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Institutional Dimensions of Integration and Trade

Regulating the Tigers:

The Institutional Dynamics of Indo-Brazilian Trade

Reflections from the Pharmaceutical Sector

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ABSTRACT

In recent years, the business of documentation and the institutional dimensions (political and regulatory) of trade between Asia and Latin America have wielded profound impact on emerging trade patterns and competitive structures in the pharmaceutical industry in Brazil. This paper explores the flow of investment and goods from India to Brazil, trends in Brazil's institutional and regulatory structures in the pharmaceutical sector and the national political frameworks in which they are emerging. It provides a picture of how current trade dynamics are playing out through national procurement and firm-level supply strategies. Experience from Indo-Brazilian trade in pharmaceuticals over the last decade suggests that the institutional framework in which foreign companies compete affects the shape of their investments and the quality of the goods they trade.

Keywords: trade, pharmaceutical regulation, industrial policy, APIs, generics, public procurement, public health, India, Brazil

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1 Introduction

The history of the pharmaceutical industry, it has been said, is the history of regulation. Be it the building blocks of the pharmaceutical sector—bulk organic chemicals[1] or the finished formulations found across the counters of local pharmacies, the cross-border exchange of pharmaceutical products depends on institutional rubrics and trends defining legality, legitimacy and ultimately, access to the customer. Without legal and regulatory approval, a pharmaceutical producer has no market: in the words of an Indian API supplier to Latin America, "I may have a phenomenal product, but without the papers, I've got nothing. This business is all about documentation."[2]

In recent years, the business of documentation and the institutional dimensions (political and regulatory) of trade between Asia and Latin America have wielded profound impact on emerging trade patterns and competitive structures in the pharmaceutical industry in Brazil. This paper explores trade between India and Brazil, trends in Brazil's institutional and regulatory structures in the pharmaceutical sector and the national political frameworks in which they are emerging. It provides a picture of how current trade dynamics of competition and sourcing between Asia and Latin America are playing out through national procurement and firm-level supply strategies.

Since 1997, eleven Indian firms have established operations in the Brazilian market, on the whole with the intent of creating a base for Latin American operations, marketing generic medicines and bulk pharmaceutical chemicals. Hundreds of Indian firms have become API suppliers to an industry in which 98 percent of all bulk pharmaceutical chemicals are imported. Over the last decade, India has gone from being the 33rd supplier of bulk medicines to Brazil, to the 2nd.[3]

The shift of outward Asian investment and exports to Brazil's pharmaceutical sector mimics a global trend underway over the last decade. In particular, Asian firms from China and India—so called Dragons and Tigers of the global economy—have made strides in exploring outside markets and in building international networks. The impact of the ascendance of Asian firms has been felt globally. A recent OECD paper describes the influence of the Asian economies on Latin America as distinctly dichotomous, both angelic and impish.[4] UNCTAD has explored the more benign outcomes of increasing partners for developing countries.[5] We argue that at least in the case of Brazil, the timing

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[1] Also known as active pharmaceutical ingredients, and henceforth referred to here as APIs.
[2] Kleber Oliveira Miranda, API Head - Latin America, Glenmark Pharmaceuticals. Interview, Sao Paulo, April 28, 2006.
[3] By liquid kilo weight.
[4] See the OECD's larger project, "Asian Drivers and their Impact on Development" and in particular, Working Paper No. 252, "Angel or devil? China's Trade Impact on Latin American Emerging Markets, Jorge Blázquez-Lidoy, Javier Rodríguez and Javier Santiso, June 2006.
[5] The United Nations Commission on Trade and Development has described the rise of a "new geography" of trade, investment and information among the countries of the global "South," including lower, middle and upper-income developing countries (UNCTAD, 2004a). The rise of "a new geography of international investment relations" has been particularly notable in Latin

and shape of institutional parameters regulating the industry have greatly affected trade outcomes.

The challenges of confronting emerging Asian competitors are far from confined to Latin America. In the pharmaceutical sector, for example, Europe has long been a locus of global active pharmaceutical ingredient production. But in recent years, its position both within Europe and in emerging markets has been rapidly eroded by Indian and Chinese suppliers.[6] National industrial pressures have spurred the call for tighter regulations on inputs at a transnational level. This paper suggests that the degree to which governments in Latin American have grappled with the entrenchment in their markets of bulk pharmaceutical products from Asia illuminates the dynamics faced by governments on a global scale.

We embark with a brief look at early seminal works on institutions and trade. We integrate recent contributions and set out the scope of institutions in this paper. In the second section, we summarize key changes in Brazil's national regulation of the pharmaceutical industry over the last decade, arguing that key changes in the institutional dynamics in this sector opened the door for new opportunities in international trade. Building on analysis of these transformations, we examine outcomes in Indo-Brazilian pharmaceutical trade, drawing from interviews with policy makers, industrial representatives, Indian and Brazilian firms, and national public laboratories to show how changes in regulation and the adoption of institutions to monitor the pharmaceutical industry shaped new patterns of trade and public procurement.

We conclude with a review of the context of pharmaceutical regulation, and draw brief contrasts with Brazil's experience to recent trends and changes in bulk chemical regulation in the European Union. We suggest that institutional approaches to the regulation of imported active pharmaceutical ingredients provide an occasion for analysis of the shared challenges and opportunities facing Europe and Latin America as they seek to regulate new sources of international trade.

1.1 A Brief Look at Institutions and Trade

Traversing national boundaries with goods, services or capital, enterprises engaging in multinational economic activities face the standards and regulations of least two governments, home and host. This interface provokes a range of possible outcomes, spanning "conflict or congruence between two government's policies or between governments and multinational firms" (Grosse 2005, 3).

The interstitial tissues of these relationships embody an institutional trade framework (ITF)—encompassing how the rules and policies regarding trade are constructed, implemented, abided and maintained—between governments and businesses engaged

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America, where Asian partners and competitors have assumed an unprecedented role (UNCTAD 2004b, ECLAC 2004, IDB 2005).

[6] More than half active pharmaceutical ingredients used in European manufacturing processes were imported from China and India in 2006.

in international economic activity.[7] This research adopts the term 'institutions' from Douglass North's (1990) description of formal (widely referred to rules) and informal conventions (widely referred to as standards) of society. North (1989, 1990) asserts that institutions provide the preconditions for economic systems grounded in interpersonal exchange and describes institutions as "rules, enforcement characteristics of rules, and norms of behavior that structure repeated human interaction" (North, 1989, p. 1321). Such rules and standards may include contracts and guarantees, bankruptcy laws, the legal system property rights and trademarks, cultural practices, habits norms and customs.

Consensus over the last years on a definition of institutions has spurred a deluge of work in economics which applies game theory and contract theory to disentangle the influence of a variety of institutional forms on economic agents and outcomes in the overall economy.[8]

But a plethora of writers have taken a qualitative approach to explore the role of institutions and trade through the dynamics of business-government relationships. Their work typically is spun from within the multiple angles of the social science disciplines. Each brings a different perspective to the relations between firms and businesses. Branches within institutional theory have sprung from roughly two origins; deriving from economic perspective (Clague 1997; Coase 1998; North 1990, 1995) or sociological perspective (DiMaggio and Powell 1983). Both branches of theory consider the contexts or institutionalities of exchange to be paramount in interpretation of the mirco-level structure of exchange or production, be it through the prism of a firm or market.

In the next sections, we briefly review some of the early work which shaped the business-government relations institutions literature, and more recent seminal or innovative works which have redefined the role of the state and attempted to measure its impact on trade.

Early Work on Bargaining and State-Business Relations

An early departure point in looking at the nexus of international economic activities and the role of government's was Hymer's 1960 thesis, which proposed that multinational firms extended their operations across borders to internalize transaction costs (efficiency) and to achieve market power through the building of monopolies (equity). Hymer did not focus on the relationship of these activities in regards to governments. But through his attention to the firm´s strategy of cross-border expansion as a means of monopolization, he highlighted how such activities could be curtailed by government intervention. Other writers picked up on this distinction. Around the same time of Hymer's work, Jack Behrman (1960, 1962) investigated the potential for economic

[7] See Sweet (2006) for more on the changes in the institutional trade framework characterizing the political economy of trade relations between Latin America and Asia over the last decade.
[8] Such work has looked at the way that rules such as changing the voting franchise has effected the economy, or electoral rules such as presidentialism versus parliamentarians on fiscal policy (Persson, Gerard and Tabellini, 2000).

development through foreign direct investment, highlighting policy initiatives which could be taken to capture the welfare-enhancing potential. Behrman took the first step in synthesizing the interests of government and firms for mutually positive outcomes.

In looking at the activities of a firm commencing business activities abroad, Robinson (1964) emphasized the importance of a firm establishing legitimacy in the eyes of the government. He argued that firms establish legitimacy by taking national interests seriously. He further suggested that most multinational projects did not take national interests seriously and therefore were vulnerable to nationalization and restrictions imposed by their foreign host. Vernon (1971) further explored the strategy of multinational firms via foreign states by introducing the notion of an "obsolescing bargain" situation which emerged between the foreign enterprise and the host government. He noted that before the company entered the market, it had all the incentive to negotiate with the government on certain grounds. Once the firm moved forth with its investment in that country, Vernon saw its bargaining potential diminish. With the allocation of capital in the country, Vernon believed it became captive to the whims of the local government.

Though Behrman (1962, 1960) observed the potential for congruence among the interests of firms and governments, the main thrust of these early works showed emphasized that the institutional trade framework in place in foreign host governments could provide a major constraint to investors. The perspective reflected the time, in the sense that most of the investment and trade was driven by colonial powers that were being driven out of then third world economies by political nationalization movements.[9] Three decades later, issues of legitimacy and expatriation had not completely subsided, but a range of works described a cooperative role emerging between firms engaged in international activities and the states that hosted their endeavors abroad.

Triangular Diplomacy and Empirical Evidence of Institutions in Trade

The traditional notion of the state in international affairs was that it sought to gain influence through controlling territory. Susan Strange and John Stopford (1991) offered an alternative to this view in the early nineties, introducing the idea that states no longer vie for expanded domain of land, but rather, for the means of creating capital. As the principle mechanisms for capital creation, Strange and Stopford argued that corporations had become the new darling of national states. States no longer feared the arrival of multinational enterprises, or threatened them with nationalization, they beckoned them to invest in their territories and promised cut-rate deals for their capital. Competition between states for land was subsumed by competition between states for firms.

A "new diplomacy" emerged forged by common interests; "firms have become more involved with governments and governments have come to recognize their increased

[9] Nonetheless, a degree of conflict remains relevant today. The case of a the Chinese State Oil company's a bid for Unocal, of the US's provoked consternation in the US and a hearing at the US House Arms Service Committee.

dependence on the scarce resources controlled by firms."[10] Under the Strange Stopford rubric, the traditional state-state diplomacy joined with state-firm and firm-firm diplomacy to form *triangular diplomacy* in international political economy.

Many other writers have identified the state's role in building an institutional framework which fosters and promotes trade, be it through the expansion of sovereign firms, or the attraction of foreign capital. But how to measure the impact of the state's role in economic diplomacy? Berkeley economist Andrew Rose offers some unique empirical results examining this problem and shows a positive outcome generated through economic diplomacy. Rose (2005) focuses on embassies and consulates, arguing that because of the falling costs of communication, the traditional role of these institutions has changed over time, from sources of "information gathering" and "decision making" to "economic agents," or as Strange and Stopford might have call them a decade earlier, economic diplomats. Rose then asks if such economic diplomacy is effective, drawing from a cross-section of data covering 22 exporters and 200 import destinations. He shows that bilateral exports rise by 6-10 percent for each additional consulate.[11]

Nitch (2007) further examines the impact of the state's efforts to facilitate and improve trade relations. He investigates the effects of state visits on international trade, drawing from a data set of the travel activities of heads of state from France, Germany and the US between 1948 and 2003. Nitch finds that official and state visits have a positive effect on export, with a typical visit associated with as much as a 8 to 10 percent increase in bilateral exports. While economic research has shown the prohibitive effect of wars or other sources of political conflict on trade (Morrow, Silverson and Tabares, 1998), Nitch and Rose make the first steps in quantitative literature to illustrate a link between the forging of institutional networks via visits and established consulates and embassies and growth in bilateral trade.

Researchers in business literatures began to highlight the influence of the state in multinational economic activities nearly forty years ago. Over the last decade, writings grounded in international political economy have shown how these relationships have shifted from one of contrary to mutual interest and economic diplomacy. Recent works in trade economics have acknowledged the growing role of the state as a promoter of economic diplomacy and have sought to measure the impact of state forged institutional networks on trade outcomes. The intersecting interests and actions of state and business players comprise what may be called an institutional trade framework. We build on the work thus described, to see how changes in the institutional trade framework between India and Brazil has evolved over the last decade, and the impact of these institutional dimensions on the pharmaceutical sector.

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[10] Strange and Stopford, 1991, 1.

[11] Interestingly, Rose also looks at Brazil, and it's network of economic diplomacy. He highlights that both Brazil and Belgium exported $17 billion of goods to the United States in 2003, though Belgium's economy is twice as big as Brazil's. Rose asks if Brazil's maintanence of 7 consulates (and one embassy) and Belgium's 4 consulates (and one embassy) provides a "material advantage" of networks for its firms to export to the US market.

2 India and Brazil? Outlines of Trends in Trade

> "India's exports to Latin America have increased from US $ 124 million in 1991-1992 to US $ 1.77 billion in 2003-2004. Let's keep the ball rolling!"[12]

Trade among developing countries has been expanding at constant pace since the 1980s. So-called South-South trade has been growing at more than 10 percent annually since the early 1990s, at twice the rate of global trade (World Trade Report, 2003). Reaching US $ 640 billion in 2001, South-South trade accounts for more than 40 percent of trade among developing countries, nearly one third of merchandise trade and one fourth of trade in services.[13] Two decades ago, trade among developing countries accounted for less than 25 percent of global trade in merchandise.

The shift in world trade from predominantly North-South or North-North driven flows to include a South-South dynamic has been described in a literature which highlights the rise of what Brazilian President "Lula" da Silva heralds as the birth of a "new commercial geography."[14] For Latin America, a new commercial geography entails the growth of trade in Mercosul and the heightened role of Asia as a trading partner. The rise of Asia as a buyer of commodities and supplier of cheap goods has garnered increasing attention among scholars and policy makers alike, who see to determine how to maximize the benefits of strong Asian economies, and protect themselves from the new sources of competition which have emerged.[15]

In this section, we introduce some descriptive statistics to show how the rise of Indian exports in Brazil has evolved over the last decade, introducing the rise of Indian imports in the pharmaceuticals segment. In the next section, we will look more closely at the evolution of Indo-Brazilian trade, drawing from the perspectives of industry leaders and policy makers to highlight how changes in the regulation of pharmaceuticals at a domestic level has effected the strategy of Indian firms.

Before the mid 1990s, India exported almost nothing to Brazil, with the 1980s annual export average barely reaching 7 US million dollars. During the 1990s, trade flows

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[12] R. Viswanathan, Joint Secretary, Indian Ministry of External Affairs. Consul General of India to Sao Paulo (1996-2000), *Interview*, New Delhi, July 2005.

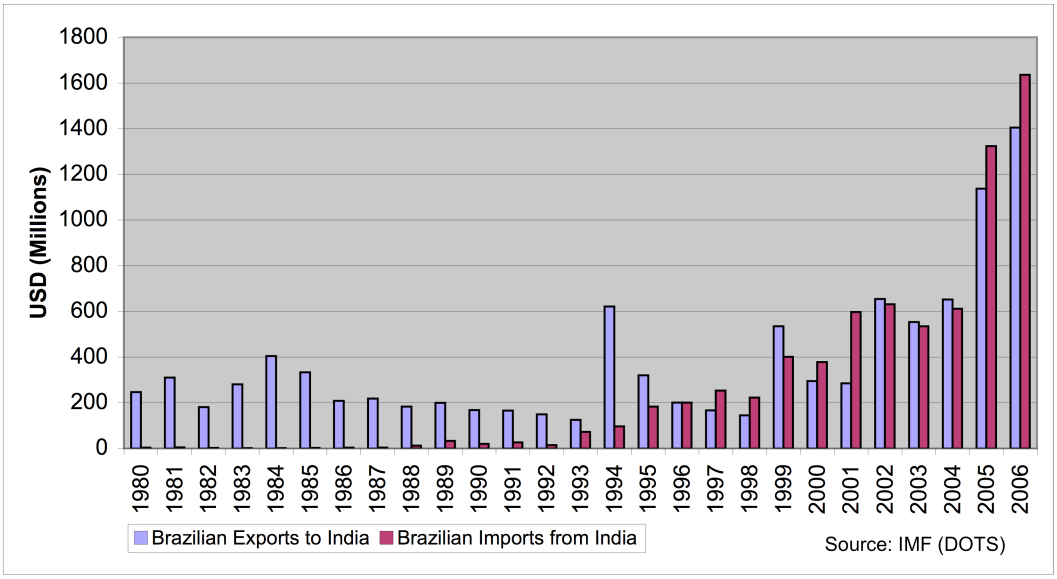
[13] The growth Asian economies has served as the primary engine of this expansion. CEPAL (2007) shows that "in the last seven years, Asia has contributed more than twice as much to global economic growth in PPP terms as the European Union, Japan and the United States combined." Latin America and the Caribbean contributed 7-8 percent of growth during the same period. Inter-Asian trade presents the most robust growth in South-South trade.

[14] In an interview with India's largest newspaper, *The Hindu,* Minister of External Relations Celso Amorim explains the notion of "new commercial geography" in relation to economic and political linkange through the India-Brazil-South Africa (IBSA) alliance. *The Hindu*, "Interview with Minister of External Relations Celso Amorim," July 17, 2007. http://www.mre.gov.br/ingles/politica_externa/discursos/discurso_detalhe.asp?ID_DISCURSO=3144&Imprime=on.

[15] Osvaldo R. Agatiello, "South-South trade in Latin America and the Caribbean: Challenges, benefits and options." Inter-American Development Bank, Integration, Trade and Hemispheric Issues, October 2005. See ww.iadb.org/ethics.

increased more than 21 fold, with the average across the decade reaching approximately 149 million dollars a year. By 2006, India's exports to Brazil reached 1.64 billion dollars.[16] Brazilian exports to India also grew during this period, presenting higher volatility and in recent years, lagging behind Indian expansion. A moderate take off characterizes Indian exports in the mid-1990s, and a more marked increase commences from recent years.

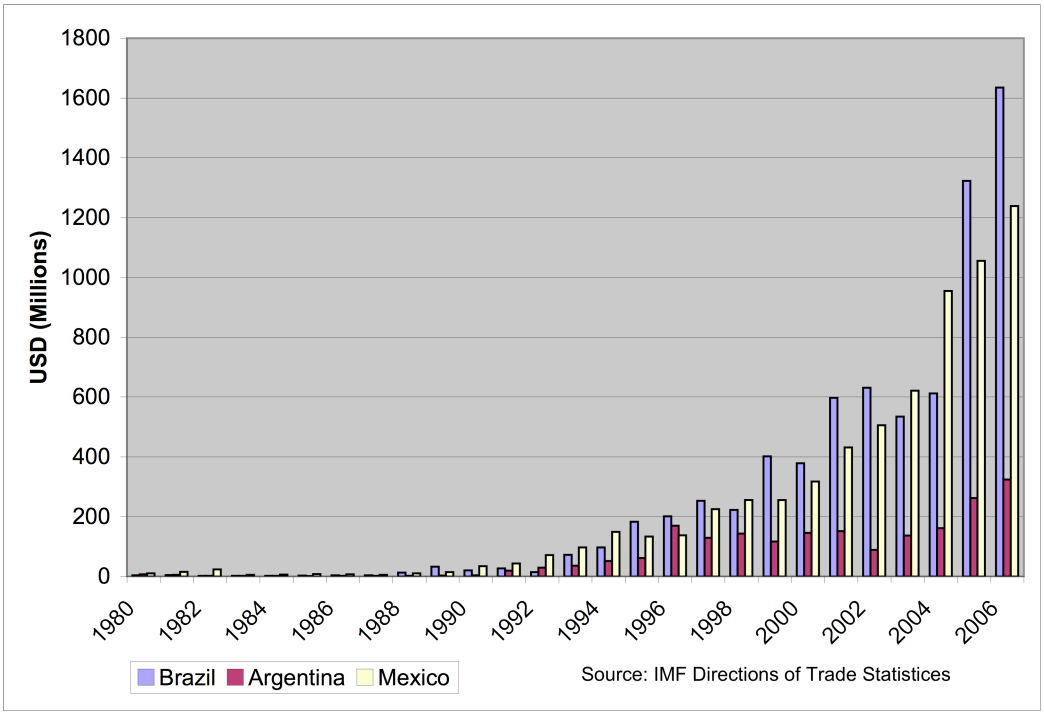
Figure 1: Indo-Brazilian Trade Progression, 1980-2006



As a whole, India's exports to Latin America grew over the past two decades. Looking at the progression of Indian exports to Latin America's three largest economies (Figure 2)[17], Mexico leads Brazil as a source of Indian imports until 1995, when imports destined for Brazil began to rise. Latin America's third largest economy, Argentina, has been a much smaller player for Indian exports.

Figure 2: Indian Exports to Leading Latin American Markets

[16] This was an increase of over twelve thousand percent from 1980. Brazilian Ministry of Industry and Commerce Trade Statistics, "Alice web."
[17] We must take into consideration the size of the economies of these countries, with the nominal GDP in US millions of Brazil 1,067,706, Mexico 804,021 and Argentina 212,702. IMF, 2006.



Examining Brazil's top trading partners over the last decade, the rise new players is evident. By 2006, Asia had clearly become a large source of trade for Brazil, with four countries, China, South Korea and Taiwan and India in the top twenty category of importers. India, which in 2000 was around number 50, had moved up to Brazil's 14th largest source of imports by 2005, passing Spain, the United Kingdom and Canada.

Given the rise of this new dynamic in trade, our motivation is to examine the institutional environment in which these changes are evolving. Work thus far which has examined the outcome of increasing Asian trade with Latin American has focused on the impact of China, in particular on its appetitive for Latin American commodities and its investment in the region. We offer a look into the value-added area of pharmaceuticals, heavily driven by local regulation, distribution and marketing channels to investigate major transformations in Indo-Brazilian institutional trade framework. In this way, we hope to identify some of the driving factors in the increasing trade, and their impact on the Brazilian pharmaceutical sector.

2.1 Indian Pharmaceuticals in Brazil

> It is destination Brazil for Indian generic drugmakers as companies are making a beeline for the Latin American Country.[18]
>
> *Kitna jigra hai chati mein.* How strong is your chest.[19]

Apart from an agreement signed between India' major petroleum company Reliance and Brazil's Petrobras to share refineries, pharmaceuticals and organic chemicals are the top items imported by Brazil from India over the last 10 years.[20] In the area of pharmaceuticals, over the last decade India rose from the 34th to 2nd largest exporter of medicines by liquid kilo weight in 2006. What accounts for this stark rise in trade and specifically, for India's ascendance as a major supplier of medicine to Brazil? In the next section we suggest that a confluence of changes in Brazil's national regulatory system opened the door for Indian products.

In classic trade theory, foreign direct investment is expected to follow increases in trade in merchandise. In the case of Indian investment in Brazil, the pattern has evolved more swiftly, with investment arriving almost concomitantly with increases in trade. In 1999 no Indian pharmaceutical company had operations in Brazil. By 2005, eleven companies (6 of the top 10 and 5 of the top 20 in India) had set up local affiliates, most with the aim of marketing and registering their products, but some with manufacturing and processing capacity. Pharmaceuticals led software, engineering and chemicals in this first wave of Indian firms establishing a local base in Brazil.[21]

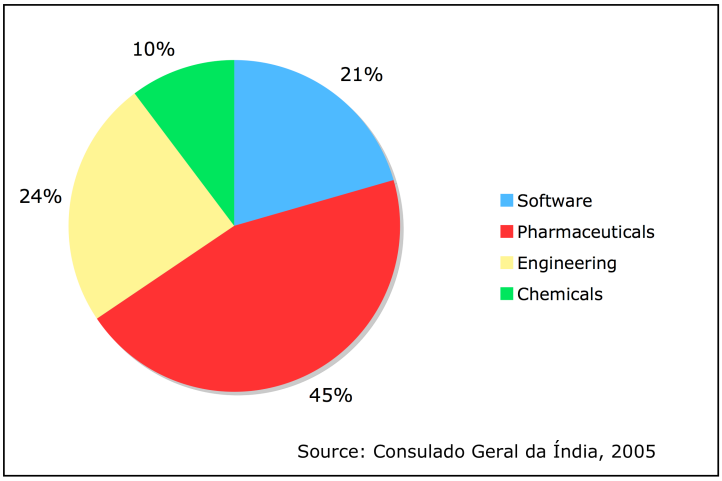
Figure 3: Indian Operations in Brazil by Sector

[18] "Indian generic drugmakers line up for Brazil," CNBC, Moneycontrol.com, May 18, 2007, http://www.moneycontrol.com/india/news/business/indian-generic-drugmakers-linefor-brazil/282079.

[19] Unichem representative in Sao Paulo, quoting Hindi parable to describe the strength demanded from Indian entrepreneurs entering what he called a "highly competitive and locally controlled market." Interview, Sao Paulo, June, 2006.

[20] The code for pharmaceutical products in the NCM system is (30), for organic chemicals, which includes APIs for human and vetinary uses, fertilizers and industrial chemicals is (29).

[21] There are indications that there will be increases in the software industry. (New article).



With sales of over $11 billion annually, the Brazilian pharmaceutical market ranks as one of the 10 the largest pharmaceutical markets in the world, vying with Mexico for the position of the leading pharmaceutical market in Latin America. The size of the Brazilian market and perceived potential, drove early Indian interest. As the director of one of India's top three firms has reflected, "size of the market was the first criterion." But in addition to the market size, several structural and political factors contributed to a quick and concentrated entrance of Indian firms into the Brazilian market. "The main impetus for our company: We noticed a match between our capabilities and the market openings."[22]

In the next section, we look more carefully at "openings" in the Brazilian market to analyze the role of institutions in affecting the emerging trade with India. First, Table 1 shows patterns in the asset allocation decisions among Indian firms. The predominant choice among Indian firms is to enter Latin America via the Brazilian market. Also significant characteristic which becomes apparent is the short time period in which the firms entered the market, and the high concentration of their activities in wholly owned subsidiaries under their direct control. The majority of the firms focused their efforts in marketing and registration of their products, but some established manufacturing facilities with varying degrees of production levels.

Table 1: Locations, Ownership and Activities of Indian Generic Drug Firms in Latin America

Company	Latin American Affiliate	Location	*Entry Year*	Ownership	% of Interest	Activities

[22] Most of the representatives from Indian and Brazilian firms have been provided anonymity due to the sensitive commercial nature of questions for both interviews and surveys. Throughout the study, each representative is provided a code. These codes will be available to the public in the Cambridge University Library ex-post 2 years from the thesis submission date. Vice president and Head of Operations, CC58, June 2006.

Aurobindo	AB Farmo Quimica	Brazil	2000	Subsidiary	99.8%	M&M
Dr. Reddy's	Dr. Reddy's Farmaceutica do Brasil	Brazil	1998	Subsidiary	100%	Marketing
	Aurantus Farmaceutica			Associate	50%	-
Glenmark	Glenmark Farmaceutica	Brazil	1999	Subsidiary	100%	Marketing
	Laboratorios Klinger	Brazil		Purchase	100%	Manufacturing
	Serveycal	Argentina		Purchased	100%	M&M
Ipca	Ipca do Brasil	Brazil	1999	Subsidiary	100%	Marketing
Orchid Chemicals	-	Brazil	1998	-	-	-
Ranbaxy	Ranbaxy Farmaceutica (Formerly	Brazil	1999	Subsidiary	80%	M&M
	Ranbaxy SP Medicamentos)	Brazil	2001	Subsidiary	100%	Marketing
	Ranbaxy do Brasil	Panama	-	Subsidiary	100%	Marketing
	Ranbaxy Panama, SA	Peru		Subsidiary	100%	Marketing
	Ranbaxy PRP	Mexico	-	Subsidiary	100%	Marketing
	Ranbaxy Mexico S.A. de C.V.					
Strides Arcolab	Strides Latina	Brazil	2000	Subsidiary	100%	Marketing
	Cellofarm	Brazil				M&M
	Farmaceutica	Brazil				
	Infabra	Uruguay			60%	
	Goodlanza	Venezuela			80%	
	Biopharma	Mexico				
	Solara SA de CV					
Torrent	Torrent do Brasil	Brazil	2000	Subsidiary	100%	Registration and Marketing
Unichem	Unichem Farmaceutica	Brazil	2002	Subsidiary	100%	Registration and Marketing

	do Brasil					
Wockhardt	Wockhardt Farmaceutica do Brasil Wockhardt Mexico SA de CV	Brazil Mexico	2000	Subsidiary	100%[23] 51%	Marketing
Zydus Cadila	Zydus Cadila	Brazil	2000	Subsidiary	100%	Marketing and Registration

*Reported. Key: M&M = Marketing and Manufacturing, - = unknown
Source: Compiled by Author

From the overview provided by this chart, we see that India's pharmaceutical industry's investment in operations in Latin America since 1999 occurred over a short period, and concentrated overwhelmingly in marketing operations based in Brazil. Why? Despite its size, Brazil is considered to be a somewhat high risk market due to crisis in 2001 and 1997.[24] Other markets in Latin America have higher per captia drug expenditures than Brazil and less tumultuous recent economic histories. In the following sections, we provide analysis of critical changes in Brazil's domestic regulation which shaped the timing and investment of Indian operations.

3 Emerging Frameworks in Trade: Changes in Regulation and Opening Doors

> "As emerging MNEs now start to invest in other developing countries, the impact of their behaviours on the host economies becomes by itself worth of additional research."[25]

In this section we explore key changes in the domestic regulation of pharmaceuticals in Brazil. We examine Brazil's involvement in the political economy and regulation of the pharmaceutical industry during the 1990s and provide the perspectives of Indian entrepreneurs and local industry and policy makers to show how changing institutional dynamics affected outcomes in trade.

3.1 Brazil's Pharmaceutical Regulation

The institutional framework of the Brazilian pharmaceutical market underwent a series of important changes in the 1990s. In this section, we review shifts in Brazil's pharmaceutical policy and subsequently highlight two fundamental policy directions

[23] Held by two Wockhardt European Subsidiaries, The Wallis Laboratory Limited with a majority share of 90% and Wockhardt Europe Limited with 10%. (Wockhardt, Annual Report, 2005).
[24] This perception is shared among Indian entrepreneurs, in the words of one, "we knew that the market could change very quickly, but we didn't think the threat was high enough to miss this [the generics] opportunity." Director BG24, Sao Paulo, July 2006.
[25] Goldstein et al 2006, 31.

which effected both the shape of the pharmaceutical industry, and the parameters of its foreign trade.

In early 1990s, the Brazilian economy underwent radical changes with the liberalization pursued by then President Fernando de Collor, including the opening up of the Brazilian economy to imports, the founding of Mercosur, the privatization of state-owned companies and deregulation.[26] One of the changes which had the most immediate effect on the pharmaceutical industry was the rapid lowering of national tariffs from 60-70 percent to approximately 14 percent over a four year period.[27] Facing new sources of competition over a short period of time, local firms failed to adapt and over 2,000 manufacturing units went out of business between 1991 and 1994.[28] As the current Director of ANVISA's General Office of Drugs describes it, the tariff reductions meant that local firms could effectively import medicines in their finished formulation (with incipients and other additives) cheaper than making the first level of chemical formulation:

> "At the onset of the *abertura* you had tarriffs that were as high as 100 percent that were cut drastically. When you diminished this tarriff, the little bit of reaserach that you had, all of it dissapeared. Which is to say, when it was cheaper for you to import it in finished formaulation than to make the active principle in this country, that's what you very quickly did."[29]

With competition decreased, by the mid-1990s, prices in Brazil rose substantially.[30] Reintervention in the pharmaceutical market gained currency in the late 1990s, when a range of policies were implemented to regulate pharmaceuticals for the purposes of increasing competition and accessibility. A flurry of changes occurred during this period, including a complete restructuring of categories within the pharmaceutical market, pricing mechanisms and political control of sanitary and surveillance measures. Here we

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[26] For a review of the impact of these changes on Brazil's innovation system, see TIGRE, P., CASSIOLATO, J. E., SZAPIRO, M. H. D. S. & FERRAZ, J. C. (2002) Institutional Change and Technology: Impacts of Deregulation on thhe National Innovation System. IN BAUMAN, R. (Ed.) *Brazil in the 1990s: An Economy in Transition.* Oxford, Palgrave.

[27] ABIFINA, Interview, 2006.

[28] According to Laura Gomes, Manager of Foreign Trade for Febrafarma, "Our sector was forced into suicide. It was dismembered. Collor entered into power and said, tomorrow, we are going to import everything." Interview, Sao Paulo, April, 2006.

[29] Antonio Carlos da Costa Bezerra, General Office of Drugs – GGMED, Brasilia, June, 2006.

[30] "We perceived during this period when tariffs were lifted and the prices were 'free' that they [the pharmaceutical companies] had the capacity to raise the price and diminish the quantity of the medicine sold. But the patient has a dependent relationship with medicine. So even if the companies raise the price, he is captured. He doesn't have anywhere to run. This is what we call inelasticity of the demand according to price. You can raise the price of the medicine and the demand does not fall proportionally because the consumer is refen to the medicine. The consumption is essential. And there is still one more characteristic which is prescription by the doctor. The doctor, and this is not with bad intentions—"*não e por maldade*"—but many times he is in a social economic situation very different from that of the patient, so he may prescribe the name-brand medicine, which is the most expensive." ANVISA Regulatory Director, BG39, Brasília, June, 2006.

focus on two key policies which we argue radically transformed the Brazilian pharmaceutical market and opened it for the kind of products Indian firms were equipped to supply—APIS and generics: The enactment of Lei 8.666 and the formation of the generics category under the stewardship of a national pharmacological surveillance agency.

3.2 Public Procurement: The Enactment of Lei 8.666

The economic impact of the liberalization or '*abertura'* policies pursued during the Collor presidency has been widely analyzed.[31] But one significant aspect of the Collor legacy in political economy which has been largely overlooked was the implementation of a law to regulate government purchases. As the first democratically elected president of Brazil, Collor's removal from office via impeachment proceedings has been observed as particularly traumatic for Brazilian public institutions, which immediately thereafter struggled to regain legitimacy in the eyes of the electorate.[32]

Law 8.666, the "*Lei de Licitações*," or literally translated, Law of Tenders, was enacted by the Brazilian Congress in 1993 to try to reestablish legitimacy in the contracting and payment of public entities.[33] The law stipulates that public purchases made at the municipal, state, or federal level must be made via open auction systems, with awards granted to the lowest possible offering via a rigid price criteria. The law does not take into consideration the quality of the product offered or the reputation of the service provider, but focuses merely on price differentials.[34]

Over twenty-six percent of the value of Brazil's 11 US billion dollar pharmaceutical market is accounted for by government procurement. In terms of volume, the proportion

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[31] Amann (2000) offers a review of liberalization's impact for industrial competition across various sectors. Packenham (1994) provides a comparative review of the pace of change set by Collor's liberalization program to that in Menem's Argentina.

[32] Collor was accused by his brother in 1991 of selling influence through his campaign treasurer, Paulo Cesar Farias, provoking an investigation by the Federal Police, Congress, and "caras-pintadas" mass protests. Collor resigned just before the Senate was to vote on his impeachment. Weyland (1993) explores the climate of corruption in Brazil and offers a view as to why Collor's presidency fell so spectacularly when similar cases have been overlooked. In an interesting post-note, the scandal which marred his presidency did not dissuade Collor from further pursuing a life in Brazilian politics. In 2002, he ran for office as governor of Alagoas, but lost. In 2006, he was elected to the Brazilian Senate representing Alagoas with 44% of the vote.

[33] Full version available at Presidência da República, Casa Civil, Lei Nº8.666 de Junho de 1993, http://www.planalto.gov.br/ccivil_03/Leis/L8666cons.htm, *redações*, or edits over the years, are highlighted and linked to the full amendments.

[34] An exception to this standard appears in Article 46, in a redação enacted in 1995, which states that quality *and* price can be taken into consideration, but exclusively for "services of a predominantly intellectual nature": "*Os tipos de licitação "melhor técnica" ou "técnica e preço" serão utilizados exclusivamente para serviços de natureza predominantemente intelectual, em especial na elaboração de projetos, cálculos, fiscalização, supervisão e gerenciamento e de engenharia consultiva em geral e, em particular, para a elaboração de estudos técnicos preliminares e projetos básicos e executivos, ressalvado o disposto no § 4o do artigo anterior*."

of government purchases is much higher. The system of purchasing by the Brazilian government is highly fragmented.[35]

Opening Doors: The Impact of Lei 8.66

With local Brazilian pharmaceutical industry experiencing a swift de-acceleration during the first half of the 1990s, and regulation of public purchases establishing a rigid framework for purchasing based on price level, a new opportunity emerged for providers of cheap raw chemicals and generic formulations from India. Indian entrepreneurs from firms specializing in a wide range of therapeutic segments note the role of the early legislation in their company's decision to enter and explore the Brazilian market.

> "Almost all Indian firms started their businesses in Brazil through beating out the competition in national auctions (*atraves do pregão*). Tender calls at a federal level gave Indian companies reliability [of payment] and quantities."[36]

Another managing Director of an Indian subsidiary in Brazil echoed this sentiment:

> "The APIs first sales in public, then private sectors, provided the doorway with which Indians could enter and make a mark for themselves….APIs allowed for the firm to come into the Brazilian market, get used to it, figure out the lay of the land and grow."[37]

The emergence of Indians as suppliers to the Brazilian government was initially seen as providing important advantages for public health initiatives. The supply of low-cost active pharmaceutical ingredients to the 12 national pharmaceutical labs which provide medicine both to federal and state administrated programs allowed for significant price reductions. In the case of the country's national HIV/AIDs program, the steady supply of cheap APIs of generic ARVs and the potential to find a quick reliable source for importing patented ARVs, enabled the government to engage with patent holders to lower their prices on branded products.

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[35] Article 196 of the 1988 Brazilian Constitution makes health services (and access to basic medicine) a right. Financing of this system occurs partly through the Sistema Única de Saúde (SUS) which is connected to the Ministry of Health. Purchases of medicine through this system take place at a federal, state and municipal level. Each year, a number of medicines are identified as those that will be acquired by the Ministry of Health through the Secretary of Science, Technology and Strategic Medicines' purchasing unit known in short version "DAF", Department of Pharmaceutical Assistance and Strategic Raw Materials (*Insumos Estratégicos)*. For the year 2006, this list included 181 item categories totaling 1,001 billion US $ in federal expenditures. The remaining medicines are acquired in arrangements between the 26 states and 5,560 municipalities. Source: DAF internal document, "Processos de Aquisição dos Medicamentos 2006. Brasilia.

[36] Consultant CC72, Sao Paulo, May 2006.

[37] Regional Manager, CC61, Sao Paulo, June 2006.

> "The possibility in the last decade to produce locally some first generation ARV drugs and to import APIs from China and India made it possible for Brazil in the last decade to negotiate reduction of prices with multinational pharmaceutical enterprises."[38]

During the period in which negotiations with northern multinationals took place, Indian firms were unofficially told by several Ministers of Health, first by Jose Serra in 2001, to be on "standby"[39] to supply generic APIs for HIV/AIDs production should a compulsory license be issued. When a compulsory license was instituted by President da Silva in May 2007 for Merck's efavirenz, the Indian firm Aurobindo was selected as the key supplier for the APIs.

In recent years however, dependence on Indian suppliers has spurred a backlash among Brazilian pharmaceutical producers. Representatives from local industrial groups argue that the denationalization of the Brazilian industry during the early 1990s put local firms in a position of vulnerability, compounded by the current importation of APIs and finished formulations such that they present a "strategic" threat to public health priorities.

National production is particularly absent in the area of APIs, in which, according to one chemist and member of the national Fórum de Competitividade da Cadeia Farmacêutica, by 2005, only five Brazilian companies have the capability to produce APIs—Nortec, Globe Quimica, Cristalia, Labogen and Formil and Microbiologica. Often overlooked in the broader discourse regarding ARV access, APIs are the primary juggernaut of ARV production.

> "The biggest challenge in ARV production is not producing final formulations, but producing the active pharmaceutical ingredients (APIs) necessary to produce final formulations. ARV production is feasible for most manufacturers, while APIs are enormously expensive and difficult to produce, requiring substantial inventories of raw ingredients and costly equipment." (Treat Asia 2005)

Since the ARV supply demands of the National STD HIV/AIDS Program were set into motion in 1996, Brazil has looked toward its national laboratories to supply cheap off patent ARVs. The mothership of national Brazilian investment has been the Far Manguinhos public laboratory, which from 1997-2000 experienced a 20-fold increase in investment in research and production facilities. In the same period, Far Manguinhos' production expanded by more than seven-fold (Cassier and Correa 2003). Far Manguinhos is responsible for 40 percent of Brazilian-produced ARVs provided to the national program. Even as debate regarding supply of the national STD HIV/AIDS program has focused increasingly on fortifying national production (vigorously supported by the national chemical and pharmaceutical industry, see Brasil de Oliveira 2005), data

[38] Cristina de Albuquerque Possas, National Program of Sexually Transmitted Diseases and AIDS, Unit of Research and Technological Development, Ministry of Health, Interview, Brasilia, June 2006.
[39] Director CC68, Sao Paulo, April 2006.

shows that during this first period of public lab expansion API purchases from Asian suppliers were on the rise (Grace 2005, 15).

In 2002, 74 percent of Far Manguinhos' API purchases were from Asian firms. By 2003, 94 percent of API purchases were from Asian firms.[40] In this segment, India has been a leader in API production, with over 13 firms engaged with WHO pre-qualification status. Chinese producers are increasing their share of API production, and recently the link in Indo-Chinese trade has been amplified by Indian firms locating production facilities in China and coordinating with Chinese firms.[41]

Representatives of local industry, as well as scientists and national health representatives, pose heavy reliance on import of Asian APIs as a problematic strategic dependency on a foreign resource, which, like petroleum or gas, could be disrupted by shifts in the political climate or national interest of supplying countries:

> "What I see as complicated is that we are very dependent on them [Indian companies], every time more and more dependent. Wanting active principles, wanting intermediates, wanting finished formulations. And, what if they change their politics? Like Bolivia, all of a sudden. 'Now [say the Bolivians] the gas is ours.' And so they [the Indians] could say, now the medicines are ours. Where is our sovereignty?"[42]

In addition to questions of dependency, representatives from Brazilian public laboratories have complained about the level of quality of the Indian and Chinese APIs they have been purchasing via the *pregão*—public call for tender system. "We have received large quantities of APIs of doubtful quality, or that which is simply bad…..It's ten years that this has been going on. Law 8.666 "*atrapalha mesmo*"—really gets in our way."[43] In an interview in June 2006, Eduardo Costa, Director of Brazil's largest public laboratory, Farmanguinhos, described the law as greatly inhibiting the laboratories ability to produce ARVs of quality and within a certain time period.

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[40] These data are from Farmanguinhos' former director Eloan Pinheiro, according to Grace 2005.

[41] The Indian firm Aurobindo has been a leader in building facilities in low-cost Chinese provinces. But Indo-Chinese economic integration is also taking place at high levels of economic diplomacy. In March 2005 India and China announced the birth of a "strategic partnership" which included negotiation of a free trade agreement which would cover the largest markets in the world. Bilateral trade increased by nearly 80 percent from 2003 to 2004 following five years of increases http://www.ciionline.org/common/92/ countryDetail.asp?countryCode=26&countryInitial=C.

[42] Scientist, Commission Member, BG53, Rio de Janeiro, July 2006. On May 1, 2006, President Evo Morales of Bolivia sent military forces to its oil fields through a decree which nationalized all hydrocarbon reserves. The move caused considerable consternation in Brazil, with Petrobras' operations were taken over militarily, and the Brazilian industry highly dependent on Bolivia's natural gas. Over 40 percent of the energy for the Sao Paulo industry is derived from reserves in Bolivia. The incident spurred a crisis of *mal-estar* between the two countries, which was sought to resolve at a conference in Puerto Iguazú, Argentina (May 4, 2006) with limited success. Six interviewees referred to the nationalization of Bolivia's natural gas reserves as analogous to Brazil's dependent on Asian pharmo-chemicals.

[43] Carmen Lucia Batista Matias, Director, IQUEGO Public Pharmaceutical Lab, (Telephone Interview) Minas Gerais, July 2006.

> "My hands are tied. Within the limitations of 8.66, I can only by the cheapest product. That product may not have the best quality, but that's what I have to buy. We spend more money and time refining the product than we would if we bought a decent product from the start. But that is just the way the law is."

By 2007, however, Costa had circumvented the restrictions of 8.66 on the lowest cost offering. In an arrangement designed by the *Procuradora Federal*, or Federal Prosecutor's Office, Farmanguinhos sourced its APIs directly through national producers Nortec Química e Globe Química, at as much as 94 percent more expensive than that sourced by the Fundação para o Remédio Popular (FURP), Sao Paulo's public laboratory in a pregão which excluded foreign API suppliers.[44]

Demands on procurement set out in 1993´s law 8.66 determined the source of API supply for Brazil´s public laboratories for over a decade. With the recent project initiated at Farmanguinhos to source from local suppliers, it remains to be seen if all national laboratories will adopt a pro-national sourcing stance. The immediate impact of the decision to source locally will likely have positive impacts for local industry. But given the limited number of suppliers available at a national level, it remains to be seen how transparent the selection process will be for these firms, and what the impact of the heightened price for bulk chemical sourcing will be for public health initiatives.

3.3 ANVISA and the Creation of the Generics Catagory

Another change in the institutional framework of Brazil's pharmaceutical industry wielded significant impact on the course of trade with Asian suppliers in recent years. In 1999 the National Health Surveillance Agency (ANVISA) was created through Lei 9782 and shortly thereafter, the category of generics was created to be regulated under the ANVISA stewardship. ANVISA has a range of autonomous powers including, financial independence, administrative ruling, its own directorship and policing power and the mission to promote health protection through control of services and products.[45] ANVISA initiated a new level of standards in the pharmaceutical industry.

> If you look at it from 1998, that year onwards Brazilians started to take regulations seriously. Before 1998 scenario was something like, wild, there was no control in Brazil. Things in English labels. No quality control.

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[44] FARMANGUINHOS PAGA MAIS CARO DO QUE A FURP PELA MESMA MATÉRIA-PRIMA, INFORMA O GLOBO. Agencia de Noticias da AIDS, January 25, 2007. As accessed January 29, 2007, http://www.agenciaaids.com.br/noticias-resultado.asp?Codigo=7058.

[45] Through ports, airports, international borders, looking at drugs, medical devices, food, cleaning products and tobacco products. But ANVISA's role is not limited to sanitary regulation. One of the most direct ways in which ANVISA affects the pharmaceutical market is through price controls. About 800 medicines prices are freely set in Brazil. 19,000-20,000 are regulated through ANVISA's General Office of Drugs (GGMED). Antonio Carlos da Costa Bezerra, Director, GGMED, Brasília, June 2006

> ANVISA became very proactive. 30-40 companies busted the first year because they couldn't meet minimum standards.[46]

The new regulatory structure benefited Indian firms, which have the highest number of approved production facilities outside of the US and were keen to enter a market in which a baseline of quality was established and respected.

> Since 1999 to date, I would like to congratulate the people behind ANVISA…they have really grown quite strong in terms of what they demand from any manufacturer and that has from a commercial aspect, been looked upon very uncomfortably from the foreign companies. But ANVISA has not discriminated national companies from foreign companies. And Indian companies have benefited because the standards made for a playing field where qualified firms like us have a chance.[47]

The creation of the generics category to be regulated under the ANVISA structure represented the most dramatic shift of Brazil's institutional and political means of creating competition in the pharmaceutical segment.[48] A generics law enacted in 1999 (Lei 9.787/99) comprised seven critical elements, thoroughly reviewed by Hasenclever *et al.* (2000). The law included an array of requirements for the promotion, packaging and sale of generics. It endowed the Ministry of Health the task to educate the public about the changes in the generic laws, and the differences of generic drugs from their name-brand alternatives.[49] In the three years since its introduction as a regulatory category, the Brazilian population had become familiar with the generics category through ANVISA's large scale education campaign. By 2002 ANVISA had conducted research showing that 90 percent of the population was aware of the existence of the generics category and over 51 percent had purchased generics more than once.

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[46] Country Manager, CC73, Sao Paulo, April 2006.

[47] Country Manager, CC73, Sao Paulo, April 2006.

[48] Generic drugs are either an identical or bio-equivalent form of a branded drug. Generics should be identical in quality, dosage, safely, therapeutic characteristics, strength, and intended application. Generics are typically marketed at a significant discount from their "name band" counterparts. Generics enter the market following the expiration of the patent for the branded drug.

[49] Bermudez (2006) et al provides an overview of generic regulations in Latin America. They observe three patterns, those countries which foster support for competing medications, promote the use of INNs (or the generic chemical names) and have no restrictions on innovative (proprietary) medicines. This category includes Argentina, Columbia, Costa Rica, Ecuador and Paraguay in this category. A second group of countries which forges policies that demand therapeutic equivlance, recognition of generics by their INN and distinctive labeling. Brazil, Mexico, Panama and Venzuela fell into this category. Finally, they note a third group of countries, Barbados, Bolivia, Guatemala, Nicaragua and Peru that are "at the beginning stage in the process of regulation." They find that the wide range of difference among generic reforms in Latin American countries, in particular, the similar naming of regulations with different meanings, leads to confusion and that bsational policies to "stimulate competition" should take these differences into account.

In the area of marketing and packaging, the generics law stipulated that generics price should be at least 33 percent lower than that offered by the name-brand company. It required generics to be labeled with the name of the active principle, and that the active principle name should not be smaller than twice the size of the company's logo. The previous type of generics, would now be called *similares,* which would be identified by their commercial name.

Figure 4: ANVISA Generics Packaging Requirements

Source: ANVISA Generics Website, 2006

The generics law delegated the regulation of generic medicines to ANVISA and required that generics take preference in SUS purchases. Before this law, the regulation of registrations for generics was inexistent. Ex ante there were medicines sold as generics, but without the technical guarantee of bioequivalency.

Today generics account for 10-12 percent of the market. Regulations for generics have now become more stringent in Brazil than in any other Latin American market because the bioequilvalence tests have to be made with local labs, and the GMP practices. (Valente, Journal of Generic Medicines 2006, 4, 30-36.)

Opening Doors: Opportunities and Outcomes in Generics

> If you chose India as your enemy, she will be your enemy and will be a ferocious one. But it you treat Indian as a potential partner, and are able to work with them, you will hitch a ride on this Indian *arrancada*—force.[50]

Indian interest in the Brazilian market solidified in 1999 with the implementation of a national generics law which regulated and brought to the mainstream generics products. The Minister of Health, Jose Serra rallied for the enactment of legislation which would ensure a platform for public health in his upcoming face-off for the presidency.[51]

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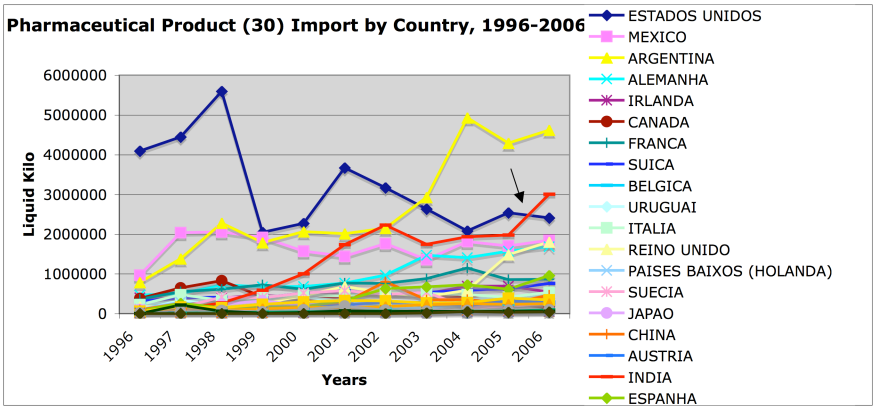
[50] Guilherme Lacombe, President Director, ABEDEC, *Interview*, Sao Paulo, June 2006.
[51] In addition to creating the institutional framework for generics competition in Brazil, Health Minister also went to India in 2000.

As the Brazilian generic market was solidified within the parameters of the new competitive framework, foreign firms began to enter the market. Indians were among the group of generic companies which began the processes of establishing local subsidiaries. While most were focused solely on building local operations for the purposes of guiding products through the newly established regulatory process and introducing the product to the market through distribution and marketing mechanisms, some began to establish production facilities.[52]

Ten of the eleven Indian firms interviewed highlighted generic legislation and government efforts to attract generic competitors as a driving factor in choosing to enter the market. The chart below highlights the increasing share of Indian pharmaceuticals among imported products by volume. Note India did not rise dramatically in dollar values (from 15 to 7). But over the course of the decade, India became the source of a large share of low-cost medicines.

Before 1999, Indian pharmaceutical companies were already active in the Brazilian market, but their presence increased markedly after that point (see Figure 7). This year, India became the second largest importer of pharmaceutical products by volume, surpassing the United States, which one decade earlier had sold 4 times more products than the top importer.

Figure 5: Import by Country



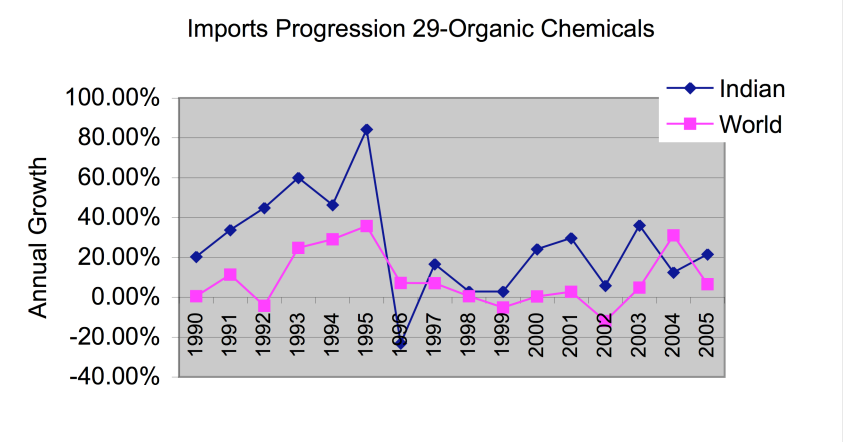
Source: Compiled by author from Ministry of Development, Industry and Foreign Trade, Brazil data. 09/06

In addition to growth in pharmaceutical, or fixed formulations, Indian firms have experienced growth in organic chemical or API exports. Only two times over the last fifteen years have Indian chemical exports to Brazil grown at a rate lower than the world

[52] BECK, M. (2002) Índia vai produzir genéricos no Brasil: Laboratórios estrangeiros estão de olho num mercado que cresce 8% ao mês. *O Globo.* In 2002, it was reported that Ranbaxy would invest R$ 46.8 in building a plant in Espírito Santo. Cellpharm and Glenmark have also established production facilities.

average, in 1994 and 2003. Over the last 15 years Indian organic chemicals have grown at a rate consistently higher than that on the previous year.

Figure 6: Annual Growth, Indian vs. World Imports (1990-2005)



Source: Ministry of Development, Industry and Foreign Trade, Brasilia. Data was cross-checked with reference to Brazil.Mercantil.com, with listings of over 1,697 pharmaceutical firms and traders.[53]

Despite the successes illustrated by the charts above, the greatest beneficiaries of the generics law were national generic manufacturers, who currently command the majority of sales in the generics market.[54] According to the Director of one of India's top 5 firms in Brazil, the institutionalization of generics in Brazil was expected to benefit foreign multinational firms, "everybody thought there would be a huge influx, but Jose Serra was very clever."[55] In two trips to India, Serra wooed Indian firms to enter the Brazilian market, thus "making the local companies face them," and creating a "dual advantage" of widening the space for national firms and raising the level of their competitiveness.[56]

Interestingly, many of the top Brazilian firms in generics are the largest consumers of Indian APIs. Data from Brazil's Ministry of Development, Industry and Foreign Trade shows that in 2006 the top two importing firms of Indian goods were Indian subsidiaries, but four of the largest Brazilian firms—EMS, Aché/Biosintetica Farmaceutica[57], Medley and Eurofarma were all top ten importers from India in the pharmaceutical category. In interviews with these firms, it was confirmed that they import on average from 50-100

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[53] http://www.mercantil.com/rc/default.asp?browse=companies&accion=2&area_code=10. As accessed August 14, 006.

[54] National firms quickly took dominance, maneuvering through the regulatory approvals system and gaining the vast majority of approvals in generics. In addition, national firms already had distribution channels established and local name brand value.

[55] Balaji C. Subramaniam, AB Farmo Quimica, Sao Paulo.

[56] Balaji C. Subramaniam, AB Farmo Quimica, Sao Paulo.

[57] In part of the consolidation occurring among top Brazilian generic producers, Ache acquired Bio in 2005. Combined they have 91 products.

Indian suppliers a year. According to ANVISA regulations, one generic product cannot have more than 3 different suppliers and it would appear that the majority of generic Brazilian products have at least one Indian input. The prevalence of Indian APIs in the Brazilian pharmaceutical industry shows how over the last decade, the rapid emergence of Asian trade partners has affected Brazilian industry. Though Indian firms may be seen as a source of competition, they have also become an important source of inputs for local pharmaceutical firms. As one of the purchasing managers from a top Brazilian generics firm notes:

> "If you cannot fight the enemy, you should join. So we cannot fight them (Indian firms) as far as API production in other aspects. So we might as well take advantage of what they have as expertise. What we should have here in Brazil is the help of the government, as keeping pharmaceutical industries as a priority."[58]

While the purchaser wants access to the expertise—cheap and reliable APIs—Indian suppliers provide, he also wants the Brazilian pharmaceutical industry to be a government "priority." Indeed, debate over the impact of Indian imports in Brazil highlights a clash of interests in the Brazilian pharmaceutical industry. On one hand, the large domestic generic firms, in particular, the top five which account for more than 60 percent of sales in this category, use the accessibility of Indian APIs to their advantage, sourcing high-quality inputs and finishing the last stages of pharmaceutical production, and marketing their goods to the Brazilian markets.[59] This is to a great extent what is occurring on a global level, as major multinationals outsource API formulation to established suppliers in Asia. Brazilian generic companies control for the quality of their sourcing networks, and they reap the benefits of competitive inputs accessible through globally integration.

On the other hand, Brazilian pharmo-chemical producers note that the overwhelming import of APIs renders significant innovation in the Brazilian pharmaceutical industry obsolete. And they suggest that importing products makes Brazil dependent on a foreign source which should be strategically protected:

> "I believe the pharmo-chemical market of medicines is a market so important that the ideal would be for you to be completely strategically free. If you could be almost completely integrated with an internal market. It's easier for you to control it. Its strategically eaiser, you cut all the external dependencies. I think this affects alot of people, and all countries are going to be thinking about this."[60]

Many in the Brazilian indstry are concerned about the rise of India, as a source of competition both globally and in their home turf. An article published in the Brazilian

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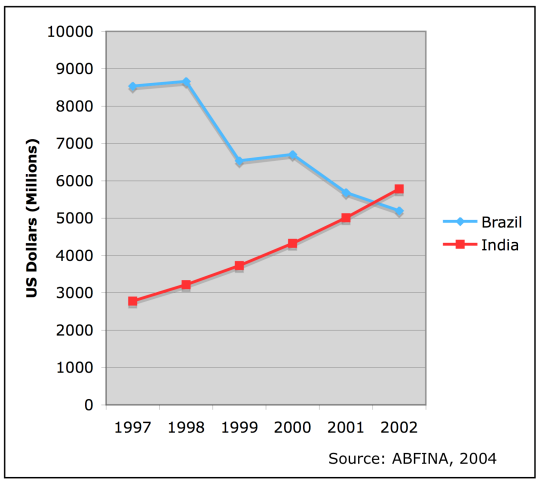
[58] Brazilian Generics Manager, CC74, *Interview,* Sao Paulo, July and October 2006.
[59] Eurofarma has started sales to Portugal, but the majority of the firm's sales remain domestic.
[60] Nicolao Lages, Director, Nortec Quimica, *Interview*, Rio de Janeiro, July 2006.

Association of Fine Chemicals, Biotechnology and Especialities' (ABIFINA) magazine highlights the awareness among Brazils regarding India's increasing capacity.

> "…We can say that the pharmo-chemical sectors of India and Brazil have followed opposite paths. While India grows, diversifying and on the conquest for larger segments of global commerce, we are in retreat, importing final pharmaceutical products, even from India."[61]

Figure 7: Pharmaceutical Production in India and Brazil (Formulation and Bulk)



The original politics of bringing down prices, and of introducing more competition into the pharmaceuticals sector has provoked a backlash from the Brazilian pharmaceutical industry. With very few firms that are integrated from active principles through to finished formulations, industry representatives question the sustainability of the current situation:

> "The big question that I see is, that this API is in their hands, or intermediate, is in their hands. If they want they can begin to increase the price. And so you see the unfeasibility. We are no purchasing these ingredients so cheap, that it just doesn't make sense for you to make it here. Nobody is making intermediates, nobody is making active principles, practically nobody making medicines. And so you go and purchase."[62]

In 2007, a new "strategic alliance" was introduced between Brazil's National Development Bank (BNDES) and the Ministry of Health to confront this issue. The driving idea of the alliance is to use the purchasing power of the Ministry to amplify the demand for medicine, while BNDES creates financial instruments to induce the execution of new projects in the pharmaceutical industry. With the aim of preparing the national industry for global competition, the policy would involve public laboratories,

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[61] NICOLOSKY, R. & FÉRÉZOU, J.-P. (2004) Índia-Brazil: caminhos cruzados. *Abifina Informando.*

[62] Forum member, BG53, *Interview,* Rio de Janeiro, July 2006.

national private laboratories, and has the potential for partnerships with multinational subsidiaries (pending agreements on transfer of technology). Over the last four years, the BNDES' policy has comprised three programs with lines of credit which included finance for the production and modernization for adaptation to ANVISA rules, financing for mergers and acquisitions activities (restricted to firms of national capital) and finance for innovation of products.[63]

Another strategy for supporting local industry has also developed in the shape of direct equity investments. For example, BNDES has entered as a socio in companies it has considered important to strengthen, such as Nortec Quimica. Also Genoa, a micro-firm which develops research in the area of genetics and Bioinovation, a micro-firm in technological development. In all three of these arrangements, the bank holds 20% value, providing a source of stable capital for the local innovation projects.

> "With the sale of generics, companies such as Ache, EMS, Eurofarma and Medley are building blocks to achieve the innovation of more sophisticated products. This was the trail blazed by the Indians."[64]

Profarma policies are a part of the larger debate in Brazil about the role of the government in industrial policy. According to Sérgio Conte from the economic consultancy group Tendências, the financial instruments offered by BNDES to national firms are discriminatory and inefficient. He highlights the installation of price controls from 1999 through the expansion of credit at reduced rate for national industry as a continuum of "discriminatory" preferences for local firms.[65] According to Laura Gomes, Manager of Foreign Trade for Febrafarma, concerns about efficiency may be superceded now by those for local industrial development and it has "stopped being a strange thing for the industry to work with government."[66]

Many local representatives in Brazilian industry see the rise of industrial politics in the pharmaceutical sector as justified, especially in the case of competition with firms from India. According to the Brazilian Chemical Industry group ABIQUIM, in 2006, net revenues in the sector experienced a "vegetative evolution of 2.3%" On a more positive note, they predict that the country's demand for chemical products will rebound, but that local industry will remain far from the central supplier:

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[63] Current funding in the pharmaceutical sector by BNDES has reached approximately 1 Billion Reais (or….) including operations which have been already contracted, approved, under analysis and in review from 2004 to 2007. The total number of projects which have been approved totals 48. Thus far R$ 523,7 million were allocated in the farmacos projects, 334 to mergers and acquisitions activities of national companies and 114,7 for 12 companies with innovation projects, including the Biolab, Libbs, Baumere Bioinovation, among others. The major focus of the bank is the project in innovation, which recently reduced the interest rate on loans in innovation categories from 6 percent to 4,5 percent annually.

[64] DURÃO, V. S. (2007) BNDES e Saúde elaboram plano para a indústria farmacêutica. *Valor Online.* Rio

[65] FEBRAFARMA (2005) Rumos de Política Industrial para o Setor Farmacêutico. *Revista Indústria Farmaêutica.*

[66] Laura Gomes, Manager of Foreign Trade for Febrafarma, Sao Paulo, July 2006.

> "The acceleration of the Brazilian economy's growth rates will increase, inevitably, the demand for chemical products and, should nothing be done, the Country will increase its dependence on foreign suppliers."

In sum, the 1990s proved a heady decade for the Brazilian pharmaceutical industry. The first years were characterized by the state's withdrawal from industrial policy and the difficulties faced by national industries to compete in this new framework. Mid-decade was marked by the Collor scandal and the efforts to regulate public purchases through tighter laws on public procurement. The later years witnessed the government's re-entry into the sector through the construction of the regulatory agency ANVISA—the new institutional node for realizing and monitoring regulation and construction of the generics market. With the framework for generics created, a slew of firms entered the Brazilian market, lowering prices and changing the competitive patterns.

Legislation changing laws in public procurement allowed for Indians to enter the market by supplying government programs. Legislation providing for a well regulated and competitive generic category enabled the entrance of India APIs as inputs in Brazilian generic firms, and as generic competitors marketed by the nascent wave of Indian subsidiaries. Indian firms provided advantages to private Brazilian producers and helped lower prices through generic competition. However, new competitive pressures have spurred a current of nationalism in the Brazilian industry, and new institutions to regulate trade and promote the competitiveness of Brazilian industry.

4 Global Dynamics of Institutions and Trade in Pharmaceuticals

The rush to the Brazilian market during the late 1990s witnessed by Indian firms is very much under way in the European market. In 2006 an unprecedented number of deals between Indian and European pharmaceutical companies occurred through merges, acquisitions and outsourcing contracts.[67] This is the outcome of India's highly competitive prices and its fundamental strength in industry sciences, with research and development activities buttressed by 150,000 MSc Chemistry graduates per year. With India currently producing more than 22% of the worlds generics drugs (Indian Pharmaceutical Alliance, IPA, 2007) it is expected to climb the chain from generic and contract manufacturing to innovative drug discovery.

The institutional dynamics of Indo-Brazilian trade show that Indian firms offering low cost pharmaceutical products are keen to enter markets as both suppliers of inputs or APIs,

[67] A slew of European acquisitions by Indian pharma firms characterized 2006. Ranbaxy Laboratories and Dr Reddy's led the acquisitions, but others on the top ten list joined the shopping spree. In the first five months of 2006, Ranbaxy took over three companies; Belgium's Ethimed, Romania's Terapia and GSK's Italian unit. Dr Reddy's bought out Germany's Betapharm. Aurobindo Pharma acquired UK generics firm Milpharma in February. Mid-sized firms have also joined in with Shasun Chemicals, Matrix Laboratories, Unichem and Dishman Pharmaceuticals all striking significant deals. Dishman Pharmaceuticals made its second acquisition in Switzerland, buying the assets and business of Swiss-based Solutia Inc for US$ 74.5 million.

as well as to compete in finished formulation segments. India's entrance into Brazil's market has possibly reduced its bargaining power, a la Vernon (1971), but it's heavy integration in the supply chain of Brazilian generic producers seems to assure that it will remain a significant source of bulk pharmaceutical chemicals. Changes underway in the public sector however, indicate that Indian firms may not count on public procurement as a stable gateway for sales in the Brazilian market.

In Europe, changes regarding the regulation of APIs have been underway. The European Union's 2005 codification of Directive 2004/27/EC regarding goods manufacturing practice (GMP) process requirements for APIs confers the task of enforcement to national regulators. Important questions remain regarding the current state and future predicaments of trans-European regulation of the pharmaceutical industry, from the European Directorate for the Quality of Medicine's (EDQM) issued certificates to national auditing capabilities of these certificates.

At the moment much of the actual auditing of fine chemicals in Europe is undertaken at the behest of the European firm. A lack of enforced regulation maintaining quality in this segment has likely affected strategy of both local European firms, and Asian suppliers. It is likely that European-based manufacturers, like Brazilian-based generic manufacturers, will continue to verticalize their supply chains to ensure the most stable and qualified supply lines from Asian producers.

Stories from state laboratories like Farmanguinhos and FURP seem to indicate that the Brazilian public sector has had a rough time in sourcing from qualified Asian producers. But the irony is that while Brazil's public laboratories are moving away from souring from foreign API producers, national generic companies are sourcing ever more from Asia API producers. This is because the private generic companies have created stringent quality requirements. Rather than do the same, the Brazilian public sector has moved toward national restrictions for purchasing. This may have a positive effect for bolstering an industry which was hit hard by the last decade's competitive pressures. But it will likely not guarantee the lowest price for public health programs in which the price is imperative. The institutional changes opening doors for Indian suppliers in the 1990s may be closing by the mid-2000s with more national pressures to source and bolster the Brazilian industry.

These are interesting and pressing questions confronting Brazilian policy makers as they confront proposals to change national legislation toward tighter regulation of imported goods, and preferences for national pharmaceutical firms.[68] Experience from Indo-Brazilian trade in pharmaceuticals over the last decade suggests that the institutional

[68] Recently Brazil's Minister of Health, José Gomes Temporão, presented to the Casa Civil of the President a proposal to implant a program of "industrial policy for the pharmaceutical sector" with the aim of reducing the Industry's deficit, and using public procurement measures to foster growth in the domestic chemical industry. It remains to be seen how these proposals will be enacted by the Brazilian congress, and their impact on national production and trade. In his presentation, Temporão highlighted the case of India as one in which national industrial policy had fortified the pharmaceuticals sector.

framework in which foreign companies compete affects the shape of their investments in the country and the quality of the goods they trade.

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