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GOVERNANCE AND PRODUCTIVE STRUCTURE OF THE PHARMACEUTICAL INDUSTRY IN GLOBAL VALUE CHAINS: AN ANALYSIS OF CONTEMPORARY LINKS AND CHALLENGES

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Abstract *This study aimed to analyze the governance model and operational dynamics of the productive links in the pharmaceutical industry from the perspective of global value chains. The configuration of the productive and governance structure of this industry is investigated in the face of the contemporary scenario of fragmentation and internationalization of production. The methodology is based on a qualitative approach, of an exploratory and descriptive nature, and grounded in a bibliographic survey of physical and digital collections, encompassing specialized technical and scientific literature. The analytical framework adopts a prior attempt at chain link decomposition. The results indicate that the pharmaceutical industry fits into the producer-driven chain model, given that technological control, research and development activities, and intellectual property are concentrated in leading companies. The governance structure of the pharmaceutical industry is predominantly manifested in the Hierarchical and Captive types. Understanding these dynamics is essential for policymakers to guide the sovereign integration of countries into global value chains and promote economic and social development.*
Keywords: *Governance; international trade; fragmentation of production; pharmaceutical industry.*

GOVERNANÇA E ESTRUTURA PRODUTIVA DA INDÚSTRIA FARMACÊUTICA NAS CADEIAS GLOBAIS DE VALOR: UMA ANÁLISE DOS ELOS E DESAFIOS CONTEMPORÂNEOS[4]

Resumo O objetivo deste artigo é analisar o modelo de governança e a dinâmica operacional dos elos produtivos da Indústria Farmacêutica sob a ótica das Cadeias Globais de Valor. O estudo investiga a configuração da estrutura produtiva e de governança dessa indústria diante do cenário contemporâneo de fragmentação e internacionalização da produção. A metodologia ancora-se em uma abordagem qualitativa, de natureza exploratória e descritiva, fundamentada em um levantamento bibliográfico em acervos físicos e digitais, abrangendo literatura técnica e científica especializada. O arcabouço analítico adotou o referencial de Gereffi e Fernandez-Stark (2016) para a decomposição dos elos da cadeia. Os resultados indicam que a Indústria Farmacêutica enquadra-se no modelo de cadeia liderada pelo produtor (*producer-driven chains*), dado que o controle tecnológico, as atividades de P&D e a propriedade intelectual concentram-se nas empresas líderes. Conclui-se que a estrutura de governança da Indústria Farmacêutica manifesta-se predominantemente nos tipos Hierárquico e Cativo, evidenciando que o entendimento dessas dinâmicas é indispensável para que formuladores de políticas públicas possam orientar a inserção soberana de países nas CGVs e promover o desenvolvimento econômico e social.

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Palavras-chave: Governança; comércio internacional; fragmentação da produção; indústria farmacêutica.

1 Introduction

The deepening of globalization has heightened both competition and competitiveness in the international market. Domestic industries compete with local competitors and adjacent production chains, as well as with international competitors and global production chains. This dynamic has significantly reshaped the global economy, creating intricate and interconnected trade networks (Zanotto, 2023).

In this context of accelerated globalization, many industries that once operated strictly within national borders strived to be integrated in organizationally fragmented and globally dispersed business networks. This shift led to the division of production stages across different firms and countries. Consequently, countries and regions began specializing in specific activities rather than handling every stage involved in the production, distribution, and after-sales services of a product, good, or service. This shift allowed them to leverage comparative advantages and economies of scale for individual tasks, activities, and processes. These global production systems are commonly known as global value chains (GVCs). Governed by complex, global-scale governance structures, GVCs are characterized by "lead firms"[5] that control a vast network of suppliers and consumers of goods and services (Baldwin, 2012; Sturgeon *et al.*, 2013; Carneiro, 2015; Oliveira, 2015; Gereffi & Fernandez-Stark, 2016).

The internationalization of industries, coupled with significant growth in international trade, increased foreign direct investment (FDI), and the rise of global production networks, has fostered new approaches to the development of countries. Inevitably, it has also transformed global economic organizations and international trade relations (OECD, 2013; Carneiro, 2015).

The emergence of GVCs clearly stems from the transformations in international trade over the past three decades, which have reshaped the global economy through production fragmentation, the restructuring of the capitalist mode of production, and a new international division of labor. The rise of GVCs brought new dynamism to trade and revealed numerous challenges (Pandjiarjian, 2024), given the increasing integration of the global economy and trade relations into these networks.

The pharmaceutical industry (PI) operates precisely within this challenging landscape of shifting global production systems. It is a complex, highly specialized industry with sophisticated,

[5] According to Bezerra (2021), firms can be characterized by their role and function within the production network. They are identified by their leadership (lead firm) and the flexibility of their role, acting at times as a strategic partner or supplier (specialized and/or generic), and at other times as a client. According to Gereffi *et al*. (2001), lead firms are predominantly based in developed countries and include multinational manufacturers as well as major retailers and branded firms. They play a significant role in specifying the output, processes, and producers of manufacturing.

knowledge-intensive processes driven by science and technology. This industry is subject to specific and strict regulations, possesses unique characteristics, exhibits low demand elasticity,[6] and is highly internationalized, with the largest firms operating on a global scale (Capanema; Palmeira Filho, 2004; Miranda; Hasenclever; Paranhos, 2022; SCMED,[7] 2024). Given these contemporary challenges and the complexity of the PI, the present study addressed the following research question: How are the production and governance structures of the PI configured within the context of GVCs? To address this question, this article analyzed the governance model and operational dynamics of the PI's production stages through the lens of GVCs.

Our methodology relies on a qualitative approach. The research design is both exploratory and descriptive. Exploratory research serves as the initial stage of a broader investigation. Its primary purpose is to develop, clarify, and refine concepts and ideas, ultimately helping formulate more precise research problems or testable hypotheses for future studies (Gil, 2008).

The data collection for our research consisted of a literature review using print and digital collections, encompassing technical and scientific publications related to the sector. The search parameters were defined by the keywords "pharmaceutical industry" and "global value chains." For data analysis, the study employed the framework formulated by Gereffi and Fernandez-Stark (2016). This approach allowed for the disaggregation of the PI's production chain into its various developmental stages, mapping the structural interactions that define the global sector rather than relying on a purely narrative analysis.

This research is justified by the strategic importance of the PI, which rests on four fundamental pillars: scientific (driven by innovation and biotechnological advancements), political (owing to its direct influence on public policy formulation), economic (given its impact on GDP and the creation of skilled jobs), and social. Regarding the social pillar, this study is particularly relevant as it aligns with the Sustainable Development Goals (SDGs), specifically those aimed at reducing inequalities and achieving universal health coverage by promoting equitable access to essential treatments. In current Brazilian industrial policies, the PI is recognized as a strategic sector as evidenced by its inclusion in the New Industry Brazil initiative and New Growth Acceleration Program.

2 Contextualizing the Concept of Global Value Chains

[6] It measures the extent to which buyers and sellers respond to shifting market conditions. A measure of the responsiveness of the quantity demanded or supplied to a change in one of its determinants (Mankiw, 2013).
[7] The Executive Secretariat of the Drug Market Regulation Chamber (SCMED) is an administrative unit managed by the Brazilian Health Regulatory Agency (ANVISA). Established under Article 7 of Decree No. 4,766 of June 26, 2003, it operates under the purview of the Office of the agency's chief executive officer.

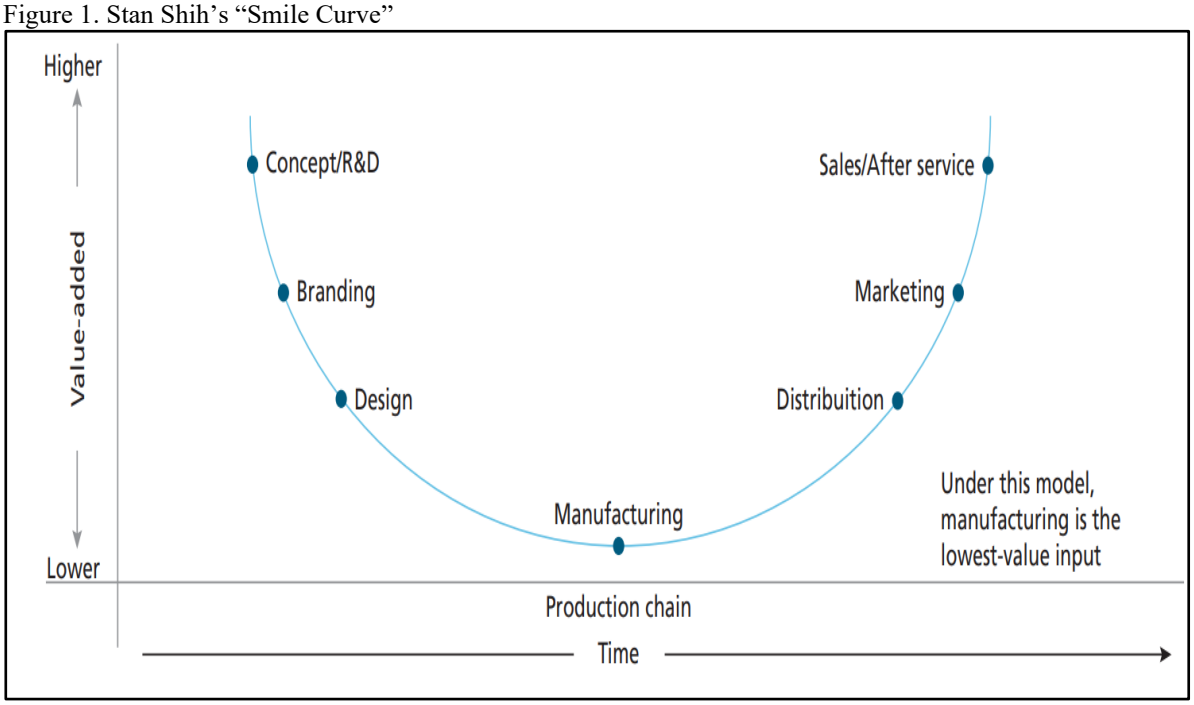
The term "global value chains" originated in management literature. It was later incorporated in the economics literature owing to its rising significance in international trade, gross domestic product (GDP), and global employment (OECD, 2013; Gereffi & Fernandez-Stark, 2016). Consequently, the study of GVCs has evolved into a multidisciplinary field, influencing and reshaping research agendas across disciplines such as economics, business administration, and international relations (Carneiro, 2015). This evolution is tied to both recent global economic trends—such as geopolitical fragmentation and protectionism—and the maturation of academic debate, which underscores the concept's broad and multifaceted nature.

The proposed new conceptual framework known as GVCs emerged from a workshop titled "Spreading the Gains from Globalization," hosted by the Institute of Development Studies at the University of Sussex in the United Kingdom in 1999 (Bezerra, 2021). The event aimed to develop a research agenda to better elucidate interconnections at the macro (global), meso (industry and country), and micro (firm and community) levels. According to Gereffi (2018, as cited in Bezerra, 2021), the term GVCs was adopted for three main reasons. First, scholars recognized the need to move away from the term "commodity chains" to avoid potential confusion with Wallerstein's world-systems theory.[8] Second, "commodity" is broadly and indiscriminately associated with primary products (e.g., agricultural goods, crude oil, or raw minerals) rather than manufactured goods and services. Finally, the term "value," closely tied to the concept of value-added, highlights the processes of value creation, capture, and retention within supply chains.

As Zhang and Schimanski (2014, p. 75) noted, "global value chain is a term that practitioners, academics, and international organizations began using in light of the growing fragmentation of the production cycles of goods and services across different countries." In other words, the stages from a product's inception to its final delivery to the consumer are carried out by a global network of firms. The value chain concept encompasses the full range of activities that firms and workers undertake from its initial conception to its final consumption (Gereffi & Fernandez-Stark, 2016). As such, this framework covers the entire product flow, from sourcing raw materials and developing the design to commercialization strategies, distribution, and after-sales services. Each stage of this sequence or set of activities adds a portion of the product's overall value, which is why it is called a "value chain" (Carneiro, 2015). Shih's "Smile Curve" (2014), shown in Figure 1, illustrates a product's value chain. It represents the entire production cycle and categorizes activities into high and low value-added segments starting from pre-production stages such as conceptualization and design to manufacturing and after-sales services.

[8] Immanuel Wallerstein's primary contribution to World-Systems Theory is his seminal four-volume work, *The Modern World-System*, which he began writing in 1974.

Figure 1. Stan Shih's "Smile Curve"



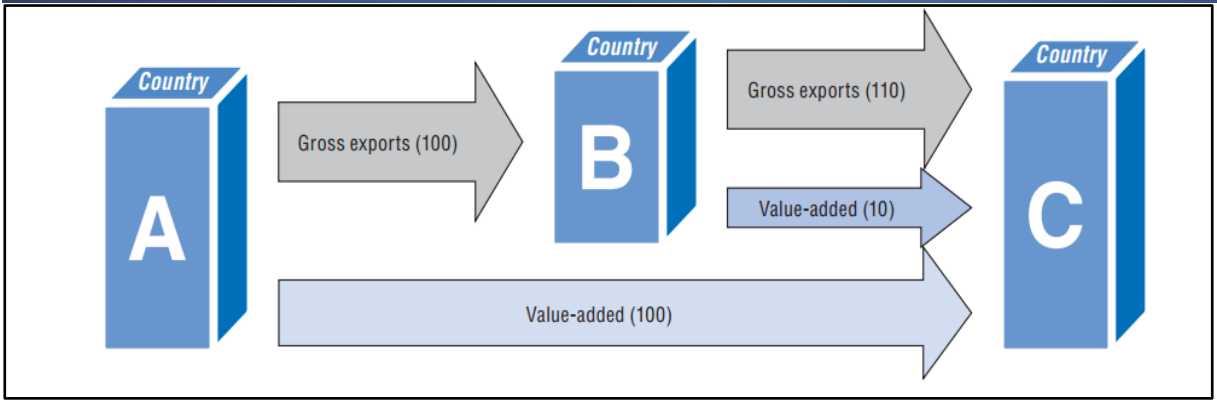
Source: Shih (n.d., as cited in Zhang & Schimanski, 2014, p. 74).

The activities with the highest value-added are research and development (R&D) and after-sales services. Manufacturing, located at the bottom of the curve, yields the lowest value-added. Broadly speaking, this figure implies that countries and firms operating at the ends of the curve can achieve better economic outcomes and capture a larger share of the wealth generated throughout the production cycle. In this regard, Baumann (2023) noted that a value chain

> [...] compreende o conjunto de atividades e processos requeridos para transformar itens isolados, fabricados em diversas partes do mundo, em produtos para consumo final. Assim, o grau de participação de uma economia em cadeias de valor pode ser avaliado pelo componente de valor adicionado no país. Esse valor adicionado pode ser obtido ao se isolar, no montante exportado, o valor adicionado em outros países, ou a intensidade de bens e serviços importados que compõem os produtos exportados. (Baumann, 2023, p. 210)

Given these points, value chains operate through a production structure that is fragmented across multiple firms and geographically dispersed, functioning as a complex value-added system. Figure 2 illustrates this complex system by demonstrating trade in value-added using three hypothetical countries: A, B, and C.

Figure 2. A Simple Value-Added Trade System



Source: OECD (2013, p. 55).

In Figure 2, Country A exports raw materials valued at 100 to Country B. Country B then processes these inputs, adding domestic value. When Country B exports the final product to Country C for a gross value of 110, traditional trade statistics record the entire amount as an export from B, even though 100 units of that value were originally generated by A. This phenomenon highlights the issue of double counting in global trade: Country B's contribution is statistically overestimated because gross metrics fail to separate the domestic value-added (only 10) from the imported inputs (OECD, 2013).

This complex system makes it difficult to measure international performance or the contribution of exports and, consequently, an economy's level of participation in a GVC (OECD, 2013). Furthermore, participating in GVCs involves an ongoing dynamic of both synergy and competition, as firms and countries seek the largest share of the global value-added. The extent of value capture within the chain depends on the power wielded by the lead firm, as well as the chain's overall structure and governance (Pinto, Fiani, & Corrêa, 2015).

Additionally, participating in GVCs is not simply a matter of choice (Baumann, 2023). An economy cannot simply apply to participate in a GVC; its inclusion depends on the decisions made by the primary producers and traders of the relevant goods and services. For this reason, policymakers must understand how GVCs impact their national economies (OECD, 2013). In other words, policymakers must understand how these chains operate, how they affect economic performance, and which policies can maximize domestic benefits.

Gross trade data are limited because they fail to separate the value of imported intermediate goods from the value actually added domestically. The Trade in Value Added (*TiVA*) methodology is essential to correct these distortions. It breaks down exports into their value-added components, revealing each sector's true contribution to the global production chain.

The *TiVA* project was jointly developed by the Organisation for Economic Co-operation and Development (OECD) and World Trade Organization (WTO) to provide statistical data based on value-added rather than gross data. The initial release of this project, whose results were

published in January 2013, analyzed statistical data from 1995 to 2009. The sample covered 57 nations, accounting for approximately 95% of global GVC-linked production (OECD, 2013; Carneiro, 2015). The *TiVA* project serves as a global benchmark for estimating countries' participation in international production, providing empirical evidence on GVC dynamics. However, its statistical approach does not capture the complexity of internal firm operations, nor does it reflect the power dynamics and cooperative relations among actors within the chain.

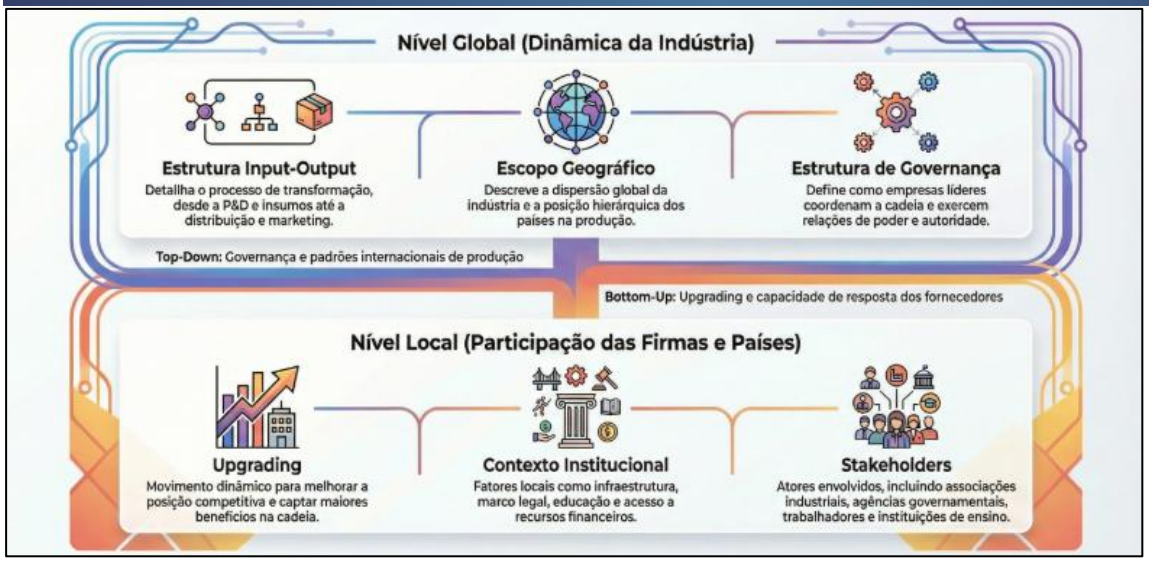
Beyond statistical metrics, a key feature of production integration is the multiplier effect generated by trade transactions between interconnected economies (Baumann, 2023). These dynamics trace back to Hirschman's (1961) concept of production linkages, which are divided into backward and forward types. Backward linkages occur when the demand for inputs stimulates the creation of supplier industries and strengthens upstream sectors. Conversely, forward linkages relate to the potential emergence of new activities that use the resulting products as inputs in their own production lines, particularly when these products are not intended exclusively for final consumption.

The GVC literature focuses on assessing the implications, challenges, and opportunities inherent in this highly dispersed and fragmented production model. The primary goal is to identify effective integration strategies, providing a foundation for public policies designed to foster economic and social development, particularly in developing economies.

2.1 Dimensions of the GVC Framework

The methodological framework developed by Gereffi and Fernandez-Stark (2016) at Duke University's Center on Globalization, Governance & Competitiveness has become an essential tool for analyzing the structure and configuration of global industries. This framework investigates the structures and dynamics of the various actors within the chain, enabling the mapping of global production patterns that link geographically dispersed activities. It provides a comprehensive analysis of global industries through two complementary lenses: a top-down perspective, focusing on governance and global structures, and a bottom-up perspective, which emphasizes the realities and development trajectories of local actors. Gereffi and Fernandez-Stark's (2016) methodology outlines six core dimensions for mapping GVCs, as shown in Figure 3.

Figure 3. Six Dimensions of Global Value Chains



Source: Prepared by the authors (2026), generated via NotebookLM based on data from Gereffi and Fernandez-Stark (2016).

As Figure 3 illustrates, the framework is divided into two levels of analysis: global and local. The first level encompasses international elements driven by global industry dynamics: (i) input-output structure, (ii) geographic scope, and (iii) governance structure (focusing on lead firms and industrial organization). The second level, focusing on the local and firm levels, explains each country's mode of participation in GVCs: (i) upgrading, (ii) institutional context, and (iii) stakeholders. The key characteristics of each dimension, based on Gereffi and Fernandez-Stark (2016), are summarized below:

1. Input-Output: This structure details the process of transforming raw materials into finished products. The primary segments of a chain typically include R&D, inputs, production, distribution and marketing, sales, and post-consumer recycling. The input-output structure encompasses both goods and services, along with various supporting industries.

2. Geographic Scope or Reach: This describes the global dispersion of the industry and elucidates a country's hierarchical position within international production. It highlights that GVCs operate across geographic scales (local, national, regional, and global).

3. Governance: This structure governs GVCs through the control and coordination exercised by lead firms. Governance is a core concept in GVC analysis.

4. Upgrading: This refers to the dynamic movement of firms within the value chain as they seek to improve their competitive position in GVCs to capture benefits or gains.

5. Institutional Context: This encompasses relevant issues and outcomes generated by actors within economic, social, and institutional relations, including factors like infrastructure, legal frameworks, access to finance, female labor force participation, and education.

6. Stakeholders: This dimension includes the various actors involved in GVCs or the participants in global industries. These include industry associations, workers, educational

institutions, and government agencies (such as export promotion and investment attraction departments, as well as ministries of foreign trade, economy, and education). All actors within the value chain are mapped and described, highlighting their primary roles in driving change and contributing to the upgrading of global industries.

This methodological framework is a useful tool for tracking shifts in global production patterns. Examining GVC structures and dynamics enables the identification of the roles played by both developed and developing countries, offering a comprehensive view of global industries from both a top-down (lead firm) and bottom-up (supplier) perspective (Gereffi & Fernandez-Stark, 2016). GVCs have introduced notable changes to the global trade system through not only in its structure and composition but also in its implications for global rule-making regarding production, sanitary conditions, labor, and industrial policies.

3 Governance Models in GVCs

GVCs are driven by governance models that rely on the coordination of economic activities by lead firms. According to Fernandez-Stark, Bamber, and Gereffi (2011), the governance model refers to the global organization of an industry, focusing on the coordination of economic activities and on the key strategic drivers among the different actors in GVCs. In other words, governance models represent the power and authority dynamics that dictate how financial, material, and human resources are allocated and flow throughout the chain. This makes governance one of the central topics in the study of GVCs.

Gereffi *et al*. (2001) noted that governance stems from the power wielded by lead firms, as they coordinate and determine the activities performed by other firms in the value chain. This authority allows lead firms to set product specifications, regulate processes and quality requirements, manage input–output dynamics, and provide technical support to suppliers.

To analyze the governance model and how the generated value is distributed among participating firms, one must first map the stages and interactions within the GVC. GVC analysis provides a framework for examining trends in outsourcing and offshoring in economic activities. This transition, however, is mediated by key factors: the industry's technical architecture, which determines the feasibility of modularization, and the reliability of mechanisms used to transfer technical and managerial knowledge (Carneiro, 2015).

Gereffi, Humphrey, and Sturgeon (2005) argued that production fragmentation has driven transnational firms to redefine their core competencies to reach the higher value-added segments of production. These competencies involve the following: 1) product innovation and

commercialization activities; 2) marketing strategies; and 3) reduction of non-core[9] functions, which encompass generic services and volume production.

Beyond competencies, the evolution of GVC governance forms shows that trade flows are embedded within interdependent contractual frameworks. As Gereffi, Humphrey, and Sturgeon (2005) argued, specializing in niche competencies yields better results than fully internalizing production or pursuing strategically incoherent diversification. Indeed, governance structures emerge primarily in response to two distinct needs (Gereffi *et al*., 2001). The first is the number of firms involved in manufacturing a product, which shapes the development of such structures. The second is the exposure to performance risks and supplier failures: the greater this exposure, the tighter the control and monitoring over the supply chain.[10]

As Gereffi (1994; 2011, as cited in Baumann, 2023, p. 15) explained:

> [...] dentro da cadeia, o poder é exercido pela empresa líder em virtude de sua capacidade de influenciar as outras firmas da cadeia, dado o seu poder de produtor (*producer-driven chains*) ou de comprador (*buyer-driven chains*). Por um lado, as firmas líderes produtoras aparecem em setores produtivos intensivos em tecnologia e em capital, tais como automóveis, eletrônicos, aviões, indústria farmacêutica etc. Como essas empresas controlam a tecnologia, P&D e, consequentemente, a propriedade intelectual, elas situam-se a jusante (*downstream*) e controlam a concepção do produto e o processo de fragmentação da cadeia em diferentes países. Por outro lado, as firmas líderes compradoras são encontradas em setores menos intensivos em capital e que requerem menos trabalhadores qualificados, tais como os serviços, o comércio varejista, vestuários, alimentos, calçados, brinquedos etc. As empresas líderes são aquelas que controlam as vendas e as marcas que são os eixos diretivos desse tipo de produção. Com isso, essas firmas, localizadas a montante (*upstream*), podem terceirizar todo o seu processo de produção (*outsourcing*) por meio de uma rede global de fornecedores, concentrando-se no *marketing* e nas vendas (Gereffi, 1994; 2011) *apud* (Baumann 2023, p. 15).

Classic examples of producer-driven chains include the automotive, aerospace, pharmaceutical, and electromechanical industries. In these chains, R&D activities are strategic competencies that lead firms seek to control. Conversely, the footwear and apparel industries exemplify buyer-driven chains, characterized by low capital intensity and a reliance on less skilled labor.

Gereffi, Humphrey, and Sturgeon (2005) identified three key variables that distinguish GVC governance: 1) complexity of transactions (transactions within the chain, related to product and process specifications); 2) codifiability of information (degree of information standardization); and 3) supplier capabilities (capacity of the current and potential supply base). Identifying these variables enables one to address the issue of asset specificity, as outlined in transaction cost economics, alongside the costs of coordinating activities across the chain.

[9] Non-essential

[10] Christopher (2018) defined supply chains as networks of connected, interdependent organizations working cooperatively to control, manage, and optimize the flow of raw materials and information from suppliers to end consumers.

Table 1 identifies the five types of GVC governance proposed by Gereffi, Humphrey, and Sturgeon (2005). These types of governance are determined by the interplay of three variables: complexity of inter-firm transactions, degree to which this complexity can be mitigated by codifying information, and suppliers' ability to meet buyers' requirements.

Table 1. Determinants of GVC Governance

Tipos de Governança	Complexidade das transações	Habilidade para codificar as transações	*Capabilities* dos fornecedores	Grau de coordenação e assimetria de poder
Mercado	Baixa	Alta	Alta	Baixa
Modular	Alta	Alta	Alta	
Relacional	Alta	Baixa	Alta	
Cativa	Alta	Alta	Alta	
Hierárquica	Alta	Baixa	Baixa	Alta

Source: Adapted from Gereffi, Humphrey, and Sturgeon (2005).

Based on the intersection of three fundamental variables determining inter-firm coordination, Gereffi, Humphrey, and Sturgeon (2005) proposed five distinct types of GVC governance (Figure 4): Market, Modular, Relational, Captive, and Hierarchical.

a) Market: In this type of governance, transactions are relatively simple, and the cost of exchanging information is low for both buyers and suppliers. These "arm's-length transactions" require little to no formal cooperation. Products have low specificity, and transactions are easily codified. Consequently, this model does not require a high degree of coordination and control.

b) Modular: Products are manufactured to the customer's specifications. Suppliers typically take full responsibility for the process technology but are constrained by the use of standardized technologies. Transactions and information exchanges are more advanced and complex than those in pure market linkages.

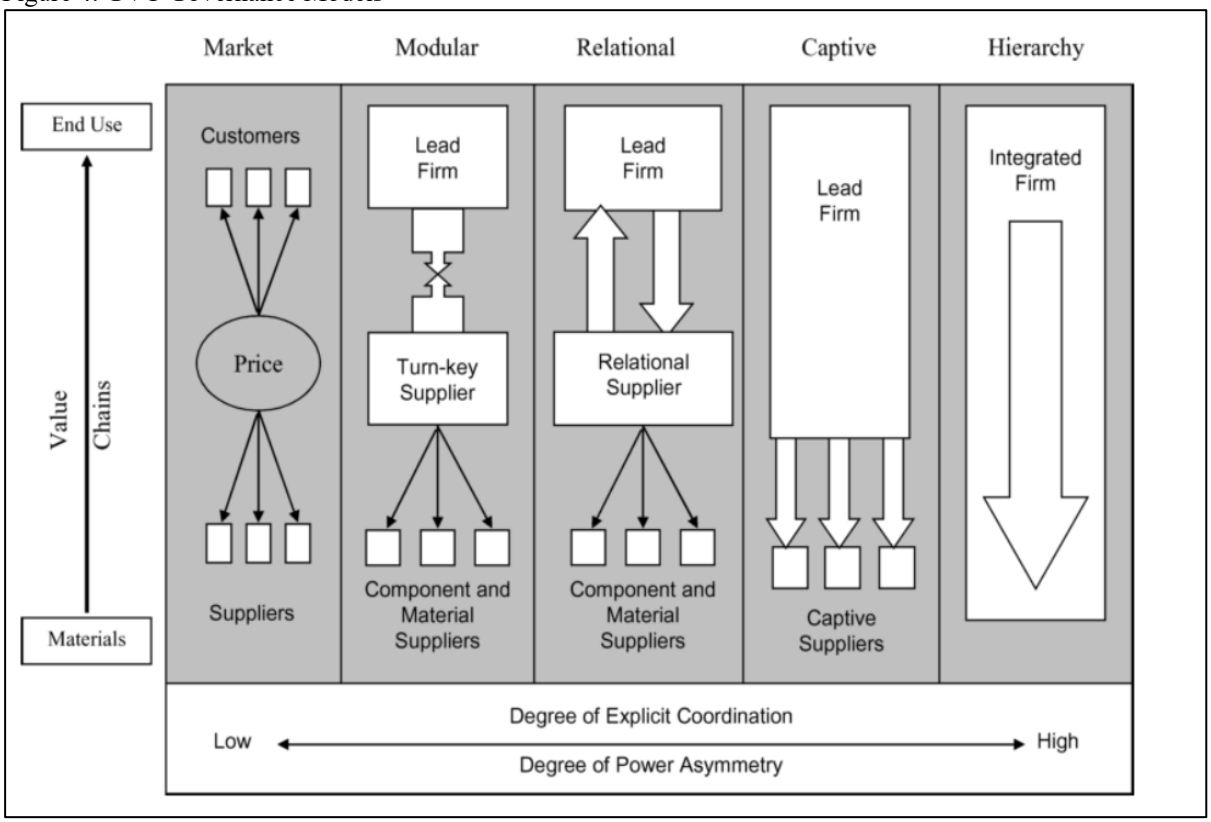
c) Relational: This type of governance emerges when buyers and suppliers rely on complex information that is not easily transmitted. This creates mutual dependence and high asset specificity, fostering relationships built on geographic proximity, long-term trust and reputation, or even family and ethnic ties. Producers in relational chains are more likely to provide differentiated products based on quality, geographic origin, or other unique features.

d) Captive: This describes a scenario where small suppliers are dependent on large buyers. These suppliers face high switching costs and are subject to high levels of monitoring and control by the lead firm. This arrangement generally yields greater benefits for the lead firm.

e) Hierarchical: This type of governance is characterized by vertical integration. The high

complexity of products and the difficulty in codifying their specifications limit the search for external suppliers. Consequently, finding highly capable suppliers becomes challenging, forcing firms to internalize all stages of the production process.

Figure 4. GVC Governance Models



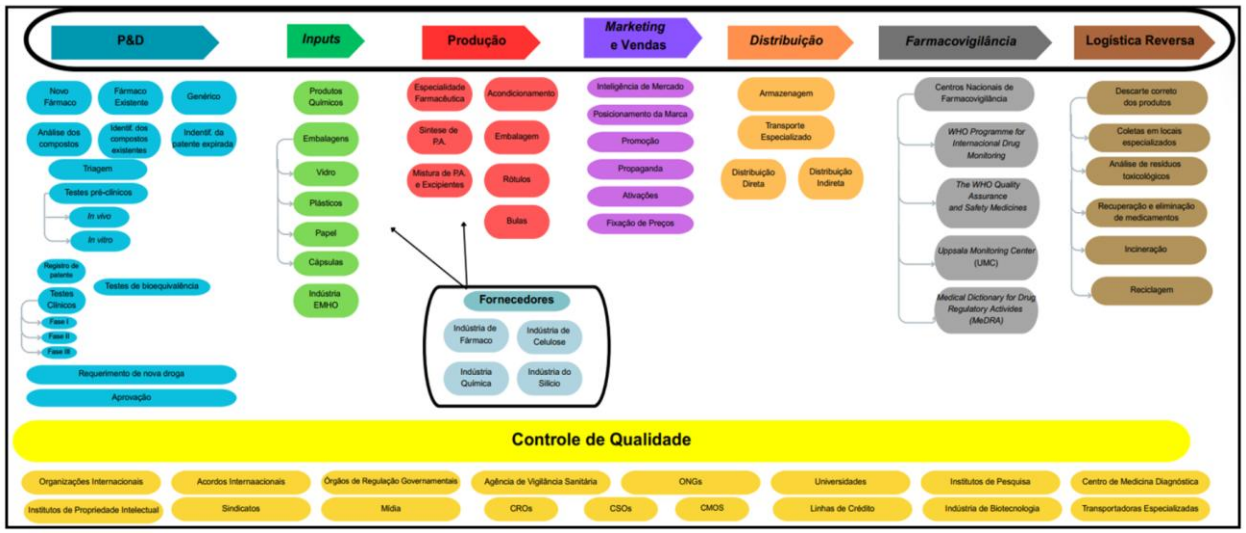
Source: Gereffi, Humphrey, and Sturgeon (2005, p. 89).

As shown in Figure 4, the degrees of explicit coordination and power asymmetry increase as chains move toward hierarchical models. This typology, developed by Gereffi, Humphrey, and Sturgeon (2005), is based on the high/low degrees of three key variables, allowing for a rigorous classification of the five types of governance presented.

4 Analytical Framework

The PI encompasses the production of drugs, active pharmaceutical ingredients (APIs), blood products, vaccines, diagnostic reagents, sera, and toxins. The production stages vary in complexity, ranging from drug R&D to the marketing and commercialization of finished products (Santos, Tejada, & Jacinto, 2017). Figure 5 illustrates the stages of the global pharmaceutical value chain, detailing the specific activities and sequential stages of its production process.

Figure 5. Production Chain of the Pharmaceutical Industry



Source: Prepared by the authors, based on Albuquerque Neto, Peixoto, and Zorovich (2016) and Coelho *et al.* (2014).
Note: R&D stands for research and development; API stands for active pharmaceutical ingredient; EMHO (Equipamentos Médicos, Hospitalares e Odontológicos) refers to the medical, hospital, and dental equipment industry; NGOs stand for non-governmental organizations; CMOs are contract manufacturing organizations, which specialize in manufacturing drugs for other firms under contract; CSOs are contract sales organizations, which provide marketing and sales solutions; and CROs are contract research organizations, which offer outsourced research services.

As shown in Figure 5, the pharmaceutical GVC consists of seven stages: R&D, Inputs, Production, Distribution, Marketing and Sales, Pharmacovigilance, and Reverse Logistics. Activities within each stage are carried out by a diverse array of actors, involving multiple direct and indirect stakeholders across the chain:

> Os *stakeholders* são os agentes que influenciam de maneira direta e/ou indireta as diretrizes operacionais e administrativas dos elos da cadeia de valor da indústria farmacêutica, iniciando-se no P&D indo até a logística reversa. Vale ressaltar ainda que, apesar de haver uma harmonização de padrões internacionais de boas práticas da indústria farmacêutica, toda região possui particularidades regulatórias e legislativas, o que torna essencial o acompanhamento dos cumprimentos de normas e leis estabelecidas por parte das empresas inseridas neste setor (Albuquerque Neto, Peixoto e Zorovich, 2016, p. 13)

GVC actors also organize into innovation networks for drug production and commercialization (Rosenberg, Derengowski, & D'Avila, 2008). These networks include firms from other industries, research-intensive institutions (e.g., universities and public/private research centers), funding bodies, regulatory agencies, governments, public and private health care systems, physicians, consumers, and industry associations.

Scientific research is the primary foundation of the PI. This is evident in the very first stage of the pharmaceutical production chain: investment in R&D. During this initial phase, firms develop new products (APIs and drugs) that are typically highly technology-intensive. Owing to patent protections, these innovations grant firms market power and competitive advantages (Vasconcelos *et al.*, 2023).

Innovations occur within these R&D processes (Palmeira Filho & Pan, 2003). Accordingly, the pharmaceutical sector holds a prominent position in national innovation systems across OECD

countries. It accounts for a substantial share of domestic value-added, employs highly skilled labor, and contributes significantly to the trade balances of these nations (Grupo FarmaBrasil, 2023).

Meanwhile, the risks associated with R&D investments are substantial, given that only a small fraction of newly developed drugs ultimately receive approval following clinical trials (Capanema & Palmeira Filho, 2007). For this reason, R&D costs act as a barrier to entry, serving as a determining factor in the industry's differentiated oligopoly structure (Palmeira Filho *et al*., 2012). Given the high costs of R&D activities, firms striving for competitiveness cannot rely solely on internal investments in R&D; they must establish external partnerships to acquire new knowledge (Paranhos & Hasenclever, 2015). According to Radaelli (2008), this trend stems from the realization that no single firm possesses all the resources required to innovate. By forming corporate innovation networks, firms can effectively spread the numerous risks inherent in pharmaceutical R&D. Therefore, pharmaceutical innovations play an important role in technological diffusion owing to the sector's connections to other sectors, such as chemicals and agribusiness (Magalhães, 2006).

The second stage of the chain—Inputs—encompasses the raw materials and components used to manufacture and package drugs (Coelho *et al.*, 2014). As shown in Figure 5, the green elements in this stage represent the procurement of the resources needed to initiate drug production. The transition to the third stage, Production, involves three primary phases: initiation, specialization, and packaging. These phases cover the synthesis of the API, which is subsequently formulated into the finished drug product (Albuquerque Neto, Peixoto, & Zorovich, 2016). The red boxes in Figure 5 highlight the industry's linkages with upstream suppliers, including the glass, chemical, cellulose, and API sectors.

Drug development is an extremely complex process. Spanning from initial research and clinical trials to final marketing and commercialization, the process can take 15 years or more (Françoso & Strachman, 2013). From a technical standpoint, a drug consists of the API and excipients (additives). The API or drug base (raw material) is the active substance responsible for the drug's intended therapeutic effect. Excipients are substances added to the API to modify or enhance its properties, such as its organoleptic characteristics, routes of administration, physicochemical state, and absorption rate. Mixing or combining the API and excipients creates a pharmaceutical formulation, resulting in the finished pharmaceutical product (Palmeira Filho & Pan, 2003).

Essentially, industrial drug production encompasses extraction, purification, chemical synthesis, fermentation, and pharmaceutical processing, drawing from various raw material sources. The primary source is pharmachemicals (raw materials derived from the chemical synthesis of organic compounds). However, inputs also include raw or extracted plant materials

(used in herbal medicines) and materials of biotechnological origin, with the latter resulting from processes that employ molecular biology (Bastos, 2005). Biotechnological production processes rely on genetically modified cells or microorganisms (Reis, Landim, & Pieroni, 2011).

Pharmachemicals are chemical substances possessing pharmacological activity (i.e., they interact with biological systems to produce a medicinal effect) used in drug production (Hasenclever, Manhães, & Miranda, 2021). ANVISA defines pharmaceutical inputs as the "raw materials" used in drug production, indicating the starting point of the PI's production chain. The agency uses the term API to describe the specific substance that gives a drug its pharmaceutical characteristics; in other words, it is the component that makes the drug work (ANVISA, 2025).

Before an innovative pharmaceutical product can be marketed, it must first obtain approval from relevant health authorities, such as the Food and Drug Administration (FDA) in the United States and ANVISA in Brazil. The product must undergo various testing stages; only upon final approval is it cleared for market release (Palmeira Filho & Pan, 2003).

Production is closely linked to the fourth stage, Marketing and Sales, which, alongside R&D, accounts for the largest portion of investment within the chain. Activities in this stage facilitate the market entry of new products and ensure brand loyalty even after patents expire (Radaelli, 2008). Pharmaceutical firms use medical conferences and/or conventions as market penetration strategies to reach physicians and sales representatives (Albuquerque Neto, Peixoto, & Zorovich, 2016). Another market entry strategy is digital marketing, a channel that has expanded alongside globalization and the advancement of information technology. This development enables patients to seek more information online, promoting the growth of e-commerce for over-the-counter medications, known in Brazil as medicamentos isentos de prescrição[11] (Albuquerque Neto, Peixoto, & Zorovich, 2016).

As shown in Figure 5, the yellow element represents Quality Control, which is a strategic sector responsible for ensuring the safety, reliability, and efficacy of drugs for their intended use. These activities require an integrated set of operations, including planning, coordination, and execution (Albuquerque Neto, Peixoto, & Zorovich, 2016).

Following quality control and marketing planning, products move to the fifth stage, Distribution. This highly coordinated stage involves the warehousing and transportation of products to buyers, health clinics, pharmacy chains, hospitals, and directly to end consumers (Coelho *et al.*, 2014). The penultimate stage of the chain, Pharmacovigilance, involves evaluating and preventing adverse drug reactions in the population; it is linked to after-sales service

[11] These drugs are exempt from price-setting or adjustment criteria. They include over-the-counter medications, herbal medicines, traditional herbal products, and injectable local anesthetics for dental use, as outlined in CMED Resolution No. 2 of March 26, 2019, and CMED Communiqués Nos. 4, 5, and 10 of 2019.

(Albuquerque Neto, Peixoto, & Zorovich, 2016; Coelho *et al.*, 2014).

Importantly, the PI plays an active role in pharmacovigilance. The growing demand from regulatory agencies for rigorous post-market monitoring has resulted in a significant increase in pharmacovigilance globally. This landscape has led to the development of innovative monitoring systems, significantly improving the safety profile of newly launched drugs (Albuquerque Neto, Peixoto, & Zorovich, 2016).

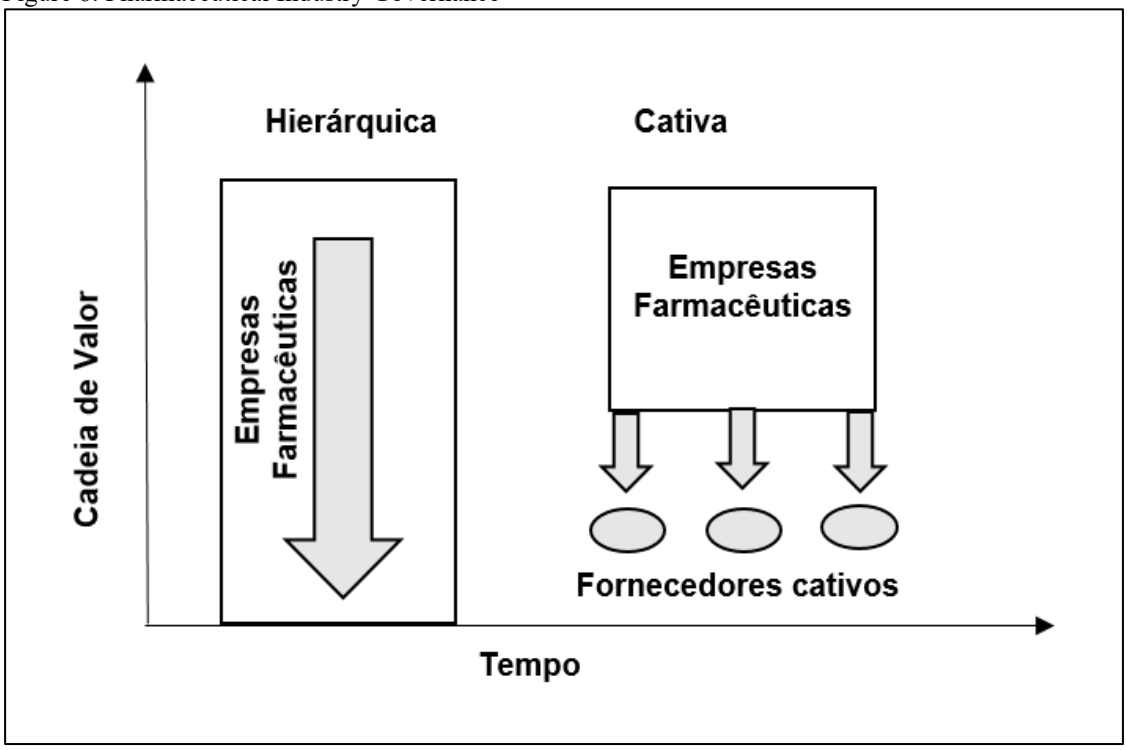
Finally, the Reverse Logistics stage handles the proper disposal and recycling of products. The OECD defines extended producer responsibility as shifting the responsibility for a drug's entire lifecycle to pharmaceutical firms, including post-consumer waste management and environmentally sound disposal (Albuquerque Neto, Peixoto, & Zorovich, 2016). Consequently, the industry bears responsibility from production through to the proper disposal of products, aiming to minimize environmental impact. Retail pharmacy chains serve as intermediary channels between producers and consumers (Coelho *et al.,* 2014).

Within the GVC, stages involving R&D and services add the most value to the final product, whereas physical manufacturing adds the least (Zhang & Schimanski, 2014). Therefore, firms operating in the R&D stage capture higher returns. In the context of GVCs, as Sturgeon *et al*. (2014) noted, a product's value chain consists of discrete, value-adding activities that can span multiple countries and firms, rather than being vertically integrated within a single firm or location.

According to Carneiro (2015), mapping the stages and relations within the value chain provides essential insights for analyzing governance structures and understanding the distribution of value generated by each participating firm. This approach also enables the analysis of outsourcing and offshoring opportunities, requiring attention to factors such as the industry's technical characteristics and capacity to securely transmit knowledge and codified instructions. The offshore services industry has delivered significant economic and social benefits to emerging nations, providing access to new markets, creating more and higher-quality jobs, and offering secure income during global downturns (Fernandez-Stark, Bamber, & Gereffi, 2011). Recently, the COVID-19 pandemic accelerated this trend, intensifying the search for offshoring and efficiency strategies (Lima, 2021).

The shift toward outsourcing and offshoring occurs when large lead firms reduce their costs by contracting out and relocating tasks, activities, or production chain stages to other firms and countries. This shift signals a transition from hierarchical to captive governance. Lead firms coordinate and control the chain under this structure. Meanwhile, some lower value-added activities can be transferred to third-party suppliers, who remain subordinate to the lead firm (Gereffi & Fernandez-Stark, 2016). Figure 6 illustrates the types of governance present within the PI's value chain from this perspective.

Figure 6. Pharmaceutical Industry Governance



Source: Adapted from Gereffi, Humphrey, and Sturgeon (2005).

Ultimately, the PI features a concentrated, oligopolistic market structure with barriers to entry. These barriers include patent protections backed by the international intellectual property system, control over the supply of active pharmaceutical ingredients, substantial R&D investments, high advertising and marketing costs, and the established brand reputations of leading laboratories (Big Pharma) (Capanema & Palmeira Filho, 2004; Bastos, 2005; Palmeira Filho *et al*., 2012). Innovation is a key determinant of competitiveness, serving as the primary driver for launching new drugs and treatments (Hasenclever *et al.,* 2020).

6 Conclusion

We analyzed the governance model and operational dynamics of the PI's production stages through the lens of GVCs. This framework proved essential for understanding how such a vital and strategically important sector operates. The analysis demonstrated that the PI is a complex, oligopolistic, and strictly regulated environment, characterized by highly technology- and R&D-intensive activities.

The production structure of the pharmaceutical GVC is complex, consisting of 7 primary stages that span from R&D to reverse logistics. As illustrated by Shih's "Smile Curve," value added is distributed unevenly across this chain. The highest value-added activities are concentrated at the extremes: R&D at the beginning, and Marketing, Sales, and after-sales services at the end.

These activities yield the greatest advantages and benefits for the countries and firms that perform them. Conversely, the manufacturing (production) of the product itself adds the least value. Consequently, firms that invest in R&D and secure patent protection consolidate their market power and competitive advantage, enabling them to capture the highest returns.

In terms of governance, the PI fits the classic model of a producer-driven chain, as control over technology, R&D, and intellectual property is held by large lead firms. The industry's governance structure is predominantly characterized by Hierarchical and Captive models. The trend of outsourcing and offshoring lower value-added activities, such as API manufacturing, to other firms and countries signals a shift from a Hierarchical model to a Captive one. Under this arrangement, suppliers remain subordinate, subject to high levels of monitoring and control by the lead firm. In this context, power is largely underpinned by patent protection and the stringent international intellectual property system.

GVCs have brought notable changes to the global trading system, reshaping not only its structure and composition but also its impact on global regulations, health standards, and industrial policies. An economy's participation in GVCs depends on the decisions of major producers. Therefore, an understanding of the PI's governance dynamics and production structure is crucial for policymakers. This knowledge is essential for guiding developing nations' integration in GVCs, helping them capture a larger share of global value added and promoting economic and social development.

One limitation of this study is that it did not segment the analysis by therapeutic class, opting instead for a broader perspective on the industry's integration in GVCs. Therefore, future research should explore this specific topic in greater depth. In the current landscape, scholars must investigate the PI's structural vulnerability and resilience in the face of threats to national sovereignty. This debate is increasingly urgent given global instabilities, such as armed conflicts in Europe and the Middle East, U.S. protectionism, and the climate crisis. These factors undermine the stability of the international flow of inputs.

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