, is a textbook instance of a dangerous product defect. Yet extraterritorial acquisition thins the remedy: where the Brazilian consumer bought a counterfeit from a seller operating across the border, the chain of suppliers reachable under the Code may be short or absent, and the conflict-of-laws considerations discussed in Section 3.3 condition which liabilities a Brazilian court can in fact impose. Counterfeiting is thus doctrinally easy to condemn and practically hard to redress, and the difficulty is again a function of the border rather than of any defect in the substantive law.

Patent analysis adds a further layer even within the first category. Tirzepatide-related inventions may be covered by multiple patents or applications concerning the compound, formulations, manufacturing processes, delivery devices, or therapeutic uses, each of which must be assessed claim by claim and jurisdiction by jurisdiction; this article does not purport to have reviewed Eli Lilly's complete patent family, only the market-level outcome reported by Paraguay's industry association. The methodological advantage of the case is nonetheless intact: chemically identical or similarly labeled products occupy verifiably different legal positions in Brazil and Paraguay depending on filing decisions, authorization, and authenticity, and the molecule crosses the border as a physical and commercial object while the legal entitlements and approvals attached to it do not.

4.2. Patent Protection and Regulatory Divergence

Patent rights and pharmaceutical authorization are frequently discussed together because both affect market entry, but they are not sequential stages of a single regime. Patent law grants a right to exclude within a defined territory. Pharmaceutical regulation grants permission to place a product on a market after an assessment of quality, safety, and efficacy. A product may satisfy one regime and fail the other. Any analysis of tirzepatide in the border economy must therefore keep the two axes separate.

On the patent axis, the relevant questions include whether a patent or application exists in the jurisdiction, whether it is in force, what claims it contains, who owns or licenses it, whether the challenged conduct falls within those claims, and whether an exception or exhaustion rule applies. These are territorially determined questions. A Brazilian court cannot infer infringement merely from a label or from the existence of a foreign patent; it must identify a Brazilian right and compare the relevant conduct with its legally enforceable claims.

On the regulatory axis, the questions include whether the product has received marketing authorization, whether the manufacturer and supply chain comply with applicable standards, whether the batch is authentic, whether importation is permitted, and whether the product is dispensed under the required prescription controls. ANVISA's prohibition of an unregistered product does not require proof of patent infringement. Public-health enforcement can proceed on the independent ground that the product was not evaluated or was falsified.

Cross-border integration links these axes by allowing a product's treatment in one jurisdiction to affect incentives in another. A supplier operating in Paraguay may encounter a different set of patent, registration, pricing, and enforcement conditions than a supplier operating in Brazil. Brazilian consumers may respond to those differences by purchasing across the border. Once the product enters Brazil, however, Brazilian law governs its importation, distribution, sale, and use within Brazilian territory. The integrated market transmits regulatory differences; it does not neutralize them.

The magnitude of the resulting price differential is documented rather than assumed. According to Cifarma, the absence of patent protection allows Paraguayan-manufactured tirzepatide products to retail at roughly 40 percent of regional prices (La Nación, 2026). Brazilian press reporting corroborates the pattern at the retail level: Lipoless was reported selling in Paraguay for approximately R$550 per box, against R$1500 or more for the least expensive Mounjaro presentation available in Brazil, a ratio patients themselves describe as threefold (Midiamax, 2025).

That differential should not be attributed to the absence of patent protection alone. The absence of a Paraguayan patent is best understood as a permissive condition—it is what allows a competing manufacturer to exist at all—rather than as a measure of the distance between the two retail prices. At least five further drivers operate on the Brazilian side of the comparison, and each is independently documented. First, price formation for medicines in Brazil is regulated: Law No. 10,742 (Brazil, 2003) created the Medicines Market Regulation Chamber (CMED), which sets a maximum consumer price built up from a factory price and adjusted for the applicable tax burden, so that the Brazilian retail figure reflects an administratively constructed ceiling rather than an unconstrained market outcome. Second, the tax wedge differs sharply: taxes account for a substantial share of the final price of medicines in Brazil, principally through the state ICMS together with the federal PIS and COFINS contributions, whereas Paraguay applies a reduced value-added

tax rate of five per cent to the sale and importation of products registered as human medicines under Law No. 6380 of 2019 (Paraguay, 2019). Third, the two products embody different cost structures: an originator price recovers research, development, and global regulatory expenditure and is set within an international pricing strategy, while a domestically manufactured competitor that did not bear those costs prices against local demand. Fourth, distribution differs: the Brazilian chain typically interposes distributors and retail pharmacy margins that are themselves inputs into the regulated price, and the two markets differ in scale, currency, and purchasing power. Fifth, compliance costs diverge: the registration, pharmacovigilance, cold-chain, and traceability obligations attaching to a product lawfully marketed in Brazil are not equivalent to those borne by the Paraguayan competitor.

The economic literature on international pharmaceutical price differences supports this multi-causal reading. Danzon and Chao found cross-national price differences for pharmaceuticals to be large and to be driven substantially by regulatory regime, market structure, and the composition of the products compared, rather than by patent status alone (Danzon & Chao, 2000). Kyle showed that price-control regimes shape not only prices but the sequencing of product launches across countries (Kyle, 2007), with the relationship among patents, price controls, and global market entry also examined by Lanjouw (2005), and Cockburn, Lanjouw, and Schankerman found that patent regimes and price regulation jointly determine where and when new drugs are launched, each effect operating independently of the other (Cockburn, Lanjouw, & Schankerman, 2016). Kanavos and Costa-Font's study of parallel trade in Europe further shows that price differentials between adjacent regulated markets persist, and are exploited by intermediaries, even inside a single customs union with harmonized patent and marketing-authorization rules (Kanavos & Costa-Font, 2005). The claim defended here is therefore a limited one: the absence of a Paraguayan patent is a necessary condition for the existence of the cheaper Paraguayan product, and the resulting price gap is what makes the border market operate, but the magnitude of that gap is overdetermined, and this article does not purport to decompose it.

This is the first manifestation of institutional mismatch. The relevant legal systems classify the product territorially, but the market forms through comparison across territories. A consumer's decision may depend on the combined price and availability landscape of Brazil and Paraguay. No single national database captures that decision environment. Patent and regulatory analysis remain national, while market analysis becomes transnational.

4.3. Cross-Border Circulation and the Limits of National Market Assumptions

Conventional patent analysis often assumes a market bounded by the jurisdiction in which the right exists. This assumption is usually workable because infringement and remedies are territorially defined. In a border economy, however, the

assumption may conceal the source of the challenged conduct. Demand in Brazil may be supplied through transactions in Paraguay; advertising may be directed across the border; products may be carried by individual consumers, intermediaries, or organized distributors; and price signals may circulate independently of the product itself.

The resulting market is not legally unified. A purchase in Paraguay and an importation into Brazil are distinct acts that may attract distinct rules. Yet they are economically connected parts of a single transaction. Treating them as wholly separate national events makes the legal analysis formally neat but institutionally incomplete. The border market is the mechanism connecting the lawful or unlawful opportunities available under each system.

Exhaustion doctrine illustrates the difficulty. TRIPS Article 6 leaves members substantial autonomy concerning exhaustion for purposes of WTO dispute settlement. National rules may distinguish goods placed on a foreign market with the patent holder's consent from unauthorized copies or falsified goods. Even where international exhaustion is recognized, health regulation may independently prohibit importation of an unregistered medicine. The lawful sale of a genuine product abroad therefore does not necessarily establish lawful commercialization at home, and patent consent does not substitute for regulatory authorization.

Brazilian law gives this abstract point a concrete form. The Industrial Property Law (Law No. 9279 of 1996) limits the patent right, in Article 43, IV, as to a product placed on the internal market directly by the patent holder or with its consent—a formulation generally read as adopting national, rather than international, exhaustion, so that a lawful first sale abroad does not by itself exhaust the corresponding Brazilian patent. In the tirzepatide case, however, exhaustion is largely beside the point for the DINAVISA-registered Paraguayan products: because no Paraguayan patent was obtained, there is no foreign patent right whose exhaustion could even be argued. The barrier to their lawful sale in Brazil is regulatory, and any patent barrier would arise not from exhaustion but from the Brazilian patent's own territorial effect against unauthorized importation.

The same separation applies to personal importation. A legal system may tolerate or regulate limited importation for individual use while prohibiting commercial distribution. Such distinctions are sensible within domestic law, but an integrated border economy can generate scale through the aggregation of individual transactions. Repeated personal purchases may collectively alter the competitive environment without any single purchase resembling conventional commercial importation. This does not make every purchase unlawful; it shows that the market effect may exceed the categories used to regulate each act.

These dynamics are not hypothetical. Brazilian patients living near the border have described routine monthly trips to Paraguay to purchase Lipoless, carrying the product across the Ponta Porã-Pedro Juan Caballero crossing in insulated coolers together with a Brazilian medical prescription, a pattern that predates and continued after ANVISA's November 2025 prohibition (Midiamax, 2025). At the

same time, Paraguayan reporting documents conduct clearly outside any personal-use exception: in April 2026, a Brazilian traveler was detained crossing from Ciudad del Este into Brazil with tirzepatide vials taped to his legs, and a separate shipment of tirzepatide was stolen and later recovered in Itacurubí de la Cordillera, indicating that criminal actors treat the product as valuable enough to justify organized theft along transport routes (La Nación, 2026). The same reporting describes a broader wave of robberies targeting tirzepatide shipments in the border region. These episodes illustrate, more concretely than a doctrinal description alone could, that the aggregate effect of an integrated pharmaceutical border market is not reducible to the personal-importation exceptions that domestic law is designed to accommodate.

The boundary these episodes test is itself drawn by positive law, on two axes. On the patent axis, the Industrial Property Law exempts, in Article 43, I, acts performed by unauthorized third parties in private and without commercial purpose, provided they cause no economic prejudice to the holder—a limitation that shelters genuine individual use but not distribution. On the sanitary axis, ANVISA's regulation on the importation of medicines by natural persons conditions and quantitatively limits personal importation, so that what exceeds the permitted personal quantum is not a tolerated exception but an unauthorized import (ANVISA, 2008). The aggregation problem noted above operates precisely at the seam between these norms: each individual purchase may fall within the private-use limit of both axes while the cumulative cross-border flow exceeds anything those exceptions were designed to permit. The exceptions are drawn for the isolated act; the integrated market supplies volume through their repetition.

Digital intermediation further complicates territory. Sellers can promote products to Brazilian consumers while physically operating outside Brazil. Payments, communications, delivery arrangements, and medical advice may occur in different places. The location of infringement, offer for sale, advertising, importation, and consumer harm may therefore diverge. Territoriality still supplies the governing rules, but establishing the relevant territorial connecting factors becomes more fact-intensive.

Tirzepatide exposes these dynamics because the product's value and demand justify cross-border search. It would be mistaken, however, to infer that the problem is unique to anti-obesity medicines. Similar interactions can arise for oncology medicines, biologics, fertility treatments, vaccines, rare-disease therapies, medical devices, and agricultural technologies. The case identifies a general institutional pattern: high-value regulated products move through markets whose functional geography differs from the geography of legal authority.

4.4. Territoriality Remains Legally Coherent

Tirzepatide does not show that patent territoriality is obsolete. The territorial system continues to identify the rights enforceable in Brazil, the rights enforceable in Paraguay—including their conspicuous absence in the latter—and the authorities

competent to decide disputes in each country. Eli Lilly's choice not to file in Paraguay, DINAVISA's registration of Lipoless, and ANVISA's prohibition of the same product in Brazil are each, individually, straightforward applications of territorial competence. Cross-border circulation creates difficult facts; it does not erase the jurisdictional structure that produced those facts in the first place.

Nor does the case establish that a supranational patent would solve the underlying problem, and the Andean comparison developed in Section 2.2 makes this concrete rather than speculative. Even under Decision 486's directly applicable, centrally adjudicated patent regime, marketing authorization, product authenticity, prescription requirements, pricing, and customs enforcement would remain separately administered national functions. A unitary tirzepatide patent covering Brazil and Paraguay might close the specific gap this case exploits, but it would leave the broader architecture of institutional mismatch intact: the border market would still connect national decisions on registration, pricing, and enforcement that a patent-only fix does not touch. The temptation to treat territoriality as the problem arises from a category error. Patent law is asked to organize the market when its principal function is to allocate exclusive legal authority; it cannot by itself align national health systems, equalize prices, authenticate products, or supervise every border crossing. Those tasks belong to other institutions, and the case supports a defense of territoriality accompanied by a correction in analytical method: preserve the territorial allocation of rights while recognizing the border economy as an autonomous field of interaction requiring coordination among patent, health, customs, consumer-protection, and law-enforcement authorities.

4.5. The Institutional Mismatch Thesis

Institutional mismatch is a condition in which the territorial scale at which legal authority is allocated differs from the functional scale at which the regulated market is organized. It has four elements: more than one territorially autonomous legal order governs aspects of the same category of goods; material differences exist in rights, approvals, enforcement, price, or availability; recurrent cross-border interaction transmits the effects of those differences; and no single institution possesses authority over the entire functional market. The Brazil-Paraguay tirzepatide market satisfies all four: Brazilian and Paraguayan patent and health authorities are each competent only within their own territory; tirzepatide is patent-protected and expensively priced in Brazil but unpatented, DINAVISA-registered, and priced at roughly 40 percent of the regional level in Paraguay; consumers, couriers, and even thieves move the product across the border at a documented, non-trivial scale; and neither ANVISA, DINAVISA, INPI, DINAPI, nor MERCOSUR observes the connected market as a single object—each observes only the slice that falls within its mandate.

The fourth of these elements requires substantiation rather than assertion, because the two States are not without coordination machinery. Four mechanisms are relevant, and each is limited in a way that leaves the connected market unob-

served.

The first is sectoral harmonization within MERCOSUR. Working Subgroup No. 11 ("Health") and its Commission on Health Products have produced a body of Common Market Group resolutions harmonizing the requirements for the registration of pharmaceutical products across the member States. What is harmonized, however, is the content of the national requirement; the registration decision itself remains national. That is precisely why DINAVISA could register Lipoless and ANVISA could exclude the same product without either State departing from the harmonized standard.

The second is intellectual property. MERCOSUR's Protocol on the Harmonization of Intellectual Property Norms, approved by CMC Decision No. 8/95 (MERCOSUR, 1995), covers trademarks, indications of source, and appellations of origin only; as to patents, the member States undertook merely to seek additional agreements in the future, and no such instrument has been concluded. Patent competence within MERCOSUR is therefore not merely decentralized but expressly left outside the harmonization achieved for other industrial-property rights.

The third is customs and integrated border management. The Recife Agreement and its implementing rules (MERCOSUR, 2000) provide for Integrated Control Areas at MERCOSUR crossings, in which the customs, migration, sanitary, and transport controls of both States are carried out sequentially or, where possible, simultaneously at a single location. The mechanism coordinates the sequencing of controls over declared cargo at a fixed point; it is not designed to produce a shared picture of a product market, and at the Foz do Iguacu-Ciudad del Este crossing the integration actually achieved has in practice been confined to particular agencies and commodity classes. It also engages formal commercial traffic, whereas much of the circulation described in Section 4.3 travels as accompanied personal baggage or through channels that never present themselves for control at all.

The fourth is regulatory convergence outside the bloc, principally through the Pan American Health Organization's Pan American Network for Drug Regulatory Harmonization (PAHO, n.d.), which promotes convergence of technical standards and mutual reliance among national regulators. Its instruments are recommendatory, and its unit of action is the national authority's own regulatory capacity rather than the transboundary market.

Taken together, these mechanisms harmonize inputs—requirements, procedures, control sequences, technical standards—and facilitate flows. None of them constitutes an authority, or even a standing forum, charged with observing the demand, pricing, and circulation of a given medicine across the two territories as a single object, or with deciding what to do about what it observes. That is the sense, and the only sense, in which the claim of unobserved wholeness is advanced here.

The mismatch is not equivalent to a regulatory gap, and it is not evidence of

any institution's failure. The conduct is densely regulated: DINAVISA evaluated and registered Lipoless; ANVISA evaluated and rejected it for the Brazilian market; Eli Lilly made a filing decision inside a coherent, if administratively demanding, procedural framework. The difficulty lies in the absence of a perspective capable of integrating these separately correct decisions. This is also where the comparison to the Andean Community is instructive rather than merely decorative: Decision 486 demonstrates that the territorial scale of patent law can be enlarged by consent, and the Andean Tribunal of Justice demonstrates that a regional body can meaningfully harmonize outcomes within that scale (Helfer, Alter, & Guerzovich, 2009). MERCOSUR has not made that institutional choice for patents, and nothing in the tirzepatide case compels it to. What the case does compel is more modest: an acknowledgment that formal compliance with TRIPS, or even a hypothetical future harmonization of Brazilian and Paraguayan patent law, would not by itself integrate the market these two States' pharmaceutical regulators, customs services, and law-enforcement agencies currently observe only in fragments.

The thesis therefore has a modest normative implication. It does not prescribe a regional patent office, a uniform pharmaceutical code, or stronger exclusivity. It calls for administrative coordination that stops short of legal fusion: information-sharing between ANVISA and DINAVISA about products such as Lipoless before, rather than after, they accumulate cross-border distribution networks; a standing distinction, in enforcement communications, between the registration ground on which the November 2025 prohibition rests and the counterfeiting ground on which the 2026 seizures rest, so that patients and press do not conflate a generic-competition story with a trademark-fraud story; and border-level cooperation between Brazilian and Paraguayan customs and police, of the kind already implicated by the theft and recovery of tirzepatide shipments in Itacurubí de la Cordillera. None of this requires dissolving territorial competence. It requires the territorially competent institutions to notice each other.

4.6. Private Ordering and the Limits of Contractual Territoriality

The analysis so far has treated territoriality as a public allocation of authority. But patent holders do not rely on public law alone. Where a patent exists, its territorial exclusivity is routinely reinforced by private ordering: exclusive and selective distribution agreements, territorial and customer restraints, and licensing structures that assign markets to designated intermediaries. These instruments attempt to reproduce, through contract, the market segmentation that the patent secures by public grant. In the border economy, they encounter the same functional geography that unsettles the public regime.

Two limits are nonetheless decisive. The first is structural to contract itself. A contract binds only its parties; under the general private-law principle of the relativity of contractual effects (*res inter alios acta*), it creates no obligation for those who never consented to it. In the tirzepatide case this limit is stark. Eli Lilly has no contractual relationship with the Paraguayan laboratories that developed Li-

poless and comparable products, nor with the Brazilian consumer who crosses the border to buy them. Where no Paraguayan patent exists, the holder retains neither a right to exclude nor a contract capable of reaching those actors. Private ordering can discipline an authorized distribution network; it cannot bind a lawful competitor operating in a jurisdiction where the invention was never protected.

The second limit is external. Even among parties, territorial and vertical restraints are not freely enforceable. They are subject to competition law, administered in Brazil under Law No. 12,529 of 2011 through the Administrative Council for Economic Defense (CADE). Brazilian law does not treat vertical territorial or customer restraints as unlawful in themselves. Article 36 of Law No. 12,529 defines an infringement of the economic order by reference to actual or potential anticompetitive effects, irrespective of fault, and its third paragraph lists conduct—including the imposition on distributors, retailers, and representatives of resale prices, discounts, payment conditions, minimum or maximum quantities, profit margins, or any other conditions governing their dealings with third parties—which constitutes an infringement only where those effects are present (Brazil, 2011, art. 36 and para. 3, IX). The statutory structure is thus effects-based rather than per se, and that is the sense in which Brazilian practice is described as applying a rule of reason to such restraints. The same orientation appears in CADE's own guidance. Annex I to CADE Resolution No. 20 of 1999—long the reference text on the point, and now revoked—defined vertical restrictive practices as restraints imposed by a supplier upon vertically related markets and set out criteria for weighing their anticompetitive effects against their efficiencies rather than condemning them categorically (CADE, 1999). CADE's Guide for the Analysis of Non-Horizontal Concentration Acts, published in 2024, continues that approach in structural review, assessing foreclosure risk against market position and recognized efficiencies and treating transactions below a market-share threshold as unlikely to raise concerns (CADE, 2024). A patent holder cannot use contract to recreate an exclusivity that neither the patent system, for want of a Paraguayan right, nor competition law, for want of an unconditioned territorial restraint, will supply. And once a product has been lawfully placed on a market by the holder or with its consent, the patent right over that unit is exhausted, so that downstream contractual restrictions on resale lose their patent foundation and stand or fall on competition law alone.

For present purposes the point is narrow. Whether a given territorial or customer restraint is enforceable in Brazil depends on an effects analysis conducted by a Brazilian authority, under Brazilian law, in respect of the Brazilian market. Even a restraint that survives that analysis binds only those who consented to it. Neither the analysis nor the instrument reaches the Paraguayan manufacturer or the cross-border purchaser, which is why private ordering reproduces the mismatch rather than curing it.

Private ordering therefore reproduces the institutional mismatch rather than curing it. Its instruments are relational: they operate between identified parties bound by consent. The border market is anonymous and transboundary, popu-

lated by competitors, couriers, and consumers who are strangers to any relevant contract. The mismatch identified in Section 4.5 thus has a private-law counterpart. Neither the public allocation of patent authority nor the private allocation of markets by contract observes or governs the connected whole; each reaches only the actors, and the territory, that fall within its own logic of attribution.

5. Conclusion

This article asked whether territorially allocated patent systems can adequately govern pharmaceutical innovation in economically integrated border regions where neighboring States maintain materially different patent and pharmaceutical-regulatory institutions. The answer is affirmative with respect to the legal function territorial systems were built to perform, and qualified with respect to their capacity to describe the market in which patented products actually circulate. The Brazil-Paraguay tirzepatide market supplies more than an illustration of this qualification: Eli Lilly's Brazilian patent and its absence in Paraguay, DINAVISA's registration of Lipoless and ANVISA's subsequent prohibition of the same product, and the documented price differential and physical movement of the product across the border together show a market that no single territorial authority observes in full, even though each authority's own decisions are individually well founded.

The article's principal contribution is the concept of institutional mismatch, developed in Section 4.5 and situated against legal geography's broader claim that territorial legal categories are never simply neutral descriptions of space (Section 2.4), and against the Andean Community's contrasting institutional choice to centralize patent adjudication regionally (Section 2.2). Read together, these three moves locate the article's claim precisely: mismatch is not an inherent property of patent territoriality, nor a discovery unique to this case, but a contingent and remediable feature of how MERCOSUR, specifically, has allocated authority over an economically integrated pharmaceutical border market.

That contingency is not one private law can cure in the State's place. The border market escapes not only the reach of any single territorial authority but also the reach of contract, whose instruments bind only their parties and whose territorial restraints answer to competition law; and the physical movement of the product across the border reorders its treatment under the importing State's patent, health, consumer-protection, and conflict-of-laws rules alike. The mismatch is therefore a feature of institutional design in both its public and its private dimensions, which is why the remedy defended here is coordination among the competent authorities rather than the substitution of one spatial logic—whether supranational patent or private ordering—for the other.

The study remains doctrinal and qualitative, and its empirical claims should be read with the limits of their sourcing in mind. The claim that no Paraguayan patent application was filed for tirzepatide rests on a public statement by an industry-association official, corroborated but not replaced by the patent-family check

reported in Section 1, which establishes only that no Paraguayan member of the family is indexed in the international collections consulted and cannot substitute for a search of the DINAPI register itself; the article has not conducted a claim-by-claim review of Eli Lilly's full patent family in either jurisdiction; and the scale of cross-border circulation is documented through press reporting and regulatory notices rather than through customs or sales data. Each of these is a legitimate target for future empirical work: a direct DINAPI and INPI registry search would confirm or correct the patent-filing account offered here; transaction-level data, where obtainable, could quantify the volume implied by the robbery and personal-importation reports cited in Section 4.3; and the institutional mismatch thesis itself could be tested against other border regions, other pharmaceutical classes, and regional blocs positioned between MERCOSUR's intergovernmentalism and the Andean Community's centralization—the Pacific Alliance is one plausible candidate. The analytical conclusion, however, does not depend on resolving these open empirical questions. Territorial patent systems allocate legal authority; integrated border markets organize pharmaceutical circulation functionally; and the tirzepatide case shows, with more specificity than the abstract proposition alone could, why law should attend to the interaction between the two rather than treating either spatial logic as a complete account of the other.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

Abente Stewart (n.d.). *Considerations of the Patent Cooperation Treaty: Paraguayan Path to Its Inclusion. Legal 500 Thought Leadership*.

Agência Nacional de Vigilância Sanitária (ANVISA) (2008). *Resolução da Diretoria Colegiada—RDC No. 81 of November 5, 2008 (Technical Regulation on Imported Goods and Products for Sanitary Surveillance Purposes), as Amended*.

Agência Nacional de Vigilância Sanitária (ANVISA) (2023). *Mounjaro® (tirzepatida): Novo registro*. Government of Brazil.

Agência Nacional de Vigilância Sanitária (ANVISA) (2025a). *Nota Técnica No. 200/2025/SEI/GIMED/GGFIS/DIRE4/ANVISA*.
https://www.gov.br/anvisa/pt-br

Agência Nacional de Vigilância Sanitária (ANVISA) (2025b). *Anvisa informa sobre proibição de ingresso de canetas emagrecedoras*.

Agência Nacional de Vigilância Sanitária (ANVISA) (2026a). *Anvisa deter-mina apreensão de canetas emagrecedoras sem registro sanitário*.
https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/anvisa-determina-apreensao-de-canetas-emagrecedoras-sem-registro-sanitario

Agência Nacional de Vigilância Sanitária (ANVISA) (2026b). *Anvisa determina apreensão de lotes falsificados de Mounjaro*.
https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/anvisa-determina-apreensao-de-lotes-falsificados-de-mounjaro

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

(1994). *Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization*.

Alter, K. J., & Helfer, L. R. (2017). *Transplanting International Courts: The Law and Politics of the Andean Tribunal of Justice*. Oxford University Press.

Andean Community (2000). *Decision 486: Common Regime on Industrial Property*. https://www.wipo.int/wipolex/en/legislation/details/9451

Blomley, N. (1994). *Law, Space, and the Geographies of Power*. Guilford Press.

Blomley, N., Delaney, D., & Ford, R. T. (2001). *The Legal Geographies Reader: Law, Power and Space*. Blackwell.

Bodenhausen, G. H. C. (1968). *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967*. United International Bureaux for the Protection of Intellectual Property (BIRPI).

Braverman, I., Blomley, N., Delaney, D., & Kedar, A. (2014). *The Expanding Spaces of Law: A Timely Legal Geography*. Stanford University Press.

Brazil (1942). *Decree-Law No. 4657 of September 4, 1942 (Law of Introduction to the Norms of Brazilian Law—LINDB), as Amended*. https://www.planalto.gov.br/ccivil_03/decreto-lei/del4657compilado.htm

Brazil (1990). *Law No. 8078 of September 11, 1990 (Consumer Defense Code)*. https://www.planalto.gov.br/ccivil_03/leis/l8078compilado.htm

Brazil (1996). *Law No. 9279 of May 14, 1996 (Industrial Property Law)*. https://www.planalto.gov.br/ccivil_03/leis/l9279.htm

Brazil (2003). *Law No. 10,742 of October 6, 2003 (Creating the Medicines Market Regulation Chamber—CMED)*. https://www.planalto.gov.br/ccivil_03/leis/2003/l10.742.htm

Brazil (2011). *Law No. 12,529 of November 30, 2011 (Brazilian Competition Defense System)*. https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei/l12529.htm

CADE (Conselho Administrativo de Defesa Economica) (1999). *Resolucao No. 20 of June 9, 1999, Annex I: Definition and Classification of Horizontal and Vertical Restrictive Practices (Revoked)*.

CADE (Conselho Administrativo de Defesa Economica) (2024). *Guia de analise de atos de concentracao nao horizontais (Guia V+)*. CADE.

Cockburn, I. M., Lanjouw, J. O., & Schankerman, M. (2016). Patents and the Global Diffusion of New Drugs. *American Economic Review, 106,* 136-164. https://doi.org/10.1257/aer.20141482

Conselho Federal de Farmácia (CFF) (2023). *Tizerpatida: Anvisa aprova novo medicamento promissor para o tratamento de diabetes tipo 2*.

Conselho Federal de Farmácia (CFF) (2025). *Novas apresentações do Mounjaro chegam às farmácias brasileiras*.

Correa, C. M. (2007). *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*. Oxford University Press.

Danzon, P. M., & Chao, L.-W. (2000). Cross-National Price Differences for Pharmaceuticals: How Large, and Why? *Journal of Health Economics, 19,* 159-195. https://doi.org/10.1016/s0167-6296(99)00039-9

Delaney, D. (2010). *The Spatial, the Legal and the Pragmatics of World-Making: Nomospheric Investigations*. Routledge. https://doi.org/10.4324/9780203849101

Dinwoodie, G. B., & Dreyfuss, R. C. (2012). *A Neofederalist Vision of Trips: The Resilience*

of the International Intellectual Property Regime. Oxford University Press. https://doi.org/10.1093/acprof:oso/9780195304619.001.0001

Essigmann, H. T., Aguilar, D. A., Perkison, W. B., Bay, K. G., Deaton, M. R., Brown, S. A. et al. (2022). Epidemiology of Antibiotic Use and Drivers of Cross-Border Procurement in a Mexican American Border Community. *Frontiers in Public Health, 10,* Article ID: 832266. https://doi.org/10.3389/fpubh.2022.832266

Estado de Minas (2025). *Anvisa aprova Mounjaro para perda de peso e tratamento de obesidade*. https://www.em.com.br/saude/2025/06/09/anvisa-aprova-mounjaro-para-perda-de-peso-e-tratamento-de-obesidade.html

Flyvbjerg, B. (2006). Five Misunderstandings about Case-Study Research. *Qualitative Inquiry, 12,* 219-245. https://doi.org/10.1177/1077800405284363

Giovanella, L., Guimarães, L., Nogueira, V. M. R., Lobato, L. d. V. C., & Damacena, G. N. (2007). Saúde nas fronteiras: Acesso e demandas de estrangeiros e brasileiros não residentes ao SUS nas cidades de fronteira com países do MERCOSUL na perspectiva dos secretários municipais de saúde. *Cadernos de Saúde Pública, 23,* S251-S266. https://doi.org/10.1590/s0102-311x2007001400014

Helfer, L. R. (2004). Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking. *Yale Journal of International Law, 29,* 1-83.

Helfer, L. R. (2009). Regime Shifting in the International Intellectual Property System. *Perspectives on Politics, 7,* 39-44. https://doi.org/10.1017/s1537592709090069

Helfer, L. R., Alter, K. J., & Guerzovich, M. F. (2009). Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community. *American Journal of International Law, 103,* 1-47. https://doi.org/10.2307/20456720

Hoen, E., Berger, J., Calmy, A., & Moon, S. (2011). Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All. *Journal of the International AIDS Society, 14,* Article No. 15. https://doi.org/10.1186/1758-2652-14-15

Kanavos, P., & Costa-Font, J. (2005). Pharmaceutical Parallel Trade in Europe: Stakeholder and Competition Effects. *Economic Policy, 20,* 758-798. https://doi.org/10.1111/j.1468-0327.2005.00150.x

Keohane, R. O., & Nye, J. S. (1977). *Power and Interdependence: World Politics in Transition*. Little, Brown.

Kyle, M. K. (2007). Pharmaceutical Price Controls and Entry Strategies. *Review of Economics and Statistics, 89,* 88-99. https://doi.org/10.1162/rest.89.1.88

La Nación (2026). *El boom de la tirzepatida: Se agota el stock en las farmacias*.

Laboratorio de Productos Éticos (Eticos Paraguay) (n.d.). *Presentamos Lipoless: Innovación en el control del peso y la diabetes*.

Lanjouw, J. O. (2005). *Patents, Price Controls, and Access to New Drugs: How Policy Affects Global Market Entry (NBER Working Paper No. 11321)*. National Bureau of Economic Research.

Mattli, W. (1999). *The Logic of Regional Integration*. Cambridge University Press. https://doi.org/10.1017/cbo9780511756238

MERCOSUR (1991). *Treaty of Asunción*.

MERCOSUR (1994). *Protocol of Ouro Preto: Additional Protocol to the Treaty of Asunción on the Institutional Structure of MERCOSUR*.

MERCOSUR (1995). *Protocol on the Harmonization of Intellectual Property Norms in*

MERCOSUR Concerning Trademarks, Indications of Source and Appellations of Origin (CMC Decision No. 8/95).

MERCOSUR (2000). *Acuerdo de Recife: Agreement on the Facilitation of Trade through Integrated Border Controls, and Its Implementing Rules (as Approved and Amended by CMC Decision No. 4/00)*.

Midiamax (2025). *Proibição de tirzepatida do Paraguai preocupa pacientes: "No Brasil é três vezes mais caro"*.

Pan American Health Organization (PAHO) (n.d.). *Pan American Network for Drug Regulatory Harmonization (PANDRH)*.

Paraguay (2000). *Law No. 1,630 of November 29, 2000 on Patents of Inventions, as Amended by Law No. 2,593/2005*. https://www.bacn.gov.py/leyes-paraguayas/119/ley-n-1630-de-patentes-de-invenciones

Paraguay (2019). *Law No. 6380 of September 25, 2019 on the Modernization and Simplification of the National Tax System*. https://www.bacn.gov.py/leyes-paraguayas/9332/ley-n-6380-de-modernizacion-y-simplificacion-del-sistema-tributario-nacional

Paris Convention for the Protection of Industrial Property (1883). *As Revised at Stockholm on July 14, 1967, and Amended on September 28, 1979*. https://www.wipo.int/wipolex/en/text/288514

Patent Cooperation Treaty (1970). *Washington, June 19, 1970, as Amended*. https://www.wipo.int/wipolex/en/text/288637

Riggirozzi, P. (2014). Regionalism through Social Policy: Collective Action and Health Diplomacy in South America. *Economy and Society, 43,* 432-454. https://doi.org/10.1080/03085147.2014.881598

Rivera, J. O., Ortiz, M., & Cardenas, V. (2009). Cross-Border Purchase of Medications and Health Care in a Sample of Residents of El Paso, Texas, and Ciudad Juarez, Mexico. *Journal of the National Medical Association, 101,* 167-173. https://doi.org/10.1016/s0027-9684(15)30831-2

World Intellectual Property Organization (WIPO) (n.d.-a). *Paris Convention for the Protection of Industrial Property: Official Text*. https://www.wipo.int/treaties/en/ip/paris/

World Intellectual Property Organization (WIPO) (n.d.-b). *PCT Contracting States*. https://www.wipo.int/pct/en/pct_contracting_states.html

World Trade Organization (WTO) (n.d.). *Agreement on Trade-Related Aspects of Intellectual Property Rights: Official Text*. https://www.wto.org/english/docs_e/legal_e/27-trips.pdf