Brazilian Health Biotechnology Innovation System: an essay about the public policy rationale

Carlos Bianchi [1]

ABSTRACT:

The emergence of biotechnology is one of the most important changes in the health innovation systems. This paper discusses the rationale that has supported the public policies oriented to boost health biotechnology development in Brazil during 2004 and 2014. Based on a thorough revision of policy documents and on an extensive fieldwork, the study highlights the accumulative path followed by the Brazilian public policies. This research shows how these policies followed an uneven accumulative path were several rationales cohabited integrating explicit and implicit policies. Finally, the boundaries of policy action are discussed, stressing two critical dimensions that delimit the scope of policy action: i) the change of policy orientation and rationale, ii) that pose new governance's challenges, which, in turn require new coordination with other implicit policies.

Keywords: Biotechnology; Health; Brazil; Public Policies.

[1] Doutor em Economia da Indústria e da Tecnologia pela Universidade Federal do Rio de Janeiro, UFRJ. Docente na Universidad de la Republica Uruguay, UDELAR, Uruguai. cbianchi@iecon.ccee.edu.uy

Nowadays, several studies draw the attention to the growing capabilities of some developing countries in health biotechnology (Thorsteinsdóttir 2012; Göranson & Pålsson 2011). Among them, the Brazilian case has been regarded as one of the new players in the production of healthcare solutions based on biotechnology research (Rezaie et al. 2008).

Brazil has a small but significant amount of firms devoted to human health biotechnologies as well as a large accumulation of scientific capabilities in this field (Torres Freire 2014). During the period 2004-2014, the Brazilian innovation and productive policies stressed the strategic relevance of biotechnology as a tool to deal with national health challenges as well as to promote new knowledge based activities.

Based on international experiences and in the evolution of the Brazilian health biotech innovation policies, this paper revisits earlier analysis of the public policies devoted to health biotech in Brazil (Bianchi 2013a) discussing the policy rationale. The paper deals with two main question: What has the rationale of biotech policy been? Has the theoretical basis of these policy rationales changed?

The general hypothesis states that several rationales cohabit during the period 2004-2014 supporting different objectives and instruments. Even though this process has been erratic, it allows the emergence of adequate institutional solutions to deal with some of the most relevant challenges of the Brazilian health biotechnology system.

The second section presents a brief revision of the theoretical basis of the Brazilian biotechnology policy rationale. The general hypothesis states that this rationale is based on theoretical ideas built on the experiences of developed countries, mostly built on the United State (US) biotechnology industry. In section three the Brazilian Health Biotechnology Innovation System (BHBIS) is analyzed contrasting its most significant features to some stylized facts of the U.S. health biotechnology innovation system. This comparison allows stressing the intermediate mechanisms operating in each case and particularly, to point out the relative importance of market and state mechanisms. Finally, the conclusions discuss the boundaries of public policy action, by analyzing how some systemic features delimit the potential action of policies.

1. A Policy Rationale: What are the theoretical assumptions behind policy programs?

From a static point of view, a biotechnology health system is defined as a web of relationship in which different types of agents and institutions participate in working on the biotechnology health development process. It involves government agencies in charge of public policy design and research funding, research institutions, public and private firms fully or partially devoted to biotechnology,

healthcare institutions, and intermediary institutions dedicated to link different agents and support innovative biotechnology activities.

Complementing this vision from a dynamic approach implies the analysis of how this web of relationship changes through time, varying its size and functions (Dodgson et al. 2008). The aim of this paper is to discuss how a specific feature of the Brazilian health biotechnology innovation systems changed in the period 2004-2014. It refers to the public policies oriented to promote the health biotechnology development and, specifically to the rationale of these policies. The general hypothesis states that national public policies oriented to boost the development of health biotechnology in Brazil has been based on the expectation to reproduce some stylized patters of the U.S. experience.

1.1. HUMAN HEALTH BIOTECHNOLOGY: AND OPERATIVE DEFINITION

Although there are several debates about what modern biotech is and what is not, there are more coincidences than differences related to the biotechnology technical definition (Fonseca 2009; Orsenigo 1989; Pisano 2006; Hopkins et al. 2007). Regarding the coincidences, biotechnology is defined in this paper as a body of knowledge and a comprehensive set of procedures and technologies that analyses the attributes of the cells allowing the molecules, DNA and proteins to create or modify products or processes for specific uses with various applications.

Even using a general definition of biotechnology, several authors contend that there is not an evident definition of biotechnology in the health sector, because of the variety of biotechnological, chemical and bioinformatics techniques that are introduced into health related industries. In this regard, there are different operative definitions, which have been proposed according to the specific objective of each research, but there is not a consensual definition. Taking into account this discussions, this work follows a wide definition of health biotechnology that embraces the discovery of therapeutic agents that are used in healthcare as well as rational drug design, drug delivery systems, and manufacturing of drugs, serum, vaccine and others biotech developed products (Niosi & Reid 2007).

1.2. THE EVOLUTION OF MODERN HEALTH BIOTECHNOLOGY INDUSTRY: FROM THEORY TO POLICY MODELS

The history of the upsurge of biotech in the industrial health complex, especially in the pharmaceutical industry, has been widely exposed by several authors. This history has always been related to the experienced of developed countries, mainly U.S. Rather than recalling the history once again, this section is focused on three stylized facts of the widespread theoretical explanations on this process (Bianchi 2013a).

i) Modern biotechnology has changed the health innovation process;
ii) While small dedicated biotech firms (DBF) emerge from science-production relationships, the incumbent big pharmaceutical firms follow different diversification strategies;
iii) The market mechanisms functioning works under a new institutional dynamic characterized by venture financial systems and intellectual property right (IPR) regulation.

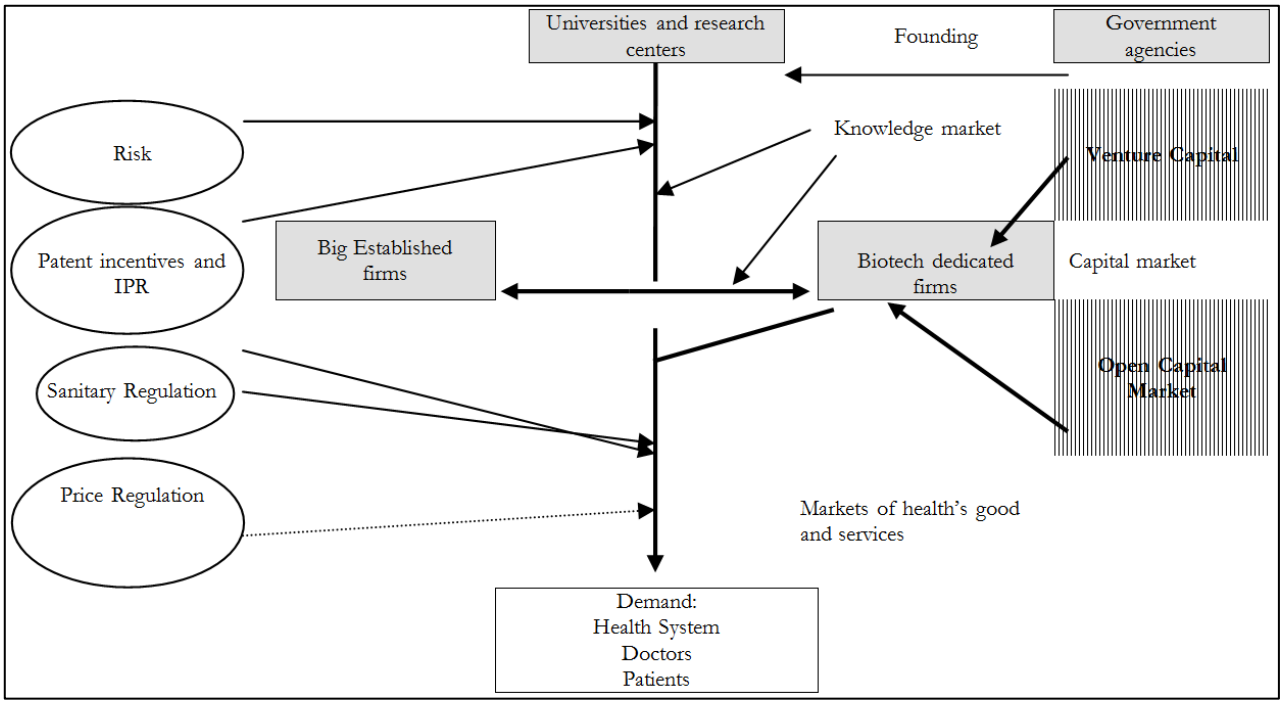
Several authors stressed that the advent of modern biotechnology creates a new knowledge basis has been changing the drug innovation process (Gadelha 1990; McKelvey et al. 2004; Pammolli et al. 2011). This change has happened while new linkages between research organizations and firm arose. The development process of new therapeutic solutions requires strong linkages with scientific research (Brännback et al. 2009; McMillan et al. 2000; Kneller 2010). It shows a systemic dynamic where the scientific research activities influence in the goods and services health production while a growing influence of the industrial criteria in the scientific production is perceived (Orsenigo 1989; Pisano 2006). It implies successive ramification of knowledge, from some general questions to emerge new specific hypothesis oriented to solve the development of a new drug for a new problem. The emergence of new problems is the results of the new discovery process in a successive solved problem chain (Orsenigo et al. 2001).

These changes boosted the appearance of new small and medium enterprises (SMEs) devoted to biotechnology creating different inter-firm relationships and different business models (Mangematin et al. 2003; Audretsch & Feldman 2003). While the biotechnology health innovations emerge from SMEs and research centers, the big pharmaceutical firms adopted different strategies of diversification of the technological basis and product portfolio (Mittra 2007; Gutman & Laravello 2010)-in the initial stages- a strategy of *wait and see* to know the potential impact of the new emergent technologies (Hopkins et al. 2007).

On the other hand, at the same time that new firms entering in the market with a significant impact on the industrial structure, it is possible to observe a market concentration process led by the big firms. This process was promoted by market and institutional factors, but mainly by the structural features that are inherent to the health related industry. It has traditionally been a monopoly or oligopoly industry. In the case of pharmaceutical, the market works as an oligopoly segmented according to different therapeutic classes. Moreover, it is a market where the main products –ethical medicines- have low price elasticity, new firms find high barriers to entry (Caravaglia et al. 2006)

Finally, all these transformations were accompanied by institutional changes creating a "market of ideas" through venture financial systems and intellectual property right regulation (Pisano 2006; Coriat et al. 2003).

Figure 01. Anatomy of the US Health Biotech System



Source: adapted from: Pisano (2006:81).

Figure 1 was adapted from Pisano (2006) and –with a few adaptations- shows the stylized characteristics of the US Biotech Health System. It emphasizes the relevance of the IPR regime as well as the capital markets, which are regarded as the key institutions that make the existence of market knowledge possible. That market is the base for the entrance of new firms and to start the selective process which is not smooth and, in fact, is plenty of uncertainty.

Several authors state the importance of these aspects to explain the singular characteristics of US biotech health system. The behavior of the *start-up* firms in U.S. highlights the relative advantages of cooperation as SMEs' commercial strategy, are related to the existence of a specific regulatory framework. Early in the nineties the US Congress Office for Technology Assessment (OTA), stated that biotechnology firms that surged in US, could only be replicated in a similar regulatory environment and with the support of a mature capital market (OTA 1991). These are the aspects that sustain the question: *"Does biotech reflect a new science-based innovation regime?"* made by Coriat et al. (2003) in order to analyze the US biotech innovation system. These authors classified the U.S. biotech health system as a new variety of innovation regime based on science, which integrated itself new specific regulatory and financial institutions, adapted according to the technological specificities of the new regime.

After a relative long period were economics studies on biotechnology were focused on developed countries, a growing accumulation on biotechnology innovation system in developing countries has appeared (Göransson & Pålsson 2011; Guennif & Ramani 2012). Many of them show the differences between a specific national case and the previous accumulation on the experience of developed countries (Kang & Park 2012; Dodgson et al. 2008; Reid & Ramani 2012; Gutman & Lavarello 2010) Meanwhile, other studies analyzed the biotechnological evolution in developing countries comparing with developed countries' experience (Thorsteinsdóttir et al. 2004; Niosi et al. 2012. Abuduxike & Aljunid 2012). However, less attention has been paid to the role of public policies and specifically to their rationales (Guennif & Ramani 2012. Vargas & Bianchi 2013).

Within this general landscape, a singular case is India. This is a national case which has been studied from the role of policies, its evolution, supporting actors and rationale (Ahn et al. 2012; Watkins et al. 2015; Reid & Ramani 2012; Ramani 2002). These works stress the significance of the State's role in the Indian biopharmaceutical development, and how it was linked to a national strategy of gradual learning to became a global player in the biopharmaceutical market (Kale & Huzair 2015).

Considering this background, the general hypothesis of this paper states that many features of the U.Ss health biotechnology system have been taken as a policy model in the Brazilian public policies oriented to promoted health biotechnology. It is particularly clear through the relevance given in the national explicit policies to create new dedicated biotechnology firms (DBF) and to boost patents of new molecules through university-firm collaboration agreements (Governo Federal 2007 & 2008). These policy objectives was presented almost as the normal way to develop commercial health biotechnology. However, at the same time, public effort were also oriented to boost the national pharmaceutical industry (Palmeira et al. 2012; Pimentel et al. 2013).

In this point it is worth revisited the concept of implicit and explicit innovation policies (Herrera 1973; Galhardi 1994). The later refer to scientific, technological, innovation or industrial policies which explicitly pursue an effect on the biotechnology development. On the other hand, the implicit policies could be any other public policy that implicitly affect the biotechnology development. Typical examples are macroeconomic policies which affect, in one or another sense, the agents' decisions; i.e. the investment decision. In the case of the Brazilian health biotechnology, the more important implicit policy is the national health policy, which regulate the demand and delivery of most health service in Brazil. The universal healthcare system is one of the most relevant social pacts in the Brazilian society after the democracy recovery (Vargas 2009). The BHBIS cannot be understood without considering the Brazilian universal healthcare system.

The second hypothesis of this paper states that the Brazilian health biotechnology policies have been incorporated new policy models both from developed and developing countries. Many of these changes implied a growing concern with demand side policies and public private productive agreement rather than the earlier concern with firm creation and intellectual property rights.

The analysis of the BHBIS is conducted in a comparative and dynamics way. In this regard, the U.S. experience allows a useful comparison to analyze the institutional policy specificities of the BHBIS. Based on the thorough revision of public document and in an extensive fieldwork of interviews, this research stresses the difference between the BHBIS and the U.S. Health Biotechnology Innovation System. It makes possible to analyze the policy rationale and how it has evolved. The period of analysis was defined considering two criteria. First, in 2004 the new orientation of developmental policies was initiated through the launching of the Industrial, Technology and Foreign Trade Policy (Governo Federal 2003) both science, technology and innovation policies and industrial policies. In addition, the analysis end in 2014 because it marks the beginning of the contractive phase of the economic cycle, which can affect the policy design and rationale.

2. THE BRAZILIAN HEALTH BIOTECH SYSTEM

The economical and policy features of health biotechnologies in Brazil has been widely studied during the last 30 years (Anciães & Cassiolato 1985; Guimarães & Vianna 1994; Sant'Ana & Aucélio 2006; Torres-Freire 2014). Brazil has a long research tradition on life science strongly related with medical research and clinic (Weltman 2002). Moreover, there is a significant amount of research groups currently working in modern biotechnology (Bianchi 2012) and there is a small but dynamic number of firms fully or partially dedicated to produce biotechnological products or service for human health (Torres Freire 2014). However, the BHBIS is still weak, particularly regarding cooperation efforts. Inter firm and public private firm collaboration have only recently gained relevance (Chu & Andreassi 2011).

In the last years new and more accurate information about health biotech in Brazil has been produced (BRBIOTEC 2011; Torres Freire 2014; Bianchi 2012 & 2013b; Reis et al. 2010). Even though, the landscape of the BHBIS is still incomplete, it is possible to analyze the main features of five key actors: i) dedicated biotechnological firm; ii) incumbent diversified firm, iii) the State as policy maker and regulator; iv) the research institutions and v) the intermediate institutions (Figure 2).

The number of firm fully or partially devoted to health biotech is not exactly known but, the most recent sources show that there are around 50 active firms working on modern biotechnology for human health (Torres Freire 2014; Bianchi 2013b). Within the private productive agents, there are

incumbent firm, which diversified their production incorporating biotechnological products, and new DBF. The diversified firms are mostly traditional pharmaceutical companies.

The Brazilian pharmaceutical industry has traditionally been a knowledge receptor and a producer of traditional goods. Some of them have shown a innovative pathways. However, it is still a traditional industry. Arguably, one of the main weakness of the Brazilian health related industries is the dependency on imported intermediate inputs, even ones that the local industry is able to produce (ANVISA 2012; ABIQUIFI 2011). This was a structural feature throughout the nineties, accumulating a millionaire trade sectoral deficit (Capanema et al. 2008; Vargas & Bianchi 2013). In this situation, Brazilian biotechnological policies, both form innovation and industrial side as well as form the health side, pointed out the great challenge to take the advantage of biotechnology to boost national production. Recently, some big national firms, which had followed a strategy of "wait and see", are investing in new plants, incorporating biotechnology technicians' teams and production project in this area (Vargas 2009). In addition, new public private agreements have been carried out pursuing an increase in national production (Vargas & Bianchi 2013).

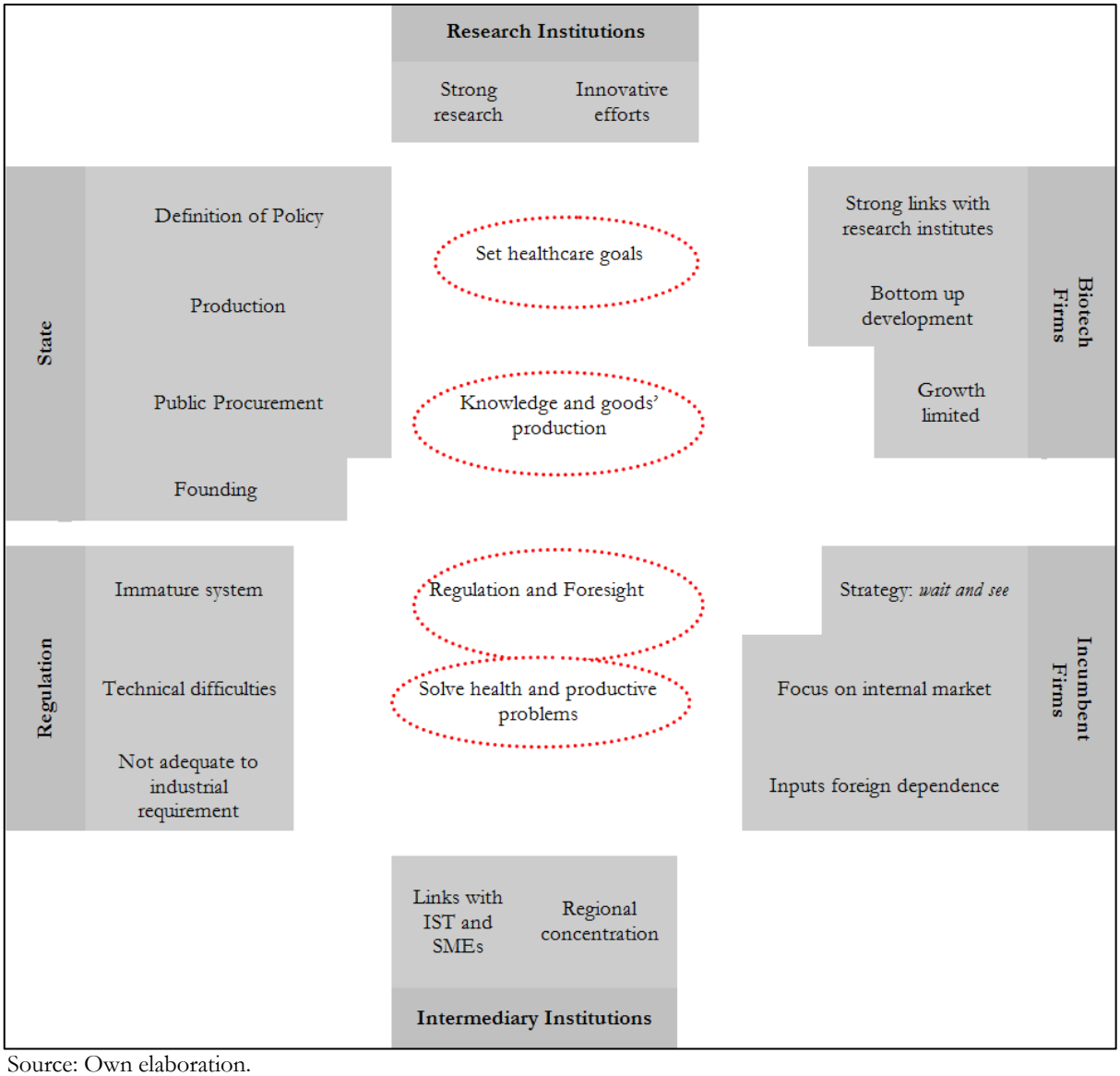
Regarding the creation and development of DBF, earlier works stressed that the biotech development in Brazil is strongly associated to local factors. The main development poles of BHBIS are in the southeast region, mainly in Minas Gerais (MG) and Sao Paulo (SP). Both cases show strong research capabilities and dynamic intermediary institutions. Nevertheless, Fonseca (2009) distinguished between the patterns followed by these states, stressing that in MG prevailed a *Science Park Model,* based on the relationship university-enterprise, and in the upsurge of several start-up firms from the four Federal Universities located at this State that conduct biotech research programs. In this case, the role performed by the Biobrás has had a demonstration effect (Cassiolato et al. 2011). This author notes that in MG university-industry relationships led to a model based on business incubators and start-ups, while SP experience can be characterized as a network-based model. Arguably the best example of this model was the *Projeto Genoma.* This project presents a typical network-model, composed by more than twenty laboratories along all the country and involving hundreds of researchers. Despite the remarks posed above about the scarce results that the genome project reached in the production of new healthcare methods this experience was the base for a networking process between several research institutes and biotech firms located in SP.

A general feature is that, with varying intensity, every biotechnological firms have strong ties of cooperation with universities or research institutes and with foreign institutions. But there are few experiences of collaboration between local biotechnological firms (Rezaie et al. 2008).

On another hand, the Brazilian State is a key actor of the BHBIS. It not only acts as a policy maker and regulator. Indeed the State acts as healthcare services provider, drug producer and buyer. Particularly, the role of public laboratories both in R&D and production activities is one of the basis of the BHBIS (Costa et al. 2014).

Comparing figure 1 and 2, the BHBIS presents the same mains actors as the US biotech system. Nevertheless, there are clear differences in the development of capital markets and IPR regime. This does not imply that the BHBIS does not have financial instruments, but they are mostly concentrated on the public agencies. In Brazil, even the ventures capitals funds are composed by state owned firms that operate in private regime.

Figure 02. Brazilian Health Biotechnology Innovation System.



Source: Own elaboration.

Moreover, the other institutions that compose the BHBIS do not bear great "anatomic" differences when compared to US's. The differences are mostly found on the operation of the system rather than on its composition.

As Figure 2 shows, the BHBIS presents a different level of development (size of grey area) in each of their actors and a relatively weak development in the linkages among the agents. The central circles expose the dynamic dimension of the BHBIS: the expected results, that have been not fully achieved yet. There are many studies that stress a critical diagnosis of the BHBIS (Cassiolato et al. 2011. Marques & Gonçalves Neto 2007. Rezaie et al. 2008). The critical remarks are mainly related to the micro and meso dimensions of Brazilian system, such as regulation and management innovation dimensions. In addition, some authors stressed the disappointment of firm's managers with some public programs that show an academic research bias (Barbosa et al. 2007).

In this sense, several agents stressed the relative low private sector development and to the gap between research capabilities and innovation results. Actually, this is one of the patterns that characterize the biotech development in the peripheral countries is the major strength in the phase of generation of knowledge –research and discovery- rather than in product development and commercialization (Quach et al. 2006). In this general frame, SMEs entrance in the market is relatively easy -through science-push strategies-, but then they found strong difficulties to achieve and conserve a market position as final or intermediate product suppliers.

3. THE BOUNDARIES OF POLICIES

The stylized facts of the BHBIS presented in this paper show many of the goals pursued by public policies during the last decade. To understand the evolution of the policies and their rationale it is relevant considering that any policy is a deliberate effort to impact on economics and society which may confront with several problems through its implementation which, in turn, limit their effectiveness and potentially undermine its legitimacy (Giesecke 2000).

The *limits* that the Brazilian health biotechnology policy confronts can be analyzed considering two main dimensions related to the evolution of policies: i) the change of policy orientation and rationale, ii) that pose new governance's challenges, which, in turn require new coordination with other implicit policies.

Even though the evolution of public policies between 2004 and 2014 has been erratic and even uneven, there is a significant change in the rationale of policies. Since the PITCE proposal until the most recent measures of Public Private Partnership, policies have pursued the explicit goal of

coordinate productive, commercial and technological policies. However, at the beginning of the period this objective was mainly pursued through instruments oriented to create a private supply of biotech, mainly by new DBF and patents. Recently, a demand side policies, articulated with the healthcare goals have been implemented though the public private partnership.

This change, involve a complex transformation on the policy rational that only was partially presented in this paper. Dealing with complexity require high capabilities and more fluent governance resources.

The governance's problems are related to the basic features of biotechnology. Since it is a technology area rather than a economy sector, health biotechnology cannot be pigeonholed in the classical sectoral government structure, for instance, in only a sectoral ministry. It is not a problem, it is mostly a challenge; and probably it is not a new one. Coordination difficulties are as old as the public policy. Nevertheless, it establishes a serious limit to the effectiveness of policies.

Regarding the BHBIS, public governance have to deal with sectoral goals organized in an horizontal manner, mainly to coordinate with the implicit policies of the Healthcare System. Arguably, one of the more relevant aspects regarding public policy effectiveness is related to its coherence with other policies. Recent effort have been focused on health technological public procurement and public private partnership that include pre-commercial public procurement commitment.

Governance problems, basic resource and the articulation of different policies are undoubtedly very important to understand the effectiveness of the policies. However, the real limits of the policies are established by the behavior and preferences of the economic agents, specifically by the firms' behavior. Every policy documents begin with a chapter which exposes the motives that justify the initiative. All of them make –implicit or explicit- reference to the general interest and their relationship with individual benefits, and all of them try to change some kind of organization or behavior in order to pursue the general interest. Obviously, it is very difficult to agree about what the general interest is, and even more complicated is to agree on how to achieve it.

As is well known, policies are based on several assumptions about the agent behavior. The limit of the policies exists because –fortunately- the policies cannot impose rigid rules to the behavior's agent. Then, they can propose incentives to promote or inhibit determined actions.

It is probable that the great difficulties resulting from the combination of social, innovation and industrial policies in a technical environment in permanent change, would lead to new changes In

this regard, the Brazilian health biotechnology policies face strong limits, but the evolution of the BHBIS appears mostly dependent on the state strategy rather than strong local market mechanisms

The limits that can found the policies are well known in developing countries. Nowadays, biotechnology has a relevant place in the public agenda in many of them. This fact shows the expectation to pursue the windows of opportunity that are opening by the emergent technologies. Nevertheless, this hope may end in frustration if the complex dimensions that intermediate between policy design and their effective application are not taken into account.

Finally, as Hopkins et al. (2007) highlight the analysis of these kinds of intermediate problems is a specific issue of the social science research, whose investigators has the responsibility of promoting realistic public expectations, avoiding the association of the biotech paradigm with magical solutions. This is particularly relevant for the underdeveloped countries, which should not find new frustrations in the implementation of development strategies. This does not mean that the technological opportunities should be always regarded as myths or as frustrations. It is clear that the promises of a biotech revolution may be taken with caution by countries with a weak industrial infrastructure.

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O Sistema Brasileiro de Inovação em Saúde Humana: Um ensaio sobre a lógica das políticas públicas

RESUMO

O surgimento da biotecnologia é uma das transformações mais importantes dos sistemas de inovação em saúde. Este artigo visa discutir a lógica das políticas públicas de promoção da biotecnologia para saúde humana no Brasil no período 2004-2014. Com base num exaustivo trabalho de revisão documental e levantamento primário de dados, o artigo salienta como as políticas públicas brasileiras seguiram um roteiro de desigual acumulação, onde convivem diferentes fundamentações teóricas para as políticas, sejam elas explícitas ou implícitas. A análise conclui com a discussão dos limites das políticas publica, salientando duas dimensões que afetam o alcance das mesmas: i) a mudança na

orientação e na lógica das políticas, ii) que coloca novos desafios para a governança, os quais, por sua vez, requerem novas coordenações com outras políticas implícitas.

Palavras Chave: Biotecnologia; Saúde; Brasil; Políticas Públicas.

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