THE FEDERAL UNIVERSITY OF RIO DE JANEIRO

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PATHOLOGIES OF POWER: INTERNATIONAL TRADE, INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO ESSENTIAL MEDICINES

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Master's thesis presented to the Post-graduate program in International Political Economy at the Federal University of Rio de Janeiro, as part of the requirements necessary to obtain the title of Master in International Political Economy.

Advisor: Prof. Dr. Andrés E. Ferrari Haines

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SAMANTHA ROSE SAVARESE

PATOLOGIAS DO PODER: COMÉRCIO INTERNACIONAL, PROPRIEDADE INTELECTUAL E ACESSO A MEDICAMENTOS ESSENCIAIS

DISSERTAÇÃO APRESENTADA AO CORPO DOCENTE DO INSTITUTO DE ECONOMIA DA UNIVERSIDADE FEDERAL DO RIO DE JANEIRO COMO PARTE DOS REQUISITOS NECESSÁRIOS À OBTENÇÃO DO TÍTULO DE MESTRE EM ECONOMIA POLÍTICA INTERNACIONAL.

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ABSTRACT

Pathologies of Power: International Trade, Intellectual Property Rights and Access to Essential Medicines

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Advisor: Prof. Andrés E. Ferrari Haines

Summary of the master's thesis presented to the Post-graduate program in International Political Economy at the Federal University of Rio de Janeiro, as part of the requirements necessary to obtain the title of Master in International Political Economy.

One of the great public health debates today is the growing disparity in access to essential medicines between the world's rich and poor. This thesis will investigate these disparities in the context of international trade, intellectual property and asymmetrical power relations within the modern world system. Using French historian Fernand Braudel's discussion on capitalism and the "anti-market" as inspiration, we look at how the pharmaceutical industry has, with state support, been able to "capture" a global market to reap extraordinary profits. We focus in particular on the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and Big Pharma's role in defining the initial agenda. In doing so, we shed light on how TRIPS has created a homogenized neoliberal framework for patents; one constructed to privilege the interests of multinational pharmaceutical corporations, as well as the developed nations in which they operate. Finally, we consider how the HIV/AIDS epidemic has put the public spotlight on Big Pharma and illuminated key structures of the "anti-market." We highlight the experiences of Brazil and South Africa, as they reflect certain challenges, power dynamics, and opportunities in securing access to affordable medicines.

Key words: Fernand Braudel, Capitalism, Anti-market, Pharmaceutical Industry, Intellectual Property Rights.

RESUMO

Patologias do Poder: Comércio Internacional, Propriedade Intelectual e Acesso a Medicamentos Essenciais

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Resumo da dissertação de Mestrado apresentada ao Programa de Pós-Graduação em Economia Política Internacional, do Instituto de Economia / Núcleo de Estudos Internacionais, da Universidade Federal do Rio de Janeiro, como parte dos requisitos necessários à obtenção do título de mestre em Economia Política Internacional.

Um dos grandes debates na saúde pública hoje é a crescente disparidade entre o acesso de ricos e pobres aos medicamentos essenciais. Esta dissertação pretende investigar essas disparidades, no contexto do comércio internacional, propriedade intelectual e relações assimétricas de poder dentro do sistema mundial moderno. Usando a discussão do historiador francês Fernand Braudel sobre o capitalismo e o "anti-mercado" como inspiração, observamos a indústria farmacêutica e como ela conseguiu, com o apoio do Estado, "capturar" um mercado global e atingir lucros extraordinários. Nos concentramos em particular sobre o Acordo do TRIPS (Aspectos Relacionados ao Comércio e Direitos de Propriedade Intelectual da Organização Mundial do Comércio), e o papel da Big Pharma em definir a agenda inicial. Assim, mostramos como o TRIPS criou um padrão neoliberal e homogeneizado de patentes, construído para privilegiar os interesses das corporações farmacêuticas multinacionais, bem como as dos países desenvolvidos em que operam. Finalmente, consideramos a epidemia de HIV / AIDS e como esta delineou as estruturas principais desse "anti- mercado." Destacamos as experiências do Brasil e da África do Sul, que refletem certos desafios, dinâmicas de poder e oportunidades em assegurar o acesso a medicamentos a preços acessíveis.

Palavras-chave: Fernand Braudel, capitalismo, anti-mercado, indústria farmacêutica, Direitos de Propriedade Intelectual

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Dedicated to L. Lightbody, my postcard from Rio.

A WORKER'S SPEECH TO A DOCTOR:

By Bertolt Brecht

When we come to you

Our rags are torn off us

And you listen all over our naked body.

As to the cause of our illness

One glance at our rags would

Tell you more. It is the same cause that wears out

Our bodies and our clothes.

The pain in our shoulder comes

You say, from the damp; and this is also the reason

For the stain on the wall of our flat.

So tell us:

Where does the damp come from?

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INTRODUCTION

In 1948, the World Health Organization (WHO) defined health as a "complete state of physical, mental and social well-being,[1]" not merely the absence of disease. This definition represented an important shift in the public health paradigm – from a more technical view of disease to a holistic one – and placed health in the larger context of its significant social, economic and political influences. Indeed, as physician and medical anthropologist Paul Farmer (2003) claims, health is not determined simply by pathologies of disease, but also by "pathologies of power." These macro forces, shaped by our political economy, together contribute to an uneven global experience of health.

In this spirit, we examine one of the great public health issues today: the growing disparity in access to essential medicines between the world's rich and poor. WHO (2008) estimates that approximately one-third of the world's population – between 1.3 and 2.1 billion people – lack access to essential medicines [2] and adequate medical treatment. Nowhere is this problem more pervasive than in developing countries, as reflected in various indicators: shorter life spans; decreased quality of life; higher rates of disease, disability, and death; greater severity of disease, etc. Securing access to essential medicines has always presented a critical dilemma in public health, since access is generally lowest where disease burdens are highest. In the words of Ugandan doctor Peter Mugyenyi (2000), referring to the HIV/AIDS epidemic in Africa: "We have upside

[1] This definition is found in the Preamble to the Constitution of the World Health Organization (WHO) as adopted by the International Health Conference, New York, June 19- July 22, 1946; and entered into force on April 7, 1948. The definition has not been amended since 1948.

[2] Essential medicines, as defined by WHO are "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." WHO has published a model list of essential medicines, and encourages countries to make their own lists. *(*http://www.who.int/topics/essential_medicines/en/)

down access to AIDS drugs in this world. Where are the drugs? The drugs are where the disease is not, and the disease is where the drugs are not."

Of all the goods and services traded in the world economy, pharmaceutical drugs are among the most contentious. Though produced by private companies, they also constitute a public good, both because they can prevent epidemics and because healthy people generally function better than sick people as members of society. Pharmaceuticals also carry a moral weight that most privately traded goods do not, due to a prevalent belief that all people have a right to health care. However, access to drugs continues to be unequal, divided between those who can afford to pay and those who cannot. As such, it represents one of the great debates in public health today. On one side, the pharmaceutical industry, herein referred to as Big Pharma[3], defends the legitimacy of its business model and large profits, especially through the strengthening of intellectual property (IP) rights. On the other side, critics claim that the industry better at "price gouging" than innovation, and that its exceptional profits reflect monopoly prices rather than real value

While the barriers to treatment are manifold, the high price of medicines is recognized as a significant prohibitive factor, especially in the developing world. The HIV/AIDS crisis starting in the 1980's made this challenge especially clear. As life-saving drugs came to market, the disease was no longer a death sentence – at least for those who could afford the expensive medications, initially sold for between USD$10,000 and USD$12,000 per person per year (UNAIDS, 2004). However, for most of the developing world, high prices kept treatment out of reach, and HIV/AIDS rates grew exponentially. As health activists and governments fought for access to these life-saving treatments, it cast a public spotlight on the patent-holding pharmaceutical companies, sparking a series of debates linked to trade, intellectual property and generic competition. The public

[3] 'Big Pharma' is a collective name given to the top pharmaceutical companies, generally defined by their rank in global sales of prescription drugs.

questioned the pharmaceutical industry and its power to shape the market globally via supposedly “neutral" forums. Many blamed “free market capitalism” and the “commodification of health” for creating a world of “haves” and “have-nots” (Farmer, 2003). As such, the suffering and death of millions around the world were understood as a by-product of a “heartless” capitalist system, where health is no more than a commodity to be bought and sold.

In recent years, the term crony-capitalism has been increasingly cited to explain rising costs and inequalities in health care. The term is refers to an economy in which financial success depends on close relationships between business people and government officials. Crony-capitalism has also been described as “hollowing-out market economies” and replacing them with what may be described as “political markets” (Gregg, 2014). In such political markets, the focus is no longer on prospering through creating and offering products and services at competitive prices. Instead, economic success depends upon people’s ability to harness government power to “stack the economic deck in their favor” (ibid). While the market’s outward form is maintained, its inner mechanisms are rigged to ensure that governments, legislators and regulators realize profits despite any social costs. In that sense, crony capitalism is said to constitute a form of redistribution, where profits and funds flow away from the taxpayers, consumers and the “true” capitalists, and towards the powerful and politically connected.

With a wealth of historical data, French scholar Fernand Braudel (1902-1983) suggests a different interpretation. Contrary to common perception, Braudel argues that capitalists have always been monopolists, not entrepreneurs operating in a competitive free market. For Braudel, crony-capitalism is a tautology, since *all capitalism essentially involves cronyism*. Basing his ideas in a holistic view of history, Braudel reconstructs the understanding of economic development during the XII and XVIII centuries. He shows how capitalism has historically relied on non-competitive practices; its commodities have never been

neutrally set by supply-and-demand dynamics, but rather reflect the agendas of powerful economic decision makers above. Consequently, Braudel considers capitalism and the market to always have been different entities. He underlines this fact by calling capitalism the *anti*-market.[4]

The repercussions of Braudel's conceptualization of capitalism for the contemporary world cannot be underestimated. The distinction that he makes between the different economic layers, and the essential role of power in this separation, opens an important dialogue on accelerated accumulation of wealth and the limits of many dominant economic theories today. Using Braudel's discussion on capitalism as our theoretical inspiration, we look at how the pharmaceutical industry operates as a kind of anti-market in the modern world system. In particular, we examine how Big Pharma, backed by the United States government, has been able to use intellectual property rights as a powerful tool to capture a global market. Identifying the deeper dynamics which shape the industry and drive up costs is imperative for understanding the problem of access to essential medicines and for ultimately finding feasible solutions.

In the first chapter, we present the work and ideas of Fernand Braudel, looking at its alleged strengths and criticisms. In particular, we consider his masterpiece – *Civilization and Capitalism 15th to 18th Century* – and extract its most relevant points to structure the distinction between the market economy and capitalism. Building on the methodology of Marco Bulhões Cecilio (2012), we then identify four general historical reoccurrences that make up the Braudelian framework. They are, briefly: (1) The anti-market is the rule, not the exception; (2) The anti-market cannot exist without State support; (3) "The roots" of capitalism are in society as a whole (ibid); and (4) The capitalist enjoys the privilege of choice, i.e. the opportunity to take advantage of his position, both vis-à-vis society and the State, to not only construct anti-markets but also to continually reshape them.

[4]The original term in French is Contre-marché; Siân Reynolds translation to English opted for the term anti-market.

In the second chapter, with these Braudelian themes in mind, we look at the ways in which Big Pharma has created an anti-market, and the role of the State and society in maintaining this privileged space. We first give an overview of the global pharmaceutical market, its segmentation, and its concentration among a handful of large transnational firms, mostly located in the United States. It is important to note that our overview is *not* intended to be an exhaustive analysis of the sector, but rather to show that these firms are highly profitable, and thus point us in the direction of a Braudelian anti-market. Through this lens, we then evaluate the research and development argument of the industry and, in finding certain "loopholes," observe the ways in which Big Pharma has manipulated market forces and restricted competition. We focus in particular on its quest to strengthen intellectual property rights – both nationally and abroad via the World Trade Organization's (WTO, 1995) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement – and Big Pharma's role in defining the initial agenda. We shed light on how TRIPS created a homogenized neoliberal framework for patents; one constructed to privilege the interests of multinational pharmaceutical corporations as well as those of the developed nations in which they operate, namely the United States[5]. In doing so, the historical re-occurrences in Braudel are made contemporary, and we gain important perspective for the access to medicines debate today.

In the final chapter, we use the HIV/AIDS crisis of the 1980's and 1990's to look deeper into the pharmaceutical anti-market. The economic and social impact of the crisis generated important media coverage and a number of investigations, which helped to illuminate the inner workings of Big Pharma. Confrontation over access to life-saving antiretroviral (ARV) treatments, which were patented by Big Pharma, revealed important power dynamics and asymmetrical relationships at work in the pharmaceutical industry. Looking at the cases of Brazil and South

[5] This is not to deny the importance of EU or Japanese pharmaceutical companies regarding the actual TRIPs negotiations, and their own respective domestic political agency. Nevertheless, the TRIPs agreement was overwhelmingly an American initiative (Sell 2003) and we focus on the US aspect for lack of space.

Africa in particular, we see how Big Pharma, backed by the United States government, challenged national efforts to produce or purchase generic drugs, even in the face of severe health emergencies. The extent to which Big Pharma and the United States government worked to protect profits abroad reveals important continuities between the patterns observed by Braudel and contemporary times.

CHAPTER ONE:

PRESENTING BRAUDEL

Our starting point is Fernand Braudel, the French intellectual and former leader of the *Annales* School, regarded by many as one of the most important historians of the 20th century. With an emphasis on the larger social and economic factors in making and writing history, Braudel sought to reach a deeper and more comprehensive understanding of humanity. Looking at these forces over great arcs of time (the so-called, longue durée[6]), Braudel based his ideas about the modern world system on detailed historical research rather than on elaborate theoretical arguments. In doing so, he sought to avoid being "deceived by the mesmerizing waves and storms of the sea" and to focus instead on the "deeper waters and currents," i.e. the deeper structures which play a more critical role in shaping our political economy (Braudel, 1992, p.369).

In *Civilization and Capitalism, 15th–18th Centuries* (herein referred to as *Civilization),* Braudel traces the social and economic history of the world from the Middle Ages to the Industrial Revolution[7]. Spanning 1600 pages, *Civilization* is a masterpiece of historical scholarship. However, Braudel offers much more than a simple narrative of past times; he attempts to uncover the entities that give shape and direction to an emerging capitalist system. Examining the construction of privileged positions throughout history that have generated exceptional profit, Braudel arrives at two unique structures. First, Braudel describes the world economy as being organized around a central "pole," surrounded by secondary and competing powers, with a third peripheral zone that is exploited by the first

[6] The longue durée is a style of history characteristic of the French "Annales" school, including Braudel. The approach looked at very long term patterns and shifts in society, contending that human factors change slowly and are not easily recognized in any single moment.

[7] Although *Civilizations* geographically covers the whole world, the focus is on the "civilized" parts of it, and particularly on Western Europe. This euro-centricity has been a source of criticism of the series.

two zones. Secondly, and rather controversially, Braudel proposes a three-layer hierarchy of economic activities: with the bottom layer consisting of a subsistence economy, guided primarily by custom and under no influence of the market; the second layer being the market economy, where transparent activities are governed by regular exchange processes; and, finally, the top layer being the anti-market, the home of "true capitalism." Here, asymmetrical power relationships bend market forces, allowing a privileged few to earn profits far greater than what the market could normally bear.

Braudel received praise from many peers for the boldness and meticulous attention to detail of his work (Dustier, 2010; Cecilio, 2012). Perhaps most noteworthy was the breadth of Braudel's vision and his ambition in looking at such a broad geographical area. However, the series also received criticism, especially regarding the perceived weakness of its theoretical structure, and Braudel's imprecise use of terms and concepts, particularly in relation to his discussion of capitalism (Dursteler, 2010). Braudel's tendency to privilege description over theory led some colleagues to label him a great historian but a poor theorist. Charles Tilly (1981) commenting on *Civilization*, observed:

> *"He (Braudel) approaches a problem by enumerating its elements, savoring its ironies, contradictions, and complexities, confronting the various theories scholars have proposed, and giving each theory its historical due. The sum of all theories, alas, is no theory" (p. 369).*

While Tilly critiqued Braudel's (lack of) a theoretical framework, others have claimed that Braudel's merit lies precisely in his ability to not limit himself to any particular theory. By setting aside rigid economic models that simplify reality, Braudel instead tackles the "raw material of history" (Cecilio, 2012). His unique approach allows us to see firsthand how exchange really takes place in a capitalist system, helping us to uncover patterns over the long term and to identify subtleties that would otherwise remain hidden in history (Arrighi, 2001). While Braudel's work could lead us in many directions, and open countless dialogues, for the purposes of this paper we choose to focus on his polemic distinction between the market and capitalism - the anti-market.

1.1 Braudel's Provocation: Capitalism versus the Market

Braudel's distinction between the market and the capitalism, which he labels the anti-market, is based in his tripartite vision of the economy. He begins by describing the ground level, what he calls the layer of "material life." In this tier, he includes most subsistence activities, such as the farmer who raises chicken for his own consumption. In this case, the price of the chicken on the market has little impact on production, which is based more on custom than on market forces. The "impermeability" of this layer leads Braudel to describe it as "the stratum of the non-economy, the soil into which capitalism thrusts its roots but which it can never really penetrate" (Braudel, 1982, ps. 21-2, 229). Braudel also speaks of the opaqueness of this layer: while significant in terms of volume, it can be difficult to analyze for lack of historical records. Braudel thus spends considerable time observing and describing those elementary activities. He claims that they form a frontier, or a lower limit of economy. Everything at this bottom layer has "use value," while anything that reaches the marketplace acquires "exchange value." In other words, only when an individual or "agent" crosses the frontier into the market is he included in open exchange, or what Braudel calls "economic life."

This next layer of open exchange Braudel equates with the market economy. He distinguishes it from the bottom layer of "routine, unconscious daily round of material life" and refers to it as "self-conscious open activity" (Braudel, 1977, p. 50). According to Braudel, this intermediate layer is composed of transparent, regular exchanges, such as "wheat or wood being sent to a nearby city" (ibid). The operative mechanism here is predictable and constant, and profit always limited by competition. Thus trade on a broad scale could even be included in this layer, as long as it were "regular, predictable, routine, and open to both small and large merchants; for example, the shipping of Baltic grain from Danzig to Amsterdam during the seventeenth century, or the oil and wine trade between

southern and northern Europe" (ibid). Braudel notes that these easily observable processes became the basis on which economic science was originally founded; however, with the third layer he shows us that this is not the whole picture.

On top of the market economy, Braudel locates a third layer, which he controversially identifies as capitalism. For Braudel, this is the zone of exceptional profits via monopolies and via the State, in so far as it is the guarantor of these monopolies. Here, market forces do not obey the rule of supply and demand, but rather the will of those with power and influence:

> *At this exalted level, a few wealthy merchants in eighteenth-century Amsterdam or sixteenth-century Genoa could throw whole sectors of the European or even world economy into confusion, from a distance. Certain groups of privileged actors are engaged in circuits and calculations that ordinary people knew nothing of. Foreign exchange, for example, which was tied to distant trade movements and to the complicated arrangements for credit, was a sophisticated art open only to a few initiates at most. To me, this second shadowy zone, hovering above the sunlit world of the market economy and constituting its upper limit so to speak, represents the favored domain of capitalism…Without this one, capitalism is unthinkable: this is where it takes up residence and prospers (Braudel, 1981, p.24).*

Considering different civilizations throughout time, Braudel shows us how this upper layer – the home of capitalism – is distinct from the market economy. In fact, he underlines this distinction by choosing to call capitalism the *anti*-market. In doing so, Braudel challenges a number of common assumptions regarding the capitalist system. Most controversially, he contends that *capitalism is inherently anti-competitive*: those in power are able to manipulate market forces to realize exceptional profits. Exclusivity and privileged access to information are key to realize these types of operations. Braudel points out that, while the bottom layer of material life is "hard to see for lack of adequate historical documents," this upper layer is hard to see because of the actual invisibility and complexity of its activities. Describing these nontransparent and unequal exchanges, Braudel (1982) asserts: "When there was a relationship of force of this kind, what exactly did the terms supply and demand mean?" (p. 176). In other words, the whole point of capitalism – real capitalism, as observed historically over the "longue

durée" – has been the effort to suppress the freedom of the market in order to maximize profit. As such, capitalism *must* be considered the *anti*-market.

World-systems analyst Immanuel Wallerstein, one of Braudel's great promoters in the contemporary social sciences, summarizes the differences between the concepts of "economic life" (the market) and capitalism (the anti-market):

> *"Here, then, is our picture. Economic life is regular, capitalism unusual. Economic life is a sphere where one knows in advance; capitalism is speculative. Economic life is transparent, capitalism shadowy or opaque. Economic life involves small profits, capitalism exceptional profits. Economic life is liberation, capitalism the jungle. Economic life is the automatic pricing of true supply and demand, capitalism the prices imposed by power and cunning. Economic life involves controlled competition; capitalism involves eliminating both control and competition. Economic life is the domain of ordinary people; capitalism is guaranteed by, incarnated in, the hegemonic power" (Wallerstein, 1991, p. 358).*

The value behind these distinctions should emerge clearly in this paper: anti-markets are the opposite of what is usually considered by mainstream economics to be the regular flow of the market. If such anti-markets are not an anomaly to the system, but an ever-present recurrence in economic life as Braudel claims, there should be a strong continuity between the patterns observed by Braudel and the ones observed in recent decades. Before we can evaluate the importance of Braudel's ideas for understanding the present, we must first shape our analytical lens for a contemporary view; in other words, extract the most relevant elements of his work and of other key authors that structure this distinction between market economy and capitalism.

1.2 Shaping Our Lens for a Contemporary View

Do Braudel's ideas have an important role for understanding the spaces of high profitability in the contemporary world? Marco Bulhões Cecilio investigated this same question in his analysis of the American financial sector (2012), and found a strong continuity between what was observed by Braudel and recent times. To facilitate his discussion, Cecilio identified several main historical recurrences in

Braudel's work, i.e. patterns that seem to repeat throughout centuries XII to XVIII, and thus constitute distinctive characteristics of the wealth accumulation and polarization processes. These are, generally:

> *(1) The anti-market is the rule, not exception; (2) The anti-market cannot exist without state support; (3) The roots of capitalism are in society as a whole; and, (4) The capitalist enjoys the privilege of choice (Cecilio, 2012, p. 45).*

Applying these main themes, Cecilio looked at how the financial sector, backed by the United States government, created an extremely lucrative anti-market. For the purpose of this paper, we consider these same historical recurrences in organizing our own discussion of the pharmaceutical industry. We dedicate less time to the fourth theme, the privilege of choice, which we treat as a common thread between the others relating to State and society. Together, these patterns help us to better understand the deeper structures that have shaped the pharmaceutical market and the access to essential medicines debate today.

The first historical recurrence identified in Braudel's work is the perennial presence of anti-markets in the world economy. In other words, monopoly "is the rule, not the exception" when looking at the capitalist system. This idea is grounded in Braudel's distinction between the market and capitalism, the *anti*-market, as explained in his tripartite model of the economy. Braudel offers various examples of anti-markets throughout European history to support this hypothesis. From Venice in the 14th century, to Florence in the 15th, Amsterdam in the 18th, and London in the 19th, he shows that there have always been capitalists who generated exceptional profits by manipulating the market and/or restricting competition. These activities are central to the capitalist system as enablers of rapid wealth accumulation and the large-scale transfer of resources from secondary areas to central ones. As such, anti-markets can be considered a key determiner of the "winners" and the "losers" of each historical period.

Importantly, Braudel claims that anti-markets are temporary, meaning that the privileged position is always disrupted over time. Nevertheless, they offer a

critical advantage to those in economic power via quick earnings, which allow them to be "one step ahead of the game." In this way, dynamics of power are continuously reproduced, allowing for the accumulation of wealth in the hands of a privileged few. Looking at the world economy, we see how the dominant pole maintains its position in part through its leading economic agents that control the privileged spaces of the economy. Braudel's historical narrative therefore can be placed at the intersection of history of the rise and fall of each dominant pole and the history of main economic activities of each period (Cecilio, 2012).

In labeling capitalism the "anti-market", Braudel broke away from classic economic models, which mainly deal with perfect competitive markets. Indeed, Marxists and liberals alike consider market forces to be the driver of capitalism, whether they find this desirable or not. Traditional economic theories tend to focus on "regular" exchanges, considering any other operations that generate exceptional profits to be atypical. Likewise, their theoretical treatment of such phenomenon is limited to so-called imperfect markets, i.e. monopolies, oligopolies, and cartels, etc. These imperfect markets are analyzed using models such as game theory to determine optimal levels of price and production.

Anti-markets described by Braudel are much broader, diverse and complex than the simple manipulation of output to maximize prices. His approach goes beyond the short-term conclusions of economic models, allowing us to articulate more nuanced realities about the accumulation and polarization of wealth. By readjusting our analytical lens according to Braudel, we begin to see how anti-markets are a regular and essential part of the capitalist system. Taylor calls this "Braudel's provocation" (Tayler, 1999). Instead of monopoly being "a spreading rot in the fabric of competitive capitalism," as is commonly supposed, monopoly is itself capitalism (Shepherd 1970, p. 14).

Braudel is careful to show that capitalists alone do not create anti-markets. Other forces enter the market place to restrict competition and sustain superior profitability for some. There are always unseen forces at hand. Braudel draws a

connection here between capitalism and the State, leading to the second historical reoccurrence: Capitalism only triumphs when it becomes identified with the State, "when it is the State." Wallerstein (2001) reflects on this special relationship:

> *No one can ever succeed in dominating an economy, stifling it, constraining market forces, without political support. It requires force, the force of some political authority, to create noneconomic barriers to entry into the market, to impose outrageous prices, to ensure that people buy things they do not urgently need. The idea that one can be a capitalist (in Braudel's sense of that term) without the state, not to speak of in opposition to the state, is quite absurd. I say without the state, but of course this is not necessarily the capitalist's own state. Sometimes it is some quite other state (p. 204).*

Conventional views depict the State as regulator, ensuring the competitive and fair functioning of the "free" market. However, as Wallerstein and Braudel point out, the State has also frequently acted as a guarantor of monopolies throughout history, and hence an accomplice in their creation. One prominent example is the Dutch monopoly on Orient spice trade. The Dutch East India Company, which focused on trade, exploration and colonization throughout the 17th and 18th centuries, is considered to be one of the first and most successful international corporations. Backed by the Dutch State, the hegemonic economic power in Europe at the time, the Company established headquarters in many different countries, created a monopoly over the spice trade and enjoyed semi-governmental powers, in that it was able to begin wars, negotiate treaties and establish colonies. Similarly, the British East India Company also enjoyed state support, and conquered vast territories in India to squeeze economic surpluses. In both cases, state power was essential to build and sustain the anti-markets. With such examples, Braudel shows that capitalism involves a two-way relationship, one in which the State serves the capitalist, helping to create anti-markets, and the capitalist contributes financially to State, helping to provide the resources to keep it competitive.

While Braudel discussed the link between State and capital, some critics have claimed that he never fully developed the connection. Vries (1979) for instance

claims that Braudel's system lacks an economic engine, and thus leaves an "explanation vacuum" (Cecilio, 2012, p. 65). In other words, there is no intrinsic logic to Braudel's model to explain economic expansion. Fiori (2009) points out that Braudel's error was not to link capitalism and the State, but rather the "shyness" of this movement. Looking deeper into this connection should allow us to identify the real engine of the system. Fiori traces the birth of our interstate competitive system, observing how states competed for more power and secure financial support by establishing anti-markets.[8] In this context, we can appreciate how anti-markets are supported by a State, which is driven to this race for accumulation of capital by its own need for funding to keep expanding its power in the world system. Fiori (2009) points out that such a competitive system does not accept indifferent powers; in fact the mere preservation of existence demands expansion.[9] Thus, war or at least preparation for it becomes a chronic and systematic activity Machiavelli (2003). This expansive and competitive nature can be thought of as the "software" of the system, which remains it driving force until today.

With Fiori's interpretation in mind, it becomes clear that the "engine of the system" is not economic but rather based in power (Cecilio, 2012, p. 65). Since competitive territorial units are under a systemic pressure to expand, the State must have economic resources available for this expansion. Historically capitalist nations have secured these necessary resources through the creation and sustenance of anti-markets which not only consolidate funds in the hands of a few domestically, but also have the power to extract wealth from international trade and relations. This dynamic, which contributes to the maintenance of higher

[8] Fiori (2009) goes back to the 13th and 14th centuries, when the first connections were made between power and capital. He describes this moment as the "big bang" of the modern interstate system. Unlike what occurred in Asia, where power was less dispersed, the European units at that time went through a highly competitive and highly conflictive process of concentration of power.
[9] As the German sociologist Norbert Elias (1994) argued, ever since the onset of this system and its state of permanent competition, "Who does not rise, falls." This logic led to warfare becoming the main activity of the first European territorial powers, and later the basic activity of the nation states.

profit rates for the monopolies, can only be achieved by a strong expansionist policy pursued via the support and active intervention of the State.[10]

In order to refine our analytical lens further, it is necessary to discuss certain evolutions in these power dynamics. Whereas in the past state intervention to further wealth accumulation depended largely on military might, there is an increasing reliance on "soft power." Bureaucratic and legal frameworks exist today to regulate such relations, so that it is no longer "acceptable" to invade a territory and physically dominate rivals, as the Dutch or British did in the past. Such frameworks are usually presented as fair and impartial, since they offer all a theoretical right to be equal, competing under the same rules. However, due to existing asymmetries and hierarchies, those at the bottom rarely execute their rights. The strongest and most powerful shape the institutions to their advantage. This dynamic is clearly illustrated in the case of the Trade-Related Aspects of Intellectual Property Rights Agreement, as discussed in Chapters Two and Three.

Susan Strange (1988, 1996) helps to understand how power is increasingly exercised through structures rather than direct relations. She argues that looking only at the role of the State is too narrow – it is necessary to consider its broader environment with private enterprises, international finance actors, the credit system, technology, etc. As such, Strange distinguishes between two forms of exercising power in the world economy: relational power and structural power. Relational power refers to the scenario in which "A forces B to do something it would not do by itself." Structural power, while more subtle, is increasingly important as we approach contemporary times. In essence, it is the power to define the rules of the game, i.e. "to shape and determine the structures of the global political economy within which other states, their political institutions, their economic enterprises and (not least) their scientists and other professional

[10] Braudel points out that some states were able to do this more effectively than others. For this reason, the hegemonic power, as the guarantor of the whole system, tends to possess the largest monopoly.

people have to operate (Strange, 1988, p. 24-25).[11] Exercising this power usually involves some kind of ideology promoting something as natural or beneficial to all. Thus, we find that the dominant state has repeatedly promoted a liberal ideology. The United States, for instance, has promoted open-deregulated markets as this allows it to easily impose its advantages on other countries. The creation of necessary conditions for the emergence of anti-markets benefits American capital and allows the country to expand its power base.

Looking at different civilizations over time, Braudel identifies recurrent inequalities in power, influence and wealth between the social classes. This observation leads us to the third historical recurrence: "the roots of capitalism go beyond economics and politics; they are found in society as a whole" (Cecilio, 2012, p. 45). Braudel suggests that the connections among the elites of different hierarchies – be they government, academic, business, etc. – have played an essential role in the creation and maintenance of anti-markets. These elites, while sometimes competing among themselves, also form cooperative ties that ensure the perpetuation of their privileged positions, offering to a select few access to inside information, profitable deals, easy credit, among other advantages:

> *"Our capitalist, we should not forget, stood at a certain level in social life and usually had before him the decisions, advice and wisdom of his peers. He judged things through this screen" (Braudel, 1982, p. 401).*

In other words, the most advantaged agents in a society form a powerful network of connections among themselves, which increases their chance of enjoying privileged economic spaces now and in the future. What distinguished Braudel from other economists was the fact that he always "injects society, the social structures, in the economy" (Daix, 1999, p. 630).

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[11]As Susan Strange notes in *The Retreat of the State: The Diffusion of Power in the World Economy* (Cambridge, UK: Cambridge University Press, 1996), p. 19, the concept bears some similarity to Joseph Nye's concept of "soft power" in his *Bound to Lead: The Changing Nature of American Power* (New York: Basic Books, 1990).

With historical examples, Braudel shows that the fate of capitalism depends on its interaction with social hierarchies. Nearly everywhere the bourgeoisie and merchants became the backbone of the State and vice-a-versa. In capitalism's first great phase – of the Italian city-states of Venice, Genoa, and Florence – power was concentrated among the moneyed elite. In seventeenth century Holland, the aristocracy of the Regents governed in close proximity with businessmen, merchants, and moneylenders. Likewise in England, the Glorious Revolution of 1688 marked the rise of a business environment similar to that in Holland. In each moment, Braudel shows how these leading social groups benefited from a privileged position to create the anti-markets of their time. They were also best positioned to adapt to change and be the winners in a new situation, leading us to the fourth recurrence: there has always been a small top layer of the population that enjoys the privilege of influencing key decisions about to whom and where the money flows.

The implications of Braudel's observations are significant. One can no longer explain exceptional profits as the result of "natural" market forces, regulating capitalists and states to mere hostages – instead of drivers - of these processes. As we will see, in the case of pharmaceutical industry, the United States has taken decisive action to establish conditions that allowed anti-markets to arise – actions that not only have led to accelerated accumulation of American capital, but also played an essential role in furthering US structural power via international forums.

As a result, pharmaceuticals today operate in a global space, where leading firms are backed by a dominant state, the United States, acting in accordance with its own strategic agenda. In the case of pharmaceuticals, strengthening intellectual patent laws and limiting generic competition is advantageous to the US because it implies securing high capital returns and maintaining its structural power over the rest of the world – in other words, ensuring that economic and political interests converge to preserve its privileged position. The lower classes in the US

join other countries in the peripheries as the "losers in this arrangement" (Cecilio, 2012). In the case of the pharmaceutical market, the stakes are even higher, since being a "loser" can be a matter of life or death.

By adopting a Braudelian-inspired perspective, we aim to examine the deeper structures that have shaped the political economy of health and the access to medicines debate. Braudel's attentiveness to the movements of the economy and power relations help us to understand how capitalists have guaranteed high profits historically. Applying that information to the contemporary pharmaceutical industry, we examine the ways in which Big Pharma – backed by the United States – has created a type of anti-market, and shed light on the dynamics of wealth accumulation and polarization in the world today.

CHAPTER TWO:

THE PHARMACEUTICALS ANTI-MARKET

2.1 Big Pharma, Big Profits: An Industry Overview

Pharmaceuticals, unlike most other commodities, carry a unique social weight due to a widespread belief that health is a human right. Still, access to essential medicines remains highly unequal, divided between those who can pay and those who cannot. As such, it represents one of the great debates in public health today. In this context, Big Pharma's very high profits have been a source of controversy (Angell, 2003). Here, we provide a brief overview of the industry, with the aim of opening a discussion on a contemporary anti-market.

For the past several decades, the pharmaceutical industry has consistently ranked among the most lucrative in the world. According to a report by IMS Health (2012), total global sales of pharmaceuticals reached US$ 875 billion in 2011 – corresponding to approximately 1.4% of world GDP and to 4.4% of world industrial production – and this figure is expected to increase to an estimated US$ 1.1 trillion by 2015 (ibid). Despite fast growing rates in "pharm-erging" countries such as China, India and Brazil, sales remain highly concentrated in developed regions. The three largest markets, North America (38%), Europe (29%) and Japan (12%) accounted for approximately 79% of global pharmaceutical sales revenue in 2010. Thus, developing regions accounted for only 21% of sales that year, despite accounting for over 85% of the world's population. The United States is the largest pharmaceutical market in the world in terms of sale value, with a market size today of approximately $400 billion (IMS Health, 2012).

Figure 1:

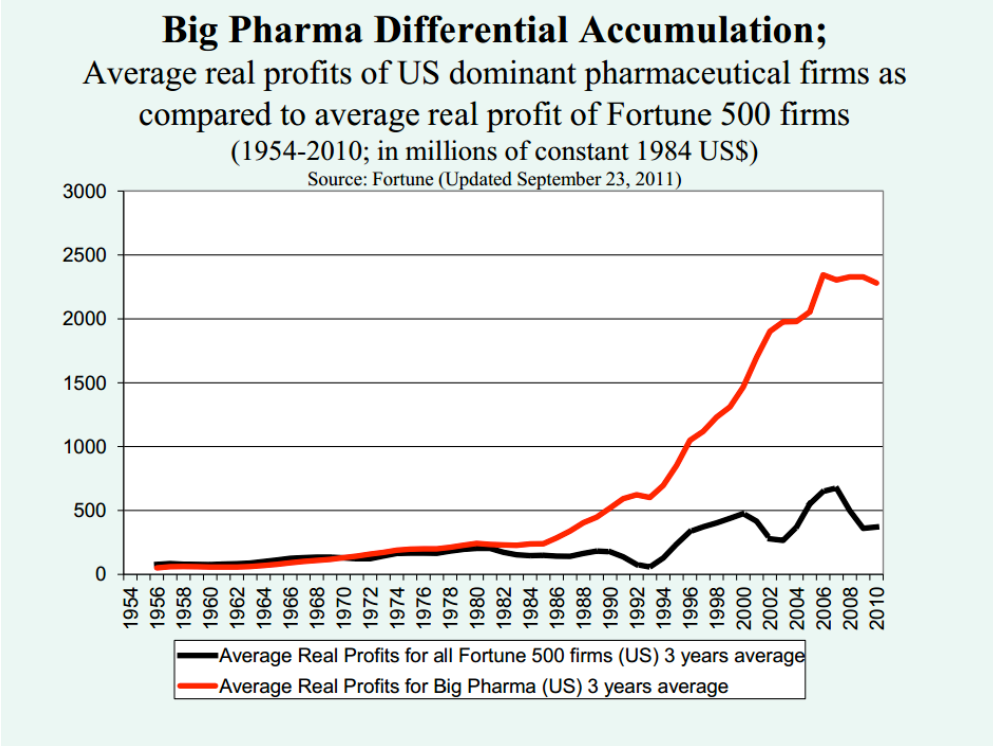
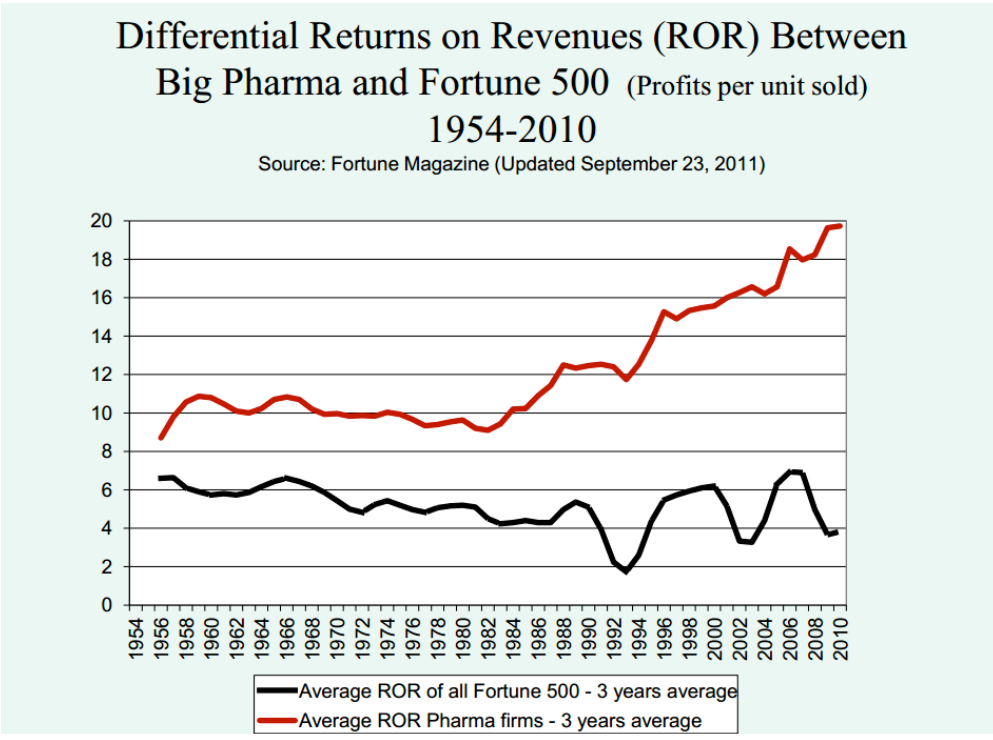


Figure 2:



The global pharmaceutical industry is highly concentrated, with ten to fifteen transnational companies dominating the market.[12] These companies, often collectively referred to as Big Pharma, include some of the most profitable in the world. Not surprisingly, a majority of these companies are based in the United States,[13] the epicenter for pharmaceutical sales. The differential accumulation between Big Pharma and other industries is impressive. Since 1982, the industry has topped the Fortune 500 List for return on revenue, and has been at or near the top for return on equity since, prompting Public Citizen (2001) to refer to the industry's success on the list a "rite of spring." Even with the economic downturn in 2002, the ten drug companies in the Fortune 500 ranked far above all other American industries in average net return, whether as a percentage of sales (18.5 percent), of assets (16.3 percent), or of shareholders' equity (33.2 percent) (Fortune, 2002).[14] These are exceptional margins. For comparison, the median net return for all other industries in the Fortune 500 that year was only 3.3 percent of sales that year.

The industry has undergone a process of further consolidation in the last two decades, with a record number of mergers and acquisitions (Du Boff, 2001). Besides economies of scale in manufacturing, clinical trials and marketing, M&As allow companies to pool resources and diversify their future drugs portfolio, making them more stable in the long term. For instance, through its acquisition of Pharmacia in 2003, valued at $56 billion, Pfizer increased its total assets by 152% and its sales by 38.5%, solidifying its position as the largest drug company in the world. As the number of such "mega-mergers" (with purchase prices of over USD $1 billion) has increased in recent years, so has the acquisition of smaller biotechnology start-ups that are research-focused. Large firms can

[12] Dominant pharmaceutical firms appeared mostly in the 19th century; since the 1920s, only one new firm (Amgen) joined the select group of pharmaceutical companies in the late 20th century.
[13] The rise of the US pharmaceutical industry occurred especially with the production of penicillin during the Second World War. For more about the development of antibiotics, and the establishment of cartels that served to propel the American companies to dominance *see* Dutfield (2003); Liebenau (1984); Swann (1988).

"siphon" off drugs that are already in the last stages of development, effectively reducing their own costs and risks.[15] These restructuring practices illustrate the Braudelian idea that the capitalist enjoys a "privileged position" – in this case access to excess capital – which enables further rapid growth.

A critical aspect of Big Pharma's profitability is intellectual property rights (IPR) and patents. To appreciate the significance of IPR to the industry, it is necessary to provide a brief overview of market segmentation and the Big Pharma "blockbuster" business model. The global pharmaceutical market is divided between prescription drugs and non-prescription drugs, also known as over-the-counter (OTC) drugs. Classification of OTC products differs among countries; and as a result, the value of global OTC sales depends on what is considered as OTC drugs. For example, the Economist (2006) valued the global market for OTC drugs at $117 billion in 2008, whereas IMS (2006), using a narrower definition, valued it at $60 billion. OTC drugs thus represented roughly between 11% and 19% of global sales that year. Prescription and OTC drugs can be further classified as either brand name or generic. Generic refers to any drug that replicates a brand-name product for which intellectual property (IP) protection has expired. As we will see, IP protection is usually provided by a pharmaceutical patent which grants market exclusivity for 20 years.

Without intellectual property protection, competing manufacturers can produce the same drug and offer it at a lower price, since there is no need to duplicate R&D costs. Generic drugs end up costing on average 30 to 80 percent less than their original equivalents (GPA, 2009). In several major markets, such as Canada, Germany and the U.K., generics account for at least 40% of prescriptions today, and they now account for 50% of prescriptions in the United States (ibid).[16] Despite their significance in volume, the worldwide generics market is less

[15] Preclinical expenditures have been estimated to be 67 to 73 percent of the total development costs (DiMassi 1991). In other words, when the government is responsible for the pre-clinical discovery, 2/3 to 3/4 of the costs of the drug are already paid for.
[16] IMS Health predicts that usage of generic pharmaceuticals will increase further as cost pressure on healthcare continues to rise.

important in terms of value: in 2003, it represented US$ 43.4 billion in sales, as compared with US$ 466.3 billion in total sales for pharmaceuticals (ibid), meaning that generics accounted for only 9.3% of the global pharmaceutical market that year. The crux of pharmaceutical wealth accumulation is clearly in brand-name prescription drugs, which are patented by Big Pharma.

The association of profits and revenues to a few specific drugs has become central to the Big Pharma business model. At the turn of the century, the most profitable drug company owned the most blockbusters (a total of four). According to Public Citizen (2002), Pfizer led US pharmaceutical companies with $7.8 billion in profits in 2001, earning 24 cents on each dollar of sales (ibid). Pfizer also owned the highest-selling drug at the time, a cholesterol reducer called Lipitor, which had sales of $4.5 billion last year. The company produced three other blockbuster drugs including Zoloft ($2.1 billion in sales), Norvasc ($1.7 billion) and Neurontin ($1.4 billion in sales). Thus, Pfizer derived almost one-third of its revenue from these four drugs. In this context, where one well-protected and well-marketed drug could become a "blockbuster" (with revenue of over $1 billion), firms have become increasingly motivated to operate as an anti-market.

Generics exert an increasingly competitive force in an otherwise limited market, and thus pose a significant threat to Big Pharma's mega profits. For manufacturers of blockbuster drugs, the market entry of competing generics could mean a loss of hundreds of millions of dollars a year. With such high profits at stake, Big Pharma has gone to great lengths to strengthen patent rights both on the domestic and international levels.

The high profitability and concentration of the pharmaceutical industry point to the presence of an anti-market. However, to simply identify it as such would be to only partially complete the exercise. Through a Braudelian lens, we look at the ways in which Big Pharma has influenced market forces to guarantee high profits, and the role of the State and society in maintaining this privileged space. In doing

so, the historical re-occurrences in Braudel are made contemporary, and we can gain an important understanding of the access to medicines debate today.

2.2 The Research & Development Myth:

At the heart of the pharmaceutical anti-market is a core belief – propagated by the industry and its advocates – that drug companies need extraordinary profits in order to conduct expensive and risky research on innovative new drugs. Big Pharma warns that if anything is done to moderate this revenue, R&D will suffer and, consequently life-saving treatments may never come to market. Marcie Angell calls this the drug industry's "R&D scare card," (Angell, 2005). President of the PhRMA (Pharmaceutical Researchers and Manufacturers of America), Alan Holmer, played this card on National Public Radio's "Talk of the Nation" program:

> *"Believe me, if we impose price controls on the pharmaceutical industry, and if you reduce the R&D that this industry is able to provide, it's going to harm my kids and it's going to harm those millions of other Americans who have life-threatening conditions" (NPR, 2001).*

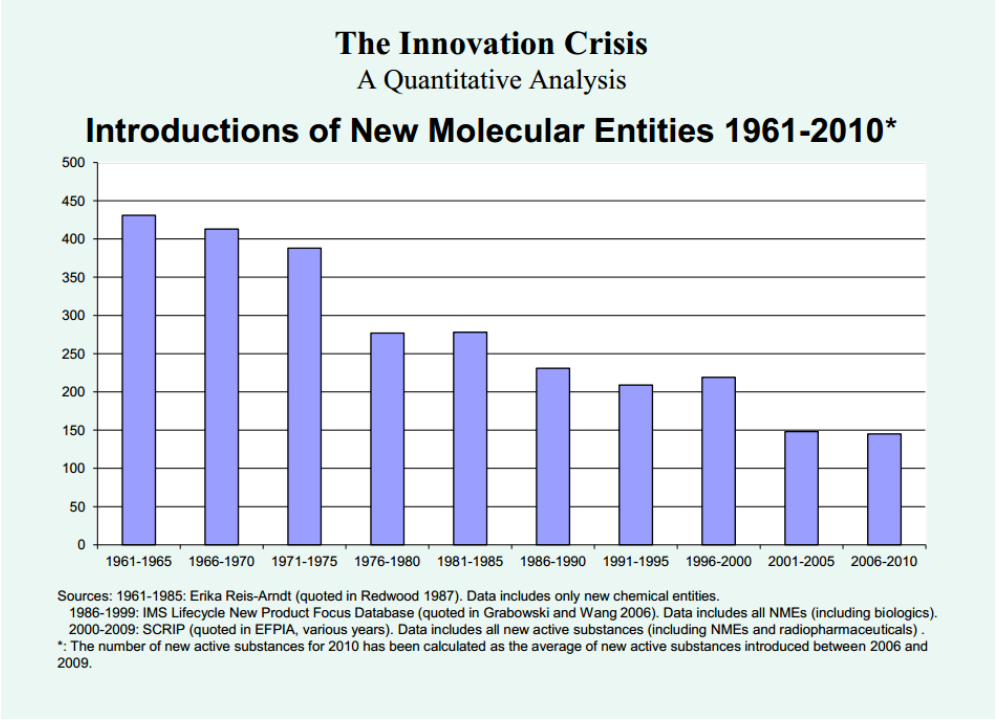
The magic words here are *research, innovation, American*. In fact, this rhetoric has become so pervasive that anything that threatens Big Pharma's revenue is quickly labeled as 'anti-American,' 'anti-innovation,' or even 'anti-free-market' (Angell, 2005). The high cost of R&D has been the industry's rationale for high prices in the developed world, and the basis for claims that companies cannot afford research into primarily developing-world diseases, where Big Pharma cannot charge high prices. However, industry critics point out that this "R&D scare card" is built on several myths, falsehoods and misunderstandings.

Data suggests that Big Pharma is investing more in selling its products than developing innovative drugs.[17] Curiously, the increase in profitability over the

[17] Curiously, this increase in profitability has not been the commensurate "reward" for increased innovation in the industry, which has been evidently falling throughout the period, as seen in Figure 3. Of the new drugs approved in the US between 1989 and 2000, only 15 per cent were of the highly innovative class of drugs that provide a significant improvement over existing drugs

past several decades has not been the commensurate "reward" for increased innovation in the industry, which has been evidently falling throughout the period (Figure 3). Of the new drugs approved in the US between 1989 and 2000, only 15 percent were of the highly innovative class of drugs that provide a significant improvement over existing drugs (NIHCM, 2002, p. 9). This implies that high drug prices could reflect the success of numerous other tactics employed by Big Pharma, i.e. marketing and legal "strategy." With a Braudelian lens, we can detect certain loopholes in the industry's argument and see deeper into the "murky waters" of its profitability. We find an uncompetitive market (an anti-market), where powerful agents bend the forces of supply and demand to reap high profits.

Figure 3:



(NIHCM, 2002, p. 9). This implies that high drug prices could reflect the success of numerous other tactics employed by Big Pharma, i.e. marketing and legal "strategy."

Big Pharma is reluctant to publicize information regarding its real expenditures. This can be illustrated by the fact that major companies fought, and won, a nine-year battle to keep congressional investigators at the General Accounting Office (GAO) from seeing the industry's complete R&D records. Congress can subpoena the records but has failed to do so. As a result, it is very difficult to estimate these costs with any precision; information in the public domain can vary wildly and lacks evidential backing. Critics argue that this lack of transparency has allowed industry leaders to mislead the public into thinking that high drug prices are justified in order to recoup the huge R&D costs, which they have incurred. Furthermore, companies allow access to certain economists, often at institutions that they support, and who in turn help to develop methods for showing how "large" costs and risks are[18].

Of course, pharmaceutical companies have a strong vested interest in maximizing costs for R&D, and for financially supporting centers or researchers who help them do so. This conflict of interest becomes evident when looking at industry-touted figures regarding the average cost of producing a new drug. Big Pharma claims that this cost today is equal to $1.3 billion (adjusted from $802 million in 2002). This figure – which is widely accepted at face value by governments, journalists and other experts – derives itself from a single study by economists at the Tufts University Center for the Study of Drug Development. Industry leaders and advocates cite this impressive figure over and over again to support their arguments for regulatory concessions and other pro-industry legislation.

Critics of the Tufts study claim that it is in many ways misleading and represents a serious conflict of interest, since the Center receives substantial industry

[18] Opaqueness" is an essential characteristic of the anti-market, according to Braudel. As he points out, while the bottom layer of material life is "hard to see for lack of adequate historical documents," this upper layer is hard to see because of the actual invisibility and complexity of its activities. Privileged access to information is key in realizing these types of operations; and this asymmetrical knowledge results from exclusive networking between key members of the social hierarchy – be they government, industry, academic, etc.

funding. Light and Warburton[19] (2011) argue that the $1.3 billion and $802 million estimates are highly inflated: To start, the study does not represent "average" cost of developing a new drug, since the analysis was restricted to New Molecular Entities (NCES) developed entirely within drug companies. NCES constitute only a small percentage of all new drugs, and are the most expensive to develop. Second, neither of the estimates includes the substantial contributions made by taxpayers through research grants and tax write-offs.[20] Perhaps most disingenuous, half of the industry estimates for R&D are not real costs, but rather "the cost of capital," i.e. estimates of profits that companies might have made if they had not developed the drugs but instead put the money into the stock market. As Light and Warburton (2011) note, the industry "cannot have it both ways":

> *"Even if one were to accept the argument that profits foregone should be included as a 'cost' [which no other industry does], US government guidelines call for using three percent, not the 11 percent used by [the Tufts group]" (p. 8).*

In other words, the industry should not treat R&D costs as if they are a long-term capital investment when tax authorities do the industry the favor of treating them as an ordinary business expense, fully deductible each year. Independent researchers have estimated the cost of drug development to be closer to $200 million, a substantial reduction from the industry estimates (Public Citizen, 2002).[21]

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[19] Light & Warburton (2003a, 2003b) were among the first to criticize the Tufts study for its questionable methodology, see also Angell (2005: 41) and Public Citizen (2001b).

[20] The drug industry's effective tax rate is about 40 percent less than the average for all other industries (Angell, 2005).

[21] Where then do Big Pharma's real costs lie? While impossible to know the exact breakdown of the budget, Big Pharma tends to spend two to three times more on marketing than it does on R&D (Public Citizen, MSF 2001, WHO, 2014). Critics have argued that the industry has shifted the core of its business away from the unpredictable task of creating drugs and toward the steadier business of marketing them. This trend has intensified since the US relaxed its rules on Direct-to-Consumer (DTC) advertising in 1997.

Another strike against the R&D myth perpetrated by Big Pharma is the use of publicly funded research institutions and universities for the benefit of the product pipeline. As Braudel observes, the anti-market relies on the State; and, in the case of pharmaceuticals, industry risks and costs are significantly reduced by taxpayer-funded research. According to an internal National Institutes of Health (NIH) document, obtained through the Freedom of Information Act, taxpayer-funded scientists conducted 55 percent of the research projects that led to the discovery and development of the top five selling drugs in 1995 (Public Citizen, 1997). Increasingly, Big Pharma is entering into financial arrangements with academic and research institutions, so that can "siphon off" close-to-finished products. This arrangement not only signifies much lower costs and risks for the major pharmaceutical companies, but also has important implications for the objectivity and credibility of clinical research (Medawar and Hadron, 2004). For example, in contracts with academic researchers, pharmaceutical companies may control how the research is done and reported, and whether the results will be published.

The industry's symbiotic relationship with academic and research institutions was solidified by a series of laws passed by Congress in the 1980s, which facilitated the translation of tax-supported basic research into new products. During this period, the US was experiencing losses in its share of world trade as sizable trade surpluses turned to massive deficits. Concurrently, there was a growing recognition of the importance of knowledge-based industries for the American economy. The process, known as "technology transfer," was meant to improve the position of American tech businesses and pharmaceuticals in world markets. The most noteworthy of these laws, the Bayh-Dole Act, named after its sponsors, allowed universities and small businesses to patent discoveries stemming from research sponsored by the National Institutes of Health (NIH), the major distributor of tax dollars for medical research. Prior to Bayh-Dole, taxpayer-funded discoveries were considered public domain, available to any company that wished to use them. Given that the majority of drugs produced by

the industry are a quasi-public product, general criticism contends that there should be some public sharing in the 'fruits of its investment.'

Through our Braudel-inspired lens, it becomes clear that such pro-industry legislation is not self-originating, nor is the R&D myth self-perpetuating. Instead, these activities and ideas, which define and legitimize the pharmaceutical anti-market, reflect the agenda of powerful economic players and a dominant state, working together to maintain a privileged position in a competitive world system. In this way, the industry affects government, and vice-a-versa.

2.3 The Political Weight of Big Pharma

In recent years, the term "crony capitalism" has been widely used to describe the pharmaceutical's close relationship with Washington, and to explain the industry's high profitability. However, by Braudel's account, crony capitalism is a tautology, since cronyism is *intrinsic to capitalism*. Under capitalism the hegemonic state has historically served as a guarantor of monopolists rather than as the protector of competition as usually portrayed. Co-opting state power can occur in many forms, such as legislation that raises the threshold of entry to help keep competitors out, or may be exhibited by favoritism in the distribution of government grants, special tax breaks, and so forth. Whatever the method, the goal is to protect profits, and with such large profits at stake, it is no surprise that Big Pharma has invested a huge amount of money in protecting these privileges.

This is especially true in the United States, the epicenter of a multibillion-dollar pharmaceutical market. Here the industry extends its power, political might and social influence over the nation's governments and agencies, its health care systems, its doctors, hospitals, and even the psyche of the American people[22]. With its staggering profits Big Pharma and over 1,100 paid lobbyists – more than

[22] For a nuanced discussion on Big Pharma and the "pharmaceuticalization" of health, see: Nguyen and Peschard (2003); Biehl (2007).

half former members of Congress, their staff or government employees – the industry enjoys powerful leverage on Capitol Hill[23] (Public Citizen, 2001). Between 1998 and 2013, for example, the American pharmaceutical industry spent nearly $2.7 billion on lobbying expenses — more than any other industry during that time, and 42 percent more than the second highest paying industry (Ibid). In 2003 alone, the industry expended nearly $116 million lobbying the government. Importantly, that was the year that Congress passed, and President George W. Bush signed, the Medicare Modernization Act of 2003, which created a taxpayer-funded prescription drug benefit for senior citizens, an extremely lucrative government program for the pharmaceutical industry. Through our Braudelian lens, we see how lobbying represents a "positive feedback loop" (Tyfield, 2008, p. 15): where profits afford further penetration of pharmaceutical lobby activities into government which, in turn, produces legislative action to further bolster industry profitability.

Big Pharma's lobbying efforts have not stopped at the White House, as we will see in Chapter 3. This anti-market involves a sustained effort around the globe to protect its enormous profits. As recently as January 2014, several major pharmaceutical companies were accused of planning a covert, well-funded campaign to delay the implementation of legislation in South Africa that would facilitate access to generic drugs. Leaked documents revealed that US companies had invested $450,000 into the campaign, which involved a high-profile consultancy based in Washington, DC. More than protecting its monopoly profits in South Africa, PhRMA expressed concern about the precedent that could be set. The efforts of Big Pharma to undermine national law should not come as a surprise, since as we see in Chapter 3, nearly a decade earlier these same companies, backed by the US government, sued the South African government for allowing generic AIDS/HIV drugs.

[23] The Pharmaceutical Research and Manufacturers of America (PhRMA), is the industry's powerful Washington-based lobbying arm. For a more detailed critique of the pharmaceutical lobby and its political influence see the Center for Public Integrity (2005) complete report: http://www.publicintegrity.org/2005/07/07/5786/drug-lobby-second-none

In addition to aggressive lobbying, Big Pharma enjoys political influence through a so-called "revolving door" between government and industry. Angell points to the United States Food and Drug Administration (FDA) as a prime example (Angell, 2005). After working at the FDA long enough to have established important connections, many employees leave the administration and are hired by pharmaceutical companies at a considerable pay increase. Even more boldly, some executives go directly from drug companies into influential positions at the FDA, only to return to the drug companies later at higher salaries. This well-greased "revolving door" between the FDA and pharmaceutical companies serves the purpose of making certain that the interests of the major drug producers are well represented in the agency. According to a USA Today study:

> *… More than half of the experts hired to advise the government on the safety and effectiveness of medicine have financial relationships with the pharmaceutical companies that will be helped or hurt by their decisions. These experts are hired to advise the Food and Drug Administration on which medicines should be approved for sale, what the warning labels should say and how studies of drugs should be designed. The experts are supposed to be independent, but USA Today found that 54% of the time, they have a direct financial interest in the drug or topic they are asked to evaluate. These conflicts include helping a pharmaceutical company develop a medicine, then serving on an FDA advisory committee that judges the drug (Cauchon, 2000).*

The Today study highlights how a “revolving door” policy has created a pro-industry atmosphere within the FDA. Although Federal law generally prohibits the FDA from using experts with financial conflicts of interests, according to the article the FDA has waived the restriction more than 800 times since 1998. These pharmaceutical experts, who total about 300 on 18 Advisory Committees, make important decisions that affect the health of Americans and billions of dollars in drug sales. The FDA is not the only government agency characterized by this “revolving door” and regulatory capture. Another prominent example is the United States Trade Representative (USTR), where dozen of officials have taken jobs with corporations that favor stronger copyright and patent protection.

Through its close relationship with the State, Big Pharma has also been able to promote its most important agenda: the strengthening of patent rights both domestically and abroad through supposedly “neutral” forums.

2.4 Defining an Intellectual Property Rights Regime

Intellectual property rights (IPR) have become one of the industry’s most potent weapons in defending its profits. Using Braudel’s discussion of the anti-market as our inspiration, we can trace Big Pharma’s movement to create a pro-industry IPR regime, as well as the role, and interest, of the State in creating this privileged position.

Patents are a form of intellectual property (IP) providing exclusive rights over a product to the inventor. They are granted by sovereign states, and give the inventor the right to exclude others from making, using, or selling the invention for a set period. The general rationale behind patents is to enable the inventor to make a profit on their invention, thus incentivizing innovation and benefiting society as a whole. In the case of pharmaceuticals, patents grant exclusive manufacturing rights for a period of 20 years from the date of filing for the patent, after which other companies are permitted to manufacture generic versions of the same medicine.

Big Pharma defends its pharmaceutical patents by underlining the “risky nature” of the business and the high costs that go into producing a new drug. Without patents to stimulate innovation, industry leaders and advocates argue that life-saving treatments would never come to market. They maintain that drug patenting promotes technology transfer, stimulates direct foreign investment and guarantees product quality. The PhRMA website goes as far as to proclaim: "Drug patents are good for our health" (PhRMA, 2012a).

On the other hand, critics contend that patents pose a serious barrier to health, and question the industry's rationale that IP rights are required for companies to recover large investments in R&D. Given the "loopholes" previously discussed, they argue that patents reward misplaced pharmaceutical R&D priorities, i.e. creating incremental improved treatments for diseases prevalent in wealthy countries and ignoring diseases that cause devastation in the developing world. They point out that drug companies increasingly employ "ever-greening[24]" as patents are about to expire, allowing them to extend monopoly protection and keep the profits flowing. In such ways, the current patent system has contributed to a deepening of health inequalities between the rich and poor, without any of the industry-touted benefits in terms of real innovation of new therapeutic treatments. [25]

This paper does not attempt to evaluate the efficacy or morality of the contemporary patent system, but rather show how Big Pharma – backed by the United States – has shaped it according to its own interests, thus representing a key element of the anti-market. Whatever one's position on patents, the effect of these monopoly rights on prices is clear: the patent-holder can set a price many times greater than the cost of production. Only a small proportion of the price of a drug is accounted for by manufacturing costs. As a result, the value that is attributed to intellectual property is large and controversial. The effect of patents on prices is demonstrated by data which compare prices of patented products and those of generic products; prices of the same product sold in different countries; and the prices of raw materials used in the production of medicines, in the open competitive market. The difference in price is often dramatic and has a large effect on Big Pharma's returns.

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[24] Patent "ever-greening" refers to a strategy of obtaining multiple patents that cover various aspects of the same product. Even though it is not a formal concept of patent law, patent owners utilize this process to extend their monopoly privileges. For a more thorough discussion of how Big Pharma extends patent monopolies, see Angell (2003).

[25] For a detailed analysis of the patents debate see Sell (2003) and Ryan (2008).

With such large profits at stake, pharmaceutical companies rely heavily on their patents and will often go to extreme ends to sustain and extend their patent lives. Over the past several decades, Big Pharma has worked with Washington to strengthen domestic patent law and policy and subsequently expand those rights across the globe. Consequently, the intellectual property (IP) regime – once limited to a set of relatively weak treaties – has been transformed by a dense array of new institutions and agreements that dramatically expand IP law, especially for drugs. An active pharmaceutical industry started working with government as early as the 1970s and early 1980s to push this agenda.

During this period, the US was experiencing losses in its share of world trade as sizable trade surpluses turned to massive deficits. At the same time, there was a growing recognition of the importance of knowledge-based industries for the American economy. Starting as early as 1977, the so-called "copyright industries" grew at an annual average rate double that of economy as a whole (Ryan, 1998, p. 10).[26] The stakes for the US economy were high, and Big Pharma made sure that Washington was aware of this fact through aggressive lobbying campaigns. Under industry pressure, the US – historically more concerned with abuses of monopoly power than with IPR protection (Sell, 2001) – began to broaden areas in which patents could be received and instituted a new unified Court of Appeals for the Federal Circuit to hear appeals on patent cases from all district courts. As we saw, the United States also granted universities and government laboratories the right to patent and license the output of publicly funded research, which provided a substantial financial incentive to partner with the industry. After securing important legislation domestically, Big Pharma and the United States sought to bring intellectual property rights issues into the realm of international trade policy and negotiations.

In 1980, the United States pharmaceutical industry joined an initiative, started by agricultural chemical companies, to lobby US government for support in

[26] An estimated 40% of the value of publicly traded American companies came from intangible assets (Cukier, 2005, p. 3).

pressuring foreign government's IPR laws. Via the lobbying power of the ACTPN, PhRMA (then called the PMA), and the International Intellectual Property Alliance (IIPA) among others, the initiative successfully influenced important changes to US trade law (Sell & Prakash, 2004). In particular, in 1984 the Trade and Tariff Act was amended to include certain IPR violation criteria within its Section 301 and Generalized System of Preferences (GSP) provisions (Drahos & Braithwaite, 2002; Matthews, 2002). As a result, IPR issues were institutionalized at the forefront of US trade policy, and the US could wield two new punitive measures against perceived IPR 'enemies': the Section 301 and the GSP.

The Section 301 and the GSP punitive measures clearly illustrate the power of the State in defending the privileged space of its leading economic agents. In the case of Section 301, the USTR could proactively and without industry-supplied evidence authorize penalties, such as trade sanctions, against foreign countries seen to be failing in their IPR requirements (Bhagwati & Patrick, 1990). This move could be proceeded by placing a country on a 301 'watch list' (Richards, 2004), which Palast (2000) calls a "kind of Death Row for trading partners." In the case of the Generalized System of Preferences (GSP), the penalty involves eliminating a bilateral trade privilege program designed by the UN in the 1960s to foster trade between minority and majority countries (Drahos & Braithwaite, 2002; Santoro & Paine, 2003). These IPR-adjusted mechanisms of 301 and GSP represent what Susan Strange calls "structural power," or the power to define and enforce the "rules of the game".

US bilateral policy on patents is closely tied to Big Pharma's agenda, especially its quest to restrict generic competition for the most lucrative patented drugs (Oxfam, 2002). Although IPRs were not considered free trade issues at the time, the developed countries, together with Big Pharma, eventually pushed through the Agreement on Trade Related Aspects of intellectual Property Rights (TRIPS) in 1994 under the auspices of the World Trade Organization (Drahos and Braithwaite, 2004). While not precisely harmonizing IPRs across different

countries (Richards, 2004), TRIPS set the minimum requirements of domestic IPR laws mandatory for all WTO members. The TRIPS agreement stipulated that by January 2005, all member states of the WTO had to grant patents on all medicines for a period of 20 years, with limited concessions for compulsory licensing and parallel import in special cases (Correa, 2007). Failure to comply could be enforced by the WTO through the Dispute Settlement Mechanisms. The aforementioned Section 301 and GSP sanctions would serve as "weapons" (Richards, 2004, p. 125) by which the US could exert pressure to enforce the TRIPS Agreement, even in the face of public health emergencies.

It is essential to remember that institutional arrangements such as TRIPS are not natural evolutions, but rather choices made by an elite few. These frameworks are usually presented as fair and impartial, since they offer all a theoretical right to be equal, competing under the same rules. However, due to existing asymmetries and hierarchies, those at the bottom rarely execute their rights. The strongest and most powerful shape the institutions to their advantage. This dynamic becomes clear as we look more closely at the case of Big Pharma and the TRIPS Agreement.

2.4.1 The TRIPS Agreement – Exporting the American Model:

For many commentators, the TRIPS Agreement is regarded as the culmination of the concerted efforts of key players in the knowledge intensive industries, including Big Pharma (Drahos & Braithwaite, 2002; Matthews, 2002; Richards, 2004). Indeed, important industry actors led the initiative, lobbying domestically and internationally for regulatory IPR change. As Drahos and Braithwaite (2002) described, TRIPS marked a "quiet revolution in the way that property rights in information were defined and enforced in an emerging global knowledge economy" (p. 19). Looking more closely at the leading actors in this 'revolution,' starting in the 1970s and culminating in the TRIPS Agreement, helps us to

illuminate certain power structures which define the pharmaceuticals anti-market.

At the front of the movement to strengthen intellectual property rights (IPR) on an international level were the major pharmaceutical companies, in particular the US-based company Pfizer (Drahos & Braithwaite, 2002; Matthew, 2002). In 1972, Pfizer's new chairman, Edmund T. Pratt, launched a new policy of aggressively defending the company's patent rights on key medicines (Santoro & Paine, 2003). At the time, IPR were considered only a niche aspect of international business, and their purview relegated to the appropriate forum at WIPO (Matthews, 2002). Pfizer later shifted its focus to integrating IPRs into the trade agenda, thus generalizing their relevance to business and political interests (Drahos & Braithwaite, 2002). With the multilateral trade forum, the General Agreement on Tariffs and Trade (GATT), about to start a new round of negotiations – the so-called 'Uruguay Round' – a new platform was available for such action. Pfizer and other knowledge intensive industries seized this moment to implement what Ryan (1998) refers to as a "GATT strategy" (p. 559), or attempt to "shift forums" to the more amenable environment of multilateral trade negotiations. [27]

An important component of the "GATT strategy" was to universalize the previously niche concern of IPRs, so that it represented a common interest and solution to US economic prospects (Ryan, 1998, p. 559). Big Pharma and other knowledge intensive industries sought to identify IPR violators as the "enemy" and blamed them for the loss of American competitiveness. This argument was supported by a widely cited US International Trade Commission study estimating that in 1986 the US industry lost between US$43 and US$ 61 billion worldwide due to insufficient IPR protection abroad (USITC, 1988). Playing on growing fears of lost US economic dominance to emerging economic powers, IPRs were thus

[27] As Matthews (2002) observed, at the start of the GATT's Uruguay Round, few trade negotiators had knowledge about IPRs. However, by the round's culmination, IPRs formed one of the three legal pillars of the GATT's new incarnation as the World Trade Organization (WTO).

positioned by Big Pharma as a symbolic issue whose strengthening would protect US jobs and ideas (Drahos & Braithwaite, 2002).

GATT was considered attractive by Big Pharma because – unlike WIPO, where IPRs were considered on their own merits – in this trade forum, other economic relationships would be considered when negotiating IPR deals (see Pratt, in Santoro & Paine, 2003). The trade-IPR equivalence would offer what Ryan (1998) referred to as "linkage bargain diplomacy" (p. 535), where stronger IPR protection could be negotiated in exchange for concessions in other sectors, such as apparel or agriculture. Given the historic separation between trade and IPR issues, as well as IPR protection's anti-free trade connotations (Machlup & Penrose, 1950), Pfizer needed to first convince others to support this agenda (Drahos & Braithwaite, 2002). In order to achieve this goal, Pfizer began to expand its presence in various networks across the world (Santoro & Pain, 2003), and to spread the IPR-trade message: "like the beat of a tom-tom […] along the business networks to chambers of commerce, business councils, business committees, trade associations and peak business bodies" (Drahos & Braithwaite, 2002, p. 69-70).

An important focal point for the industry was the President's Advisory Committee for Trade Policy and Negotiations (ACTPN), an industry-based group established to provide private sector advice to the USTR on trade agreements (Drahos & Braithwaite, 2002; Ryan, 1998). In 1981, Edmund Pratt (Pfizer) became Chair of the ACTPN, and for six years led this committee in:

> *… Pursuing an aggressive trade agenda […] As head of ACTPN, Pratt was at the forefront of a revolution in thinking about trade and investment. He and others dissolved the conceptual boundaries that had previously separated these two issue areas and supported institutional structures to reflect the new insights (Santoro & Paine, 2003, p. 347).*

In this way, Big Pharma's brought its agenda to a new and powerful state-backed forum. The previously isolated discourses of trade and IPRs were joined into a common argument. As Sell and Prakash (2004) observed, this process formed a new discourse built around the assumptions "patents = free trade + investments

= economic growth" (Sell & Prakash, 2004, p. 145). This discourse eventually became institutionalized in US trade policy (Richards, 2004).[28]

It is important to remember, however, that the dominant IPR-trade discourse did not self-evidently emerge, but rather was driven by a number of actions by Big Pharma and backed by the State. As we saw, in the 1980s, the various "copyright industries", under the shared identity of IPR-strengthening, began to lobby the US Congress together (Sell & Prakash, 2004). This collaboration became institutionally formalized in 1986 with the formation of the Intellectual Property Committee (IPC), set up by the ACTPN under Pfizer's Pratt.[29] In order to spread the IPR message amongst their international counterparts, the IPC created a tripartite coalition with the European Union of Industrial Employers' Confederations and the Keidanren, a private federation of Japanese business interests (Matthews, 2002; Santoro & Paine, 2003; Sell, 2003). By the end of 1986, the coalition produced a document outlining their negotiating agenda to the USTR, the so-called 'Basic Framework.' This document would ultimately become the guiding text for the TRIPS agreement (Drahos & Braithwaite, 2002). John A. Young, CEO of Hewlett-Packard, remarked on this accomplishment for the industry:

> *This effort was "unprecedented…the first time that the international business community has jointly developed a document of this magnitude and such substantive detail for presentation to our government negotiators" (Young, in Santoro & Pain, 2003, p. 350).*

While Young calls this effort "unprecedented," it comes as no surprise when one considers Braudel's view of capitalism, in which the State lends its support to define and defend the borders of the "anti-market." This close relationship is illustrated clearly via the substantial involvement of Big Pharma in the drafting of the TRIPS Agreement.

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[28] Harvey (2005) and Hesmondhalgh (2008) discuss further how the integration of IPR protection into the free trade agenda became a cornerstone of globalized neoliberal governance.
[29] The Intellectual Property Committee wielded considerable influence, consisting of 13 CEOs from the biggest American companies at the time (Matthews, 2002; Santoro & Paine, 2003; Sell, 2003).

Big Pharma and powerful developed countries with comparative advantages in innovation, such as the United States, were a significant driving force behind the adoption of TRIPS. The overall American goal in negotiating TRIPS was clear: to obtain rules that would ensure that US innovators' Intellectual Property (IP) rights were as extensively protected abroad as domestically. Despite strong opposition among developing country members to the negotiation of IP rights within the forum of the WTO, they eventually succumbed to the pressure of the US and other western governments. The agreement, which essentially set harmonized standards of intellectual property rights protection, entered into effect on January 1, 1995.

The TRIPS Agreement has been criticized for failing to fully take into account the complex links between intellectual property protection, development and health. Critics question the agreement's homogenized approach, which clearly favors Big Pharma and the developed countries in which they operate. South African former President Nelson Mandela at the Second Ministerial Conference (Mandela, 1998) expressed this sentiment about the Uruguay Round:

> *The developing countries were not able to ensure that the rules accommodated their realities…it was mainly the pre-occupations and problems of the advanced industrial economies that shaped the agreement.*

In light of the HIV/AIDS crisis, TRIPS came under intense criticism for frustrating access to life-saving treatments. After sustained pressure from civil society and some developing country governments, the fourth WTO ministerial conference adopted the Doha declaration on the TRIPS Agreement and Public Health in 2001 (WTO, 2001). In doing so, the WTO affirmed that TRIPS should be implemented in a manner that supports the right of countries to 'protect public health, and in particular, to promote access to medicines for all.' Paragraph 5 of the Doha Declaration provides a list of policy flexibilities that can be used to overcome intellectual property barriers to access of medicines. These include the freedom of each member state to determine the grounds on which compulsory licenses could be granted without the consent of the patent holder, and confirms that the

agreement should not limit countries' capacity to allow parallel trade in patented medicines.

Despite the flexibilities outlined in the Doha Declaration, developing countries have faced enormous pressure to accede to the new global IPR regime embodied in the TRIPS Agreement[30] (Baker, 2004a). The challenges in utilizing TRIPS flexibilities became increasingly more obvious with the HIV/AIDS epidemic of the 1980s and 1990s, and the widely publicized confrontation over access to life-saving antiretroviral (ARV) treatments.[31] The extent to which Big Pharma and the United States government have protected profits abroad reveals important elements of the pharmaceuticals anti-market, and continuities between certain patterns observed by Braudel and contemporary times.

[30] The US has controversially pursued a TRIPS-plus agenda through a series of bilateral and regional trade agreements (MSF 2004). These have included, for example, patent term extensions beyond those required by TRIPS, and conferring exclusive rights to pharmaceutical companies for the patient data used to secure regulatory approval.

[31] Difficulty in utilizing TRIPS flexibilities has also been limited by a number of burdensome administrative procedures (Baker, 2003). According to a statement by twenty civil society groups, the WTO took a 52 word mechanism endorsed by the EU in 2002 and created a "3200-word maze" of red tape "plainly designed to frustrate and undermine the objective of protecting public health and promoting access to medicines to all" (joint NGO Statement, 2003).

CHAPTER THREE:

HIV/AIDS: PATHOLOGIES OF POWER

The HIV/AIDS crisis, widely considered the most devastating health epidemic in recent history, sparked a highly publicized debate on access to medicines. As governments and health activists challenged Big Pharma's monopoly prices in order to secure life-saving treatments, all eyes were on the industry. In the public spotlight, perhaps more clearly than any other moment, the deeply entrenched global disparities between the developed and developing world were glaring. Commenting on these disparities, 't Hoen (2002) observed that:

> *The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines they need to treat disease or alleviate suffering. The high cost of AIDS medicines has focused attention on the relationship between patent protection and high drug prices (p. 1).*

Here t'Hoen highlights the importance of the crisis in drawing attention to the relationship between access to medicines, patents and prices. With our Braudelian lens, the crisis serves as a unique window of opportunity to look into the "opaque" pharmaceutical industry, helping to illuminate some of the key structures that define the anti-market today.

3.1 Overview of the HIV/AIDS Crisis

First identified in 1981 by the United States Center for Disease Control (CDC), AIDS quickly grew into a worldwide pandemic in the 1980s and 1990s. The disease – caused by the HIV virus – is almost always fatal within 6 months to 10 years if left untreated (WHO, 2004). During the 1980s, there was no effective treatment for HIV/AIDS, leading to a worldwide research effort to find a cure. While neither a cure nor vaccine has been found, a number of successful drugs

were developed to suppress the HIV virus, the so-called antiretrovirals (ARVs). The first ARV drug to be approved by the FDA and sold on the American market was AZT in 1987. At the time, roughly 10 million people around the world were living with HIV/AIDS, and the disease had become sufficiently important to be discussed by the UN General Assembly. By the mid-1900s, a series of ARVS emerged that, when used as a combination therapy (or, ARV cocktails), could dramatically lower levels of HIV in the body and extend the life expectancy of patients by at least a decade. These drugs were patented and marketed by American-based multinational pharmaceutical firms.

Thanks to the antiretroviral combination therapy, AIDS/HIV was no longer a "death sentence" – at least for those in the developed world who could afford the medicines. AZT was initially priced at $USD 10,000 per year, or about $3 a capsule, in the United States when it came on the market in 1987. Protease inhibitors, when released in the mid-1990s, were sold for about $USD 6,000 per year. By the late 1990s, the combined costs for ARV cocktails varied between $USD 10,000 and $USD 15,000 (UNAIDS, 2004). The global market for ARVs at this time, not surprisingly, consisted almost entirely of the US and Europe. As would be expected, the number of AIDS deaths in these regions soon declined significantly. The developing world, however, experienced a different story. The disease continued to wreck havoc, as life-saving treatments remained priced out of reach for most of its citizens. This disparity became especially pronounced in Africa: by the late 1990s, Africa accounted for two-thirds of the people living with HIV/AIDS, despite comprising only eleven percent of the world's population (UNP, 2010). While a number of factors contributed to the uneven spread of the epidemic, the high price of patented ARVs is widely recognized as a primary factor in limiting access to treatment.

In order for life-saving medicines to reach people living with AIDS in the developing world, the price desperately needed to come down. However, when governments and health activists challenged Big Pharma's stronghold on ARVs, it

became clear that this would not be an easy task. At each opportunity, the pharmaceutical companies, backed by the US government, defended its lucrative anti-market. The subsequent confrontation over access to ARVs reveals key facets of the pharmaceutical industry, including: (1) The dramatic drop in prices of AIDS drugs represents the extent to which the anti-market allows companies to inflate prices; (2) The actions by the US government to defend Big Pharma's stronghold abroad illustrate the essential role of the State in upholding the anti-market; and (3) The lobbying, political campaigning and strategic relationships show how Big Pharma leverages its privileged position in order to acquire further influence and capital.

3.2 The Access to Medicines Debate

In the face of growing criticism during the HIV/AIDS crisis, Big Pharma continued to defend its actions with the same research and development (R&D) ideology outlined in Chapter Two. Industry leaders and advocates claimed that high prices of ARV drugs were necessary to recoup costly R&D processes and to ensure continued innovation. This ideology was so prevalent that many Americans, including even some AIDS activists, opposed promoting access to treatment in Africa. They felt that cheap drugs in Africa might discourage R&D in the western world. Looking closer at these arguments, however, we again detect certain myths and falsehoods, which help to illuminate the more obscure structures of the anti-market. In completing this exercise, we find many of the same dynamics as identified by Braudel in his discussion of capitalism as the anti-market.

Many in the western world feared that Africans would not comply with treatment and develop resistance to AIDS drugs, which could come back to kill Americans and Europeans. In 2001, the Chief of the United States Agency for International Development (USAID), Andrew Nations, echoed this sentiment, explaining to the

US Congress why the agency opposed giving antiretroviral therapy (ART) to Africans with HIV:

> *"If we had [HIV medicines for Africa] today, we could not distribute them. We could not administer the program because we do not have the doctors, we do not have the roads, and we do not have the cold chain… [Africans] do not know what watches and clocks are. They do not use western means for telling time. They use the sun. These drugs have to be administered during a certain sequence of time during the day and when you say take it at 10:00; people will say what do you mean by 10:00?"*

Other senior officials of the World Bank were quoted in the Lancet (2001) saying: "[ART] is not…a technology that most poor people could adhere to … [Further] The use of public funds to subsidies the treatment of patients in the poorest countries who are most able to comply…would be highly inequitable."

Ironically, most AIDS drugs, like many other drugs, were not produced under the R&D of the pharmaceutical companies that market them. AZT, the first breakthrough drug to treat AIDS, is a prominent example. First discovered in 1963 by Jerome Horowitz at the US National Cancer Institute (NCI) in 1963, its use to suppress the AIDS virus was discovered nearly two decades later by National Institutes for Health (NIH) researcher Hiroaki Mitssuya. Only then was the drug licensed to the pharmaceutical company Burroughs Wellcome (a forerunner of GlaxoSmithKline) and, even then, still developed through a unique partnership with the publically funded NCI. AZT not only received public support for its research and development, it also enjoyed the advantages of an orphan drug[32] designation from 1987 to 1994 (Love, 2001). As a result, Burroughs Welcome received a 72 percent subsidy of the clinical costs at that time, as mandated per the Orphan Drug Act.

[32] The federal Orphan Drug Act, signed January 4, 1973, grants special status to a product to treat a rare disease or condition upon request of a sponsor. An orphan drug is a pharmaceutical developed to treat a disease that affects fewer than 200,000 people. Nonetheless, criticism has been leveled at the high price of many orphan drugs and at the fact that some have become very profitable products.

When Burroughs Welcome tried to claim that it was responsible for the original research of the AZT drug, five scientists from the National Institute of Health and Duke University responded strongly in a revealing letter to the New York Times (NYT):

> *"The September 16 letter from T.E. Haigler Jr., President of the Burroughs Wellcome Company, was astonishing in both substance and tone. Mr. Haigler asserts that azidothymidine, or AZT, was essentially discovered and developed entirely by Burroughs Wellcome with no substantive role from Government scientists and government-supported research…Indeed, one of the key obstacles to the development of AZT was that Burroughs Wellcome did not work with live AIDS virus, no wish to receive samples from AIDS patients. In a number of specific ways, Government scientists made it possible to take a drug in the public domain with no medical use and make it a practical reality as a new therapy for AIDS. It is unlikely that any drug company could have found a better partner than the Government in developing a new product. We believe that the development of this drug in a record two years, start finish, would have been impossible without the substantive commitment of Government scientists and Government technology" (NYT, 1989).*

AZT was not the only anti-AIDS drug that received funding for R&D in part from taxpayer dollars. The antiretroviral d4T also was discovered on a NIH grant; its use for HIV/AIDS discovered at Yale on another government grant; and its subsequent phase I trial sponsored by the NIH. AIDS activist James Love points out that when the government funds the discovery of a drug, like the case of d4T, the taxpayers have in fact paid for the most expensive part of the research and development process (Love, 2001). A drug company entering the pipeline at this point avoids investments, risk and time – the three critical elements of a cost study. Furthermore, developing the second or third line drug within a therapeutic class is often less expensive than the first, since the risks are much less. One can therefore assume that second and third line ARVS treatments did not involve as much R&D as the original, despite high prices charged by the industry for all (ibid). This information has important implications, especially when considering the industry's argument for patents on HIV/AIDS drugs.

Considering how a drug's patent life can be extended well beyond 20 years is also important. In some cases, Big Pharma achieves these extensions by adding numerous patents to multiple aspects of a single product that expire at different

times. The patent history of AZT is a good example. Before the patent on AZT expired in 2005, Glaxo "developed" a new anti-AIDS product that combined AZT and another drug, lamivudine, into one pill. While the new combination reduced the number of pills that a patient needs to take, it did not involve the invention of any new chemical entities. Still, GSK was able to market this "new" product under the brand name Combivir and to secure patent protection until 2017. As Dr. Yusuf Hamied, chairman of Cipla Limited, points out in the documentary *Fire in the Blood (2013)*, this means that AZT, directly and indirectly, will be covered under a patent until 2017, some 54 years since it was first invented. Hamied asks us to reflect, "Is that what patents are all about?"[33]

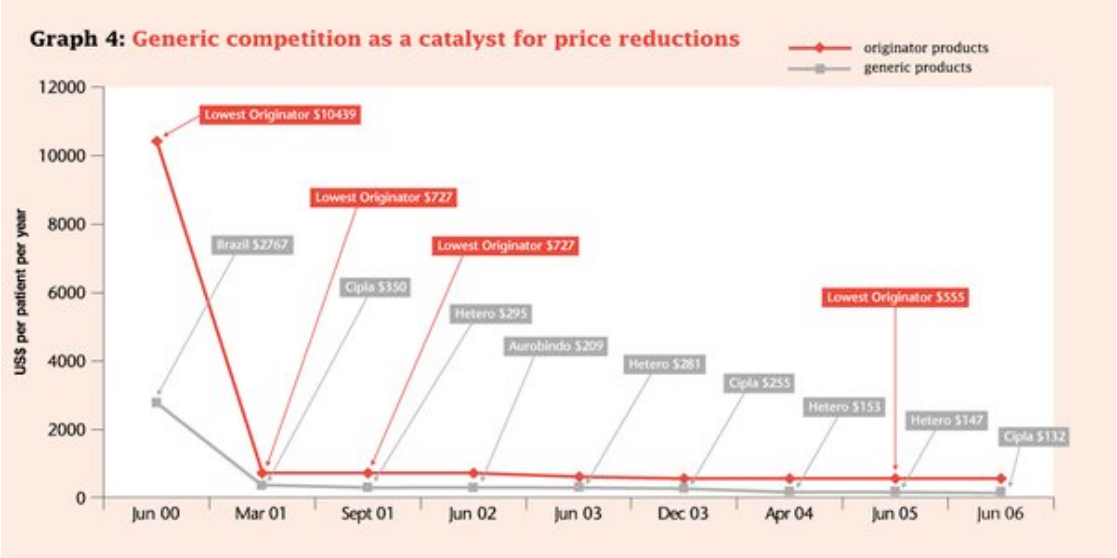
As governments and AIDS activists fought to secure access to affordable ARVs, they argued that: pharmaceutical companies were among the most profitable in the world; that these companies provided insufficient financial accounting information - particularly with respect to their R&D costs - to justify the prices of their products; that R&D costs were more than recovered from sales to people in developed countries, so there was no need to keep prices high in poorer countries; and, that the initial discovery of many drugs, including HIV/AIDS drugs, and their subsequent development were in fact financed in part by governments and non-profit agencies. Despite the growing magnitude of the crisis, their cries for justice remained largely unheard. Only when generic competition for ARVs emerged in India – and international decision makers were faced with independent information regarding the true manufacturing costs of anti-AIDS drugs – was there a global reassessment of the feasibility of providing treatments to millions of infected persons.

[33] A second combination of AZT, lamivudine and abacavir sulfate is now sold as Trizivir. Together, Combivir and Trizivir generated more than $1 billion in sales in 2003 (Alison and Bird, 2006).

3.2.1 The Influence of Generic Competition

The generic production of ARV drugs and subsequent dramatic reduction in price is the perfect illustration of what happens when monopoly pricing is broken and competition ensues. As described in Chapter 2, this open competition between different manufacturers is exactly what Big Pharma has sought to avoid.

Figure 4:



In 2001, Indian generic drug manufacturer, Cipla, announced that it could sell a generic copy of a triple-therapy antiretroviral for US$350 per patient per year.[34] This price was a sharp contrast to brand name ARV cocktails selling for between $USD 10,000 and $USD 12,000 at the time. The announcement sparked an ideological and price war between branded and generic drug makers. This competition, coupled with pressure from activists, non-profit organizations, and governments of poor countries with severe HIV epidemics, dramatically reduced prices of ARVs. By the middle of 2001, triple combination therapy was available from Indian generic manufacturers for as little as $USD 295 per person per year,

[34] This was possible because India did not have to abide by TRIPS legislation at this time and was therefore able to ignore the patents on the drugs.

which comes out to roughly $ 1 a day per person – a remarkable 98 percent reduction in price, as illustrated in Figure 4 (Lucchini et al., 2003).

The market entry by generic suppliers in India and elsewhere, and the subsequent "battle" with Big Pharma, had important implications. For the first time, policy makers had access to independent information regarding the true manufacturing costs of anti-AIDS drugs, leading to a global reassessment of the feasibility of providing treatments to millions of infected persons. Although the price of ARVs was now a fraction of what it had been, it remained largely out of reach to the developing world. This was because in most countries, patents held by multinational companies, and backed by the US government, continued to block production and importation of cheaper generics. Keeping in mind Braudel's ideas of capitalism, this fight for access to essential medicines illuminates key structures of the pharmaceutical anti-market.

With such high profits at stake, the arrival of generic drugs to Africa caused great concern among global pharmaceutical companies. The easing of patent restrictions in developing countries, even on humanitarian grounds, was seen as a potential threat to their future profits in key western markets. Certainly there could be political consequences if Americans realized that they had to pay $USD 10,000 dollars for a year's treatment while someone in another country was paying $150 dollars. Seeing a threat to its monopoly system on the horizon, Big Pharma launched a number of media and political campaigns that intentionally blurred the lines between generics and counterfeit drugs,[35] implying that generics are not as good as the original branded drugs, and that they compromise Americans' health and safety. Big Pharma also vigorously mobilized western governments, led by the US, to use the World Trade Organization (WTO) as a vehicle to force developing countries into adopting strict western style patents on medicines, among other forms of intellectual property. As we saw in Chapter 2,

[35] For a more in-depth look at how Big Pharma has strategically blurred lines between generic and counter-fit drugs, see the online article, "Fake Drug Plague or Pharmaceutical Industry Attack on Generics" (http://www.corpwatch.org/article.php?id=15742)

the protocol they used to do this is known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Although certain flexibilities were included in the Doha Declaration to help developing countries accommodate public health needs, it has proven difficult in many cases to interpret the laws and implement the appropriate policy mechanisms. Efforts by developing countries have been frustrated in part by lack of necessary technical expertise; however, the most significant block has come from the pharmaceutical companies and the Northern governments that back them. The widely discussed cases of South Africa and Brazil illustrate the difficulties in securing access to AIDS medications, and show the extent to which the State is essential in sustaining the parameters of the pharmaceutical anti-market.

3.3 Confrontations over Access to ARVs

We look at the cases of Brazil and South Africa in obtaining access to antiretroviral medication against HIV/AIDS in order to better understand the nuances of the pharmaceutical anti-market. While policymakers in the two countries were able, with the support of civil society groups, to utilize flexibilities provided in TRIPS to secure access to affordable treatments, their efforts met intense resistance by the global pharmaceutical corporations and government agencies of the North, especially the US. Looking at this confrontation over ARV prices can help reveal important power dynamics and asymmetrical relationships at work in the pharmaceutical industry. It should be noted that this exercise is not an attempt to compare and contrast the two experiences,[36] nor to provide a technical analysis of the legal actions taken by each country; rather it is an exercise to better understand the Braudelian concept of an anti-market as it applies to contemporary occurrences.

[36] For an in-depth comparative analysis between South Africa and Brazil, see Mauchlin (2008).

In the late 1980s, both Brazil and South Africa faced major and widely publicized HIV/AIDS crises, with "important aspects of the epidemic following a similar pattern in both countries" (Gauri and Lieberman, 2004, p. 2). With national incomes at similar levels and public health expenditures constituting a similar share of public expenditures, the governments of the two countries were equipped with a similar resource base to fight the disease.[37] There are of course a number of divergences between the two cases, primarily the fact that absolute number of HIV cases in South Africa is orders higher than those in Brazil. This constitutes a massive difference in the resources required to provide universal access. The political transitions experienced also varied. Yet, it is interesting to note that the countries went through similar policy phases, in particular when governments confronted the costs of ARVs.

As the Governments realized this cost barrier – coming up against resource and financial shortages in implementing health policy – they sought to utilize TRIPS flexibilities to lower the costs of treatment. While the precise actions varied between South Africa and Brazil, both created possibilities for domestic production and generic importation. These efforts continued after in an effort to keep the cost of public provision manageable.[38] However, throughout this laborious process, South Africa and Brazil experienced strong pressure from the

[37] Notwithstanding Brazil's greater external foreign debt exposure; in short, based on economic and social positioning, South Africa would have seemed to be at least in a similar if not better position to fight the HIV/AIDS pandemic than Brazil; yet the opposite occurred: While the Brazilian government rolled out the ARVs free of charge in 1996 (AZT as early as 1991), the South African government only started doing this in 2003.

[38] Although a substantial reduction in the price of many ARV drugs occurred between 2000 and 2005, most drug price reductions and multi-country deals apply to older drugs and first-generation treatments (Barnett & Whiteside, 2006; Anderson, 2006).
Scientific development has made second- and third- generation treatments an essential part of national treatment regimens, but these are all patented medications due to TRIPS compliance. As a result, the more advanced drugs are absorbing increasing proportions of national treatment budgets (Ford, et al., 2007).

United States to limit their use of these flexibilities, facing threats of trade sanctions and other punitive measures[39]. (Ford, et al., 2007).

3.3.1 The Case of South Africa

Although South Africa is the wealthiest country in Africa, and considered a developed country under the terms of TRIPS, approximately 80 percent of its population, primarily black, lives in poverty. When Nelson Mandela became President of South Africa after the first democratic elections in 1994, the country's healthcare system clearly reflected this division. Approximately 20 percent of the population, mostly white, was covered by private health care, while the black majority relied on a weakly funded and poorly organized public system. With most South Africans lacking access to decent health services, health care reform became one of the most important items on the agenda of the newly elected post-apartheid government. This action item was in line with the mandate in the new South African Constitution to take reasonable measures to ensure universal health care for its citizens.

At the time, South Africa was facing a rapid increase in HIV infection rates, while dealing with funding setbacks from austere structural adjustment programs. In this context, the Government's commitment to universal healthcare hardly seemed achievable. In the mid-1990s, the overall adult prevalence rate approached the 20 percent mark, and South Africa soon became the country with the highest absolute number of people living with HIV/AIDS. Health advocates estimated that nearly 1,000 South Africans were dying from AIDS-related illnesses every day. However, with an average annual income of $USD 2600, most South Africans suffering from HIV/AIDS could not afford to pay for treatment with antiretroviral drugs, which at that time cost about $USD 1,000 per month

[39] Both South Africa and Brazil have reasonably sized manufacturing sectors and thus represent a threat not only for domestic production of generics but parallel exporting. (Ford, et al., 2007), making the stakes higher for Big Pharma.

(UNAIDS, 2004). Life expectancy at birth dropped significantly in the country, and the number of orphans was increasing steadily. The impact of these demographic developments on South Africa's productivity could not be underestimated.

To address the mounting public health crisis, in 1994, the new Minister of Health, Dr. Nkosanzana Zuma, established a national committee to develop a health policy. On the basis of the Committee's report, and on discussions held with key stakeholders, a National Drug Policy (NDP) was developed. Its goal was to "...ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers" (NDP, 1996, p. 3). The NDP recognized that procuring expensive pharmaceutical products licensed to highly profitable international drug companies intensified the problems South Africa faced in meeting its public health policy objectives. One means of easing the fiscal constraint identified by the NDP would be to gain deep savings by purchasing generic pharmaceutical products for a fraction of the price of brand name drugs, including versions of antiretrovirals to treat HIV.

Following this logic, Minister of Health Dr. Zuma argued for parliamentary passage of the Medicines and Related Substances Control Amendment Act (MRSCA), which eventually passed in 1997. The most controversial clause of the Act – 15c – includes the following passage:

> *The registrar shall ensure that such an application in respect of medicine which appears in the latest Essential Drugs List or medicine which does not appear thereon but which, in the opinion of the Minister, is essential to national health is subject to such procedures as may be prescribed in order to expedite the registration…The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may…prescribe the conditions on which any medicine which is identical in composition, meets the same equality of standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic…may be imported (MRSCA, 1997).*

The clause had two important implications, that: (1) South Africa could seek the cheapest world price for a drug through parallel importing, and (2) It could

impose "compulsory drugs licensing," i.e. the right to make copies of patented drugs without the approval of the patent holder in cases of national health emergencies. Importantly, compulsory licensing is permissible under the TRIPS agreement, so long as certain safeguards are followed and royalties paid to the patent owner. However, the pharmaceutical industry – fearing a domino effect, where the weakening of patents in South Africa could undermine patents elsewhere, threatening the entire structure of the anti-market – quickly condemned South Africa's new law. In the fall of 1997, an association of 40 pharmaceutical firms – about one third from South Africa, one third from Europe, and one third from the US – challenged the law in South African courts, on the grounds that the Medicines Act specifically violated parts of the TRIPS agreement.

Big Pharma worked vigorously to mobilize the US government to support its complaint against South Africa, and the subsequent actions of the Clinton Administration are a clear demonstration of how government and industry work "hand in hand." The US government threw its full force behind the industry, putting intense pressure on South Africa to repeal the contested legislature. To start, Section 15c was added to the agenda for high-level bilateral trade talks between the US and South Africa. South Africa was also put on the Special 301 'watch list' both in 1998 and 1999 upon a determination by the US Trade Representative (USTR) [40] that South Africa lacked adequate intellectual property protection to an extent that merited bilateral attention. Furthermore, in February 1998, forty-seven members of Congress sent a letter to the USTR calling for a response to the MRSCA. The letter stated that Section 15C violated specific parts of the TRIPS agreement; even though most trade experts conceded that South Africa's actions were permissible under international law (Guari, 2004). Later that year, the USTR used its discretion to take severe action and withhold trade benefits for a range of South Africa products that had previously been approved

[40] Abdurrazack "Zackie" Achmat, co-founder of the Treatment Action Campaign, pointed out, "It took nearly 40 years for the US Government to put apartheid South Africa on the sanctions 'watch list', but it took less than 3 years to put democratic South Africa trying to make medicines affordable to its people onto a sanctions 'watch list', at the behest of drug companies."

under the Generalized System of Preferences (GSP) program. Furthermore, a provision was inserted into an omnibus appropriations act in October 1998 that conditioned US development assistance to South Africa on the Secretary of State's written report on steps being taken by the US government to work to "negotiate the repeal, suspension or termination of Section 15C (ibid)." [41]

Throughout the South Africa debate, the posture of the US government closely mirrored the position of Big Pharma, and vice-a-versa. John Judis, editor of the neoliberal New Republic, commented on this collaboration in the July/August 1999 edition of American Prospect:

> *"Pharma is of course acting like a lobby – pressing the interests of its clients even when their case is weak and morally repugnant - but what is **astonishing** is that the Clinton Administration has thrown its full weight behind their complaint…The Clinton administration has regularly put the export and investment concerns of American businesses above human rights and even security considerations. But in most of these cases, it could claim that is was acting in the national interest…Gore's willingness to do PhRMA's bidding in this case may indicate that on the issues that impinge upon his high-tech network of supports, he is willing to do the wrong thing to keep them happy – and keep them in his corner."*

The above passage highlights the intimate relationship between pharmaceutical industry and the State, which Judis claims is "astonishing." However, the administration's bidding on behalf of Big Pharma is not so surprising when we remember Braudel's observations regarding the State and the anti-market. There was a very active pharmaceutical industry prodding the US government to force a repeal of South Africa's Medicines Act - an industry which, as we saw in Chapter 2, has seemingly unlimited financial and public relations resources, generous campaign contributions, and revolving doors with US bureaucracy. Indeed, drug companies had substantial motivation to kill the South African Medicine Act, and US Congress members had ample reasons to back Big Pharma. For example, at

[41] This report was submitted in February 1999, stating that all relevant agencies of the US government "have been engaged in an assiduous, concerted campaign" to persuade South Africa to withdraw or modify Section 15C, which the State Department held to be inconsistent with South Africa's obligations under TRIPS. *See* United States Department of State Report on U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(C) of the South African Medicines and Related Substances Act of 1965 (February 5, 1999).

the time of the lawsuit against South Africa, the Centre for Responsive Politics (2000) estimated that from 1997 to 1998, the pharmaceutical industry spent more than $148 million lobbying Congress and the President - second only to the insurance industry and more than Big Tobacco.

Braudel helps us to understand how such links between the political and business world also reflect a social hierarchy, where a small advantaged class enjoy an exclusive network. This network represents a privileged position, facilitating the reproduction of power dynamics in society. The ties of then Vice President Al Gore – who also served as co-chairman of the US-South Africa Binational Commission[42] – with the pharmaceutical industry and its lobbyists, provide a perfect example of the "coziness" of this elite club. To start, Gore's domestic policy advisor, David Beier, was the former head lobbyist for Genetech, a major US pharmaceutical company; Tony Podesta, a top Gore advisor and brother of Clinton's chief of staff, was a contracted lobbyist for PhRMA and most other US drug interests; Tom Downey, a close Gore associate and former congressman, once lobbied for Merck pharmaceuticals; Gore's fundraiser Peter Knight was a former Schering-Plough lobbyist, and so on. Given his central position for negotiating US AIDS policy, Gore became a main target of AIDS activists who pointed out the glaring conflict of interest, and urged the US government to change its positioning towards South Africa.

Leading up to the US presidential campaign in 2001, the high stakes of the controversy with South Africa attracted substantial attention in the media, and mounting public pressure ultimately led to a shift in the US Administration's policy towards South Africa. In September 1999, the USTR and the South African government announced that the controversy was resolved and that the US government would no longer pressure South Africa. In return South Africa promised to adhere to its obligations under TRIPS. HIV/AIDS activists celebrated

[42] The US-South Africa Binational Commission was established in March 1995 to facilitate bilateral cooperation between the United States and post-apartheid South Africa.

the step forward, however there are many signs that the anti-market is alive and well today. [43]

3.3.2 The Case of Brazil

In 1992, the World Bank warned that Brazil would face immense challenges confronting the AIDS crisis, and forecasted that Brazil would have 1.2 million people living with HIV by the year 2000. At the end of 2003, Brazil had an AIDS prevalence of approximately 660,000, and today is home to one of the largest public AIDS treatment programs in the world (UNAIDS, 2004). The program halved AIDS-related deaths over the last two decades and dramatically reduced AIDS-related morbidity (ibid). Today Brazil is heralded as a model of a successful response to the epidemic, particularly for countries of low and middle-income status. However, as we will see, Brazil also met significant resistance from pharmaceutical companies and the United States governments in its quest to secure access to affordable HIV/AIDS treatments.

Like South Africa, Brazil was in the midst of political transition when the AIDS crises became an international concern. In 1985, democracy was restored to the nation, after it had spent most of the 20th century under a military dictatorship. The ensuing process of democratic transformation would have a significant effect on the overall national response to HIV/AIDS in Brazil. As the epidemic grew, human rights activists called for decisive government action to ensure that citizens had access to life-saving treatments. These demands were reflected in the new Constitution of the Federation of Brazil, established in 1988, which

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[43] Despite the "victory," the anti-market shows signs of being alive and well: January 2014, leaked documents showed that pharmaceutical companies planned a $450,000 campaign, involving a high-profile consultancy based in Washington, DC, against changes to intellectual property laws in South Africa that would enable their patents on new medicines to be bypassed in the interests of public health. *See The Guardian (2014).*

declared health care the right of all Brazilian citizens. The National AIDS Program, established in 1986, would respond to the HIV/AIDS crises according to these principles. Brazil became the first developing country to guarantee free and universal access to antiretroviral therapy in 1996[44].

A key factor in ensuring broad public access to ARVs in Brazil has been the local manufacturing of cheaper generic equivalents of these drugs. Brazil could produce or import low-cost versions of several ARV drugs since the country did not adopt pharmaceutical patenting until 1996. After the implementation of TRIPS, however, Brazil no longer had the option of local generic production of new drugs for HIV/AIDS, or any other diseases. To help ensure that new drugs remain affordable, Brazil has utilized flexibilities in both the TRIPS agreement and its 1996 Industrial Property law. Especially through using compulsory licensing as a bargaining chip and last resort, the government has secured deep discounts on brand-name drugs.[45] These steps have helped to cut treatment costs dramatically in Brazil and made it possible for the country to treat many more people than would have been possible otherwise.

While the outcomes of Brazil's approach have been positive in terms of curbing the epidemic, the process was not an easy one. As in the case of South Africa, the major pharmaceutical companies, backed by the US Government, worked tirelessly to block Brazil's efforts to secure affordable HIV/AIDS treatments. In fact, political, economic and legal pressure from the US Government over Brazil's intellectual property rules had an early start. PhRMA lobbied against the Brazilian patent law, which excluded medical products from patent protection, as early as 1988 (Marques, 2002, p. 43, Tachinardi, 1993, p. 67). When the Brazilian government issued a revised patent law in 1996, which included the protection of pharmaceutical patents, it still remained unsatisfactory to PhRMA as it limited the scope of some pharmaceutical rights.

[44] Access was established as a legal right in 1996, but public delivery of antiretroviral drugs (ARVs) started as early as 1991.
[45] In 2009, combination antiretroviral therapy was delivered to nearly 190,000 AIDS patients (PLWHA), covering more than 90% of estimated need according to previous 2006 WHO guideline.

The most controversial stipulation of the new Law was paragraph 68, which requires pharmaceutical companies to produce their drugs locally within three years of patent approval. If the patent holder fails to meet this requirement, the Brazilian Government can override the patent and either permit manufacturing by a third-party manufacturer (compulsory licensing) or allow the import of the patented product from the cheapest international source (parallel importing), without the patent holder's consent. The US argued that this "local working" requirement discriminated against imported products and violated Article 27 of the TRIPS Agreement. Brazil retorted that the stipulation did not interfere with any international laws, as it is simply a safeguard that can be invoked in a case of "abuse of rights or economic power" by a patent holder. PhRMA, fearing the implications of Brazil's stance elsewhere, pushed the US Government to put pressure on Brazil through bilateral negotiations, as well as through keeping Brazil on the USTR's Special 301 'watch list'.

The United States and PhRMA also opposed a decree issued by Brazil's President Fernando Henrique Cardoso on compulsory licensing in October 1999. The Decree regulates the implementation of Article 71of the Law, allowing for the granting of a compulsory license during national emergency situations. In December 1999, the Brazilian Government also issued the "Medidas Provisorias" (Temporary Measures) that gave the new drug regulatory agency, Agencia National de Vigilancia de Sanitaria (ANVS), authority to approve all patent applications related to pharmaceutical products or processes. Brazil argued that if it were to lose these safeguards, it would be less able to negotiate affordable prices with pharmaceutical companies, leaving them freer to charge what they want for drugs, or even to refuse to supply a market.

Prodded by domestic pharmaceutical lobbies, the US challenged Article 68 within the framework of the World Trade Organization's TRIPS dispute mechanism for allegedly discriminating against imported products. (Article 71 and the "Temporary Measures" law, much to the chagrin of many companies, were not

included in the US complaint). Throughout the ordeal, Brazil remained on the United States Special 301 'watch list', opening the possibility for "unilateral sanctions, and individual companies also threatened to pull out of the Brazilian market altogether. Advocates of intellectual property rights (IPR) loudly condemned the actions of the Brazilian government. Slavi Pachovski (2005), a leading member of the Institute for Trade, Standards and Sustainable Development, claimed that:

> *If this trend proceeds, it will be a global pandemic of AIDS that will grow uncontrollable because the Brazilian move will destroy the whole legal order that is the basis for developing new drugs and continuing research.*

As Pachovski's statement reveals, the pharmaceutical companies were not just afraid of the immediate loss of the Brazilian market; they were afraid of the larger implications if other developing and emerging market countries followed Brazil's example.

In the wake of protests by the global AIDS activist and the subsequent public relations disaster, the United States eventually dropped its WTO dispute. Brazil, in turn, agreed to notify the US government in advance if it found it necessary to issue a compulsory license. For years the Brazilian government continued to threaten to invoke compulsory licenses for AIDS drugs, without actually going ahead. This approach has led to substantial health savings of an estimated USD $1.1 billion since the start of Brazil's universal ARV programs[46] (Teixeira, 2003).

In sum, only after extensive conflict with Northern powers was Brazil able to ensure the world-class polices which today are referred to as the "Brazilian model" for AIDS treatment – i.e. universal access to treatment, production of generic ARVs, and negotiated prices for patented drugs. The resistance from the pharmaceutical companies and US government clearly delineates the shape of an anti-market, and shows how the State and industry act together to protect profits. Thanks to the Brazilian and South African cases, transparency about drug prices

[46] Brazil only carried out such a compulsory licensing threat for the first time in May 2007, on efavirenz, produced by Merck (Nunn et al, 2007, 12-13).

has been promoted in other developing countries. Their strong stance in the AIDS crisis has greatly influenced treatment provision globally, highlighting the opportunities for treatment provision if monopoly prices are broken.

CONCLUSION:

This examination of the pharmaceutical industry through a Braudel-inspired lens has proven to be a rich exercise, pointing to the value of his model in understanding situations of high profitability in the world today. Even if one does not completely agree with Braudel's classification of capitalism as the anti-market, the essence of this distinction becomes clearer through this work: capitalism is indeed separate in many ways from what we usually consider the fair and competitive game of the "free" market. As observed in the pharmaceutical industry, there exists a superior layer of economic activities where a privileged few can manipulate market forces to realize exceptional profits. In this sense, our work supports the Braudelian idea that anti-markets are the rule rather than the exception in the capitalist system, and that the State and society have an important role in defining these privileged spaces. As Braudel himself commented (1992), "The important thing is to distinguish the simple strands of the fairly constant relations among structures from the complex web of the present" (p. 59).

In the first chapter, we presented Braudel and extracted the most relevant points in order to structure his distinction between the market economy and capitalism. Next, we offered four general historical recurrences that make up the Braudelian framework (Cecilio, 2012): (1) The anti-market is the rule, not the exception; in the capitalist system, there have always been activities characterized by some type of manipulation of the market or restriction of competition. For this reason, there can be profits above the patterns obtained in other sectors. (2) The State plays an essential role in supporting the anti-market. For this, it is necessary to understand the interstate system as an inherently competitive one. We note that structural power plays an increasing role as we approach contemporary times. (3) The roots of capitalism are in society as a whole. Here, Braudel shows that certain hierarchies in society – be they ideological, cultural, academic, etc. – are essential for creating and legitimizing anti-markets. Finally, (4) The capitalist

enjoys the privilege of choice, not only to construct anti-markets, but also to continually reshape them as competition enters and threatens monopoly profits. Together, these patterns help us to shape the Braudelian lens for a contemporary view.

With these Braudelian themes in mind, we looked at the ways in which Big Pharma has created an anti-market, and the role of the State and society in maintaining this privileged space. In Chapter two, we evaluated Big Pharma's research and development argument and, in finding certain "loopholes," observed the ways in which it has manipulated market forces and restricted competition. We focused in particular on its successful quest to strengthen intellectual property rights, both domestically and abroad, via the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The substantial role of Big Pharma in drafting TRIPS was used to illustrate several main themes in Braudel, since it replicated the industry's privileged position on a global scale. Indeed, far from a neutral trade framework, TRIPS created a homogenized neoliberal regime for patents – one constructed to privilege the profits of multinational pharmaceutical corporations as well as those of the developed nations in which they operated. In doing so, the historical recurrences in Braudel are made contemporary, and we gain important perspective for the access to medicines debate today.

In the final chapter, we utilized the HIV/AIDS crisis of the late 20th century to look deeper into the pharmaceutical anti-market. The economic and social impact of the crisis received wide media coverage, and the public spotlight helped illuminate some of the more opaque activities of the industry. The dramatic reduction in the price of antiretroviral (ARV) drugs once generic competition entered the market – from roughly $USD 15,000 per person per year to less than $USD 300 per person per year – revealed the extent to which Big Pharma had inflated prices. While the industry tried to defend its high prices and profits with the same research and development argument described in Chapter two, we

showed how it was based on a number of falsehoods. The confrontation over access to life-saving ARV treatments revealed important Braudelian power dynamics and asymmetrical relationships at work in the pharmaceutical industry. Looking at the cases of Brazil and South Africa in particular, we showed how Big Pharma pressured the United States government to challenge national efforts to produce or purchase generic drugs, even in the face of sever health emergencies. The extent to which Big Pharma mobilized the United States government to protect its profits abroad showed numerous continuities with patterns observed by Braudel, especially the role of the State in protecting the anti-market.

Given the time restrictions of this work, many avenues could be further explored. A possible follow-up to this work, for instance, could investigate more closely the relationship between the pharmaceutical industry and the United States government, tracing the emergence of a Pharma-industrial complex after World War Two. Through a Braudel-inspired lens, one could examine the ways in which Big Pharma aligned itself with the goals of the State, and vice-a-versa, and the strategic implications of these actions. Another valuable extension of this work could look more intimately at structural power and its increasing role as we approach contemporary times. Through investigating important structural changes in the global economy and evolving dynamics of power, the Braudelian model could be updated in important ways.

As Wallerstein pointed out, there are a number of intellectual and practical repercussions of the distinctions made by Braudel, especially for policy in the contemporary world. If capitalism is monopoly and not the "free" market, as commonly assumed, then our anti-systemic movements might require different approaches than tried in the past. The recent publicity disaster for Big Pharma in South Africa, where it had organized a covert lobbying campaign to change a national patent law that threatened its profits, shows that the forces of the anti-market are alive and well in 2014. The distinction that Braudel makes between the market economy and capitalism, and the essential role of power in this

separation, thus continues to be relevant and useful for those who seek to understand the accumulation of wealth by a privileged few in our capitalist world system. As such, it cannot be underestimated as a valuable tool for being able to pinpoint and tackle the forces that shape inequality in the world today, especially in the area of health.

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