

The politics of multinational participation in the Brazilian pharmaceutical market

by Sita Shah

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Abbreviations

Note: Italics denote Portuguese

Alanac	Associação dos Laboratórios Farmacêuticos Nacionais
Anvisa	<i>Agência Nacional de Vigilância Sanitária</i>
API	active pharmaceutical ingredient
ARV	antiretroviral
CAGR	compound annual growth rate
CEME	<i>Central de Medicamentos</i>
CMED	<i>Câmara de Regulação do Mercado de Medicamentos</i>
Fiocruz	Oswaldo Cruz Foundation
FDA	Food and Drug Administration
GSK	GlaxoSmithKline
INPI	National Industry Property Institute
IPR	intellectual property right
ISI	import substitution industrialisation
LPI	Industrial Properties Law
MoH	ministry of health
MPC	multinational pharmaceutical company
NDP	national drugs' policy
OTC	over the counter
R&D	research and development
RDC	Collegiate Board Resolution
PI	parallel imports
PPP	public-private partnerships
PSF	Family Healthcare programme
RENAME	<i>Relação Nacional de Medicamentos Essenciais</i>

SPS	supplementary private system
<i>SUS</i>	<i>Sistema Único de Saúde</i>
TRIPS	Trade Related Aspects of Intellectual Property Rights
TB	tuberculosis
WHO	World Health Organization
WTO	World Trade Organization

Abstract

This paper discusses the strategies available to multinational pharmaceutical companies (MPCs) to expand their activities in Brazil through the national drugs policy. MPCs have existed in Brazil for decades, but they are increasing their focus on emerging markets as growth in developed markets slows. Despite the potential for market expansion, this paper considers the political factors that could promote or constrain their strategy. Since the 1990s, Brazil's national framework on healthcare and more specifically pharmaceuticals has shifted considerably. On the domestic front, Brazil has created a public health system, introduced regulation on patents and established a thriving generics sector, while it has become more pro-active internationally, as highlighted by the AIDS epidemic. This paper argues that MPCs should respond to the political changes in Brazil and the global industry-specific pressures by adapting corporate strategies to the local context rather than a one-size-fits-all approach.

Introduction

MPCs are facing an unprecedented crisis as their business model appears unable to sustain billion-dollar sales from “blockbuster” drugs. Companies need to expand in fast-growing, emerging markets to offset declining return of investment in developed markets, as they face patent expiries of blockbusters, increased generic competition and a dearth in innovation. For example, US-based Pfizer, the world’s biggest pharmaceutical company, will suffer substantial losses when its best-selling drug Lipitor (atorvastatin), which accounts for about a third of the company’s total revenues, loses patent protection around 2012. As the second biggest emerging pharmaceutical market after China and among the world’s top 10, Brazil offers huge potential for MPCs to expand.

IMS Health, a healthcare consultancy, predicts that the Brazilian pharmaceutical market will grow at a compound annual growth rate (CAGR) of 7-10% from 2008-2013. By contrast, the US is likely to experience negative 1-2% growth and the top five European countries just 2-3% growth (IMS, 2009). Many MPCs are well established in Brazil, but only recently did they explicitly announce their intention to develop their domestic base, motivated primarily by commercial reasons. However, MPCs must consider the wider social, economic and political realities of Brazil and look beyond the commercial potential because pharmaceuticals are more than mere commodities. The pharmaceutical industry plays an important social and economic role in society by improving public health and developing a “knowledge and skills-based” economy geared towards research, innovation and competitiveness (www.eaecp.org, 06-06).

From a socio-economic perspective, the scope for expansion is vast. Brazil's sheer size, in terms of geography and with a population of almost 200 million, means that there are many unmet medical needs. Despite being a rising middle-income power, Brazil suffers from huge inequalities in the distribution of wealth, resulting in persistent poverty and huge regional disparities. In 2004, the lowest 10% of the population in terms of income received only a 0.5% share of Brazil's wealth. By contrast, the highest 10% of wage earners received 46.7%, compared with 27.4% in India, 33.1% in China, 36% in the Russian Federation and 29.9% in the US (World Bank, 2004:60). This skewed distribution of wealth directly affects access to and the ability to pay for pharmaceuticals, including basic treatments. Around 80% of the population pays for medicines out of their own pocket (Madrid and Fefer, 1998), with the poor spending a disproportionate amount of their income on pharmaceuticals compared with the middle and upper classes.

The Brazilian government is becoming an influential player in the pharmaceutical sector as it seeks to improve equity and efficiency within the healthcare and pharmaceutical system. It has been making concerted efforts to develop the domestic pharmaceutical industry, by investing in public laboratories, in an attempt to manufacture cheaper medicines and to reduce its dependence on drug imports. As Gereffi (1983:167) says, the pharmaceutical industry already operates in a highly politicised environment. However, the emergence of an activist state is threatening MPCs' political dominance as the balance of power shifts within the sector. If the state appears to be moving away from MPCs to pursue a divergent pharmaceutical strategy, how can they participate within this new framework?

Much of the literature on MPC expansion concentrates on market opportunities, while political studies tend to focus on opportunities for the government to increase its role in the pharmaceutical sector, particularly through its AIDS policy. This paper seeks to bridge this gap by exploring MPC expansion within the context of Brazil's pharmaceutical framework, with reference to its AIDS policy but not as the main focus. The politics surrounding access to medicines and the merits or disadvantages of intellectual property legislation are beyond the scope of this paper. Its main purpose is to examine the politics surrounding MPCs in Brazil in relation to the global pressures they currently face.

This study argues that there is enormous scope for MPCs to participate in the Brazilian pharmaceutical market through this framework if they adapt their corporate strategy accordingly. Among the changes needed are: differentiation through innovation and brand promotion; increased focus on mergers and acquisitions and partnerships, and on providing treatment in under-served areas; appropriate pricing policies to facilitate consumer access; and a commitment to work with regulations, to adapt to the needs of the population, and to improve the industry's image in developing countries. Many companies in Brazil and other emerging markets such as China and India are becoming MPCs in their own right, with many Indian companies entering Brazil, for example. However, this study will focus on companies headquartered in Europe and the US that have been present in Brazil for several years as these are the ones that need to re-evaluate their strategy.

The study is divided into three sections. The first chapter examines the development of Brazil's national drugs' policy in the context of democratisation and healthcare reform. The transition to democracy in 1988 and the creation of a new constitution, in which access to healthcare was declared a universal right, spurred on transformational changes to Brazil's healthcare policy. This chapter analyses the politics of healthcare reform through universalism and decentralisation, and its effects on the development of pharmaceutical policy.

This sets the context of policies affecting the evolution of the pharmaceutical market in Brazil, which is the focus of the second chapter. While the 1980s and early 1990s focused on healthcare reform, the mid to late 1990s heralded a shift in pharmaceutical policy. Brazil introduced TRIPS, the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights, international legislation which obliges countries to enforce patents on pharmaceutical products. At the same time, the government authorised the creation of a generics industry to provide cheaper, off-patent versions of essential medicines and create more competition within the sector.

Against this backdrop, the third chapter examines the politics of MPCs and the avenues for their participation in the Brazilian market through policies of co-operation and differentiation. It will examine arguments made by domestic pharmaceutical companies against MPCs and the counter-arguments by MPCs.

This study draws on a wide range of primary and secondary data. The primary material, gained during a two-week field trip, comprises interviews with key stakeholders representing different segments of the Brazilian industry. These include MPCs, industry associations representing MPCs and domestic pharmaceutical companies, and experts from the Brazilian drugs regulator. The interviews are complemented with a variety of additional material including company presentations, reports and press releases. The study also draws upon press reports as an additional means of supporting or criticising a particular policy, rather than as a principal source of evidence.

Chapter 1

Brazil's national drugs' policy (NDP) was instrumental in extending the founding principles of the national public health system, free and universal access, to pharmaceuticals. The Brazilian health system, the SUS (*Sistema Único de Saúde*), was conceived in 1988 based on the philosophy of an integrated healthcare system provided by the state. This was a deliberate attempt to fundamentally reform a frail and inefficient infrastructure, underpinned by Brazil's return to democracy. The right to free pharmaceuticals was implicit, but it was the NDP, issued 10 years later, that assured the free provision of essential drugs through the SUS.

Despite the establishment of the NDP, access to drugs remains a continual challenge, particularly in poor states where many people lack even basic treatments. While household expenditure on items such as food and clothing fell between 1987/88 and 1995/96, spending on health rose from 5.3% to 6.5%. Of this, medications and medical supplies were the single biggest expense for poor families. Although spending on drugs fell during the period, it still accounted for 59% of total health expenditure for a family with up to two minimum wages, compared with 19.4% for a family with incomes of more than 30 minimum wages (Medici, 2003:4, 8). Notwithstanding, the NDP has transformed the nature of drugs provision and public health in Brazil from clinical care and prevention to "medicamentation" (Biehl, 2004:113). This was only made possible by fundamental shifts in the concept of healthcare and broader political changes.

This chapter will examine the NDP as an integral part of healthcare reform because the pharmaceutical framework developed within this context. It will consider the NDP not only as an instrument for advancing health policy in Brazil, but also for achieving the goals of democratisation and societal reform.

Before we can analyse the NDP we first have to understand healthcare reform in its own right. Healthcare reform in Brazil occurred amid economic turmoil, provoked by the region-wide debt crisis, and democratisation. The country's transition to democracy was a gradual and uneven process, but was characterised by the emergence of an extensive civil society mobilised around citizenship. The concept went well beyond the political meaning of citizenship to include social and economic rights (Friedman and Hochstetler, 2002:31). The high level of state-society institutionalisation and consolidation of democracy was to set the scene for a different type of healthcare system in the region.

Most Latin American countries embarked on healthcare reforms based on neoliberal economic policies to reduce the cost of healthcare services and increase efficiency to overcome the economic crisis. By contrast, Brazil sought to achieve free universal coverage through a supply-side public system (Medici, 2002:1). This policy aimed to make a financially and organisationally weak system more effective and efficient, and help consolidate democracy; sometimes two conflicting goals. The proposal was unique in the region because it was an answer to a political crisis in the authoritarian regime rather than to the economic

crisis and structural adjustment policies; the motivation was political and ideological (Fleury, 2000:8).

Brazil's 1988 constitution established health as a basic citizen right and required that the state provide universal and equal access to health services through a unified healthcare system. It institutionalised the reforms, laying the foundation for a more equitable and efficient health system, with an emphasis on services for the local community, known as primary care. Healthcare provision under the former military regime had been uneven and reserved for a minority, reflecting the broader antidemocratic nature of society. It was insurance-based, highly centralised, based predominantly on specialised, hospital-based care (secondary care) and provided as part of social security. This meant that only workers in the formal employment sector benefited from medical care. Consequently, the social security system grew politically and financially at the expense of public health and primary care (Lobato and Burlandy, 2000:9).

The reforms brought the health sector under the co-ordination of the Brazilian ministry of health (MoH) and integrated it with social security, a measure that transformed financing of the system. Funding came through taxes, social contributions by companies, and contributions from employees and employers. The constitution created a single administration for the public system, with a supplementary private system (SPS) where services could be contracted to the private sector, the "public contract model". Londoño and Frenk (2000:32) say it creates more options for the population and greater

opportunities for autonomy and competition for providers, who are paid according to productivity and quality of service provided. However, the lack of an “explicit articulation function” can lead to financing deficits and fragmented delivery of services, making the control of costs and quality extremely problematic.

The unified system provided integrated care based on the epidemiological profile of the population, and guaranteed universal access to all levels of care. Civil society had an important role in governance, and funding and healthcare provision was decentralised to states and municipalities, enabling greater social and political participation. Decentralisation was part of a broader political, fiscal and administrative process that had been occurring in Brazil under military rule but which gained momentum during the democratisation process. The constitution accelerated the process of municipalisation by transferring more funding and responsibilities to local governments. Municipalities gained legal status as federal entities, giving them autonomy in the organisation of healthcare services, with technical and financial assistance from the states and federal government (Samuels, 2004:90).

The municipalities have strengthened the provision of primary care services through programmes such as Basic Assistance Floor and Family Healthcare Programme (PSF). The PSF was a policy rather than a programme set up in 1994 to change healthcare delivery by creating interdisciplinary teams in healthcare units to increase basic health coverage. These units operate in specific geographic areas and engage in the promotion, prevention, treatment, and rehabilitation of the more common diseases and health problems. The PSF

started in the poorest areas but has expanded rapidly across Brazil and to areas of varied income (Cohn, 2008:77). Gómez (2008:62) argues that the government may have decentralised funding, but failed to develop procedures on how and when states should provide transfers. This has created tension between states and municipalities, imbalances in administrative and technical capacity and uncertainty about funding. Moreover, in practice healthcare provision is still centrally funded with federal government accounting for the majority of public health expenditure.

Total health expenditure rose from 7.9% to 8.5% of GDP from 1990-2002; however, the public share was stagnant during this period, while the private share expanded consistently (Mesa-Logo, 2007:193). In reality, the private sector still remains an important source of healthcare provision. Although higher earners can afford private health insurance, poor families also rely on the private segment because health authorities are still failing to target lower-income populations. In 1998, 48% of people classed as higher education graduate did not use the SUS; however, 12% of those with incomplete elementary schooling also did not use the service (Arretche, 2004:181). As Dr Caio Netto (2009) says, Brazil has very good doctors but it is a big country, making it difficult to give free assistance to everyone.

Drugs are one area where free and universal access can help reduce poverty substantially, but they are often overlooked in reform policies. This began to change in the 1990s following the World Bank's influential Development Report 1993: Investing in Health (1993:12). The report stated that in the short term, reforms in pharmaceutical usage offered the greatest efficiency gains for developing countries' health systems. It recommended that

countries draw up national essential drugs lists containing inexpensive, generic medicines to reduce procurement costs of drugs for the public sector. Therefore, as a crucial component of healthcare, it seemed only logical that pharmaceutical services would be restructured in line with the healthcare reforms. However, pharmaceutical reform in Brazil occurred only after political and social forces pushed the issue to the forefront of the political agenda, most notably during the AIDS epidemic.

In the late 1980s and early 1990s, NGOs and civil society mobilised around a public policy for the poor to demand that the state provide access to prevention and treatment services for AIDS. NGOs framed the discourse as discrimination and a violation of human and citizenship rights (Nunn, 2009:133). In 1990, the MoH committed itself to providing AIDS treatment and began producing generic antiretrovirals (ARVs) in 1993. Three years later, Congress passed Law 9.313, making Brazil the first country to guarantee free and universal treatment to all HIV/AIDS sufferers in the country. Brazil's AIDS policy marked a turning point as it began to develop a comprehensive pharmaceutical policy based on the principles of universality and equality.

The politicisation of AIDS showed the need for a pharmaceutical framework that could respond adequately to the epidemiological profile of the population. Brazil faces a complex disease situation, characterised by chronic conditions found in developed countries and a persistence of diseases associated with poverty and social inequality. In 2005, high blood pressure (20% of all deaths), high cholesterol (11%), tobacco (7.6%) and obesity (6.5%) were

the main causes of death in Brazil (Abegunde *et al*, 2007:1933). At the same time, it is estimated that most of the neglected tropical disease burden in Latin America now occurs in Brazil. This includes virtually all of the cases of blinding trachoma and leprosy, and the majority of ascariasis, dengue, hookworm infection, schistosomiasis, and visceral leishmaniasis (Hotez, 2008).

In 1998, Brazil established the NDP, the first drug policy consistent with the World Health Organization (WHO)'s guidelines on essential drugs. The NDP included proposals on guaranteeing safety, effectiveness and quality of drugs, promoting rational use and universal access to essential medicines, re-orientating pharmaceutical services and promoting scientific and technological development. In alignment with WHO guidelines, Brazil established the National List of Essential Medicines (*Relação Nacional de Medicamentos Essenciais* - RENAME). The latest version, updated in 2008 (MoH, 2008), includes 552 formulations of 342 drugs, and focuses on drugs for the central nervous system, cardiovascular disease and blood conditions.

Responsibility for administering basic medicines programmes has been decentralised to the states and municipalities. The federal government finances R\$1 on a per capita basis and the states and municipalities finance at least R\$1 together. Federal government spending on basic medicines rose considerably from R\$45 million in 1998 to R\$160 million in 1999 (Cohen, 2000:16). However, a study on 61 essential drugs in primary care centres in 11 cities found that none of the drugs was fully available, with a fifth of drugs out of stock in all the

centres visited in Brasília, Macapá and Porto Velho (Karnikowski *et al*, 2004:291). This indicates insufficient funding and a lack of co-ordination in administering the programmes, mirroring the larger problems associated with decentralising healthcare policies. According to Cohen (2000:17), most local governments lack the human and institutional capacity to manage the procurement and distribution of pharmaceuticals effectively.

However, responsibility for financing and distribution of drugs for diseases such as AIDS, diabetes, tuberculosis and leprosy remains with the federal government; there is also a RENAME for exceptional/high-cost medicines. In recent years, more and more patients have taken health authorities to court to secure their rights to medicines. Patients can claim for medicines not on the list of essential medicines and for new drugs that have yet to be approved for reimbursement. The judicialisation of healthcare in Brazil stems from the right to healthcare as advocated in the constitution and essentially holds the government accountable for providing these services.

A study of 170 cases brought against the municipal government of São Paulo found that 62% of drugs appeared on the SUS lists, suggesting that municipalities are failing to observe the NDP. At the same time it reduces resources for drug purchasing because the state is obliged to pay for the medicines being demanded (Vieria and Zucchi, 2007:2-6). On the other hand, some cases can have a beneficial effect if it makes a medicine more widely available. For example, in 2000 there was a rise in the number of cases demanding exceptional medicines such as mesalazine, for ulcerative colitis, peg-interferon for hepatitis C and infliximab, for

autoimmune diseases. Consequently, in 2002, the state of Rio de Janeiro added these medicines to its list of essential medicines for exceptionals (Messeder *et al*, 2005:532).

The explicit right to healthcare does not mean that the patient will automatically be awarded a medicine. However, the judicialisation of healthcare raises questions about the role of courts in determining healthcare policy. Successful litigation, in the narrow sense of winning in court, may not necessarily improve a patient's health or that of the wider population. By contrast, a loss in court may benefit society in the long term by providing an effective focal point for social mobilisation and advocacy (Gloppen, 2008:25). Healthcare litigation in Brazil is an example of legal mobilisation where individuals or groups are pushing for new rights, rights that are not yet recognised to become legal. The 1988 constitution raised expectations that its provisions would be upheld, especially because the constitution itself was a result of widespread consultation (Sieder *et al*, 2005:4).

The NDP is far from perfect, with further room for improvement in funding, efficiencies and defining policy. However, as a concept, the NDP was truly historic. For the first time, treatment became more aligned to health needs and the medical needs of a population became an integral part of wider social and human rights. The NDP might have started out on as a political tool but it soon became a healthcare policy in its own right. Public expenditure on pharmaceuticals has grown according to the government's commitment to healthcare, rising from R\$1.93 billion in 2002, 5.8% of total health spending, to R\$4.14

billion in 2006, representing 11.2% of the health budget (Opas, 2008). Pharmaceuticals are no longer just a point of care, but a strategic part of the health sector.

Chapter 2

Brazil's pharmaceutical market has undergone dramatic changes in the past 10 years as the government strives to fulfil its commitment to the NDP. The NDP was influential in increasing the government's involvement in the sector, not only as service provider but also as a producer of low-cost medicines, following the creation of a generics segment. However, the international pharmaceutical industry also played an important role in shaping the Brazilian market, strengthened by the introduction of patent legislation on pharmaceuticals. The relationship between patented medicines and generics was to have a profound influence on the balance of power as well as specific policies within Brazil's pharmaceutical market.

This chapter will analyse the importance of domestic policies and international factors in the development of Brazil's pharmaceutical market. This conjunction is key to understanding not only the nature of the market, but also the role of the actors that determined the development path. Unlike other areas of the healthcare sector, pharmaceuticals are part of a market; therefore demand is conditioned by purchasing power rather than health needs and achieving social objectives such as equity. Moreover, pharmaceuticals are not simply about a set of services, but also involve goods which are traded internationally. Therefore, global trade issues on pharmaceuticals will affect domestic policies (Madrid and Fefer, 1998:2).

As Brazil integrates itself into a new globalised political and economic world order, where health and production are becoming increasingly transnationalised (Montero and Samuels, 2004:15), it can no longer ignore demands from international actors. This is even more the case in an industry that operates on a global level and is dominated by multinational corporations. As a result, Brazil had to raise its game to comply with international trade standards involving pharmaceuticals. At the same time, globalisation has widened the access gap to medicines between developed and developing countries, prompting Brazil to take action to reduce this disparity (Huttin, 2002:4).

Paradoxically then, TRIPS also created an opportunity for the government to become a strategic player in a market that can improve public health but also contribute to the country's economic and social development. Civil society groups, which had successfully lobbied the government on AIDS, added another dimension as they turned their attention to TRIPS and organised against what they perceived as an infringement on citizenship rights. In this context, Brazil's pharmaceutical market became a focal point for new actors looking to exert their influence while established players, MPCs, sought to maintain their power. To understand this dynamic, we first have to assess the historical nature of MPCs in Brazil and the environment in which they operated.

MPCs started buying out local firms in Brazil in the 1950s and came to dominate the market by the 1970s, despite the government abolishing patent protection for pharmaceuticals in 1969. The transnationalisation of Brazil's pharmaceutical market occurred amid import

substitution industrialisation (ISI). This was a trade and economic policy that Latin America adopted from the 1930s onwards to reduce foreign dependency through the local production of industrialised products. The focus of ISI shifted away from raw materials to industrial sectors, such as pharmaceuticals, which require advanced technology and organisational skills. Dependency theory, which arose in the 1950s, sought to explain the rise of ISI by arguing that poor countries at the “periphery” were impoverished because resources flowed to a core of wealthy states.

Cardoso and Faletto (1979:2) argued that the region had to base industrialisation on domestic markets and diversification if it were to develop and complete the development cycle. In 1971, the government implemented Law No. 5772 on Industrial Policy, which allowed local firms to develop technical skills to make copies of patented drugs via “reverse engineering”. The long-term goal was to enable local firms to export their products, develop their own research and development (R&D) capabilities and to become self-sufficient in the production of active pharmaceutical ingredients (APIs) and drugs, as well as making drugs cheaper (Cohen, 2006:16). This policy created a category known as similars, which are pharmaceutically equivalent but not therapeutically equivalent to the original product, and therefore not the same as generics. Generics have to show bioequivalence, the same strength as the original drug, and bioavailability, the extent to and rate at which the drug enters systemic circulation, thereby accessing the site of action (Merck, 2007).

Brazil was intent on developing a national pharmaceuticals industry, but multinationals were essential for deepening ISI in terms of providing the necessary investments, technology and skilled managerial organisations. The main aim of these companies was no longer the export of primary commodities but instead industrial production to serve the country's growing internal needs (Gereffi, 1983:33, 36). Dependency theory has since been criticised for failing to account for the social and political aspects of development and ISI eventually failed. Although a discussion on dependency theory and ISI is not the focus of this chapter, the main point is that a national industry already existed together with MPCs before the 1990s. However, the introduction of TRIPS and the creation of a generics segment were to change the balance of this relationship.

Recent studies have shown that the pharmaceutical industry places the highest importance on patents compared with other research-intensive industries, given the time and money required to discover new medicines (Grabowski, 2002:850-851). Therefore, the introduction of TRIPS was a landmark event for the pharmaceutical industry, creating the most comprehensive legal regime at the multilateral level regarding intellectual property rights (IPRs; Lanoszka, 2003:183). TRIPS became more pertinent in Brazil because as a member of the WTO, it had to abide by the rules of the international system.

In 1997, Brazil implemented the Industrial Properties Law (LPI), well ahead of the 2005 transition date, and shifted the balance of power towards patent holders. The number of patents filed by MPCs rose from about 500 in 1997 to more than 1,100 in 2003. By contrast,

the number filed by national companies increased from about 50 or so to around 100 during the same period (Jannuzzi *et al*, 2008:10). From the very outset, TRIPS was highly controversial. Professor Frederick Abbott, an expert on international IPRs and global economic issues, said at an international seminar on patents held in Rio de Janeiro this year that Brazil had made “a negative adjustment, with enormous damage to the national pharmaceutical sector”. Several MPCs are trying to extend the life of a drug as patent expiry draws nearer by increasing the number of patents for one product, the so-called multiple patents. Professor Abbott said this practice had forced developing countries such as Brazil to change its laws while impeding therapeutic advances [Alanac (*Associação dos Laboratórios Farmacêuticos Nacionais*), 2009].

IP protection on pharmaceuticals in Brazil was more extensive than in many other developing countries, classified as TRIPS-plus, because it exceeded multilateral obligations. This meant that more drugs would be patented but it would be more difficult to launch alternative drugs on the market or induce competition through generics (Shadlen, 2007:9). For example, it disallowed parallel imports (PI), where patented medicines that are in circulation in one market are then imported into a second market without the authorisation of the local owner of the IPR. Pharmaceutical companies claim that PI substantially reduces their profits and in turn their ability to innovative. However, public authorities in many developing countries argue that PI enables them to buy drugs from the cheapest sources possible (Maskus, 2001:1). Even more contentious was the granting of pipeline patents, a provision which has caused one of the greatest tensions between MPCs and the national industry.

Patent protection in Brazil is not retrospective and does not apply to existing innovative drugs already on the market before 1995, enabling local companies to make generic versions of these drugs. However, the pipeline clause validates patents that have never been filed in Brazil but have been filed and granted abroad. Pipeline patent applications are only subject to a formal analysis. They do not have to be submitted to the Brazilian patent office, the National Industry Property Institute (INPI), for technical analysis of patentability requirements – novelty, inventiveness and industrial application. In 2001, the LPI was modified by Law No. 10,196, which said that that all pending pipeline applications should be granted except for process patents filed between 1 January 1995 and 14 May 1997.

Civil society groups and national companies contend that the pipeline provision grants patents to drugs that are already in the public domain and therefore severely restricts innovation and access to medicines (Chaves *et al*, 2008). Earlier this year, the attorney general filed a case on behalf of NGOs claiming the unconstitutionality of the pipeline mechanism. Interfarma, the Brazilian association of MPCs, has launched a counter challenge and the case is currently in the Supreme Court. This incident shows that despite the introduction of TRIPS, national actors can influence international policy if there is consensus among them and if the political will exists.

Yet even with TRIPS, the granting of patents is not automatic, and does not always work in favour of MPCs. In June this year, the INPI rejected the patent for Gilead's ARV Viread

(tenofovir), saying that it failed to fulfil the novelty and inventiveness requirements of granting a patent. The decision sets an important precedent, sending a warning to other MPCs that they cannot simply hide behind international legislation; they also have to comply with national requirements. Moreover, the move was an important step forward for domestic pharmaceutical policies in reducing the price of the most expensive drugs within the government's ARV budget (Rebrip, 2009). AIDS changed the Brazilian government's drugs' policy and so too did it change the nature of IP legislation on pharmaceuticals. The issue not only focused the government's attention on access to medicines, but the government also became more prominent in initiatives to reform national IP legislation, most notably through compulsory licensing.

Compulsory licensing is a TRIPS flexibility that allows someone else to produce the patented product or process without the consent of the patent owner. In October 1999 Brazil issued a presidential decree that allowed compulsory licensing during national emergency situations, such as the AIDS epidemic. Since 2001, Brazil has repeatedly threatened to invoke compulsory licensing to reduce the price of patented ARVs. This led to substantial process reduction, in some cases more than half, of Merck & Co's Stocrin/Sustiva (efavirenz) and Crixivan (indinavir), Roche's Viracept (nelfinavir), Bristol-Myers Squibb's Reyataz (atazanavir), Abbott's Aluvia (lopinavir/ritonavir) and Gilead's Viread. Consequently, the government's yearly spend on ARVs fell from \$3,810 per patient in 1996 to \$1,374 per patient in 2004, even though the number of patients rose from 8,924 to 147,500 (de Mello e Souza, 2007:41-46).

Brazil finally issued a compulsory licence for Stocrin/Sustiva in May 2007, the first and only time to date that it has used the provision. However, issuing such a licence is not, as Bird (2008:2) says, “flipping a switch that opens the floodgates for affordable medicines”. It can improve access to medicines, but the process has to be managed carefully because it can lead to more harm. Compulsory licensing is costly as governments have to pay reasonable compensation to the patent holder. Negotiations can take a long time, the patent specification may not provide sufficient information to copy the drug, and ultimately, it may harm political relationships (Roffe *et al*, 2006:14). Although other countries have also issued compulsory licenses, Brazil came under international scrutiny because it was not simply about access to medicines, but a matter of national sovereignty. Nowhere was this clearer than in Brazil’s dispute with the US.

Brazil’s patent legislation states that a patent holder must work the patent in Brazil, as in produce innovation within Brazil, to enjoy full patent protection; otherwise it could be subject to a compulsory licence. In January 2001, the United States Trade Representative launched a formal WTO trade dispute against Brazil, saying that its LPI violated TRIPS.

According to Nunn (2008:128), this was an indirect attack on Brazil’s AIDS policy. However, many diplomats knew that Brazil could not win the dispute through legal discussions alone and sought to frame it in terms of human rights and an issue of life or death. The government attracted huge media attention and support from the global AIDS movement, forcing the US to eventually withdraw its complaint.

Back home, the government's power was growing in the domestic pharmaceutical market, cemented by the creation of a generics segment. The generics law, passed in 1999, was an essential component of fulfilling the requirements of the NDP by making inexpensive essential medicines available. At the same time, generics aimed to drive down the price of patented medicines and reduce government expenditure on medicines by creating competition in the market (Katrak, 2004:317-318). More importantly, the legislation created a segment that would legally have to show bioequivalence and bioavailability as innovator products. The focus on creating high-quality but cheaper drugs meant that the government could finally start reducing its dependence on drug imports, ideology that had existed since 1971 (Bermudez, 1994:369).

However, the generics law was not simply about cost reduction and greater access to affordable medicines, but also about regaining national control over the industry. The legislation has led to the emergence of a growing private and public sector specialising in generics, with the government being the largest purchaser of generic drugs for the public health system (Cohen, 2003-04:23). National drug production is also part of a wider industrial strategy, *Complexo Industrial da Saúde* (MoH, 2008), which considers pharmaceuticals a key sector for economic and social growth. The strategy aims to reduce Brazil's pharmaceutical trade deficit and stimulate research and innovation in the private and public national sector. Increasing the capacity of the public laboratories and public vaccine manufacturers are among the key measures, to which the government has allocated R\$551 million and R\$216 million respectively between 2008 and 2011.

Industrial instruments to stimulate R&D and promote the local industry can often cause tensions with health policies designed to improve the quality and availability of pharmaceuticals. Kaplan and Lang (2005:1, 21) argue that developing countries should only invest in local medicines production if it is more cost effective than importing pharmaceuticals on the open market. However, by the authors' own admission, the value of local production in Brazil was "strikingly" on a par or exceeded that of certain European countries, making Brazil competitive beyond its national borders. Brazil's domestic pharmaceuticals policies are not only putting Brazil on a more equal footing with developed markets, but show that the government can and is willing to play by international standards.

The safety, quality and efficacy of drugs are one area where Brazil has made tremendous efforts to comply with international regulations. In 1999, Brazil created the Brazilian National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária, Anvisa*) to regulate the quality of medicines, marking an important step forward in protecting public health. Anvisa was the government's response to a series of scandals on counterfeits, which turned drug quality into a national issue (Piovesan and Labra, 2007:7). The government saw Anvisa as a way of eliminating corruption and a replacement for CEME (*Central de Medicamentos*), a supplier and producer of medicines created by the military government. However, CEME was considered ineffective and corrupt in its procurement methods and was directed towards satisfying the needs of public and private manufacturers rather than those of state and city health departments (Cohen, 2000:15).

Anvisa was modelled on the US Food and Drug Administration (FDA) and the European Medicines Agency, but has since become an important body in its own right, with strict procedures on registration and pricing. Anvisa has an important role in approving patents as a patent is only issued after the agency offers prior consent, a measure that stems from pipeline protection. However, its policies on pricing have created enormous friction between the government and the industry, both national and multinational. Brazil re-introduced price controls around 2000-01 and in 2003, the Lula administration created CMED (*Câmara de Regulação do Mercado de Medicamentos*), housed in Anvisa, to define and adjust prices. Generics must be at least 35% cheaper than the innovator product. The price of similars must be the average price of those that already exist on the market and the price of new medicines must be no higher than lowest price in nine comparator countries. New combinations of active ingredients can be no higher than existing treatments (WTO, 2005:5-6).

Dan Gedankien (2009), the communications manager at Febrapharma, the Brazilian Federation of the Pharmaceutical industry, which represents both MPCs and national companies, said that price controls have negatively affected the introduction of new drugs. New medicines were introduced in Brazil on average about two years after Mexico, which has no price controls. Moreover, if the reason behind price controls is to offer medicines at lower prices, it was failing as prices of older medicines had stayed the same, he said. However, Bruno Abreu (2009), head of Anvisa's monitoring market office, maintained that price controls had not prevented MPCs from launching new products in Brazil.

On the surface, MPCs appear to be losing power at the hands of a growing national industry and an activist state, with considerable international leverage. The government's policies have certainly created competition for MPCs, but MPCs still have an important role to play in Brazil's pharmaceutical market. Generics may help to expand the sector, but they cannot meet all the medical needs of the population, given the wide range of diseases affecting Brazil. It needs innovative medicines more than ever before, particularly in an era where citizens are becoming more aware of their rights as patients and consumers. With or without TRIPS, Brazil needs products that are tailored to the specific needs of its population and in many cases, only MPCs can provide that service. Brazil may be a key market for MPCs but the challenge is whether MPCs can adapt their politics to suit Brazil.

Chapter 3

The rapid growth of generic medicines has had a strong impact on the opportunities available for MPC participation in Brazil's pharmaceutical market. The public and private generics sectors are expanding their activities to include research into new products, an activity that had traditionally been the domain of MPCs. However, generics alone cannot meet all the medical needs of the population and especially for diseases that require new types of drugs. Therefore, MPC participation in Brazil's pharmaceutical sector remains crucial for its development. However, given the recent changes, MPCs have to adapt their politics if they are to be valuable but also unique partners (Woll and Artigas, 2007:126).

This chapter will assess how MPCs can expand in Brazil by pursuing dual policies of differentiation and consensus. MPCs' ability to differentiate themselves from their competitors is core to their global strategy, and Brazil is no different. Contrary to stereotypes, competitors in developing countries are acquiring more know-how as they seek increasingly sophisticated technology (Lister, 2004:2). At the same time, co-operation on other issues will allow MPCs to expand their footprint in areas where they have a low presence. MPCs have to adapt their models designed for Western markets to the realities of the Brazilian market, but they should be clear and transparent about their strategy. This will not only help MPCs to focus their activities, but give a better indicator to investors who want to see a clearly articulated business strategy in emerging markets (Pharma Futures, 2009:3).

MPCs account for about 70% of Brazil's pharmaceutical sector, but it is highly fragmented (Homedes *et al*, 2005:6). In the past few years, domestic firms have been growing much more rapidly and are increasing their market share. In 2006, EMS, a domestic pharmaceutical company, overtook France's Sanofi-Aventis to become the top-ranking pharmaceutical company by revenue. In 2007, according to IMS, EMS's sales rose by 29.4% to R\$1.42 billion, while those of Sanofi-Aventis grew by just 7.3% to R\$1.27 billion. Sales of the five leading players, except for Ache Labs, grew by double-digit figures and they now account for just under a quarter of total retail pharmaceutical sales. By contrast, sales of the top five MPCs were limited to single-digit growth, with Bayer and Pfizer posting sales declines of 0.6% and 1.8% respectively (IMS, 2008).

Brazil's pharmaceutical market consists of three main types of medicines: innovative or reference patent-protected medicines, generics and similars, often referred to as "branded generics" as they are sold under a brand name. Pharmacists can substitute original brands for generics but not with similars. In the SUS, doctors must prescribe medicines by their international non-proprietary name and generic names must be printed on product packs, and packaging must display a yellow stripe and capital G.

Odnir Finotti (2009), president of ProGenericos, Brazil's generics industry association, says that generics account for about 20% of Brazil's total pharmaceutical market and should eventually increase their share to about a third. Affordability is a key reason behind the growth of generics, particularly as most people pay for drugs out-of-pocket. However, there

is a wide disparity in pricing even among some generics. Data from the CRF-DF (de Oliveira, 2009), the regional council of pharmacists that audits dispensing in Brasilia, showed that between November and December 2008, the price of the antibacterial ciprofloxacin ranged from R\$33.96 to R\$92.40. Similarly, the price of amoxicillin varied from R\$8.70 to R\$23.37. This means that consumers could pay almost three times more for the same product depending on a doctor's prescribing or the pharmacist's dispensing preferences.

Moreover, generics are not always the cheapest medicines; similars usually tend to be the lowest in price. However, there is still great confusion between generics and similars. In a survey of 3,182 people, the first population-based study investigating the knowledge and utilisation of generic drugs in Brazil, the majority of interviewees were knowledgeable about the pricing and quality of generics. However, almost half of respondents incorrectly classified a similar as a generic (Bertoldi, 2005:1810).

Many consider similars inferior drugs. Although they have the same APIs as original medicines, they currently do not have to meet the same standards as generics. However, similars will have to show bioequivalence by 2013. Carlos Alexandre Geyer (2009), president of Alanac, which represents national companies, has defended the use of generics. He says that without them, the government would be unable to have such an extensive programme of free and widely available pharmaceuticals. Of around 11,000 medicines registered with Anvisa, almost 8,000 are similars. In some cases, doctors are more familiar with a similar than the product for which it is a reference, Mr Geyer says. Therefore, if price is the main

determinant in choosing a medicine and the government wants to expand access to drugs, similars will remain an important part of the market for the foreseeable future.

The continued importance of similars and the rise in generics is empowering national companies to branch out into new areas, particularly research. Marcelo Liebhardt (2009), head of economic affairs at Interfarma, said that national generics companies had “muscled up” and were ready to enter other areas, particularly incremental innovation. For example, EMS (2009) has the largest number of sales reps in Brazil, with a team of 1,500 people who make around five million visits to doctors, the company says. The entrance of generic companies in research and innovation is blurring the boundaries that used to distinguish MPCs from domestic companies (da Silva and Oliveira, 2007:74).

Innovation is the main area where MPCs can usually differentiate themselves from domestic players. In recent years, the global decline in genuinely innovative products from MPCs is narrowing the gap between them and generics manufacturers in Brazil, as they both look towards incremental innovation. Many national companies and governmental institutions argue that MPCs have unjustly benefited from the LPI’s acceptance of second-use and polymorph patents, which extend the protection of already known products. A bill to eliminate the use of second-use and polymorph patents, supported by the MoH and Anvisa, has passed a first round debate in Congress. However, Jorge Raimundo, president of Interfarma’s advisory board, said that second-use patents were “the most common patents in the world”, therefore banning them could lead to a significant loss of investment from

MPCs. Moreover, it would remove an important incentive for domestic firms to conduct their own R&D (Bruce, 7-7-2009).

However, although the public market is well served by generics manufacturers, there is a large market that cannot be fulfilled by off-patent drugs alone, as Brazil still urgently requires new drugs. In the short-term, MPCs need to differentiate themselves by continuing to and speeding up the introduction of new medicines already approved in Europe and the US. In May, GlaxoSmithKline (Hussain, 6-5-2009) launched in Brazil two new products already licensed in other major markets and plans to launch another nine or so within the next two to three years.

Targeting the right types of medicines to the right customers and doctors is another important strategy for MPCs. Rubens Pedrosa (2009), president of AstraZeneca (UK) in Brazil, said that sustained growth of Brazil's GDP had triggered greater social mobility, creating 15-20 million new customers who want more sophisticated and segmented products. AstraZeneca's portfolio in Brazil will be based on global brands such as the cholesterol lowering drug Crestor (rosuvastatin) and Seroquel (quetiapine fumarate), indicated for bipolar disorder and schizophrenia. However, selling mature brands that are no longer patent-protected in Brazil, such as the cardiovascular drug Atenol (atenolol; also sold as Tenormin, Tenormine and Prenormine) or the hospital-antibiotic Meronem (also sold as Merrem) are also part of the company's strategy. Mr Pedrosa said that these drugs still

made significant volume sales and were important for markets such as Brazil, where branding remains an important asset.

Meanwhile, other MPCs are seeking to deliver innovation by diversifying their portfolio in Brazil, a strategy that is also part of a wider trend within the global industry. For example, over-the-counter (OTC) medicines are a strong pillar of Swiss-based Nycomed's strategy globally and for Brazil, in addition to its innovative, prescription medicines line. Nycomed's Neosaldina (dipyrone and isometheptene), for headache relief, was the sixth leading brand in Brazil in 2007, based on the retail market at ex-manufacturer prices, with sales growing by 19.6% to R\$129.8 million. Sanofi-Aventis's OTC Dorflex (dipyrone and orphenadrine), a muscle relaxant launched more than 30 years ago, was the number one product in Brazil in 2007, with sales rising by 11.4% to R\$172.3 million (IMS, 2009).

Product differentiation is key for MPCs. According to Luiz Eduardo Violland (2009), head of Nycomed Brazil, competitors were very aggressive in offering high discounts to pharmacies and drugstores. Therefore, relationships with pharmacies and drugstores were critical in surviving this competitive market, he said. Nycomed plans to expand its workforce, including commercial support staff, as prescribing and dispensing require entirely different sales teams.

However, differentiation alone will not guarantee MPC expansion in Brazil. In many developing countries, the pharmaceutical industry is often perceived to be exploiting poor

communities through dishonest practices in pricing and the promotion of medicines, in a bid to maximise its profits. Lexchin (1996:1) says that the prices of medicines in some developing countries have risen by 400-500%. With greater attention focused on the industry by the media and civil society, MPCs will be keen to improve their image to show that they are ethical and responsible actors. In the aftermath of the AIDS epidemics, MPCs' pricing policies have come under renewed attack by civil groups. National organisations formed alliances with transnational groups, using the "boomerang effect" (Keck and Sikkink, 1999:12) to pressure the government to take action and challenge MPCs on their pricing policies.

The government's bargaining on pricing has helped to reduce its pharmaceutical budget, but it has also showed that it could gain the upper hand with MPCs. Manufacturers of high-cost/exceptional medicines are obliged to give a 25% discount on the entry price, a measure known as CAP. In June, Anvisa (www.anvisa.gov.br, 2009) announced that it would intensify the monitoring of CAP after it found that manufacturers and distributors in several states were failing to comply with the regulation. As seen from the previous chapter high prices can trigger Brazil issuing a compulsory licence.

In pricing negotiations for AIDS, Cohen and Lybecker (2005:219) show that a MPC may move first and offer a minimal or deep discount. The MPC would prefer to offer a minimal discount over a deep discount but it would also prefer a deep discount over a compulsory licence. Although MPCs have reduced the prices of AIDS medicines, prices for other

medicines in Brazil remain high. A comparison of retail prices of 132 essential drugs between Sweden and Brazil found that overall prices in Brazil were 1.9 times higher than in Sweden. Even widely used drugs with multiple manufacturers, such as paracetamol and mebendazol, had retail prices 50 times higher than the international bulk price. This suggests that these drugs reach consumers at prices far above the cost of production (Nóbrega *et al*, 2007:120-121).

Many MPCs are adopting tiered pricing to make prices in developing countries more equitable. Danzon and Towse (2003:184) argue that under well-designed differential pricing, prices in affluent markets exceed the marginal cost of production and distribution by enough to cover the joint costs of R&D. This balances out lower prices in developing countries and still preserves incentives for R&D. GSK (4-8-2009) is offering a tiered-pricing policy for its new H1N1 pandemic flu vaccine and has allocated 20% of its manufacturing site to developing countries from September onwards. A competitive bidding process could also create more appropriate pricing in Brazil. In 2003, MPCs and generics entered a region-wide competition in Latin America to reduce the cost of AIDS medicines. Having established a base bid price for the region, the successful bidders (generics manufacturers and one MPC) negotiated with each nation. The competition resulted in reduced prices for generic and originator drugs and introduced innovation in the development process (Haddad, 2004:10).

Pricing is just one area that will improve MPCs' image; medicines promotion and working within the confines of Brazil's national legislation are equally important. A report on new trends in drug promotion in the late 1990s found that the "worst excesses of misleading and unethical drug promotion" continued to occur in developing countries (Mintzes, 1998:1). This is particularly worrying if promotional activities of MPCs are the main source of information for the medical community. In the early 1990s, MPCs in Brazil spent 28% of their sales on promotion, the largest share of a sample of seven developing countries across the world (Lexchin, 1992:9,12).

Educating health professionals and the public about the safe use of medicines is crucial, but prescribers and users cannot review all the available information on pharmaceuticals. Therefore, comprehensive national legislation governing drug promotion to ensure its safety, quality and efficacy is needed (Homedes *et al*, 2005:697). However, sometimes, the problem lies with the legislation itself rather than the industry. Nascimento (2009:869,872) argues that legislation in place between 2000 and 2009, the Collegiate Board Resolution (RDC) 102/2000 published by Anvisa, was too weak, particularly in terms of punishment, to prevent irregularities in advertising. For example, in 2004, Anvisa issued 222 fines totalling R\$6.3 million. However, in 2006, the industry spent R\$978.9 million on marketing alone. In June 2009, Anvisa replaced 102/2000 with Resolution 96/08, which includes stricter rules on the promotion of OTCs and bans gifts to doctors, pharmacists and the public (Barreto Ferreira, Kujawski, Brancher e Gonçalves, 2009). Several MPCs and national firms believe it is too extensive and are trying to reverse some of the provisions (Violland, 2009).

The registration of medicines is another area where MPCs are not above the law and have to show a commitment to work with national authorities. One multinational pharmaceutical executive who wished to remain unnamed said that Anvisa favoured the registration of generics by domestic companies over innovative products by MPCs. In 2003, it took on average 12-14 months to register a new medicine, costing \$2,700-27,000 depending on the size of the manufacturer, and eight to 12 months for a similar and cost \$7,000. Generics have an accelerated registration process of six to eight months and cost \$2,000 (Homedes *et al*, 2005:5).

Mr Finotti said that the timeframe in Brazil was similar to other major countries, and Anvisa treated national companies no differently to MPCs. Jorge Samaha (2009), head of the evaluation of safety and efficacy of drugs at Anvisa, said that MPCs shared some of the responsibility for the delays. In some cases they just submitted a summary of the trial data even though Anvisa required the complete data. Many companies hoped that Anvisa would approve the drug simply because it had been approved by the US FDA, he added. However, in general, MPCs respected and followed the criteria in Brazil, Mr Samaha said. Anvisa plans to recruit more staff within the next few years to increase internal capacity for reviewing trial data and speeding up the registration process.

In other areas MPCs have taken the initiative in working with the legislation. In February, Anvisa introduced a new resolution on pharmacovigilance, RDC No.4, to strengthen the notification and analysis of adverse affects of drugs already on the market. Many MPCs

already have a pharmacovigilance department, but the new legislation outlines for the first time the procedures and responsibilities that companies must undertake in pharmacovigilance. This is an important step in advancing the production and registration of medicines because pharmacovigilance is an essential component of a quality assurance system (Cohen, 2000:20). In response to the legislation Bayer is one the first MPCs that plan to increase the capacity of its pharmacovigilance unit in Brazil. Horstfried Läßle, head of Bayer Brazil, said in an interview with *Gazeta Mercantil*, that 37 people were currently involved in the project, and by 2010, the programme should have more than 100 people (Franca, 18-02-2009).

The above initiatives show that not only are MPCs becoming more pro-active about working within Brazil's pharmaceutical framework, but also highlight another strand in their policy: co-operation. Angela Fan Chi Kung (2009), partner of the lifesciences team at the law firm Pinheiro Neto, said that in the beginning, when the generics law came into effect, things were difficult between domestic companies and multinationals. However, the two sides are now co-existing well. Both national and multinational companies agree that there should be more cooperation between the two segments, particularly in the form of research partnerships to improve market access.

Domestic producers, public and private, have shown that they can quickly become a key part of innovation in Brazil. In vaccines for example, the Butantan Institute, tied to the secretary of health of the State of São Paulo, produced 588.6 million doses of different

vaccines between 2003 and 2006 using technology developed in-house. It manufactures about 80% of domestic human vaccine antigens in Brazil and has recently built a production facility for influenza vaccine in an attempt to reduce the country's dependence on imports (*Rezaie et al*, 2008:2). Furthermore, several domestic companies are exporting their products abroad as they too become international players. EMS was the first domestic company to enter Europe, forming a joint venture with Germed in Portugal.

However, domestic companies and public laboratories still lack the skills, technology and research capacity of MPCs. For example, Far-Manguinhos, a public laboratory, has been instrumental in developing the government's AIDS programmes. It has not only produced cheap ARVs, but has also helped to contribute to local knowledge by using reverse engineering techniques to produce versions of ARVs not protected under TRIPS. However, this industrialisation process has reached "a major stumbling block" because the number of domestic firms that are able to receive and implement the technologies is limited (*Cassier and Correa*, 2003:104). Furthermore, there will always be a need for new AIDS drugs, ones that generic manufacturers are unable to produce, because patients develop immunity and treatment regimes need adjustment (*Shadlen*, 2007:565).

Technology transfers through research partnerships between domestic players and MPCs is one way of harnessing innovation. TRIPS explicitly states that patent holders should transfer and disseminate technology as a means of improving social and economic welfare. However, there is little information on the best strategies to achieve and speed up

technology transfers (Rovira, 2006:235). In May 2008 the MoH published a list of 57 pharmaceutical APIs that were considered of strategic interest to the public healthcare sector in Brazil, spanning from ARVs to biologics to address diseases like multiple sclerosis. The aim is to improve access by reducing overall costs and to decrease Brazilian dependence on drug imports. During the first quarter of 2009 the MoH announced that 10 public-private partnerships (PPPs) were already in place, involving Brazilian API manufacturers, local companies, MPCs and public institutions. According to Mr Pedrosa (2009), PPPs have the potential to give pharmaceutical companies, MPCs and national ones, more opportunities to participate in the public sector and broader market access. And for local companies, PPPs are a way of developing their model and technology, enabling them to move away from a pure generics strategy.

Mr Raimundo (2009) said that if MPCs failed to transfer technology, the public laboratories would simply get the medicines or technology from elsewhere. MPCs would rather have a good relationship with the government than conflict, he added. For example, GSK (17-8-2009) signed a research and development collaboration with Brazil's Oswaldo Cruz Foundation (Fiocruz) this August to develop a vaccine for dengue fever. GSK will also give Fiocruz access to Synflorix, GSK's 10-valent conjugate vaccine for paediatric pneumococcal disease. Elsewhere, Genzyme (11-12-2008) has had research collaboration with Fiocruz since 2007 to develop treatments for neglected diseases, focusing initially on Chagas disease. This is part of its Humanitarian Assistance for Neglected Diseases initiative, for which it won the 2008 Scrip Award for Corporate Social Responsibility.

Co-operation in technology transfer, particularly for neglected diseases, puts MPCs in a new light. An examination of more than 60 neglected-disease projects showed that commercial motives for re-entering the field were largely irrelevant. Instead, the decision stemmed from longer-term factors including corporate social responsibility, improving the industry's public image and a way of expanding in developing markets. Moran (2005:3-4) says this partnering model enables MPCs to participate in neglected-disease research while still protecting shareholder value and they can manufacture and distribute the product at no mark-up. This means that the public sector will benefit from MPCs' knowledge and patients will obtain medicines at not-for-profit prices.

Although MPCs will continue to focus on innovation, some companies are starting to see opportunities beyond their traditional sectors, most notably in generics. Earlier this year, Sanofi-Aventis, which is already in a strong position in Brazil, became the first MPC to enter the generics segment in Brazil through the acquisition of Medley, one of Brazil's leading generics companies. The move into generics is part of the MPC global strategy to diversify its business. The model is starting to trickle down to Brazil, as firms realise that they have to act in local markets if they want to maintain their position. Local media reported this September that Pfizer plans to buy the national company NeoQuimica for \$525 million (Parra-Bernal, 2-9-2009).

But at the same time, just because Brazil has a strong generics market does not mean that MPCs should necessarily enter the generics segment. For example, Bayer has said at the

global level that it will not enter the generics markets, even in emerging markets, because it believes that generics do not create value (Shah, 5-3-09). The opportunities for each MPC will be different and it is important that they carve out their own strategy.

Conversely, the government also needs to attract MPCs if it is serious about improving access to medicines, especially in under-served areas. The consumption of pharmaceuticals is mainly concentrated in the states of São Paulo and Rio de Janeiro. Cohen suggests that the government could create incentives for the private sector to assume a greater role in drug supply and distribution in under-served areas (Cohen, 2000:13). Novartis is going one step further and has decided to build a vaccines facility in partnership with the state of Pernambuco.

Andrin Oswald (2009), head of Novartis's vaccines and diagnostics division, said that Brazil was chosen over Italy and Singapore because it was a significant regional and global market in which Novartis wanted a local presence. National laboratories are already present in Pernambuco, but Novartis will be one the first MPCs there. Mr Oswald said the plant would create greater access to medicines as manufacturing would be cheaper in Brazil than in Europe and the government is financing some of the production. In addition, he said that building infrastructure was a better alternative to technology transfer as it would allow Novartis to focus directly on Brazil.

Initially, the opportunities for MPCs in Brazil seemed limited, confronted with an innovative generics sector and exacerbated by global industry challenges. However, MPCs are rising to the challenge on both fronts, by adapting their business model for Brazil but also reaching a level of maturity in its relations with domestic companies. The persistent need for new treatments means that MPCs will always have an important role in Brazil's pharmaceutical market. Yet in recent years, they are going beyond conventional ideology to explore opportunities in areas that would have seemed unimaginable previously, be it through differentiation or consensus. And in years to come, the boundaries between multinational and national companies will change again to create a new paradigm in Brazil's pharmaceutical market.

Conclusion

As MPCs seek to diversify their business model and expand in emerging markets to boost sales, Brazil will be more important to them than ever before. At the same time, Brazil's domestic pharmaceutical policies continue to rely on MPCs to increase market access by developing and supplying new treatments. In recent years, MPCs have become important political actors with significant influence on pharmaceutical policies, but so too have the state and domestic players. Therefore, the politics of MPCs in Brazil are being shaped not only by the pharmaceutical framework, but also by the broader political and socio-economic context.

With the advent of globalisation and a transnationalisation of the healthcare sector, some commentators have raised an important question about how far health sectors are being reshaped around the requirements of MPCs (Abel and Lloyd-Sherlock, 2000:7). From the 1970s onwards, this became a real concern in Brazil, after healthcare became increasingly privatised, and MPCs came to dominate the pharmaceutical market specifically. The military government made strong efforts to develop a domestic industry, and succeeded to a large extent by allowing national companies to make copies of innovator drugs. However, the creation of a national industry was more the result of an inward-looking nationalist industrial policy rather than a genuine regard for increasing access to medicines, given that most people were excluded from pharmaceutical services. MPCs faced relatively little challenge from the domestic industry, but the policies of MPCs were to alter following democratisation.

Democratisation heralded a profound shift in the ideology governing healthcare and pharmaceuticals as the government enacted reforms based on free and universal access to services. Several authors argue that democratisation does not intrinsically lead to better health. Lobato and Burlandy (2000:19) say that Brazilian healthcare reform was much more evident in the political sphere by democratising services rather than in terms of improving health indicators. This may be true, but many other factors, including violence and poverty, influence health indicators. Besides, health indicators will improve only after services that can adequately respond to the needs of the population are in place.

Democratisation was crucial not only in terms of modernising an ailing healthcare system, but also in establishing a framework for instituting these changes. Nowhere was this more evident than in pharmaceutical policy. Reforming pharmaceutical policy is one of the key challenges of the SUS because many people do not have access to pharmaceuticals in the first instance. In 2000, it was estimated that 70 million people, about 41% of the population, did not have access to drugs (Vieira and Zucchi, 2007:2). Through the NDP, the government laid the groundwork for guaranteeing universal access to essential medicines that were safe, effective and of high quality. Importantly, the NDP created a regulatory and legislative framework for the provision of pharmaceuticals, but also for strengthening the leadership of the government and influencing the actions of other actors (Backman *et al*, 2008:1685).

Cost containment of medicines is a central feature of the NDP, thus creating an impetus for strengthening the public sector and the local production of medicines. Although the

government has become the largest purchaser of low-cost medicines, in most instances it is also the only purchaser of new, high-cost medicines. This has put MPCs under some pressure to reduce their prices, such as the mandatory 25% discount on the price of new medicines entering the Brazilian market. Yet for the first time, MPCs had to act within a specific framework that sought to make medicines affordable and accessible in different geographical regions. Within this framework, the introduction of TRIPS and the legislation on generics brought the politics of MPCs to the fore.

As seen in chapter 2, TRIPS was a major achievement for MPCs as Brazil implemented TRIPS-plus legislation concerning patents on pharmaceuticals. However, according to Cohen (2006:15), Brazil stands out for its approach towards ensuring access to essential medicines, most notably for ARVs, while meeting international obligations. Brazil set about counterbalancing the favourable provisions to MPCs through its particular interpretation of the law. These included the clause saying that MPCs had to work a patent in Brazil and taking advantage of TRIPS-flexibilities, particularly compulsory licensing of patented ARVs. Although the government has not always succeeded in reducing prices of new ARVs, MPCs are reluctant to be at loggerheads with the government because of the politicisation of AIDS. Moreover, following the generics legislation, MPCs have to tread carefully because they know that Brazil has strong capacity for local production.

Brazil has shown that it is more than capable of producing drugs to international standards, as illustrated by the regulatory agency Anvisa. Although national and multinational

companies constantly criticise its policies on price controls and MPCs claim it is too slow in registering new medicines, Anvisa is another sign of Brazil's growing professionalisation in the domestic and international pharmaceutical sector. Anvisa may have been modelled on the US FDA but it has created its own rules on medicines registration and has become admired globally for its strict but fair standards (Flynn and de Oliveira, 2009:17). With the government's active involvement in the sector and the rise of national companies, it would initially appear that such policies have created deep tension between MPCs and domestic players.

At the start, this dissertation stated that it would assess the nature of the relationship between MPCs and domestic companies. Although there is friction between the two on certain issues, notably patent protection and the extension of patent rights, the generics sector has created a new dynamic in terms of supply and pricing. On the whole, MPCs and domestic companies co-exist well because they are two parts of one strategy that can provide broader opportunities for market access to medicines. Mr Raimundo (2009) said that Brazil's generics legislation was very good, with generics companies developing high-quality products based on good technology and raw materials. MPCs have acknowledged the value of generics, as many national companies move away from a traditional generics model towards innovation of their own. As a result, some MPCs are acquiring leading national generics companies as part of their expansion strategy in Brazil.

The acquisition of generics companies is part of the evolving relationship between MPCs and domestic players. Moreover, adding generics to their portfolio is another way in which MPCs can provide value as innovation slows down, with the “golden age” in drug discovery (19 Gereffi, 1983:248) a thing of the past. However, MPCs have an opportunity to launch innovative products already licensed in other major markets as more and more patients exercise their civil rights and demand access to these medicines. On the one hand, the judicialisation of healthcare can reinforce inequalities by giving priority to consumers who have the resources to take their complaints to the courts (Gloppen, 2008:24). On the other hand, however, it shows that the need for and access to innovative drugs remains a major problem in Brazil.

In 2006, the MoH launched the National Policy for Primary Care Provision to tackle some of the most prevalent diseases in Brazil. It included the elimination of Hansen’s disease and the control of tuberculosis (TB), arterial hypertension and diabetes. An analysis of new drugs approved from 2000-04 showed that although 49,366 new cases of Hansen’s disease were registered in 2004, no new drug was registered for its treatment. About 80,515 cases of TB were reported in the same year, but only two drugs were registered for treatment (Vidotti, *et al*, 2008;39). Novartis’s decision to build a vaccines facility in Pernambuco could prompt other companies to expand into other parts of the country, and perhaps new therapeutic areas to help extend market access in poorer states. Moreover, the government support is not limited to domestic companies; Brazil’s development bank BNDES is helping to finance eight developmental projects led by Brazilian subsidiaries on MPCs (Capanema *et al*, 2008:8).

MPCs concede that they are losing market share to domestic companies, but this has prompted them to seek new ways of doing what they do best: innovation. For now, the balance of power may be shifting towards domestic companies, but as this paper shows, power is far from static. A robust generics sector is dependent on a strong innovative sector. Therefore, if MPCs fail to deliver on their expansion strategy in Brazil, innovation from domestic companies will only be as good as their predecessors. Brazil is to hold elections next year, and although there may be a change in government, many believe that there will be little change in the pharmaceutical sector. As Mr Finotti (2009) says, "It's about evolution, not revolution." Similarly, MPCs are keen to evolve their expansion strategy in Brazil, but as partners rather than as an individual entity in a key market.

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