



Actor-networks, interests and boundary objects in the Cuban biotechnology sector and vaccine industry

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Work in progress, please do not quote

Abstract

Which social and political interests have been influential in the creation of the Cuban biotechnology sector? Is it the needs of the national public health system that are being served, is it scientific knowledge production that is given priority, or are commercialization and generation of export earnings the primary objectives? And how are potentially diverging interests mediated and articulated, and how are such controversies settled and resolved? This paper is a first approximation to these questions.

It turns out that the conceptual toolbox of field of innovation system studies is poorly developed for studying such issues, so by way of a criticism of the lack of agency and interest perspectives in the concept of 'institutions' in innovation system studies an alternative theoretical framework is developed based on actor-network theory.

A second field work in Cuba is being planned, and the objective of this paper is to identify some research strategies for that field work.

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Introduction

Empirical rationale

Several authors have studied Cuban science and technology policies, and a few have focused on the biotechnology sector. One of the first comprehensive accounts was provided by Feinsilver (1993), who devoted an entire chapter of her published Ph.D. dissertation to a historical account of the creation of the biotechnology sector. She relates the biomedical initiative to construction of symbolic power by the national leadership. A recent article, Reid-Henry (2007a), locates Cuban biotechnology in a discursive setting, by addressing issues of post-socialism, post-colonialism and transition economies. Reid-Henry's other paper (Reid-Henry 2007b) is about the 'epistemic spaces' and 'experimental milieu' prevailing in Cuban biotech. None of these publications deal explicitly with innovation.

Majoli's (1999) unpublished doctoral dissertation at the University of Havana is a quite detailed empirical study of the sector, but the theoretical perspective is that of social development generally, and not innovation or innovation systems. Thorsteinsdóttir et al. (2004) have in fact studied the Cuban biomedical sector in an innovation studies perspective, and the paper gives a good overview of the field. However, the article format of *Nature Biotechnology* gives little space for a thorough analysis of institutional factors and strategic decisions.

Other authors, like Brundenius (2002), Brundenius & Monreal (2004) and Fernández (1999), are dealing with Cuban S&T policies on a more general level, without treating the biotechnology sector in any detail, if at all.

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Consequently, nobody has performed a detailed study the Cuban biotechnology sector in an innovation perspective. In my view, there is a need to study the governance mechanisms and institutional factors prevailing in the Cuban biotechnology sector, both in order to contribute to our general understanding of innovation systems as such, and in order to enhance our understanding of vaccine innovation for low-revenue markets in particular.

Theoretical rationale

The purpose of this paper is to start to bring together the mutual roles of the ‘institutional’ and ‘organizational’ dimensions of the process of innovation at the firm level. We are rather under the impression that recent studies of innovation, focusing on one or the other of these dimensions, that have indeed allowed a better knowledge and understanding of the highly complex mechanism of knowledge generation, *have, until now, largely remained separated and ignorant of one another.* Coriat and Weinstein (2002), p 273, original italics

Reijo Miettinen, in his critique of innovation studies, states:

[...] system descriptions tend to be content with identifying the relevant groups of actors and their role in the system [...]. As a consequence, the emergence, change and development of the networks and systems, the content of the interactions, the key mechanisms in innovation process (such as trust formation or learning) have been neglected. Miettinen (2002), p 116.

As a way out of the impasse he proposes a more truly interdisciplinary approach inspired by different sociologies of economic institutions, based on dynamics of social relationships, regional studies, science technology and society studies (STS), learning and

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change in working life, and organizations and innovation networks (Miettinen 2002) (p 131).

In line with these authors I am proposing a theoretical framework for studying institutional factors that is based on insights from the field of organization studies, and I am also drawing on actor-network theory, which originated in the STS (Science, Technology and Society) field.

Research methods

The Cuban biotech sector is regarded a sensitive and strategic national asset, and to the average Cuban it is a rather closed part of the Cuban society. To put it briefly, appearing in Havana in 2001 as a national citizen of a close ally of the arch enemy of the Cuban state turned out to be a predictor for a frustrating and time-consuming five month field work. I interviewed whoever agreed to see me at all (and who also kept the appointments that were made), and my pile of documents is on the thinner side and generally wanting of hard facts and statistics. A delay of almost five years for practical reasons has made much of the data in dire need of updating. Working with such patchy data sometimes seems to resemble the task of an archaeologist trying to reconstruct a medieval galley on the basis of a few ancient disjointed planks, plugs and nails. A three-week short, final, wrap-up field work is planned for in January 2009.

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Objective of the paper

The objective of this paper is to define a research strategy for the field work. The aim is to find ways of generating data that could be used to answer some of the questions about actors, power and interests that are raised in this paper.

The present paper will be part of my Ph.D. dissertation with the working title '*Vaccine innovation for low-revenue markets. Technological capabilities in permanent and temporary organizations*'. Main research questions are: How does vaccine development and manufacturing directed at low revenue markets take place? How are technological capabilities in vaccine development and production for low revenue markets created and sustained? What are the risks, main obstacles, challenges and critical scientific, political, economic and organizational factors?

Outline of this paper

After a brief introduction about the Cuban biotechnology sector I present a critique of the concept of institutions used in innovation system studies. The core of my argument is that the field of innovation system studies has put too much emphasis on systemic and structural aspects, and ignored or downplayed the role of human agency and political controversies.

Then I introduce the concept of 'boundary objects', which is based on actor-network theory. The theoretical idea is to study how social interests and power are mediated and articulated by way of concrete texts or artifacts (and even concepts and ideas) that are produced at the interfaces between the main social actors. Boundary objects may be texts,

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like for instance planning documents and research and development contracts, and artifacts, like for instance collaborative research projects. This way the social and political dynamics of the biotechnology sector may be understood.

The following section of the paper is a historical briefing of the fields of science, health and education in Cuba, from colonial through post-colonial to post-revolutionary epochs. This includes a brief account of how the biotechnology sector was created from 1981 and onwards.

Then I proceed with identifying the main actors that potentially influence on the biotechnology sector. Core actors are the State Council, the different Ministries, consultative entities, the Communist Party, the Scientific Pole, and of course the research and production centers themselves. I also present the social or political *interests* that these actors may potentially represent.

The paper ends with sketching out two complementary strategies for the wrap-up field work in Havana that is under planning.

The Cuban vaccine industry and biotechnology sector – an overview

The Cuban vaccine industry is an integral part of a larger complex of organizations working in the field of biotechnology, the so-called Western Scientific Pole (hereafter ‘the Scientific Pole). As of 1997 there were 15 scientific poles altogether in Cuba, of which this one is dedicated to biotechnology.

The most important of the institutions of the Scientific Pole are located in a western suburb of the capital of Havana. In 1997 some 12,000 workers were employed, of which 1440 were researchers, and 4046 held university degrees (CITMA 1997). Biotechnology

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now ranks among the top three foreign exchange earners of Cuba, along with bauxite and sugar. The vaccine industry is not a delimited sector, but an integral part of the Scientific Pole. Several centers fulfill different tasks in vaccine development and production.

The biotechnology venture was initiated by a pilot project in 1981, when a small group of researchers managed to produce recombinant interferon in record time. Since then some US\$ 1 billion has been invested in the biotechnology sector. The vaccine industry started off somewhat independently, but simultaneously, when the Institute for Hygiene and Epidemiology started to develop a meningitis vaccine in its combat against an epidemic in the 1980s (Valcarcel, Rodriguez and Terry 1991).

In parallel a legal framework has been developed, with patent legislation in operation since 1983, and a drug regulatory agency gaining increasing independence over the same period (Ratanawijitrasin and Wondemagegnehu 2002). An important historical precondition for the biotechnology (and vaccine) industry has been the Castro regime's steady and high priority for health, science and education ever since its takeover in 1959.

Governance of the biotechnology sector

In my view, the key words to understanding what may be called the three axes of governance of the Cuban biotechnology sector are *actors* and *interests*. These concepts are not widely used in innovation system studies literature, so in the next section of the paper I will spend a few pages discussing them against the traditional notion of *institutions* found in that literature.

The governance of the biotechnology sector follows several different axes. First and foremost, the five core research and production centers are under the direct control of the

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State Council,² which is at the core of the political leadership in Cuba. To its support the State Council has established a consultative entity called The Biological Front.

The second axis is the Government. All the other organizations in the Scientific Pole belong to different ministries, primarily the Ministry of Public Health and the Ministry of Science, Technology and the Environment. The third axis is the Scientific Pole itself, as well as other integrative structures, which was briefly described above. All these axes relate directly to specific organizations, that is, to identifiable, discrete *actors*.

There are several different motivations or *interests* that have influenced on the establishment of the biotechnology sector. At the base one finds the emphasis on education, science and health that was declared by the revolutionary government from the very beginning. However, priorities emanating from public health concerns do not necessarily coincide with strategies that emphasize scientific development, be it in health or other fields. Education is clearly a facilitating factor in building up a R&D intensive sector, and it must be asked to what extent the educational system has been designed to meet the workforce demands of the biotechnology sector.

Next, Feinsilver (1993) has argued that a driving force behind the development of the Cuban health system and the biotechnology sector has been to foster the ‘symbolic power’ of the political leadership. Finally, economic interests have played a role, and on the ‘output side’ the biotechnology sector has been expected to be both an import substitution producer and a foreign currency earner. Evidently, on the ‘input side’ issues of cost and investment must have been considered against investments needs in other sectors of the national economy.

² The State Council: El Consejo de Estado.

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The next question then, is how the interests of the different actors are articulated and mediated. What phenomena can be found at the interface or boundaries of the organizations that operate in this field? So far I have identified two governing tools, namely the Research Programs and the annual research and production plans. Below I wish to explore the role that these instruments have in mediating potentially conflicting interests concerning the strategies and activities of the research and production centers, but first a theoretical discussion is needed.

A critique of the concept of institutions in innovation system studies

Institutions

A core concept in the innovation studies literature is the concept of ‘institutions’. The basic thesis is that the institutional ‘set-up’ influences on and therefore explains the different outcomes of economic activity in different sectors, nations or regions. Institutions are commonly defined as sets of common habits, norms, routines, established practices, rules, or laws that regulate the relations and interactions between individuals, groups, and organizations (Edquist 2005). There can be no doubt that these factors are highly influential in structuring the agency of firms and organizations in a society. The problem with this definition is that it is so heterogeneously composed that it risks becoming meaningless. Let me sort out the different elements.

Laws appear in the form of texts, and are results of some sorts of formal political procedures, usually by the national legislative. Rules may be written or not, but according to this definition the informal procedures of a national arbitration service are on level with the ‘please keep the door shut’ sign on a shop floor. ‘Norms’, in turn, belong in the

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discursive realm, and ‘established practices’ and ‘habits’ are somehow related to human action. I fail to see what these phenomena have in common, except that they in different ways structure human agency. The lack of a clear actor perspective is also visible: Whose rules are in question? Whose norms? How were they established? For which purposes? To the benefit of whom? Whose habits? Whose routines?

In my view it is not quite sound to say that these phenomena are on the same level in a way that would warrant the common term ‘institutions’. From a theoretical perspective I would rather regard these phenomena more loosely as *institutional factors*. Such factors should be understood in terms of concrete actors, their interests and power, the various discourses that are in play, as well as the interfaces between the organizations where innovation (processes) take place and the (local, regional, national or international) organizations that influence on their agency.

From the perspective of my present research project it must be added that it is in fact difficult to tell micro from macro, or ‘context’ from ‘text’, so to speak. Since the organizations operating in the Cuban biotechnology sector are all owned and governed by the state it is difficult, if not right-out meaningless, to try and tell where the organizations end and the contextual ‘institutions’ start. Let me quote Miettinen again:

In a local network, actors are present on all levels: an international partner or client represents the global dimension [...], and the representative of a funding organization represents a national institution [...], a supplier represents a relationship characteristic of a cluster, and a collaboration of a firm and a research group industry/university interaction. Therefore, it can be stated that a local network of actors can be regarded as a unit, in which the representatives of national

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(and international) institutions are interacting to achieve something, and in which the tensions and bottlenecks of an activity and its rules become visible in a concrete manner. For that reason a careful analysis of an innovation network can tell much of the conditions and workings of the innovative activity. Miettinen (2002), p 121.

In other words, what is needed is a conceptual framework that is not based on the micro–(meso)–macro distinction.

Human agency, power and political interests

My next criticism of innovation system studies is that it lacks any systematic understanding of agency, power and social or political interests. Its systemic approach is mainly focused on learning processes, and of evolving institutional set-ups, but less is written about human agency, either on the individual or organizational level. Consequently, conflicting interest groups and use of and creation of power are phenomena that also remain invisible, and so are the dynamics of social and political interests and their consequences for the very (innovation) systems that are at the core of the analysis.

Struggle and resistance to change (i.e. innovation) is regarded as ‘inertia’, ‘lock-in’ or ‘trajectory dependency’, and social harmony seems to be the natural state of society.

Interactive learning, including elements of creative forgetting, may be seriously hampered if, for example, the norms and habits of workers make them reluctant to communicate and cooperate with other ‘levels’ of the firm. Factors like trust and legitimacy, which may depend on institutional factors like participation and job security, as well as suitable procedures for reaching compromises, are important

here. Tight and intense work supervision might reduce workers' willingness to interact positively in an innovation process. Traditional barriers between different skill groups and conflicts over the distribution and income, both in individual firms and in society at large, tend to make communication more difficult. Johnson (1992)

Is it always the case that the workers have common interests with management in developing new ('novel') products and processes? Isn't it a legitimate position for a worker to be unwilling to 'process innovate' himself out on the street, for instance? Is management *always* right in their strategic decisions? Is 'cooperation' just a matter of management's ability to communicate and convince? Is it really unimaginable that the much acclaimed hands-on 'tacit' knowledge of the production workers could make them capable of critically evaluating and even actively opposing plans and strategies emanating from the 'fog attic'.³

As an illustration of the lack of actor perspective in innovation system studies I made a crude 'bibliometric' analysis of the subject index of 'The Oxford handbook of innovation' (Fagerberg, Mowery and Nelson 2005). The purpose is to demonstrate the relative importance of different kinds of phenomena in innovation system studies. I selected some terms and divided them into three categories: 1) system-related concepts, 2) agency-related concepts, and 3) interest-sensitive concepts. Then I counted the number of entries of each term, and displayed them in Table 1 in diminishing order.

'Innovation' is counted primarily as a benchmark. System-related terms like 'diffusion', 'networks' and 'economic growth/development' are frequent, but I am a bit surprised that 'regulation' and 'cooperation' are so rare. Other frequent system-related terms are

³ The 'fog attic' is the literal translation of the Norwegian expression 'tåkeloftet'. In Norwegian industrial workplace discourse it means company direction in general and its 'strategy' or 'quality management' department in particular.

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‘service sector’, ‘intellectual property rights’, and ‘catch-up’. Perhaps a bit surprising is the modest score of 18 for ‘institutions’. Could that term be less important in practical innovations system research than its theoretical status seems to suggest?

Table 1. Number of entries of selected terms in the subject index of ‘The Oxford handbook of innovation’ (Fagerberg, Mowery and Nelson 2005).

| System related concepts | | Agency related concepts | | Interest-sensitive concepts | |
|------------------------------|----|-------------------------|----|-----------------------------|----|
| innovation | 93 | firm | 47 | employment | 52 |
| diffusion | 92 | government | 19 | capitalism | 8 |
| economic growth/development | 76 | entrepreneur | 11 | labor market | 7 |
| organizational innovation | 74 | leadership | 10 | labor mobility | 5 |
| networks | 69 | decision making | 9 | unemployment | 4 |
| catch-up | 63 | management | 7 | wage polarization | 4 |
| technology/technological* | 58 | organization | 6 | trade unionism | 3 |
| service sector | 43 | ownership | 4 | arbitration | 0 |
| systems of innovation | 43 | Actor-Network Theory | 1 | class | 0 |
| intellectual property rights | 35 | corporate change | 1 | conflict | 0 |
| innovation processes | 33 | corporate finance | 1 | consumers | 0 |
| sectors | 21 | agency | 0 | cooperation | 0 |
| institutions | 18 | actor | 0 | corruption | 0 |
| clusters | 13 | capabilities | 0 | down-sizing | 0 |
| structural holes | 4 | CEO | 0 | environment | 0 |
| regulatory systems | 1 | corporate management | 0 | exploitation | 0 |
| legislation | 0 | department | 0 | industry associations | 0 |

| | | | | | |
|------------|---|-------------|---|-----------|---|
| regulation | 0 | division | 0 | interests | 0 |
| | | failure | 0 | lay-offs | 0 |
| | | ministries | 0 | poverty | 0 |
| | | power | 0 | profits | 0 |
| | | shareholder | 0 | strike | 0 |
| | | strategy | 0 | wages | 0 |
| | | subsidiary | 0 | | |

* All entries of expressions starting with 'technology' and 'technological' were counted.

On the other hand, all terms that would imply or underscore agency are relatively rare; even 'entrepreneur', so central to the late, now almost iconic, Joseph Schumpeter, occurs only 11 times. 'Power' and 'strategy' are absent.

In fact, in the world of innovation system studies there seem to be no actors operating inside the firm itself, although 'firm' has 47 entries. The term 'CEO' or 'chief executive officer' does not appear at all, neither does 'shareholder', 'subsidiary', 'department' and 'division'. Terms starting with 'corporate', as well as 'ownership' and 'management' have very low scores. Although Lam's {, 2005 #955} contribution to the volume deals with organizational innovation specifically, her focus is mainly on organization *structures* and (systemic) knowledge creation, and not on agency and strategy.

Terms that are more sensitive to politically contested matters are virtually absent. The three entries for 'trade unionism' all occur in the same chapter (Lazonick 2005), and 'industry associations' are missing. And while the pleasant 'employment' has 52 entries, unpleasant '*unemployment*' has only four.

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This little subject index survey is based on the relatively safe assumption that the 'Handbook' is 'canonical' and representative of the field of innovation system studies. It is possible that some terms that are omitted in the subject index still can be found somewhere in the 600 plus page volume, but in my view the omission in itself would be indicative of the lack of importance that is attributed to those concepts. I would like to add that a swift look at the subject indices of for instance (Mowery and Nelson 1999) and (Malerba 2004) seem to give similar results.

This is symptomatic of a theoretical universe that has ended up ignorant to important social phenomena: agency is heavily downplayed, while the lack of sensitivity to politically contested phenomena is in my view tantamount to passively taking side politically. By assuming such matters as unproblematic or non-existent the field of innovation system studies in fact risks to unconsciously ally itself with some very particular political interest, namely those of economic growth oriented, high level public bureaucrats, corporatist labor movement leadership, and of course, the capitalist class.

For the practical purposes of this paper the need for concepts that can capture agency and political and social controversies is becoming evident. But I would like to add that it has been argued on a more theoretical and less political basis that the system approach in innovation systems studies rests on very weak conceptual foundations. As mentioned above, Miettinen (2002) (p 58) proposes a more truly interdisciplinary approach based on other disciplines of the social sciences, among them the sociology of science and technology, to which actor-network theory has made some important contributions.

An alternative approach

Interestingly, a national innovation system was originally defined as

[...] a *network* of institutions in the public and private sectors whose activities and interactions initiate, import, modify, and diffuse new technologies. Freeman (1987), quoted in Miettinen (2002) p 41, italics added

In order to construct an alternative conceptual framework for understanding ‘institutional’ phenomena I wish to draw on actor-network theory. It must be added that it is a realist interpretation of early actor-network theory (Plahte forthcoming), based primarily on Latour (1987) and Law (1992), that will be applied here, as well as Star & Griesemer’s (1989) concept of boundary objects.

The basic idea in actor-network theory is that actor-networks are emergent results of heterogeneous resources (humans, texts, artifacts, natural objects and hybrids of these) being ordered in particular ways. The *actors* try to mobilize, translate and enroll heterogeneous resources into a network that serves their own particular *interests*. For instance, one can say that organizations, being constituted by members or employees (humans), technological equipment (artifacts), mandates or constituting documents (texts), and financial resources (hybrid of artifact and text) are one particular kind of actor-networks.

Actor-network theorists have their own tribal tongue, for which I intend to spare the reader. On the contrary, it is my aim to make actor-network theory as invisible as possible in the following; it will be used primarily as a tool for defining and

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conceptualizing the terms that will be used in my analysis. For instance, the concept of the 'boundary object' is based on actor-network theory in such a way.

Boundary objects

The concept of 'boundary objects' was introduced by Susan Leigh Star and James Griesemer (1989) and is defined as an object that is capable of bridging organizational and disciplinary boundaries in its capacity of being meaningful to the different actors, *but not unambiguously so*. Its interpretation is both sufficiently robust to structure the collaboration between the actors, and sufficiently flexible to allow the different actors to enroll it and use it in their own strategies and pursuits of their respective subjective interests. A boundary object is given a sufficiently common interpretation by the different actors to allow for a coordinated effort, but requires no 'deep sharing' of meaning. A boundary object may be a human (or the position that is occupied by a human), a text, an artifact or a natural object (Nicolini, Mengis and Swan 2007; Star and Griesemer 1989).

Since a boundary object is subject to different interpretations, it may also be subject to controversies and disputes between the involved organizations. What should be the shared meaning of it? Thus, a boundary object simultaneously mediates collaboration *and* provokes debate and controversy.

By identifying boundary object in a field of study it becomes possible to identify the subjective interests of the involved actors, and it becomes possible to understand how collaboration is mediated. It also becomes possible to identify what issues, goals and interests that are at stake in a compounded work process. The idea is that one or several boundary objects can be identified at the interface(s) between two or more actors.

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In my view, the boundary object may also be a determinant of spatial organizational patterns. It may be imagined that some boundary objects are more easily constructed in a collaboration that stretches across long physical distances than others. I will, however, not elaborate on this issue any further in this paper.

The danger of using the boundary object concept is that one could risk writing about the boundary object in its own right, thereby committing fallacies of reification and fetishisation. The objective of applying the concept must be to say something about the actors and the social processes they engage in by means of identifying the boundary objects that structure their interaction.

Interestingly, Miettinen has in fact employed a variant of the concept of boundary objects in his analysis of how the concept of National Innovation System (NIS) became the theoretical foundation for the science and technology policies in Finland. In his view, NIS worked as a boundary *concept*, which made

[...] it possible for people with different backgrounds and from different institutions to speak of the same issue and still maintain their own world-view and intentions. Miettinen (2002), p 139

Boundary concepts are

[...] loosely defined concepts which, precisely because of their vagueness, are adaptable to local sites and may facilitate communication and cooperation.

Miettinen (2002), p 139

So obviously, in spite of their theoretical weaknesses, ‘fuzzy’ concepts have their virtues too.

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Actor-network theory, boundary objects and institutional factors

In order to capture the different elements of ‘institutions’ I have introduced a conceptual framework based on actor-networks, interests and boundary objects. Laws and regulations (texts), the organizations (actor-networks) that enforce them (drug and IP regulatory agencies for instance), and the educational system (actor-networks) make up the social context of the Cuban biotechnology sector. The different branches of the government (other actor-networks), use research and production programs and annual plans (texts and boundary objects) in their governance of the individual organizations. In my research I will try and identify other boundary objects, like for instance specific R&D projects, at the interfaces of the organizations that comprise the Scientific Pole.

One ‘class’ of institutional factors is omitted here, namely the discursive, or cultural, aspects. Studying such phenomena would have required an ethnographical method, which for practical (or rather political) reasons proved to be unfeasible for me to undertake in the Cuban biotechnology sector.

This conceptual framework also captures the agency dimension that I demonstrated was missing in much innovation system studies literature. Actor-network theory contributes to explaining how actors are constructed, and its emphasis on interests helps zooming in on political and value-dependent issues and controversies. (But beware: actor-network theory has also been criticized for its lack of reflection about political issues (Fuller 2000)).

The history of the biotechnology sector

This paper is not just about how a biotechnology sector is governed, it is also about how the organizations of which it is composed were created. An important strategy of the Cuban leadership has been massive expenditure and investment in education, science and health. A much cited Fidel Castro quote from 1962 goes like:

The future of our country is by necessity a future of men of science [...], because that is exactly what we are sowing; [...]. Sáenz (1990), p 110

But Cuban science did not start from scratch in 1959. Although illiteracy was widespread and rural health services poorly developed (or almost non-existent), the country does have pre-revolutionary antecedents in these fields, which are regarded as part of the national heritage. Let us have a brief look at these fields in pre-revolutionary Cuba.

Science

One of the first universities in the New World was founded in the city of Havana in 1728 (García Capote and Sáenz 1989). In spite of limited resources and lack of interest on part of the colonial power, there seems to have been a vivid and internationally updated scientific community in Cuba in the second half of the 19th century. For instance, Charles Darwin's theories were actively debated, and even some original ideas and opinions were developed (Pruna 1984; Pruna 1994).

In 1901 the Cuban scientist Carlos J. Finlay (1833-1915) in cooperation with Walter Reed of the US established that the mechanism of transmission of yellow fever was by way of the mosquito species *Culex* (García Capote and Sáenz 1989).

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In 1937 the University of Havana founded its first research centre; the Institute of Tropical Medicine. In the neo-colonial period (1902–1959) this was the only Cuban research organization to gain an international reputation (anon. 2004). In 1951 a foundation for cardiovascular disease research was founded by Agustín Castellanos, who was subsequently nominated for the Nobel Prize in medicine. This was however closed in 1960, when its founder left the island (anon. 2004). In 1958 there were only 21 registered scientific and technological organizations in Cuba, the majority of which was connected to agriculture, and the few universities that existed did not conduct any research (Fernández 1999).

To sum up, Cuban has a long tradition of science and intellectual life dating back to the 18th century, with a few but quite spectacular accomplishments, in particular in medicine. These achievements seem to have been results of individual excellence rather than organizational strength, since the research organizations seem to have been small and poorly funded.

Health

By the end of the 19th century there were four health systems in operation in Cuba; the state hospitals, the private clinics, the mutualist (cooperative) clinics, and the military hospitals. However, during the independence war 1895-8, which ended by the military invasion by the USA, the health services were left in shambles (Figueras and Pérez 1998).

From 1898 the US occupant administration embarked on a program of hygiene and sanitation, which resulted in eradication of killers like smallpox, bubonic plague and

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yellow fever, and dramatically reduced mortality rates of these diseases to the level of among the lowest in the world (Figueras and Pérez 1998). Cuba had a higher physician density than most other Latin-American countries at that time, although they were highly concentrated in the capital.⁴

In the first part of the 20th century the mutualist movement, based on paid membership, continued to grow out of the ethnic Spanish societies. Some labor unions also operated mutualist clinics, most notably the Transport Workers Union of Havana, by which the blacks in 1938 for the first time were included in a mutualist scheme. The mutualist movement was confined to the large cities, with a heavy concentration in the Capital (Feinsilver 1993) p31.

Thus, the health status of the Cuban population in the 1950s, in particular in the rural areas, was characterized by malnourishment, high prevalence of tuberculosis and parasitic diseases, infant mortality rates of 79 per 1000, and virtually no access to affordable medical services (Figueras and Pérez 1998).

The encounter of Fidel Castro's insurrectionist army with such poverty convinced the leadership – several of whom were physicians, like Ernesto “Che” Guevara – about the importance of public health services, and soon the Castro movement provided free medical services to the peasants in the areas under its control (Feinsilver 1993) p32.

Education

In 1958 of a population of about 7 million only there were almost a million illiterates, and only half of the children attended primary school (García Capote and Sáenz 1989; NHSB

⁴ Personal communication with Pedro Marino Pruna Goodgall, 30 June 2001.

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1999). In the late 1950s about 10,000 Cubans had a degree in scientific or engineering disciplines, half of whom left the country shortly after the revolution (Fernández 1999).

Revolution in health and education

This was the situation confronting the revolutionary government in 1959: Long scientific traditions, but weak organizations. A disintegrated health system concentrated to the large cities. Widespread illiteracy and a politically motivated brain drain. And poverty.

The immediate response was meeting basic needs. The internationally awarded literacy campaign that was initiated by the Castro government in 1961 soon raised literacy levels.

The initial period after the takeover also witnessed some ambitious nationwide public health interventions, and a universal, national public health system was created (Figueras and Pérez 1998). In the first mass vaccination campaign in 1962 an oral polio vaccine was distributed to all children under 15 years of age, reaching a rather impressive coverage rate of 87.5%. Repeated campaigns have resulted in the virtual eradication of polio in Cuba since 1963 (Más Lago 1999). Tuberculosis incidence rates were reduced by 63% by introduction of BCG vaccines and chemotherapy (Marrero et al. 2000). Also malaria was soon eradicated, and the incidence of tetanus and diphtheria was significantly reduced (Más Lago 1999).

Also long term measures were taken. By August 1960 there were only 19 professors left at the Faculty of Medicine at the University of Havana (Figueras and Pérez 1998). In 1962 the University of the Oriente (in Santiago) established its School of Medicine, and the Instituto Superior de Ciencias Básicas y Preclínicas 'Victoria de Girón' in Havana was created as a medical school and an organization for education of cohorts of medical

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professors, who in turn were deployed as teachers as new medical schools were founded in other cities (Figueras and Pérez 1998). Decentralized medical training commenced in 1968, by establishing several medical schools in the major urban centers of the island (Feinsilver 1993) p 33, (Figueras and Pérez 1998) p 53. The number of physicians has increased from 6,152 in 1970 to 64,863 in 1999. The density is one medical doctor to every 172 persons living in Cuba (NHSB 1999), p 76.

Today the number of university graduates in the workforce can be calculated to about 460,000 based on the figures in Table 2. Since the Revolution some 74,648 medical doctors have received their licenses in Cuba, almost half of which during the 1990s (NHSB 1999). Similarly, in chemistry, biochemistry, biology, microbiology, nutrition and pharmacy, the other professions that dominate the Scientific Pole centers, a total of 14,837 have been graduated since 1959, of which 7023 during the 1990s.⁵

Table 2. Educational attainment of the Cuban labor force, 1953, 1978, and 1998. From (Brundenius 2002).

| Year | Total workforce (000) | University degree | At least upper secondary | At least lower secondary |
|------|-----------------------|-------------------|--------------------------|--------------------------|
| 1953 | 3,487 | 1.5 % | 4.5 % | 12.4 % |
| 1978 | 2,540 | 3.9 % | 20.2 % | 46.4 % |
| 1999 | 3,826 | 12.8 % | 52.7 % | 83.0 % |

Which *interests* lay at the basis for this political strategy? To a high degree the Cuban government measures its success in terms of basic, but somewhat crude, health

⁵ Statistics provided to the author by the Ministry of Higher Education, 2001.

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indicators: Low infant mortality rates, low general morbidity rates, and high average age of death (Feinsilver 1993).⁶ And although education has been a strong political interest in its own right, it is fair to say that the system for higher education has made high priority for the professions that would support the health system, the medical sciences and auxiliary disciplines: The above figures show that almost 90,000 out of a total of 460,000 university graduates fall in these categories.

The first research centers

During the 1960s and early 1970s some 100 research centers were established at the universities, at the ministries and at the Academy of Sciences (Fernández 1999). Of these there are some important research centers in medicine and related disciplines that would be of great importance in the later development of the biotechnology sector.

While ‘Victoria de Girón’ educated medical professors, the National Center for Scientific Research (CNIC), established in 1965, served a similar purpose in disciplines related to biomedicine, with research activities and training of scientists in physics, chemistry, biochemistry, biophysics, microbiology, mathematics and computer science (Bravo 1998).⁷

The same year 10 centers dedicated to research into the most important medical disciplines were established. Some of these were based on former hospital departments. The mandates were threefold: research, tertiary medical service, and education in medical specialties (2004; Figueras and Pérez 1998).

⁶ The concept of average age of death is more commonly known as the more confusing term ‘life-expectancy at birth.’

⁷ Personal communication with Emilio García Capote, July 3 2001.

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In other words, Castro's (unfortunately somewhat sexist) slogan about 'a future of *men* of science' was no empty phrase. It becomes evident that at a very early stage the revolutionary government was laying the foundations for a national medical science and technology base in the broadest sense, with almost exclusive use of national human resources, but at the service of a national public health system. The emerging picture is that of a highly integrated system of health, science and education. Now it was time to add biological and pharmaceutical production.

The morbidity and mortality transition

By the 1970s the morbidity and mortality patterns in Cuba were starting to resemble those of countries in the North rather than the South. The infant mortality rate fell from 38.7 per 1000 in 1970 to 19.6 per 1000 in 1980, and heart diseases and cancer were replacing infectious diseases as major causes of death (NHSB 1999). Simultaneously, in order to further reduce the infant mortality rate, congenital disorders would have to be addressed (Feinsilver 1993). It was becoming evident that the traditional public health interventions like immunization and sanitation were inappropriate in the efforts of further improvement of the general health indicators. A need for high-tech health interventions like for instance mass screening based on genetic markers and cancer treatment based on modern immunology and genetics was emerging.

The biotechnology initiative

Simultaneously, genetic engineering was becoming a promising technology for health interventions. Inspired by a visit to Cuba in 1978 by the US cancer specialist R. Lee

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Clark, Castro decided to initiate a pilot project in interferon production. In early 1981 Kari Cantell of the at the Finnish Serum Institute in Helsinki was surprised by a request made to him by the Cuban embassy in Finland, asking whether his Interferon Laboratory would kindly receive a delegation of Cuban scientists for training in production and purification of human leukocyte interferon. At that time interferon was hailed as a potential 'magic bullet' against both cancers and viral diseases, and Cantell's lab had earned a reputation as a world leader on interferon research. Six Cuban scientist stayed with Cantell for a few weeks, and back in Havana the group produced interferon in its own laboratory just a few months later (Cantell 1998). In less than two years the Cubans were producing recombinant interferon for use in clinical trials, and soon several research and production centers were under construction in what must be one of the most ambitious programs for public sector biotechnology development yet to be seen on this planet.

The interferon pilot project was converted into a permanent research center, the Centre for Biological Research (CIB).⁸ In 1992 the flagship organization of Cuban biotechnology, the Centre for Genetic Engineering and Biotechnology (CIGB),⁹ was inaugurated, which has its main focus on recombinant technologies in vaccines as well as in other fields of medical, industrial and agricultural biotechnology.

The Finlay Institute evolved out of a meningococcal vaccine development project that was initiated in the late 1970s to combat a meningitis epidemic. The institute has several processing lines for bacterial vaccines, and heads the national program for human and veterinary vaccines.

⁸ CIB: Centro de Investigaciones Biológicas.

⁹ CIGB: Centro de Ingeniería Genética y Biotecnología.

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Together with these three organizations two other centers make up the core of the Scientific Pole: The Immunoassay Centre (CIE)¹⁰, which develops and produces a range of diagnostics, and the Centre for Molecular Immunology (CIM)¹¹, whose research and product portfolio is geared towards cancer in general and monoclonal antibodies in particular. These five research and production organizations are governed directly by the State Council.

Other centers play a more auxiliary role. BioCEN specializes in production of vaccines and a range of other biologicals. The Institute for Tropical Medicine 'Pedro Kourí' does research in a range of infectious diseases, and performs clinical trials on vaccines. The Center for Laboratory Animals (CENPALAB), which was created as early as in the mid 1980s, produces laboratory animals to the other centers in the biotechnology sector.

In short, the 38 units comprising the Western Scientific Pole include several research and production centers, a number of research institutions, two faculties of the University of Havana, a consultancy agency, the national drug regulatory agency, a hospital, the national blood bank, and more. The Scientific Pole is a cross-sectoral organization, in that the member institutions belong to eight different ministries as well as the State Council. The main tasks of the scientific poles are coordination, cooperation and strategic planning (CITMA 1997).

The pharmaceutical industry

A few paragraphs about the role of the Cuban pharmaceutical industry in the creation of the biotechnology sector are relevant. In 1959 the Cuban pharmaceutical industry

¹⁰ CIE: Centro de Inmunoensayos.

¹¹ CIM: Centro de Inmunología Molecular.

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consisted of some 110 private nationally owned laboratories and about 10 branch plants of US multinationals (Lilly, Pfizer, Lederle, etc.). During the 1970 the by then nationalized activities were concentrated to a total of 14 laboratories, in which investments were made for increased productivity and product range with the main aim of generics manufacturing for import substitution. Today about 70% of the approximately 1500 different pharmaceuticals that are licensed in Cuba are produced nationally, and there are 54 licensed pharmaceutical manufacturing establishments in the country (Figueras and Pérez 1998; Ratanawijitrasin and Wondemagegnehu 2002).¹²

Perhaps surprising, the link between the pharmaceutical industry and the biotechnology sector does not seem to be particularly strong. Cuban sources seem to view the biotechnology initiative as a sector that was developed independently of the pharmaceutical industry (Bravo 1998; Figueras and Pérez 1998). Granted that the chemical technologies that are used in traditional pharmaceutical production are very different from biotechnology. As a consequence the pharmaceutical industry is dominated by professions like chemists and pharmacists, while in the biotechnology sector biochemists, microbiologists and physicians predominate.¹³

Yet, by the 1970s the Biological Products Company “Carlos J. Finlay” (not to be confused with the Finlay Institute) produced tetanus, diphtheria, smallpox, BCG, and rabies vaccines, as well as culture and diagnostics media. So it is reasonable to assume that the biotechnology industry benefited from having a pool of labor trained in pharmaceutical production at its disposal, a prominent example of which is the pharmacist and member of the Cuban Politburo Ms. Concepción Campa, who worked at

¹² Personal communication with Celeste Sánchez, CECMED, May 29 2001.

¹³ Personal communication with Celeste Sánchez, CECMED, May 29 2001.

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the above “Carlos J. Finlay” factory prior to heading the group that invented the Cuban meningococcal vaccine.¹⁴

The main actors, their interests, and boundary objects

It is time to identify the main actors that influence on and determine the priorities for the research and production organizations that constitute the core of the biotechnology sector. Below I present the different main actors, and I make some hypothetical assumptions about their main *interests*. Then I move on by identifying possible boundary objects, and I also introduce the theoretical concept of ‘obligatory passage points’. The focus is on preparing questions and issues for further investigation for the final field work in Havana in 2009.

Interested actors

Firstly, there are the research and production centers themselves. A core idea about these centers is the integration of research and production under the same roof and within the same organizational entity. The purpose is to strengthen the links in the innovation line, that is, to facilitate that the results of the research activities would proceed along the line through development, to pilot production, pre-clinical and clinical testing, and finally commercial production. It has been debated whether this ended up sacrificing basic research to the advantage of applied research (Bravo 1998; Feinsilver 1993), but that is outside the scope of this paper.

¹⁴ Personal communication with Franklin Sotolongo, Finlay Institute, September 4 2002; and with Celeste Sánchez, CECMED, May 29 2001.

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There are potentially two main *interests* that could emanate out of such an organization, and those are research for the sake of *knowledge production*, and *income generation*. The latter interest could be further subdivided in *commodity production*, *joint ventures creation*, and *selling technology* as such. And the commodity production could potentially be directed at *meeting domestic demand*, be it by *substituting imports* or *supplying unique Cuban products*, or directed towards *export production*. We are getting the feeling that there should be some potential for strategic controversy in this material.

Secondly, the most powerful actor is undoubtedly the State Council. Formally, the State Council functions as the working committee of the National Assembly in the five year terms between its sessions. It is headed by the President, who is also both Chief of the State and Chief of the Government.¹⁵ Earlier this year Raúl Castro succeeded his brother Fidel in this position. In spite of its formal status as the executive branch of the National Assembly, in my view the State Council rather resembles a personal secretariat for the President. This is the body where the major national strategic decisions are made.

It must be added that one of my sources¹⁶ has made an in-passing reference to a so-called ‘consejillo’, *i.e.* literally a ‘little council’, which seems to be another entity involved in the governance of the Scientific Pole. It is possible that this is another term for the ‘Pole Office’ at the State Council. This issue has to be clarified in my further research.

In order to provide analyses of scientific and technological trends and strategic advice to the State Council, the Biological Front was created by Fidel Castro in 1981 as an advisory and policy making body made up of a number of prominent Cuban scientists. This think-tank is (by 1998) led by Ms. Rosa Elena Simeón, Minister of Science,

¹⁵ Chief of the State: Jefe de Estado

¹⁶ Personal communication with José de la Fuente, March 11 2002.

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Technology and Environmental Issues and former President of the National Academy of Sciences, and played a pivotal role in founding and designing the main biotech centers. (Bravo 1998; Feinsilver 1993).¹⁷

Granted that such a construction holds the potential of becoming just a hostage to the caprices of a powerful president. However, this is not my impression of the Cuban case. On the contrary, it seems like this entity to a high degree has been functioning as intended and contended. If that is the case, it must be assumed that the State Council has been under influence by representatives presenting a range of *interests*, the details of which can only be disclosed by looking at the composition of the Front and at the documents that have emanated from it.

Thirdly, the Ministry of Health is said to play an important part in defining and communicating the needs of the national public health system. A user–producer interaction between the Ministry and the biomedical sector has been identified (Thorsteinsdóttir et al.), so the issue is rather about the importance of the *interests* emanating from its political goals of disease prevention, diagnosis and treatment, *relative* to the interests of the other actors.

Fourthly, there are the interests of the other ministries, in particular those that govern the other research and production centers in the Scientific Pole. It is possible that the Ministry of Higher Education, which is formally in control of four of the research centers in the Scientific Pole, would advocate issues relating to *knowledge production* and the interaction between the biotech sector and the universities and other research and education organizations. The Ministry of Science, Technology and the Environment, controlling three centers, could possibly be promoting interests of general *technology*

¹⁷ Personal communication with Emilio Carcía Capote, 3 July 2001.

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development in a national perspective. The priorities of the Ministry of Agriculture, with a portfolio of five centers, must be expected sometimes to be at odds with those of Public Health. Other ministries must also be assumed to be stakeholders, like for instance Defense and Finance.

The main questions are: Apart from the direct control of particular centers, how are the interests of the different ministries communicated and articulated into the biotechnology sector? One channel is the research programs and the annual plans. Another would be through the President, in his double capacity of Chief of the Government and Chief of the State. A third question is how the foreign currency income of the centers is redistributed – the sales revenues from all the centers go directly to the State Council, and it is not entirely clear who influences on the priorities in the redistribution. It is claimed that the biotech sector as such has been self-financed in terms of foreign currency since 1996.¹⁸

A fifth actor is the Cuban Communist Party. Although it is rarely mentioned neither by sources in Cuba nor in the international literature, one author reports increasing influence by this actor from the mid-1990s and onwards (de la Fuente 2001). José de la Fuente was the Vice-Director of Regulatory Affairs at the CIGB until he was fired in 1998. De la Fuente, who defected in 1999, describes increasing political ‘correctness’ replacing academic freedom, removed protection from ‘voluntary work’¹⁹ (for instance in construction work or mosquito eradication campaigns) and

[...] a political crusade against scientists occupying prominent positions who defended ideas that diverged from the hard line dictated by the Party. (de la Fuente 2001) p 907

¹⁸ Personal communication with Agustín Lage, CIM, May 11 2001.

¹⁹ Personal communication with José de la Fuente, March 11 2002.

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Thus, the political interests of the Communist Party must be added to our list of potential influential actors.

A sixth group of actors could be the drug and intellectual property regulatory authorities. In this setting, however, it must be assumed that their role as influential stakeholder is relatively limited. Suffice it to say that both the drug regulatory agency CECMED²⁰ and the IP regulatory agency OCPI²¹ have been gradually developed to increasingly conform to ‘western’ standards along with their legislation over several years.²²

Interests evolving over time

Of course, *interests* are not necessarily stable over time, and it is convenient to distinguish between at least three historical phases that have influenced on Cuban biotech in different ways. The first phase is from the revolutionary takeover in 1959 and up to 1981, which can be called the foundational phase.

The second phase is introduced by the interferon pilot project in 1981 and ends with the dissolution of the CMEA²³ cooperation in 1991. This phase is characterized by investments in new centers, and was to some degree based on a strategy of exporting reverse engineered patented (or off-patent) products to other socialist countries (Feinsilver 1993).

The third phase is initiated by the gradual collapse of the CMEA between 1989 and 1992, which provoked a 72 percent reduction in imports, a 67 percent reduction in exports, a drop in the investment rate from 26 percent to 7 percent, and a GDP reduction of 33

²⁰ CECMED: Centro para el Control Estatal de la Calidad de los Medicamentos.

²¹ OCPI: Oficina Cubana de la Propiedad Industrial.

²² Personal communication with Celeste Sánchez, CECMED, May 29 2001, and Ana Ivis Hernández, OCPI, May 24 2001.

²³ CMEA: Council for Mutual Economic Assistance, *i.e.* the eastern bloc.

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percent over three year only (Fernández 1999). In the midst of declaring an austerity measures package dubbed ‘The Special Period in Time of Peace’ President Castro also declared continued dedication to three sectors: food supply, tourism and biotechnology (Sáenz et al. 1991). Investment in the two latter continued throughout the Special Period (which to my knowledge still has not been officially called off); for instance, the Centre for Molecular Immunology (CIM) was inaugurated in 1994, which is commonly regarded as the economic turning point (in other words the year in which the Cuban economy touched bottom).

Some sort of shift seems to have taken place in about 2001, when the long time Managing Director of CIGB and interferon pilot project pioneer Manuel Limonta was replaced by Luís Herrera,²⁴ and José de la Fuente was fired, along with the former Managing Director of the BioCEN biological production facility. This act seems to have been preceded by the fact that Fidel Castro, who had had a close supervision and control of the sector from his State Council office, in about 1993 or 1994 somehow made one step backwards and left the responsibility of the Pole Office to the Secretary of the State Council José Miyar Barruecos.²⁵ Apart from the increasing influence by the Communist Party reported by De la Fuente above, it seems like this latest phase involves a more aggressive commercialization by licensing and selling technologies (de la Fuente 2001) and prioritization of production quality and capacity investments at the cost of research.²⁶

²⁴ Curiously enough, Herrera is now also member of the State Council – which means that he is a member of the entity that controls the organization of which he is still the Managing Director.

²⁵ Personal communication with José de la Fuente, March 11 2002.

²⁶ Personal communication with anonymous source #1, June 3 2008.

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Boundary objects: plans and projects

We may now ask *how* these interests are being articulated and mediated. First of all, another concept based on actor-network theory must be introduced, namely that of the ‘obligatory passage point’. The idea is that some actors are able to order the heterogeneous resources constituting the actor-network in such a way that they become a node through which all the other actors have to pass in the pursuit of their interests. It seems like the director of the ‘Scientific Pole Office’ at the State Council is such a point, and it must be assumed that whatever actor who is able to place a representative in that position becomes a powerful entity in the Cuban biotechnology sector. It has already been suggested that Mr. Miyar, the Secretary of the State Council and in charge of the biotech sector, at least to some extent represents the interests of the Communist Party. There is a need for further clarification of this issue: what is the relative influence or power of the first axis (the State Council) or the second axis (the Ministries)?

The Cuban National Innovation System

Cuba has explicitly adopted the National Innovation System as a governing concept in its technology policies. The System for Science and Technological Innovation of the republic of Cuba (SCIT).²⁷ This system is comprised by 1) the Government with its ministries, and the agencies of CITMA²⁸, 2) research organizations, 3) integrative entities, like the scientific poles, the Academy of Sciences, the Union of Workers of Science, and so on, and 4) national, sectoral and territorial research programs (Brundenius and Monreal 2004).

²⁷ SCIT: Sistema de Ciencia e Innovación Tecnológica

²⁸ CITMA: Ministerio de Ciencia, Tecnología y el Medio Ambiente, *i.e.* Ministry of Science, Technology and the Environment.

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The National Programs for Science and Technology

In 2000 there were 15 national research programs in total, of which three were of direct importance to the biotech sector: Agricultural biotechnology, Biotechnology, and Human and veterinary vaccines (Brundenius and Monreal 2004). The preceding year the 15 programs were supporting a total of 572 research projects, and 155 projects had been concluded (Faloh Bejerano et al. 2000). By 2004 17 programs were in operation, with a total portfolio of 786 active and 537 concluded projects (GEPROP 2004).

Judged by the official documents, at first glance the Cuban research programs resemble those of any other country in the North: for instance the evaluation criteria for the project proposals include relevance, novelty, scientific quality, scientific merits, and so on, and peer review evaluation (CITMA 1995). However, there is a certain emphasis on application, since socioeconomic impact is one of the evaluation criteria.

Over the ten year period from 1995-2004 a total of 162 million peso have been distributed through these programs. Of these funds the three biotech related programs (Vaccines, Agricultural Biotechnology and Biotechnological Products) have distributed a total of 33.5 million peso, and the Vaccines program 2.5 million. However, even when converted into man-years using the average scientists' extremely modest monthly salary of 440 peso per month (approximately USD 20), the biotech related programs would cover no more than 634 man-years annually. And that is if all funds cover personnel costs only. In 1997 the Cuban biotech sector employed about 12000 workers, of which 1440 researchers (CITMA 1997). It is evident that the National Programs account for just a minority share of the total funding of the biotech sector.

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In 1998 the annual export revenues from pharmaceutical and medical products were USD 130 million (Reid-Henry 2007a). And one of my sources estimates the current annual export revenues of CIGB alone at USD 40 million,²⁹ which is 263 times more than the total annual contribution from the National Programs to the biotech sector. Those export revenues are collected by the State Council and redistributed among the research and production centers in the biotech sector.

The expert committees (of the vaccines and medical biotechnology programs) are almost exclusively composed of scientists from organizations belonging to the biotech sector (GEPROP 2004). For instance, except for one CITMA representative on each committee there is no representation whatsoever from other ministries. So how are the research priorities of the public health system articulated? One source indicated that the Ministry of Public Health files an annual letter to the State Council expressing its priorities for the research, investment and production activities of the biotech sector,³⁰ which was subsequently used in the planning process. The question is, with what relative importance?

Judged by their relative financial contributions the National Programs seem to play a minor role in making priorities for the R&D activities in the biotech sector. And the official documents are void of any information about the specific criteria that are used to make priorities in each program (CITMA 1995; Faloh Bejerano et al. 2000; GEPROP 2004). Is it possible that the expert committees of the National Programs approve of the project proposals that meet the formal evaluation criteria, and then it is up to the State Council to make the real priorities by allocating the real funding? If this is the case then it

²⁹ Personal communication with anonymous source #1, June 3 2008.

³⁰ Personal communication with anonymous source #2, May 2001.

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is possible that all the R&D projects in the R&D portfolio of each research and production centre would be formally approved of by the National Programs, but only some of them would be truly prioritized by funding by the State Council.

The National Programs, the project proposals submitted to them, and the ensuing research contracts are all boundary objects, and the main social interests mediated by them seem to be that of general scientific and technological relevance and quality. But R&D is just one of the tasks of the biotech sector, and as mentioned above lately commercialization and production seem to be given much higher priorities. It must be mentioned that the public health system pays the research and production centers for their purchases of pharmaceuticals, so the centers get some funding buy this means. However, decisions about investments in production capacities, involving extensive use of foreign currency, must be assumed to reside with the State Council, or the first axis.

The relative power of the three axes

The third axis of power that was mentioned above is the horizontal, integrative measures and mechanisms, of which the Scientific Pole, made up of 38 organizations connected to the biotech sector, seems to be of most relevance here. Although some informants stress the importance of this entity it is not clear what kind of power factor this body represents.

Says Agustín Lage, the Director of CIM

It is not an administrative organization, nor an arena for executive decisions or for making business agreements. It is rather a space for strategic discussion. [...] The Pole is simply that the managing directors of these institutions meet about once a month for discussions and exchange of information. Present at these meetings are

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also the Secretary of the Council of the State, and often the ministers of Health, Agriculture, Higher Education and so forth, depending on the agenda. Occasionally, also Fidel Castro attends a meeting.³¹

Is it mainly about collaborative use of facilities and equipment and coordination of joint research projects, or is it imaginable that the centre directors in some matters would have some common interests that would somehow diverge from those of the State Council? I would incline to the former, since my informants, including Dr. Lage, emphasizes the consensual nature of the Scientific Pole meetings.

The true power over the biotech sector seems to reside with the so-called '(Scientific) Pole Office' at the State Council, whose Director José Miyar Barruecos is occupying an 'obligatory passage point' in that the collection and redistribution of export revenues in the biotech sector to a certain degree is a matter of his personal discretion. It must be assumed that the planning documents that circulate between the research and production centers and the 'Pole Office' at the State Council are important boundary objects. It is possible that the 'Pole Office' produces an annual budget and activity plan that is presented to the State Council, presided by the Comandante (Raúl Castro), for formal approval. It is also necessary for me to find out more about the role of the Biological Front, the advisory body of the State Council on biotechnology related issues.

Hopefully, it will also be possible to cast some light on the decision making processes that introduced the different phases or epochs of the biotech sector: the initial, foundational phase, the CMEA exportation oriented and biotech centre creation phase, the 'Special Period' phase, and the shift during the late 1990s.

³¹ Personal communication with Agustín Lage, CIM, May 11 2001.

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Conclusion: How may *interests* be studied?

So far, it is fairly clear that the main channels of influence over the biotech sector run through the State Council, or the first axis. The main issue to be resolved seems to be how different (sectoral) interests are influencing on, and have been influencing on, and mediated to this organization. So far it seems like my theoretical framework may give interesting, meaningful and policy relevant results.

Vaccine innovation for low-revenue markets

But the Cuban biotechnology sector must be studied from the perspective of my own *interest*, namely the question of what are the social determinants for creating and sustaining national vaccine innovation capabilities. ‘Big pharma’ vaccine manufacturers in the North market their vaccines at tiered prices. Sales in Northern markets are based on high-price/low-volume, while the low-revenue markets in the South are based on prices approaching marginal cost and high volumes (Plahte 2005). Although some national manufacturers in the South have access to some national high-price private sector markets, like the Indian Serum Institute, vaccine manufacturers in the North are facing an economic reality quite different from those in the North.

It is my intention that in the course of working with the other chapters of my Ph.D. dissertation it will be possible to identify how the interest of maintaining a steady supply of cheap, high quality vaccines delivered in presentations and formulation that are appropriate for use in low-income countries may be aligned with the interests of vaccine manufacturers operating in these low-revenue markets.

Research strategies

I believe I have two complementary research strategies at my disposal. One is to make a few more shots at getting some interviews with key decision makers or representatives of the main actors. The risks, or weaknesses, of this strategy are that people may still be reluctant to giving interviews, and in case they agree to see me, it is not obvious that they will admit that there have been any controversies over diverging interests at all. As mentioned above, several of my interviewees have emphasized the cooperative and consensual culture that purportedly dominate in Cuban industrial relations. Nevertheless, it is possible that during future interviews a focus on my part on boundary objects like planning documents and collaborative research and development projects, rather than on (potentially diverging) personal opinions, may reveal a great deal about the interests and positions that have been articulated during decision making processes.

The other strategy is to look at outputs and outcomes, and then try and infer on the basis of assumed or documented interests the relative influence of the different actors. This strategy depends to a large extent on the availability of hard facts, like income sheets and sales statistics, publication records, general or special indicators of improvement or deterioration of the health system, investment records, and so on.

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