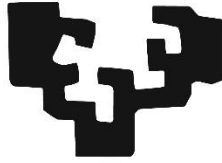


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Universidad  
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Establishing a sustainable nanogovernance in Argentina  
Nanotechnology *with and for* society

2015

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## Abstract

Nanoscience is the study of phenomena at the nanoscale, where materials have different properties from those presented in classical physics. In the daily work of laboratories, science and technology are integrated giving birth to a common practice denominated Nanotechnoscience. This field configures a complex practice that co-creates a market with expected social and economic benefits, while generating new and unknown risks, both in terms of human health and the environment. This market is a sociotechnical network under which agents maximize their interests through economic calculations and where conflicts are solved through prices.

The benefits of nanotechnology could be traced across economic sectors, promising new solutions to social problems. These aggregated promises, which are in permanent interaction with public policies, forge future expectations and put pressure on the process of allocation of national public resources, and shape the future of society in its whole. Hence, it is crucial to involve society in the governance of the nanotechnoscientific network from its early developments in order to achieve social responsibility. Experts, private companies, government agencies and society should be involved in an interactive process of responsible innovation, allowing a deliberative confrontation between different views and interpretations that would provide sustainable governance.

Following Actor Network Theory, investments in the nano market could be interpreted as one of the most important inscriptions and translations of network interactions. Hence, it is crucial to develop tools to socially and economically value these investments, both from the point of view of private investors and from the governments. While the traditional perspective on economic investments revolves around the notion of *equilibrium* and only offers actuarial assessment tools, the dynamic economic, social and political perspective of this thesis allows the integration of previously neglected social and environmental issues into a valuation framework that could be used by policy makers and investors.

This thesis contributes to the theory of techno-scientific governance by unpacking the nano-practice, its market and associated risks. It examines how the nano-practice, its industrial dynamics and society interact to create a market with new risks and benefits. After a demarcation and articulation of the concepts of *sustainable nanogovernance* and *RRI responsible*, this thesis evidences that the nanotechnology dynamics in Argentina is regulated by a *de facto* governance. Even though the State steers the productive sector (through funding and regulation) to address social inclusion, its *top-down* perspective to policy making excludes society from the different stages of the decision-making process. As a response to this finding, this thesis recommends the incorporation of a *bottom-up* public management approach that integrates the recognition of the centrality of the interactions between society and nature - allowing policy makers to work *with and for* society.



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## Extended Summary

Nanoscience and nanotechnology are integrated into the daily work in the laboratories, leading to a practice called technoscience (Nordmann, 2012). The term refers to a different way of doing science, demanding exchange and communication between different practices (Galison, 1997; Galison, 2006) and seeking explanations by an eclectic use of various closed theories. In this new field, different disciplines and institutions converge, giving rise to a new practice.

This practice helps to create its corresponding market, understood as a socio-technical network where agents maximize their interests through economic calculations and where conflicts are resolved by fixing prices (Callon, 2012). This innovative market requires investments that are: (i) irreversible, due to the inability to recover the initial payment; (ii) uncertain, future profit flows are unsafe; and (iii) flexible, investors could leave the project (Dixit and Pindyck, 1994).

On the one hand, this new market has placed nano-products in our society, which creates new risks for humans (Cui *et al.*, 2005) and for the environment (Colvin, 2003). Universities and companies that produce these nanomaterials are directly responsible for them. On the other hand, these organisations manage them using engineering methodologies regulated by the state (Medley and Walsh, 2007) and they also pay a premium to an insurance company that identifies, analyses, evaluates, and diversifies the remaining risk (Lloyd, 2007). However, this practice of enterprise risk management (ERM) is not socially sustainable because it does not contemplate social and environmental aspects, it only deals with business and regulators.

In the American literature regarding technological regulation, one of the most influential works is *Responsive Regulation*, where Ayres and Braithwaite (1992) propose the image of a pyramid of technological regulation. It is cycle that starts with a flexible approach based on starting by a self-regulation (*soft law*), latter on it is accompanied by a growing state intervention. Finally, the government impose a strict regulation (*hard law*). Unlike the American program, the European Program Converging Technologies for the European knowledge society (CTEKS)



emphasizes the importance of the technological policy for the creation of a knowledge society guided by the precautionary principle.

Currently the nano-market has a *de facto* governance built on an interaction of actors with conflicting interests. This context requires effective participation of market actors, governments and general public from the early stages of the innovation process to ensure a socially responsible nano-dynamic, a *Sustainable Governance*.

This thesis proposes a sustainable governance of the nano-practice, its market and its associated risks. For doing this, it is important to understand how the practice is constituted from the relations between human and artefacts in a permanent transformative interaction and how it co-constitutes new risks in the society and creates a market. *Sustainable Governance* extends the traditional approach of a purely economic-actuarial methodology, and incorporates social and environmental interests in a socially responsible dynamic. A key feature is its ability to adapt to an uncertain process. This requires a government with decentralized institutions operating under rapid changing scenarios and high uncertainty levels (Olsson *et al.*, 2006). While this governance must necessarily adapt to the dynamic, the associated political process must be thoughtful and deliberative to be sustainable over time. Moreover, although an exclusive regulation of experts appears to reflect of order and control, it clearly marginalizes alternative perspectives reinforcing the hegemonic vision of technology.

This thesis aims to understand the nano-dynamic in Argentina and analyses it from a *Sustainable governance* perspective. To achieve this objective, this thesis is divided into four chapters. The first one begins with different views of nanotechnology: researchers, governments, academia, the third sector and the insurance sector. Then, an eclectic theoretical framework is proposed to research the nano-field which redefines the practice as a techno-scientific process.

The second chapter examines how the practice is co-constituted with its market. The transformative power of the nano-industrial dynamics is presented, with emphasis on nanomedicine. Then the literature on design and creation of markets

is analysed in the contexts of a new market of nano-carriers. Finally, it analyses the rationality of investors in the sector and develop two quantitative decision models.

The third chapter identifies nanotechnology risks. They are co-constituted both, in the techno-scientific practice and in the unfolding of the market dynamics. In particular, the risks of nanotechnology to humans and the environment are analysed. Finally, the point of view of industry is discussed.

After understanding the practice, its market and its risks, chapter four presents the perspective of *sustainable governance* to achieve a socially responsible nanotechnology dynamics in the long term. It begins by analysing how expectations construct a socio-technical network, and then the concept of sustainable governance is introduced. The second section applies this approach to Argentina. It presents the governmental narratives of nanotechnology, the public expectations and the inscriptions set up in the country. As examples, four public-private partnerships are presented. Finally, it analyses if the nano-dynamic in Argentina is socially responsible in the context of a sustainable governance.

### *Chapter 1: The Nano-Techno-Scientific Practice*

What is nanoscience and what is nanotechnology? In order to address these questions, this chapter will examine the perspectives of different stakeholders: the government, the scientific community, private companies and the third sector.

Alfred Nordmann (2006) proposes the use of the concept techno-science (Nordmann, 2012). Researchers pursue the goal of building nano-materials, not to prove their existence. When envisioning the future of the nanotechnology, it is important to assess how the past achievements of other technologies have been textually produced. The story of the past is an essential element when imagining the future (Thompson, 2011). This story is combined with future expectations to define the field (Selin, 2007). The nano-laboratory is not isolated from society. The relationships among stakeholders infuse meaning to the technology and claim for regulation.

According to the economic theory, expectations about the future course of technological innovation are one of the most important features to consider by the

investor when choosing whether or not to adopt a new technology. These aggregated business decisions and their dialectical relationship with public policies contribute to shape future expectations and reproduce them. There is no possibility of sustaining over time future expectations that are not synchronized with the market dynamic, at least in the Western capitalist world that concerns us.

Roco, Mirkin and Hersam (2011) presented the US vision by describing the National Nanotechnology Initiative (NNI), its current situation and its expected development in the long term (2000-2020). It pursues the formation of an interdisciplinary academic community with a market orientation. This is reflected in the definition given by the NNI:

*Nanotechnology is the ability to understand, control, and manipulate matter at the level of individual atoms and molecules, as well as at the “supramolecular” level involving clusters of molecules (in the range of about 0.1 to 100 nm), in order to create materials, devices, and systems with fundamentally new properties and functions because of their small structure. (Roco, 2007 p.3).*

Meanwhile, the British government defines:

*Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, Where Significantly Differ from Those properties at a larger scale.*  
*Nanotechnologies are the design, Characterisation, production and application of structures, devices and systems by controlling shape and size at nanometer scale.*  
*(The Royal Society & The Royal Academy of Engineering, 2004 p.5)*

These definitions imply a unifying platform of science and engineering at the nanoscale, a technological approach to strengthen the productive sector.

There are no theories specially adapted to the complexity of nanoscale world that could explain the relationship between the structure of a given material and its properties. The researcher deploys partial explanations taken from various theories, forcing them beyond their scope (Winsberg, 2006). The practice in the laboratory has an engineering perspective, which constructs nanomaterials by using eclectic frameworks (Rip, 2013). Traditional theories are extended to face the challenges of the world at the nanoscale.

Nanotechnology public initiatives are excellent business opportunities for risky investors. Within the market logic, it is important to note the role of insurance companies as moderators of this dynamic, because their business is to collect

money in advance to cover their customers' future contingencies. Current regulation of nanotechnology sector is insufficient. In response to this situation, the insurance industry demands greater transparency and better regulation (Lloyd, 2007).

After the report of different visions of the nano-world, the challenge is to understand how agents communicate the expected benefits to get more funding from governments. The narratives of past technologies are essential to imagine the future of nanotechnology, given that some of their traits remain. Chris Tourney (2006) selects the theory of myths developed by Malinowski (1954) to unpack what narratives has been useful to make sense of nanotechnology development.

After analysing the narratives of the past, it is important to understand expectations about the future of nanotechnology. Cynthia Selin (2007) explores how different actors operate to define the field and what problems are legitimated. This highlights the ways in which different actors intend to colonize the future and try to legitimize their present. The fight between actors revolves around the question of what nanotechnology is and, crucially, what should be. Two groups emerge clearly, the so-called *visionaries* and *scientists*. Drexler (2013) embodies the former group, dominating the official discourse during the last decade of the past century (Stix, 2001; Selin, 2007). The second group is mainly represented by the academic community.

The views and narratives about nanotechnology build a new techno-scientific practice, which could be understood using the actor-network theory (ANT). According to this perspective, the relationship between agents instils meaning to its existence. Moreover, technologies involved are not only useful tools, but also defined within the boundaries of symbolic struggles (Latour and Woolgar, 1986; Bijker and Law, 1992). ANT approach is adequate to understand the nano-practice because it demands the observation of the activity in the laboratory at the micro level, and a theoretical concern with the organization of society, opening new possibilities for the study of the political role of science. In the next chapter ANT will be used to understand how the industrial nano-dynamics is established.

## *Chapter 2: Nano-Industrial Dynamics and the Constitution of a New Market*

This nano-techno-scientific practice is a fertile ground for the convergence of variety of disciplines, which impacts on its industrial dynamics (Bozeman *et al.*, 2007; Andersen, 2011). A specific branch of nanotechnology of particular importance for this thesis is nanomedicine. It is defined as the medical applications of nanotechnology, which involves the development of new procedures to diagnose and cure diseases (Paradise *et al.*, 2008). This chapter analyses the market of nano-carriers and its patents. The methodology proposed by Callon and Muniesa (2005) helps to unpack this market and offers tools for analysing their risks.

After the analysis of the process of formation of the nano-market, this thesis focuses on the role of investors. Firstly, it explains the process of creating new businesses and identifies some lessons learned from the first generation of entrepreneurs. Then, a valuation model is presented, focusing on investments in the pharmaceutical industry. Finally, the last sections propose a mathematical model representing pooled investment decisions among a small nanotechnology company that owns the patent of a nano-carrier (possibly a spin-off) and a large pharmaceutical company.

Future expectations about nanotechnology transcend industrial innovation, having the potential to transform other industries (Bozeman *et al.*, 2007). A question immediately arises: Is Nano-industrial dynamics similar to other technologies such as microelectronics or biotechnology? A group of scholars argues that the nano market is being controlled by large multinationals with in house R&D as in the case of microelectronics (Larédo *et al.*, 2009). From a different perspective, other authors argue that the organization of nanotechnology resembles biotechnology, where the *spin-off* university has played a prominent role (Darby and Zucker, 2003). New nano-companies face great uncertainty (Hite and Hesterly, 2001) and the circulation of knowledge has been interpreted as the equivalent to the movement of researchers or engineers in the field (Bozeman and Mangematin, 2004).

Nanomedicine is defined as the set of medical applications of nanotechnology, including the development of new procedures to diagnose and cure diseases

(Etheridge *et al.*, 2013). Reformulating a drug into nano-sized crystals generates a different version of the existing drug, with higher solubility. This reduces the required dose, diminishing adverse side effects. For instance, the insertion of a drug using a nano-capsule aims to target specific tumour cells (Bawarski *et al.*, 2008; Davis, 2008). Another application of nanotechnology is medical diagnosis. For example, by using different types of *labels*, some nanostructures can detect the presence or activity of specific molecular entities within the body. (Van Kasteel, 2009; Kamaly *et al.*, 2013).

In March 2009, the *Food and Drug Administration* (FDA) established a partnership with the *Alliance for NanoHealth*<sup>1</sup> to expand the knowledge about how nanoparticles impact on biological systems, aiming to develop processes that will reduce possible risks. This collaboration had two main objectives (te Kulve and Rip, 2013). First, it has aimed at encouraging the progress of nanomedicine, starting with preclinical stages of development, continuing with clinical and, finally, supporting the marketing of new products. Second, it has improved understanding of the risks and benefits.

Applying for a patent in nanomedicine is not easy, due to evaluators' concerns with health risks and human safety (Bawa, 2007; Martins *et al.*, 2013). The experience of the biotech industry about licensing strategies, development and financing have certain characteristics in common with nanomedicine: the new industrial applications in both sectors rely heavily on intellectual property (IP) and R&D are costly, complex and uncertain (Stewart, 2005).

The markets have clear advantages that make them irreplaceable in a capitalist Western context: their autonomous agents innovate, they allow their coordination, and they facilitate contracts between parties. However, the markets have clear limitations: they are not designed to achieve the public good and they produce negative externalities on human groups (Callon, 2009). Therefore, it is necessary to reconsider basic questions about markets efficiency and analyse how we can ensure that the new nanotechnology market could be *socially* efficient.

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<sup>1</sup> FDA issued a press release in the news section of FDA.gov announcing it: <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01971.html>

Economic theories always are performative, and in this particular case, nanomaterials and technologies also play an important role in the process of market creation (Barry y Slater, 2002; Callon, 2010). This interaction between technoscience and markets produces what Marilyn Strathern (2000) calls the proliferation of new identities, creating constantly new uncertainties about the constitution of the collective. This process transforms the economy, the politics and the technoscientific practice surrounding it (Callon, 2009).

Nanotechnology market efficiency requires: (1) density, to attract a sufficient number of participants, (2) smoothness, to overcome congestion problems that can bring down the number of agents operating, and (3) safety and simplicity. Moreover, it should exclude operations based on moral reasons (Roth, 2008).

Following Callon and Law (1997), this thesis argues that market players are collective hybrids in constant constitution, in which people, devices and texts interact. There is no difference between the person and the network of institutions in which she operates, or more precisely, between the person and the network of entities acting through it. The same idea applies to the market as a whole, its agents do not act isolated, they are collective hybrids. These agents interact performing arithmetic operations, so they are *collective hybrid computing devices* (Callon and Muniesa, 2003).

The calculation is a feature of any market, but who does the calculation and how? In the literature, there are two contrasting perspectives to answer these questions. From a neo-classical point of view, agents' ability to calculate is innate. Conversely, from the perspective of social anthropology, the calculation is an ex-post rationalization. In this thesis, I would avoid these two extremes. On the one hand, people should not reduce to mere agents who calculate. On the other hand, calculation should not be ignored nor dissolved by ethnographic descriptions (Callon and Muniesa, 2003).

In the market, the valuation process of assets arises from exchanges between agents making cross calculations: the calculating devices (Çalışkan and Callon, 2010). They include tools that actively constitutes reality and they struggle to impose prices one to another (Rose and Miller, 2008; Weber, 1978 [1922]; Stark, 2009).

The calculation is distributed among humans, formulas and artefacts (Latour, 1987; Lepinay and Callon, 2009).

Nano-carriers are nanoscale elements that are introduced in the body and carry the drug to the place where the body needs it (Torchilin, 2012). To manufacture these products a patent is needed (Carbone *et al.*, 2013). The process of transforming patents into transactional goods starts with a process of singling out its properties, so it can enter the world of the business that uses it to produce nano-carriers. Once the company placed the patent into its network, the production process of the nano-carrier starts – which is then transformed into a good that would be exchanged by money in the market.

There are clear asymmetries in this market. On one hand, the producer normally is a large multinational pharmaceutical company with a lot of calculation power. On the other; the consumers are able only of making simple calculations.

After analysing the process of market creation, the focus of the thesis is understanding the role of investors in nanotechnology projects. In general, their initial goal is to register (buy or rent) a patent. Then -under its protection-, they begin production and sell the products. The valuation methodologies of these technology assets can be classified into two main groups (Mun, 2003). On the one hand, the traditional one, which involved costing and income calculations, and, on the other hand, innovative methods including *real option* (Schwartz, 2013). In the case of nanotechnology projects, valuation methods need to take into account that: i) they require large investments, ii) their costs are sunk, iii) their final product have uncertain futures prices, and iv) their investor could abandon the project (Vimpari and Junnila, 2014; Brealey and Myers, 2003).

Hardly a single organization undertake a nano-medical project, usually joint investments are required. This thesis develops a mathematical model to analyse the commercial interaction between a company specializing in the development of nano-carriers and a pharmaceutical large company. While the former develops research *in vitro* / *in vivo* testing to achieve a patent; the latter has the drug and can produce it. This interaction is modelled using game theory and real options.



### *Chapter 3: Risk as a Co-Created Process*

In contemporary culture, risks are present in a wide range of practices and experiences (van Loon, 2000). The concept of risk is a topic widely debated among experts, politicians, philosophers, media professionals and the public in general. In Western societies, the sense of risk has evolved with the development of social institutions, the economy and the welfare state. The rapid expansion of scientific, technological and medical knowledge advances have created a set of experts in the calculation, assessment and management of risk (Mythen, 2004). In the late modern period, public awareness of risk has also been influenced by the expansion of the media and the growth of new information and communication technologies.

In social sciences, it is possible to identify four paradigms attempting to unpack *risk* in contemporary societies (Mythen, 2004). Firstly, inspired by the work of Mary Douglas (1966), there is an anthropological approach where differences in risk perception are explained by patterns of social solidarity, different worldviews and cultural values. Secondly, in the field of social psychology, psychometric paradigm has focused on individual cognition of risk (Slovic, 1987). Thirdly, the government's approach to risk has been addressed by Michael Foucault (Gordon *et al.*, 1991). Fourthly, the risk society perspective led by Ulrich Beck (1992) has illuminated the pervasive effects of risk in everyday life. He argues that the process of modernization has created a unique collection of humanly produced risks (Beck, 1999). In the last decade, the *risk society* has been very influential as a stimulus for academic, environmental and political dialogue (van Loon, 2000). The prospect of the risk society can discuss the constitution of risk and its effects on various social fields, enabling an analysis that extends the actuarial, financial or engineering risk protocol.

From the hegemonic point of view, social production of wealth inevitably leads to social production of risks. Moreover, modern culture of risk suggests that stability is a *failure* and that taking risks is the only way to be innovative and successful (Sennett, 1998). In this context, many entrepreneurs are turning their attention to the nano-market and betting on risky new innovations as business opportunities.

Without proper regulation, this implies that there is an unstoppable race to promote innovations without increasing risk levels for society.

This risk is co-constituted within the techno-scientific practice and in the course of the market dynamics. This chapter examines nanotechnology risks to humans and the environment. Here, the industry's point of view is discussed. It presents both the traditional methodologies used in industry for valuing projects and their limitations. Then, the *real options approach* is presented as an alternative to overcome the flaws and weaknesses of traditional methodologies. Real options integrates key aspects of any innovative project: uncertainty, flexibility and irreversibility. Following, this chapter examines the role of the insurance sector: limiting, measuring and imposing prices (premium) to risks. In the last section, two new quantitative models are introduced. They offer tools to improve public policy decision making.

The phenomenon of risk society becomes visible when dangers arose from human decisions exceed the possibility of any insurance company to cover it. Nanotechnology risks are caused by humans, through government decisions, industry investments and society choosing a certain lifestyle involving particular risks (Beck, 1992; Matten, 2004). They are global risks. In other words, they are neither limited by traditional national boundaries of industrial societies, nor limited to a certain place or to specific groups in society (Beck, 1999).

Technological innovations are presented by the market as secure, with high expectations of future profits and with diffuse risks. Global regulatory policies consolidate the hegemony of certain economic groups. Current risk regulation are in the hands of *technical experts*, excluding the participation of other social actors. The former contribute to the production of a discourse that transforms potential risks for society into business *opportunities* (van Loon, 2002).

While some studies analyse the impact of industrial activity on the governance of risk (Meyer *et al.*, 2009), few dispute the impact of industrial dynamics on the direction of technological change (Robinson, 2009). In particular, Rafols *et al* (2011) argue that the specific features of industrial dynamics of nanomaterials have strong implications for their governance. At the moment, the market have a *de facto*

governance built by conflicting actors (Rip, 2010). This is not controllable from a *top-down* approach; on the contrary, Rafols *et al* (2011) propose a bottom-up management to account for the distributed interactions in the system (Rip, 2010).

From the methodological point of view, the investment projects involving research and development challenge financial valuation. These projects encompass multiple sources of uncertainty and learning processes of different actors. Furthermore, the total cost of the investment is uncertain. Each stage of the investment is subject to exogenous and endogenous sources of uncertainty or catastrophe, putting the completion of the project at risk. Dixit and Pindyck (1994) argue that most investment decisions in innovative projects have three key features that demands the use of the methodology of *real options* instead of traditional approaches. Firstly, these investments are mostly irreversible (fully or partially). Secondly, there is uncertainty about the future return on the investment. Future prices of assets are unpredictable and profit flows are uncertain. Thirdly, investors have the option of waiting for better information about future prices (Pindyck, 1991; Trigeorgis, 1996; Brennan and Schwartz, 1985; Trigeorgis, 1993; Insley and Wirjanto, 2010; McDonald and Siegel, 1986).

For an effective nanotechnology policy management, this thesis proposes the inclusion of two quantitative tools in the decision making process. Based on the financial structure of the project, this section introduces a tool able to address the uncertainty of future benefit and to assess the appropriateness of investing in the project. If the government chooses to fund the project, the second financial tool would help to identify the most socially efficient way of giving incentives.

Although there is a vast literature on the precautionary principle used in the European community (Monaghan *et al.*, 2012), it is difficult to operationalize it as a quantitative tool available for policymakers (de Sadeleer, 2012). In this thesis, the first proposed financial tool presents a model that quantifies the social value of *caution*. This tool overcomes the standard methodology of cost-benefit that proposes to carry out every project with positive expected net benefits. However, if uncertainty and irreversibility of the project is contemplated, this threshold is greater than zero (Farrow, 2004). The literature recognizes two main categories of

government incentives: *push* (paid before a project starts) and *pull* (paid if a project is successful) (Nemet, 2009). Nanotechnology projects usually rely on government funding (Hsu and Schwartz, 2008). The second financial tool introduced in this thesis identifies the most effective government response to a particular project in different scenarios. In general, the more efficient incentive are hybrid contracts that gives an initial sum to projects (*Push*) but also reward the project that is socially responsible and achieved a solution to a public problem (*Pull*).

This chapter argued that enterprise risk management and government regulation are not enough to contemplate social and environmental risks. Technicians perform risk management without considering impacts on society.

#### *Chapter 4: Process for Establishing a Sustainable Nano-Governance*

As analysed in Chapter 1, public perception of nanotechnology moves between two extremes: those who argue that nanotechnology is the salvation for humanity and those who assimilate it to apocalyptic nightmares (Mekel, 2006). While some groups produce narratives where the imagined future is a promise of small programmable machines capable of curing diseases or clean the planet from pollution, others assert a vision where the panic against the possibility that these machines achieve autonomy is paramount (Highfield, 2003). As discussed in the first chapter, various disciplines and institutions interact to create expectations, often conflicting, about future profits. In recent years, nanotechnology future expectations have added economic value to investment projects, attracting new public and private investors. The nano-industrial dynamics has developed from a mere discourse in the early millennium to an economic reality today.

Firstly, this chapter examines how nanotechnology actors coordinate expectations by innovating and shaping a complex and controversial dynamics. Researchers, businesses, governments and NGOs interact in a network of relationships from positions often conflicting with each other. Secondly, the State role is interpreted as a distributed computation agency. This section critically analyses North American and European regulation. It concludes that the European precautionary principle is compatible with *sustainable governance*. Next, it is argued that the

market for nanomedicine is a dynamic non-equilibrium system contrasting with the orthodox approach hegemonic *market equilibrium*.

Next, this chapter unpacks the Argentine case using the sustainable governance approach. In the early stages of the nanotechnology field in this country, public funding aimed at fostering technology and productive innovation. However, in response to the negative reaction of different social groups, the national government started to considerate social impact as a key aspect to fund projects. This chapter describes four recent experiences of collective hybrids. They have acted as agents of change (public-private partnerships with clear objectives to innovate in the nanotechnology context) with specific plans aiming to address social problems in Argentina.

Economic theory, since the 1970s, asserts that expectations about the future course of innovation is crucial for business decisions about technology (Rosenberg, 1976). These private expectations compete for allocation of national public resources, defining the future of society as a whole (van Lente and Rip, 1998; van Lente, 1993). Nanotechnological promises are functionally important to the new market (Konrad, 2006). In the early stages of this market, such promises provided a framework that launched the nano-dynamics. However, after a while, the later needed to address specific demands and had to offer measures of success (van Lente, 1993). A dual dynamic is then established, where specific promises give legitimacy and credibility to the general one, and the last one gives sustainability to the first one (Parandian *et al.*, 2012).

The Western hegemonic thinking understands the relationship between nature and society from the perspective of equilibrium (Worster, 1977; Worster, 1993). This idea is culturally rooted in political, academic and lay discourses. In the context of a crisis, policymakers usually seek to regain the equilibrium of the economic system. A clear example of this is the reaction of First World governments to the latest international financial crisis, where they promoted policies to return the system to its equilibrium. This perspective clearly has reinforced the power of the dominant group and has silenced voices of dissent, denying the complex dynamics

of the co-constitution of the dynamic previously described in this thesis (Scoones *et al.*, 2007).

Within this complex dynamics of expectations, the State is a fundamental actor. Modernity has conceptualized the State as an element of modern social order, seeing the *state as an actor* (Passoth and Rowland, 2010). However, other perspectives have interpreted the state as a distributed network of agents, not necessarily coordinated (Carroll, 2006; Latour, 2000; Passoth and Rowland, 2010). In this view, no government entity is *per se* an actor, state action only acts in relation to socio-technical networks in a continuous process of transformation (Carroll, 2006).

This network also involves private actors, leading to a mixed system of governance with negotiations made at different levels. At the regional and international levels, this negotiation is particularly complex because the industry representatives meet agents of various governments, which often pursue conflicting interests. Moreover, the economic structures are subject to historical change and this is reflected in changes in their modes of governance. Kornelia Konrad (2010) proposed the concept of governance *of and by* expectations to capture the different ways of how expectations are coordinated and shape the technological dynamics.

This conceptualization provides a comprehensive approach that focuses on the different modes of production and coordination of expectations in markets where different actors interact respecting rules but following their own interests. It is crucial to analyse the social construction of *nature* in the scientific and policy discourse (Forsyth, 2003), being fundamental to break the separation between nature and society (Latour, 2004) and accept the complexity of the network (Scoones, 1999).

Traditional definition of sustainability emphasizes a necessary balance between present and future human needs (Brundtland, 1987). However, in the case of Nano-medicine this static approach is insufficient due to its complex and uncertain dynamics. The valuation of human needs is a process of permanent constitution, with agents interacting with divergent prospects.

How States should respond to network disturbances/shocks and how it would be possible to achieve sustainable governance of innovative technology? If the shock is short lived and internal, the response to the problem requires *stability* and encourages the restoration of the lost equilibrium. If the source is external, on the contrary, the policymaker needs *resilience*. If the disturbance is long lasting and internal, *durability* is required. If the shock is long lasting and external, the network must to react with *strength* (Scoones *et al.*, 2007).

While the concept of responsible innovation has been analysed in the literature for almost a decade, it only appeared in the European official discourse in May 2011<sup>2</sup>. The European model of responsible innovation is based on the principle of inclusion and requires the participation of all stakeholders throughout the innovation process. Owen, Macnaghten and Stilgoe (2012) highlight three main features of the European official policy discourse on the subject. First, they highlight the concept of *science for society*, which means research and innovation should be promoted in order to solve concrete problems of society in the context of a deliberative democracy. These authors identify the notion of *contribution to the future development* and the explicit link between innovation and responsibility (Owen *et al.*, 2012) as significant.

In particular, the European commission outlines six principles for responsible innovation. Firstly, it asserts the need of the commitment with the responsible innovation process from researchers, entrepreneurs, policy makers and civil society in the process. Secondly, it also demands a commitment to gender equality. Thirdly, it remarks the importance of creative learning. In other words, Europe should not only increase the number of researchers, but also have to educate future stakeholders to be able to fully engage in a responsible manner with all sorts of innovation processes. Fourthly, it states an ethical principle. Fifthly, it proposes that innovative processes must be transparent and accessible to the general population. Finally, it proposes that innovations should be designed *for and with* society (Stilgoe *et al.*, 2013).

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<sup>2</sup> Opening Conference of the *workshop* held at the *Directorate-General Research* (Brussels) in May 2011 by Octavi Quintana, quoted by Owen, Macnaghten and Stilgoe (2012).

In this view, a responsible innovation process has to be anticipatory, reflexive, deliberative and responsive. It has to be anticipatory because it requires an analysis of all impacts that might arise during its development, whether at economic, social, and environmental levels. It has to be reflexive because it must reflect on the goals, motivations and impacts on every project, allowing discussion about what is known and what not. It should be deliberative because it needs dialogue, compromises and debates, in order to incorporate the perspectives of all stakeholders. It has to be responsive because it must be inclusive and open to a learning process (Owen *et al.*, 2013).

In a newspaper article (La Nación 2004), the Argentina's economic minister stated:

*Nosotros acabamos de lanzar un programa para el desarrollo de las nanotecnologías. Tomando contacto con centros de excelencia, identifiqué a quien dirigió las tesis de cuatro argentinos que trabajan en nanotecnología en la que es probablemente la empresa más importante del mundo en la materia, Lucent. (Caligaris, 2004 p.1)*

the minister was aware of the importance of coordination with companies, but the agreement only with *Lucent* was questioned by various actors (Andrini and Figueroa, 2008). This monopoly contract was immediately rejected by the political opposition and researchers. In 2005, the national state created the Argentina Nanotechnology Foundation (FAN), aiming to develop human and technical resources for the industrial sector. From 2004, the government has set future expectations to encourage research and give monetary incentives to move the industry. Researchers has also claimed for funding to pursue their own agendas.

In 2006, after a conflict between political parties, the government published *Plan estratégico nacional de ciencia, tecnología e innovación Bicentenario (2006 - 2010)* where it explained the governmental strategic view about nanotechnology in Argentina (SCTIP, 2006). Here, the government recognised that its efforts have been insufficient to create a market and called for proposals aiming to solve productive and social problems. In 2007 the government organized the first congress called *Nanomercosur 2007. Science, Business and the Environment*. Although the name of the event suggests wide range of participants, the analysis of the programme of the event reveals that only technology experts and government officials participated.



In 2010, The Argentina Nanotechnology Foundation published a document called *Who's Who in Nanotechnology in Argentina*. Here, the Secretary of Planning and Policy of the Ministry of Science, Technology and Productive Innovation, Ruth Ladenheim, presented the government guidelines on nanotechnology policy. The key aim of the policy is to promote the production of nano-technological improved goods rather than nano-products. In the Ministry's own words:

*La tendencia es a que no haya nanoproductos, sino los productos clásicos con importantes mejoras por la intervención de la Nanotecnología (FAN, 2010 p.13).*

In April 2012, the Minister of Science, Technology and Innovation, Dr. Lino Barañao, explained Argentine techno-scientific policy during a conference at the Institute of Experimental Biology and Medicine (Barañao, 2012). He translated the presidential social inclusion discourse into the techno-scientific field. He remarked that investment in science and technology is being made by the government and companies, and it should be oriented to solve social demands. To achieve this, the government strongly relies on partnerships, collective hybrids that act as agents of change. One example is POTENCIAR project, which was a collective project that articulated government, academia, business and international actors. It brought together doctors, chemists, physicists, biologists, and engineers (among others), constituting a small sociotechnical network whose aim was to develop and commercialize biomedical implants developed with advanced nanotechnology. The socio-technical network is built around a material: *ultrananocrystalline diamond* (UNCD). A second examples is another innovative project born out of a government initiative to promote nanotechnology applied to the production processes of clothing. This project has sought to develop clothing that repels mosquitoes to prevent the contagion of dengue in Argentina.

After presenting nanotechnology in Argentina and its process of constitution, this chapter analyses it from the *Responsible Research and Innovation* (RRI) perspective. With regard to the first principle, the ministers in charge of the innovation policy have specified that public funding must have productive and social goals. However, only experts, private companies and relevant government agencies are involved in the process of decision making. Society remains marginalized.

Secondly, in relation to the commitment to gender equality, the new interdisciplinary nanotechnology domain follows a hybrid gender dynamic, intimately linked with the features of the disciplinary fields that converge in its production. Physics, engineering and chemistry have been mainly masculine in Argentina (and in the world); whereas in biology or medicine there has been a steady increase of the participation of women in recent years. In this sense, nanotechnology presents new opportunities and challenges to achieve gender equity (Meng and Shapira, 2011). In this foundational stage in Argentina, it is important to achieve greater gender diversity in laboratories, companies and government agencies, in order to achieve sustainable governance. Although the government should be a key player in promoting gender equity, the FAN directory is made up by seven men and only two women.

Thirdly, with regard to the promotion of creative learning as part and parcel of RRI, the Argentina government has increased the number of researchers associated with nano-technological projects. However, it still falls short with regard to the promotion of learning spaces and opportunities for social actors to be able to fully engage and participate in the decision making process associated with the public funding of nano-technological innovation and research.

Fourthly, with regard to the RRI principle that demands great social relevance and acceptability of the innovation process, Argentina follows international regulations that protect workers who are exposed to nanotechnology risks. However, this policy does not address local issues or pay attention to local stakeholders.

Fifthly, RRI requires transparency and accessibility. The Argentine government, through the FAN, deploys various initiatives in this regard. For example, the *Nanotechnology for Industry and Society* initiative holds regular meetings open to the public. Another example is the government's efforts to coordinate actions with different regulatory agencies under the *Nano-sustainable* program. This fosters interactions between government agencies, researchers and industry.

Finally, with regard to the overarching concern of RRI with promoting a nano-technological field *for and with* society, the Argentine government has deployed various initiatives to disseminate innovation and promote interactions without

promoting open public debates. The last attempt to promote public dialogue has been the launch in October 2014 of a public consultation process around nanotechnology on the Internet. However, up to now, the official website does not show comments, suggestions or requests from the public. This lack of strategies to engage different publics has been harshly criticised by various actors (such as NGOs).

### *Conclusion*

This thesis has argued that Argentina does not have a sustainable nano-governance. Although in this country nanotechnology has been linked to social inclusion and impact on levels of employment, it has a clear top-down governmental approach that has excluded society from the policymaking decision process. A RRI responsible nano-governance should involve an anticipatory, reflexive, deliberative and receptive dynamic.

Anticipation requires analysing in detail all the impacts that might arise at economic, social and environmental levels. Government funding should be accompanied by multi-faceted *impact* analyses. For example, in the case of clothing –such as the new mosquito nano-repellent mentioned above-, it is crucial that governmental agencies examine in advance how this innovation would modify the economics relations in the sector as well as its environmental impact.

Reflexivity demands reflection on the motivations and promotes honest discussions about what is known and what is not. As it is explained above, although Argentine governmental motivations seem clear, there is no place for wider debate. Moreover, governmental risk analysis is only based on international standards. In this sense, although this could be efficient for certain Western post-industrial countries, it could be harmful for Argentine society. More research focuses on the Argentine nanotechnology context is needed in order to foster a responsible approach to public policies.

Deliberation demands the inclusion of stakeholders' perspectives through dialogue. The Argentine top-down approach only takes into account the government's vision of nanotechnology. This thesis has argued that it is important to give more participation to the Congress and to universities. Public interactions

of conflicting views about nanotechnology will help to find a new and socially more efficient path for its sustainable governance.

Receptivity fosters an open inclusive learning process. In this sense, this thesis has shown the relevance of developing updated databases with information on all sorts of nanotechnology projects (whether successful or not). This will allow researchers to unpack them and propose best practices for the future.

This thesis has made several contributions to unpack the process of nano-governance in Argentina. The first chapter proposed the use of *Nano-technoscience* as a fruitful concept to capture the convergence of the scientific and technical aspects of research, is an engineering way of doing science. The interaction of scientists, their artefacts and materials in the laboratory define the nano-practice.

The second chapter analysed the construction process of the nano-market, particularly, patenting and production of nano-carriers. To do this, it stressed the importance of analysing transactions between collective hybrid agents (human and artefacts) interacting in a constant process of co-creation. Their ability to calculate reflect its economic power in the market (ability to impose prices). In particular, it presented the market for nano-carriers as an algorithmic configuration.

The third chapter conceptualized the nano risk as co-constituted, both during the techno-scientific practice and within the associated market. Firstly, it examined the industry's perspective, where uncertainty is taken as part and parcel of the decision-making process. Secondly, it argued that the methodology of *real options*, which integrates uncertainty, flexibility and irreversibility, is socially efficient for the valuation nano-medicine projects. Moreover, this chapter argues that the *enterprise risk management* procedures –although complying with governmental regulations– cannot be considered *responsible* due to their disregard of social and environmental aspects.

This thesis has argued that Argentina has a *de facto* governance of nano-technology built on conflicting interests. The State sets the context of political discussion and controls the nano-dynamic with a top-down regulation. To be sustainable and socially responsible, reflection, discussion and confrontation between different

interpretations are needed. This requires that the State changes its governance practices and has to widen its scientific vision into a socially inclusive one.

From the presented analysis, it is possible to delineate different lines of inquiry for future research in Argentina. First, it would be important to analyse, using qualitative and quantitative methodologies, how private companies deal with the Argentine nano-market and to establish if they could be considering RRI *responsible*. Secondly, it would be relevant to examine local nanotechnology risks and the role of insurance companies in their management. Thirdly, it would be crucial to carry out comparative analyses of national public policies in order to identify possible alternative solutions to shape Argentine's public policy agenda and, in particular, its regulatory orientations in this field.

## Introduction

*Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where significantly differ from those properties at a larger scale.*

*Nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometer scale.*

*(The Royal Society & The Royal Academy of Engineering, 2004 p.5)*

In the daily work of laboratories, nanoscience and nanotechnology are integrated giving birth to a common practice denominated Nanotechnoscience. This term accounts for a way of doing research, different to the traditional way used in chemistry and physics, which demands exchange and communication between different scientific and technological practices (Galison, 1997) and looks for explanations using several theories. Under this new field several disciplines, public and private institutions converge giving birth to a new practice. It is a process that co-constitutes itself with its corresponding market, understanding the latter as a sociotechnical network under which agents maximize their interests through economic calculations and where conflicts are solved through prices (Callon, 1999; Guesnerie, 2006).

This complex field configures a market that promises benefits on a number of areas (Paradise *et al.*, 2008), while generating new and unknown risks both in terms of the environment and human health (Kimbrell, 2006; Faunce, 2014; Arnall, 2003). Nanotechnology is currently still on its embryonic phase, yet, judging by the international public and private movement generated by it, we are facing a whole new way of analysing and studying matter, a new chapter on human development altogether, which is to have a high impact on social and productive structure.

The benefits of nanotechnology could be traced across industries, promising new solutions to social problems while growing industrial productivity. These aggregated promises, which are in permanent interaction with public policies, sustain future expectations, pressuring the process of allocation of national public resources, and defining the future of society in its whole (van Lente and Rip, 1998; van Lente, 1993). In order to mobilize resources towards their projects, nanotechnologists present narratives anticipating States' agendas and formulates strategic promises knowing that they will contribute to shape its priorities and

concerns (Rip *et al.*, 2010). These uncertain promises play a key role in the production of innovative markets such as the nanotechnology market because they assign future economic value to current investments.

One of the most important global social problems is the provision of sufficient food to a growing world population. Some nanotechnological applications may offer some solutions (Lyons *et al.*, 2011; Prasad *et al.*, 2014; Agrawal and Rathore, 2014). Over the last few years, nanotechnology has contributed to the productivity growth of both agriculture (Prasad *et al.*, 2014; Parisi *et al.*, 2014) and animal husbandry (Garg, 2014). Some examples of products that are already on the market include nanoparticles which are used to transport active principles, the use of nanofibers as environmental biosensors, and nano-compounds for the exploitation of agricultural residues (Parisi *et al.*, 2014).

Another economic sector impacted by nanotechnology is the textile industry, which has developed fibres that solve diverse social needs (Kakad *et al.*, 2015). An example is the inclusion of carbon nanofibres<sup>3</sup> on clothes to effectively increase fibres resistance to traction, thus granting it with greater durability (Karwa *et al.*, 2012). Another key application is the production of cloth that has functionalities; for example, cloth that repels stains (Popescu and Popescu, 2013), water (Anitha *et al.*, 2013), insects (Van Langenhove and Paul, 2014), or detects a patient's health condition (Rai *et al.*, 2014), or localizes its user by GPS (Syduzzaman *et al.*, 2015).

The global industrial framework requires high levels of electrical consumption for its functioning, therefore there is a need for new and more efficient ways of producing and consuming power, which must also contemplate environmental impacts (Menegaki, 2014). In this respect, through the inclusion of nanotechnology, it has been possible to produce plastic solar cells that have greater electrical efficiency (Oh *et al.*, 2012; Kim *et al.*, 2012), less contaminant fuel such as hydrogen obtained through the process of nano-catalysis on water (Li *et al.*, 2011), and long lasting batteries capable of absorbing great quantities of lithium ions without damaging electrodes. These innovations have contributed to the

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<sup>3</sup> Nanofibres may be defined as fibres with a diameter lesser than 1 mm or 1.000 nm, and are characterized by having a high superficial area to volume and a small pore size in the form of fabric.

decrease of environmental pollution, which is one of the expected benefits of nanotechnology for our society (Liu *et al.*, 2014).

Another area of great importance for an inclusive global society is that of the provision of clean water for human consumption. Currently, only 2.5% of the planet's water is potable so it is urgent to find new methods of water treatment. The alternatives that nanotechnology proposes are diverse. Firstly, the use of nano-membranes and nano-clay for water filtration (and its desalination) increases efficacy over other methods<sup>4</sup>. Secondly, processing waste waters with activated nano-particles allows for its re-use. Thirdly, the use of nano-sensors can help monitor the quality of water by detecting bacteria, heavy metals, and toxins (Bhattacharya *et al.*, 2013; Qu *et al.*, 2012). Water treatment on the basis of nanotechnology includes the use of nano-membranes and filters based on carbon nanotubes (Liu *et al.*, 2013), nano porous ceramic (Mittelman *et al.*, 2015), and magnetic nano particles (Si *et al.*, 2012). Lastly, the use of nanomaterials such as silver and titanium dioxide with antimicrobials characteristics can supply an alternative to chlorine treatment (Liga *et al.*, 2011).

Another global challenge that may be overcome with the help of nanotechnology is the urban pollution levels. The air pollution can be monitored using nanotechnology (Penza and EuNetAir, 2014). Different nano-filters may be applied on automobiles and other vehicles with exhaust gases to filter its contaminants before they enter the atmosphere. In this way, the technology of nano-catalyzers used on the vehicle's catalytic converters removes contaminants and increases the driving quality. At the same time, nano-sensors that can detect very low concentrations of toxic gases on the atmosphere have already been developed (Penza and EuNetAir, 2014).

Nanomedicine is one of the fastest growing sub-disciplines of nanotechnology and has been the object of high expectations with regard to its impact on human health. It is an interdisciplinary sector that gathers fields such as biology, materials science and engineering, and information technology. The challenge for researchers is to

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<sup>4</sup> Nanotubes made from carbon have proven to be very effective on water filtration, reducing significantly the costs from desalination (Brame *et al.*, 2011). In addition, magnetic nano-particles can decompose organic contaminants and remove salts and heavy metals allowing for the recycling of waste waters (Waijarean *et al.*, 2014; Neyaz *et al.*, 2014).



understand the explicative mechanisms of a certain disease and to intervene on a nanoscale. The constitutive basic blocks of life are nano-structures. Hence articulating nanomaterials with biological structures at this level open up new opportunities. For example, a biosensor typically used on the field of medicine has a biological detection component, a physical transducer to generate a measurable signal, and an informatics component to process the generated data (Yao *et al.*, 2014).

Nanotechnology impacts on diverse branches of medicine: early and precise diagnosis, image diagnosis, highly specific drug handling, and regenerative medicine. Currently, the industry counts with nano-gadgets used as biosensors for monitoring, implants, drug transporters for cancer therapy, or surgical tools. In particular, the nano-pharmaceutical field supplies with an efficient drug management, as nanoparticles identify specific objectives and release precise doses of drug into them, minimizing secondary effects (Grossman and McNeil, 2012; Schroeder *et al.*, 2012; Bertrand *et al.*, 2014).

On the year 2010, there were 35 million people suffering from some degree of Alzheimer (Pouryamout *et al.*, 2012). A search for the cure is currently being undertaken on an international level, in particular, a new drug denominated RNS-60 from the company Revalerio is being tested on humans, the effectively prevents and may cure Alzheimer. It is a nanostructure composed of a functional platform of Sodium Chlorine, Hydrogen, and Oxygen<sup>5</sup>. What makes this drug innovative is that it includes the action mechanism with no side effects (Modi *et al.*, 2013). Another globally extended and growing disease is diabetes, which is the main non-traumatic risk factor of amputation of the lower limbs. Currently several methods to avoid amputation are available. One of the most effective consists of the infiltration of a saline solution through several injections directly on the wound, which has the inconvenient of being a very painful treatment. On the year 2007 the *Centro de Ingeniería Genética y Biotecnología de la Habana* (Cuba) registered the WO2007087759A2 patent that proposes the use of nano-spheres as a epidermal

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<sup>5</sup> For its production, a 10% saline solution (sodium chlorine) is subject to a patented process under which cavitations are generated, this help the oxygen nano-bubbles adhere to the sodium chlorine creating a stable structure similar to a platform.

growth factor of parenteral application, which has the advantage of producing a faster cicatrisation of the wound<sup>6</sup> (Vicedo, 2015).

Products containing nanomaterials have also reached the cosmetic and solar protector sectors (Nohynek and Dufour, 2013). Sunscreen with titanium dioxide or zinc oxide are used to prevent burns. Creams made of mono-crystalline particles are being replaced by nano-crystalline structures making the creams transparent instead of white. Nano-silver and nano-gold particles are also used for its antibacterial characteristics (Balasubramanian, 2014).

Another field where nanotechnology is being applied is the aerospace industry, where nanotechnology finds application in minimizing the size, weight, and electrical consumption of relevant gadgets (Pedai and Astrov, 2014). Nano-crystals are paving the way for the production of plastics that are resilient to extreme situations (Leung *et al.*, 2013), reinforcing the original atomic structure, granting both lower weight and greater resistance to the materials (Zhou *et al.*, 2013). Another area of impact is that of NRAM memory development industry, namely, the development of high density, non-volatile, and aleatory access memories based on carbon nano-tubes.

After mention some of the diverse applications of nanotechnology, it is legitimate to ask oneself about the nature of its industrial organizational dynamics. As a first step to answer this, one could ask whether nanotechnology is similar to previous technologies, such as microelectronics, and biotechnology. Since the 1970s, the top-down approach allowed the microelectronic industry, constituted by big corporations with strong vertical integration and R+D departments, to reduce the size and increase the circuit density of the semiconductor. Subsequently, during the 1980s, the biotechnological industry was formed on the basis of new small companies (Invernizzi, 2011). While nanotechnology is somewhat similar to earlier technologies, its practice constitutes an industrial dynamics of its own. The first marketed nano products were just nano aggregates of pre-existing products, mainly produced by big corporations with massive markets. Nevertheless, thanks

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<sup>6</sup> Centro de Ingeniería Genética y Biotecnología, La Habana, Cuba. "Patente de invención WO2007087759, 2007". Recovered from <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2007087759>

to the State's financing of academic institutions, during 1990s university *spinoffs* started to emerge and develop nano products, many times patenting their products (Robinson, 2009).

This dynamics of nanotechnology requires a global institutionalization of patents and standards. Patents are intangible assets that allow *persons* (either organizations, States or humans) to protect their interests by creating barriers of entry to avoid market competition (Somaya, 2012). Patents have emerged from a multidisciplinary nanotechnoscientific practice articulated with the market adding economic value to its owner (Chen *et al.*, 2013). At the same time, in order to develop a nanotechnological market, it is fundamental to count with industrial standards to produce good quality goods and to protect workers' physical health. A global regulation is required that allows us to speak a common language, allowing similar production everywhere. Although the technology advances at a very fast pace, bureaucratic structures struggle to keep up with its impact on the knowledge economy. To fill this gap, it is necessary to create efficient standards (Kica and Bowman, 2012; Murashov and Howard, 2011).

The establishment of patents and standards is necessary, but it is not sufficient to activate a nano market. Studies show that one of the main problems for companies that decide to initiate nanotechnology companies (*start-ups*) is the lack of enough funding for hiring highly qualified professionals, acquiring expensive equipment, and buying (or licensing) patents during the first stages of the production process (Fu, 2014). Getting an investor willing to not receive profit for years is a serious problem, even in the presence of state funding for the development of nanotechnology. Only certain informed and solvent investors interested on the technological business (*angels*) invest their own capital and involve themselves in the company for it to be successful (Prowse, 1998).

Governments are investing on R+D projects, yet investors require more information to take part into projects as some of them are not familiar with the complexities and expected future growth of the technology. There is a need for economic valuation methodologies of nanotechnological projects showing potential investors future benefits (Beaudry and Allaoui, 2012). Moreover, this

patent and goods market requires large long-term risky investments which have distinctive features. They are irreversible due to the impossibility of recovering initial payments; uncertain -as the future benefits are unknown-; and flexible –due to the fact that investors could join after the beginning of the project or could leave it before it ends (Dixit and Pindyck, 1994; Smit and Trigeorgis, 2012).

Although the market is relatively new, the first companies created in the 1990s have gained valuable experience. The literature on the matter identifies some lessons from the first generation of entrepreneurs. Firstly, they have shown the importance of focusing on the necessities of the market instead of concentrating on the technological platform. Secondly, it is not convenient to start hunting for funds in the exchange stock market before obtaining sale profits. While the importance of patents is recognized, intellectual property has a low value if it is not paired with the production and selling of concrete products. The first generation of entrepreneurs destined large sums of capital to create of patents but low sums to develop products. Thirdly, it is also fundamental to anticipate delays associated with the approval of regulators, and not underestimate regulative obstacles. Lastly, the effective marketing of nanotechnology based products requires to raise as much capital as possible when the capital market is open. This is explained by the long term and high capital requirements inherent to the marketing of nanotechnology. Successful companies should be capable of subsisting during diverse phases of economic cycles, in particular during economic recessions. (Maebius and Jamison, 2009).

From the point of view of the State, nanotechnological development should serve to purposes such as the reduction of pollution, the solution of social problems, and the decrease of electrical consumption. Nevertheless, governments must face the risks that these innovations may involve to both humans (Cui *et al.*, 2005; Lam *et al.*, 2004), and the environment (Colvin, 2003). Risks are co-produced by a complex socio-technic network through articulations and performances. Risks cannot be regulated in isolation.

While universities and nanomaterial companies have a direct responsibility over the existence of risks produced by their activities, these organizations internally

identify risks in their fabrication processes and manage them through engineering methodologies regulated by the State (Medley y Walsh, 2007). Afterwards, in order to cover for the unidentified dangers, companies pay a premium to an insurer that identifies, analyses, evaluates, and diversifies the remaining risk (Lloyd, 2007). However, this practice of engineering and actuarial risk management is not socially sustainable, as it does not contemplate human and environmental aspects.

The new nanotechnological dynamics leads to new risks for human beings and for the environment which are only partially managed by these organizations. In this context, State policies gain centrality as tools for protecting society and promoting sustainable markets. The American literature on technological regulation proposes a *regulation pyramid* to illustrate a flexible approach that has companies' self-regulation (*soft law*) at its base; as we go up the State's intervention increases leading up to the top of the pyramid, where regulation is strict (*hard law*) (Ayres and Braithwaite, 1992). Unlike the American program, the European one *Converging Technologies for the European knowledge society* (CTEKS) stresses the State technological policy as a tool for the creation of a *knowledge society*, guided by the precautionary principle (Klinke *et al.*, 2006).

In order to develop efficient public policies, it is essential to have *investment valuation tools* and financing instruments. An efficient economic-financial analysis which also evaluates social impact is needed to provide decision instruments for policy makers. Traditional tools for project valuation have serious limitations to reflect the complexity of the economic and social aspects this new market involve. They do not include regulatory aspects, policies, market behaviour, manpower cost uncertainty, among other complexities of innovative nanotechnological projects (Paxson, 2003; Pennings and Lint, 1997).

Nowadays, a *de facto* governance is operating in the nano products market, built on everyday choices and decisions made by dissimilar actors with conflicting interests (Rip, 2010). Hence, it is necessary a different approach, a sustainable one, in order to constitute a socially innovative nanodynamic that is socially responsible in the long-run. Therefore, it is necessary that technoscientists interact from the very start of the innovative process with market agents, the State, and the general

public. In this scenario, the State has the possibility to regulate through incremental regulation the existing *de facto* governance, making space for a dialogue between parts. Dealing with the incredible potential of the nanotechnological network and the uncertain associated risks demands the State intervention through policies protecting society and promoting a sustainable market aligned with society's requirements.

Nano-technological innovation opens up a debate on public policies that intervene on research funding, price fixation, and the socially optimal degree of patent use, taking into account the uncertain costs, future income, and effects on human health and the environment. What is necessary is the use of valuation models that contemplate this complex process. For the State, it is essential to have a long-run sustainability (Dhingra *et al.*, 2010; Eason *et al.*, 2011). To achieve this, it is important to propose diverse instruments of public-private funding and the creation of incentives for the private sector (Roco *et al.*, 2011). Due to the impact of investments on economic growth and the magnitude of the new challenges, it is necessary to develop *responsible* public-private financing tools that contribute to technological innovations. Responsible public policies encompass an improvement on the population's living conditions, as far as they are anticipatory, reflexive, deliberative, and receptive (Owen *et al.*, 2012).

This thesis assumes an individually reflexive and socially deliberative approach, which would contribute to the creation of an innovative nano dynamics where controversies are made explicit. It argues that a sociotechnical network needs to be sustainable, innovative, responsible, and inclusive (Rip, 2014). Its focus is on the analysis of the nano dynamics on the Argentinean context. Currently the nanotechnologic sector in Argentina is configured by a network of scientific and technological institutions, funding bodies, bilateral institutions, and technology based companies, wherein the State promotes the development of the internal market by promoting new associations that articulate what is public and what is private to stimulate the productive framework with a socially inclusive impact (Foladori *et al.*, 2012; Vila Seoane, 2011).

With respect to the Argentinean agro-industry, the *Instituto Nacional de Tecnología Agropecuaria* (INTA) is the most active organisation within the nano-sociotechnic network. Variety of products are currently being developed and researched. For example, the application of self-cleaning patterns characteristic of biological surfaces to the agro sector is being studied<sup>7</sup>. In addition to this, in the environmental monitor area, it is being developed equipment designed to detect agro-chemical molecules combining micro-fluidic, plasmon resonance on nano-structures metal substrata and molecular recognition elements<sup>8</sup>.

Regional economies are important for a socially inclusive growth of Argentina (Bekerman and Dalmaso, 2014; Casparri *et al.*, 2014; Miguez, 2014). One of them -linked to the ovine production- has grown considerably reaching a production of 14.859.486 heads on a national level in March of 2015 (Mueller, 2013). However, one disease - the ovine Brucellosis - is threatening the industry by producing economic loss to both the producers and the State (Robles 1998). The application of a nano-vaccine developed and patented by INTA prevents this disease, having a positive local impact on ovine production<sup>9</sup> (OIE, 2012; SENASA, 2014; INTA, 2013; INTA, 2015; Manazza *et al.*, 2006).

The State funded and promoted various projects related to the principal areas of scientific innovation, through the *Sectorial Argentinean Fund*<sup>10</sup> (FONARSEC). The government aims to steer innovation in such a way that it contributes to the solution of social problems. For instance, it has funded the development of functional textiles. Among the different functions that may be added to textile, researchers have been focusing on the development of insect repellence targeting disease vectors, such as dengue (Tallone, 2015). An example of a nano-technological private company (which receives governmental support) is Unitec Blue in 2012. The investment demanded more than US\$1000 million for the creation of a factory of chips commonly used on micro and nanotechnology. The

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<sup>7</sup> <http://inta.gob.ar/noticias/inta-con-otro-premio-bajo-el-brazo-1/>

<sup>8</sup> A Start-up called Nanotedecion is currently on incubation state on the CITES centre, located in the city of Rafaela, Santa Fe. <http://www.fan.org.ar/proyectos-presemilla/dr-nicolas-tognalli>

<sup>9</sup> The development consists of a lipidic molecule inserted on a nano-vehicle, which transports the synthetic molecule that directs an antigen to certain cells of the immune system. This optimizes the prophylactic action of the vaccine, allowing it to adhere to the receptor of the dendritic cell of the immune system, the molecule is thus directed to a certain cell that activates the immune system.

<sup>10</sup> The FONARSEC is a tool of the Ministry of Science, Technology, and Productive Innovation that supports projects to develop critical capacities on high impact areas and with transference to the productive sector. 7 areas were defined in this sense, Nanotechnology being one of them.

company produces chips to be used for the traceability of drugs, cattle-herding, auto-parts, identity documents, mobile communication systems, credit cards, and LED monitors (Enriquez, 2015).

In an attempt to address some of the key challenges of the nanosociotechnical network, this thesis contributes to the theory of technological governance. It argues that the network has been constituted by its practice, risks, and interactions between the market, the State, and users; and it needs a sustainable and responsible governance that is *co-constituted* with this nanotechnological innovative dynamics. In addition, the proposed approach will be used to examine the case of nanotechnology in Argentina.

To achieve this contribution, this thesis has six specific objectives. Firstly, to understand how the practice is constituted on the basis of relations between agents, both human and artefacts in a permanent transformative interaction inside the laboratory. Secondly, to comprehend how this practice spills over the construction process of a sociotechnical network giving birth to a market. Thirdly, to understand how the network co-constitutes risks for the human being and the environment. Fourthly, to elaborate a project valuation model where joint investments take place. Moreover, this model also must contemplate the necessary cooperation between the market actors, the market uncertainty, and regulation and incentives from the State. Hybrid agents (human-matter) interact in a controversial manner, contributing to the formation of the nanotechnological sociotechnical network. It is a complex, uncertain, and conflictive process, where relations, human needs and limitations are articulated in a process of permanent constitution. It is crucial to align this process with the requirements of society as a whole for a sustainable and responsible nano-governance that analyses and reflects on these processes and proposes alternatives. Fifthly, this thesis aims to understand the role of the regulatory framework in the constitution of the nanotechnoscientific market, focusing on the role of the State; it argues that is necessary to forge a sustainable nano-governance, extending the traditional economic-actuarial equilibrium to an integration of social and environmental interests. This thesis has an individually reflexive and socially deliberative approach, which allows to claim for an innovative socially responsible nano dynamics. Finally, the last specific objective



of this thesis is to assess if the governance of the nanotechnoscientific dynamics in Argentina could be considered sustainable and *Responsible Research and Innovation* (RRI) *responsible*. To do so, the inscriptions, translations, and black boxes of the constitutive process of the sociotechnical network in Argentina are analysed. Furthermore, it offers some guidelines on how this network could move towards a sustainable nanogovernance.

To achieve its goals, this thesis is divided into four chapters. The first one examines the constitution process of the nanotechnoscientific practice. The second one studies how this practice spill over beyond the lab, constituting a new market. At the same time, this nanotechnological industrial dynamics co-constitute risks for the society and nature, this is analysed in chapter three. Lastly, the fourth chapter proposes an approach of sustainable nanogovernance and RRI *responsible*, which it will be used to analyse the nano problematic in Argentina. Next, the content of these four chapters is detailed.

The first chapter starts examining diverse agents' views on nanotechnology. The US government, for example, states that nanotechnology is a unifying platform between science and engineering. In other words, it is a technological approach to science, supported by strong public financing, aiming to establish American companies as global leaders (Roco *et al.*, 2011). From a scientific perspective, nanotechnology works in a context where nature starts to behave in a *quantic* manner, being necessary a re-statement of the *micro* theory (Nordmann, 2010). For the market, the emergence of nanotechnology is a business opportunity and it promotes *soft* government regulation. In addition to this, insurers have economic incentives to ask for more regulation (Swiss Re, 2005; Lloyd, 2007). After introducing these different visions, the chapter problematizes the constitution process and unfolds its eclectic theoretical framework.

This nanotechnoscientific laboratory practice has a pragmatic approach situated between the classic and quantic theories (Roukes, 2001). Laboratory researchers search for a partial explanation through the eclectic use of several theories, articulating speeches about past technologies and future expectations. Past speeches allow to construct a nanotechnological myth, helping to imagine the

future of nanotechnology (Tourney, 2006). Moreover, expectations about the future from different actors also define the field, each of them is aiming to conquer the future and legitimating its present interests (Selin, 2007). Finally, as a way to integrate what was presented before, this chapter introduces actor-network theory (ANT) proposed by Bruno Latour (2005). This methodology is used to describe and explain the sociotechnical network as a constitutive process. It articulates laboratory observations at a micro level with concerns over the organization of society. This methodology will be used in the second chapter to account for how the industrial dynamics is constituted.

The nanotechnoscientific practice described has the potential to make several disciplines converge, which is key to understand the constitution of its transforming industrial dynamics. To understand this process, the second chapter starts by studying the literature on market design and constitution. Markets have advantages, its agents stimulate innovation, its structure allows for the coordination of expectations and its organization facilitates contracts between the parts that would not surge in a context of central planning. Nevertheless, they are not designed to achieve *common good*, so they could produce negative impacts on humans (Callon, 2009). Therefore, it is necessary to answer basic questions about markets and analyse how we can guarantee that their operations are socially responsible. This chapter examines nano technological markets, leaving aside abstract debates, by recognizing the growing role of experimentation in their inception, the fundamental role of technology, and the performative role that economic theory plays (Barry and Slater, 2002; Callon, 2010). After discussing the theory of market constitution, the chapter argues that the nano industrial dynamics has a transformative power over the economy in general. The evolution of the sector is analysed starting from early products, which were an aggregate of nano technology into traditional ones, to current developments such as nanocarriers (nano-dispositive that transport drugs to specific places of the human body). Following Callon and Muniesa (2005), the production and marketing of these products is thoroughly analysed using ANT. After understanding the constitution process of the market, this part analysis the role of investors in it by scrutinizing the role of new companies and revising some of the lessons learnt from the first

generation of nano entrepreneurs. From an economic perspective, a model of quantitative investment valuation for the pharmaceutical industry is examined. Lastly, this section presents a mathematical model that represents joint investment decisions between a small nano company that owns the patent of a nanocarrier (usually *spin-off*) and a big pharmaceutical that has both the drug to be transported and the access to the market.

This nanotechnological dynamics co-constitutes risks which are analysed on the third chapter of this thesis. Firstly, several approaches to the problematic of risk are presented (Adam and van Loon, 2000; Mythen, 2004), with a particular emphasis on the *risk society* approach (Beck, 1992). For the hegemonic Western thought, the production of wealth is associated with inevitable social risks. On the contrary, this thesis conceptualizes nano risk as co-constituted both during the technoscientific practice as well as in the dynamic of the associated market. Additionally, risks for the environment and the human being are analysed. Consequently, it is also argued that the nano industrial dynamics have implications for its governance.

From the point of view of the industry, uncertainty is taken as a constitutive part of the company's decision process. Hence, the traditional methodologies used for the valuation of investment projects are analysed, emphasising that they do not account for the complex dynamics of nanotechnology. To surpass this limitations, this work proposes the valuation methodology known as *real options*, which lets consider the uncertainty, flexibility, and irreversibility that exist in innovative nano projects (Trigeorgis, 1993; Kumaraswamy, 1996; Schwartz, 2013). Subsequently, the role of insurance companies - bounding, measuring, and pricing risks - and the risk evaluation process are examined, focusing on how experts calculate price without contemplating the impacts on society and without a clear understanding of the properties at nanoscale. It is important to create new standards to account for toxicity and for the effects of nano size. Next, this chapter focuses on the role of public policies. In so doing, it presents two mathematical models. The first model allows for the quantitative evaluation of whether it is optimal to start a given project in accordance to the precautionary principle. The second quantifies the social

benefits of two different kind of State incentives (known as *pull* and *push*). This tools helps governments' decision making process, quantifying costs and benefits.

This nanotechnoscientific practice that interacts with its market, building a sociotechnical network of controversial relations that co-constituting new risks, requires an adequate approach of sustainable governance. Chapter four starts with an examination on how expectations enlarge and strengthen the sociotechnical network through private and governmental actions. Without forgetting that State is an actor and recognizing that it is constituted through a historical process as a distributed agency, the State is modelled in this thesis as *collective hybrid of calculus* (Passoth and Rowland, 2010). Moreover, State institutions are decisive for the generation of aggregated macro effects fuelled by the actions of agents. In this context, the challenge is to understand causal mechanisms that promote an adequate governance. Then and there, the conflictive constitution of the nano sociotechnical network in the European context is analysed from the European perspective known as *Responsible Research and Innovation (RRI)* (Owen *et al.*, 2012). The starting point is a technical, economic, and political knowledge that requires reflection and confrontation between diverse points of view and interpretations to achieve a *dynamic sustainability*. It is an approach characterised as individually reflexive, socially deliberative, anticipatory, and receptive of the best practices.

Following, the nanotechnology in Argentina is examined through the operationalization and application of the key concepts of the RRI. To explore if the Argentinean nanotechnoscientific dynamics is *sustainable and RRI responsible*, firstly, the discourse of the governmental agencies is studied. Next, it analyses the proposed regulatory mechanisms and the degree of citizen participation in the process, describing narratives, expectations, and inscriptions that are in a process of constitution. Then, five examples of public-private associations are presented. Although the public policy is oriented towards the promotion of socially inclusive innovative production, this approach is a *top-down*, so it excludes society from the decision making process. Finally, strategies for the current nano dynamic in Argentina to be sustainable and RRI responsible are proposed.

# 1 La práctica nanotecnológica

## Summary

What is nanoscience and what is nanotechnology? In order to address these questions, this chapter will examine the perspectives of different stakeholders: the government, the scientific community, private companies and the third sector.

Alfred Nordmann (2006) proposes the use of the concept techno-science (Nordmann, 2012). Researchers pursue the goal of building nano-materials, not to prove their existence. When envisioning the future of the nanotechnology, it is important to assess how the past achievements of other technologies have been textually produced. The story of the past is an essential element when imagining the future (Thompson, 2011). This story is combined with future expectations to define the field (Selin, 2007). The nano-laboratory is not isolated from society. The relationships among stakeholders infuse meaning to the technology and claim for regulation.

According to the economic theory, expectations about the future course of technological innovation are one of the most important features to consider by the investor when choosing whether or not to adopt a new technology. These aggregated business decisions and their dialectical relationship with public policies contribute to shape future expectations and reproduce them. There is no possibility of sustaining over time future expectations that are not synchronized with the market dynamic, at least in the Western capitalist world that concerns us.

Roco, Mirkin and Hersam (2011) presented the US vision by describing the National Nanotechnology Initiative (NNI), its current situation and its expected development in the long term (2000-2020). It pursues the formation of an interdisciplinary academic community with a market orientation. This is reflected in the definition given by the NNI:

*Nanotechnology is the ability to understand, control, and manipulate matter at the level of individual atoms and molecules, as well as at the "supramolecular" level involving clusters of molecules (in the range of about 0.1 to 100 nm), in order to create materials, devices, and systems with fundamentally new properties and functions because of their small structure. (Roco, 2007 p.3).*

Meanwhile, the British government defines:

*Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, Where Significantly Differ from Those properties at a larger scale.*

*Nanotechnologies are the design, Characterisation, production and application of structures, devices and systems by controlling shape and size at nanometer scale.*

*(The Royal Society & The Royal Academy of Engineering, 2004 p.5)*

These definitions imply a unifying platform of science and engineering at the nanoscale, a technological approach to strengthen the productive sector.

There are no theories specially adapted to the complexity of nanoscale world that could explain the relationship between the structure of a given material and its properties. The researcher deploys partial explanations taken from various theories, forcing them beyond their scope (Winsberg, 2006). The practice in the laboratory has an engineering perspective, which constructs nanomaterials by using eclectic frameworks (Rip, 2013). Traditional theories are extended to face the challenges of the world at the nanoscale.

Nanotechnology public initiatives are excellent business opportunities for risky investors. Within the market logic, it is important to note the role of insurance companies as moderators of this dynamic, because their business is to collect money in advance to cover their customers' future contingencies. Current regulation of nanotechnology sector is insufficient. In response to this situation, the insurance industry demands greater transparency and better regulation (Lloyd, 2007).

After the report of different visions of the nano-world, the challenge is to understand how agents communicate the expected benefits to get more funding from governments. The narratives of past technologies are essential to imagine the future of nanotechnology, given that some of their traits remain. Chris Tourney (2006) selects the theory of myths developed by Malinowski (1954) to unpack what narratives has been useful to make sense of nanotechnology development.

After analysing the narratives of the past, it is important to understand expectations about the future of nanotechnology. Cynthia Selin (2007) explores how different actors operate to define the field and what problems are legitimated. This highlights the ways in which different actors intend to colonize the future and try to legitimize

their present. The fight between actors revolves around the question of what nanotechnology is and, crucially, what should be. Two groups emerge clearly, the so-called *visionaries* and *scientists*. Drexler (2004; , 2013) embodies the former group, dominating the official discourse during the last decade of the past century (Stix, 2001; Selin, 2007). The second group is mainly represented by the academic community.

The views and narratives about nanotechnology build a new techno-scientific practice, which could be understood using the actor-network theory (ANT). According to this perspective, the relationship between agents instils meaning to its existence. Moreover, technologies involved are not only useful tools, but also defined within the boundaries of symbolic struggles (Latour and Woolgar, 1986; Bijker and Law, 1992). ANT approach is adequate to understand the nano-practice because it demands the observation of the activity in the laboratory at the micro level, and a theoretical concern with the organization of society, opening new possibilities for the study of the political role of science. In the next chapter ANT will be used to understand how the industrial nano-dynamics is established.

## **Introducción**

¿Qué es nanociencia y qué es nanotecnología? Para empezar a caminar posibles respuestas, en este capítulo se transcribirán, analizarán y contrastarán diferentes visiones: la gubernamental, la científica, la de la empresa privada y la del tercer sector.

En cuanto a lo disciplinar, es Alfred Nordmann (2006) quien describe ciertas características de la investigación nano y propone el uso del concepto *Nanotecnociencia*, donde el término tecnociencia significa un modo de investigación diferente al científico tradicional (Nordmann, 2012). Peter Galison (2006) señala que los investigadores nano persiguen el objetivo de construir, no de demostrar existencia<sup>11</sup>. Es importante remarcar que, como los investigadores provienen de diferentes formaciones básicas, habitualmente difieren en qué teorías utilizan, pero todos coinciden en qué instrumentos y qué programas de ordenadores

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<sup>11</sup> Se trata de una forma ingenieril de hacer ciencia, extendiendo marcos teóricos existentes hacia uno ecléctico.

utilizan. Estos artefactos se transforman en los referentes comunes en la comunidad y adquieren una importancia extrema.

A la hora de imaginar el futuro de una nueva tecnología, siempre es importante evaluar la forma en que se describen los logros pasados de otras tecnologías. En el contexto particular de la aparición de la nanotecnología, Chris Tourney (2006) postula que el relato del pasado es fundamental a la hora de imaginar el futuro de la nanotecnología. Esto se conjuga con las expectativas futuras para definir el campo (Selin, 2007). Claramente, se ponen de manifiesto las maneras en que los distintos actores pretenden utilizar la historia y las expectativas para colonizar el futuro y legitimar sus intereses presentes.

Desde un punto de vista de la teoría económica, las expectativas sobre el curso futuro de la innovación tecnológica son uno de los factores más relevantes a tener en cuenta por el empresario a la hora de elegir si adopta una nueva tecnología. Esas decisiones empresarias agregadas y su relación dialéctica con las políticas públicas sostienen estas expectativas futuras y las reproducen. Sin dudas, no hay posibilidad de sostener en el tiempo expectativas futuras que no estén sincronizadas con la empresa, al menos en el mundo occidental capitalista que nos concierne. Notoriamente, el análisis de la dinámica de las expectativas es un elemento clave en la comprensión científica y en el cambio tecnológico.

Ahora bien, para un entendimiento acabado de la práctica nanotecnocientífica, es necesaria la caracterización social que la acompaña. La relación entre los actores involucrados le infunde significado, legisla su existencia y la materializa. Las tecnologías no son sólo herramientas que se utilizan o aplicaciones de la ciencia, sino que más bien se definen a través de argumentos y contraargumentos que, en algún momento futuro, se estabilizan en un plano social y se materializan sus estructuras (Latour and Woolgar, 1986; Bijker and Law, 1992). Y, más importante aún, se deberían estar estudiando los efectos sociales, cualquiera que sea su forma material, si queremos dar respuesta a las preguntas *macro* sobre la estructura, poder y organización<sup>12</sup>. En este sentido, lo tecnocientífico es siempre social y se vincula

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<sup>12</sup> El análisis sociológico necesita incorporar a la materia como un actor, para entender en forma acabada la reproducción (Law, 1992). La reputación de un investigador o instituto, su inclusión en los planes de estudio,



a las cuestiones de legitimidad y de construcción de credibilidad en las comunidades (Shaw, 2012).

Para analizar la práctica nanotecnocientífica, este capítulo primeramente analiza diferentes visiones sobre el concepto: Desde los propios investigadores, de los gobiernos, la academia, del tercer sector y desde el sector asegurador. Luego, se propone un marco teórico ecléctico para dar soporte a la investigación en el campo nano. Ahora bien, esta práctica se construye, también, con relatos. La sección tercera continúa planteando relatos del pasado que permiten construir el mito nanotecnológico y analiza cuales son las expectativas de futuro. Finalmente, en la última parte, se plantea el enfoque de la teoría de actor-red (ANT) sobre la práctica tecnocientífica y se la caracteriza como una dinámica divergente de búsqueda.

## **1.1 Diferentes visiones nano**

Para comenzar a responder posibles respuestas a la pregunta con la que iniciamos esta subsección *¿qué es nanociencia y qué es nanotecnología?*, se transcribirán, analizarán y contrastarán las definiciones que expresaron, en los últimos años, actores claves del campo: La *National Nanotechnology Initiative de EEUU* (Roco, 2004; Roco *et al.*, 2011), la oficina de patentes de EEUU (Lee *et al.*, 2006), la FDA de EEUU (Kimbrell, 2006), el Gobierno Británico (The Royal Society & The Royal Academy of Engineering, 2004; Bensaude-Vincent, 2012), la organización ecologista Greenpeace (Huw Arnall, 2003), la visión que tienen los científicos (Tahan, 2007) y el sector privado empresarial y asegurador (Swiss Re, 2005; Lloyd, 2007; Marchant, 2014).

### **1.1.1 Visión gubernamental**

Roco, Mirkin y Hersam (2011) presentan la visión de EEUU en un trabajo donde se describe la génesis de la Iniciativa Nacional de Nanotecnología (NNI)<sup>13</sup>, su situación actual y su probable evolución en el largo plazo (2000-2020). Desde el

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en las citas científicas o técnicas, artículos, o el éxito con la recaudación de fondos, podrían servir para apoyar una idea.

<sup>13</sup> La NNI es un compromiso a largo plazo de investigación y desarrollo (I + D) en EEUU, que se inició en el año 2001 (actualmente, coordina 25 agencias independientes). El total de inversión en I + D en los años fiscales 2001-2005 fue de más de 4.000 millones de dólares.

comienzo, se persiguió la formación de una comunidad académica interdisciplinaria en nanotecnología con una fuerte llegada al mercado.

Para que el largo plazo sea sostenible, es esencial la planificación y el establecimiento de prioridades en la gestión pública. En ese sentido, propone un fuerte financiamiento público y privado para el futuro, y nos ofrece la promesa de aumentar la eficiencia en las industrias tradicionales y llevar radicalmente nuevas aplicaciones a través de las tecnologías emergentes. En este documento, Roco referencia la definición de la NNI que establece que la Nanotecnología

*... is the ability to understand, control, and manipulate matter at the level of individual atoms and molecules, as well as at the "supramolecular" level involving clusters of molecules (in the range of about 0.1 to 100 nm), in order to create materials, devices, and systems with fundamentally new properties and functions because of their small structure. (Roco, 2007 p. 3).*

Esta definición implica una plataforma unificadora entre la ciencia y la ingeniería a nanoescala. En resumen, el enfoque es tecnológico y con un fuerte financiamiento para que la empresa norteamericana en el futuro pueda establecerse como líder y ser un motor fundamental en la nueva economía.

Cientos de nano-productos ya están ampliamente disponibles<sup>14</sup> y son especialmente frecuentes en los productos de cuidado personal. La FDA tiene autoridad reguladora sobre muchos de estos productos, sin embargo, hasta el momento, no ha adoptado medidas que contemplen las diferentes propiedades y riesgos asociados a los nanomateriales. G.A. Kimbrell (2006) evalúa la postura actual de la FDA con respecto a la reglamentación de los productos de consumo masivo que incluyan nanomateriales. El autor alienta a la FDA a modificar sus reglamentos para hacer frente a los nuevos riesgos humanos y ambientales, que los productos que contienen nanomateriales pudieran producir.

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<sup>14</sup> Complementando la visión norteamericana, Lee *et al.* (2006) realizan un análisis del estado actual de las patentes nanotecnológicas: si bien las actuales son, básicamente, materiales pasivos, se espera un futuro promisorio. Asimismo, la Agencia Federal de Alimentos (FDA) ha expresado su opinión sobre la aparición de productos nanotecnológicos en el mercado de consumo masivo, pero sin regular todavía.

### 1.1.2 Visión desde la academia y desde el tercer sector

Desde el ambiente académico, algunos científicos e ingenieros prefieren plantear que, en la actualidad, la nanotecnología se limita, solamente, a la fabricación de nanomateriales; cualquier otro futuro posible es por ahora, meramente, una posibilidad<sup>15</sup>. Sólo tal vez la nanotecnología del futuro incluirá la manipulación átomo por átomo, o molécula por molécula, y la posibilidad de construir dispositivos activos (Tahan, 2007). A pesar de esta visión restrictiva, es notable la cantidad de investigadores que trabajan en el nuevo campo, piden financiamiento a los políticos bajo las promesas nanotecnológicas y publican en las numerosas revistas científicas<sup>16</sup>.

Para muchos científicos que trabajan en el área de materiales, la nanotecnología es una evolución natural de la tecnología, pero que al llegar a nivel nano, muchas propiedades cambian de forma radical. Por ejemplo, partiendo de la microelectrónica, si realizamos circuitos cada vez más pequeños, se llega a un límite crítico donde los materiales se comportan de manera muy diferente: un hilo de 1 mm de espesor es conductor y sigue la ley de Ohm, pero cuando se reduce a un nanómetro, la ley de Ohm no es válida. En esos espesores, la naturaleza se empieza a comportar de manera cuántica, siendo necesario un replanteo de toda nuestra teoría, y dando lugar a la teoría ecléctica (Nordmann, 2010).

Las aplicaciones biomédicas son vastas y dan lugar a lo que se denomina nanomedicina. Los científicos la consideran una disciplina nueva, pues se relaciona con el acceso a la célula, donde las dimensiones son nanométricas (Bawa and Johnson, 2009). Si podemos acceder al interior y manipular el contenido con algún dispositivo inteligente, estamos frente a lo que llamaríamos bionanotecnología. Según este punto de vista, la nanociencia, en la medicina, es tal en tanto exista la posibilidad de acceder al interior celular y operar en él.

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<sup>15</sup> Además, existe un proyecto que detalla todos los productos nanotecnológicos que se encuentran en el mercado hoy. Claramente, son mayoritariamente nanomateriales pasivos en objetos de consumo (Project on Emerging Nanotechnologies, 2008)

<sup>16</sup> Leydesdorff y Zhou (2007) describen la evolución de la Nanotecnología como una disciplina, analizando las publicaciones en las revistas científicas. Utilizando el Índice de citas del 2003, 2004 y 2005, los autores sugieren que el nivel de citas habla a las claras de una disciplina establecida y de una comunidad académica sólida.

Por último, se trae a la discusión la voz de las organizaciones no gubernamentales. En particular, *Greenpeace* plantea que el nuevo campo multi-disciplinario propuesto por la nanotecnología y el creciente flujo de dinero público, abre la posibilidad de una nueva carrera armamentista entre los gobiernos (Faunce, 2014; Arnall, 2003). El tercer sector advierte sobre el uso de la nanotecnología, como una etiqueta para una variedad de disciplinas científicas con el fin de obtener dinero de los presupuestos gubernamentales (Arnall, 2003).

### **1.1.3 Visión desde el sector asegurador**

Ahora se prestará atención a un último actor, clave desde el punto de vista del mercado: las aseguradoras de riesgo. Estas empresas persiguen un fin de lucro en un sistema de mercado pero, a diferencia de otras empresas que buscan invertir en negocios riesgosos (tal vez nanotecnológicos), su negocio es cobrar primas en forma anticipada para cubrir a sus clientes por futuras contingencias. El valor de esas primas debería representar la probabilidad de la contingencia multiplicada por la intensidad. Claramente, el surgimiento de la nanotecnología es una oportunidad de grandes negocios, pero el cálculo de esas primas es incierto en un contexto de novedad y escasa regulación; esta incertidumbre sobre los beneficios o pérdidas futuras preocupa al sector, pues solamente sufrirá las pérdidas y no sus beneficios. Esta problemática interesó a las aseguradoras líderes a nivel mundial y han realizado informes en los que expresan su posición (Swiss Re, 2005; Lloyd, 2007).

La reactividad química de un material está relacionada con su superficie en comparación con su volumen, por lo que las nanopartículas de una sustancia determinada pueden ser mucho más reactivas que en grandes volúmenes, para un mismo peso dado de la sustancia. Los informes de las aseguradoras enfatizan que estos productos ya están en el mercado y se utilizan en productos de consumo. La toxicidad es desconocida y se pueden dispersar fácilmente. Por esta razón, la industria de seguros se propone vigilar esta situación, para evitar la quiebra de la aseguradora<sup>17</sup> (Lloyd, 2007).

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<sup>17</sup> Según las investigaciones al día de hoy, no está claro si las nanopartículas pueden causar efectos crónicos de salud, llevando a la industria a contraer deudas millonarias a futuro por efectos ocasionados hoy.

La industria reconoce los grandes beneficios potenciales, sin embargo, alerta que no debe permitirse comercializar estos productos antes de evaluar adecuadamente los riesgos asociados. Esto lo hace velando por su propia salud financiera, evitando que no se produzcan quebrantos secuenciales por una agregación sistémica de la pérdida por negocios nanotecnológicos. Asimismo, se alerta sobre el mecanismo utilizado por algunos países de dejar que los productos salgan al mercado masivo y *esperar y ver* los riesgos, siendo una forma muy peligrosa de determinar los riesgos asociados. En resumen, la opinión de este último actor, las aseguradoras, es la de mantener el ritmo rápido del desarrollo del campo, promover la formación de redes de académicos que trabajen en este ámbito y enfatizar que en la actualidad existe un vacío de regulación. La falta de reglamentación nunca es útil para los aseguradores responsables y, en este sentido, la industria de seguros debe ejercer presión por medio de lobbies para exigir una mayor transparencia y eficacia. Esto permitiría proteger la solvencia de largo plazo de la industria (Lloyd, 2007).

Luego de revisar las diferentes visiones sobre la práctica nanotecnocientífica, la siguiente sección problematiza el proceso de formación disciplinar dentro de un marco teórico ecléctico.

## **1.2 Un marco teórico ecléctico**

Es Alfred Nordmann (2006) quien recuerda que, a fines de 1940, el físico Werner Heisenberg (1971) introdujo el concepto de *teorías cerradas*. En particular, se refirió a cuatro: la mecánica newtoniana, la teoría de la relatividad, la mecánica estadística de Gibbs (Kirkwood, 1946), y la mecánica cuántica no relativista. Estas teorías son consideradas cerradas debido a que su desarrollo histórico ha llegado a su fin, constituyendo cada una un dominio herméticamente cerrado y siendo siempre válidas.<sup>18</sup> Heisenberg, asimismo, enuncia que sus dominios son acotados y no incluyen ninguna proposición cierta sobre el mundo empírico porque son una idealización del éste. Evaluar en qué medida los fenómenos experimentales pueden

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<sup>18</sup> Alisa Bokulich (2006) examina en detalle las similitudes y diferencias entre la noción de Teoría cerrada de Werner Heisenberg y el concepto de paradigma de Thomas Kuhn. Si bien Heisenberg y Kuhn comparten una concepción holista de las teorías y la noción de inconmensurabilidad, sus opiniones divergen, fundamentalmente, en lo que respecta a la cuestión del realismo científico.

ser explicados por la teoría es una cuestión de calibración, afinación, de ajuste mutuo entre fenómeno y teoría.

Por otro lado, los investigadores en nanotecnociencia no tienen como objetivo acomodar la teoría a la realidad para explicar esta última. En este sentido, se toman los fenómenos nano como un mundo complejo situado entre la teoría clásica y la cuántica (Roukes, 2001). Asimismo, no existen teorías especialmente adaptadas para tener en cuenta la particular complejidad del mundo a nanoescala, ni que expliquen la relación entre la estructura de un determinado material y sus propiedades. En lugar de utilizar teorías cerradas, el investigador busca una explicación parcial mediante un uso ecléctico de varias teorías, forzándolas, más allá de su ámbito de aplicación.

Nuevamente, Alfred Nordmann (2004) ofrece un claro ejemplo donde, para medir la corriente a través de un complejo orgánico-inorgánico, el investigador elige, indistintamente, entre reconstruir la medida en forma cuántico-química o de forma clásica. De esta manera, los investigadores utilizan teorías e instrumentos que no fueron hechos para trabajar en esta escala<sup>19</sup>. El investigador se enfrenta a un cosmos donde las propiedades clásicas, como el color y la conductividad, surgen al aumentar el tamaño desde los niveles cuánticos; y donde fenómenos, como la conductividad cuántica, emergen al reducir la escala hasta llegar al régimen cuántico (Roukes, 2001).

Para operacionalizar este marco ecléctico dentro del laboratorio es necesario construir modelos de simulación que integren varias teorías, de forma de predecir el comportamiento de un sistema a escala nano. Eric Winsberg (2006) ilustra este comportamiento emergente describiendo el uso de modelos computacionales en los estudios en esta escala. Estos algoritmos descriptivos de una dinámica se separan de la explicación causal tradicional y ofrecen un posible mecanismo de explicación *ad hoc* mediante el uso de un software específico<sup>20</sup> (Gruner, 2013).

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<sup>19</sup> Esto implica también que el núcleo mismo de las teorías se fuerza para dar cuenta de una estructura causal detrás de los fenómenos observados.

<sup>20</sup> Un ejemplo claro de lo anterior es el artículo “Conductance of a Molecular Junction”, publicado en la revista *Science* en 1997 (Reed *et al.*, 1997).

En tanto la nanotecnociencia considera el mundo como complejo, caracterizado por las leyes de la química y por actividad biológica, aspira a construir materiales *vivos* en lugar de dispositivos pasivos. Un buen ejemplo de ello es el término *superficie selectiva* que atribuye a la agencia algo que sigue siendo pasivo: las células pueden adherirse a una determinada superficie en forma diferencial, pero la selección la realiza el ingeniero que elige la superficie a fin de lograr alguna funcionalidad. Lo mismo cabe decir de conceptos tales como materiales inteligentes, movimiento autónomo, etc. Todos estos términos tienen un significado concreto y, al mismo tiempo, se refieren a algo visionario (Nordmann, 2006).

### 1.2.1 El poder de las imágenes

Si, como se dijo recientemente, el ámbito de investigación fuerza eclécticamente teorías ajenas para construir explicaciones, ¿cómo puede el investigador estar o no satisfecho con su entendimiento de un determinado fenómeno? Para Heisenberg y cualquier filósofo de la ciencia que tenga orientación hacia la física teórica, esta cuestión se reduce al poder predictivo de la ciencia cuantitativa: los valores numéricos que predice la teoría se comparan con los valores obtenidos en la medición y se verifica que se encuentren razonablemente cercanos. Esto no es posible en las investigaciones a escala nano, pues en forma explícita se manipula al realizar la medida (en general se bombardea la materia y se lee a partir de la respuesta del material).

Esta imposibilidad lleva a postular el criterio de semejanza (*likeness*). Se evalúa visualmente la semejanza entre la imagen de una simulación del modelo y otra imagen que representa la medición. Esta situación nos aleja del paradigma cuantitativo y nos propone un mecanismo cualitativo de evaluación. Lo que compara el investigador son dos representaciones, la simulación del modelo y la lectura del laboratorio<sup>21</sup>.

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<sup>21</sup> Desde ya, que esta metodología tiene muchos problemas, siendo el principal, la subjetividad del investigador al comparar imágenes provenientes de dos monitores. Uno ofrece una interpretación visual de los datos que fueron obtenidos a través de una serie de mediciones, mientras que el otro, presenta una simulación dinámica del proceso que podría haber sido la observación realizada con un software de simulación visual. En base a esas dos imágenes, se extraen conclusiones sobre los procesos de causalidad probable.

Como los investigadores provienen de diferentes formaciones básicas, habitualmente difieren en qué teorías utilizan, pero todos coinciden en qué instrumentos y qué programas de ordenadores utilizan. Estos artefactos se transforman en los referentes comunes en la comunidad y adquieren una importancia extrema<sup>22</sup>. Estas imágenes del nanocosmo son cada día más populares. Al pasar de comparaciones cuantitativas de valores numéricos a la construcción del concepto de semejanza cualitativa por imágenes, se sustituye una realidad por otra desde lo simbólico. En este sentido, el poder de las imágenes<sup>23</sup> ha convertido a la nanotecnología en lo que es (Nordmann, 2006).

Este vuelco a lo cualitativo, a la hora de contrastar el modelo con la realidad, ha molestado a filósofos de la física como Otavio Bueno (2004) y Pieter Vermaas (2006), pues se deja al relativismo de un ojo humano el comparar dos figuras. De esta forma, el poder de las imágenes plantea algunos de los problemas más graves para las nanociencias y las nanotecnologías; las imágenes en los medios producen su propia realidad que, muchas veces, contradice la intención del científico que la produjo<sup>24</sup>. En este sentido, los científicos invocan, en forma casi automática, a imágenes de transporte de electrones sin sentir la necesidad de demostrar su existencia: piensan los electrones pasando a través de una molécula como si fuera un objeto material.

Rom Harré (2003) contrasta los instrumentos científicos que sirven como prueba para evaluar causalidad, con los dispositivos (incluyendo simulaciones) que producen fenómenos. Utilizando instrumentos se obtienen medidas que pueden remontarse en la cadena causal a algún estado físico, propiedades o proceso; no ocurre lo mismo cuando se utiliza una imagen de una simulación para compararla con la imagen que produce un dispositivo de lectura. En resumen, la práctica de

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<sup>22</sup> A este respecto, es especialmente interesante el trabajo realizado por Jochen Hennig (2006) sobre la historia del microscopio *scanning probe*, como así también el de Ann Johnson (2006), que estudia el papel que ocupan los ingenieros de software en este proceso.

<sup>23</sup> Historiadores del arte y teóricos como William Mitchell (2005) o Hans Belting (1994), en particular, han puesto de relieve la diferencia entre los signos convencionales, que sólo persiguen la representación de otra cosa, y las fotografías o imágenes que encarnan visiones y deseos.

<sup>24</sup> Nordmann (2006) recuerda como ejemplo, la famosa imagen a escala nano producida por Don Eigler y Erhard Schweizer (1990). Por primera vez en la historia, los seres humanos manipularon los átomos a voluntad y dieron una imagen al mundo que fue leída como la prueba de concepto de las increíbles posibilidades de la nueva tecnología. Esto no era, precisamente, lo que Eigler y Schweizer quisieron decir; su imagen es testimonio de la dificultad y de los límites tecnológicos para el control de átomos individuales (Eigler, 1999). Pero el poder de la imagen difundida en los medios superó cualquiera de sus testimonios en contrario.



laboratorio nano tiene una perspectiva ingenieril del conocimiento, se construyen materiales utilizando un marco ecléctico específico (Rip, 2013).

### **1.2.2 Hacia una disciplina**

En la subsección anterior se presentó a la Nanotecnociencia en términos de cuestiones disciplinares (un complejo campo parcialmente explicado, mediante la extensión de teorías cerradas), metodológicas (la comparación por semejanza de imágenes, no de números) y ontológica (indiferencia).

A partir de la mecánica cuántica, hidrodinámica, etc., aparecen las teorías que sirven de guía a nanoescala. Si bien éstas son las ciencias básicas, como planteamos anteriormente, no pueden postularse como cuerpo teórico de la nanociencia. El dominio de interés para las nanociencias y las nanotecnologías comprende a todo aquello que se encuentra en la zona fronteriza entre el mundo cuántico y la física clásica. Se extienden marginalmente teorías<sup>25</sup> para enfrentar los desafíos que presenta el mundo a escala nano.

Resumiendo, no hay ningún marco teórico para lograr, en el mundo real, controlar los fenómenos de escala nano en nuestro beneficio. Sólo se puede extender el marco existente hacia uno ecléctico para explicar un comportamiento dentro del laboratorio. Pero ese trabajo, muy posiblemente, no será lo bastante robusto como para servir de base para la producción masiva de componentes nanotecnológicos. Todo parece posible, pues nuestro conocimiento actual no lo invalida. Es evidente que el mero hecho de que algo no esté en contradicción con las leyes conocidas, no es suficiente para establecer que es posible técnicamente lograr que funcione a nivel masivo y fuera del laboratorio (Nordmann, 2006). Es en el proceso de salir del laboratorio, donde los relatos del pasado y las expectativas de futuro impactan en el proceso de constitución. La siguiente sección analiza esta problemática.

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<sup>25</sup> Esta forma de trabajo “marginal” también se ve reflejada en la forma que se evalúan los riesgos toxicológicos asociados a las nanotecnologías (nanotoxicología). Además, se extienden procedimientos de evaluación de riesgos químicos a la escala nano, debido a la falta de metodologías propias. El investigador realiza modificaciones *ad hoc* a los métodos para que se adecuen al nuevo ámbito, pero no hay certeza de estar evaluando los riesgos en forma correcta, poniendo en peligro vidas humanas y al medio ambiente.

### 1.3 Relatos y expectativas del futuro

A la hora de imaginar el futuro de una nueva tecnología siempre es importante evaluar la forma en que se describen los logros que en el pasado otras tecnologías han construido. En el contexto particular de la aparición de la nanotecnología, Chris Tourney (2006) postula que el relato del pasado es fundamental a la hora de imaginar el futuro de la nanotecnología, teniendo en cuenta que algunos rasgos de ese pasado continuarían en un futuro posible. Este autor selecciona la teoría de los mitos<sup>26</sup> de Malinowski (1954) para detectar cuáles podrían ser los relatos o historias útiles a la hora de construir el relato de la nanotecnología. Para Tourney, la nanotecnología podría generar las condiciones necesarias para el relato del mito, de la misma forma que lo ha hecho la recombinación de ADN.

Los puntos a considerar del desarrollo de Malinowski que Tourney sostiene como necesarios para su hipótesis son, por un lado, que el relato del mito surge en circunstancias tensas, particularmente, cuando un grupo debe justificarse sobre otro, cuando su experiencia de la historia se modifica o cuando aparecen eventos que molestan. El resultado del relato del mito es justificar, legitimar o racionalizar las circunstancias que rodean a la gente. De esta forma, podría ser un ejercicio como para llegar a un arreglo de las tensiones actuales. Muchas de las relaciones que involucra la nanotecnología asemejarían las condiciones que genera el relato del mito en la teoría de Malinowski, en la medida que coexisten varios relatos narrados<sup>27</sup>.

Tourney (2006) organiza a las diferentes posturas en relación a la nanotecnología en cuatro categorías. La primera es la postura en extremo nanofílica, cercana a la ciencia ficción, de la cual Eric Drexler es uno de sus principales exponentes. La segunda, es optimista en cuanto a los beneficios, pero menos fantasiosa. Fue en este sentido que la administración Clinton favoreció varios proyectos, pensando en los beneficios para la salud y en la mejora de los estándares de la población. A la tercera postura la denomina como de escepticismo mesurado. Se oponen y

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<sup>26</sup> La teoría de Malinowski plantea la existencia de una relación entre las condiciones sociales del presente y los relatos de las historias del pasado. En este sentido, sostiene que una de las razones por la que la gente relata mitos, es debido a la necesidad de justificar ciertas condiciones del presente.

<sup>27</sup> En el mismo sentido que los Trobriander narran su mito.

ridiculizan a la postura en extremo nanofílica, haciendo hincapié en las consecuencias que podría ocasionar tanto en la ciencia como en la sociedad. La cuarta y última postura es la extrema hipérbole nanofóbica. Su postura es tan exagerada como la nanofílica. Esta visión realiza una analogía de la nanotecnología con la historia de Frankenstein, en la cual toda predicción se presume como peligrosa y arrogante. Asimismo, hay quienes preanuncian el fin de la humanidad (Joy, 2000).

Como dijimos anteriormente, Tourney (2006) selecciona un caso tecnológico semejante: la recombinación de ADN de 1970 (donde se cumplirían las condiciones de Malinowski)<sup>28</sup>. La posición de Tourney (2006) es que la historia de la recombinación de ADN va a ser relevante para la nanotecnología cuando estén presentes las siguientes tres condiciones. La primera, cuando la hipérbole tecnófila inspire su reacción opuesta denominada hipérbole tecnofóbica. Es válido argumentar que esta situación podría estar pasando actualmente en relación a la nanotecnología.

La segunda alude a las condiciones de Malinowski: la nanotecnología pareciera afectar a diferentes personas en diferentes modos y podría incrementar la diferencia de poder o riqueza. Algunos grupos podrían controlar la investigación y el desarrollo, mientras que otros se sentirían más poderosos. Asimismo, generaría un cambio histórico profundo y los ciudadanos podrían no entender la situación en la que se encuentran. De este modo, las tres condiciones del relato del mito de Malinowski podrían desplegarse. Finalmente, la tercera condición mencionada por Tourney (2006) plantea el desinterés por la salud pública<sup>29</sup>.

De esta forma, la lección más importante es que esa hipérbole y las condiciones de Malinowski han intensificado los valores, las esperanzas y los miedos que podrían

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<sup>28</sup> Este caso demostraría diferentes condiciones que permitirían anticipar algunos efectos en las reacciones públicas en relación a la nueva tecnología. Además, consideramos que la selección de este caso fortalece el concepto de proceso dinámico de construcción del campo nanotecnológico a partir de la interacción de los diferentes actores involucrados. Inicialmente, la recombinación de ADN trajo aparejada una considerable hipérbole tecnofílica. Sus consecuencias serían nuevos beneficios de magnitudes desconocidas: productos farmacéuticos más efectivos, comprensión de las causas del cáncer, abundantes cosechas de alimentos, hasta nuevas soluciones para los problemas de energía (Grobstein, 1977)

<sup>29</sup> Si bien este tercer elemento todavía no estaría establecido en el caso de la nanotecnología, el autor sugiere la necesidad de anticiparse a la reacción pública, indagando acerca de los riesgos que los científicos e ingenieros podrían crear, de qué manera asumirían la responsabilidad por esos riesgos, cómo los mitigarían, etc.

ser anticipados en la reacción pública hacia la nanotecnología en un futuro cercano. Si no se enfatiza en la salud y seguridad pública, la reacción seguramente será de miedo y rechazo hacia la nanotecnología. Luego, las historias que la gente relate de la nanotecnología cobrarían la forma del relato del mito al estilo de Malinowski<sup>30</sup> (Tourney 2006).

Luego de analizar las narrativas del pasado, nos concentraremos en las expectativas sobre el futuro. Cynthia Selin (2007) explora cómo las expectativas nanotecnológicas de los diferentes actores involucrados operan para definir el campo, como así también qué problemas son los legítimos, poniendo de manifiesto las maneras en que los distintos actores pretenden utilizarlas para *colonizar* el futuro y legitimar sus intereses presentes. La pelea entre los actores gira alrededor de la pregunta acerca de qué es nanotecnología y, fundamentalmente, qué debe ser. El punto de partida de la autora es simplificar este multientramado de actores agrupándolos en dos: los llamados visionarios y los científicos.

En este nuevo desarrollo del campo disciplinar, convergen diversas disciplinas, diferentes instituciones, como así también financiamientos, políticas económicas y sociales, culturales y los medios masivos de comunicación. Asimismo, es importante mencionar que estas expectativas sobre la nanotecnología siguen una dinámica que busca evidenciar beneficios futuros que permitan construir un nuevo orden mundial. Los más apasionados hasta mencionan un mundo donde esta tecnología nos libraría de los problemas de salud y limpiaría nuestro mundo de todo tipo de polución presente. Selin se refiere a un concepto de expectativa como similar a motivación y a intención (Selin, 2007 p.198).

Desde un punto de vista de la teoría económica, el profesor de la universidad de Stanford Nathan Rosenberg (1976) asegura que las expectativas sobre el curso futuro de la innovación tecnológica es uno de los factores más relevantes a tener

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<sup>30</sup> Asimismo, las representaciones narrativas compiten con otras para lograr la credibilidad y la autenticidad histórica. Es decir, se relatan diferentes historias del pasado, y según cuál sea el futuro posible, se seleccionan las principales lecciones que deben ser pensadas. Entonces, para construir el relato de la nanotecnología, los científicos e ingenieros que trabajan en estas investigaciones pueden contribuir con historias de mucho valor, que seguramente, disputarán con las historias de otros. Es válido pensar que esos otros relatos, también poderosos, pueden provenir de ciudadanos participantes que quizás tengan otros valores y otras lecciones.

en cuenta por el empresario a la hora de elegir si adopta una nueva tecnología<sup>31</sup>. Desde el punto de vista sociológico, es muy interesante el aporte que se realiza a la problemática en el número especial de la revista *Technology Analysis and Strategic Management* donde los editores invitaron a un grupo de sociólogos a discutir sobre el rol de las expectativas en el delineamiento del cambio tecnocientífico (Borup *et al.*, 2006). Para ellos, las expectativas y las visiones futuras son importantes para la sociedad en su conjunto, más allá de las opiniones de los científicos e ingenieros directamente involucrados en la tecnociencia en cuestión<sup>32</sup>.

El futuro imaginado de la nanotecnología es una promesa de pequeñas máquinas programables capaces de curar todos los males y de limpiar el medio ambiente de la polución, que nosotros mismos hemos causado. Es un futuro creado para seducir, ofreciendo soluciones mágicas a problemas que nuestra sociedad no quiere enfrentar por el camino más arduo (i.e. cambio de dieta y ejercicio físico para mejorar nuestra salud y un serio programa de reducción de emisión de gases de efecto invernadero a la atmósfera).

Ese futuro conlleva miedos, irracionalmente exagerados. Michel Crichton (2002) sitúa su novela *Prey* en un laboratorio nanotecnológico en el desierto de Nevada. Debido a un experimento fuera de control, una nube de nano-robots se ha escapado. Esta nube es autónoma, se autoreproduce y aprende. Se presenta como un ser vivo que se expande sin límite. Esta predicción futurista se ha dado en llamar *grey goo* (Highfield, 2003). Si bien el lenguaje pseudocientífico está siempre presente en el discurso, la comunidad científica contrapone teorías y experiencias, postulando la bajísima probabilidad de que esto ocurra. No es necesario imaginar enemigos irreales para encontrar seres que se autoreproducen y que amenazan a diario la sobrevivencia: virus, bacterias y, el más dañino, los seres humanos (Tahan, 2007).

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<sup>31</sup> Esas decisiones empresarias agregadas y su relación dialéctica con las políticas públicas sostienen estas expectativas futuras y las reproducen. Sin dudas, no hay posibilidad de sostener en el tiempo expectativas futuras que no estén sincronizadas con la empresa, al menos, en el mundo occidental capitalista que nos concierne.

<sup>32</sup> Dichas expectativas desempeñan un papel central en la asignación de recursos públicos nacionales, definiendo el futuro de la sociedad en su conjunto (van Lente and Rip, 1998; van Lente, 1993). Por estas y otras razones, el análisis de la dinámica de las expectativas es un elemento clave en la comprensión científica y en el cambio tecnológico.

El libro de K. Eric Drexler *Engines of Creation: The Coming Era of Nanotechnology* visiblemente describe increíbles beneficios futuros en conjunto con escalofriantes riesgos previamente impensados (Drexler, 1986). El autor plantea que la nanotecnología tiene un control exhaustivo de la materia a nivel molecular y sostiene como algo cierto en el futuro cercano la posibilidad de diseñar moléculas a voluntad<sup>33</sup> (Drexler, 1992). En un reciente trabajo K. Eric Drexler (2004) remarca que la revolucionaria visión de Feynman hizo de la nanotecnología una moda y puso en marcha una carrera a nivel global por dominarla. Sin embargo, la comunidad científica, luego de valerse de esta visión futurista para lograr financiamiento y temiendo que la preocupación pública con respecto a sus peligros pudiera interferir con dichos fondos, ha tratado de reducir las expectativas de corto plazo generadas por la nanotecnología, para excluir lo problemático de la visión de Feynman.

Drexler (2004; , 2013) ofrece definiciones para dar su opinión sobre cuatro conceptos que habitualmente se confunden: nanoreplicador, nanobot, ensamblador y fabricación molecular. Tal como se utiliza aquí, un ensamblador es un mecanismo para orientar reacciones químicas. Un nanobot genérico, entonces, puede ser un ensamblador o algún otro tipo de mecanismo robótico a nanoescala. La fabricación molecular es un proceso de construcción átomo por átomo. Por último, un nanoreplicador es una compleja y especializada especie de nanomáquina que permite la autoreplicación de los nanobots. En la visión de Drexler, estos mecanismos descritos previamente son la solución a la contaminación, a la escasez de recursos alimentarios y a la desigualdad económica. De acuerdo con muchos autores, Drexler personifica la corriente que llamaríamos *visionaria* nanotecnológica (Stix, 2001; Selin, 2007). Sin dudas, ha sido una figura clave para este nuevo paradigma tecnológico y ha dominado el discurso oficial durante todos los años 90.

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<sup>33</sup> Además, prevé máquinas moleculares programadas por nanocomputadoras para llevar a cabo tareas específicas. Así también se imagina la manipulación de átomos individuales para obtener formas determinadas. Estos dispositivos no serían simples máquinas, incluirían una componente orgánica. Dependiendo de la misión programada al diseñarla, el organismo podría romper enlaces a nivel molecular para construir nuevas formas.

Actualmente, los resultados concretos en nanotecnología son modestos y se reducen a la producción de nanopartículas<sup>34</sup>. Sin embargo, existen posibles riesgos a evaluar, que no deben ser minimizados, asumiendo que nuestro conocimiento sobre materiales en estudio hasta el nivel micro se aplica a la escala nanométrica. En consecuencia, el aumento de la superficie de contacto entre los materiales y el medio ambiente o los seres humanos aumenta su poder reactivo. Por un lado, permite que las nanopartículas de plata sean, a igual peso, más efectivas que sus hermanas mayores en tareas de esterilización. Análogamente, ese mayor poder reactivo puede tener mayor nivel de toxicidad para el ser humano (Cui *et al.*, 2005; Lam *et al.*, 2004; Shvedova *et al.*, 2003) o para el medio ambiente (Colvin, 2003).

Las promesas de beneficios futuros de la nanotecnología tardan en llegar y muchos empiezan a sospechar que, tal vez, tarden demasiado o nunca lleguen. Esta situación, claramente, se ha transformado en los últimos años, en un problema para el financiamiento de la actividad.

#### **1.4 La práctica tecno-científica**

De acuerdo a la teoría del actor-red (ANT), la relación entre los actores involucrados en una práctica científica (o tecnocientífica) es la que le infunde significado, legisla su existencia y la materializa. Asimismo, las tecnologías involucradas en la práctica no son sólo herramientas que se utilizan o aplicaciones de la ciencia, sino que más bien se definen a través de argumentos y contraargumentos que, en algún momento futuro, se estabilizan en un plano social y se materializan (Latour and Woolgar, 1986; Bijker and Law, 1992).

Si bien el materialismo relacional de este enfoque es distintivo<sup>35</sup>, tiene puntos en común con otras perspectivas sociológicas. El hecho de vincular el materialismo y

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<sup>34</sup> Si bien estos nanomateriales son la prehistoria de lo esperado por los visionarios, igualmente han producido un impacto increíble a lo largo del último decenio. El Instituto Inglés de Física editó una nueva revista llamada *Nanotechnology* en 1991. Ese mismo año, por su parte, los departamentos de desarrollo corporativos comenzaron los anuncios de desarrollos nanotecnológicos. Por ejemplo, el vicepresidente de IBM, J.A. Armstrong, ese año presentó su plan de inversiones nanotecnológicas, comparando la futura revolución con la "micro" de los 70 (Williams and Alivisatos, 2000).

<sup>35</sup> Cuando se busca describir las tecnologías y las consecuencias de su aparición, es necesario considerar una multitud de factores derivados de la heterogeneidad de los actores. En este campo, interactúan no sólo los científicos con sus artefactos, sino también los gobiernos (y sus leyes), las universidades y los centros de investigación, el mercado empresario, los medios de comunicación públicos. Asimismo, no sólo interactúan actores humanos sino también elementos materiales y discursos escritos (*inscripciones*) imponen su naturaleza,

las relaciones sociales se ha realizado tanto en el marxismo, como en muchas perspectivas feministas (Law, 1992) aunque en estas perspectivas, la relación entre estos dos elementos no se plantea de la misma forma continua como lo hace ANT. El enfoque es, pues, una teoría de la agencia, una teoría del conocimiento y una teoría de las máquinas. Y, más importante aún, se debería estar estudiando los efectos sociales, cualquiera que sea su forma material, si queremos dar respuesta a las preguntas *macro* sobre la estructura, poder y organización. El análisis sociológico necesita incorporar a la materia como un actor, para entender en forma acabada la reproducción (Law, 1992).

Según Bruno Latour,

...we study science in action and not ready made science or technology; to do so, we either arrive before the facts and machines are blackboxed or we follow the controversies that *reopen* them.(Latour, 1987 p.258).

La imagen sugiere tomar una proposición técnica e imaginarla entre comillas y en la boca de un orador. Luego, poner a todos ellos en una situación específica, en algún lugar del tiempo y del espacio, rodeado por máquinas y colegas. Se observa la controversia que se desarrolla fijando la atención en qué elementos nuevos aparecen con el objeto de convencer o seducir a sus colegas. Luego, se ve cómo la gente que ha sido captada deja de discutir, la imagen propuesta empieza a desaparecer, dando lugar a un cuadro donde sólo aparece la nueva frase técnica inscrita en un libro texto similar al inicial.

Siguiendo a Latour, se puede hablar de un *hecho* solamente cuando se estabilizó colectivamente a partir de controversias y los nuevos documentos técnicos al respecto no sólo dejan de criticar la idea, sino que empiezan a confirmarla. En la medida que las controversias aumentan la literatura, se convierte en técnica. Esta controversia se realiza con una retórica que incluye amigos para soportar el argumento propio, referencias a textos antiguos y la búsqueda de ser citado a futuro<sup>36</sup> (Mifsud, 2014).

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y se resisten. Por consiguiente, la red de actores está constituida por diversos elementos: discursos, materiales y humanos (Latour, 2012).

<sup>36</sup> Ahora bien, cabe preguntarse cómo se logra que una determinada idea sea aceptada. Latour dirá que se puede responder a través de “traducción”. Denomina *traducción* a un proceso mediante el cual los actores se definen y constituyen el uno por el otro, o bien, a la forma en que los actores atraen a otros agentes a posiciones favorables para los primeros (Callon, 1999). Por ejemplo, una vez que otros tienen una particular representación del futuro, se ha producido la traducción (Latour, 1987).



Bruno Latour (1987) analiza la construcción argumentativa como un proceso destinado a establecer legitimidad. Se refiere a los procesos de traducción original, como a la interpretación dada con la esperanza de atraer el interés de los demás. El éxito de una traducción implica inscribir a otras personas para sus intereses. Latour esbozó varias estrategias para traducir los intereses (Latour, 1987 p.108-9), y denominó aliados no sólo a los recursos que únicamente incluyen cifras y ecuaciones, sino también a otras asociaciones que representen a autoridades tanto de orden científico, social o político. La reputación de un investigador o instituto, su inclusión en los planes de estudio, en las citas científicas o técnicas, artículos, o el éxito con la recaudación de fondos, podrían servir para apoyar una idea. En este sentido, lo tecnocientífico es siempre social y se vincula a las cuestiones de legitimidad y de construcción de credibilidad en las comunidades.

#### **1.4.1 La ciencia en la sociedad**

En esta subsección, se contrasta la teoría propuesta por Bruno Latour con la de Bloor, defensor de una explicación social del conocimiento científico, y uno de los más importantes exponentes de la *Sociology of scientific knowledge* (SSK). Si bien Latour comparte la importancia de lo social, se separa de la explicación puramente social del conocimiento científico de SSK, para sostener una visión ontológica del trabajo realizado por la actividad científica y le interesa el rol social de la ciencia, siendo su objeto de estudio la ciencia en la sociedad.

Eve Seguin (2000) argumenta que, a pesar del ataque masivo a la teoría de Latour hecho por David Bloor (1999), el debate no se basa en un desacuerdo, sino en una incomprensión fundamental por parte de Bloor con respecto a cuál es el campo en cuestión. De hecho, la dificultad en aceptar el trabajo de Latour tiene que ver con el hecho de ser abordado desde el punto de vista de SSK. Bloor (1999) sugiere que los dos enfoques están destinados a explicar el mismo fenómeno de diferentes maneras. Para Bloor, Latour trata de desarrollar una alternativa a SSK para el estudio de la ciencia como conocimiento.

La ciencia difiere profundamente de otras cosmologías. La diferencia entre la ciencia y otras formas de conocimiento se encuentra en la actividad del laboratorio.

Esto significa que la ciencia no debe ser considerada como una colección de creencias. Se trata de un conjunto de procedimientos que se activan en una realidad, mostrando, claramente, que ya no estamos en el estudio de la ciencia como conocimiento<sup>37</sup>. Latour teoriza sobre la función social ejercida por la ciencia, queriendo explicar la sociedad, compuesta por cosas, hechos y artefactos, sin necesidad de utilizar explicaciones sociales<sup>38</sup>.

Callon y Latour son taxativos al decir:

We have never been interested in giving a social explanation of anything, but we want to explain society, of which the things, facts and artifacts, are major components.(Callon and Latour, 1992 p.348)

Latour, en su libro *Politics of Nature: How to Bring the Sciences into Democracy*<sup>39</sup> aporta un nuevo enfoque a las discusiones ontológicas sobre la naturaleza (Latour, 2004). Se propone un cambio radical en las actuales concepciones de la ecología política. Si separamos lo humano de lo no humano, los intereses sociales de la naturaleza y la política de la ecología, ponemos en peligro los cimientos de la democracia. La naturaleza no está para ser conquistada, pero tampoco para ser protegida como un objeto pasivo. Por el contrario, nuestras concepciones de hechos naturales y realidad deben ser reexaminadas para dar cabida a una política ecológica más amplia. Latour comparte con la tecnocracia un fuerte interés en dar cuenta de la centralidad de la ciencia en la sociedad contemporánea, y afirma que él "...simplemente busca que la filosofía de la ciencia no haga solamente la mitad del trabajo de la filosofía política en las sombras" (2004).

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<sup>37</sup> Si bien se reconoce el logro de SSK de secularizar el conocimiento científico, Latour plantea que el análisis de la ciencia en términos de creencias tiene un valor limitado, ya que ignora el carácter distintivo de la "ciencia como práctica". Los seguidores de SSK no abordan esta cuestión porque su objetivo es eliminar la brecha que la epistemología establece entre la ciencia y las creencias 'irracionales'.

<sup>38</sup> Por otro lado, SSK busca arrojar luz sobre los intereses sociales que condicionan la formación del conocimiento científico, su objeto puede ser llamado "la sociedad en la ciencia". Sin embargo, ambos enfoques tienen algo muy importante en común, comparten un micro-enfoque marcado por una preferencia de conocer detalladamente "estudios de caso"; si bien SSK se inscribe en la tradición que examina las condiciones de posibilidad de la tarea científica (e.g. Marxismo, feminismo), donde la única función que la ciencia puede ejercer es la de reproducir los intereses sociales dominantes y el orden existente. Sin embargo, introduce como novedad un análisis cuidadoso de los micro-mecanismos que explican el contenido de los conocimientos científicos (Seguin, 2000).

<sup>39</sup> El libro mencionado teoriza sobre el papel de la ciencia en forma de un tratado de filosofía política, argumentando que nuestra vida pública está compartimentada en dos: la política y la ciencia. La primera se ocupa de los valores y la sociedad; la segunda se refiere a hechos y a la naturaleza (y es oficialmente apolítica). Este autor presenta a esta organización como defectuosa y postula que la ciencia es un régimen absolutista por el cual el "orden natural" es construido por científicos a puertas cerradas. Para Latour, esta lucha exige una transformación republicana y el estudio de la ciencia es una forma de entender la sociedad en su conjunto.

Resumiendo, el enfoque de Latour es original por cuanto combina una observación de la práctica científica a nivel micro, con una preocupación teórica sobre la organización de la sociedad, abriendo nuevas posibilidades para el estudio de la función política de la ciencia<sup>40</sup>. Es por eso que esta perspectiva será extendida en el capítulo segundo para dar cuenta de cómo se constituye la dinámica industrial a partir de esta práctica.

#### 1.4.2 Régimen de búsqueda

El progreso científico de los últimos años ha sido impulsado por tres áreas: ciencias de la vida, de la información y de los materiales. Debido al gran impacto de estas nuevas disciplinas, es importante preguntarse si son sustancialmente diferentes de las consolidadas con respecto a su práctica científica y a su emergente dinámica industrial. El análisis en detalle permite anticipar consecuencias para la formulación de políticas y en tal sentido, para la sociedad. Andrea Bonaccorsi (2008) desarrolla la noción de *régimen de búsqueda* como una caracterización de la dinámica de la ciencia. Se proponen tres dimensiones: la tasa de crecimiento, el grado de diversidad interna y la naturaleza de la complementariedad. En su trabajo sostiene que las nuevas ciencias siguen un patrón diferente de las ciencias establecidas.

Las nuevas ciencias amplían la búsqueda de la explicación causal a fenómenos nuevos y más complejos. Analizan sistemas mucho más complejos<sup>41</sup> que los sistemas físicos o químicos, por lo que requieren descripciones más *largas* y generan teorías de validez local (no grandes teorías unificadas). Si bien sigue siendo la aspiración reduccionista la que impulsa la búsqueda de explicaciones causales en la ciencia de materiales, su complejidad es creciente, lo cual produce

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<sup>40</sup> En particular, para el análisis del funcionamiento del discurso científico y el impacto de su práctica en la esfera pública (Seguin, 1996; , 2001).

<sup>41</sup> Si bien complejidad es un concepto controversial, este trabajo asume complejidad cuando existe un gran número de variables y formas de retroalimentación (Kline, 1995), cuando se presenta con un gran número de niveles jerárquicos interdependientes (Simon, 1981) o cuando las condiciones iniciales modifican la propia dinámica del proceso (Ruelle, 1993).

algunas explicaciones unificadas, al mismo tiempo que produce una cantidad creciente de subteorías especializadas (Heimeriks and Leydesdorff, 2012).<sup>42</sup>

Para explicar la dinámica de estos sistemas complejos, se necesita información sobre los elementos constitutivos, pero también conocer la arquitectura sobre la cual aquéllos se articulan (Kline, 1995). Los materiales a escala nano son sistemas complejos que presentan una jerarquía de dimensiones espaciales con fuertes interacciones entre los distintos niveles. El estudio de los sistemas complejos no reduce el número de teorías. En el nivel local, coexisten subteorías que compiten por explicar el comportamiento de los nanomateriales, siendo todas plenamente coherentes con una teoría general sobre los elementos constitutivos. Los nanotecnocientíficos comparten una teoría fundamental común a nivel de elementos constitutivos, pero difieren en las explicaciones causales de aplicación local a cada jerarquía (espacial o temporal) del sistema complejo.

Si bien esta complejidad imposibilita obtener nuevas estructuras directamente desde propiedades macroscópicas, se puede descomponer y agregar información de la arquitectura. De esta forma, los materiales pueden ser diseñados; se observa y se manipula el material al mismo tiempo. La nanotecnociencia se inscribe entre la ciencia y la tecnología (ingeniería). Bonaccorsi presenta a la ciencia de materiales como una nueva ciencia con metodología reduccionista, cuya dinámica rompe los límites entre lo natural y lo artificial.

Como se ha indicado al comienzo de la sección, Andrea Bonaccorsi (2008) propone tres dimensiones para analizar las propiedades dinámicas de la nanotecnociencia: la tasa de crecimiento, el grado de diversidad, el tipo de complementariedad. La evidencia preliminar presentada por el autor, utilizando métrica de publicaciones científicas<sup>43</sup>, habla de una disciplina que crece rápidamente, en diferentes direcciones y hace uso de nuevas formas de complementariedad. Los estudios específicos confirman que el patrón de crecimiento en la primera década ha sido

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<sup>42</sup> Esta dinámica afecta las nuevas prácticas científicas y su política asociada. Si bien se presenta contraintuitiva, es útil remitirse a la literatura sobre el problema de los límites al conocimiento científico y la imposibilidad de explicación (Casti and Karlqvist, 1996) (Barrow, 1999)

<sup>43</sup> Según el autor, el único objeto de observación es el resultado producido por los científicos en la literatura. Se centra en algunas propiedades estadísticas de las palabras nuevas: la tasa de crecimiento después de la primera entrada, el efecto de la composición (relación entre las palabras nuevas y viejas en las disciplinas) y el índice de concentración.

exponencial con una tasa constante de crecimiento del orden del 14% de magnitud (Darby and Zucker, 2003). Este autor sostiene que la nanotecnociencia es un *régimen de búsqueda divergente*, un modelo dinámico donde las conclusiones de un proyecto dan origen a nuevas hipótesis que se constituyen, luego, en nuevos programas de investigación. Asimismo, propone una visión interesante sobre el tipo de complementariedad que se observa en nanotecnociencia. Gran parte de los inventores (patentes) son también autores de artículos científicos, y una gran parte de los fundadores de nuevas empresas son también inventores o autores. El autor encuentra evidencia de un sistema de conocimientos altamente interconectado en el que los logros científicos se traducen en resultados patentables y formación rápida de empresas donde los científicos tienen un papel preponderante. Durante los últimos 15 años, la nanotecnología ha crecido por encima del crecimiento de la ciencia y de la tecnología en general (con cifras sorprendentes para los artículos: 14% contra un promedio de 2%) y es una disciplina divergente (utilizando como indicador la tasa anual de aparición de nuevas palabras clave).

Si bien la nanotecnología tiene antecedentes disciplinarios en la física y en la química, su práctica es diferente y claramente es necesario analizarla en la dinámica industrial de la ciencia. En primer lugar, los nuevos campos de investigación dentro de la nanotecnociencia crecen en forma exponencial con el tiempo. En 10 años (1993-2003), cerca de 100.000 científicos de todo el mundo se incorporaron y miles de nuevas instituciones entraron en el campo. De hecho, gran parte de esta dinámica se explica por un explosivo proceso de entrada de nuevas palabras claves en las publicaciones (Bonaccorsi and Vargas, 2010).

En segundo lugar, la nanotecnociencia sigue una dinámica divergente<sup>44</sup> de búsqueda donde nuevas hipótesis se generan a partir de los paradigmas establecidos. En particular, se observa un patrón de comportamiento donde, dadas ciertas premisas comunes, las conclusiones originan nuevas hipótesis (y nuevos programas de investigación) (Bonaccorsi, 2008).

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<sup>44</sup> En oposición a un “régimen búsqueda convergente”, aquel modelo dinámico en el que de ciertas premisas comunes; cada conclusión es una premisa para otras conclusiones (Bonaccorsi, 2008).

En tercer lugar, surgen nuevas formas de complementariedad. Andrea Bonaccorsi (2008) plantea tres formas: Cognitiva, técnica e institucional. En la nanotecnología la complementariedad cognitiva está regida por la necesidad epistémica de diferentes *realidades* observadas en el laboratorio y el límite difuso entre lo natural y lo artificial. Las complementariedades técnica e institucional están dadas por la necesidad de articular diferentes laboratorios con diversas posibilidades técnicas y de presupuesto (Bonaccorsi, 2008).

## **Conclusión del capítulo**

Se ha propuesto el uso del concepto Nanotecnología, mediante el cual se da cuenta de un modo de investigación en el cual confluyen lo científico y lo técnico, siendo una forma ingenieril de hacer ciencia. Los investigadores no tienen como objetivo encontrar una teoría nano sobre la realidad para explicar esta última. En el laboratorio se trabaja dentro de un contexto complejo situado entre la teoría física clásica y la cuántica, donde se buscan explicaciones parciales mediante un uso ecléctico de varias teorías, forzándolas, más allá de su ámbito de aplicación tradicional. En otras palabras, el núcleo mismo de las teorías se fuerza para dar cuenta de una estructura causal detrás de los fenómenos observados a escala nano.

Los investigadores, los materiales y los artefactos dan lugar a la constitución de una práctica nanotecnológica. Los actores humanos provienen de diferentes formaciones básicas, por lo que, habitualmente, difieren en qué teorías utilizan para trabajar, pero todos coinciden en qué instrumentos de medición y qué programas de computadoras utilizan. Estos artefactos se transforman en los referentes comunes en la comunidad y adquieren gran importancia en la dinámica de la propia práctica.

Además, y debido a la necesidad de los grupos científicos de conseguir fondos gubernamentales, la narrativa del pasado (de tecnologías similares) y las expectativas de futuro juegan un rol crucial a la hora de entender las interacciones nano. Esta interacción entre agentes humanos, una teoría ecléctica, materiales y artefactos se constituye como práctica. Para dar cuenta de lo expuesto, se ha utilizado la teoría del Actor-Red para describir las relaciones entre los nodos y se

ha analizado el proceso de formación y la dinámica de la práctica nanotecnocientífica.

## 2 La dinámica industrial nano y la constitución de un nuevo mercado

### Summary

This nano-techno-scientific practice is a fertile ground for the convergence of variety of disciplines, which impacts on its industrial dynamics (Bozeman *et al.*, 2007; Andersen, 2011). A specific branch of nanotechnology of particular importance for this thesis is nanomedicine. It is defined as the medical applications of nanotechnology, which involves the development of new procedures to diagnose and cure diseases (Paradise *et al.*, 2008). This chapter analyses the market of nano-carriers and its patents. The methodology proposed by Callon and Muniesa (2005) helps to unpack this market and offers tools for analysing their risks.

After the analysis of the process of formation of the nano-market, this thesis focuses on the role of investors. Firstly, it explains the process of creating new businesses and identifies some lessons learned from the first generation of entrepreneurs. Then, a valuation model is presented, focusing on investments in the pharmaceutical industry. Finally, the last sections proposes a mathematical model representing pooled investment decisions among a small nanotechnology company that owns the patent of a nano-carrier (possibly a spin-off) and a large pharmaceutical company.

Future expectations about nanotechnology transcend industrial innovation, having the potential to transform other industries (Bozeman *et al.*, 2007). A question immediately arises: Is Nano-industrial dynamics similar to other technologies such as microelectronics or biotechnology? A group of scholars argues that the nano market is being controlled by large multinationals with in house R&D as in the case of microelectronics (Larédo *et al.*, 2009). From a different perspective, other authors argue that the organization of nanotechnology resembles biotechnology, where the *spin-off* university has played a prominent role (Darby and Zucker, 2003). New nano-companies face great uncertainty (Hite and Hesterly, 2001) and the circulation of knowledge has been interpreted as the equivalent to the



movement of researchers or engineers in the field (Bozeman and Mangematin, 2004).

Nanomedicine is defined as the set of medical applications of nanotechnology, including the development of new procedures to diagnose and cure diseases (Etheridge *et al.*, 2013). Reformulating a drug into nano-sized crystals generates a different version of the existing drug, with higher solubility. This reduces the required dose, diminishing adverse side effects. For instance, the insertion of a drug using a nano-capsule aims to target specific tumour cells (Bawarski *et al.*, 2008; Davis, 2008). Another application of nanotechnology is medical diagnosis. For example, by using different types of *labels*, some nanostructures can detect the presence or activity of specific molecular entities within the body. (Van Kasteel, 2009; Kamaly *et al.*, 2013).

In March 2009, the *Food and Drug Administration* (FDA) established a partnership with the *Alliance for NanoHealth*<sup>45</sup> to expand the knowledge about how nanoparticles impact on biological systems, aiming to develop processes that will reduce possible risks. This collaboration had two main objectives (te Kulve and Rip, 2013). First, it has aimed at encouraging the progress of nanomedicine, starting with preclinical stages of development, continuing with clinical and, finally, supporting the marketing of new products. Second, it has improved understanding of the risks and benefits.

Applying for a patent in nanomedicine is not easy, due to evaluators' concerns with health risks and human safety (Bawa, 2007; Martins *et al.*, 2013). The experience of the biotech industry about licensing strategies, development and financing have certain characteristics in common with nanomedicine: the new industrial applications in both sectors rely heavily on intellectual property (IP) and R&D are costly, complex and uncertain (Stewart, 2005).

The markets have clear advantages that make them irreplaceable in a capitalist Western context: their autonomous agents innovate, they allow their coordination,

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<sup>45</sup> FDA issued a press release in the news section of FDA.gov announcing it: <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01971.html>

and they facilitate contracts between parties. However, the markets have clear limitations: they are not designed to achieve the public good and they produce negative externalities on human groups (Callon, 2009). Therefore, it is necessary to reconsider basic questions about markets efficiency and analyse how we can ensure that the new nanotechnology market could be *socially* efficient.

Economic theories always are performative, and in this particular case, nanomaterials and technologies al play an important role in the process of market creation (Barry y Slater, 2002; Callon, 2010). This interaction between technoscience and markets produces what Marilyn Strathern (2000) calls the proliferation of new identities, creating constantly new uncertainties about the constitution of the collective. This process transforms the economy, the politics and the technoscientific practice surrounding it (Callon, 2009).

Nanotechnology market efficiency requires: (1) density, to attract a sufficient number of participants, (2) smoothness, to overcome congestion problems that can bring down the number of agents operating, and (3) safety and simplicity. Moreover, it should exclude operations based on moral reasons (Roth, 2008).

Following Callon and Law (1997), this thesis argues that market players are collective hybrids in constant constitution, in which people, devices and texts interact. There is no difference between the person and the network of institutions in which she operates, or more precisely, between the person and the network of entities acting through it. The same idea applies to the market as a whole, its agents do not act isolated, they are collective hybrids. These agents interact performing arithmetic operations, so they are *collective hybrid computing devices* (Callon and Muniesa, 2003).

The calculation is a feature of any market, but who does the calculation and how? In the literature, there are two contrasting perspectives to answer these questions. From a neo-classical point of view, agents' ability to calculate is innate. Conversely, from the perspective of social anthropology, the calculation is an ex-post rationalization. In this thesis, I would avoid these two extremes. On the one hand, people should not reduce to mere agents who calculate. On the other hand,

calculation should not be ignored nor dissolved by ethnographic descriptions (Callon and Muniesa, 2003).

In the market, the valuation process of assets arises from exchanges between agents making cross calculations: the calculating devices (Çalışkan and Callon, 2010). They include tools that actively constitutes reality and they struggle to impose prices one to another (Rose and Miller, 2008; Weber, 1978 [1922]; Stark, 2009). The calculation is distributed among humans, formulas and artefacts (Latour, 1987; Lepinay and Callon, 2009).

Nano-carriers are nanoscale elements that are introduced in the body and carry the drug to the place where the body needs it (Torchilin, 2012). To manufacture these products a patent is needed (Carbone *et al.*, 2013). The process of transforming patents into transactional goods starts with a process of singling out its properties, so it can enter the world of the business that uses it to produce nano-carriers. Once the company placed the patent into its network, the production process of the nano-carrier starts – which is then transformed into a good that would be exchanged by money in the market.

There are clear asymmetries in this market. On one hand, the producer normally is a large multinational pharmaceutical company with a lot of calculation power. On the other; the consumers are able only of making simple calculations.

After analysing the process of market creation, the focus of the thesis is understanding the role of investors in nanotechnology projects. In general, their initial goal is to register (buy or rent) a patent. Then -under its protection-, they begin production and sell the products. The valuation methodologies of these technology assets can be classified into two main groups (Mun, 2003). On the one hand, the traditional one, which involved costing and income calculations, and, on the other hand, innovative methods including *real option* (Schwartz, 2013). In the case of nanotechnology projects, valuation methods need to take into account that: i) they require large investments, ii) their costs are sunk, iii) their final product have uncertain futures prices, and iv) their investor could abandon the project (Vimpari and Junnila, 2014; Brealey and Myers, 2003).

Hardly a single organization undertake a nano-medical project, usually joint investments are required. This thesis develops a mathematical model to analyse the commercial interaction between a company specializing in the development of nano-carriers and a pharmaceutical large company. While the former develops research *in vitro* / *in vivo* testing to achieve a patent; the latter has the drug and can produce it. This interaction is modelled using game theory and real options.

## Introducción

La práctica nanotecnocientífica tiene el potencial de hacer converger varias disciplinas, lo cual se manifiesta en su dinámica industrial transformadora del entramado productivo (Bozeman *et al.*, 2007; Andersen, 2011). Si bien comparte el carácter innovador de otras industrias del sector, tiene particularidades que la definen y la constituyen. En particular, comparando con la dinámica de la microelectrónica o con la de la biotecnología, existen al menos tres diferencias importantes. La primera refiere a la diferente forma de interacción entre las grandes empresas industriales y los nuevos emprendedores (*start-ups*). La segunda se refiere al grado de concentración geográfica y la tercera es su organización industrial (Larédo *et al.*, 2009).

Una rama específica de la nanotecnología, de particular importancia para este trabajo, es la nanomedicina. La misma se define como las aplicaciones médicas de la primera, incluyendo el desarrollo de nuevos procedimientos para diagnosticar y curar enfermedades<sup>46</sup> (Paradise *et al.*, 2008). Para entender la formación del mercado de comercialización de nanotransportadores y de sus patentes, se aplica la metodología propuesta por Callon y Muniesa (2005), comprendiendo este mercado para luego analizar sus riesgos y sus métodos de valuación de inversiones.

Este capítulo está dividido en cuatro secciones. En la primera se presenta el poder transformador de la dinámica industrial nano, con énfasis en la nanomedicina.

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<sup>46</sup> La nanomedicina comercial se encuentra en desarrollo aunque ya se han producido algunos productos realmente innovadores. Asimismo, tiene importantes desafíos por delante relativos a aspectos legales, ambientales, de seguridad, de ética y, en particular, los relacionados a la reglamentación de las patentes.

Luego analiza críticamente la literatura sobre diseño de mercados, el rol de los experimentos y el rol performativo de las teorías, agentes y práctica nanotecnológica en el proceso de constitución. En la sección tercera, se presenta el mercado de nanotrasportadores como un proceso de co-constitución dentro de la dinámica propuesta. La última sección se pregunta por las decisiones de inversión y la valuación de los proyectos en el sector de nanomedicina y se propone una formalización matemática de la cuantificación de las decisiones.

## 2.1 El poder transformador de la dinámica nano

Luego de analizar la práctica tecnocientífica en el capítulo anterior, este trabajo se vuelca ahora a comprender las relaciones entre dicha práctica, las instituciones y los agentes económicos. Como se ha planteado en el capítulo anterior, la práctica nanotecnocientífica hace converger varias disciplinas<sup>47</sup>. Es más, las expectativas de la nanotecnología trascienden la innovación industrial, teniendo el potencial de transformar otras industrias<sup>48</sup> (Bozeman *et al.*, 2007).

Una cuestión que surge en forma inmediata es preguntarse si la dinámica industrial nano será similar a otras tecnologías, tales como la microelectrónica y la biotecnología. Por un lado, en la industria microelectrónica surgida en los años 70 del pasado siglo, las actividades innovadoras estaban centradas en las empresas tradicionales con fuerte integración vertical. Claramente este enfoque *top-down* (en consonancia con la Ley de Moore) permitió a la microelectrónica reducir tamaño y aumentar la densidad de los circuitos en el semiconductor. Por el contrario, durante los primeros años de la industria biotecnológica (años 80 del pasado siglo), la creación de nuevas empresas desempeñó un papel catalizador en el proceso de constitución del nuevo mercado, vinculando los descubrimientos de los laboratorios con las empresas tradicionales (Invernizzi, 2011).

Teniendo en cuenta la experiencia de las tecnologías anteriores, la literatura plantea dos posiciones diferentes con respecto a la evolución de la nanotecnociencia. Un

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<sup>47</sup> Los partidarios de la transformación masiva hablan de la convergencia de las NBIC (Nanotecnología, Biotecnología, Tecnología de información y comunicación) o de BANG (*Bit, Atom, Neuronal y Gene*) (Wetter, 2006).

<sup>48</sup> No quedando claro si será mediante la creación de un nuevo mercado o como una nueva tecnología disponible dentro de los existentes (Larédo *et al.*, 2009).

grupo de académicos argumenta que el mercado nano está siendo controlado por grandes multinacionales, respaldadas por empresas específicas de I + D (Larédó *et al.*, 2009). Si bien las pequeñas empresas desempeñan un papel importante en la comercialización, esta línea de pensamiento sostiene que los países con más multinacionales tienen más probabilidades de convertir descubrimientos de laboratorio en aplicaciones comerciales (Shapira *et al.*, 2010). Desde una perspectiva diferente, otros autores argumentan que la organización de la nanotecnología se asemeja a la de la biotecnología, donde los *spin-off* universitarios han jugado un papel destacado. Darby y Zucker (2003) prevén un modelo de desarrollo similar a la biotecnología<sup>49</sup>, con la presencia de científicos de renombre, vínculos estrechos entre las universidades y la industria, una organización eficaz de transferencia de tecnología, la creación de empresas basadas en la investigación y el capital riesgo para financiar las fases iniciales de desarrollo<sup>50</sup>. La nanotecnociencia plantea una dinámica diferente a las anteriores tecnologías. Lo primero que se comercializó fueron agregados de tecnología nano en productos existentes, lo cual ha otorgado fundamental importancia a las inversiones realizadas por grandes empresas líderes mundiales en sus respectivos mercados masivos, de acuerdo al primer grupo de autores mencionados<sup>51</sup>.

La nanotecnología se encuentra en estadio inicial de su ciclo de vida y todavía falta acumulación de conocimiento para fomentar innovaciones. Esto no descarta el papel de la creación de nuevas empresas, pero requiere de un reposicionamiento en relación con la comprensión de la dinámica de un campo emergente<sup>52</sup> (Darby and Zucker, 2003; Zucker and Darby, 2005). Hite y Hesterly (2001) señalan que durante las primeras etapas de una nueva industria, las nuevas empresas enfrentan

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<sup>49</sup> Es más, incluso en la biotecnología ha habido relativamente poco desplazamiento de los operadores tradicionales, impulsando la idea de que la "destrucción creativa" se llevó a cabo dentro de las grandes empresas existentes (especialmente, las empresas farmacéuticas).

<sup>50</sup> Donde sí hay acuerdo en la literatura es sobre la lentitud de la comercialización de la nanotecnología, a pesar del crecimiento exponencial de las publicaciones científicas. Por ahora no se encuentran explicaciones a este fenómeno (Andersen, 2011).

<sup>51</sup> Un segundo horizonte, que recién empieza a desarrollarse ahora, plantea la integración de los conocimientos ("convergencia NBIC") y se basará en la creación de empresas que iniciarán nuevos nichos de mercado (Larédó *et al.*, 2009), de forma similar al argumento del segundo grupo de autores.

<sup>52</sup> En general, el grado de madurez de una nueva tecnología define tanto las condiciones cognitivas como la dinámica industrial de creación de conocimiento. En la práctica científica, la exploración de hipótesis se lleva a cabo en un ambiente turbulento, donde la introducción de nuevas soluciones técnicas amplifica la incertidumbre en lugar de reducirla. En el mercado, la llegada de una tecnología radicalmente nueva genera nuevos proyectos (Bozeman *et al.*, 2007), tanto en las industrias existentes o estimulando la creación de nuevas.

una gran incertidumbre y la circulación del conocimiento equivale a la circulación de los investigadores o ingenieros<sup>53</sup> (Bozeman and Mangematin, 2004).

Esta dinámica industrial innovadora descrita se ve claramente en el caso de las aplicaciones médicas, donde un pequeño *spin-off* de universitarios patenta un nanotransportador que debe complementarse con la gran farmacéutica para lograr llegar al mercado con una determinada droga. La siguiente subsección introduce a las aplicaciones médicas de la nanotecnología.

### 2.1.1 Nanomedicina

En el presente trabajo se define Nanomedicina como el conjunto de las aplicaciones médicas de la nanotecnología, lo cual incluye el desarrollo de nuevos procedimientos para diagnosticar y curar enfermedades (Etheridge *et al.*, 2013). En particular, se están produciendo comercialmente nuevas drogas, dispositivos de diagnóstico e implantes utilizando nanotecnología, los cuales serán brevemente descritos a continuación.

La reformulación de la droga en forma de cristales de tamaño nanométrico genera versiones de fármacos existentes que tienen mayor solubilidad. Esto reduce el volumen necesario de dosis, disminuyendo los efectos secundarios adversos. Por otro lado, la inserción de las drogas dentro de una nanocápsula puede permitir la administración de fármacos específicamente a las células tumorales<sup>54</sup> (Bawarski *et al.*, 2008; Davis, 2008).

Otro campo de acción es el de diagnóstico médico. Mediante el uso de diversos tipos de etiquetas, ciertas nanoestructuras pueden detectar la presencia o actividad de entidades moleculares específicas en el cuerpo<sup>55</sup>. Asimismo, se han desarrollado

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<sup>53</sup> Zucker, Darby y Armstrong (2001) proponen que la ciencia y la tecnología, en sentido amplio, son acumulativas. Hacen hincapié en la proximidad geográfica, en la creación de empresas de alta tecnología y en la circulación de conocimiento tácito a través de los recursos humanos, similar a la historia reciente de la biotecnología (Zucker *et al.*, 2007).

<sup>54</sup> Un ejemplo es el medicamento Abraxane que se utiliza para enfrentar la metástasis del cáncer de mama (de la empresa Abraxis, Los Ángeles, California). El mismo es una reformulación como nanopartículas del paclitaxel, realizado mediante la técnica de polímeros conjugados. La formulación nano evita la reacción de hipersensibilidad asociada con el disolvente “Cremophor EL” utilizado con el paclitaxel tradicional<sup>54</sup> (Bawarski *et al.*, 2008).

<sup>55</sup> Un ejemplo son los “puntos cuánticos”, nanocristales semiconductores fluorescentes que identifican las células cancerosas en el cuerpo al unirse a las células tumorales y emitir diferentes colores dependiendo del estado de enlace (Chan, 2006).

varios tipos de dispositivos de diagnóstico de mano que pueden verificar la existencia de una determinada proteína<sup>56</sup> (Van Kasteel, 2009; Kamaly *et al.*, 2013).

El uso de nanomateriales en dispositivos médicos implantables posee una oportunidad de mercado en los EEUU, debido a que en el mercado se espera un aumento del 9% anual durante los próximos años sobre los 27 mil millones de dólares anuales que mueve este mercado (Durmus and Webster, 2012). Cada vez es mayor el alcance que debe darse a la satisfacción de las necesidades de dispositivos implantables, básicamente por la perfección con la cual se deben realizar los mismos para evitar que éstos sean rechazados ante la colocación, y que los mismos puedan llegar a causar alguna enfermedad (Harris and Graffagnini, 2007). Existen diferentes empresas que se dedican a la fabricación o perfeccionamiento de dispositivos implantables a través del uso de nanomateriales. La empresa AcryMed utiliza nanopartículas de plata para prevenir las infecciones al realizar los implantes y no alterar sus funciones. Por su parte, Nanotecnologías Altair trabaja con el Consejo Nacional de Investigación de Canadá para realizar revestimientos ortopédicos con dióxido de titanio, lo que otorga dureza y resistencia en los implantes. *Nanotech Catheter Solutions* desarrolla catéteres y *stents* con nanotubos de carbono. Nanicopeia es una empresa que desarrolla la incorporación de nanomateriales para mejorar los dispositivos médicos, así como la creación de recubrimientos avanzados y formulación de nuevas drogas (Harris and Graffagnini, 2007; Santos, 2012).

Claramente, los incentivos que impulsan a las empresas a utilizar nanotecnología en la medicina se relacionan con el aporte que genera a la producción de nuevas y mejores drogas, debido a la reducción del consumo de energía al producirlos, al abaratamiento de los insumos que se requieren en la producción, al uso de nuevos materiales que suplantán a materiales que contaminan el medio ambiente y a la posibilidad de establecer nuevas patentes. Si bien los incentivos son muchos,

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<sup>56</sup> Un ejemplo es el método de detección de proteínas de alta sensibilidad denominado Nano-ELISA. El mismo es la realización por medio de nanopartículas del procedimiento *enzyme-linked immunosorbent assays* (ELISAs). Nanopartículas de oro se modifican con un detector de anticuerpos monoclonal y con *Horseradish peroxidase* (para aumentar la intensidad de la señal), de forma de generar señales ópticas que reflejan la cantidad de la proteína en cuestión. Este método es tan simple como ELISA y de mayor sensibilidad, por lo que puede ser utilizado, entre otras aplicaciones, para detectar marcadores de proteínas de tumores (Jia *et al.*, 2009).



también existen problemas con el uso de esta tecnología desde el punto de vista empresarial. Los desincentivos de las empresas en el uso de nanotecnología vienen dados por el tiempo que se tarda en comercializar los productos desarrollados, los riesgos que pueden acarrear el patentamiento de los productos, la contaminación ambiental con algún nanomaterial, así como la percepción pública de estos riesgos del uso de nanotecnología, la cual puede acarrear una oposición frente al uso de esta (Bhattacharya, 2007).

Se vislumbran claros problemas con el uso de nanotecnología tales como los riesgos ambientales y el posible monopolio por uso de patentes exclusivas (Bhattacharya, 2007). En Marzo del año 2009, la *Food and Drug Administration* (FDA) realizó una asociación con la *Alliance for NanoHealth*<sup>57</sup> para ampliar el conocimiento de cómo las nanopartículas impactan en los sistemas biológicos, de forma de desarrollar procesos que reduzcan los posibles riesgos asociados. Las partes dejaron claro que esta colaboración tiene dos objetivos principales<sup>58</sup>. En primer lugar, incentivar el avance de la nanomedicina, comenzando con las fases preclínicas de desarrollo, continuando con las clínicas y, por último, apoyar su comercialización. En segundo lugar, comprometerse a trabajar para mejorar la comprensión de los riesgos y beneficios del desarrollo de productos nanoingeniería médica en la medida en que esta información puede ayudar a la regulación y evaluación de productos nanomédicos. En particular, las partes reunidas en Octubre del año 2008 establecieron siete prioridades que desagregan los dos grandes objetivos mencionados. La primera, determinar la capacidad de distribución de los portadores de nanopartículas. Luego, se mencionó la importancia de entender las dosis administradas por las mismas. La tercera y cuarta prioridad marcan la necesidad de desarrollar modelos matemáticos (y computacionales) que permitan predecir los diferentes riesgos y beneficios de su uso. La quinta enfatiza la necesidad de establecer normas para los protocolos de los materiales. La sexta se relaciona con el transporte masivo en el cuerpo humano. Finalmente, la última, se propone el desarrollo de un conjunto de herramientas

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<sup>57</sup> FDA publicó un comunicado de prensa en la sección de noticias de FDA.gov en Marzo 2009 anunciándolo. El mismo puede consultarse en <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01971.html>

<sup>58</sup> El "Memorandum of Understanding" entre las partes está publicado por el registro Federal de EEUU el día 13 de Marzo de 2009 (72 FR 10927).

analíticas para la fabricación de nanopartículas con fines médicos (Maebius and Jamison, 2008).

Luego de esta descripción general de la nanomedicina, la siguiente subsección detalla el rol fundamental que tienen las patentes en la formación y evolución del mercado.

### **2.1.2 Patentes**

La nanomedicina comercial se encuentra en la etapa de desarrollo aunque ya se han producido algunos productos realmente innovadores. Sin embargo, la industria tiene muchos desafíos por delante en los aspectos legales, ambientales, de seguridad, de ética y, en particular, los relacionados a la reglamentación de las patentes. Solicitar una patente en nanomedicina no es algo fácil, debido a la preocupación de los evaluadores sobre si se puede considerar que la nanotecnología no produce riesgos en la salud y la seguridad de las personas. La experiencia de la industria biotecnológica acerca estrategias de licenciamiento, desarrollo y financiamiento a la nanomedicina. Tienen las siguientes características en común: las nuevas aplicaciones industriales en ambos sectores dependen fuertemente de la propiedad intelectual (IP) que surge de los laboratorios (tanto universitarios o corporativos). Por otro lado, la investigación y desarrollo es costoso, complejo e incierto. Por último, la empresa que desarrolla la tecnología puede no ser la misma que lleva el producto final al mercado (Stewart, 2005).

Uno de los problemas para el futuro desarrollo de la industria es la aprobación de las patentes<sup>59</sup>. Se se deben cumplir ciertos requisitos, a saber: debe poder ser considerado una invención nueva con respecto a todo lo que fue patentado en el pasado; debe tener utilidad; y debe estar bien descrito a manera de demostrar su posesión, entre otras características<sup>60</sup> (Bawa, 2007; Martins *et al.*, 2013).

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<sup>59</sup> Tener un derecho de propiedad intelectual implica tener un activo intangible pero como la ley que los regula se ha modificado según las necesidades del mercado, es necesario tener en cuenta que no todas las innovaciones son susceptibles de ser patentables.

<sup>60</sup> Por otro lado, el cumplimiento de los requisitos no es garantía del otorgamiento de la patente, debido a que este es un proceso largo, caro y tedioso por el hecho de tener que pasar por el proceso de examen (revisión de la patente), de persecución (intercambio de documentos entre los que examinan y los abogados de quienes piden la patente), y de aviso de derecho de emisión (el cual se da si la patente cumple con los requisitos)

El pedido de patentes se realiza en base a un incierto flujo de beneficios futuros, que los inversores consideran que les generaría ganancias a posteriori (por lo que realizan la inversión en investigación y desarrollo). Claramente, entonces, los pedidos de patentes son un indicador de actividad y es relevante, económicamente, su cuantificación. Para medirlas se toman en cuenta distintos parámetros: el alcance, la aplicabilidad en otros campos, entre otros. Sin embargo, los expertos consideran que el sistema de patentamiento hoy en día produce una limitación por las batallas legales a las que deben enfrentarse para el otorgamiento de la misma (Murray *et al.*, 2012). Esto genera ciertos temores ante la posibilidad de que el otorgamiento de las patentes retarde en cierto sentido el avance en la industria tecnológica. Ahora bien, por otro lado, un exceso de patentes en el mercado obligará al gobierno en cuestión a actuar para evitar comportamientos monopólicos, defendiendo una competencia leal para fomentar una mayor cooperación (Bouchard, 2012).

### **2.1.3 De la universidad al mercado: el caso de Nanosphere Inc.**

Nanosphere Inc. es la empresa que se considera como pionera en nanotecnología; una de las primeras empresas de nanotecnología en llegar a hacer una oferta pública. La empresa fue fundada en el año 2000 por los doctores Robert Letsinger y Chad Mirkin de la Universidad Northwestern. Ellos han logrado un prototipo de proteína sensible de diagnóstico molecular del ADN que permite detectar proteínas. Durante los primeros años de vida, la empresa logró convertir su tecnología en propiedad intelectual protegida (IP). Su tecnología está basada en el diagnóstico *in vitro* (IVD), ahora conocido como Sistema *Verigene* (Beal *et al.*, 2013), en torno al cual se construye una cantidad de sistemas médicos de diagnósticos. El objetivo corporativo es cambiar el mercado de IVD con el desarrollo de sus dos proyectos denominados Verigene I y II, y ser la única empresa capaz de beneficiarse con los desarrollos de esta parte de la medicina (Shalleck, 2009).

Nanosphere ha construido sus ingresos en base al sistema de pruebas IVD; sin embargo, este sistema le ha ocasionado grandes pérdidas a causa del bajo volumen de ventas que se proyectan para los próximos años. IVD representa el 30% de todo

el mercado de diagnóstico médico, el cual incluye el diagnóstico médico de imágenes en vivo<sup>61</sup>. Según Alan B. Shalleck (2009), existe una serie de supuestos en los que se proyecta el negocio de la compañía. Primeramente, *Verigene* se considera la primera plataforma nanotecnológica habilitada para generar pruebas moleculares y ser capaz de probar proteínas. Luego, proporciona menores costos y tiempos de respuestas más rápidos con una plataforma más fácil de usar. Además, posee una sensibilidad al menos 100 veces mayor para las pruebas de proteínas en los ensayos, y ofrece altos recuentos en la multiplexación de capacidades y ofertas para el futuro en la línea de desarrollo de pruebas moleculares.

Muchos de los expertos encuentran a la tecnología de Nanosphere como excelente; su sistema *Verigene* fue aprobado por la FDA en 2007 y los usuarios se encuentran satisfechos con el rendimiento de éste. Sin embargo, se dificulta el desarrollo del sistema en otras áreas y esto hace más difícil de lo esperado el despegue del producto, provocando que la generación de ingresos sea menor a la esperada, aunque crece (al igual que las pérdidas). Es así que se propuso introducir, en el 2009, dos productos innovadores con ingresos proyectados para el 2010 en 3 ó 4 millones de dólares. A pesar de ello, si las pérdidas continúan, la empresa se enfrenta a una decisión estratégica importante: ¿podrá la empresa sostener un crecimiento con la recaudación que tendrá?, o bien ¿deberá obtener capital antes de lanzarse nuevamente al mercado? (Shalleck, 2009).

Los problemas estratégicos para el inversor en la empresa incluyen el intento de tratar de determinar si la empresa nunca obtendrá beneficios de gestión para las proyecciones que se hacen con respecto a la rentabilidad de sus productos. Asimismo, se debe tratar de determinar si el precio pagado inicialmente, en propiedad intelectual, se justifica (Shalleck, 2009).

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<sup>61</sup> Por otra parte, aparece como competencia el diagnóstico molecular (MD), el cual proporciona un diagnóstico temprano e información básica para la medicina preventiva. No obstante, estas pruebas requieren técnicos altamente calificados y un complicado procedimiento de preparación que es muy costoso y largo de desarrollar. De esta manera, surge una medicina preventiva orientada a los sistemas IVD por causa de cuestiones de procedimiento y costos de las pruebas de MD. Las pruebas de IVD requieren dos exigencias: a) especificidad de las medidas de precisión del sistema y b) sensibilidad en los sistemas de diagnóstico.

## 2.2 Diseño y constitución de mercados

Esta dinámica nano, descrita en la sección anterior, constituye un nuevo mercado mediante la interacción entre práctica tecnocientífica, gobierno, agentes económicos y usuarios. En esta sección se presenta la literatura sobre diseño y constitución de mercados en general y se detalla aquella que se utilizará en la siguiente sección para analizar el mercado específico de nanotransportadores.

Los mercados tienen indudables ventajas<sup>62</sup> que los hacen insustituibles en un contexto occidental capitalista: sus agentes autónomos innovan, permiten la coordinación de agentes y facilita contratos entre partes que no surgirían en un contexto planificado centralmente. Ahora bien, los mercados tienen claros límites: no están diseñados para lograr el bien público y producen externalidades negativas sobre grupos humanos que no son tenidos en cuenta (Callon, 2009). Por tanto, es necesario volver a considerar las cuestiones básicas sobre los mercados y analizar cómo podemos garantizar que funcionen correctamente.

Para ello, es primordial prestar especial atención al rol de los experimentos realizados en el mundo real, los cuales despiertan una controversia que abre un debate superador del enfoque meramente económico, incluyendo aspectos políticos, regulatorios y sociales. Lo anterior permite asegurar entonces que el diseño es un proceso de mutua interacción, el proyecto necesita ser validado por la experimentación y ésta actúa sobre el primero (Roth, 2008). Estos mercados cuentan con agentes económicos que interactúan en ellos para lograr la constitución del mismo con características experimentales. Este trabajo interpreta a estos agentes como híbridos colectivos de cálculo y a los mercados como acuerdos socio-técnicos.

La propuesta del presente trabajo es focalizar en mercados reales, dejando de lado los abstractos, reconociendo el creciente papel de los experimentos en la concepción de los mercados, destacando el rol fundamental que las tecnologías

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<sup>62</sup> Ciertos defensores a ultranza del mercado sostienen que éste permite la iniciativa privada, regula la escasez de recursos y logra, mediante innovaciones, satisfacer las necesidades de la sociedad en el largo plazo. Si bien estas ventajas del mercado están en discusión, el planteo tradicional no aborda la cuestión fundamental: si los mercados se presentan como solución, ¿qué tipos de mercados se deben diseñar y cuál es su organización socio-técnica? (Callon, 2009).

tienen en la constitución de los mercados económicos y el papel evidentemente performativo de las teorías económicas (Barry and Slater, 2002; Callon, 2010). Esta interacción entre la tecnociencia y los mercados produce lo que Marilyn Strathern (2000) denomina la proliferación de nuevas identidades, creando, constantemente, nuevas incertidumbres acerca de la constitución de lo colectivo<sup>63</sup>. Un primer punto de partida es discutir el mismo diseño de los mercados.

### 2.2.1 El diseño de mercados

Los economistas han adquirido una experiencia considerable en el diseño de mercados concretos en los últimos años (Roth, 2008). Estas experiencias de diseño enseñan que las operaciones y las instituciones son más importantes que lo que anteriormente se suponía, por lo que se ha ido reemplazando la tarea tradicional del análisis estilizado de los mercados por el desafío de diseñar los mismos<sup>64</sup>. Esto exige un análisis detallado que involucra diversos actores: empresarios, políticos, reguladores, abogados matemáticos, etc. Wilson (1992) presenta un amplio panorama de la literatura sobre diseño de subastas<sup>65</sup>, donde se destacan los trabajos teóricos de Myerson (1981) y Bulow y Roberts (1989). Asimismo, es importante la literatura orientada empíricamente al estudio de la evolución de los mercados de trabajo (Roth, 1984) y la vinculada con los mercados de energía eléctrica, los cuales son un buen ejemplo de la importancia del diseño en un contexto donde lo económico se encuentra inexorablemente vinculado con lo político y lo regulatorio (Wilson, 2002; Cramton and Ockenfels, 2012).

Para el diseño de un nuevo mercado se puede aprender mucho de la historia de los mercados relacionados. En la década de 1990, la teoría de juegos comenzó a tomar un papel muy importante en el diseño de mercado, dando lugar a una nueva

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<sup>63</sup> Estas nuevas identidades se constituyen en su interacción con otras y con objetos materiales, requiriendo nuevos procedimientos, nuevas instituciones y, fundamentalmente para resolver la cuestión del tratamiento democrático y participativo de la tecnociencia, se necesita entender la relación entre mercado y democracia (Callon *et al.*, 2001).

<sup>64</sup> A nivel técnico, muchos de estos nuevos mercados presentan el problema de tratar con productos complementarios, no sustitutos. Además, el diseño frecuentemente requiere rapidez; en algunos casos transcurre tan sólo un año entre que se requiere y se implementa (Roth, 2002). Un ejemplo claro de esta urgencia fue la subasta de las bandas 3G de telefonía móvil que se realizó en Reino Unido. Al realizarla luego de EEUU, el gobierno británico necesitaba urgente las reglas del nuevos mercado para realizar la subasta (Binmore and Klemperer, 2002).

<sup>65</sup> La literatura económica sobre diseño de mercados se remonta al artículo de Vickery sobre subastas (Vickery, 1961).

disciplina que Alvin Roth (2002) propuso denominar *design economics*<sup>66</sup>. Los encargados de diseñar un nuevo mercado no pueden trabajar sólo con los modelos conceptuales simplificados propios de discusiones teóricas sobre mercado, el diseño exige un enfoque ingenieril que complemente la teoría de juegos con experimentos y la resolución de modelos computacionales (Roth, 2002).

### 2.2.2 El rol de los experimentos económicos

Jean-Baptiste Say (1841) fue uno de los primeros autores en afirmar que la economía es una ciencia experimental y debería dedicarse a la observación y a la recolección de los hechos a fin de señalar las regularidades causales. Sin embargo, dejó claramente a la economía fuera del laboratorio, reservado para las ciencias naturales. La economía recién entra en los laboratorios a principios de la década de los sesenta del pasado siglo (Smith, 1962). Desde su creación, la economía experimental ha tenido que justificar su validez fuera del laboratorio (Guala, 2002). Es importante notar que, al definir las condiciones para la validez externa de un experimento económico, Vernon Smith (1989) establece que el laboratorio experimental debe ser real, contar con personas reales, bienes reales y dinero real (Deck and Smith, 2013).

Una segunda característica de la economía experimental es su capacidad manipuladora, se interviene sobre la materia de diversas formas. Por ejemplo, si el objeto es un coche a testear, la manipulación puede ser desde hacer un *focus group* con usuarios que abren y cierran puertas, hasta implicar la destrucción del objeto. Esto lleva a un tercer aspecto importante de la economía experimental: su objeto. Según Vernon Smith, los experimentos son un medio para contrastar teorías económicas; su objeto son las teorías, no el comportamiento humano (Muniesa and Callon, 2007). El entorno experimental pretende imitar las teorías económicas, no la actividad económica concreta (Smith, 1994). El contexto es, por consiguiente, un sistema micro-económico controlado y estable donde los agentes económicos (caracterizados con funciones de utilidad) interactúan. El conocimiento así producido es legítimo en la medida en que permite contrastar hipótesis derivadas

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<sup>66</sup> Si bien la teoría de juegos económica proporciona un contexto desde el cual abordar el diseño, es fundamental un análisis detallado alejado de los modelos económicos estilizados.

de las teorías económicas en cuestión. La generalización de los resultados experimentales se complica debido al localismo de los experimentos en cuestión<sup>67</sup>, pero no es un impedimento (Burlando and Guala, 2005).

En resumen, los experimentos económicos tienen un impacto performativo sobre los mercados; los investigadores describen un objeto producido por ellos mismos<sup>68</sup>. Cada vez más, los experimentos económicos son un elemento fundamental en el proceso de construcción de mercados. Y, sobre todo, en el caso de los experimentos a escala real la controversia abre la posibilidad de ampliar el debate superando el enfoque meramente económico e incluir aspectos políticos, regulatorios y sociales.

### **2.2.2.1 La co-constitución del mercado**

El diseño de mercados es un proceso de mutua interacción; el proyecto necesita ser validado por la experimentación y ésta actúa sobre el primero (Roth, 2008). Ahora bien, estos experimentos pueden ser *in vitro* (desarrollados dentro de un laboratorio) o *in vivo* (experimentos en el mercado real) coexistiendo en un proceso de permanente intercambio (Muniesa and Callon, 2007). Para esto, deben existir redes que organicen y faciliten las relaciones entre ellos de manera de permitir el avance de los conocimientos teóricos sobre los mercados, por un lado, y los dispositivos materiales e institucionales, por el otro. Estos experimentos se han ido estableciendo progresivamente en los mercados y han permitido su mejoramiento permanente. En particular, en los nuevos mercados, donde todo tiene que ser inventado, ni los economistas, ni los agentes económicos habituales pueden diseñarlos sin ayuda. Tienen que cooperar y aceptar que otros actores están involucrados y que, en contextos de incertidumbre, el proceso de diseño debe consistir, necesariamente, en un largo proceso de ensayo y error (Callon, 2009).

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<sup>67</sup> Muchas veces el objetivo de un experimento es convertir una teoría compleja en un conjunto explícito de reglas y comportamientos. Este vuelco hacia lo explícito ya estaba presente en los primeros experimentos de (Chamberlin, 1948). Los experimentos pueden llevarse a cabo en las aulas, dentro de sistemas informáticos o en un mercado real (Muniesa and Callon, 2007).

<sup>68</sup> Si bien esto es claro cuando se trabaja dentro de un laboratorio, resulta más evidente en experimentos que utilizan un mercado real como su campo de testeo; al realizar el experimento en mundo real ya están construyendo el nuevo mercado. Por ejemplo, cuando se permite utilizar una medicina en un área controlada determinada del país se está testeando y creando a la vez (Muniesa and Callon, 2007). En los mercados financieros muchas veces se experimenta con nuevos productos (por ejemplo, derivados exóticos) (MacKenzie and Millo, 2003). Es más, muchas veces las economías nacionales pueden convertirse en un experimento para probar una doctrina económica (Ghannadian and Goswami, 2004).



La eficiencia de un experimento de mercado radica en organizar la discusión de los asuntos de interés que emergen de su propio funcionamiento, contemplando los desbordes (externalidades). Se deben establecer procedimientos para facilitar la evaluación de soluciones teóricas o prácticas a esos problemas. Este enfoque otorga centralidad a los experimentos y abre los debates; se presenta como un par problemático indivisible: lo económico y lo político (que muchas veces intenta ser excluido)<sup>69</sup> (Callon, 2009).

Los mercados, en fase experimental, resaltan este proceso de reconfiguración conjunta. Este enfoque permite una problematización multidimensional, constituyendo una red de problemas. Es más, la configuración del mercado puede dar prioridad a un enfoque sobre otro y esto no es casual sino que es parte del diseño. Se puede encontrar, entonces, que la dimensión política quede reducida a su mínima expresión.

En el experimento aquéllos que diseñan e implementan los nuevos mercados deben contestar preguntas emergentes, tratando de no encerrarse en organizaciones existentes y permitiéndose innovar en busca de la solución. Incorporando esta problematización en el proceso de diseño se construye una economía política compleja. Asimismo, en este proceso, las ONG se convierten en socios legítimos e inevitables. Este mercado en proceso de diseño evoluciona transformando la economía, la política y la ciencia que lo rodea, por lo que experimentar nuevos mercados tiene un carácter performativo de la realidad y es una acción política. Los procedimientos que se diseñan en el mercado son dialógicos. Se debe permitir que todos los actores concernidos por el diseño y el funcionamiento de un mercado puedan expresarse y, luego, analizar las cuestiones y comparar las soluciones propuestas<sup>70</sup> (Callon, 2009).

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<sup>69</sup> En los mercados emergen cuestiones donde la incertidumbre es tal que no se sabe cuál es el enfoque adecuado para resolverlos. No es claro si el abordaje debe ser político, económico o tecno-científico. Callon sostiene que ni la economía ni la política ni la ciencia pueden ser consideradas como realidades acabadas y estancas. Callon centra su posición entre el constructivismo social (que considera que lo como el político, económico y científico es simplemente el resultado de un enfrentamiento entre grupos que luchan por imponer sus propios puntos de vista) y el esencialismo (hay una o más definiciones de la política, la economía y la ciencia, que proporcionan criterios objetivos que permiten decir, a priori, si un comportamiento, forma de pensar o dispositivo es político, económico y científico).

<sup>70</sup> Si la teoría de juegos va a ser un instrumento fundamental para el diseño, deberá contener no sólo el herramental formal para el desarrollo de conceptos a partir de modelos sencillos, sino también incluir las complicaciones de los mercados concretos. Alvin Roth (2002) señala dos tipos de complicaciones. Primeramente, las complicaciones en el entorno estratégico, en los resultados posibles y en las estrategias

El diseño debe anticiparse a cómo las personas se comportarán en el ambiente delineado. Asimismo, es importante asegurar la sustentabilidad del proyecto en el largo plazo, pero verificando su posibilidad de corto plazo. Tradicionalmente, el énfasis formal al analizar sistemas estuvo puesto en los equilibrios en infinito; es indispensable verificar la viabilidad del corto plazo para alcanzar ese equilibrio futuro. Los métodos computacionales cumplen un rol fundamental al permitir el análisis de juegos complejos, imposibles de resolver analíticamente. Los experimentos de laboratorio, por su parte, informan sobre cómo se comportará la gente cuando se enfrenta a estos ambientes que estamos diseñando y cómo adquieren experiencia.

Los experimentos<sup>71</sup> son un ejemplo claro de la característica performativa de la economía. Un experimento es un crisol en el que las teorías, discursos, textos, prácticas, intereses y materiales interactúan y se co-constituyen.

### 2.2.3 Mercados eficientes

Roth sostiene que el funcionamiento eficiente de los mercados requiere (1) densidad<sup>72</sup> (para atraer a un número suficiente de participantes), (2) superar los problemas de congestión que puede traer la cantidad de agentes operando (realizar transacciones con suficiente rapidez que permitan a los agentes tomar decisiones), y (3) que sea seguro y simple. Asimismo, debe contemplarse que algunas operaciones están moralmente excluidas, lo cual es una limitación a tener en cuenta al diseñar el mercado. Por último, el autor destaca el rol que tienen los experimentos en el diagnóstico y la comprensión de las deficiencias del mercado,

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disponibles para los jugadores. En segundo lugar, las complicaciones en el comportamiento de los agentes económicos reales que no se comportan como meros maximizadores de beneficio.

<sup>71</sup> Muniesa y Callon (2007) presentan una distinción entre tres configuraciones esquemáticas de experimentación que se diferencian por su grado de apertura: el laboratorio, la plataforma, y el experimento *in vivo*.

<sup>72</sup> Tradicionalmente, se reconoce la importancia de la densidad de los mercados, pero no siempre se contemplaron los temas de la congestión, la seguridad y la sencillez. Una forma de evitar la congestión de los mercados es emplear una cámara de compensación centralizada para coordinar el mercado donde un algoritmo aprobado realice las asignaciones. Ahora bien, Roth (1984) demuestra que la evolución de los mercados puede hacer imposible que el algoritmo funcione eficientemente frente a transformaciones. La congestión es un problema, especialmente, en mercados en los que las transacciones son heterogéneas y las ofertas no se pueden hacer a todo el mercado. Aunque las operaciones se realicen rápidamente, al tener que dirigir la oferta hacia agentes particulares, se corre el riesgo de que otras oportunidades desaparezcan.

en contrastar el éxito de un diseño y en la comunicación de resultados a los responsables políticos (Roth, 2008).

### **2.3 El mercado de nanotransportadores como un proceso de co-constitución**

La tradición occidental ha establecido una clara distinción entre el individuo y lo colectivo<sup>73</sup>, generando una relación dialéctica que ha dominado la producción en ciencias sociales (Callon and Law, 1997). En el caso particular de la ciencia económica, la noción de racionalidad limitada de Herbert Simon (1982) ha obligado al *homo economicus* a reconocer un contexto de objetos que lo condiciona. Las sociedades humanas son heterogéneas y se constituyen en conjunto con tecnología, textos, bienes y capital, capturando la complejidad que conlleva una asociación colectiva de entidades heterogéneas donde los objetos y procedimientos no son simples recursos o restricciones, sino que pueden intervenir activamente para impulsar la acción en direcciones inesperadas (Callon and Law, 1997).

Dentro de esta sociedad heterogénea, los mercados tienen indudables ventajas que los hacen insustituibles en un contexto occidental capitalista. Sus agentes autónomos innovan y se coordinan facilitando la concreción de contratos entre partes. Sin embargo, tienen claros límites: no están diseñados para lograr el bien público y producen externalidades negativas sobre grupos humanos que no son tenidos en cuenta. Por tanto, es necesario volver a considerar las cuestiones básicas sobre los mercados y cómo podemos garantizar que funcionen correctamente (Callon, 2012).

El presente trabajo analiza un mercado en particular que se encuentra en proceso de constitución como tal: el de la nanomedicina, definido como las aplicaciones médicas de la nanotecnología, lo cual incluye el desarrollo de nuevos procedimientos para diagnosticar y curar enfermedades (Paradise *et al.*, 2008). Para ello, se estructura en tres secciones. Primeramente, se define el concepto de

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<sup>73</sup> Esta distinción no se da en otras culturas como, por ejemplo, la japonesa (Callon y Law, 1997).

híbrido colectivo, el cual interactúa para constituir un mercado y se postula que la capacidad de cálculo es fundamental para entender las relaciones de poder. En la segunda sección se aplica lo expuesto al mercado en desarrollo de la nanomedicina, analizando cómo interactúan los agentes para objetivar, singularizar y hacer calculable (poner precio) a dos productos en particular: los nanotransportadores (de droga en el cuerpo humano) y sus patentes. Por último, se analiza cómo las diferencias en capacidad de cálculo establecen asimetrías en el mercado.

### **2.3.1 Interacción entre entidades colectivas**

En un contexto de interacción entre entidades colectivas heterogéneas, el mero concepto de *mercado* es problemático. Muchas veces es presentado como un espacio abstracto en el que la demanda agregada y la oferta se cruzan entre sí y, a través de ajustes sucesivos, terminan por definir el precio (Cournot, 1838). Esta concepción presenta dificultades lógicas y teóricas, sobre todo, cuando se trata de explicar los mecanismos de agregación. Para superar la oposición entre los mercados abstractos y los concretos, se debe tomar como punto de partida la propia transacción, no la macro-estructura hipotética. La propuesta es, entonces, focalizarse en mercados reales, reconociendo el creciente papel de las interacciones a nivel micro.

Se presenta, de este modo, al mercado como un conjunto de localidades donde el debate entre los grupos emergentes define las diversas maneras de organizarlos, dependiendo de cuestiones relacionadas con los tipos de productos e interpretaciones del derecho de propiedad. Las transacciones se describen mediante un doble proceso de entrelazamiento de actores y su posterior separación (Callon, 1998). Esto no significa que no hay proceso de estructuración de los mercados sino más bien, que el proceso en sí es lo que se debate (Barry and Slater, 2002). En otras palabras, el mercado se presenta como una red de muchas y complejas relaciones, donde el doble movimiento de entrelazamiento y separación explica cómo se forman los negocios bilaterales.

Esta red, que se constituye como mercado, puede ser entendida como un acuerdo socio-técnico (STA), con tres características destacables<sup>74</sup>. Primeramente, permiten organizar la concepción, producción, circulación y transferencia de bienes. En segundo lugar, se presentan como un conjunto de componentes heterogéneos: normas, instrumentos técnicos<sup>75</sup>, narrativas, conocimientos, así como las competencias y habilidades incorporados en los seres vivos. Y, por último, son un espacio de confrontación y luchas de poder que producen múltiples y contradictorias valoraciones de los bienes (Çalışkan and Callon, 2010).

Ahora bien, si utilizamos esta noción de acuerdo socio-técnico, dejamos implícita una división entre humanos que organizan, y las cosas que se dejan pasivamente utilizar. Para introducir en forma explícita la capacidad de actuar de ciertas cosas, Deleuze y Guattari (1998) propusieron la noción de *agencement*<sup>76</sup>. En otras palabras, *agencements* refiere a acuerdos socio-técnicos considerados desde su capacidad de actuar, acorde a su diversidad de fuerzas (Çalışkan and Callon, 2010). Éstos se componen de seres humanos y dispositivos materiales, técnicos y textuales, dependiendo de las configuraciones particulares<sup>77</sup>.

Siguiendo a Callon y Law (1997), esta tesis propone capturar la idea presentada utilizando el concepto de colectivo híbrido en constitución<sup>78</sup>. En ese proceso interactúan personas, dispositivos y textos, no habiendo diferencia entre la persona y la red de entidades en las que actúa. O más precisamente, entre la persona y la red de entidades que actúan a través de ella, constituyéndose como el producto de un proceso de composición conjunta. Lo mismo ocurren el mercado, sus agentes

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<sup>74</sup> Claramente, esta definición general permite distinguir a los mercados de otros tipos de organización. Contrariamente a lo presentado, el constructivismo social se centra en los mecanismos "sociales" y analiza los mercados como una organización social más, perdiendo de vista la especificidad propia de la dinámica del mercado. Asimismo, reduce sus dimensiones materiales y técnicas a nociones generalizadas abstractas como "recursos" o "capital". Las relaciones sociales son el único elemento explicativo (Bloor, 1991).

<sup>75</sup> El especial énfasis en materialidades y tecnicismos para entender los mercados no es una idea nueva se encuentra ya presente en los escritos de Weber (1978 [1922]). (Weber, 1978 [1922])

<sup>76</sup> *Agencement* es una palabra francesa cuyo significado está muy cerca de "acuerdo", transmitiendo la idea de una combinación de elementos heterogéneos que se han ajustado entre sí.

<sup>77</sup> Asimismo, estos *agencements* pueden ser deliberativos (McCarthy and Kelty, 2010), pueden tener capacidad de cálculo o no, pueden ser colectivos o individuales (Callon and Law, 2005). Es, asimismo importante destacar que estas entidades mencionadas no son naturales, sino efectos relacionales. Por lo tanto su forma, su contenido y sus propiedades son producto de ese proceso relacional, y su identidad surge en el curso de la interacción. Son procesos de transformación, de compromiso mutuo y de negociación (Callon and Law, 1997).

<sup>78</sup> Por ejemplo, Bruno Latour (1999) nos presenta un ejemplo de lo anterior: "Pasteur". Claramente el ser humano Pasteur ha logrado realizar lo que figura a su nombre porque una red de elementos a su alrededor le dio la posibilidad de realizar su práctica científica diaria.

no actúan, solamente, gracias a su capacidad mental individual, son también híbridos colectivos<sup>79</sup>.

Estos agentes interactúan en el mercado realizando operaciones de cálculo, por lo que se propone, entonces, conceptualizarlos como dispositivos híbridos colectivos de cálculo (Callon and Muniesa, 2003). Ahora, si bien, notoriamente, el cálculo es una característica del mercado, la pregunta es: ¿quién realmente calcula y cómo? En la literatura, se encuentran dos respuestas antagónicas. Mientras que, para la teoría económica neo-clásica, los agentes calculan ya que está en su naturaleza hacerlo, desde una perspectiva de antropología social, el cálculo es una racionalización *ex post* de las decisiones que, realmente, se toman en base a otras lógicas. Estas dos visiones son extremos que se deberían evitar para entender el mercado. Por un lado, no debe tomarse la visión formal económica de los mercados, que reduce a los agentes económicos a sus preferencias y aptitudes de cálculo pero tampoco hay que deshacerse de la idea de cálculo y disolverla mediante descripciones etnográficas (Callon and Muniesa, 2003).

El proceso de valoración de los bienes surge de los intercambios mercantiles mediante la realización de cálculos cruzados<sup>80</sup>. Los agentes involucrados en estas operaciones son los dispositivos de cálculo (Çalışkan and Callon, 2010). Éstos cuentan con herramientas disponibles que no sólo permiten alcanzar ciertos fines, sino que contribuyen, activamente, en la constitución de su realidad (Rose and Miller, 2008). Estas valoraciones y cálculos se manifiestan, públicamente, como precios, luego de una lucha entre agentes que tratan de imponerse uno al otro (Weber, 1978 [1922]; Stark, 2009). Los agentes calculan estos precios sobre la base de sus valoraciones<sup>81</sup>, elaborando fórmulas de cálculo (Lepinay and Callon, 2009). Es importante notar que varios estudios han demostrado que los actores vinculan directamente la cuestión de la equidad de los precios a sus fórmulas de cálculo,

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<sup>79</sup> A modo de ejemplo, imaginemos una alta ejecutiva de una gran empresa que es la presidenta durante un proceso de crecimiento exponencial de la corporación y cuenta con una experiencia notable en el mercado. Es fácil imaginar, entonces, que es una estratega ejemplar, activa y energética. Ahora bien, ¿qué pasaría si elimináramos sus teléfonos, su fax y los informes que tiene sobre su escritorio? Seguramente, dejaría de ser la estratega empresarial conocida.

<sup>80</sup> Los encuentros pueden ser múltiples y se pueden producir cálculos superpuestos.

<sup>81</sup> Incluyendo otros precios, aunque se trate de una operación bilateral (Guyer, 2004).

reclamando que la construcción de las fórmulas sea justa (Guyer, 2009; Muniesa, 2003).

Ahora bien, para especificar la noción de cálculo presentada, se propone partir de la idea de *centro de cálculo* desarrollado por Bruno Latour (1987), y conceptualizar los agentes económicos como híbridos colectivos de cálculo. Agencias equipadas con instrumentos, donde el cálculo no se realiza sólo en las mentes humanas, sino que se distribuye entre los seres humanos y artefactos. Se postula una definición general de cálculo como un proceso de tres pasos<sup>82</sup>: En primer lugar, las entidades en cuestión deben ser separadas y colocadas en un espacio determinado. Luego se asocian entre sí, se manipulan y transforman materialmente. Finalmente, se extrae un resultado que se convierte en una entidad separable que puede circular en el mercado (Callon and Muniesa, 2003).

Los mercados con su propia dinámica generan externalidades que impactan en la sociedad, impulsando espacios políticos de discusión e interacción. Si bien el enfoque tecnocrático económico tradicional propone dar cuenta de estas externalidades incluyéndolas en los modelos como variables, estos desbordes exceden lo técnico e impulsan una discusión claramente política. Se presenta, entonces, una confrontación entre el enfoque tecnocrático abstracto que intenta cuantificar externalidades sociales por un lado<sup>83</sup>, *versus* un enfoque político que propone un espacio de discusión por el otro.

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<sup>82</sup> El concepto de configuración algorítmica del mercado ayuda a entender cómo es posible tener representaciones abstractas del mercado, que se pueden utilizar para actuar en mercados concretos. Ellos hacen explícito lo que llamamos las configuraciones algorítmicas del mercado, las cuales son acuerdos socio-técnicos, dispositivos de cálculo en el sentido que Callon y Muniesa (2003) le dan al término. En primer lugar, delimitan el grupo de agencias de cálculo haciéndolas identificables y numerables. Seguidamente, explicitan el proceso de conexión y, por último, establecen las reglas que gobiernan el orden en que las conexiones deben ser realizadas. Estas configuraciones algorítmicas de los encuentros no son estructuras existentes en las que las agencias de cálculo sólo circulan y se desarrollan. Los agentes participan en diversos grados en el diseño de los mercados en los que operan.

<sup>83</sup> Polanyi, que tanto contribuyó a la comprensión de los mercados, también sostiene una definición abstracta de los mercados pues considera el mercado como un espacio de encuentro entre demanda y oferta (Polanyi, 1957).

El mercado no puede ser entendido como una categoría unificada<sup>84</sup>. No existen las macroestructuras que sostienen las transacciones; lo que existen son relaciones en constante co-constitución en un nivel micro<sup>85</sup> (Callon, 2009).

Los mercados son una combinación de reglas definidas por los poderes públicos y agentes privados. Algunos se estructuran de tal forma que favorecen la creación de asimetrías, mientras que otros están más abiertos al debate sobre su funcionamiento y a su posible reorganización. Es más, el análisis de los diversos dispositivos de cálculo con los que cuentan los STA permiten entender las relaciones de dominación que definen los diferentes mercados. Son las diferencias en el poder de cálculo las que posibilitan que las agencias más poderosas sean capaces de imponer sus valoraciones y presionar por una mayor parte de la distribución de riqueza (Bourdieu, 2005).

Una forma de concebir las relaciones de dominación que atraviesan los mercados es inscribirlas en relaciones de cálculo (Hirschman, 1977). Es cada vez más difícil de ocultar las luchas de poder detrás de las transacciones comerciales<sup>86</sup>. Ahora bien, este escenario de asimetrías y relaciones de poder nos lleva a preguntarnos: ¿cómo es posible realizar un cambio? Callon y Muniesa proponen que una de las primeras tareas de un estudio es identificar las fuerzas que participan en estas redes y entender cómo se interrelacionan. En este sentido, es fundamental el rol performativo de los experimentos en el proceso de aprendizaje para lograr mercados democráticos. Esto moviliza una verdadera ingeniería económica sobre la base de ensayo y error, abriendo la posibilidad de concebir nuevas formas de organización y teorización (MacKenzie, 2009; Callon, 2009).

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<sup>84</sup> Como lo ha sido hasta la primera mitad del siglo XX.

<sup>85</sup> Su organización depende de las actividades profesionales y de las tecnologías involucradas, de forma que las metáforas de amplia difusión en la literatura de “infraestructura subyacente” o la de *embeddedness* (Granovetter, 1985) dejan de ser útiles.

<sup>86</sup> Algunos mercados se estructuran de tal forma que favorecen la creación de asimetrías, mientras que otros están más abiertos al debate sobre su funcionamiento y a su posible reorganización. No sólo el mundo privado interviene en su creación; los mercados son una extraña combinación de reglas definidas por los poderes públicos y agentes privados. En particular, el análisis de los diversos dispositivos de cálculo que actúan en los mercados permite entender las relaciones de dominación y sus asimetrías.



### **2.3.2 La constitución del mercado**

Como fue mencionado anteriormente en el presente trabajo, el concepto tradicional de mercado remite a la existencia de un espacio abstracto en el que la demanda y la oferta se encuentran y, por sucesivos ajustes, terminan por definir el *precio*. El problema de este enfoque aparece cuando los mercados son incompletos, en formación o con pocos agentes negociando; en estos casos es claramente necesario rastrear las interacciones para poder entender el proceso de formación de precio. Este es el caso de la nanomedicina. Para entender la formación del mercado de comercialización de nanotransportadores (Parveen *et al.*, 2012) y de sus patentes (Martins *et al.*, 2013), este trabajo aplica la metodología propuesta por Callon y Muniesa (2005).

Esta metodología de analizar transacciones concretas entre agentes del mercado se conoce en economía como *microfundación*. La noción refiere a entender el efecto macro de un conjunto de transacciones limitadas entre un número limitado de agentes, un número limitado de productos y en un marco regulatorio en cambio. En particular, esta sección rastrea las relaciones que, partiendo de la práctica científica (registro de patentes), transfiere a las empresas (uso de patentes y producción de nanoportadores) y permite que la nanomedicina llegue a los usuarios (facilitado por sus médicos). Este rastreo explicita el proceso de constitución del mercado como una configuración algorítmica donde híbridos colectivos interactúan.

#### **2.3.2.1 Objetivación y singularización**

En una transacción de mercado, un bien se vende por un precio que, como consecuencia, conlleva un cambio de manos del producto, dejando al vendedor y al comprador satisfechos con la transacción. El bien se separa del mundo del vendedor y se adjunta a la del comprador (Muniesa and Callon, 2007). En el caso bajo estudio se encuentran dos bienes objetivables. El primero que surge es la patente. Si bien es intangible, claramente es material y un bien transable. El

segundo es el nanotransportador como producto masivo, cuya materialidad es obvia<sup>87</sup>.

Es importante destacar que ambos son valiosos, solamente, si sus propiedades representan un valor para los potenciales compradores. Esta evaluación puede ser expresada como un precio que el comprador está dispuesto a pagar para apropiarse de la cosa, es decir, apegarse a él, para incorporarlo a su mundo. Una vez que él o ella han adquirido este bien, el comprador se convierte en el propietario. La transformación es doble: no sólo es el bien poseído por el dueño, sino que también se convierte en parte del mundo del propietario.

El proceso de singularización de la patente consiste en una definición progresiva de sus propiedades, de tal manera que pueda entrar en el mundo de la empresa que la utilizará para producir el nanotransportador. A lo largo de este proceso de calificación, el objeto *patente X* se transforma, progresivamente, en un bien a ser vendido. Cuando una empresa compra una patente (u obtiene permiso de uso por tiempo determinado), ésta entra a formar parte de las relaciones socio-técnicas que constituyen el mundo corporativo.

Una vez que la empresa colocó en su red la patente, puede iniciar el proceso de producción del nanotransportador para luego iniciar el proceso de individualización del mismo, que consiste en una definición progresiva de las propiedades del producto, en una interacción con los profesionales de la medicina y los usuarios finales. El producto entra en el mundo del usuario por medio del profesional médico que recomienda su uso en el cliente, por lo que el largo proceso de calificación del producto, se realiza en íntima relación con el médico. La objetivación y la singularización de la patente se producen al mismo tiempo, siendo las propiedades objetivadas aquéllas que permiten a la patente unirse al mundo de la empresa compradora.

A la hora de pensar las propiedades de las patentes es necesario construirlas en contexto. Es más, la compra es el resultado de un encuentro entre sujeto y objeto;

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<sup>87</sup> Es importante aclarar que el alquiler o permiso poseen materialidad, de la misma forma que la venta total de la patente a un tercero. En el caso de los nanotransportadores, la materialidad es obvia debido a que son objetos físicos separables. En otras palabras, son materiales en la nanoescala (1-100 nm de diámetro) que pueden llevar múltiples medicamentos a un tejido destino del organismo humano (Parhi *et al.*, 2012).

un proceso de relación que califica los productos y que termina en la singularización de sus propiedades. Esta co-producción de las propiedades requiere la participación de un gran número de profesionales del mercado (marketing, productoras, anunciantes, diseñadores, comerciantes, vendedores, etc.)<sup>88</sup>. El científico, como híbrido colectivo, y en relación con sus ayudantes y colegas, construye el objeto. Claramente, la lectura de revistas científicas, la interacción con el exterior (por ejemplo, con médicos) y las políticas públicas de financiamiento co-elaboran las propiedades del intangible. Es más, una parte importante de su materialidad es contar con una buena documentación de los procedimientos involucrados para que el comprador asigne un valor económico lo más alto posible a la patente (Hall and Harhoff, 2012). Asimismo, el grupo de investigación debe saber que ciertas propiedades, perjudiciales para la salud, impedirán que el trabajo termine con una patente aprobada. Ahora bien, el comprador de la patente adquiere con ella el derecho (no la obligación) de producir nanotransportadores. Para definir las características del producto, es fundamental entender las necesidades médicas concretas (seguramente, intuitas por el científico que logró la patente), ya que es fundamental una relación estrecha. Antes de la producción masiva, se requiere una serie de fases de testeo clínicos para lograr la aprobación del producto por parte de los entes reguladores. Cumplir con el regulador y lograr un producto deseable por parte de los médicos (y los usuarios) no es suficiente para entender el valor económico del producto.

Como hemos detallado anteriormente, el proceso de singularización consiste en una serie de operaciones que resultan en la posibilidad de realizar un cálculo sobre la mercancía en cuestión. Es más, estudiar la competencia de mercado consiste en establecer un espacio de cálculo en el que se puede conectar y comparar el producto en cuestión con una lista finita de otros productos. Comparabilidad y la posibilidad de sustitución se encuentran en el corazón de los métodos de fijación de precios. Cuanto más complejo sea un producto, su comercialización planteará mayores problemas en términos de singularización. El producto oscila entre un alto nivel de

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<sup>88</sup> Este proceso de adaptación también implica una exploración extensa y sistemática de las redes de vinculación que constituye el comprador (potencial) del mundo. Uno de los principales requisitos, que los diseñadores y los vendedores tienen que cumplir, es el estudio de las necesidades de los compradores con el fin de ser capaces de proponer nuevas.

singularización (sustitución débil) y un alto nivel de estandarización (sustitución fuerte).

La patente en cuestión se convierte en singular y calculable después de una operación de extracción, traducción y cambio de formato. Es necesario vincularla con otras patentes para lograr una correcta clasificación, como así también hacerla comparable con otras para que pueda calcularse su valor en el mercado. En el vocabulario de los profesionales de marketing, esto tiene un nombre: el posicionamiento. Durante la vida útil de la patente, seguramente, tendrán lugar una larga serie de reposicionamientos.

Una vez que se cuenta con la patente, lograr construir el objeto nanotransportador, requiere muchas conexiones en la red sociotécnica en cuestión. Durante la etapa de I+D, intervienen científicos que han descubierto la tecnología y aquéllos que realizarán las pruebas clínicas. Asimismo, cuando el producto llega al mercado, compite con otros productos similares y, al cruzarse con la demanda, definen precio.

El nanotransportador sufre un proceso similar al de la patente para hacerse calculable. Se trata de un proceso de clasificación, agrupación y clasificación que hace que los productos de dos compañías sean comparables pero diferentes. Asimismo, este proceso de vinculación de agentes, implica, entre otras cosas, el establecimiento de controles de calidad que permitan medir y objetivar ciertas propiedades, de forma que un producto pueda ser reconocido por los usuarios como mejor, y ellos le asignen un mayor valor económico.

En conclusión, tanto la patente como el nanotransportador son objetivados y singularizados para poder ser calculables. Al lograr estabilizar las propiedades de los mismos, se puede describir una fórmula que permita calcular sus precios<sup>89</sup>.

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<sup>89</sup> Una vez objetivado, el bien deja el mundo de la empresa que lo oferta y penetra el mundo del comprador, que se ha configurado para recibirlo con la ayuda del médico. El nanotransportador, visiblemente, pasa ser parte del organismo del usuario y opera en su cuerpo para lograr el efecto requerido. Ahora bien, ahí no termina la relación comercial, el vendedor debe recordar su responsabilidad por daños del producto.

### 2.3.3 Asimetrías en el mercado

La existencia de una multiplicidad de formas prácticas de confrontación entre la oferta y la demanda para definir un mercado se denomina configuración del mismo. Esta tiene una gran relevancia a la hora de definir precios y relaciones comerciales, a la vez que identifica a los agentes autorizados para participar en una transacción. Dentro del contexto que plantea la regulación estatal, interactúan la oferta y la demanda. En particular, existen normas regulatorias que el Estado impone, que restringen la producción de nanoportadores (como producto medicinal) y normas que obligan al usuario a contar con un médico que avale el uso del producto en su cuerpo. Estas restricciones al mercado, necesarias para la actividad médica, claramente, son parte fundamental del proceso de formación de precios<sup>90</sup> (Vashist *et al.*, 2012; te Kolve and Rip, 2013).

Con nuevas tecnologías de información, el poder y la diversidad de las tecnologías de encuentro se amplifican en el mercado (Chaboud *et al.*, 2014) y las configuraciones se convierten en objetos por derecho propio en los que puede ser llevado a cabo la investigación y la experimentación<sup>91</sup>. Esta configuración algorítmica, donde se desarrollan los encuentros entre gobierno, usuarios, empresas, científicos y médicos, no son estructuras que ya existen. Son los agentes participantes los que lo diseñan y para analizarlos, Callon y Muniesa (2005) proponen preguntarse dos cuestiones que refieren a la relación entre un mercado concreto de nanomedicina y el abstracto que surge de un modelo económico-financiero. La primera refiere a la relación entre la elección de determinadas formas de organización de mercado y su impacto en el mercado agregado. La segunda refiere a las condiciones de validez de los modelos abstractos que proporcionan una descripción sintética y permiten calcular precios.

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<sup>90</sup> Estos procedimientos de formación de precios en un contexto regulado se constituyen como una configuración algorítmica. Visiblemente, son dispositivos de cálculo, pues identifican las agencias de cálculo, organizan sus encuentros y establecen las reglas.

<sup>91</sup> Un ejemplo es la red creada por NanoKTN para promover y aumentar las relaciones en el mercado de la nanomedicina. Si bien se realizan encuentros donde exponen líderes de la industria y académicos de renombre, el mayor flujo de intercambio es virtual a través medios tecnológicos, que exploran formas de avanzar en la comercialización de los productos.

Las agencias de cálculo<sup>92</sup> son híbridos colectivos equipados con los instrumentos de cómputo. El modelo matemático que permite valorar patentes médicas (Guo *et al.*, 2013) en base a ciertos parámetros es una herramienta, así como la computadora, donde el modelo se ejecuta. Asimismo, es necesario que profesionales puedan calibrar los parámetros e interpretar los resultados del modelo<sup>93</sup>.

Callon y Muniesa (2005) proponen un análisis de estas asimetrías en base a dos criterios. Las agencias de cálculo se caracterizan por su poder de cálculo y por su grado de autonomía. Una agencia de cálculo será tanto más fuerte cuando sea capaz de: a) establecer una lista larga de entidades diversas, b) permitir relaciones complejas entre las mismas, y c) formalizar los procedimientos y los algoritmos de forma de multiplicar las jerarquías y las clasificaciones posibles entre estas entidades. Es fácil entender que el poder de cálculo, así definido, se distribuye en forma desigual entre los organismos de cálculo. Se consideran dos explicaciones para esta desigualdad: el grado de complejidad y riqueza de los dispositivos de las agencias de cálculo, y la red de interconexiones entre ellos.

El mercado, en el caso de las patentes (Sandner and Block, 2011), implica, por lo menos, dos agencias de cálculo: la empresa que compra la patente para utilizar en la producción de nanotrasportadores y el científico (o grupo) que realiza la patente. En primer lugar, la empresa compradora realiza una valuación de la patente, involucrando referencias de terceros, prestigio del científico y todo tipo de información pública disponible por parte del gobierno (Chari *et al.*, 2012). El marketing que realicen los científicos de su patente mediante revistas científicas, eventos<sup>94</sup>, etc., constituye un sistema de conocimiento distribuido que participa, activamente, en el proceso de valuación y singularización de la patente en cuestión.

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<sup>92</sup> Las capacidades de las agencias de cálculo están vinculadas a su equipamiento distribuido. Esta caracterización permite tener en cuenta las asimetrías de poder de cálculo, un tema clave en el análisis de las guerras comerciales (Callon and Muniesa, 2005).

<sup>93</sup> La estimación se realiza en base a información histórica disponible y en base a preguntas a expertos. Claramente, es un agente distribuido de cálculo el que se presenta a valorar una patente. Mediante la introducción de estas nuevas entidades (modelos, estimación de parámetros, computadoras), se han ampliado las capacidades de los actores humanos.

<sup>94</sup> Los investigadores de los laboratorios saben que sus innovaciones necesitan ser comunicadas, por lo que existe una clara maquinaria de marketing para crear mercado (Berman, 2011).

Por otro lado, la empresa compradora, seguramente, requerirá la realización de pruebas con la patente y la discusión de los resultados.

Independientemente de qué tan fuerte es la agencia de cálculo del científico que registra la patente, sigue siendo débil en comparación con la potencia de cálculo con la que cuenta una empresa farmacéutica<sup>95</sup> que evalúa su uso. Frente a un científico de un laboratorio, generalmente, del otro lado hay una multitud de profesionales armados con computadoras, estudiando sus patentes y calculando con poderosos algoritmos cuál es el flujo futuro esperado de la patente. Sin embargo, esta relación de poder no es inmutable<sup>96</sup>.

Ahora bien, en la medida que el científico tiene más prestigio, más patentes y mayor soporte de la institución que lo cobija, su poder de cálculo aumenta (D'Angelo and Benassi, 2015). Adquiere herramientas que le permiten cambiar el equilibrio de poder, siendo más activos en términos de cualificación y singularización. Este cambio de la geopolítica de las competencias de cálculo es, probablemente, más visible en el contexto de bienes intangibles como las patentes, que en otros contextos industriales de producción de bienes tangibles masivos. Tan pronto como una patente se establece como hegemónica en un mercado, su éxito impulsa a otros a invertir en posibles competencias cuyo impacto puede ser devastador para los intereses establecidos.

En el caso del nanotransportador como producto de consumo médico, es fundamental el rol que juega el médico que tiene que aconsejar el uso del nanoportador, para lo cual realiza evaluaciones que implican referencias y evaluación de productos de varias marcas. El médico constituye un sistema de conocimiento distribuido que participa, activamente, en el proceso de calificación y la singularización del nanoportador. Es más, los médicos requerirán pruebas de la efectividad de la tecnología y discutirán los resultados con la empresa proveedora (Vizirianakis, 2014).

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<sup>95</sup> Como muestran diversos estudios, las grandes farmacéuticas tienen altas rentabilidades y utilizan un poder de mercado casi oligopólico (Spitz and Wickham, 2012; Suarez-Villa, 2014)

<sup>96</sup> En estos últimos años varios billonarios filántropos han traído financiación sin precedentes para hacer el tratamiento para la malaria, el SIDA y la tuberculosis a disposición de los pobres. A la vez los beneficios de las grandes farmacéuticas se van reduciendo. Esto obliga a ir pensando en una nueva dinámica tal vez en unos años (Pollock, 2011).

Pero, independientemente, de qué tan fuerte es la agencia de cálculo de los usuarios (y sus médicos), sigue siendo débil en comparación con la potencia de cálculo de la empresa proveedora (especialmente, si es una gran farmacéutica), ya que utiliza una serie de profesionales para analizar el mundo de la demanda e integrar mejor el producto. En otras palabras, la diferencia entre la capacidad de cálculo del médico y la del vendedor es, esencialmente, la consecuencia de la asimetría de los equipos distribuidos de cálculo con los que cuentan cada uno de ellos. En aquellos países con transparencia de la información y con asociaciones médicas fuertes y responsables, permite cambiar el equilibrio de poderes, habilitando que la demanda sea más activa en términos de cualificación y singularización.

Si pensamos que el productor es una gran multinacional farmacéutica, ésta cuenta con unidades de negocio descentralizados, que se comportan como agencias de cálculo distribuido. Pero se agregan, a la hora de contribuir, a la rentabilidad de la empresa. El consumidor rara vez tiene la posibilidad de movilizar y controlar un gran número de organismos autónomos de cálculo. El estudio de estas conexiones, su naturaleza y su forma, nos permite plantear la cuestión de la autonomía relativa de las agencias: una conexión puede conducir a una dependencia pura si un organismo está en condiciones de tener acceso sin restricciones al poder de cálculo a otro organismo.

## **2.4 Decisiones de inversión y la valuación de proyectos**

Luego del análisis de la sección anterior que permite entender el proceso de constitución del mercado, esta sección pone foco en el rol de los inversores en el mismo. La primera parte explica el proceso de creación de nuevas empresas y recorre algunas lecciones aprendidas de la primera generación de empresarios nano. A continuación, se analiza la valuación económica-financiera de activos intangibles separables e identificables, en particular, activos basados en la tecnología, tales como patentes, procesos y conocimientos técnicos. Luego se presenta un modelo de valuación de inversiones en la industria farmacéutica. Por último se presenta un modelo matemático que representa las decisiones de inversión conjuntas entre una pequeña empresa nanotecnológica que posee la



patente de un nanotransportador (posiblemente un *spin-off*) y una gran farmacéutica que tiene la droga a transportar y con llegada al mercado masivo.

#### **2.4.1 Creación de nuevas empresas**

Cuando un grupo de emprendedores se plantea un proyecto de inversión en el área de nanotecnología va a necesitar un manejo financiero eficiente que le permita obtener fondos externos<sup>97</sup>. En particular, los fundadores de una empresa de nanomedicina deben llevar a cabo varias tareas para lograr un negocio exitoso.

Primeramente, seleccionar las estrategias del producto y armar un plan de negocios. Para continuar, se debe negociar un acuerdo de licencia con la Universidad (o gobierno), logrando términos comercialmente razonables para asegurar el éxito del lanzamiento. Armar un consejo de administración del negocio y otro Consultivo Científico, negociando los salarios y/o participación en las ganancias de cada uno. Solicitar capital a los inversores de riesgo y negociar su participación en las ganancias (Stewart, 2005).

La mayoría de los acuerdos implican exclusividad para la empresa<sup>98</sup>. A modo de ejemplo, en el año fiscal 2003 en EEUU, el 94% de los acuerdos otorgó exclusividad, pero limitando el uso de la licencia a un tipo particular de producto. Asimismo, es muy común que la empresa entregue acciones a la universidad. En el año fiscal 2003 en EEUU las universidades recibieron acciones en el 67% de los acuerdos y el porcentaje de participación oscila entre 1% y el 10% (Bastani *et al.*, 2004). Por encima de las acciones muchos acuerdos requieren que la empresa entregue efectivo a la universidad en diferentes instancias del negocio. Primeramente es usual que se requiera dinero para cubrir el gasto de patentamiento del descubrimiento, también es práctica habitual exigir pagos durante el desarrollo

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<sup>97</sup> La mayoría de los inversores prefieren una sociedad anónima, la cual está gravada al impuesto a las ganancias pero a nivel empresa (no de accionistas). Los inversores “Ángel”, sin embargo, son una excepción pues generalmente requieren la formación de una sociedad de responsabilidad limitada al inicio del proyecto hasta que se haga la primera ronda de pedido de capital.

<sup>98</sup> La estrategia “*Out-licensing*” plantea que, a partir de una tecnología propia, el desarrollo esté financiado por una gran corporación y se licencia a la misma para que lo comercialice. Otra estrategia, “costos y ganancias compartidas”, requiere que las invenciones sean propias, los costos del desarrollo se realicen en forma compartida y el beneficio también sea compartido. La última estrategia, “integración total”, postula que partiendo de invenciones propias, la empresa autofinancie el desarrollo y su comercialización (Stewart, 2005).

cada vez que se termina una etapa y, por último, una vez iniciada la venta, se requiere un pago de royalty<sup>99</sup> (3% a 6% sobre ventas netas) (Bastani *et al.*, 2004).

Otro tema relacionado a esta problemática es el rol del grupo científico universitario que inventó la tecnología, en el proyecto. El trabajo de grupo en la nueva empresa puede ser a tiempo completo, parcial, o meramente consultivo. Por otro lado, si es uno de los fundadores de la empresa, tendrá acciones de la misma. Por último el científico también participa en las regalías en efectivo que realiza la empresa a la universidad (Stewart, 2005).

En el año 2009 la revista del sector *Nanotechnology Law & Business* realizó un listado de algunas lecciones que la primera generación de empresarios que trabajaron en el campo nano dejaron para los nuevos. Se remarca la necesidad de hacer foco en las necesidades del mercado en lugar de la creación de una plataforma tecnológica. Muchas empresas se centraron en el desarrollo de plataformas tecnológicas que se podrían utilizar para una variedad diferente de productos y casi todas estas han fracasado porque debían enfrentarse a diferentes tipos de mercado al mismo tiempo (Maebius and Jamison, 2009).

Otras de las lecciones aprendidas es que no se debe empezar la venta al público si no se dispone de una estimación de los ingresos futuros que generarán los productos. Los primeros empresarios no anticiparon correctamente la demora en comercializar los productos, debido a la necesidad de esperar la calificación del producto. Se debe tener en cuenta las complicadas cuestiones regulatorias, pues esto impone barreras relacionadas con la comercialización.

A nivel financiero del proyecto<sup>100</sup>, es importante recaudar la mayor cantidad de capital posible cuando se sale al mercado pues la comercialización ha requerido

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<sup>99</sup> Una fuente posible de financiamiento para la empresa es encontrar un socio corporativo de gran tamaño con el cual realizar una alianza estratégica. Estos socios pueden invertir solo o en conjunto con inversionistas de riesgo. La estrategia de producto debe ser determinada en conjunto con el plan financiero y las estrategias de comercialización. La estrategia óptima del producto dependerá de los fondos necesarios para desarrollar el período de investigación, el capital propio de la nueva empresa para el desarrollo y para vender el nuevo producto.

<sup>100</sup> La producción masiva de nanomateriales conlleva una gran incertidumbre técnica; existen incógnitas sobre algunos comportamientos que ocurren a nanoescala, porque es muy importante contar con parámetros en el plan de negocios que contemplen la misma. Por otro lado, es importante no subestimar las capacidades tecnológicas de los materiales tradicionales. Se debe contemplar que existe una continua innovación de las tecnologías tradicionales y no solo contemplar la tecnología nano a la hora de proponer una solución al mercado.

más tiempo y más capital del inicialmente anticipado por los empresarios. A esto se suma la última crisis financiera que ha dejado descapitalizados a muchos emprendedores. Ahora bien, es importante el correcto uso de esos capitales evitando construir capacidad instalada de producción antes de investigar a fondo la demanda a satisfacer. Por otro lado, la propiedad intelectual posee poco valor si el producto no está realizado. Muchas empresas han realizado inversiones en cartera con patentes ya otorgadas, las mismas a pesar de tener cierto valor no generan altos rendimientos hasta que el producto real sea comercializado. Por lo tanto el capital invertido en propiedad intelectual puede ser más valioso si se dirige principalmente al desarrollo de los productos (Maebius and Jamison, 2009).

La última lección compendiada por los autores mencionados enfatiza que la definición del precio puede ser tanto o más importante que la *performance* del producto final. No siempre es posible imponer un precio alto sin impactar la demanda, solamente se puede si se tiene poder monopólico (Maebius and Jamison, 2009).

#### **2.4.2 Valuación de activos tecnológicos.**

En la literatura académica, así como en las prácticas corporativas, un activo intangible tecnológico se define como un recurso que no tiene una forma de realización física, y cuya explotación industrial y económica otorga un beneficio futuro a su propietario (Lev, 2001). La presente sección se centra en analizar la valuación de activos intangibles separables e identificables (Guatri, 1989), activos basados en la tecnología, tales como patentes, procesos y conocimientos técnicos. Estos activos basados en la tecnología pueden generar ingresos (y, por lo tanto, valor) a la compañía que los posee.

Los proyectos tecnológicos tienen como objetivo el registro de una patente, para luego, bajo su protección, comenzar la producción y comercialización de productos protegidos por la misma<sup>101</sup>. Las metodologías de valuación de activos tecnológicos

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<sup>101</sup> Ahora bien, aquella es un derecho, no una obligación de hacer uso exclusivo de una invención a un precio predeterminado, por un período predeterminado de tiempo. Por consiguiente, la valuación de dichos proyectos tecnológicos, los cuales incluyen derechos de propiedad intelectual, es un desafío para los profesionales. Si bien, tradicionalmente, los enfoques se han basado en flujos de caja descontados, en los últimos años se ha puesto especial interés en la metodología de opciones reales (Serenó, 2006; Cohen, 2011).

se pueden clasificar en dos grupos principales (Mun, 2003). Por un lado los métodos tradicionales, tales como el de costo, de mercado y por ingreso y, por el otro, los métodos innovadores, entre los cuales se destaca el método de opciones reales. Estas metodologías se difunden, no sólo en la literatura académica, sino, también, en la práctica empresarial (Mullen, 1999). Las metodologías tradicionales, habitualmente utilizadas, son la metodología de costos, la valuación de mercado y la valuación por ingresos. A continuación, se describirán, brevemente, cada una de ellas.

El método de costos<sup>102</sup> evalúa el valor de los activos de la tecnología mediante la medición de los gastos necesarios para producir<sup>103</sup>. El método de valuación por costos incluye los costos hundidos de I+D para producir una patente, pero no tiene en cuenta la cantidad de beneficios económicos relacionados con la explotación de la misma. Asimismo, asume que los gastos siempre crean valor; esto es particularmente problemático para valuar inversiones de alto riesgo como la presente. Este método se utiliza, generalmente, cuando la aplicación está en una etapa temprana de desarrollo y se carece de información del posible mercado y, por ende, no se pueden estimar los futuros ingresos.

Otra de las metodologías tradicionales es la basada en el mercado, la cual estima que el precio de una tecnología es comparable con otra similar que esté, actualmente, en el mercado (Pratt *et al.*, 1998). Se mide el valor presente de los beneficios futuros, utilizando los precios de mercado disponibles hoy de bienes similares. Este método de evaluación<sup>104</sup> se basa en el principio económico de la competencia y asume equilibrio de mercado (Chiesa and Chiaroni, 2005). En general, si ya existe un mercado comparativo donde los activos se negocian activamente y, si la información sobre los costos de transacción ya está disponible, puede convertirse en un método práctico. En este sentido, si bien es eficaz para la

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<sup>102</sup> Chiesa y Chiaroni (2005) presentan diferentes definiciones posibles de costo. En primer lugar, se puede pensar el costo de evitar, el cual cuantifica el ahorro que el propietario de la tecnología (por ejemplo, patente) logra debido a contar con la propiedad de la misma. En segundo lugar, el costo histórico, donde los valores del desarrollo se cuantifican y se actualizan, utilizando un índice de inflación. En tercer lugar, el costo corriente, es decir, el costo tomado a precios actuales para desarrollar la tecnología en cuestión.

<sup>103</sup> Se basa en el principio económico de la sustitución; un inversor prudente no pagaría más por un activo tecnológico de lo que costaría crear o adquirir un bien similar. La estructura de costos utilizada puede variar.

<sup>104</sup> Para utilizar con éxito este método, se requiere que el mercado tenga una gran cantidad de transacciones de un bien similar y que la información sea pública. No contempla la posibilidad de transacciones únicas que surgen de una negociación puntual.

evaluación de propiedades inmuebles, no es eficaz para evaluar los casos de activos intangibles de propiedad intelectual o cuando el mercado es incompleto (transacciones poco frecuentes o secretas).

El último método tradicional que se menciona en este trabajo es de valuación por ingresos, el cual considera que el valor de un activo es el valor presente del flujo futuro de los beneficios financieros que se obtienen de su explotación, por lo que el valor de un activo es la suma de los valores actuales de los flujos de efectivo futuros. Esta metodología no tiene en cuenta los costes de desarrollo de la tecnología y determina el valor de la tecnología de acuerdo a sus posibilidades de creación de beneficios futuros esperados<sup>105</sup> (Boer, 2000). Este método, mientras que es conveniente para las patentes, marcas registradas, derechos de autor y otras propiedades intelectuales que pueden crear un beneficio futuro, tiene la desventaja de no poder reflejar con precisión el valor de la tecnología que no genere un beneficio directo.

Estas metodologías tradicionales tienen serias limitaciones para poder valuar correctamente inversiones innovadoras. La principal desventaja del enfoque basado en los precios de mercado es que no siempre existen tecnologías similares en el mercado. En segundo lugar, el enfoque por ingresos se basa en el valor presente de los beneficios futuros hipotéticos que la tecnología en cuestión puede proveer. Sin embargo, no contempla decisiones estratégicas. En tercer lugar, los métodos basados en el descuento de flujos de fondos ciertos futuros desconocen la naturaleza incierta e irreversible de los proyectos tecnológicos<sup>106</sup>. Por último, la regla del valor presente no puede incorporar los riesgos y los diferentes escenarios estratégicos implícitos en las decisiones de un proyecto tecnológico ya que es un enfoque estático, y la decisión de inversión sólo se puede tomar ahora o nunca. Si bien existen modificaciones que intentan dar cuenta del riesgo, por ejemplo, descontando a una tasa mayor, es difícil de justificar a qué nivel de la tasa de descuento se incorporan todos los riesgos futuros (Brealey *et al.*, 2009).

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<sup>105</sup> Entre ellos, el método de flujo de caja descontado es el más utilizado. Se construye un flujo de fondos futuros neto de costos reversibles y, luego, se lleva al valor presente mediante una tasa de descuento apropiada.

<sup>106</sup> Estos proyectos contienen diversas formas de incertidumbre. Primeramente, sobre el éxito técnico de la etapa de I+D. En segundo lugar, acerca de la protección jurídica que la patente en cuestión pueda dar al inversor durante un período y, por último, sobre el éxito comercial, una vez que entre en el mercado competitivo (Audretsch and Link, 2012).

### **2.4.2.1 Opciones reales**

En particular, los proyectos tecnológicos conllevan innovaciones, cuya introducción puede implicar grandes inversiones, generalmente, como costos hundidos. Asimismo, existe una gran incertidumbre sobre los beneficios futuros que evolucionan estocásticamente, siguiendo al mercado. Otra idea importante de los proyectos tecnológicos es que durante el mismo existen decisiones estratégicas de invertir en la siguiente etapa o no; a las cuales el inversor responde en función de la realización de eventos favorables o no, durante el proceso del proyecto (Schwartz, 2013).

Además, otro tema importante es el momento en que se realiza la inversión. En la mayoría de los casos, la inversión puede ser pospuesta a la espera de nueva información. Por ejemplo, contar con una patente tecnológica crea una oportunidad de inversión irreversible que puede o no, realizarse. En otras palabras, es una opción de compra americana (derecho, pero no la obligación de gastar el dinero ahora o en el futuro, a cambio de un activo) (Brealey and Myers, 2003). Dado que su valor futuro es incierto, hay un costo de oportunidad de invertir en la actualidad, lo cual se describe como una opción de esperar (Vimpari and Junnila, 2014).

### **2.4.3 Valuación de inversiones conjuntas en el mercado de nanomedicina**

Las inversiones conjuntas en nanomedicina requieren la cooperación necesaria entre dos empresas (una especialista en nano y una farmacéutica con llegada al mercado global), prever la incertidumbre del mercado debido a la tecnología y a la política de regulación y analizar los incentivos gubernamentales. Esta sección presenta un modelo formal que permite analizar la interacción comercial entre una empresa especializada en desarrollo de patentes nano y una farmacéutica con llegada al mercado global de medicamentos. La primera empresa desarrolla la investigación base y realiza los tests *in vitro/in vivo* para lograr el patentamiento de un determinado nanotransportador; la segunda tiene la droga a transportar y la capacidad de producir en forma global. Esta interacción se modeliza utilizando

teoría de juegos y la valuación del proyecto conjunto se realiza mediante opciones reales.

### 2.4.3.1 El modelo

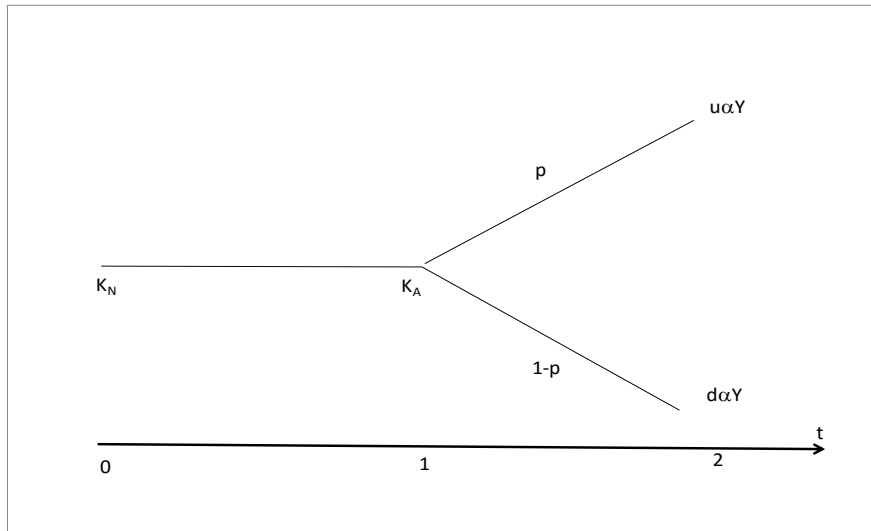
La economía consta de dos compañías, una es una pequeña empresa especializada en desarrollos de nanomedicina pero sin acceso al mercado de consumo de medicamentos. La segunda es una empresa farmacéutica con experiencia en el mercado de medicamentos. Para poder lanzar un nuevo nanotransportador que permita suministrar una droga específicamente en un lugar del organismo humano, se necesitan mutuamente. Se plantea una línea de tiempo de tres momentos: Uno inicial ( $t=0$ ) donde la empresa nano desarrolla el nanotransportador, en  $t=1$  la empresa farmacéutica realiza su inversión y, finalmente, en  $t=2$  el proyecto llega a su fin y se recibe el ingreso logrado.

Al momento inicial las empresas discuten el proyecto conjunto y acuerdan invertir ( $K_N, K_F$ ) respectivamente. Específicamente, al momento inicial, la empresa nano (N) invierte  $K_N$  en desarrollar la nanomolécula y testearla. Para el momento  $t=1$  cuenta con una patente, por lo que la empresa farmacéutica invierte  $K_F$  para comenzar la producción. Esto les permite esperar un ingreso medio  $Y$  al finalizar el proyecto. Asimismo acuerdan que el resultado final se divida entre las empresas, la empresa Nano recibe  $\alpha Y$  y la farmacéutica el resto  $(1-\alpha)Y$ .

Debido a la incertidumbre del Mercado (por ejemplo la posibilidad de que otro par de empresas logren un producto que compita) el ingreso final del proyecto en  $t = 2$  puede ser mayor del esperado ( $u.Y$ ) o debajo ( $d.Y$ ). Para tomar en cuenta esto, se asume que el ingreso final sigue un movimiento browniano, los agentes tienen aversión al riesgo cero y el proyecto tiene una probabilidad de éxito  $p$  (Hull, 2006; Luenberger, 1998).

Para asegurar que la valuación inicial es consistente con los supuestos (y realizando una aproximación de primer orden), los valores de  $u$  y  $d$  son los siguientes:

$$u = 1 + \sigma \sqrt{\frac{1-p}{p}} ; d = 1 - \sigma \sqrt{\frac{p}{1-p}} \quad (2.1)$$



Línea de tiempo y pago a la empresa nano

La estructura básica del problema se resume en anterior. En el momento inicial, la empresa nano calcula el valor presente del proyecto (utilizando un factor de descuento  $\beta$ ) y decide si invertir o no. Si decide investigar y obtener la patente aprobada, la tecnología está lista para la etapa de producción en  $t=1$ . También en el momento inicial la farmacéutica evalúa el proyecto y decide si invertirá  $K_F$  en  $t = 1$  (acordando pagar a la empresa nano una fracción  $\alpha$  del resultado del proyecto en el momento 2). Asimismo, el proyecto está sujeto a incertidumbre, representada por la probabilidad  $p$  (escenario favorable) y una volatilidad  $\sigma$ , lo cual determina dos escenarios en  $t=2$ .

#### ***2.4.3.2 Condiciones para que se realice la inversión conjunta***

Como se ha mencionado anteriormente, cada uno de los agentes evalúa la inversión conjunta desde su propio punto de vista. La empresa nano recibirá una fracción  $\alpha$  del resultado, por lo que se descuenta este valor dos períodos y se lo compara con la inversión inicial requerida al momento inicial. La farmacéutica, por su parte, descuenta su participación final un periodo para comparar con la inversión que se le pide.

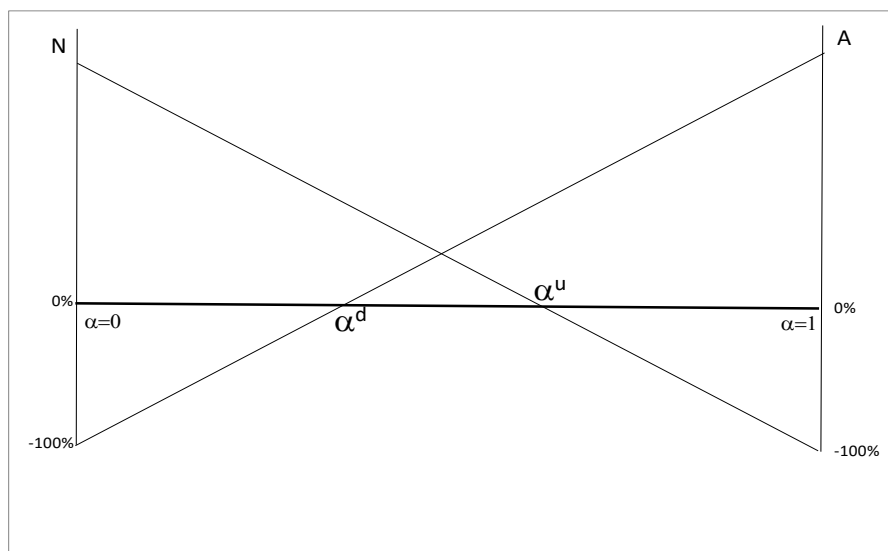


Ahora bien, para participar en el proyecto conjunto ambas empresas deben recibir al final un valor que supere (o iguale) la inversión actualizada. Por lo que las dos condiciones que deben cumplirse para que el proyecto conjunto se realice son:

$$\text{Nano} \quad \beta^2[p u Y\alpha + (1 - p) d Y \alpha] \geq K_N \quad (2.2)$$

$$\text{Farmacéutica} \quad \beta[p u Y(1 - \alpha) + (1 - p) d Y (1 - \alpha)] \geq K_F \quad (2.3)$$

De estas ecuaciones surge en forma inmediata que  $\alpha$  impacta en las ganancias de ambas empresas. Si  $\alpha = 1$ , la empresa nano recibe la ganancia máxima, mientras que la farmacéutica pierde todo el capital invertido. Por el contrario, si  $\alpha = 0$ , la farmacéutica es quien recibe la ganancia máxima.



Valor presente de la ganancia como función de  $\alpha$

El gráfico muestra que, mientras el proyecto conjunto sea rentable, la empresa nano participará si la participación es mayor que un determinado valor ( $\alpha \geq \alpha^d$ ) y el productor lo hará si  $\alpha \leq \alpha^u$ ; por lo que la inversión será exitosa si  $\alpha \in [\alpha^d, \alpha^u]$ . Asumiendo que la farmacéutica tiene mayor poder de negociación, podría imponer un  $\alpha = \alpha^d$  y maximizar su rentabilidad. Ahora bien, si presiona en exceso forzando un  $\alpha < \alpha^d$ , la inversión no tendrá lugar (la empresa nano se retira al no satisfacer su restricción).

## Conclusión del capítulo

En este capítulo se ha examinado cómo la práctica, en su proceso de constitución interdisciplinar y ecléctico, da lugar a un nuevo mercado nano que se encuentra en pleno proceso de formación y diseño. En lugar de utilizar como punto de partida la idea abstracta de mercado se ha propuesto describir y analizar las transacciones concretas.

En particular, se ha descrito el proceso de objetivación, como bien transable, de los nanotransportadores (y sus respectivas patentes). El presente trabajo argumenta que el mercado nano se presenta como una red de relaciones complejas donde hay un doble movimiento de agrupamiento (construcción de objetos transables) y separación (la venta a usuarios). Se ha conceptualizado a los agentes del mercado como colectivos híbridos de cálculo, lo cual permite fundamentar, desde lo micro, las asimetrías de poder a la hora de fijar precios. Esto es decisivo para entender en las relaciones de poder entre pequeñas empresas nano innovadoras y las farmacéuticas. Asimismo, se analizó la dinámica industrial de la nanotecnología y, en particular, a la de la nanomedicina. Se describió la problemática legal de las patentes y la necesidad de una política gubernamental que contemple la necesidad de innovación mediante la emisión de patentes, pero que también cuide la competencia, no permitiendo monopolios en el sector.

Se remarca la importancia de entender las transacciones entre agentes (humanos y artefactos) híbridos colectivos de cálculo que interactúan en un proceso de constante co-constitución y como la capacidad de cálculo de cada uno de ellos se refleja en poder económico de mercado. Asimismo, se ha conceptualizado el mercado de nanotransportadores como una configuración algorítmica y se analiza cómo las diferencias en capacidad de cálculo establecen asimetrías en el mercado.

Se concluye que la naturaleza distribuida de las agencias de cálculo (humanos y artefactos) muestra más explícitamente la importancia de la agencia no-humana para comprender el proceso de constitución del mercado de nanotransportadores y, en particular, cómo las grandes empresas farmacéuticas concentran poder en base a su capacidad de calcular y de fijar precios. A continuación, se ha analizado el

punto de vista del inversor, sus decisiones y la valuación de proyectos innovadores en el sector.

Ahora bien, estos mercados vinculados con la nanomedicina, con su propia dinámica, generan externalidades que impactan en la sociedad, impulsando espacios políticos de discusión e interacción. Si bien el enfoque tecnocrático económico tradicional propone dar cuenta de estas externalidades incluyéndolas en los modelos como variables, estos desbordes exceden lo técnico e impulsan una discusión claramente política de los riesgos nanotecnológicos. Se presenta, entonces, una confrontación entre el enfoque tecnocrático abstracto que intenta cuantificar externalidades sociales por un lado, versus un enfoque político que propone un espacio de discusión por el otro. El siguiente capítulo analizará los riesgos co-constituidos con la dinámica innovadora nanotecnológica.

### 3 Risk as a Co-Constituted Process

#### Introduction

In contemporary culture, risks are present in a wide range of practices and experiences (van Loon, 2000). The concept of *risk* is a topic widely debated among experts, politicians, philosophers, media professionals and the public in general. The rapid expansion of scientific, technological and medical knowledge advances has created a set of experts in the calculation, assessment and management of risk, additionally, public awareness of risk has also been influenced by the expansion of the media and the growth of new information and communication technologies. (Mythen, 2004). In social sciences, it is possible to identify four paradigms attempting to unpack *risk* in contemporary societies (Mythen, 2004). Firstly, inspired by the work of Mary Douglas (1966), there is an anthropological approach where differences in risk perception are explained by patterns of social solidarity, different worldviews and cultural values. Secondly, in the field of social psychology, psychometric paradigm has focused on individual cognition of risk (Slovic, 1987). Thirdly, the government's approach to risk has been addressed by Michael Foucault (Gordon *et al.*, 1991).

Fourthly, the *risk society* perspective led by Ulrich Beck (1992) has illuminated the pervasive effects of risk in everyday life. He argues that the process of modernization has created a unique collection of humanly produced risks (Beck, 1999). This perspective has been very influential as a stimulus for academic, environmental and political dialogue (van Loon, 2000). The prospect of the risk society can discuss the constitution of risk and its effects on various social fields, enabling an analysis that extends the actuarial, financial or engineering risk protocol. From the hegemonic thought point of view, social production of wealth leads inevitably to risks, naturalizing it as part of social evolution. Modern culture proposes that been cautious is synonymous of failure, successful people have to take new risks to be innovative (Sennett, 1998). Consequently, many entrepreneurs were coming to the risky nano market aiming for future benefits. Clearly, in order to protect society from this new risk and from this risky investors, it is crucial the

intervention of the States. Besides, in a global financial system this race is beyond the control of each Nation-States, hence, it is necessary a multilateral agreement.<sup>107</sup>

To analyses how this nanotechnological dynamics co-constitutes new risks, this chapter is divided in five sections. Firstly, several approaches to the problematic of risk are presented (Adam and van Loon, 2000; Mythen, 2004), with a particular emphasis on the society of risk approach (Beck, 1992). It conceptualizes nano risk as co-constituted both during the technoscientific practice as well as in the dynamic of the associated market. Secondly, it is also argued that the nano industrial dynamics have implications for its governance. From the point of view of the industry, uncertainty is taken as a constitutive part of the company's decision process. In this chapter the traditional methodologies used for the valuation of investment projects are analysed, emphasising that they do not account for the complex dynamics of nanotechnology. To surpass this limitations, this work proposes the valuation methodology known as *real options*, which lets consider the uncertainty, flexibility, and irreversibility that exist in innovative nano projects (Trigeorgis, 1993; Kumaraswamy, 1996; Schwartz, 2013).

Thirdly, the role of insurance companies - bounding, measuring, and pricing risks - and the risk evaluation process are examined, focusing on how experts calculate price without contemplating the impacts on society and without a clear understanding of the properties at nanoscale. It is important to create new standards to account for toxicity and for the effects of nano size. Fourthly, in the light of what was said on the previous sections, it is fundamental to take into account the voices of the different actors (non technoscientists) with respect to the use of nanotechnology in general and its medical applications on particular. Finally, last section it focuses on the role of public policies. In so doing, it presents two mathematical models. The first model allows for the quantitative evaluation of whether it is optimal to start a given project in accordance to the precautionary principle. The second quantifies the social benefits of two different kind of State incentives. This tools helps governments' decision making process, quantifying costs and benefits.

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<sup>107</sup> While there is a proliferation of agreements, it has not been achieved, so far, a global agreement.

### 3.1 Co-constitution of the *Risk Society*

*Risk society* becomes visible when its threats are not covered by any type of insurance (Beck, 1992). While danger always existed, risks that arise from human's decisions may exceed the insurability of the industry. In his book, Beck compares the current risk society with earlier stages of history (Sennett, 1998).

Firstly, these risks are generated by humans: through government decisions, through the industry, through society as a whole, or through the choice of a lifestyle that carries certain risks. Secondly, these risk are global: they are not limited by traditional boundaries of industrial societies, nor are they limited to a certain place, nor to certain groups and confronts political institutions (Beck, 1999). Thirdly, these new risks present a challenge to the actuarial approach. In many cases, the probability of a catastrophic event tends to zero, but its potential loss tends to infinity, which collapses the traditional normative of financial institutions. Finally, the political institutions of modern societies can't cope with these new types of emerging risks, because the responsibility is diluted<sup>108</sup>.

Taken individually, each risk has a rational concrete cause, so it can be predicted, explained and managed. However, the society of risk presents itself as a cumulative, complex phenomenon that does not admit the individual management of each risk. This leaves us with three possible paths of action: denial, apathy or transformation (van Loon, 2002). The first two are inscribed in our modern western culture, on the contrary, *transformation* requires a new way of being that becomes a force for social change. Ulrich Beck (1992; , 2000) and Anthony Giddens (1991; , 2003) call for social and political reform towards greater reflexivity to analyse the complex phenomenon of risk and society co-constitution.

Policymakers gives the control of technological risks to the technicians, setting aside all participative practice, and building a discourse that narratively transforms

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<sup>108</sup> The described situation is known as *organized irresponsibility* (Beck, 1995 p 2). The risks of our society have a logic of inadequate distribution where the poorest are more exposed to risks, while the richest are able to avoid the dangers. A clear example is the recent European crisis of 2008, where those who suffer the consequences of excessive risk in the past are the workers and the poor.

potential risks into business *opportunities*<sup>109</sup> (van Loon, 2002). In a certain way, this technocracy unwillingly produces a reaction of citizens groups that propose a globalization *from the bottom*, and that claims for an open and public debate (Beck, 2000 p.37). This risk society offers us a game where the winner takes all the wealth, probably without risk, and leaves the emerging risks to the rest of society.

### 3.1.1 A Reflexive and Democratic Process<sup>110</sup>

The political awareness may be radically altered by the experience of a catastrophe; this gives us the opportunity to think about the transformation of the *status quo*. Ulrich Beck (2006) presents catastrophes as moments of *involuntary enlightenment*, that inspires survivors and forces them to reorder their priorities and beliefs. The challenge is to re-signify such catastrophic experiences to mobilize change, creating a sense of crisis to avoid further collapses.

Clearly, the Fukuyima disaster leads us to rethink all the risks involved in innovative technologies. Although, what comes first is a collective panic against any use of technology and an overestimation of the precautionary principle, after a while it is important to make a thoughtful process that allows to propose and articulate protocols and regulations on the use of technology. Instead of the urgent reactions to crises that usually politician have, Seyla Benhabib (1986) raises the importance of analysing present contradictions, as they signal the path to a political practice that includes public participation. Political awareness can be radically altered by the experience of the catastrophe itself.

From an interpretative perspective of reality, the crisis is a way to signify disappointments and failures, and reorient actions toward the future (Benhabib,

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<sup>109</sup> A clear example of this is the market for green bonds. It is intended to simplify the complex phenomenon of global climate change through a financial instrument that gives incentives to the third world to emit less carbon to the atmosphere in exchange for money. It tries to solve a global problem that involves all of us as humans, using a financial market that magically regulates incentives of economic agents. This policy prevents urgent reflection and reconsideration and, as a result, ultimately, contributes to the proliferation of new risks.

<sup>110</sup> The ideas of this section were born from Sarah Ambler's presentation (Aston University) on January 16th, 2009 in the event *Future Ethics Workshop, A World Without Us? Imagining the end of the human*. The author presented a paper entitled "Bringing hope 'to crisis': Crisis thinking, ethical action and social change".

1986). The narrative of the crisis doesn't describe a given reality, on the contrary, it describes moments of reflection, assessment and decision on the social conditions, and it should communicate the possibility of transformation, creating a space of opportunity and hope.

The transforming function of a crisis has its greatest expression in certain traditions of traditional Marxist thought, where the revolution is set as the system that shows the contradictions of capitalism through a personal crisis. However, the reaction to the dominant ideology has many points in common with the populist policies that have proven so effective in the consolidation of conservative systems. For this reason, it is essential to contemplate demands, sentiments, and dissatisfactions generated by society<sup>111</sup> (Benhabib, 1986).

When evaluating these hypotheses, issues of equality must be considered. These ethical considerations urge policymakers to incorporate social welfare in their decisions and to achieve a smooth distribution of risk over time and space. León Olivé (2004) contrasts the expert risk assessment with the public perception of it. The technical model of risk assessment must be reconciled with democratic values, as the only way to identify and manage risks (Fiorino, 1990). In other words, if western democracy is understood as a partnership project based on common values, it is incompatible with a technocratic approach to risk management (Olive, 2004).

Technological innovations are presented as a secure, with high expectations of future profits and with diffuse risks (and far away on the time axis). It does not seem evident the possibility of human suffering and global injustice that these new financial relations crystallize. Moreover, experts have imposed a premature normativism in recent decades globally, implementing improvised policies that consolidate differences, while failing to achieve the objectives they claim. These global policies consolidate the hegemony of certain power groups<sup>112</sup>. The public

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<sup>5</sup> On the other side, and in relation to global risks, in recent years, they have become important in the study of risks, ethical and democratic considerations. Kristin Shrader-Frechette (1991) and Leon Olive (2004) argue that the specialist should reflect to discover the social impact of your practice and courses of action consistent. It is essential to consider popular opinion when managing risks. Moreover, if a scientific method of calculation indicates that some hypotheses may be valid, it must be put into question the impacts that will arise from their acceptance.

<sup>112</sup> Against this reality, Benhabib (2002) proposes a deliberative democratic model that internalizes cultural controversy in institutions and other social organizations. While certain global rules are necessary, certain types of legal pluralism and citizen participation can occur in different regions. The author argues that



sphere is presented as the intertwining of various forms of association that interact, leading to an anonymous public conversation. This issue is taken up in the next chapter when it is proposed to account for this complexity with a sustainable and democratic governance.

In summary, this work proposes that, instead of having a technocrat regulation designed by politicians, it is imperative to have an agreement of values that defines a new global ethics regarding the use of technologies. The society needs new rules for global economic and financial relations that does not harm certain social groups. This initiative implies; globalization of the political power, enforcing international cooperation and improving the international law. It is important that intergovernmental organizations, non-governmental organizations, democratic States, businesses and civil society have to be involved in the process. The active participation of citizens becomes a central point, since they vote for politicians, they are the consumers and they act through nongovernmental organizations. This new symbiosis between politics, business and civil society will allow a new governance that contributes to build a fair, sustainable and participatory society, achieving a symbiotic relationship between the rulers, civil society and business.

### **3.1.2 *De facto* Nanogovernance**

The dynamics of the nanotechnoscientific practice and its market constitutes new risks. Given this, State's policies are crucial to protect society and to promote a sustainable market. For example, in the US, the government started a program called *Converging Technologies for Improving Human Performance* (CTIHP), commonly referred as Nano-Bio-Info-Cogno (NBIC) (Roco, 2007). The nanoworld is modified to benefit governments, markets, societies, nations and human beings, which must adapt to the changing world. In the American literature on technological regulation, one of the most influential work is *Responsive Regulation* (Ayres and Braithwaite, 1992). The authors have a flexible approach and propose a pyramid of regulation which has *self-regulation* its base (*soft law*).

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democratic equality and deliberative practices are necessary for new global institutional designs. Although Benhabib (2002) clearly states that the legitimacy of the law doesn't arise from a discursive process, it requires citizen participation.

When climbing a greater state intervention appears to reach the top, where it is strictly regulated (*hard law*) (Bowman and Hodge, 2006).

Unlike the American program, the European program *Converging Technologies for the European Knowledge society* (CTEKS) emphasises the creation of a knowledge society, guided by the precautionary principle<sup>113</sup> (Echeverría, 2005; Klinke *et al.*, 2006). An interesting case to analyse is that of the UK, where the institutions emerged from the Report of the *Royal Society & The Royal Academy of Engineering* (2004) and its subsequent developments (Rogers-Hayden and Pidgeon, 2008) are a clear example of *hybrid regulation* (Dorbeck-Jung, 2007).

A new perspective regarding these issues is known as *sustainable governance*<sup>114</sup>. This concept extends the perspective of economic equilibrium, incorporating social and environmental concerns and it will be discussed in detail in the next chapter (Kemp *et al.*, 2005). This form of risk management requires collaboration between technoscientists, market players, governments and general public in the process of innovation and in its diffusion (Renn and Roco, 2006).

The question now is to understand these alternatives in the specific context of nanotechnology, a technique of general purposes that impact other industries; so it is necessary to analyse the categories of innovation proposed by Abernathy and Utterback (1978) and to differentiate between the product and the process, considering the presence or absence of nanoparticles in the final products (Laredo, 2009). Consequently, it is essential to distinguish between *embedded nano* (where there are no political implications and they propose a functional approach to regulation), from *enabled nano* (where previous asbestos experience force to consider the full life cycle) (Abernathy and Clark, 1985). Moreover, regarding the processes, it proposes the implementation of workers' safety standards and a protocol for safe intermediate goods circulation<sup>115</sup>.

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<sup>113</sup> Some authors propose a European *prudential regulation*, extending the scope beyond the purely economic (Dupuy, 2007; Dupuy and Greenbaum, 2004).

<sup>114</sup> In Europe, a group of social researchers from the Institute for Environmental Decisions have applied to understand the case of nanotechnology in Switzerland (Wiek *et al.*, 2007).

<sup>115</sup> It also intends to explore the lessons of sociology of innovation and, in particular, to rethink the role of public authorities in shaping selection mechanisms (Delemarle *et al.*, 2009), considering its global nature and its need for the learning processes.

While some studies analyse the impact of industrial activity in its governance (Meyer *et al.*, 2009), only few authors dispute the impact of industrial dynamics in the *direction* of technological change (Robinson, 2009). In particular, Rafols *et al* (2011) argues that the specific features of industrial dynamics of nanomaterials have strong implications for their governance, because they are involved in shaping technology. The key issue in relation to industrial dynamics is that nanomaterials are not generally consumer goods; they are intermediate goods that are being used by other industries. Moreover, in many cases they allow innovation in traditional mass-production manufacturing processes, so its regulation is a complex challenge.

Rafols *et al* (2011) notes the importance of three issues in the literature on nanotechnology. Firstly, nanotechnology is not a single concept, on the contrary it is a set of juxtaposed different technologies, summarizing the term is of no help for its efficient regulation (Rip, 2010; Doubleday, 2007; RCEP, 2008; Rip and Van Amerom, 2009). Secondly, there is uncertainty regarding the toxicity of nanomaterials, so these authors recommend the use of the *precautionary principle* (RCEP, 2008; Hansen *et al.*, 2008). Thirdly, the discussion of the risks and benefits should focus on the innovation *control* process. In other words, the proposal is to replace the traditional risk management approach with an efficient governance of innovations<sup>116</sup> (Felt and Wynne, 2007).

Today the market has a *de facto* governance<sup>117</sup>, that it is created by diverse actors with conflicting interests (Rip, 2010). In this market, the development of nanomaterials depends on interactions between multiple agents, and it is not controllable from a *top-down* regulation; on the contrary, Rafols *et al* (2011) proposes a *bottom-up* approach, accounting for interactions in the distributed system (Rip, 2010). They also argue that attempts to regulate must be interventions in the *de facto* governance to be effective.

Even though benefits of nanotechnology would be effective in gene therapies, creating new surgical instruments and more accurate diagnoses. The lack of a

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<sup>116</sup> A governance of innovation seeks to influence technology decisions towards socially agreed targets.

<sup>117</sup> The proposal stresses that there is a governance even in the absence of explicit regulation because existing social networks facilitate or limit future technological developments.

complete knowledge precludes proper risk measurement<sup>118</sup>. Potential nanotechnology risks include the possibility of using it for terrorist purposes and some negative externalities on human health.

### **3.1.3 Risk Co-constitution Process: From the Laboratory to the Market**

One of the first areas investigated by toxicologists is the damage caused by the inhalation of nanoparticles. In the report of the *Royal Society & The Royal Academy of Engineering* of the United Kingdom (2004), the authors argue that the greatest danger will come from the nanoparticles embedded in objects of mass consumption, due to the possibility of detaching and being inhaled<sup>119</sup>. These particles can cause damage and produce breathing difficulties in the long run. Moreover, nanotubes are highly resistant, so antibodies may die trying to dissolve them, increasing the tissue deposited in the lungs. Muller *et al* (2005) conducted a study which concluded that carbon nanotubes cause inflammation in the lung similar to the previous *asbestos* problem. Therefore, if these nanoparticles can cause similar response to asbestos inhalation in the short term, it is possible that they induce the same effects in the long term.

A recent study introduced copper nanoparticles in mice and it concluded that the animals under study developed serious kidney and liver injury (Chen *et al.*, 2006)<sup>120</sup>. These nanoparticles are being used in a number of products that come into direct contact with the skin (clothing, cosmetics and sunscreen) and once absorbed through the skin (and come in contact with blood vessels), it has the same risk of intake (Monteiro-Riviere and Inman, 2006).

The British government mentioned the unavailability of data on the potential negative impacts on the environment (The Royal Society & The Royal Academy of Engineering, 2004). Some nanoparticles, such as copper or silver, have proven to be harmful to aquatic life. They could be quickly absorbed by plants and soil or

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<sup>118</sup> Within the workshop *Mapping out Nano Risks*, held in Brussels on 1 and 2 March 2004, Goran Hermerén (2004) raised the discussion about the importance of an ethical approach to assessing the development of these new technologies and their consequences.

<sup>119</sup> There are strong similarities between inhalation of asbestos fibers in the past and possible inhalation of carbon nanotubes that appear today in various consumer goods.

<sup>120</sup> It is noteworthy that using copper microparticles the same effect was found, showing how different toxicological nano scale level.

be transported over long distances through the air or be suspended in the water. These studies warn us against the possible risks involved. In the UK it is allowed the use of nanoparticles in the environmental, but the Government encourages the industry to adopt a responsible approach. In the US, the Environmental Protection Agency (EPA ) recently published a White Book that set out its research needs (US Environmental Protection Agency, 2007).

The constitution process of the nanotechnology industrial dynamics raises specific and general issues. On the one hand, the specific ones arise in each research process in its transition from the laboratory to industry. On the other hand, the general issues are those related with how these research projects are inserted on the scientific community and the society, and how they are forwarded, controlled, and governed.

For example, particles of the same chemical composition have different properties according to their size. However, regulations on toxicity do not take this into account, it only accounts for its organic composition. This means that a substance can pass toxicity controls but, due to its nano size, be effectively toxic<sup>121</sup>. To take these effects into the discussion, Schummer (2007) suggests to define new standards and to do more research on the harmful effects associated with the size of the particles. Moreover, according to Schumer (2007), the central question revolves around the fact that nanotechnologies can cause damage to humans without being able to identify who was responsible. This requires a regulatory framework that specifies the responsibility of the manufacturers (Schummer, 2007)<sup>122</sup>.

Moreover, military applications also raise questions, since it is now possible to create a new range of biological and chemical weapons. But beyond this collective concern, many military nanotechnology projects of this kind are secret and therefore fall outside the scope of society. This situation imposes a barrier to the

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<sup>121</sup> Furthermore, the fact that the properties change depending on the size makes the effect that certain applications are unpredictable for science that, at present, only takes into account the chemical composition. This goes hand by hand with the rapid dissemination of research-based manufacturing *nano* on an industrial scale because it is in this area where massively produce new materials with these new unpredictable properties.

<sup>122</sup> Indeed, the tools manufactured at the nanoscale have the ability to produce effects on humans without the consent or knowledge of the individual involved.

development of a democratic governance. Additionally, several ethical issues arise in the field of biomedicine. On the one hand, the publicity (sometimes similar to science fiction movies) regarding the possibility of curing terminal diseases with gene therapies gives false illusions to patients. However, there is currently no scientific proof about its efficiency, so this propaganda can be detrimental to the evolution of these patients. On the other hand, professionals and medical institutions authority have been challenged by the possibility of self-healing nano-devices. In addition, there is a risk of diverting resources now applied to therapies needed by patients to the *improvement of the human race* (Schummer, 2007).

A further ethical issue is the progress of nanotechnology in developing countries, contributing to narrowing the gap between rich and poor. In this sense, there are many *property rights* barriers preventing open access to scientific information. It is a problem of regulation, since the rules of patenting are lax and unclear; implying that access to scientific progress is increasingly restricted for those outside the industrialised world.

Hermerén (2004) proposes a problem analysis model that states that, before taking a decision, all relevant information available on the issue should be detailed, as well as the current regulatory starting points. As for the relevant information, it should account for the state of the art at the time of the various feasible alternatives and their consequences, and preferences of the different groups involved or affected by each course of action available. For his part, a regulatory point of departure should establish explicit and consistently ethical and cultural characteristics of the population involved, as well as their goals and values. For analysis, Hermerén used as a regulatory framework the principles of human dignity and integrity, autonomy, the duty not to harm and justice.

According to the author, this model applies regardless the ethical approach (consequentialist or deontological)<sup>123</sup>. He also identifies the existence relevant problems that are relevant from any starting ethical point: the risk-benefit

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<sup>123</sup> The author identifies in its contribution two traditions. On the one hand, the consequentialist theory that establishes a correspondence between the moral value of a share and the value of the consequences of that action. Therefore, to decide on a certain action is necessary to assess their potential results. On the other hand, is the ethical tradition which states that the moral value of an action depends on whether such action is compatible with certain duties and rights based on religion, social contracts or natural rights.

evaluation, information and consent, privacy and integrity, costs and research priorities, fairness and justice and public confidence and transparency. As the risk-benefit evaluations regards, Hermerén, identifies some difficulties: determining which actor is the most suitable to measure risks and benefits, which are its costs, how probable are they, and who is benefitted and who handicapped. Taking into account that evaluations are subjective and depend on who performs it, a correct risk and benefit evaluation would require a continuous flow of dialogue between the parts.

### 3.2 The Dynamics of the Price Risk

While corporate strategy is essential to assess the financial suitability of an investment, traditional methods do not take it into account. However, traditional methodologies are widely used by practitioners and they play a central role in corporate finance. They usually have three stages: 1) estimation of future cash flows generated by the project; 2) find an appropriate discount rate for each cash flow ; 3) estimate the initial cost of investment (Brealey and Myers, 2003)<sup>124</sup>.

From the methodological point of view, investment projects involving research and development represent a challenge for its financial valuation since they include multiple sources of uncertainty. It is necessary to have a valuation model that take into account the learning process involved<sup>125</sup>, the uncertainty of the total cost and the uncertain time needed to develop the product (Pindyck, 1993). It is a *learning by investing* approach to innovations.

Moreover, each stage of development is subject to exogenous adverse factors, such as technical, economic or political catastrophes. In other words, the expected future benefit is actual only after successfully completing the R+D process. These possibility of success, clearly, relates to the uncertainty of the project during its development, as both, commodity prices and the expected final price of

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<sup>124</sup> These methods are easy to apply, but have the disadvantage of not reflecting the complexity of social and economic phenomena involved in many investment projects.

<sup>125</sup> Initially, they were used analytical models used to value these projects come from financial derivatives, with the Black and Scholes formula paradigmatic example (Hull, 2009). However, regardless of the enormous importance of these analytical formulas for valuing real opportunities, lack of flexibility in the description of a wide range of investment decisions in complex contexts led to the development of numerical models of valuation.

nanoproduct, fluctuate with the market. Moreover, each stage of product development has a significant probability of failure, which is associated with techno-scientific problems. Summing up, uncertainty prevents investors from knowing the duration and the possibility of success with certainty.

This section introduces the concept of *real options* and analyse the impact of uncertainty in the definition of the optimal investment. At that point, this section identifies irreversibility as a key issue in many investments (especially in technological innovations). Finally, the basic model of Dixit and Pindyck for investment valuation under uncertainty are presented.

### 3.2.1 Real Options

Traditional valuation techniques are easy to use and allows, in simple and certainty contexts, make efficient investment decisions. However, if the investment decision is strategic or takes place in an uncertain environment, or their costs are irreversible, these techniques are not appropriated, due to their limitations. In particular, one of the traditional techniques utilised by practitioners is the net present value methodology<sup>126</sup> (NPV). This valuation methodology ignores the flexibility of the investment and undervalue the investment (Brealey *et al.*, 2009). Another method is the criterion of the internal rate of return<sup>127</sup> (IRR), asking for choosing the project with higher IRR. The problem is that could exist multiple IRRs for the same project, so election process is confusing (Brealey *et al.*, 2009). While the aforementioned limitations do not invalidate the use of traditional methodologies for analysing simple projects, it is necessary to note that in complex and uncertain situations, they become invalid.

Overcoming the limitations of traditional methodologies, *Real options* allow an assessment of the investment options in all markets, either with complete or incomplete information. This method recognizes market flexibility and learning dynamics. Many studies suggest the integration of real options with the NPV. Has

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<sup>126</sup> This tool is also known as the rate of return of discounted cash flow (DCF). It is obtained as the discount rate that makes the NPV equal to zero. The criterion of this tool is to accept an investment project when the opportunity cost of capital is lower than the IRR (Brealey *et al.*, 2009).



been Trigeorgis (1993) which has quantified this approach, saying that the NPV of investment in assets equals the sum of its traditional NPV and its real options. Moreover, often the adoption of real options in R&D projects encourages long term investment (Kumaraswamy, 1996; Brealey *et al.*, 2009).

In his original work, Black and Scholes (1973) provided a framework for the valuation of a common case in finance, *European options*. After a few years, Myers (1977) proposed to analyse investments in real economy assets, using the concept of financial *option*. A real option is defined as the right (with no obligation) to conduct any business decision (usually an option to make an equity investment in a project) (Brealey and Myers, 2003).

Dixit and Pindyck (1994) argued that the investment decisions have three essential features that requires *real options* for its valuation. Firstly, investments are mostly irreversible (total or partial), and its capital costs are sunk. Secondly, there is uncertainty about the future return on investment; future prices of assets are unpredictable, so future benefit flows are uncertain. Thirdly, investors have the option of waiting for better information about future prices.

The literature on these issues is vast, but several items listed as essential reference in this field. The seminal work of McDonald and Siegel (1986), Pindyck (1991), Trigeorgis (1996) presents the basics of this method, using dynamic programming techniques. On the other hand, in the classical theory of real options, Brennan and Schwartz (1985) and Trigeorgis (1993) referred to the valuation of the investment opportunity as an integrated set of real options<sup>128</sup> (Insley and Wirjanto, 2010).

### **3.2.2 Optimal Investment in Uncertain Contexts**

This subsection focuses on understanding the impact of uncertainty in the optimal investment decision. Faced with a new business project in uncertain contexts, investors need to establish the optimal level of investment that balance current

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<sup>128</sup> In other words, the flexibility of an investment is what generates the value of real options, increasing the valuation of a project. Usually, this added value can be conceptualized as *asset net present value*, which is defined as the sum of net present value and the actual value of the associated option (Brealey and Myers, 2003; Brealey *et al.*, 2009; Brealey *et al.*, 2009).

costs and future returns. To analyse this problem this thesis proposes the *dynamic programming* perspective (Abel and Eberly, 1994). There are two main channels through which uncertainty impacts on the dynamics of investment and capital accumulation. The first reflects the nonlinearity of the operational benefits over the variables that characterize the uncertainty, the Hartman (1972) Abel (1983) and Knight (1991) effect, known in the literature as *HAC*. The second reflects frictions in capital adjustment, summarized in different forms of capital adjustment costs (Bulan *et al.*, 2009).

Following the literature mentioned, the problem of maximizing the performance of a project is formalized by controlling investment. To analyse this, an economy is postulated where there is a risk-neutral business that must decide the level of investment  $I$  optimum, so as to maximize the current expected value of future profitability  $\pi$  (minus its cost), subject to a given capital dynamic ( $K$ ) and changes in an exogenous stochastic variable  $Z$ . Using the concepts of dynamic programming we can express the problem as follows (Dixit and Pindyck, 1994):

$$F(K(t), Z(t)) = \max_t (\pi(K(t), Z(t)) - C(K(t), I(t)) + e^{-\rho dt} E_t(F(K(t+dt), Z(t+dt)))) \quad (3.1)$$

*s.a.*

$$dZ(t) = f(Z, \mu, \sigma)$$

$$dK(t) = g(K, I, \delta)$$

where  $\rho$  is the discount rate and  $\delta$  the depreciation rate of capital (Wu, 2009).

The cost function presented depends on the level of capital and investment  $C(K(t), I(t))$ . It includes both, costs of direct purchase of capital goods and costs associated with capital adjustment. These costs are a convenient way to model the friction, delaying the response to updated information about profitability (Caballero, 1991). Moreover, convexity of the cost function requires that the second derivative respect to the investment to be positive:

$$\frac{\partial^2 C(K(t), I(t))}{\partial I^2} > 0$$

While there is agreement in the literature regarding this equation, literature is divided about this cost function shape. While one group of authors (HAC), assumes that the first derivative respect to capital is zero. Another group, belonging to the macroeconomic studies on growth, assumes that the cost function is linearly homogeneous respect to investment and capital, for example Lucas y Prescott (1971) and Abel (2003).

If the cost function  $C(K(t), I(t))$  is convex and profit  $\pi(K(t), Z(t))$  is linear, the proposed objective function is concave . This ensures the existence and uniqueness of the solution to the problem. For the profit function  $\pi(K(t), Z(t))$  to be lineal it is necessary to assume perfect competition in both factors and homogeneous technology and lineal, being formally expressed by (Wu , 2009):

$$\begin{aligned}\pi(K(t), Z(t)) &= \max_{L(t)} [p(t) * K^\beta(t) * L^{1-\beta}(t) - w(t) * L(t)] \\ &= h(Z(t)) K(t)\end{aligned}\tag{3.2}$$

It is important to note that the function  $h(Z(t))$  is convex, since that, for a given capital stock, once resolved the uncertainty, the company can adjust after for compensate labour (Varian, 1992). This problem of substitution effect between capital and labour was highlighted by Hartman (1976). The convexity of operating income compared to the uncertainty, ensures a positive relationship between uncertainty and the expected investment, due to Jensen's inequality (Abel, 1983). This result is generalized by Caballero (1991) and are summarized in the literature as the Hartman-Abel-Caballero effect.

Conversely, if the cost function  $C(K(t), I(t))$  is linear,  $\pi(K(t), Z(t))$  has to be concave respect to K to ensure the existence of one only solution. It was set into a model by Pindyck (1988), and it was assumed each unit of capital can produce one unit per period time; together with the requirement of an inverse price-quantity relationship, ensures the concavity of the operating profit. To assess these effects in next subsections, all model parameters remain constant except the volatility process Z (containing the uncertainty).

### **3.2.2.1 Impact of uncertainty in the short term**

Most studies have focused on the effects of uncertainty in the level of investment by a company, assuming an uncertainty / instant investment relationship,  $\frac{\partial I(t)}{\partial \sigma}$  (Mao and Helliwell, 2012). To avoid analysing an instant effect, several authors, including Dixit and Pindyck (1994) propose to evaluate the average change in investment  $\frac{\partial E[I(t)]}{\partial \sigma}$ .

However, either formulations assume that the  $Z(t)$  process is constant, which is not true since a variation in volatility stochastic process changes the distribution of  $Z(t)$ . To compensate for this effect, empirical studies use the following relationship to contrast it with the data (Dixit and Pindyck, 1994):

$$\frac{\partial I(t)/\partial Z(t)}{\partial \sigma}$$

In other words, this expression analyses how a change of volatility impact on the responsiveness of investment to changes in  $Z(t)$ .

While in contexts of certainty a critical value exists, which separates the investment decision, under uncertainty, on the contrary, there is a range where the optimum means wait. In particular, it is important to note that the volatility of  $Z(t)$  increases the range of inaction where it is optimal to continue analysing the project rather than invest with uncertain consequences. To recognize the impact of uncertainty turns investors more cautious. Moreover, Bloom *et al* (2007) showed that under irreversible investments, increased uncertainty reduces responsiveness of the investment to changes in demand.

### **3.2.2.2 Impact of uncertainty in the long run**

Despite the importance of setting short-term capital, the stock capital is what ultimately causes the production and creates value in the company. Therefore, it is important to analyse the effects of long-term uncertainty on capital. Abel (1984) presented the first work<sup>129</sup> where explicitly the effects of uncertainty on the

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<sup>129</sup> The author uses a process of mean reversion to model  $Z(t)$ .

expected long-term capital (assuming convex costs of adjustment) are studied. The author analysed the following expression:

$$\frac{\partial \lim_{s \rightarrow \infty} E_t(K(s))}{\partial \sigma}$$

For its part, (Abel and Eberly, 1999)<sup>130</sup> separating the capital stock from irreversible investments ( $K^I(s)$ ), the one who is related to reversible projects ( $K^R(s)$ ), modifies the above expression:

$$\frac{\partial \lim_{s \rightarrow \infty} E_t(K^I(s))/E_t(K^R(s))}{\partial \sigma}$$

This subsection clearly showed the effects of uncertainty on the short and long term investments. It is now necessary to analyse how it affects the valuation of these investments (Abel and Eberly, 2012).

### 3.2.3 The Valuation of Irreversible Investments

Past century literature on *investment projects valuation* had highlighted two of its most important features. Firstly, these projects required irreversible investments, with sunk cost. Secondly, investors expected new information about prices, costs and other market conditions before committing resources<sup>131</sup>. Moreover, the irreversible nature of the investment is deeply exposed to different risks. In particular, with respect to the flow of future profits, interest rates involved in the calculation and the final cost of the investment (Pindyck, 1991).

Irreversibility arises because the capital involved in the project cannot be used productively in other investment. For example, a petrochemical plant is specific for use in the relevant industry, and can only be used to produce petrochemical items. If demand for products in this sector falls, the market value of the plant decreases. Clearly, investment in the plant should be seen as a sunk cost at least

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<sup>130</sup> The authors modelled  $Z(t)$  as a *random walk*.

<sup>131</sup> Ben Bernanke (1983) has developed a model where companies have an incentive to delay irreversible investments, so they can wait for further information. However, the author assumes that this information reduces future uncertainty, while this paper focuses on the situations in which new information is coming, but the future is always uncertain.

partially (reversible can be taken as the value of the land, for example). Another source of partial irreversibility is infrastructure investment, for example, office furnishing, computers or automobiles. These items have a low resale price instantly after the purchase.

The concept of irreversibility restates the theoretical foundation of standard neoclassical investment models, while invalidates the net present value rule. Investment makes it particularly sensitive to uncertainty over future product prices and operational costs<sup>132</sup> (Mason and Weeds, 2010).

From a mathematical modelling point of view, an irreversible investment opportunity is similar to a financial call option. The latter gives the holder the right (not the obligation) to buy an asset at the strike price during a specified future time. In the real economy a company with an investment opportunity has the option of spending money (similar to the financial strike price) now or in the future, in return for an asset (for example a project) of any value. As is the case of the financial derivatives market, the choice of the company to invest is valuable in part by the future value of the asset that the company gets through investment remains uncertain. If the asset increases in value, the profitability of the investment rises. On the contrary, if it falls in value, the company does not invest, and it only loses what they paid for the investment opportunity initially. Often these investment opportunities are not purchased, but arise from the management of the company (technological knowledge, reputation, market share)<sup>133</sup>.

A company that put money in an irreversible project, decides to exercise its option to invest. It causes a loss that should be included as part of the cost of the investment. Recent studies have shown that this opportunity cost can be large, and suggest that traditional valuation methodologies ignore it<sup>134</sup>. In addition, this opportunity cost is very sensitive to future uncertainty. Changes in economic conditions affect the perceived risk of future cash flows and have an important impact on investment spending and may be greater than a change in interest rates.

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<sup>132</sup> From the perspective of macroeconomic policy, this means that if the aim is to encourage investment, reduce institutional uncertainty may be much more important than the direct tax incentives.

<sup>133</sup> The importance of real growth options as a source of value for the company is detailed in Myers (1977) and Kester (1984).

<sup>134</sup> See for example, McDonald and Siegel (1986) or Majd and Pindyck (1987).

## *Hysteresis*

If the future value of the project is uncertain and requires an initial sunk cost, an opportunity cost of investing is created, opening a gap between the current value of the project and the direct cost of the investment. This creates an opportunity cost of closing the project (value could increase in the future). A clear example of this is the valuation of mining projects in which there are sunk costs (Brennan and Schwartz, 1985). The mine is subject to landslides and floods when it is not in use, so a temporary closure requires incurring in sunk costs to avoid damages and to reopen, also a considerable expenditure could demand. Sunk costs of opening and closing a mine can explain the observed hysteresis. In other words, when entrepreneurs face low prices, they decide to continue to put unprofitable deposits knowing that operation will open again in the future. Dixit (1989) formalized it: if there are opportunity costs to enter to investment, it increases the critical price at it is optimal. Moreover, companies that had entered into an industry when the price was very high, tend to stay there for a long time, even if prices drop below variable cost (Park, 2012).

### ***3.2.3.1 Sequence of investments***

Many investment projects require several stages before a product is ready for the market. For example, investment in a pharmaceutical drug begins with research in the laboratory, aiming to obtain a new compound to be tested. Numerous tests are performed until the final approval of the government agency responsible for regulating drugs. Only after that approval, the production plant is prepared and, when final product be ready, it will sell to users. The whole project may last up to ten years.

These sequential projects could also result in abandonment in the halfway, if the value of the final product decreases or increases the expected investment. Therefore, these investments can be seen as compound options; each stage completed gives the company an option to complete the next step. Majd and Pindyck (1987) propose a model in which a company invests continuously to complete the project. The authors propose that investment can be stopped and

restarted at no cost, imposing a maximum rate at which money can be incorporated into the project. High volatility increases the opportunity cost of waiting and also reduces the expected rate of growth of the project value for investment, so the expected return is reduced to complete. However, sequential investment often occurs in discrete steps, so to find the optimal investment rule, investor must perform retrospective induction to make an optimal decision (Hachicha *et al.*, 2011).

### *Learning*

As discussed so far in this thesis, futures prices are always uncertain. However, in some sequential investments, early stages provide information relevant for later ones. For example, investments in research and development determine the efficacy and side effects of the drug and therefore its value.

In particular, Roberts and Weitzman (1981) developed a model that considers sequential investment while learning, information in each stage reduces future uncertainty. The fundamental assumption of the model is that prices and costs do not evolve stochastically; *you learn while you invest*. The expenditure made in the early stages can gather information, adding value, increasing the information. Although net present value of a project is negative, it may be wise to invest in the early stages to lower uncertainty and achieve, in the future, a profitable project. Using this methodology, Weitzman, Newey, and Rabin (1981) evaluated whether to build pilot plant for the production of synthetic fuel plants, concluding that learning about these costs could justify initial investments<sup>135</sup> (Geng *et al.*, 2009).

### *Incremental investments*

So far, we have examined the decisions to invest in new projects that require a certain amount of investment to carry forward. However, much of the economic literature studies the incremental investment. That is, companies invest just to equalize the marginal cost of capital to the present value of expected revenues (Merton, 2012).

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<sup>135</sup> There is debate about the role of government in these matters, particularly if subsidies for pilot plants are justified. These issues are discussed in Joskow and Pindyck (1979).



This problem was studied initially by Manne (1961). He showed that, in the context of economies of scale, uncertainty about demand growth implies an increase of the optimal size of investments, incrementing the present value of the expected costs. Many times, the choice of the size of the production plant, carries a choice on which technology to use.

In his work, Pindyck (1988) determines, at the same time, the optimal level of capital and choice regarding the technological flexibility (Baker and Adu-Bonnah, 2008). In particular, he developed a model that takes into account the possibility of incremental investment in a context of irreversible projects. In his model, the company had a stochastic demand, and he showed that, in the context of high demand uncertainty, it is optimal to have smaller capital. However, although a priori, this is not intuitive, the market value of the company rises<sup>136</sup>.

As mentioned in the previous section, Hartman (1972) notes that in the case of a competitive company which combines capital and labour with a linear homogeneous production function, the uncertainty increases investment demand. Moreover, Abel (1983) extended the result of Hartman to a dynamic model in which the price follows a geometric Brownian motion with convex adjustment costs of capital. The author agreed with Hartman to demonstrate that the uncertainty increases the rate of investment in the company. Finally, following this line of argument, Caballero (1989) presented the asymmetric adjustment costs to allow irreversibility and showed that higher price uncertainty increases the rate of investment. However, it assumes constant returns and perfect competition, making the performance of the marginal product of capital, regardless of the current stock.

The papers presented in this section, especially Pindyck (1988) clearly argued that the level of uncertainty is the most important investment determinant. It assigns an undeniable relevance for the design of public policies. Particularly, Ingersoll and Ross (1992) have examined irreversible investment decisions on projects where the interest rate evolves stochastically, but future cash flows are uncertain. With uncertainty about future cash flows, it creates an opportunity cost of investing.

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<sup>136</sup> The idea that uncertainty about future demand may increase the value of a marginal unit of capital is not new. It is required that the marginal revenue product of capital has to be convex in the price.

Unlike the traditional method of present value, investment should be made only when the interest rate is below a critical rate, which is lower than the IRR. Moreover, the difference between these rates increases as the volatility of interest rates increases. Cox, Ingersoll and Ross (2012) suggested that the level of interest rates is less important and its volatility determines aggregate investment. It implies that to stimulate investment, stability and credibility may be more important than tax or interest rates incentives (Pindyck, 1991).

### 3.2.4 A Basic Model of Investment Valuation under Uncertainty

This subsection presents an elemental model for the valuation of investments under uncertainty. Firstly, an example where the use of the net present value (NPV) methodology can lead to a sub optimal investment decision is given. Then, an investment model in certain context is presented and compared with the basic methodology for the valuation of investment in uncertain contexts attributed to Dixit and Pindyck.

#### 3.2.4.1 Example: the value of wait

The next example shows that sometimes the traditional NPV criterion can lead to mistaken decisions. The starting point is a project that contemplates two future scenarios, each one with a 50% probability. The first one produces a net benefit of \$8 per period forever, the second one \$24 in the same conditions. A discount rate of 5% per period is supposed, so the actual value (VA) of the project is:

$$VA = \frac{\$8}{.05} * 0.5 + \frac{\$24}{.05} * 0.5 = \$320$$

If the initial cost is \$200, then the net actual value is:

$$VAN = \frac{\$8}{.05} * 0.5 + \frac{\$24}{.05} * 0.5 - \$200 = \$120 > 0$$

Because NPV is positive, the decision rule indicates that the investment should be made at the initial moment because it is profitable. What would had happened if the investor waits till the second period to decide the investment? Clearly on the

one hand the first payment is lost, on the other hand we are certain about what the future payments are about. Clearly there are two possible outcomes at time 2:

1. Project pay \$8, so NPV is negative:

$$VAN = \frac{\$8}{.05} - \$200 = -\$40 < 0$$

2. Project pay \$24, so NPV is positive:

$$VAN = \frac{\$24}{.05} - \$200 = \$280 > \$120$$

This exercise shows clearly that waiting is valuable, investors could avoid unprofitable investment. This aggregate value for *waiting* is denominated by the literature as the *value of the option* (in obvious reference to the financial options) (Brealey *et al.*, 2009; Brealey *et al.*, 2009).

### 3.2.4.2 Valuation under certainty

This subsection presents a model of valuation under certainty, the value of the completed project is known for sure. The investment decision allows to terminate the project if necessary and to maximise firm's value. Let us consider an investment in a project where termination cost is  $C$  is a constant, the investment rate is  $I$  (with a maximum value,  $I_{MAX}$ ) and the duration of the project is. After the project is completed, the firm receive an asset valued  $V$ . Knowing the duration of the project,  $T = \frac{C}{I_{MAX}}$ , the opportunity to invest  $F(C)$  is given by (He and Pindyck, 1992):

$$F(C) = \max \left[ V e^{-r \frac{C}{I_{MAX}}} - \int_0^{\frac{C}{I_{MAX}}} I_{MAX} e^{-rt} dt ; 0 \right] \quad (3.3)$$

Where  $r$  is the free-risk rate.

Solving the integral and reordering,  $F$  is:

$$F(C) = \max \left\{ \left( V + \frac{I_{MAX}}{r} \right) e^{-r \frac{C}{I_{MAX}}} - \frac{I_{MAX}}{r} ; 0 \right\}$$

The optimal investment rule is: to continue the project if  $F(C) > 0$  ( $C < C^*$ ). To calculate optimal cost  $C^*$ , we must find the value of  $C$  that makes the first component of parenthesis equal to zero:

$$\left(V + \frac{I_{MAX}}{r}\right) e^{-r\frac{C}{I_{MAX}}} - \frac{I_{MAX}}{r} = 0 \Rightarrow \left(\frac{r}{I_{MAX}}V + 1\right) e^{-r\frac{C}{I_{MAX}}} = 1 \Rightarrow e^{-r\frac{C}{I_{MAX}}} = \frac{1}{\left(\frac{r}{I_{MAX}}V + 1\right)}$$

If we apply logarithms to both members, we obtain:

$$\ln[e^{-r\frac{C}{I_{MAX}}}] = \ln\left[\frac{1}{\left(\frac{r}{I_{MAX}}V + 1\right)}\right] \Rightarrow -r\frac{C}{I_{MAX}} = 0 - \ln\left(\frac{r}{I_{MAX}}V + 1\right) \Rightarrow$$

$$\boxed{C^* = \ln\left(\frac{r}{I_{MAX}}V + 1\right)\frac{I}{r}} \quad (3.4)$$

The value of  $C^*$  represents the maximum value that can be rationally accepted as the total true cost of an investment; if it is higher, the project should not be continued.

### 3.2.4.3 The Dixit-Pindycks' methodology

McDonald y Siegel (1986) wrote a model that analysed in which moment it is optimal to invest, receiving at exchange a project whose value is  $V$  (which evolves in accordance with a geometric Brownian motion). The investment opportunity is equivalent to what is known in financial engineering as *perpetual buy option*. The decision to invest is equivalent to decide when to *exercise* this option. Pindyck (1991) presented a simple models for irreversible investment using *dynamic programming*.

The value of an investment project could be modelled as a geometric Brownian motion and mathematically be represented by:

$$dV(t) = \alpha V(t)dt + \sigma V(t)dz \quad (3.5)$$

In this case, the investment decision consists in choosing the optimal moment to invest  $I$  (and start the project). Assuming a discount rate  $\rho$ , the Bellman equation<sup>137</sup> for this problem is:

$$F(V(t)) = \max \left( V(t) - I, e^{-\rho dt} E \left( F(V(t + dt)) \right) \right) \quad (3.6)$$

The proposed methodology transforms it into a *stopping problem*. In fact, there exists a critical value  $V^*$  that separates the region where it is optimal to wait ( $V < V^*$ ) from the zone where stopping is the best choice.

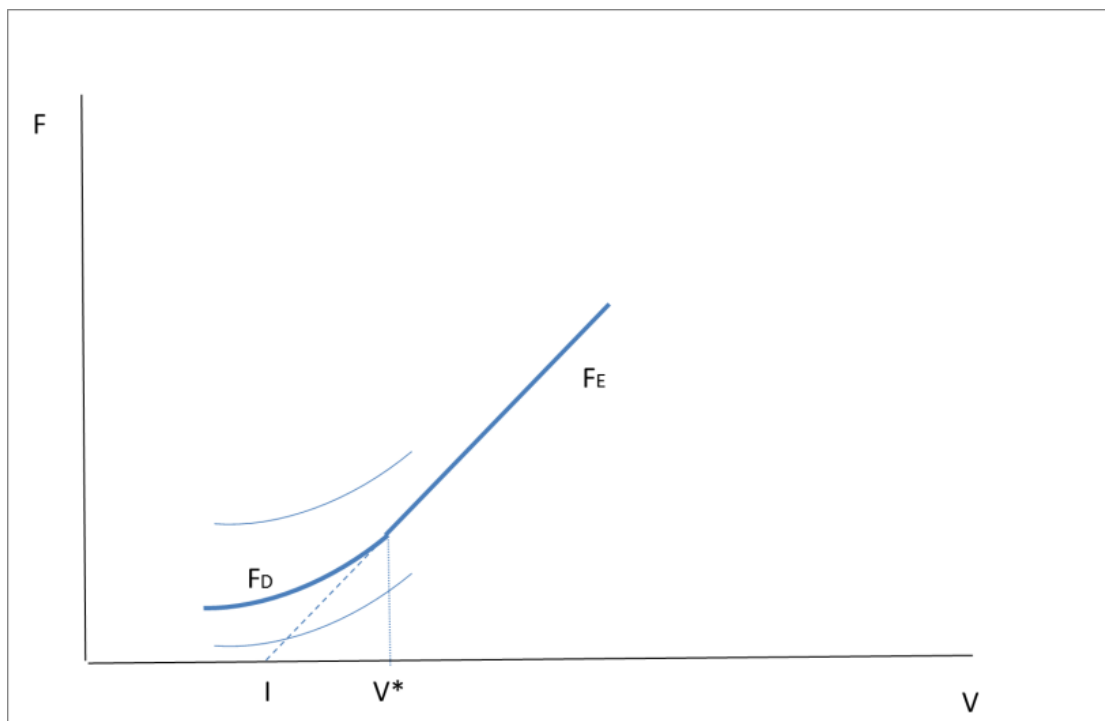
$$\text{If } V < V^* \Rightarrow F_E(V(t)) = e^{-\rho dt} E \left( F_E(V(t + dt)) \right)$$

$$\text{If } V > V^* \Rightarrow F_D(V(t)) = V(t) - I$$

$$\text{If } V = V^* \Rightarrow F_E(V^*) = F_D(V^*) \quad (\text{Continuity of } F)$$

$$\frac{dF_E}{dV}(V^*) = \frac{dF_D}{dV}(V^*) \quad (\text{Continuity of } F \text{ derivative})$$

Also, it requires that  $F_D$  and  $F_E$  compliances with monotonicity condition.



<sup>137</sup> The Bellman equation represents the necessary condition for the existence of an optimum of a dynamic programming problem.

### 3.1. The value of the waiting option of $V$

In the region where it is optimum to wait:

$$F_E(V(t)) = e^{-\rho dt} E \left( F_E(V(t + dt)) \right)$$

Multiplying both members by  $e^{\rho dt}$ :

$$e^{\rho dt} F_E(V(t)) = E \left( F_E(V(t + dt)) \right)$$

Subtracting  $F_E(V(t))$ :

$$(e^{\rho dt} - 1)F_E(V(t)) = E \left( F_E(V(t + dt)) - F_E(V(t)) \right)$$

Dividing by  $\Delta t$ :

$$\frac{(e^{\rho dt} - 1)}{\Delta t} F_E(V(t)) = \frac{E \left( F_E(V(t + dt)) - F_E(V(t)) \right)}{\Delta t}$$

If  $\Delta t \rightarrow 0$

$$\rho F_E(V) = \frac{E(dF_E(V))}{dt}$$

On the other hand, as we know that  $V$  follows a geometric Brownian motion, we can write  $dF_E(V)$  using the *Ito lemma*:

$$dF_E(V) = \left( F'_E(V)\alpha V + \frac{1}{2} F''_E(V)\sigma^2 V^2 \right) dt + F'_E(V)\sigma V dz$$

The expectation is:

$$E(dF_E(V)) = \left( F'_E(V)\alpha V + \frac{1}{2} F''_E(V)\sigma^2 V^2 \right) dt$$

Thus:

$$\rho F_E(V) = \frac{E(dF_E(V))}{dt} = F'_E(V)\alpha V + \frac{1}{2} F''_E(V)\sigma^2 V^2$$

Converting the problem to an ordinary stochastic differential equation subject to a restriction:

$$\frac{1}{2}\sigma^2 V^2 F''_E(V) + \alpha V F'_E(V) - \rho F_E(V) = 0 \quad (3.7)$$

$$\text{s.t. } F_E(0) = 0, F_E(V^*) = V^* - I, F'_E(V^*) = 1$$

The proposed solution takes the form  $F_E(V) = C V^\beta$ , so the characteristic equation is:

$$\frac{1}{2}\sigma^2\beta(\beta - 1) + \alpha\beta - \rho = 0$$

With two roots  $\beta_1 > 1$  and  $\beta_2 < 0$ .

$$F_E(V) = C_1 V^{\beta_1} + C_2 V^{\beta_2}$$

The restriction  $F_E(0) = 0$  means that the term with the negative exponential must vanish, so  $C_2 = 0$ .

Finally, using the other restrictions, the value of the integration constant  $C_1$  is given by:

$$C_1 = \left(\frac{\beta_1 - 1}{I}\right)^{\beta_1 - 1} \beta_1^{-\beta_1} \quad (3.8)$$

And the critical value in questions is:

$$V^* = \frac{\beta_1}{(\beta_1 - 1)} I \quad (3.9)$$

The critical value  $V^*$  separates the region where is optimum to wait ( $V < V^*$ ) from the region where it is convenient to abandon the project.

### 3.2.5 Schwartz's Model for the Pharmaceutical Industry

Inside the universe of technological projects, this work focuses on those that involve mobilizing a great quantity of resources in research and development

activities, and are, therefore, highly strategical. The real options methodology is the most adequate because it allows for the explicit modelling of the strategical activity and the involved uncertainty. This methodology extends the traditional static vision through a dynamic multi-period process. At the same time, it incorporates the idea that businesses actively manage their investment opportunities, adapting their investment strategies as the uncertainty resolves itself as time goes by.

In the context of the pharmaceutical industry Schwartz (2004) model is an example. The author developed a numerical model for the valuation of R+D projects protected by patents. The innovation in the pharmaceutical industry proposes a debate over the public policies referred to the financing of their research costs, over the determination of price levels, and on the social optimum regarding the use of patents. In particular, the developing of drugs is a lengthy process (10 years or more), and it is fundamental to take into account the uncertainty in its costs and the future income. Even more, once the project is approved, there is uncertainty over sales and the cash flow that those may generate.

This section overviews some aspects of the valuation of pharmaceutical projects proposed by Schwartz (2004); it uses a discrete simulation focus to determine the value of the R+D project, using the *real options* methodology. An uncertain context is assumed where key variables of the valuation, such as the cost to finish each stage of the project, the future flows of cash, and the possibility of an adverse effect (technical, economical, legal, or political) intervenes in the possibility of not finishing the project, are stochastic. The strategic decision of abandoning the project when the costs are greater than expected or when the estimated flow of cash is less than expected.

Formally, it is proposed to value R+D projects through a simulation based on a discrete real option focus that contemplates the uncertainty in costs, the flow of cash, and the possibility of catastrophic events that may endanger the possibility of finalizing the project. It is also allowed to abandon the project when the actual costs are greater than the expected costs, or when the estimated cash flows are lower than expected (Schwartz, 2004).



Considering that the investment is realized through time, it is assumed that there exists a maximum investment rate ( $I_m$ ) and that as the funds enter the project, the remaining cost to complete it ( $C$ ) is reduced. This cost is considered a random variable. On other order of things, it is frequent that a project may fail and not be able to reach completion, because of this a *Poisson* probability of project failure is assumed; if the project fails, its value is zero. At a strategical level, the investor counts with the possibility of abandonment, which he will use when the cost result greater than expected, or the flow of cash lower than expected. At last, when the project is finalized, the proprietor starts receiving the benefits of the investment, represented by a rate of net cash flow  $B$  (modelled as a stochastic process).

With respect to the investment costs uncertainty, the author postulates that the remaining costs follow a dynamic described by a diffusion process of the form:

$$dC = -I dt + \sigma(IC)^{1/2} dz \quad (3.10)$$

The first term of the process refers to the control of the diffusion process; as the investment advances, the estimated remaining cost to finish the process decreases. The second term corresponds to what Pyndick denominates technical uncertainty, and is related to the physical difficulty associated with the completion of the project, where  $dz$  is the increment of a Brownian motion.

On the other hand, the dynamic of the future flow of net benefits is modelled from a geometric Brownian motion given by:

$$dB = \alpha B dt + \sigma B dw, \quad (3.11)$$

Where  $dw$  is the increment of a Gaussian Weiner process, correlated with the market portfolio and which can also be correlated with the expected cost. The correlation between the costs and the cash flows signify simply that costs that were greater than expected reduce the expected future cash flows (is because of this that the correlation may be assumed to be negative). Something to take into account is that this flows are only perceived once the investment is completed, so flows may change as the uncertainty related to the project is decreased during the investment. Altogether, in order to observe the effects of valuation before a neutral risk, the author suggest the following risk adjusted flow expression:

$$dB = (\alpha - e)Bdt + \sigma Bdw = \alpha^*Bdt + \sigma Bdw$$

Where  $e$  is the risk premium associated with the process.

Lastly, when the project investments have been completed, the value of the project will depend on the future cash flows to be generated. Let  $V(B, t)$  be the value of the project at time  $t$ , with cash flows  $B$  and assuming that the patent of the project expires at the moment  $T$ . There is a residual value of the project as well, represented by the cash flow generated after the patent has expired:  $M \times B$ .

In this case, standard arguments imply that the value of the project must satisfy:

$$\frac{1}{2}\sigma^2 B^2 V_{BB} + \alpha^* B V_B + V_t - rV + B = 0 \quad (3.12)$$

Subject to  $V(B, T) = M \cdot B$

Before the investment is completed, the value of the project R+D,  $F(B, C, t)$ , depends on the projected cash flow rate (which is only effective if the project is completed), the remaining cost, and time. Altogether, this value must satisfy the following expression:

$$\frac{1}{2}\varphi^2 B^2 F_{BB} + \frac{1}{2}\sigma^2 I C F_{CC} + \varphi\sigma\rho B\sqrt{I}C F_{BC} + \alpha^* B F_B - I F_C + F_t - (r - \lambda)T - I = 0 \quad (3.13)$$

Subject to  $F(C, 0, te) = V(C, te)$

The difficulty inherent to the frontier condition is that the investment realization date ( $te$ ) is a random variable. The value of the R+D project at the time of completion depends not only on the cash flows at that time, but also on the duration of the investment (because the duration of the cash flows finish with the expiration of the patent).

The basic model exposed can be extended to satisfy the characteristics present in the pharmaceutical market, where the project is realized in two stages. The first stage comprises the search for a chemical compound that generates the wished effect, and a second stage that must insure that that the compound found is effective and safe to use on humans.

The development process of drugs is a sequential process; because of this it is imperative to detail at which time the investor may leave the project. This decision will depend on different factors, such as: potential beneficial therapeutic benefits, the expected frequency and severity of adverse reactions, marketing and logistics, production costs, and the estimation of future income. In this way, once the compound is a strong candidate, it must be presented before the FDA; thirty days after this presentation, clinical trials must begin on humans. These trials are produced during three different stages: the first stage of the trials is done on a small group of (generally) healthy people, and it's done basically to obtain the degree of toxicity and dosage security on humans. On stage II, the drug is administered on a bigger group of people which are considered to need the drug for a posterior recovery. On stage III the drug is administrated massively so as to find the definitive efficacy graduation, and possible adverse reactions. Once the clinical phase is completed and it is considered that the drug will be approved, it is presented before the FDA for approval, so the FDA's revision may be regarded as a fourth stage of the project's cycle<sup>138</sup>.

### **3.3 Delimiting, Measure and Price Risk**

As was mentioned on the first chapter, the insurers are private actors that, even when looking its economical benefice, pressure governments for greater regulation. Clearly a meagre regulation endangers the solidity of this companies.

To face the problematic of bounding, measure, and price risk, the first part of this section will analyse the problematic of nano risk measure. The second focuses on the specific role of insurers. Lastly, a concrete example where the industry evaluates nano-materials risk is detailed.

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<sup>138</sup> The simulation focus of the model proposed by (Schwartz, 2004) can be adapted to different investment stages "i". So the expected cost dynamics for the project are given by:  $dC_i = -I_i dt + \vartheta_i \sqrt{I_i C_i} dZ_j$ .

### 3.3.1 Nano Risk Measurement

The possibility of establishing clear rules and a quantifiable punishment for the non-observance of this institutions is limited by the weakness existent in risk evaluation. This is the starting argument from Françoise Roure (2004), who sustained, in the Brussels's nanotechnological workshop, the already mentioned hypothesis that financial risk evaluation models supply with the institutional framework necessary to face its main problems<sup>139</sup>.

A first approach in this line is being carried by the European Union whose parliament approved in 2004 a resolution on corporative governance and financial services, a ruling that supports the initiative of the European Commission in establishing the collective responsibilities in the short term and promotes the advancement towards the outline of individual responsibilities<sup>140</sup>.

Regarding the organizations with good reputation, they should articulate the variety of nanotechnological methods and principles, with its potential benefits and risks. In relation to the research, it should be widely financed and develop models of communication and information for the incorporation of public debate. The government should increase the financing to know the consequences of nano-structures on health, and the environment, revise the current regulatory framework, and develop communication strategies to keep the public informed. In addition, it should develop training programs to alleviate the scarcity of human resources and, together with the private sector, it should anticipate risks and mitigate them. Finally, the educative system should advance on work, training, and trans-disciplinary experience models, on the development of critic thought, and the relation between social sciences and technology.

Of what was previously said, some results follow. On one hand, scientific knowledge and technical advance are governance's instruments, where what matters is not the goal but the means, the innovation. Different countries have heterogeneous agendas which, in time, have consequences on the international

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<sup>139</sup> In effect, Roure (2004) expresses that both investors and insurers have the right and the duty to evaluate and announce the financial risks involved on its contractual relations.

<sup>140</sup> Roure argue that this focus should be extended to all technologic convergence projects to establish a bridge between the institutional models that separate the United States from the European Union.

theatre, where the technoscience is developed. Despite acting under the same scientific paradigm, nations have a tendency to create very different innovations. In any case, Echeverría (2005) affirms, the most important thing is to develop a rational governance that links mediums and available resources with ends and that articulates itself in the international theatre. What the author proposes is that, instead of putting its diverse agendas in competition, countries must achieve an international division of objectives.

Now well, in light of what was said on the previous chapter where it is clearly set that the industrial nano dynamics is constituted with asymmetries that clearly set conflictive power relations, the universalist view (or by country) presented on the previous paragraph is only the first step for an efficient governance. In order to surpass this vision of governance associated to countries and not to affected collectives, the fourth chapter of this thesis adds complexity to the problem in proposing that a complex nano dynamic needs a sustainable governance that will coexists with permanent conflict because of power struggles.

The ability of governments to act must regulate the technologies to minimize the conflict between the actors of the sociotechnical network. It is important to create new toxicity standards that take into account the effects of size over environmental and health risks. In addition, it is necessary to change the moral and legal scheme that supposes that only humans execute autonomous actions, in view that new nano-devices actions with autonomy from its inventor or user. At the same time, it is required to regulate the activities of it over humans so as to prohibit the usage of individuals to prove experiments. Lastly, because of equality issues, it is required to make patenting laws more flexible so that developing nations may access to the benefits of nanotechnology (Schummer, 2007).

### **3.3.2 The Role of Insurance Companies**

Another aspect to take into account at the time of analysing nanotechnology is financial risk on the part of the investors in nanotechnology. Annabelle Hett (2004) warned on the difficulties for the development of an insurance market for the

companies that invest on nanotechnology, given that this ventures have a high degree of uncertainty<sup>141</sup>.

Before this requisites, nanotechnology presents a challenge for the insurers in the measure that there exists a great level of uncertainty referring to the adverse effects of nanotechnology on the environment and over the possibility of emergent future social protests. An adequate and precise evaluation of the risks involved has not yet been made, nor is clear the regulatory framework to tackle said risk should they materialize. All of this contributes to the difficulty to celebrate contracts to insure the great mass of capital already compromised in this sector.

According to Hett, both the development of a common language, and a constant dialogue between the parties are key elements that would drive us to a clearer panorama. The former would contribute to the performing of a standardized evaluation of risks in the spirit of the comparison of scientific knowledge between dissimilar countries and industries, and also to a universal nomenclature to determine the performance requirements that the insurers impose on the insured. The dialogue that should involve regulators, businessmen, scientists, insurers, and the population in itself is, today, insufficient compared to the progress currently being made on the field. The addition of the general population to the dialogue would impose itself as necessary to know how it and assimilates and values the new projects. Furthermore, plural dialogue has a fundamental role in risk detection, as it avoids that the interested parties minimize them before the public opinion.

### **3.3.3 Expert's Evaluation**

On their work, Robichaud *et al.* (2005) performed an assessment of the relative risks associated with the production process of a sample of five manufactures nano-materials, chosen by its current or potential production, and commercialization on a massive scale. To perform this analysis, the methodology of choice was based on the scheme of each material's production process (synthesis), identifying inputs,

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<sup>141</sup> It is necessary to take into account that insurance companies carry out their business on the basis of risk assessment, identification, and diversification. In this sense, risk diversification mechanisms are limited when it is not possible to evaluate the probabilities and risks associated with a given venture, when the insurers are affected by the same contingencies than insured, or when the magnitude of events exceed the insure capacities of the firm.

products, and substances used on their production. On the basis of these inputs, a risk ranking was performed, and the corresponding risk premium was estimated for the producers that wished to insure.

The study acknowledges and separates the treatment of two risk types: those associated with inputs, waste and products of the production process, and those associated with the direct risk of nano-material. As a result, the authors show that the production process of nano-materials would imply lesser environmental risks than other types of manufactures. In conclusion, the experiment described, and carried out by Robichaud *et al.* (2005) suggested that the exposition to the considered nano-materials does not impose unknown or unusual risks in relation to those imposed by other manufactures<sup>142</sup>.

As a first step towards the analysis of the relative risks involved, Robichaud *et al.* (2005) describe, and structure a scheme of the production process of five nano-materials chosen on the basis of information availability, and its potentiality to reach an industrial level of massive scale in its production, as well as its diffusion. The chosen materials were *single-walled carbon nanotubes, bucky balls, quantum dots composed of zinc selenide, alumoxane nanoparticles y nano-titanium dioxide*.

From this scheme the authors found the realizations of the variables that they deemed important for risks analysis and that were, exclusively, those relevant from the perspective of insurers: the constitutive elements and their properties, and the parameters of the process (Robichaud *et al.*, 2005). The objective of the study of said factors was to reach conclusions on the associated relative risk, understood as the exposition probability and the danger associated to the degree of emergence of new characteristics in nano-materials, considered as: toxicity, flammability, and persistence on the environment. This properties were, at first, identified qualitatively on the synthesis process, and then, combined to calculate a risk premium for the chemical manufacturing industry, by using an actuarial protocol (Robichaud *et al.*, 2005).

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<sup>142</sup> The authors rescue the focus of insuring for the treatment of nano-materials risks. In this sense, investors and businessmen from the nano-manufacture world would benefit from lower costs, risk premiums, legal costs, loan rates, and from avoiding losses made because of consumer activists.

The exercise of adapting the collected information from the synthesis process to the risk analysis follows the scheme proposed by the authors (Robichaud *et al.*, 2005 p .8990) summarized as follows:

***Material and process identification.*** This phase implies the understanding of the synthesis processes, and the elements involved, and is comprised by two stages. On first stage, the authors revised the available information on the production methods to find the one suited for utilization on an industrial scale. On the other hand, once the method was chosen for each nano-material, they identified the characteristics of each process, of the inputs, products, and waste of the process.

***Characterization of the process.*** Each of the elements and processes of the previous phase were qualitatively ordered according to their associated relative risk. In the case of the materials, such an order emerged from an evaluation of the toxicity, water solubility, bioaccumulation, flammability, and expected emissions, according to each material on each step of its synthesis process. After this, additional information was collected and adapted to respect the requirements of the *XL Insurance database* program that allows for the calculation of *scores* of relative risks.

Regarding the production processes, they were characterized to be included in the program in accordance with the elements involved, as well as factors such as temperature, and pressure. For each process, the involved substances were classified in terms of its role in the process, its physical transformation, given the temperatures and pressures corresponding to the process, and its emissions, to determine its incidence on risks. The role of the substances was instrumental to identify the exposition probability to each one. On its part, the physical state of the substance allowed for the estimation of its mobility and persistence degree, and to complete it on the database. Lastly, evaluations on the degree of emissions tended the magnitude of matter released to the environment in terms of kilograms per ton of product. Once the contribution of each substance to the risk, the program allowed for the classification of the synthesis processes chosen according to its conditions on the direction of potential dangers.



On the other hand, the methodology present on *XL Insurance Database* was used to assign a value on the risks relative to the production process scale for each of the five materials considered on the experiment. This database is widely used on the insurance industry, which allowed to rank not only the magnitude of risk<sup>143</sup> of these five materials, but also to compare this results with the production processes of other manufactures not belonging to the world of nanotechnology from the optic of insurance.

The actuarial protocol followed for the calculations allowed for the classification of each process on three relative risk rankings: incidental risk, normal operational risk, and latent contamination risk. Regarding the first, it is the one associated with the accidents that may occur under during the production process and that imply an accidental exposition. The second one is related to the emissions expected to occur during the production process, while the third embodies the long term contamination risks of present operations.

As regards the classes of relative risks, three were established: the class of incidental probability, the class of risk quantity by danger, the class of risk by dangerous substance. This classes were incorporated on the actuarial calculations together with adjustment actuarial coefficients, giving birth to the final risk scores. From the perspective of insurance, what is relevant to calculate the final risk scores, are the constitutive substance that impose the greater risk (Robichaud *et al.*, 2005), so the risk classes acquire their relative value in function of the value of the corresponding risk to the most dangerous substance.

To analyse the results in the light of the use of the previous methodology, the authors compared the qualitative and insurance performance in terms of the risks of the nano-materials considered, with the results of other production processes of defunded materials: silicon, batteries, refined petroleum, and aspirin. This processes are heavily present on the day to day life and represent, for example, the

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<sup>143</sup> The dangers and risks of exposition associated to each process were determined from variables such as temperature, pressure, persistence, and mobility. The methodology consists on assigning a score of relative risk to each process. Then to establish a correspondence between this score and certain classes of relative risk. Lastly, this classes of risks are combined on actuarial formulae to determine the dangerousness ranking of a certain substance.

activity of the petrochemical complexes, and the pharmaceutical industry. The risk scores of this processes were obtained from the *XL Insurance Database*.

On its original work (Robichaud *et al.*, 2005), the qualitative results are presented on eleven tables that exhibit the name of the product considered (the five nano-materials and the six manufactures for comparison) followed by all of its constitutive elements. As a second entry on the table, the five categories analysed for the risk evaluation are detailed, toxicity, water solubility, bioaccumulation, flammability, and emission impact. The first four are inherent to the components, while the last emerges from within the production process. On the intersection between the component and the risk category, the authors determine the qualitative result of the risk evaluation through a circle arrangement. A white circle represents the *under risk* category, do black circles mean *high risk*, and three black circles *very high risk*. In the case of impact on emissions, the evaluation is defined in terms of a range of values.

The compared analysis between the nano-materials and the massive industrial products suggest that, as a group, the first have less constitutive elements than the second. Furthermore, they have less toxicity but higher projected emission levels. A possible explanation suggests that the lesser emission levels present on the traditional materials are owed to the fact that its production processes are so widely available that have been perfected to the point where the industry is able to recapture and recycle the dangerous elements used or produced during its production process. It also explains that they have a greater amount of constitutive elements, given that said recycling and recapture processes must involve more chemical than if they were absent.

To summarize, the group of nano-materials seems to impose less risks than the production of refined petroleum or high density plastic.

### **3.4 Public Perception**

In the light of what was said on the previous sections, it is fundamental to take into account the voices of the different actors (non technoscientists) with respect to the use of nanotechnology in general and its medical applications on particular. A

group of researchers from the University of Monash in Melbourne performed a study, using social sciences publications and newspapers as its source of information. The study intended to cast a light upon the nano perception other than the opinions of technoscientific experts (Seear *et al.*, 2009). This section reproduces some of the study's results which are relevant for our research<sup>144</sup>.

There is a clear consensus on the fact that poorer individuals and developing countries have a greater probability of not having access to this technologies, this is why there is also a consensus on the importance of the user`s and the general community perception on risk control, and on the definition of new regulations.

Regarding the issue of human enhancement, the literature debates upon the therapeutic, and diagnosis aspects, as well as those related to evolutionary design. It is a field characterized by widely divergent perspectives on the potential consequences of this, there is also a strong consensus on the necessity of a more open and rigorous debate. The authors inform that there is seldom agreement upon which policy and regulatory response is right, and even the areas where there is a built consensus exhibit a variety of opinions (Seear *et al.*, 2009).

With respect to the risk perception, polls show that, in general, there is a low level of knowledge about nano-medicine, yet the available opinions are positive. Nevertheless, it is widely agreed that social and economic consequences are closely related to issues regarding risk communication and risk perception across the general public.

It is observed that a growing debate on how and why an international response might be necessary or preferred over a national focus regulation and a debate regarding if the voluntary focus of regulation are insufficient on its own (Seear *et al.*, 2009).

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<sup>144</sup> In relation to the economic aspects, on the literature consulted by the authors, there are divergent perspectives on the size of the future market, although there is a large consensus on the great business opportunities that nano offers to certain groups (Morigi *et al.*, 2012). Nevertheless, there is a critic literature that suggests that expectations on the nano-market may be exaggerated and the companies under the sector overvalued (Rogers, 2010). At the same time, there is a literature that examines the barriers and incentives to the investment where it is argued that these are the same than in any technological innovation (Seear *et al.*, 2009).

### 3.4.1 Users' Voices

In the last decades there has been a change of focus within the State in how they regulate technologies: moving from a vision where government experts had the lead, to one where multiple actors from the civil society interacts. It is important to acknowledge that this emphasis on social interactions does not subscribes to the neo-liberalist *pro-market* perspective. On the contrary, this thesis argues that it is necessary for the State to intervene on the market at the same time that it proposes to open new questions upon the institutional and political relations that allow to understand complex interdependencies among the nanotechnoscientific practice, the market, the State, and the civil society.

Over the last years, both ethical and democratic considerations have gained in importance when it comes to the study of environmental risk. As Shrader-Frechette (1998) and León Olivé (2004) sustained, the role of the scientist must be to reflect in an ethical manner in order to discover the social impact that his evaluation on the prejudice to the environment and what course of action is best to follow will have. This is so, because the decision on environmental policy that are taken today on the basis of the acceptance or rejection of the hypothesis on environmental impact will have consequences on the interests of individuals today, and in the future.

Shrader-Frechette understand that, if the scientific method points out that some hypothesis must be provisionally accepted, and some aren't, then the scientific must, in addition, ask himself what impact would said acceptance of the hypothesis be. On the other hand, when evaluating these hypothesis, there is an equality dimension that must be accounted for as long as we are operating under the context of a democracy that invite the policy makers to revise their decisions to include the social welfare and to smooth the distribution of risk over time and space.

León Olivé<sup>145</sup> gave the principles that fundament and sustain ethically acceptable human relations are twofold. The first principle is to never treat people just as

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<sup>145</sup> León Olivé (2004) states that occidental democracy is subject to values and is functional to the real power. It is surprising the quantity of *State secrets* that first world occidental democracy has: the citizen cannot express his view; not even can he acknowledge what is the risk to which he is submitted under the real power. The author clearly contrasts the experts risk evaluation against the public perception of risk, summoning the

means (to achieve an objective), and the second, that people should always be allowed to act as rational, autonomous agents (Olivé, 2004:302). If democracy is to be understood as an association project under common values, then this definition is incompatible with any technocratic focus on risk whatsoever (Olivé, 2004).

### **3.5 Quantitative Models for the Regulation of Nanotechnology**

Given that risks are constituted together with the dynamic of nanotechnology, it is necessary to think on public policies and, in particular, to model and quantify these decisions. This section presents a model of the precautionary principle, allowing the government to make decisions on the basis of the quantification of the costs and benefits of a given policy. Then and there, an economic model analyses how to grant incentives to the nano industry in an efficient manner.

#### **3.5.1 A Quantification of the Precautionary Principle**

Despite the existence of a broad literature on the use of the precautionary principle within the European Union (Monaghan *et al.*, 2012), it is still rather difficult to operationalize the concept as a quantitative instrument for governmental choice (de Sadeleer, 2012). This section formalizes this principle, following Scott Farrow (2004), to allow for the evaluation of investment projects as part of the decision-making process.

The model articulates risk evaluation techniques, the cost-benefit analysis of projects and the valuation of irreversible investments under uncertainty. Therefore, a model that quantifies the social value of *precaution* when the possibility of forwarding an R+D project is given. The proposal is to evaluate whether if performing a given project right now is optimal or if it is preferable to wait, thus transporting to the governmental practice what the literature on risks calls *precautionary principle*.

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concept from Kristin Shrader-Frechette, that all risk is a perceived concept. If something is risky for humans and/or its habitat, then it must be perceived by some agent. There is not one only “correct” way to evaluate risk. Public participation on the identification and management of risks that affect humans or their environment is fundamental (Olivé, 2004).

The challenge is to use a method that incorporated the uncertainty and irreversibility within the criteria of risk management that are used for the analysis of regulatory public policies. If the method is successful in this matter, then it should be superior to the cost-benefit standard methodology that simply proposes to carry out an action when net benefits are positive. Nevertheless, if the uncertainty and irreversibility of the project are accounted, this threshold is greater than zero.

Following the proposal from (Farrow, 2004), the value of precaution is assimilated when facing of an investment project proposal, to a waiting option (Dixit and Pindyck, 1994). In particular, any project is associated with a socially irreversible cost (C), and most surely, social benefits (B), which are modelled through its present value net of irreversible costs.

The irreversible social cost is a value determined by the specialist, while the social benefit is modelled as a geometric Brownian motion:

$$dB(t) = \alpha B(t)dt + \sigma B(t)dz \quad (3.14)$$

Formally, if the discount rate is  $\rho$ , the Bellman recursive equation corresponding to the waiting option (F) at time  $t$  is:

$$F(B(t)) = \text{Max} \left( B(t) - C, e^{-\rho dt} E \left( F(B(t + dt)) \right) \right) \quad (3.15)$$

Where  $F(B(t))$  is the quantification of the precautionary principle from the point of view of the government in charge of regulating the activity of interest.

Next, the decision rule that allows for the decision on at what time it is optimal to invest is analysed. To achieve this, at time  $t$ , the values of the Project if it is executed today,  $[B(t) - C]$  is compared to the waiting value:

$$e^{-\rho dt} E \left( F(B(t + dt)) \right).$$

Mathematically, the resolution of this problem consist on its conversion into an *optimal stopping problem*, to find the critical value of the social benefit ( $B^*$ ) that separates the region where it is optimal to wait ( $B < B^*$ ), from that where it is optimal to start the project immediately. So that the decision rule is of the form:

$$\text{If } B < B^* \Rightarrow F_E(B(t)) = e^{-\rho dt} E \left( F_E(B(t + dt)) \right)$$

$$\text{If } B > B^* \Rightarrow F_D(B(t)) = B(t) - C$$

$$\text{If } B = B^* \Rightarrow F_E(B^*) = F_D(B^*) \quad (\text{Continuity of the } F \text{ function})$$

$$\frac{dF_E}{dV}(B^*) = \frac{dF_D}{dV}(B^*) \quad (\text{Continuity of the first derivative}).$$

At the same time, it is required that a monotonicity condition to be verified for  $F_D$  and  $F_E$  and for  $B(t + dt)$  given  $B(t)$ . So that within the region where it is optimal to wait, it is verified that:

$$F_E(B(t)) = e^{-\rho dt} E \left( F_E(B(t + dt)) \right)$$

Multiplying both members by  $e^{\rho dt}$ ,

Subtracting  $F_E(B(t))$

$$(e^{\rho dt} - 1)F_E(B(t)) = E \left( F_E(B(t + dt)) - F_E(B(t)) \right)$$

Dividing by  $\Delta t$

$$\frac{(e^{\rho \Delta t} - 1)}{\Delta t} F_E(B(t)) = \frac{E \left( F_E(B(t + \Delta t)) - F_E(B(t)) \right)}{\Delta t}$$

If  $\Delta t \rightarrow 0$

$$\rho F_E(B) = \frac{E \left( dF_E(B) \right)}{dt}$$

On the other hand, as we know that  $B$  follows a geometric Brownian motion, we can write, using Ito's lemma, the process  $dF_E(B)$  as:

$$dF_E(B) = \left( F'_E(B)\alpha B + \frac{1}{2} F''_E(B)\sigma^2 B^2 \right) dt + F'_E(B)\sigma B dz$$

The expectation is:

$$E \left( dF_E(B) \right) = \left( F'_E(B)\alpha B + \frac{1}{2} F''_E(B)\sigma^2 B^2 \right) dt$$

So that:

$$\rho F_E(B) = \frac{E(dF_E(B))}{dt} = F'_E(B)\alpha V + \frac{1}{2} F''_E(B)\sigma^2 B^2$$

Converting the original problem into an ordinary differential equation subject to restrictions:

$$\frac{1}{2}\sigma^2 B^2 F''_E(B) + \alpha B F'_E(B) - \rho F_E(B) = 0 \quad (3.16)$$

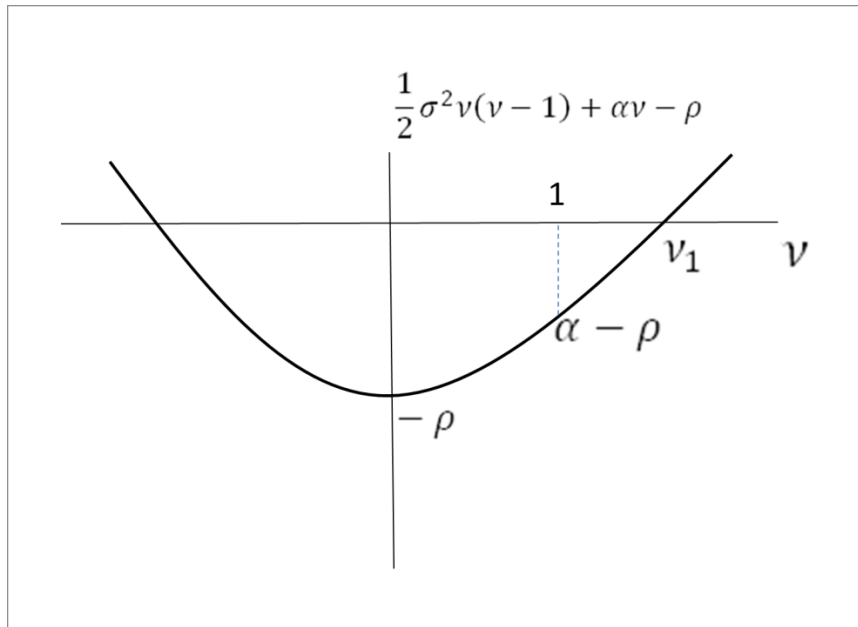
$$\text{s.t. } F_E(0) = 0, F_E(B^*) = B^* - C, F'_E(B^*) = 1$$

A solution of the form:  $F_E(B) = C B^v$  is proposed, so that the characteristic equation is:

$$\frac{1}{2}\sigma^2 v(v-1) + \alpha v - \rho = 0$$

Solving the quadratic equation:

$$v_1 = \frac{1}{2} - \frac{\alpha}{\sigma^2} + \sqrt{\left[\frac{\alpha}{\sigma^2} - \frac{1}{2}\right]^2 + \frac{2\rho}{\sigma^2}} > 1 ; \quad v_2 = \frac{1}{2} - \frac{\alpha}{\sigma^2} - \sqrt{\left[\frac{\alpha}{\sigma^2} - \frac{1}{2}\right]^2 + \frac{2\rho}{\sigma^2}} < 0$$



Quadratic solution. Source: (Dixit and Pindyck, 1994)



Summarizing, the general form of the solution is  $F_E(B) = D_1 B^{\nu_1} + D_2 B^{\nu_2}$ . But the restriction  $F_E(0) = 0$  imposes that the term with the negative exponent cannot exist, so  $D_2 = 0$ . The other restrictions impose that  $B^* = \frac{\nu_1}{(\nu_1-1)} C$  and  $D_1 = \left(\frac{\nu_1-1}{C}\right)^{\nu_1-1} \nu_1^{-\nu_1}$ .

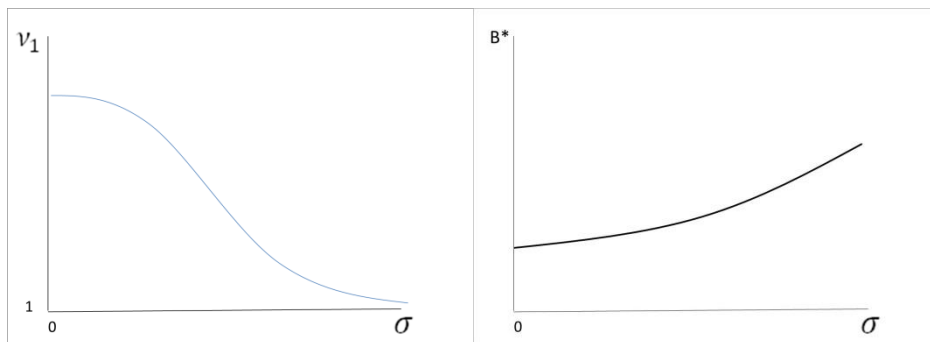
The previous statement implies that the waiting option (if  $B < B^*$ ) is given by:

$$F_E(B) = D_1 B^{\nu_1}$$

The greater the volatility, the lesser  $\nu_1$ , so the critic threshold is greater:

$$\frac{\partial \nu_1}{\partial \sigma} = 2 \frac{\alpha}{\sigma^3} + \frac{1}{2} \left( \left[ \frac{\alpha}{\sigma^2} - \frac{1}{2} \right]^2 + \frac{2\rho}{\sigma^2} \right)^{-1/2} \left( -4 \frac{\alpha^2}{\sigma^5} + 2 \frac{\alpha}{\sigma^3} - 2 \frac{2\rho}{\sigma^3} \right) < 0 \Rightarrow \frac{\nu_1}{(\nu_1 - 1)}$$

$$\uparrow \Rightarrow B^* \uparrow$$



The root  $\nu_1$  and the critic benefit ( $B^*$ ) as a function of the volatility of the process.

In the first place, the decision threshold proposed is more prudent than the traditional, where it is only required that the present value of future net benefits to be equal to the irreversible social cost of the project ( $B=C$ ). Using the precautionary principle, the project is delayed until the benefits are greater than the costs, so as to contemplate the irreversible nature of costs, and the possibility that the net observed benefit observed today is optimistic (Farrow, 2004).

The government evaluates the net benefits by analysing the expected social benefits, but also contemplating the risks for society that are attached to innovation. If at the moment of the evaluation, the expected benefit is not sufficiently greater than the

irreversible cost, the government prefers to maintain its precautionary option and not authorizing the project.

The proposed procedure to reach a governmental decision is as follows. Firstly, the government is presented with a project that it needs to authorize and agrees with the private sector the following values:

- The social irreversible cost that the Project will cause:  $C$
- The present values of the benefit net of future reversible costs at the starting moment:  $B(0)$
- The parameters of the process that this net benefit will follow  $B(y, \sigma)$  are estimated.
- Discount rate:  $\rho$

Then, the government may proceed to the calculation of the previously mentioned critical value  $B^*$ :

- Calculation of  $v_1$  on the basis of the parameters:  $v_1 = \frac{1}{2} - \frac{\alpha}{\sigma^2} + \sqrt{\left[\frac{\alpha}{\sigma^2} - \frac{1}{2}\right]^2 + \frac{2\rho}{\sigma^2}}$
- $B^* = \frac{v_1}{(v_1-1)} C$

So the government's decision rule is: If  $B(0) \leq B^*$  the waiting is in order, and the investment project should not be authorized. It should be noted that the present value of the expected benefit is required to be not only greater to the cost, but also to  $\frac{v_1}{(v_1-1)} C$ . This model contemplates the uncertainty included in the future benefit and is, therefore, more conservative than the traditional principle of comparing cost and expected benefit.

### 3.5.2 Governmental Incentives Design

In the context of public policies to foster innovations within medicine, the literature acknowledges two main categories of incentives: *push* y *pull* (Nemet, 2009). In this section, both proposals are evaluated by comparing its cost versus its social contribution (Hsu and Schwartz, 2008).

A governmental *push* incentives program is that which contributes with a part of the initial developing cost. This type of financing can be awarded to people (scholarships or research prizes) or to businesses. On the other hand, the *pull*

program fosters research by increasing the income generated by the final product. The financing could consist on a buying compromise, or a patent extension. Hsu y Schwartz (2008) also consider an hybrid incentive plan that combine both.

In the model, it is formalised the costs and benefits of a defined financing scheme:

$$\frac{\text{Net present value ( Government's cost)}}{E[Q(\tau).q.T]} \quad (3.17)$$

Where  $Q$  is the efficiency of the new product,  $q$  are the supplied units per year, and  $T$  is the number of years of the subvention contract. The authors fail to contemplate any agency problems arising from the asymmetric information between the developer and the sponsor, neither they dwell on contracting issues. It is not considered that grant translate into an ownership transference of the innovation to the government, so that the public organism lacks the knowledge to possess, manage, and distribute pharmaceutical resources in an effective manner.

On its part, Kremer (2002) concludes that the *pull* subvention programs are the most effective because they eliminate, to a great extent, *agency problems* between the sponsor and the developer. Within the *pull* alternatives, a patent extension policy is the most used to promote innovation in general. From the businesses point of view, the increased protection from patents, allows the company to maintain a monopolist market for a longer period of time<sup>146</sup>.

Within the *pull* alternatives, governments must check for the quality of the final product. Consequently, if a company that has an assured sale of the product, decides to produce it with a poor quality, the government must monitor the development and establishes quality control guidelines. Given that the quality of the developed product is observed at time  $\tau$ , within the framework of the buying compromise, the contract establishes socially optimal units for buying. In this way, the quantity that the company sales to the government depends only on  $Q(\tau)$ .

The distinctive characteristic of a *buying compromise* is that the government decides how and how much is the final product distributed. The company

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<sup>146</sup> Some activists and economists have sustained that the strengthening of the patent protection policy, or the extension of patent's life for pharmaceutical products on underdeveloped countries increases business incentives for research on diseases that are specific of these countries (Kremer, 2002).

renounces to its right to obtain a monopolist rent in exchange for the buying compromise at a pre-established price. In other words, the government hires the company to supply a socially efficient quantity. Another alternative is the shared cost financing plan; it promotes innovation in the development of vaccines through the reduction of the research cost and the broadening of production. If the expense subvention scheme is used, the company opts to supply with the monopoly's quantity that arises from the inverse demand function.

Both the buying compromise and the shared cost financing scheme may be combined to create hybrid contracts, these contracts combine the positive attributes of both subvention types. The mechanism through which the shared cost financing is more effective in promoting R+D activities, yet ineffective to induce an efficient supply quantity to the market once the vaccine has been discovered. This clearly may be relieved if both subventions are combined within a hybrid contract.

A business model widely used within the sector is the joint business of a small nano company (N) that is in possession of a patent, and a big pharmaceutical company (F) that has the capital and access to the market. This business model was analysed on the second chapter of this thesis (*joint investment valuation*). There, the variables of the model in question were detailed. This section formally analyses the situation under which the pharmaceutical company uses its market power to demand a high share on the venture's income (thus forcing the nano company to abandon the project). Yet if the project is socially important for the government, a way to intervene is to promise a Pull incentive that consists on an extra payment to the nano company once the project is over. The additional value that the government offers to the nano company is such that eliminates the possible loss of it, while leaving intact the profit of the pharmaceutical company.

Mathematically<sup>147</sup>, the problem requires that the following restrictions are satisfied for both companies to be part of the project.

$$(N) \quad \beta^2 [p \max(u Y \alpha, X) + (1 - p) \max(d Y \alpha, X)] \geq K_N \quad (3.18)$$

$$(F) \quad \beta [p u Y (1 - \alpha) + (1 - p) d Y (1 - \alpha)] \geq K_F \quad (3.19)$$

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<sup>147</sup> The used variables are the same that those use on chapter 2 to explain the business of conjunct production.

From the first restriction, corresponding to the nano company, it follows that the minimum value for the governmental promise must be  $X > \frac{K_N}{\beta^2}$  (See graphic 4.6).

It is important to point out that the incentive is paid at the end of the project, so it's a counter-cyclical governmental policy. In this way, the government may increase the employment on the technological sector in times of recession without the need of cash<sup>148</sup>. This model can be used by governments to analyse incentives on the nanotechnology sector. The main characteristic of the proposal is that it does not require a disbursement at the beginning of the project.

## Chapter Conclusion

This chapter started presenting risk as manufactured. It presented different approaches to the concept of risk, focusing on the characteristics of the so-called *risk society*. While this approach is relevant to this thesis, it is necessary to avoid its universalistic nature, incorporating nano micro complexity and its macro context.

Subsequently, it examined the viewpoint of the industry, where uncertainty is taken as part of the process and concluded that the *real options valuation methodology* is the more efficient valuation approach, because it accounts for the uncertainty, flexibility, and irreversibility of investments, all relevant for the financial evaluation of nanomedicine projects.

In addition, this chapter conceptualized nano risk as co-constituted both during the practice, as well as in its associated market. Moreover, these risks for the human being and for the environment were analysed with an emphasis on ethical questions that arose during the analysis. Accordingly, to exemplify the current risk evaluation process, this chapter analysed the risks associated to five nano-materials. It concluded that while this risk management procedure satisfies governmental regulation, it is not enough to contemplate social and environmental issues.

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<sup>148</sup> If the government is credible, it might even sell the option on the market.

On the last section, two mathematics models for the management of public policies were presented. The first one allowed to quantify the precautionary principle, so as to decide if a project should be started or not; and the second allowed for the effective distribution of innovation incentives.

As a way to account for this complexity it is necessary to possess a wider perspective that contemplates the nano market as a process, and that its governance it is, also, part of the process. On the next chapter the problematic of a sustainable governance is analysed.

## **4 Establishing a Sustainable Nanogovernance**

### **Introduction**

As analysed in chapter one, public perception of nanotechnology moves between two extremes: those who argue that nanotechnology is the salvation for humanity and those who assimilate it to apocalyptic nightmares (Mekel, 2006). While some groups produce narratives where the imagined future is a promise of small programmable machines capable of curing diseases or clean the planet from pollution, others assert a nightmare vision where these nanomachines achieve autonomy (Highfield, 2003).

This sociotechnical network articulated its practice in interaction with its market. In recent years, nanotechnology future expectations have added economic value to investment projects, attracting new public and private investors. The nano-industrial dynamics has developed from a mere discourse in the early millennium to an economic reality today. In this respect, the second chapter explained the process of companies' creation and analysed how patents and nanoproducts become transactional goods in this market. Additionally, in order to understand its constitution, it is important to be able to account for the performative role of economic theory. The market is in a process of co-constitution, where collective hybrids of calculation perform transactions, thus strengthening the network<sup>149</sup>. The

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<sup>149</sup> In the case of the nanocarriers market it was described how they are objectified and singularized in order to become tradable.

distributed nature of these calculation agencies (humans and artefacts) indicates explicitly the importance of non-human agencies to understand the constitution process of the market. Moreover, it also elucidated that big pharmaceutical companies concentrate market power based on calculation power (fixing prices).

From the investors point of view, it is important to evaluate the economic profitability of future investments. The traditional asset valuation methodologies typically used, cannot account for complex dynamics. Consequently, there is a need for technics that contemplate this multifaceted *interaction* and its social impacts *uncertainty*, and the *irreversibility* of its investments. To account for this complexity, on the third chapter of this thesis, it is argued that the methodology that best fits these needs is an eclectic articulation of *real options* and *game theory*. A company realizes the economic value of nanotechnology at the same time that it manages its associated risk in accordance with government's regulation; leaving the remaining risk to hedge with an insurance company. Clearly, this risk management procedure does not contemplate social (or environmental) implications. This thesis argued that both, an involved society and an involved State, are required from the beginning of this process to ensure sustainability and responsibility.

On the third chapter, it was analysed how these network of controversial relations co-constitutes new risks that become part of it, adding complexity and extending it. Each State could propose a different kind of regulation policies for the nanotechnology sector. For example, on the United States, the *Converging Technologies for Improving Human Performance* (CTIHP) program proposed a manipulation of the *nanoworld* for the benefit of the government, the market and the society. The idea is to allow companies regulate themselves (*soft law*) and, after some learning process, the State will intervene with a more explicit regulation (*hard law*) (Bowman and Hodge, 2006). Unlike the American program, the European Converging Technologies for the European knowledge society (CTEKS) created the idea of a *knowledge society* guided by the precautionary principle (Klinke *et al.*, 2006). This network which was analysed and described in detail on these three chapters had a *de facto* governance, built on a day-to-day basis by uneven actors, in a constant conflict of interests (Rip, 2010). In this network,

nanomaterials are produced by multiple actor interactions, thus it is impossible to regulate it using a *top-down* approach. On the contrary, Rafols *et al* (2011) proposed a *bottom-up* regulation that takes into account both the distributed interactions on the system, and its *de facto* governance (Rip, 2010).

Diverse disciplines and institutions interact inside the network establishing expectations, many times divergent, about future benefits. Each actor constitutes its expectations in a teleological manner by introjecting interests about how the technology must develop in the future. This is a flexible rhetoric instrument that attempts to provide legitimacy to the dominant position, avoiding public debate about objectives (and values) of future developments (Schummer, 2008). Over the last years, future expectations about nanotechnology have aggregated economic value to investment projects, attracting new investors, either public and private. Furthermore, a market's *forward-looking* orientation invites to reflect about the new risks co-constituted. Accordingly, it is required a nanogovernance that contemplates this complex nanotechnology dynamics, incorporating a reflexive and deliberative citizens' compromise that will ensure its sustainability (McGrail, 2010).

The dynamics of nanotechnology is a complex, conflictive, and uncertain process. Policymakers' challenge is to align it to society's necessities, hence, this requires a *sustainable governance* to reflect and deliberate about this processes, and to envision alternatives. To do it, the perspective of this thesis is individually reflexive, and socially deliberative, promoting a sustainable, socially responsible innovative process (Rip, 2014). In addition, it is of particular interest of this thesis, to analyse this process in the case of Argentina.

To achieve this objective, this chapter divides itself on three sections. The first one analyses the conflictive process of constitution of the nanotechnology network, stressing how future expectations extend the network and the necessity of State's intervention. The second section problematizes its sustainability, analysing the constitutive process of the sociotechnical network as a socially responsible one. The last section analyses inscriptions and translations of the nanotechnology process in Argentina, and, consequently, suggests guidelines about how this



sociotechnical network can converge to a *sustainable and RRI responsible nanogovernance*.

## **4.1 Conflictive Constitution of the Sociotechnical Network**

Previous chapters presented the sociotechnical network as a conflictive constitutive process, which was analysed from three integrated perspectives: the nanotechnoscientific practice, its market, and its associated risks. This section stresses the performative role of future expectation on said process. The governmental agency is conceptualized as a collective hybrid of calculus in such a way that maintains the intuition of the State as an actor, while at the same time it takes into account its complexity and its dynamics of constitution (Passoth and Rowland, 2010). This network transforms itself in the light of a narrative of technoscientific regulation and of the translation of similar experiences.

### **4.1.1 Future Expectations**

Economic theory has sustained since the 1970s of the past century, that the expectations about the future of innovation is crucial to understand how businesses adopts new technology (Rosenberg, 1976). It aggregated decisions, in permanent interaction with public policies, sustain future expectations and reproduce them. These expectations<sup>150</sup> pressure the process of public national resource allocation (van Lente and Rip, 1998; van Lente, 1993).

These uncertain future promises are functionally important to start a new market because they assign future value to the investments, transforming it. Scientists narratives aiming to mobilize resources towards their projects, meanwhile, governments define their financing policies based on their political priorities. Some visionaries researches anticipate the political agenda and strategically formulate

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<sup>150</sup> As was analysed on the first chapter of this thesis, nanotechnological expectations coordinate innovative actors, thus shaping the future of the technology while constituting sociotechnical networks. There has been over the last years a process of professionalization and commercialization of expectations. While general promises are convincing and serve a purpose on the political speech, pushing the industry to the future, its diffuse nature blocks its correct performance. Whenever only general promises are available, entrepreneurs are reluctant to invest on concrete developments, as future demand is not articulated. Therefore, we are in the presence of a complex and controversial dynamic where investigators, businesses, governments, and NGOs interact on a network of relations from positions that are in many times conflictive among each other.

promises that are contained on the agenda (Rip *et al.*, 2010). These uncertain and general future promises receive the name of umbrella promises (Konrad, 2006). While in the beginning uncertain future promises clearly deliver a framework for the take-off of the dynamics, as it evolves, specific promises must appear in order to sustain the process. These specific ones must answer concrete demands, they are expressed in concrete terms, and they have self-imposed success measures. These promises receive in the literature the name of *promise-requirement cycle* (van Lente, 1993). It is therefore established a dual dynamic<sup>151</sup> of promises, where specific promises make reference to a concrete successful performance, of the general promise (Parandian *et al.*, 2012).

Nanotechnology market is an uncertain and complex constitutive process, so it is necessary to understand the sociotechnical network that unravels future expectations. Accordingly, governments (and lobby groups) can in conjunction tackle this matters, by building guidelines that will define public policies (Scoones *et al.*, 2007). In particular, on the nanomedical field one could mention the fundamental role carried out by the *Wellcome Trust*, not only in the financing of projects, but also as an engine of the transference network of nanotechnology in the area of medicine (NanoKTN)<sup>152</sup>.

The western hegemonic thought understands the relation between nature and society from the perspective of equilibrium (Worster, 1977; Worster, 1993). This idea is culturally rooted and was not confronted until well into the past century (Elton, 1930). On the political-economic field, under the neoclassical paradigm, policy-decision deal with the perspective of economic equilibrium. Therefore, when facing a crisis, actors search for the best public policy that returns the system to its lost equilibrium. A clear example is the reaction to the last international financial crisis, many governments promoted policies aiming a return to *equilibrium*. Hence, this perspective clearly reinforces the power of the dominant group and silences the voice of the affected people. This equilibrium is imposed by

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<sup>151</sup> This dynamic gives visibility to key controversies, for example if the success (or failure) of concrete projects are attributed correctly to certain vision of the future or it owes simply to project specific circumstances. In other words, whether the risk of failure is systemic inside the dynamic or is due to a specific problem of the project under review.

<sup>152</sup> The event *Nano4Life* (which started the 11th of February of 2009) gathered scientists, market representatives (both pharmaceuticals and spin offs), the government, and the general public.

the power and it is assumed to be the only valid path towards the future, blocking alternate paths (Scoones *et al.*, 2007).

This is critical in the case of emergent and underdeveloped countries. Developed countries export its policies, without reflecting about the local context of the recipient country. As was mentioned before, nanotechnology dynamics is a contextualized process, consequently, replicating models that were effective in developed societies can be disastrous to a developing economy (Cowen and Shenton, 1996).

These processes, in different geographical and historical contexts, expose inevitable to multiple paths that include problems and its possible solutions in a process of co-constitution. Facing this complexity, there are two ways to answer it: a descriptive way, and a constructivist way (Ison *et al.*, 1997). The first one declares that complex dynamics must be detailed in order to get a picture, then and there it will formalise (generally in a mathematical language) and, finally, the proposed model will offer solutions. On the contrary, this thesis has a constructivist proposal and involves a perspective that forces decision makers to involve itself building soft procedures that helps society. In order to answer to the complexity of this dynamics it is necessary to count with a constructivist perspective that includes political processes centred on the reflexive practice and on experimental learning (Scoones *et al.*, 2007).

Consequently, our proposal is a complex perspective that understands the constitution of the dynamics, in conjunction with an explicit normative stance, allowing for a governance that goes beyond the merely regulatory point of view. At the same time, the deliberative and reflexive proposal remarks different ways to work with politically controverted objectives that must be continuously reconsidered by groups of interest (Scoones *et al.*, 2007).

#### **4.1.2 The State as an Agency of Distributed Calculus**

The concept of State has a long history and multiple meanings. With modernity, the State has been conceptualized as an element of the social order, nowadays, the conception of the State as an actor is currently the most accepted among

policymakers<sup>153</sup> (Passoth and Rowland, 2010). Towards the end of the past century James Scott (1999) published a widely cited book where it offers an image of the State as a central agency, which creates and plans public policies aiming better quality of life. This vision of a centralized State was confronted at the beginning of the century, interpreting that it is a complex conglomerate of ideas and representations that includes bureaucratic organisms, the land, and the population (Carroll, 2006).

*The state can be understood simultaneously as an idea, a system, and a country as a complex of meanings, practices, and materialities. The state idea has become a powerful discursive formation, a cognitive structure, and assemblage of institutions; the state system has become a vast organizational apparatus that is practiced with varying degrees of coherence (and indeed incoherence) from the heads of executive agencies to the most mundane aspects of everyday life (e.g. the building police who insure the plumbing is up to code); and the state country is constituted through the materialities of land, built environment, and bodies/people, transformed by the co-productive agencies of science and government, and rendered in the new forms of techno-territory, infrastructural jurisdiction, and bio-population... (Carroll, 2009 p.592)*

Hence, instead of modelling State as a simple actor, it is important to problematize its complexity. This thesis offers an approach focused on the constitutive processes of institutions, defying the idea of the State as a monolithic actor. It is rather conceptualized as a constitutive process of a distributed network of agents<sup>154</sup> (not necessarily coordinated) (Carroll, 2006; Latour, 2000; Passoth and Rowland, 2010). Recognizing the historic process that constitutes States as a distributed agency, this thesis proposes, firstly, to conceptualize this agency as a collective hybrid of calculus. Attention is focused pragmatically on relations among actors as a way to understand the constitutive process. Using this approach has immediate implications. In the first place, no governmental entity is an actor *per se*, the action

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<sup>153</sup> The idea is born together with the neo-marxist theory between the 1960 and 1970 years, where it is proposed that the State is the group of institutions that serve class interest (Miliband, 1969; Offe and Vale, 1972). Nevertheless its existence is not a given aspect, rather it constitutes itself as the result of a certain history, it is not pre-existing (Abrams, 1988).

<sup>154</sup> Historically, thinking of the State as a network surges with Michael Foucault (1977) and is linked with his concept of power. The simplified approach sees the State as an articulate of human relations and the power is a network of forces that intertwines practices. Therefore States should not be analysed as defined instruments of power, rather they constitute themselves on the basis of interaction between existing forces (Deleuze, 1988).

of the State only acts in relation to collective hybrids that articulates both humans and non-humans agents<sup>155</sup> (Carroll, 2006).

Secondly, “...*in speaking for states, states are enacted*” (Passoth and Rowland, 2010 p.829). A network of actors transforms themselves into a collective by successive translations that allow the network to become more extended and stronger. By translation we mean every negotiation, calculus or conflict that give way to a distributed agency (Callon and Latour, 1981). In the same way that on the first chapter, following Bruno Latour (1988), the figure of Pasteur was presented as a collective hybrid that represented the network he was part, here it is proposed to think the spokesmen of the State as the representative of a population. It is important to single out that when speaking as the State, the spokesmen has a simplified image of the interactions between the population, the land, the market, and the rest of the network.

Thirdly, it is fundamental to incorporate the materiality of the distributed network that we call State, to the analysis. In facing the task of analysing the constitutive process of a sustainable nanogovernance, it is important to track the relations in the network among the distributed network, making visible the inscriptions and actions within itself. At the same time, it is necessary to explain by causal mechanisms the surge, transformation, and dissolution of hybrids within the network.

#### **4.1.2.1 Causal mechanisms**

The challenge that faces a democratic State in designing public policies requires understanding the experiences of other governments and realizes a critic evaluation that allows for collective construction adequate for its own problematic. It is a matter where what is historical and what is geographic are crucial aspects; the social processes and world location determine the design. At the same time, public policies surge from a process that involves controversies rather than a mere aggregation of the independent decisions of citizens that maximize their utility.

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155 In particular, the power that governmental actors use emerges from its own network. This was clearly exemplified on the second chapter as it was described how the power of pharmaceuticals in the nanomedicine market is not *a priori*, rather it explains on the basis of differences in the power to make calculations on the network (Passoth and Rowland, 2010).

There are currently two methodological paradigms on the social sciences that dispute with each other the search for causality. On the one hand there is the dominant tradition of quantitative analysis that postulates the use of statistic correlations as a way to find causes (MacIver, 1964) (MacIver, 1942). This methodology present grave issues for empirical research that treats macro phenomena like the Welfare State, the European integration, or regulation policies of new technologies. On the other hand there are the authors that postulate the necessity of causal mechanisms as the only valid form of scientific research (Hedström and Ylikoski, 2010).

Analysing the relations of the sociotechnical network and starting a causal reconstruction process gives birth to a historical narrative. The network in question is a socio-natural hybrid very unlike the universal laws of physics. While these are supposed to be invariant in time and space, the nano sociotechnical network relies on the historical context and the cultural space to determine the explicative process (Mayntz, 2004).

In this network, the institutions are decisive for the generation of aggregate macro effects driven by the actions of agents. The main challenge is to identify the structural and institutional characteristics that organize the actions of different actors so as to produce certain macro effect, desired by public policy.

This analysis of causal mechanisms can be used to understand how decision are taken within the State. In the first place, the actions of the State are not based on a great number of individual decisions aggregated *a posteriori*, rather one collective action preceded by a deliberative process where controversies within the network find their expression.

The technoscientific network is diverse and multiple in its development. The challenge that any State has, is to evaluate which model of governance is the most adequate to address its own problematic, forwarding an issues where the historical and geographic matters play an important role.<sup>156</sup> Therefore the only way to

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<sup>156</sup> As was exposed on the previous section, working with aggregated variables built by political consensus invalidates the use of the statistic methodologies of *correlation*. The processes identified on a causal reconstruction of a particular case can be formulated as a chain of basic mechanisms if its causal structure can be found in other cases. Most of the macro phenomena cannot be explained by be the use of one model of

evaluate governance models is to find a new historical narrative that articulates the causal mechanisms that are present on the study cases and reconstruct a narrative for the network in question. This qualitative work must contemplate the historical and geographical processes overcoming what is merely descriptive.

The challenge presents itself on different levels (national, regional, and global) that relate permanently to each other, constituting a unique historical process in concrete. To exemplify this, the work of Renate Mayntz (2007) is presented immediately. The author compares three sectors of the economy in the European context (pharmaceutic, tourism, and telecommunications) and identifies the *causal mechanisms* that link different characteristics of its multilevel governance (State, region, and global).

In particular, the pharmaceutical and the telecom sectors have many characteristics derived from the technoscientific innovation associated to them. Renate Mayntz uses its theory about causal mechanisms to explain the internal relations between levels of governance and its narrative. Control is stressed as the objective of governance, the density of rules, the prevalence of public agents, and the predominance of the national level are closely intertwined in a causal chain. The objectives of governance differ between sectors centring on different parts of the production chain. Notoriously enough, in the telecom sector the objective is to maintain the quality of the service (meaning the territorial environment of communication), while in the case of the pharmaceutical industry the security of the products is the main concern. The control of negative externalities (of risks to the public health) is a more present concern in the management of pharmaceutical products (Mayntz, 2007). The objectives also differ by level (national, regional, global). On the three sectors, the legal regulation that controls the quality of products has the support of effective sanctions mainly on the national level. At the UE level, regulation serves mainly to help create the European unique market. On

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mechanisms in particular; on the contrary, it implies a chain of different mechanisms that generate the result in conjunction. If our objective is to identify social mechanisms sufficiently specific so as to have explicative value on the particular observed results, while at the same time sufficiently general so as to apply to different empirical fields, it is necessary to explicit the range of the initial conditions that can generate different series of results through a process with a determined causal structure.

the international level, the expansion of the market beyond national and regional frontiers is the main goal (Mayntz, 2007).

The presence of active private actors gives birth to a mixed regime of governance that works as a level specific system of negotiation. In the regional and international levels this negotiation is especially complex because the representatives of the industry have to meet not one but several governments whom many times follow divergent interests. The economic structure of the sectors are subject to historical change, this reflecting on the changes its governance. For example, the prevalence of public organisms in the present governance of telecoms is the result of a tradition that starts due to the ancient public condition of the service.<sup>157</sup>

The main result is that, due to the consensus, the logic that a democratic State needs, in order to regulate technoscientific sectors, the use of quantitative methodologies based on the statistical correlations, are not appropriate. Rather it is necessary to count upon a historical narrative that connects social mechanisms for its correct use, the proposal of Renate Mainz is an example of this, in her already mentioned work on multilevel governance it is illustrated how three case studies can be useful to find the appropriate narrative by understanding the connections between the social mechanisms involved.

### **4.1.3 Nanotechnology in Europe**

The *European Technology Platform on NanoMedicine* was launched in 2005 to promote the development of nanotechnology in Europe. Its foundational document<sup>158</sup> is the expression of a vision where in the future nanotechnology will become a key enabler to achieve objectives on the medical attention sector and on general European health.<sup>159</sup>

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<sup>157</sup> At the same time in the pharmaceutical industry, the increasing power of manufacturers as a consequence of the dominant market positions of big corporations, together with the development of an ever-growing and increasingly expensive public health system, has motivated governments to reinforce the reach of their regulations on the matter. These observations show the importance of a historical perspective on the analysis of macro phenomena (Mayntz, 2007).

<sup>158</sup> Available at [ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanomedicine\\_visionpaper.pdf](ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanomedicine_visionpaper.pdf)

<sup>159</sup> At the same time the document creates a sense of urgency to compete before the advancement of other world regions. Thus strict cooperation within the industry, universities, hospitals, regulatory organisms (and financiers) and patients organizations is promoted (Frima *et al.*, 2012).



Currently, concrete results are modest and they focus on the production of nanoparticles. The promises of the future benefits from nanotechnology are late to come, and public has started to suspect that maybe they will arrive to late or even never come. This situation has clearly transformed in the last years in an obstacle to the financing of the activities. While the *general* promise that nanocarriers will dramatically help to cure several diseases, in the last years there has been a surge in works that defy this hegemonic vision. It is postulated that the improvements in efficiency have yet to be proven, and that there hasn't been enough investment to try new therapies that use nano-carriers, so notable improvements on efficiency will not be perceived (Ruenraroengsak *et al.*, 2010).

The reluctance of big pharmaceutical companies to invest on the development of nanocarriers has blocked its adoption on clinics, thus, they have not delivered to patients. New concepts and ideas that were innovative for research were not developed nor exploited in collaboration with the pharmaceutical industry. Some authors have pointed out that the cause of the delay investment is twofold. Firstly, specific promises not sufficiently proven in order to invest. Secondly, the big pharmaceutical companies are reluctant to take the risks of an innovative investment in nano-carriers such as they could continue with their traditional business, in what they are a monopoly (Parandian *et al.*, 2012).

The issue observed is that, starting from a set of promises that created general expectations about the future of nano-carriers, the absence of concrete results led the sector to a recessive state. Given this new recessive dynamic, the sociotechnical network started to focus on *specific* promises so as to promote an exit to the recessive dynamic.

This interactions had their first inscription on the year 2009 through a European Union document titled (*ETP Nanomedicine Secretariat*): *Joint European Commission/ETP nanomedicine expert report 2009: Roadmaps in nanomedicine towards 2020*<sup>160</sup>. While the document acknowledges the support given by the government and the general public remained intact, the development of nano-

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<sup>160</sup> Available at [http://www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications/091022\\_ETPN\\_Report\\_2009.pdf](http://www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications/091022_ETPN_Report_2009.pdf).

artifacts was limited acknowledging the necessity of more detailed and specific recommendations in order to achieve investments from the private sector.<sup>161</sup>

Before the attractiveness of nanotechnoscience in terms of its potential to generate a scientific revolution based on the communication and manipulation of matter, both State policies and profit-seeking actions of private companies gain in importance. The European Programme *Converging Technologies for the European knowledge society* (CTEKS) stresses the importance of State's technological policies in the creation of a knowledge based society with the ultimate objective of projecting the European Union to a leadership status in knowledge by 2010.

The European Union program subjected its experts to its ten guide-principles that focus on building a European knowledge society, these guide-principles exposed in the document *Group Mandate*, which has great interest in governance. On the other hand, the document invited experts to make visible the benefits of their research so as to legitimate the project.<sup>162</sup> At the same time, the creation of a technoscientific agenda that specifies political, social and economic goals to achieve in order to transform the European Union in a competitive group in the civil sector relative to the United States. With this, the scientific and technological objectives are subordinated to the creation of a society of knowledge.

The document recognized the plurality of agendas in the programs *Converging Technologies* of the different member countries. This agendas can focus on a myriad of focuses including national defence, human capacity enhancement, Biosystems synthesis production, application to agriculture, environmental and food applications, natural languages processing, and artificial intelligence (Nordmann, 2004). In view of this diversity of national agendas, the European document concludes that human and social sciences become "capacitators" of the

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<sup>161</sup> Possibly the most important recommendation is the emergence of translational investigations, where the investigator works in direct relation with the clinic and the patient (te Kulve and Rip, 2013).

<sup>162</sup> The document also questioned itself in what was the role of the social and cognitive sciences on the program and what effects it had on education, this is also taken by the American document. Yet unlike the American document, the European one urges experts to discover and handle ethical and social questions that emerge with the advancement of the research. It also stresses the need to benefit from innovation to attain social benefits rather than individual ones. An additional difference refers to the concern over ecological questions, evidenced under the principles of *sustainability, precaution, anticipation, and risk management*.

diverse technological systems as they provide guidance for the technoscientific agendas.

In the European proposal, the civil society appears as a fundamental actor in the governance of technoscience because it should be taken into account as the *Converging Technologies* programs are carried out and its agenda is defined. It should be noted that technoscientific advancements are not an end within itself, but rather a medium to achieve diverse governance objectives stipulated by the agendas.

## 4.2 Sustainable Nanogovernance and Responsible Innovation

After analysing the conflictive constitution of the sociotechnical nano network and describing the European proposal, this work advances on the need for the constitution of a sustainable nanogovernance in a context of socially responsible innovation. It is thus important to explicit (and operationalize) the concepts of sustainability and responsible innovation within a European context, which will then be applied to the Argentinian case.

### 4.2.1 Nanotechnological Governance

Starting from a traditional perspective, Schummer (2007) presents three possible definitions of nanotechnology. The *Real Definition* focuses on the research fields are contained under it. It presents the nanotechnologies in plural, contemplating its multidisciplinary aspect<sup>163</sup>. The *Nominal Definition* considers the nanotechnology as “... *the investigation and manipulation of material objects in the 1–100 nanometre range so as to explore novel properties and develop new devices and functionalities that essentially depend on the 1–100 nanometre range*” (Schummer, 2007 p.81)<sup>164</sup>. A third definition was introduced on 1986 by the

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<sup>163</sup> In other words, the nanotechnologies contain the latest advancements in other disciplines that incorporate nano dimensions, for example, genetic engineering, organic chemistry, electrical engineering, and microscopic research, among others.

<sup>164</sup> The problem with this definition is that it does not explicit the limits of an application field for nanotechnology that is different from any biological or engineering disciplines, because all materials in nature are formed by nano-metric structures. Therefore, this definition does not present ethical dilemmas as there is not a distinct line of research to what was previously developed. This traditional vision of governance is unfit to explain the dynamics of the nano-medical market nor its governance.

software engineer Eric Drexler, the *Teleological Definition*, which defines nanotechnology in terms of its future objectives and values, such as health, wealth, and security. This focus was inspired by science fiction and the ethical problems involved were exposed in a fictitious setting, yet it remains an interesting starting point to understand the role of future expectations on governance, as they coordinate and shape innovation, especially during process of technological transition. A nanogovernance of that expectations inscribed in its constitutive process is needed.

Instead of describing the nanogovernance as something given, this work proposes to discover relations in the distributed network and its transformation process. It is in the interest of this thesis to explain the actions and discourses that are empirically observed by performing an analysis of the nanotechnoscientific. (Latour, 1983). This nanotechnoscientific practice and its market, presented in the earlier chapters of this work clearly have a performative character on its governance.

The perspective extracted from Kornelia Konrad (Konrad, 2010) proposes the concept of governance *of and by* expectations. It captures the different ways of coordinating and regulating expectations (governance *of* expectations) and the different ways under which expectations are coordinated and shape the technological dynamics and, thus, the government (governance *by* expectations). It is interest groups (much like the already mentioned *Welcome Trust* in England, or the Nanotechnological Foundation in Argentina) the ones that supply the structures where the expectations that perform the future vision, are created and contrasted. The diverse expectations are then objectivized and singularized, thus becoming tradable goods that actors use upon their interest<sup>165</sup>. It is expectations what drives innovation, give legitimacy to the assignment of State's resources in R+D, and define the structure of social debate about this new technologies (Borup *et al.*, 2006). Different persons (or groups) with different perspectives value this incipient nanomedical market in dissimilar ways<sup>166</sup>. Therefore, there are many

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<sup>165</sup> A clear example is the IBM video which shows atoms moving in order to produce images and movement; the video does not explain to the general public that what is being seen is the mere interpretation of an instrument. The expectation of being able to control an atom allows for the creation of a *safe* nano market.

<sup>166</sup> An example of this is what occurred in a London conference a few years ago. A lecturer was emphasizing the benefits of nano-carriers for the treatment of different diseases, the lecture was backed by solid data and arguments. At the end of the lecture a young man asks: “¿Is there a solution to eliminate after the therapy the

frameworks or contexts where the actors confront each other to negotiate the future of nano-medicine, these confrontations generate dynamic political processes present throughout society in its wholeness rather than only on formal government structures (Leach *et al.*, 2007). It is important for a sustainable nanogovernance to critically analyse the social construction of the representation of *nature* in the scientific and political context (Forsyth, 2003). In this line, it is fundamental to break the separation between what is natural and what is human (social) (Latour, 2004) and accept the complexity and the disequilibria of the problem (Scoones, 1999). This focus allows for the understanding of the dynamics under study: expectations create the field and its government, then they are re-interpreted in an interactive network process. The dynamics of expectations must be in conjunction with the beginning of the discussion about *possible futures* and gradually become inscribed as that expectations are managed, thus showing greater institutionalization and long term stability within our society.

#### 4.2.2 Sustainable Nanogovernance

A detailed analysis of what we understand by sustainable is due as this is one of the most widely used terms within political speech in the past years, not always with the same connotation. In the XVIII Century, the term *sustainability* was first mentioned by Hans Carl von Carlowitz in his *Sylvicultura Oeconomica* (Carlowitz, 1713), where he lists norms for the long term management of woodlands.

In the report *Our Common Future* a definition of the term is given:

Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs (Brundtland, 1987 p.43).

Many economists stress the necessity of a strong definition<sup>167</sup> that contemplate the impossibility of substituting the necessary capital and the life cycle analysis (Goodland and Daly, 1996). Clearly, these economists defy the paradigm of

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gold nano-particles that are in my body right now?" The lecturer could not answer this question, the reference framework that she had built was completely changed.

<sup>167</sup> At the beginning of the 90' of the past century, the concept gained recognition, especially during the Rio conference in 1992. Inside the economic discipline, the neoclassical concept was hegemonic and had a wide impact in the definition of public policy. This focus was supported by the theories of capital substitution (human and natural resources) to define a (weak) concept of sustainability where consume is smoothed and crises (always due to external factors) are corrected to maintain economic equilibrium.

neoclassical growth models by incorporating new complexities from the real economy. This positions within economics and public policies were recycled by the business community, where the sustainability term has been incorporated as a corporative objective (Elkington, 1998). This general vision of sustainable development grew evermore hegemonic both within businesses and inside the public policy decision process (see for example the Kyoto protocol<sup>168</sup>).

Colloquially, *sustainability* implies the maintenance of the characteristics of a system in a general sense. This is a vital concept since many actors reach deliberation with it incorporated as true. Now, to achieve a sustainable governance of nano-medicine, an operative definition of sustainability is required. While the traditional definition takes into account the concepts of human needs (both future and present) and their limitations (technical, political, economic, and social), it does so in a static manner (Brundtland, 1987). The nano-medicine has a complex, uncertain dynamic, therefore a static approach is insufficient; the valuation of the characteristics of the system, human needs and its limitation are a permanent co-constitutive process. This dynamic is constituted from agents interacting with perspectives that could diverge<sup>169</sup>.

The question remains, how should States respond to perturbations and, how to achieve a sustainable governance of innovative technologies? The public policies must account for the duration and precedence of the perturbation, to count with a procedure for systematic response. It is proposed to understand the sustainability of the network from four dimensions that interact to operationalize public responses. If the perturbation is internal and short in duration, there is a problem of *stability*, and the re-establishing of the lost equilibrium should be promoted. If the origin is external, on the contrary, there is a need for *resilience* to answer to the perturbation. If the perturbation is long term in nature and internal, the *durability* is in line, and if external, *robustness* (Scoones *et al.*, 2007). A non-equilibrium

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<sup>168</sup> After several years since the evident failure of the proposed objectives and despite successive reformulations, neither governments, nor businesses abide the signed agreements (Berkhout, 2002).

<sup>169</sup> To understand it, in the previous chapters the nanotechnoscientific practice, the market, and its co-constituted risks were introduced. To achieve this, the interactions between agents (human and material) were followed, its discourse frontiers, economic relations, and impact (spill over) were delimited. It is therefore, necessary to incorporate the dynamic dimension of the sustainability process, to dare to a sustainable practice that is deliberately and reflexively constituted on a day-to-day basis (Vogler and Jordan, 2003).

dynamic perspective is required together with a constructivist perspective (accounting for humans and materials as agents).

The proposed focus is individually reflexive and socially deliberative, a problematic and conflictive governance of nano-medicine is proposed. Firstly, the shared problematic must be constructed by the different actors of the network: the government, the market, and fundamentally, the affected public (or the needed for medical solutions to come from nano research). After that, solutions are to be looked for in accordance with the shared problematic within a network with interests (that could be conflictive). Clearly this processes are closely intertwined: different people give birth to different conceptions of the world, this dissimilar proposed contexts of discussion negotiate to reach agreement within uncertain contexts where knowledge is incomplete (Hajer and Wagenaar, 2003; Leach *et al.*, 2007). Summarizing, the proposed perspective starts from a technical, political, and economic knowledge, and requires reflection, deliberation, and confrontation for a sustainable process.

#### **4.2.3 Socially Responsible Innovation**

The previous section presented a dynamic non-equilibrium perspective, complemented with a constructivist perspective (giving agent status to both humans and materials) in an integrated manner which allowed for a sustainable nanogovernance. This section will build on this, stressing the importance of socially responsible innovations.

While the concept of responsible innovation has been analysed by the literature since almost a decade ago (Hellstrom, 2003), its appearance on a public policy linked discourse appeared first on May 2011<sup>170</sup>. The European model of socially responsible innovation is based upon the principle of inclusion, which requires the participation of all relevant actors since the first stages of any given project; a process of co-building is proposed to ensure co-accountability. Owen, Macnaghten y Stilgoe (2012) point out three of the main characteristics of the European

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<sup>170</sup> The opening conference on the *workshop* managed by the *Directorate-General Research* (Brussels) on May 2011 in charge of Octavi Quintana, cited by Owen, Macnaghten y Stilgoe (2012).

discourse on the matter. Firstly, there is a clear emphasis on the concept of *science for society*, this meaning that the research and innovation must solve the concrete problems of society in the context of a deliberative democracy. The second characteristic of the discourse is its emphasis on *science with society*, stressing the necessity to give answers to social issues and co-build future development. Lastly, it refers to the explicit link between innovation and responsibility, claiming that each actor should embrace the latter (Owen *et al.*, 2012).

The concept of *responsible innovation and research* (RRI) emerges in the discourse of the European Community in 2011, in the framework of the *Horizon 2020* program<sup>171</sup>, which focused on the ability of Europe to face social issues. The challenge is on how to govern science and innovation<sup>172</sup> accounting for future scenarios, motivating social actors to work together in an inclusive manner. It is desirable and sought to align the process and its results with the values, necessities, and expectations of the European society. The creation of a policy driven by the necessities of society and with the participation of all actors through an inclusive participative focus is proposed (Owen *et al.*, 2012).

The European commission details six principles under which innovation is deemed responsible. Firstly, it requires all social actors – researchers, businessmen, politics, and the civil society to be compromised with the process of research and innovation. Secondly, a compromise with gender equality is acquired. Thirdly, creative learning is promoted, Europe should not only increase its number of researchers, rather to train better future actors so that they count with the right tools and knowledge, necessary to take responsibility and participate in the process of research and innovation in an integrated manner. Next, the ethical principle is postulated as a way to achieve high quality results. The fifth principle proposes that innovative processes should be transparent and accessible to the whole population in general. Lastly and summarizing what was said before, it is proposed that innovation design should be made *with and for society* (Stilgoe *et al.*, 2013). A

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<sup>171</sup> <http://ec.europa.eu/programmes/horizon2020/en/>

<sup>172</sup> Historically, innovation has produced negative impacts (or externalities in a more economical language) on society, upon which the authorities have applied more controls and proposed tightening of regulatory norms. This retrospective vision aims at mitigating the impacts of innovation when this its already impacting society (Rip, 2014). Clearly, this has severe limitations when applied to nanotechnology, where both present and future impacts are unknown and there is no previous regulatory framework that contemplates the possible scenarios.



sustainable governance of nanotechnology requires a questioning, in a public and reiterative manner, about the purposes and motivation of the new nano-products proposed. Summing up, for an innovative process to be RRI responsible it must be reflexive, anticipatory, deliberative, and receptive<sup>173</sup>.

The responsibility implies two dimensions: one moral, and one epistemic. The former justifies whether an action can be deemed responsible, the latter relates to the quality of scientific knowledge (framework, method and focus). Grunwald (2011) operationalizes the concept of responsibility by dividing it into three constitutive layers: Empirical, ethic, and epistemological. The *empirical* layer invites us to reflect upon who takes responsibility, forwarding the relation with *governability* of the field, the interested parties, the people affected, power matters and its influence. The *ethical* dimension analyses the criteria of what is deemed responsible: Responsible acting criteria, the solution of the moral conflicts of ethical reflection, the reconstruction of the ethical patterns of justification, and arguing. The *epistemological* dimension studies what is known about the respective field (opportunities, risks, etc.) and what can be said about the feasibility and quality of knowledge, uncertainty, possible future scenarios, and possible risks (Grunwald, 2011).

For an innovation to be responsible, it must fulfil regulation, efficiently communicate its project and purpose, perform an anticipatory reflection of possible applications and its social impact, and, lastly, it has to articulate mechanisms to include the actors in the process. Summarizing, a sustainable governance of nanotechnological innovations is the ability of nations, organizations, and individuals to create their own desired future in a continued manner through the generation of a continuous process that accounts for resources, processes, relations with interest's groups and its impacts. The generation of a virtuous cycle of socially responsible innovations implies the introduction of economic, social, and environmental criteria.

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<sup>173</sup> Anticipatory, because it requires to describe and analyse future impacts, be them economic, social, environmental, or other. Reflexive, because on must reflect on the ends, motivations and impacts, and frankly analyse about what is known and what is unknown (risks, and other). Deliberative, because it forces us to include different visions, purposes, motivations, and questionings, through a process of dialogue, debate, and compromise, to incorporate the perspective of all agents involved. Receptive, because it must be an inclusive and open learning process (Owen *et al.*, 2013).

### 4.3 Nanotechnology Dynamic in Argentina

In this section, the purpose is to enquire into whether the technical and scientific dynamic of nanotechnology in Argentina is sustainable and responsible. A discourse analysis of public agencies is carried out, as they turn visible conflicts into future expectations and develop a sociotechnical network in Argentina<sup>174</sup>. The trail of the applied mechanisms for public agencies to extend and strengthen the network was followed by analysing regulations and citizen participation. Afterwards, the way in which state encourages public - private partnerships to achieve to have impacts on national production network is analysed. However, this network cannot be wholly understood without incorporating citizen participation and its impacts. Closing the matter, guidelines to build sustainable and responsible nanotechnology in Argentina are proposed.

#### 4.3.1 Narratives, Expectations and Incriptions

In a local newspaper (*La Nación*) by the year 2004, Argentina's Minister of Economy leading in that moment explained:

*nosotros acabamos de lanzar un programa para el desarrollo de las nanotecnologías. Tomando contacto con centros de excelencia, identifiqué a quien dirigió las tesis de cuatro argentinos que trabajan en nanotecnología en la que es probablemente la empresa más importante del mundo en la materia, Lucent. (Caligaris, 2004 p.1)*

Clearly the Minister was conscious of the significance of establishing articulation with this business, but the implementation of a monopolistic agreement with *Lucent*, was confronted; both from political opposition and from the practice, rose up voices contrasting the agreement. The network in Argentina at that time was split apart: on one side, a small group of physics starting to research on nanotechnology and, in the other side, government establishing international connection, intended to set up networks around *Lucent* (Andrini and Figueroa, 2008).

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<sup>174</sup> In particular, the creation of Argentina Nanotechnology Foundation is a *black -boxing* process, where conflicts could be hidden under a new voice that claim to represent the network. By studying actors in the dynamics of nanomedicine in Argentina, conflicts and contradictions extending and strengthening the network will be specified.

Changing its initial vision, in the following year, the government created an organisation called *Fundación Argentina de Nanotecnología* (Nanotechnology Argentinean Foundation, FAN), with the objective of promoting the development of human resources and technicians in this area, driving future expectations on nanotechnology and producing improvement on industrial structural framework competitiveness<sup>175</sup>. It became the site where disputes between government and scientists took place.

From the beginning, the government introduced *umbrella* future expectations on the network, in order to encourage research and align industry, prospecting an efficient transfer of research results to society. By the year 2004 the government organized the first national workshop on the issue, leading to a program for *vacancy areas*, to finance the first four nanotechnology networks focused in basic research<sup>176</sup> (FAN, 2010). The Argentine-Brazilian Centre for Nanoscience and Nanotechnology was created in November of that year, pushing national policy towards internationalization. This beginning favoured during the period from 2004 to 2005 a profound discussion in the scientific community about the future guidelines. By the year 2006, the network just included nanotechnology technicians and the government, leaving aside market and society. Expectations creating processes articulated by the hegemonic role of the government, encouraging researchers to apply for public funding. Next, in 2006, a troubled interaction gave place to an inscription within the socio technical network: government disclosed the basis of the pillar *nanotechnology* on the Bicentennial National Plan on Science, Technology and Innovation, which added the participation of Argentinean industrial structural framework (SCTIP, 2006). This

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<sup>175</sup> The decree which created the FAN was criticized by specific actors. Particularly, Argentina Physics Association questioned the transparency and fairness, and requested to have participation on future schedule of the NAF. In addition, political opposition in Congress Lilia Puig de Stubrin (Radical Party) claimed executive power to clarify the role of Lucent and the financing. Draft of resolution of the Chamber of Deputies (Argentina), available on <http://www1.hcdn.gov.ar/dependencias/ccytecnologia/proy/2.844-D.-05.htm> (accessed 19/10/2012).

<sup>176</sup> The networks created, according to the government document previously mentioned:

1. Laboratory on Network for Design, Simulation and Manufacturing of Nano and Micro devices, prototypes and samples,
2. Self-organization of bio and nano-structures for information transmission on molecular structure in neurobiology and biological processes,
3. Nanoscience and Nanotechnology Argentine Network: nanostructured materials and nanosystems,
4. Nanoscience and Molecular, Supramolecular Nanotechnology and Interfaces Argentine Network.

inscription has allowed to strengthen the network, from a narrative of the controversies to extend it by adding the industrial framework.

That year, 2006, the new Minister of Economy and Production created an advisory board for the FAN established conditions for allowing firms participation. The view of a government leading expectations was soon replaced by various actors taking part in the foundation (despite of government managing it by majority). The Advisory Board was composed as follows: Alberto Lamagna (National Atomic Energy Commission), as the chief, Dr. Ernesto Julio Calvo (Ministry of Science and Technology - University of Buenos Aires) as the secretary, Dr. Joaquín Valdez (National Industrial Technology Institute), Ricardo Sagarzazu (INVAP), Dr. Roberto Carlos Salvarezza (National Scientific and Technical Research Council), BA Alberto Ridner (CONAE) and Engineer Adolfo Cerioni (National Agricultural Technology Institute) (Premici, 2007). Although changes were produced, the members continued to be exclusively highly qualified technical and scientific professionals, so it would be necessary to include the civil society for an effective governance as was mentioned in previous sections.

In that year, 2006, FAN's treasurer (who then became the national minister of Science and Innovation for production) outlined the necessity of creating patents and FAN began to be more receptive to the new market suggestions. For example, a novel procedure was adopted whereby firms could apply for funding projects all year round, allowing for immediate evaluation, which sets off the credit cycle. The market could foresight an initiative of corporative governance, contributing to the strengthening of the sociotechnical network, despite of being mainly supported by public funds (Premici, 2007).

As this set of promises lost strength in the absence of transference, the government called for a new kind of funding program, asking researchers to be explicit about which are the possible benefits in a clear reference to priorities detailed in the *Argentina Strategic Areas Program*<sup>177</sup>. In 2007, the government organized the first

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<sup>177</sup> It was asked to research groups applying for funding projects to be linked to related civil organizations, as to show the social aim of the project. In the same way, they were asked to have arranges with firms' potential users of the results of the projects, in order to show also its orientation on production. Although this procedure improved last experience, mechanisms to control the transfer of results did not exist. (Andrini and Figueroa, 2008).

congress of the sector, *Nanomercosur 2007*, and researchers were invited as well as the business and the general public. With its byword *Science, enterprise and environment*, the government intended to push a greater transfer from research groups to the entrepreneurs' network. However, governance guidelines just reached a corporative level, leaving aside the decision process to civil society.

By 2008, the Secretary of Science and Technology was upgraded to Ministry, hence, nanotechnology acquired fundamental importance as a technology platform<sup>178</sup>. Additionally, the already important focus on the medical applications of nanotechnology within the sectorial public policies was specially stressed by the government in 2009. The National Scientific Information Directorate and the National Studies Directorate of Ministry of Science, Technology and Production Innovation carried out a mapping of nanotechnology's sociotechnical network. In 2010, the FAN started the diffusion of a document named *Who is who in Nanotechnology in Argentina*. This text stressed some guidelines<sup>179</sup> for a nanotechnology policy.

These guidelines can be summarised in the following manner:

*La tendencia es a que no haya nanoproductos, sino los productos clásicos con importantes mejoras por la intervención de la Nanotecnología (FAN, 2010 p.13).*

In 2010, the public financing of nanotechnology was increased. An example was the call for funding called *FS NANO 2010* by the Argentine Sectorial Fund (FONARSEC), in which public-private partnerships projects were reinforced<sup>180</sup>. Another example was the *Technology on Nanotechnology Sectorial Funds 2010*, which supported associative projects working on providing new technology platforms and promoting innovation on diverse production areas. The supporting consisted of non-refundable contributions, allowing for an execution period of up to four years, and requiring 20% of the total cost as a counterparty contribution

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<sup>178</sup> In the National Strategic Plan for Science, Technology and Innovation named "Bicentenario" (2006-2010) it is explicitly set nanotechnology as a priority, and the National Agency for Science and Technology supported more than 160 projects in the period 2000-2008.

<sup>179</sup> The Secretary set out a national positioning in applied research that focused on the final stages of life cycle of products that primarily would have social impacts and would encourage local network of productive sectors. She emphasized the aim of growing stronger the research groups in nanotechnology, by using appropriate facilities and highly qualified human resources. In particular, there was special interest in replacing traditional monodisciplinary treatment of degrees by interdisciplinary technical-scientific communities of practice (FAN, 2010).

<sup>180</sup> Details and analysis of presentations are commented in this chapter.

(Secretaría de Planeamiento y Políticas en Ciencia Tecnología e Innovación Productiva, 2013). These calls represent an intervention of the Government on the sociotechnical network encouraging partnerships and innovation to extent and strengthen it.

The FAN this year also pushed for the integration of nanotechnology research with industry. This was done by coordinating meetings and creating an incubator space, thus pursuing the aim of extending and strengthening the network with a heterodox market perspective (in which the State was both the source and moderator of the economy). A study carried on during 2011 related to the technology transfer between research groups and the business network, it concluded that there was a need of special professionals that articulate the transfer relationships. These professionals should have a fluent dialogue with researchers and at same time be able to handle commercial language. Due to a lack of professionals with this profile, the government supported a postgraduate course in technology management for managers training (or linkers) in local universities (Vila Seoane, 2011; Vila Seoane and Rodríguez, 2012).

In parallel, international linkages were established within the network. The Binational Argentine-Brazilian Nanoscience and Nanotechnology Centre was created with the objective of organizing events, enabling spaces of academic knowledge, promoting cooperation among groups in both countries<sup>181</sup>. Also the Argentine-European Union Science, Technology and Innovation Connection Office (ABEST) was created to motivate research groups, entrepreneurs and SMEs to participate in the EU 6th and 7th framework programs (in which nanotechnology was a priority)<sup>182</sup>. In addition there was an agreement for students exchange with the United States, and initiatives were signed up for cooperation with European universities (Aydogan-Duda, 2012). According to FAN (2010), the commercial performance of nanotechnology in Argentina was lower than in the rest of the world, so it was imperative to spread this technology to firms and it was implemented an heterogeneous incubation system for firms<sup>183</sup>.

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<sup>181</sup> For more information see the center web page <http://cabnn.mincyt.gov.ar>

<sup>182</sup> For more information see the web page <http://www.abest.mincyt.gov.ar>

<sup>183</sup> First, the format *spin off* was given in order to satisfy the demand of business projects that aimed to develop and commercialize nano products. Second, professionals who have ideas but no space nor management

Regarding medical applications, there was a survey in 2011 that concluded that *human health* was the nanotechnology application mostly identified by firms (FAN, 2012)<sup>184</sup>. The dynamics of the network were translated and signed up in a document written by the minister during 2012, and it was there emphasized that innovations should be applied to production and pursue social objectives. The text had performative pretensions on nanotechnology dynamics in Argentina.

#### ***4.3.1.1 Key inscription in the network: the government explicit its productive and social objectives***

As mentioned on Chapter 1, *inscriptions* play a fundamental role in understanding the dynamics and relationships in the network. In particular, in this section it is analysed a document in which it is exposed public policy, and it became immediately the promoter of future expectations.

In April 2012, the minister of Science, Technology and Productive innovation, Lino Barañao, detailed technical and scientific policy of the government in a conference in the Biology and Experimental Medicine Institute (Barañao, 2012). In that document, he gave an idea of the conflictive dynamic and translated the presidential policy of social inclusion within the network. It was also emphasized also that investment in science and technology is realized by the society, so the technical science should have as an objective the attention of social needs:

*Y nosotros creemos que la ciencia y la tecnología pueden contribuir efectivamente a crear trabajo de calidad, basado en la educación y en la investigación...Estamos convencidos de que avanzar hacia una economía basada en el conocimiento es la manera más democrática de llegar a una sociedad más justa (Barañao, 2012 p.340-341).*

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capacity were looking for, and for them a training and monitoring program was given. Finally, having had conscious of the fuzzy frontiers between institutions, it was looked innovation under “open” paradigm (Chesbrough, 2003).

<sup>184</sup> Within private environ two corporations were marked and a university working on nanomedicine. Firstly, the Lab Gador, a company from private ownership which had links to foreign companies, universities and the government. The Lab worked on research and development of pharmaceutical products and was oriented towards the reduction of toxicity in delivering, using nanotechnology technics. Secondly, the company Eriochem, which had links to public financing organisms, was focused on manufacture of injectable products for use in oncology based on biodegradable polymers synthesized (at nanoscale). Finally, Austral University specialized in design and manufacture of nanobiosensors. From the public sphere several institutions were noted in this field. The National Atomic Energy Commission - Constituyentes Atomic Center (CNEA - CAC) had been working on design and manufacture of nanobiosensors. The National University of Quilmes (UNQUI) – Strategy design of targeting of drugs lab (LDTD) had its focus on nanomedical research based on approved drugs and on the design of nanosystems of delivery of drugs. The National University of Entre Ríos (UNER) – Faculty of Engineering developed nanomaterials for biomedical applications.

To reach that objective, the government focused on research-business and state-business associations in a context of improvements on infrastructure and interdisciplinary dialogue on the network. Particularly, it is emphasized the need of supporting technology SMEs development in order to generate quality work. The minister invited to set aside the prejudice that assumes that scientists are just seeking the benefit of mankind and employers have no qualms to increase their own wealth whatsoever. The nanotechnology sociotechnical network in Argentina contains these actors and a leading role of the State is need in order to make them fulfil their social responsibility.

Putting techno science at the service of social problems requires quality and innovation in laboratories with an interdisciplinary practice. The main obstacle to this is the mono-disciplinary character of advisory committees and most journals, driving the work within a single field. The evaluation of the interdisciplinary and transfer to society activities is difficult to do, this is a problem since the State seeks to encourage techno-scientific innovation and the articulation in the production activity of technology based firms.

Nanotechnology is one of the three platforms that the government<sup>185</sup> would connect to four priority sectors. Health, would make nanomedicine had a crucial role in planning public technological policies. The minister emphasized that the translational medicine<sup>186</sup>, and expected to strengthen laboratories and hospital practice articulation, by creating units of translational medicine<sup>187</sup>. This policy extended the network by including the users.

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<sup>185</sup> The government *general expectation* is that scientific system (universities and laboratories) receive funds to produce knowledge to transfer to firms that convert it in goods consumed by users. To sustain that promise it is developing concrete experiences on interaction between firms. An example, is the company SANOFI that counts with a drug for Chagas, but it needs scientists to prove the efficiency of its compounds library. This experience is carrying on Rosario City with support from the company and the government.

<sup>186</sup> At international level, in 2008, the *National Science Foundation* organized the workshop “Re-Engineering Basic and Clinical Research to Catalyze Translational Nanoscience”. Based on this discussion and on literature review, the article “Translational nanomedicine: status assessment and opportunities” explores scientific, economics, and social aspects, linked nanomedical initiatives and its future perspectives (Murday *et al.*, 2009).

<sup>187</sup> An example is Ballestrini hospital (La Matanza), where an engineering school have place, with the objective of developing drugs for testing in the hospital.



### 4.3.2 Collective Hybrids as Agents of Change

The mentioned inscription expressed the new future expectation of the government, encouraging new associations that articulate public and private, and pursue the enhancement of the productive network with a social inclusive impact. These associations applied to several calls for funding as *hybrid collectives* performing as agents of change and building the network. In this section four Argentine hybrid collectives are described and analysed.

#### 4.3.2.1 POTENCIAR

Project POTENCIAR was a collective plan (hybrid) that articulated government, academic, enterprise and international actors. Doctors, chemists, physicists, biologists, and engineers (among others) participated in the project, exemplifying the interdisciplinary nature of nanomedicine, and constituting a small socio-technical network within itself. The objective was developed and the project commercialized biomedical implants based on advanced technology, which were built with nanomaterials and nano-coatings.

The socio-technical network was constituted around one material: the nano-coating with *ultrananocrystalline diamond* (UNCD). Having this material and the skills and networks from the rest of institutional participants, the project proposed to develop four products. First, the encapsulation of magnets that may be located in the outer wall of the eye to attract supermagnetic particles, and injected into the eye to paste the detached retina. Second, the optimization of prosthesis of hip and knee made by INVAP. Third, coating drain valves in treating glaucoma. Finally, using sheets from UNCD to coat implantable devices *Bio-Electro-Mechanical-Systems* (bioMEMS) in the eye for drug delivery. The socio-technical network was compounded of seven institutional participants<sup>188</sup>.

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<sup>188</sup> First, the INTEC (Institute for technology development for chemical industry), which was joined to adviser ANL (*Argonne National Laboratory* de USA), spread out scientific and technological knowledge from the UNCD material in form of a thin film that had the international patent. Second, to develop bioMEMS devices, it had had the support of the INTEC/Bioengineering in the Faculty of Engineering, University of Entre Ríos (Argentina). The network also was compounded of prosthesis manufacturers, INVAP, a company dedicated to the design and construction of complex technological systems, 30 years long in Argentina. For the production of magnetic nanoparticles and coating of magnets, the network had the Atomic Center Bariloche (CAB), Río Negro, Argentina. For the manufacturing of electric cardiac pacemaker, the network had the support of the company FLECHA. By the way, University of Buenos Aires (UBA), thought the Pathology

The sociotechnical network proposed would acquire the legal figure of public consortium (University of Buenos Aires, University of Entre Ríos and CONICET) and private consortium (FLECHA, INVAP and the Austral University Hospital). This network had specific articulations between nodes. First, the design group of the *BioMEMS/NEMS* and *biopackaging* (INTEC/Bioengineering-University of Entre Ríos, UNER) was complemented with groups of characterization, manufacturing, in nanotechnology and synthesis of films of UNCD. In fact, it was planned to install a plasma induced by microwaves MPCVD in the INTEC in conjunction with training of its own staff by ANL. A second articulation was established between the enterprises INVAP and Flecha. In conjunction these companies, would provide the design and manufacturing of prosthesis of hip and knee, and implantable devices, of electro cardiac pacemaker for applications respectively, and these should interact with INTEC on the nano encapsulation of the products. Also, INVAP would be responsible for evaluation of the tribological response of hip implants and the wear of the films of encapsulation. The third complementarity, was between the design and manufacturer group of magnetic nano particles on charge on Atomic Center Bariloche (CAB) and the staff of the INTEC/Bioengineering (UNER) with the objective of coating magnets with UNCD. Finally the articulation between the group of UBA and Austral Hospital for doing the preclinic and clinic phases respectively.

The project translates the future dynamics necessary to inscript a text in stages that allow for the consolidation of the public financing. Planning had seven stages, each one with its own objectives, a proposed dynamic of work and cost<sup>189</sup>. A fundamental issue that would perform the dynamic was what the future market expected of the project.

The project had a monopoly in the market since the patent was current. Once it expires the market would go in competence and all competitors would have access to the product without paying patent rights. The patent was expected for two projects of the group: the use of films of UNCD to encapsulate magnets that would

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department developed the preclinical for biocompatibility and the evaluation of intracorporeal implants. Finally, for developing the clinical phase of the project it has been available Austral Hospital (HA).

<sup>189</sup> In the appendix stages of POTENCIAR are detailed.

allow to paste the detached retina and the use of films as drain valves in the treatment of glaucoma. Commercially, these products could be sold directly to the public or by acquiring the rights of use of the patent<sup>190</sup>.

#### **4.3.2.2 Nanotechnology and Dengue**

Nowadays the manufacturing of clothes in the world is low tech but of high volume, so application of nanotechnology to the sector is attractive. The use of nanotechnology has raised in the last years, allowing to have multifunctional textiles: antibacterial, UV protection, easy cleaning, water and stains repellent. In this moment the innovation process has the focus on areas where the new principles are combined with traditional processes in order to achieve multifunctional products conserving its properties (Patra and Gouda, 2013).

Textile industry in Argentina has a definite production chain. First, the manufacturing process of fibres, in which nanotechnology provides properties as UV rays absorption, antibacterial properties, water repellent, among others. These composite fibres at nanoscale are produced by dispersing nano sized materials in a fibre matrix. Second, the process of yarn, in which carbon nanotubes are used to release fragrances easily or allow the clothing change its colour upon request (Ngo and Van de Voorde, 2014).

One of the applications with greater social impact that could have Argentina is the capacity of manufacturing clothing that allow be mosquitoes repellent in order to prevent dengue in the country. The sickness is caused by the *flavivirus* transmitted to humans by the bite of the mosquito *Aedes aegypti*, the main vector in Southern America. Infection with any of four different virus serotypes leads to flu symptoms that specifically immunizes the subject against serotype in question, but the immunity is only partially against other viruses. Moreover, a second infection with another serotype triggers more severe haemorrhagic disease, with high risk of death (Estrada-Franco and Craig, 1995).

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<sup>190</sup> Other products: Coating of prosthesis of hip and knee, use of films of UNCD for BioMEMS devices to implant in the eye that have no patent awarded. These projects could commercialize just as projects.

Since 1916<sup>191</sup> there were no indigenous cases until 1997, the year the dengue was restored in Argentina. This remains a matter of concern for the health of the population due to the presence of the vector in high densities in several places, low levels of immunity in the human population, the presence of endemic virus in neighbouring countries and the widespread presence of poor living conditions , including lack of drinking water, in areas where it is more likely that the virus would be entered (Aviles *et al.*, 1999).

Citronella oil is well established in the industry as an excellent mosquito repellent for use on clothing or curtains. Recently, the use of nanotechnology allows a slower release of oils, thus prolonging the time during which the fragrance is effective. In particular, the insect repellent is a nanoemulsion encapsulated of citronella oil, which is prepared by high pressure homogenization creating stable droplets that increase oil retention and reduce the release rate. Thus, the time is prolonged protection against mosquitoes (Sakulku *et al.*, 2009; Specos *et al.*, 2010).

In Argentina, through the Science, Technology and Productive Innovation Ministry, government supported different projects. Particularly, it raises interest the project *Nanotechnology for functional Textiles*, which pursue to develop clothing that could repel insects, directed towards the vector of dengue and had the support of National Diagnostic and research in endemic and epidemic Centre. The project consists of a public-private association made by the National Institute of Industrial Technology (INTI), the Institute for Research in Science and Technology of Materials (INTEMA), the company Guilford Argentina and the Pro Work Foundation. The project has received 3 million pesos in the period 2011-2014 (Abraham *et al.*, 2012; Tallone, 2015).

Clearly this project presents itself as a socio-technical that responsibly innovates to solve a social problematic, while streamlining the textile market.

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<sup>191</sup> Historically, several cases of dengue were reported in Argentina in the early twentieth century. In 1916, an epidemic with 15,000 reported cases occurred in the province of Entre Rios, in eastern Argentina. None of these patients had bleeding symptoms.

#### 4.3.2.3 *The case of arsenic*

In several regions of Argentina drinking water has high levels of arsenic. The national government estimates that more than 3 million Argentines are exposed to concentrations above 0.05 milligrams per liter of drinking water<sup>192</sup>, which is a serious public health problem<sup>193</sup> (Swiecky, 2006). The most affected provinces are Buenos Aires, Chaco, Córdoba, Formosa, Jujuy, La Pampa, La Rioja, Mendoza, Santa Fe, Santiago del Estero, San Luis, Salta, San Juan and Tucuman and treatment technologies currently used to purify water are primarily by filtration (reverse osmosis) (Auge *et al.*, 2010).

In particular Argentine Government define the sickness known as *Regional Chronic Endemic hydroarsenicism* (HACRE) like

*...la enfermedad producida por el consumo de arsénico a través del agua y los alimentos. Esta enfermedad se caracteriza por presentar lesiones en la piel y alteraciones sistémicas cancerosas y no cancerosas, luego de un período variable de exposición a concentraciones mayores de 10 ppb en agua de consumo diario. Estudios recientes han demostrado que la población infantil expuesta durante el período prenatal y posnatal puede tener menor desempeño neurológico que los niños no expuestos. (Swiecky, 2006)*

The residents of the 9 de Julio shanty town submitted in July 2010 an injunction against the water company, ABSA, by high levels of arsenic in the water supply. While in the first instance the Argentinian Justice forced the company to deliver cans of drinking water to the population, the company appealed the measure. On December 2, 2014 the Supreme Court of Argentina issued a ruling where the need for a solution of the problem arises and emphasized that

*... el acceso al agua potable incide directamente sobre la vida y la salud de las personas, razón por la cual debe ser tutelado por los jueces. (Corte Suprema de Justicia de Argentina, 2014 p.2)*

Nanotechnology offers new possibilities for purification of water in the affected areas, namely, a new nano-oxide methodology used to remove arsenic from drinking water by adsorption. By using the oxide nanoscale, the contact surface is increased, so hundredfold arsenic is captured. In particular studies suggest that a

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<sup>192</sup> 0,05mg/L present a serious problem, since the limit accepted by the World Health Organization is 0.01 mg/L 0.01 mg/L.

<sup>193</sup> Hay evidencia epidemiológica que indica que la ingestión de arsénico inorgánico de manera prolongada provoca hiperqueratosis palmo plantar, cuyo síntoma principal es la pigmentación de la piel y la aparición de callosidades en las palmas de las extremidades (Castro de Esparza, 2004).

dose of between 200 and 500 milligrams of nano-rust allows to effectively treat one liter of water (Rocco, 2011). Moreover, some studies compare the efficiency of different commercial products in absorbing arsenic (Bang *et al.*, 2011).

While these new methods of purification are very efficient at removing arsenic from water, there is a need for specific research around possible environmental risks and health risks from the use of nanoparticles, it is necessary to analyse whether the increased reactivity has no toxic effects in humans or the environment.

#### **4.3.2.4 Biocatalysts with nanotubes**

The chemical industry is one of the most important and most developed economic sector at global level. It is continuously introducing new technologies, allowing access to new market segments and products in analytical and synthetic applications. In particular, bio catalysis is booming, as applications of catalytic enzymes in the industry are rising rapidly<sup>194</sup> (Schmid *et al.*, 2002).

An Argentine association of public organisms, which developed biocatalysts based on a biological nanotubes support is an example of how different actors and resources can articulate to achieve registration of a patent at a national and international level, being of great potential for industry. The association involves researchers from national universities, University of Tucumán, and University of Santiago del Estero. In this line, the project was forwarded by the joint efforts from university researchers and Leloir Institute Foundation researchers. The articulation was managed by *Inis Biotech*, the exclusive representative for commercialization and industrialization of inventions and developments outcomes of the Leloir Institute. Finally, Conicet was involved also in the work group as funder, supporting salaries and infrastructure. Thus the group had four pillars that were articulated, allowed to register a patent for the new product in 2012.

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<sup>194</sup> To improve the level of efficiency of the catalysts, hard research work in industry has been made directed to optimize the carrier materials structure. In this sense, nanomaterials provide the right balance between the efficiency of the biocatalysts (surface, mass transfer resistance) and the amount of enzyme consumed in the process. Plenty of highly stable and efficient catalysts systems have been developed in nanotechnology labs, which function like molecular machines to catalyze multiple reactions, making a rapid change in biocatalysts industry (Wang, 2006). Due to biocatalysts functioning is based on the activity of the enzyme, it has advantages over the chemical treatments, because they are environmental respectful, work more efficiently, and reduce risk to operators (Bayona, 2014).

By the year 2012 the group presented, in fact, the national patent of the product named LYSOZYME AMYLOID FIBERS, SOLID CARRIER, BIOCATALYST AND PROCESSES (P20120102400), being owned by the four organizations, and leaving evidence of the inventors. In January 2014 the same group registered the patent at international system as WO2014006560 (A2)<sup>195</sup>.

Applications of this product are diverse: it allows the possibility of cleanly synthesize biodiesel, and oil modification. Ecological synthesis from vegetable oil allows to obtain fatty acids esters (biodiesel)<sup>196</sup>, which is useful for a society which needs clean energy generation mechanisms. The possibility of modifying the properties of lipids allows for more added value from oils and from cheaper fats, which is interesting for the food and pharmaceutical industries. Already there are enterprises interested in the patent, such as biocatalysts manufacturers, biofuels producers and oil processors (Bayona, 2014). Clearly, we have actors in the market that are related to each other (or can be) with the patent (or its owners) to start a process of co-constitution that allows to draw sustainable energy and to make food industry processes more efficient.

Beyond the analysis of the hybrid collectives, the following section intends to face the challenge of proposing a sustainable nanotechnology governance in Argentina. As was mentioned earlier, the European Union has incorporated the concept of *Responsible Research and Innovation* (RRI) in the narrative of the regulatory documents and in the financing of nanotechnologies. There are some articles and reports that analyse the impact of RRI in the nanotechnology sociotechnical networks in OECD countries. However, there is a lack of attention on the application in the developing countries, particular Argentina.

### **4.3.3 The Constitution of the Nano Network in Argentina**

In this section, the dynamic of nanotechnology in Argentina is studied under the perspective of RRI, and in the context of a sustainable nanotechnology governance.

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<sup>195</sup> To see details of the patent follow this link:

[http://worldwide.espacenet.com/publicationDetails/biblio?FT=D&date=20140109&DB=EPODOC&locale=en\\_EP&CC=WO&NR=2014006560A2&KC=A2&ND=2](http://worldwide.espacenet.com/publicationDetails/biblio?FT=D&date=20140109&DB=EPODOC&locale=en_EP&CC=WO&NR=2014006560A2&KC=A2&ND=2)

<sup>196</sup> Glycerol in the process is also obtained as a byproduct.

It was argued that the sociotechnical network in Argentina was neither responsible nor sustainable, in accordance with the perspective exposed in the previous section. In the following paragraphs, the aspects that sustain this argumentation are presented, and the six principles proposed are analysed.

In first place, RRI requires to be in touch with a commitment with all social actors: researchers, entrepreneurs, responsible politicians, civil society in the process of research and innovation. As mentioned earlier (4.2.1.), in 2004 the Argentine government began the building process of the nanotechnology industry by an arrangement with the company *Lucent*, trying to give direction from an unconsulted vision, imposed by the state. The call in 2010 to offer financing is a clear example in which the Argentine government intended to lead the evolution of the network, giving partial participation to the private actors and the researchers on the constitution of the practice. The minister in charge of the innovation policies explained that public funding should have production objectives, as well as social ones<sup>197</sup> and asked the engagement of all parts. However, in this new narrative, just experts the private firms and related governmental agencies were involved in the decision making process. The stakeholders of society are summoned on the discourse, yet they are marginalized from the decision process.

Secondly the RRI asks a commitment with gender equality. Nanotechnology is a new interdisciplinary techno-scientific domain; with different profiles converging on it. Professionals in physics, engineering and chemistry have been by a long time mostly man in Argentine and in the world, while in biology or medicine it has been identifying a rise in women in the last years. This nanotechnology network at work presents new possibilities and problems to the woman's role (Meng and Shapira, 2011). In this early stage in Argentina, it is important to achieve a greater degree of gender diversity within the laboratories, the companies and in government organisms, in order to achieve a sustainable nanogovernance. The government

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<sup>197</sup> In the article "*Nanotechnological approaches against Chagas disease*" authors set the issue of the illness chagas in America, responsible for over 50.000 deaths annually (chronic chagas cardiomyopathy) and they realized a critic revision on the few research works published in the last 20 years in this issue. This manifested the difficulties to the design of drugs are more effective. In particular, the nano systems of administration of drugs (nanoDDS) are useful to selectively deliver the drug into an intracellularly level, but the preclinical research in Chagas should wide to achieve enhancement the possibilities of a clinic application (Romero and Morilla, 2010).



should give the example on this matter. It is a problem for the responsible sustainability of the dynamic that the board of the FAN was composed of seven men and just two women.

Thirdly, being responsible includes carrying on a continuously creative learning process. Argentina not only has to rise its number of researchers, it is also necessary to train future actors so that they have better knowledge and tools to fully participate and assume responsibility in innovative process. One of the challenges is to prepare the new managers of nanotechnology enterprises. In this respect, The Faculty of Economic Sciences, of the University of Buenos Aires, began in 2014 the *Master in Management of Technology based Enterprises* with the objective of training professionals to be managers. This postgraduate programme has the support of private firms and public organisms for its funding. In the curricula, it is included a seminar on nanotechnology industry where it is presented a general vision and current art practice, and they set out the expected trends on diverse environments; national, regional and global. The second challenge is to achieve that schools and universities be set out a creative learning process that allows citizens to become better informed and have capability, and to understand the nanotechnology innovative processes.

Fourth, regardless of the legal and regulatory aspects in Argentina, RRI responsible innovation requires ensuring social relevance and acceptability of the results arising from the sociotechnical network. A study conducted in 2011 concluded that the Argentine nano research groups see the importance of regulatory issues and there are concerns about the toxicity of the materials involved. Although researchers in laboratories take precautions, it is necessary to ensure that when the materials are in contact with the users, they are not harmful to health, in this particular, there is an obvious emphasis on the nanomedical area. The study has two positions: some believe that the precautionary principle can control risks, others emphasize the need for a new regulation that addresses innovation and require social inclusion (Vila Seoane, 2011).

With regard to the assessment of nanotechnology risks in Argentina, they are

*abordando los temas de riesgos e impactos potenciales de la nanotecnología, articulando esfuerzos con los organismos regulatorios y, particularmente, formando parte del Comité de Nanotecnologías del IRAM. Este Comité es el encargado de la revisión y las recomendaciones relacionadas a: “Hoja de Datos de Seguridad” y “Metodología para la Evaluación del Riesgo de Nanomateriales”, entre otros. FAN (2014)*

This risk analysis performed by the Argentine state is performed on the basis of the international regulations of the *International Organization for Standardization (ISO)*<sup>198</sup>, which have been studied and included in local regulation without the participation of society. The contribution of users is crucial for the process to be responsible, it is previously required to inform the population to give all the necessary knowledge on the regulatory review. A key aspect of nanotechnology risks is to protect workers who are exposed to them, but also allowing them to participate and opine. In Argentina, the Superintendence of Occupational Risks<sup>199</sup> created in 2014 the *Nanotechnology Observatory and Workers' Health* for the purpose of disseminating information on the prevention of occupational risks in production environments or in the context of the analysis of nanomaterials. On the website of the observatory<sup>200</sup> it is provided information on nanomaterials and recommendations for safe work and analysis and discussion of qualitative methods of bands control, which are currently used in various countries in nanotechnology risk assessment. Seldom is meant from the title an intention to foster inclusive participation, in fact the project simply disseminates information to third parties without problematizing it and without analysing the relevance to Argentine workers.

With regard to medical applications, the provision 1719/2011 of the National Administration of Drugs, Food and Medical Technology (ANMAT) of the Argentine government, created the Program to Support Innovation in Medicines and Health Products (ANMAT, 2011). In its preamble, it makes clear that the new

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<sup>198</sup> This international organization is developing standards for nanotechnology industry primarily through the work of the Technical Committee 229, formed in 2005. The same has 34 participants and 14 observer countries, in joint with linking organisms including officials of the Union European and it consists of six working groups that address the following areas: terminology and nomenclature, measurement and characterization, environmental health and safety, material specifications, consumer and social issues, and a group that works on sustainable development.

<sup>199</sup> This organism was created by Law No. 24,557, and it depends on the Ministry of Social Security of the Ministry of Labor, Employment and Social Security of Argentina. Its purpose is to ensure the effective implementation of the right to health and safety of workers.

<sup>200</sup> <http://www.srt.gob.ar/index.php/prevencion/observatorio-de-nanotecnologia>

generations of drugs (among them, the nanomedical drugs <sup>201</sup>) require new approaches. The main objective of the program is to have a platform developed to accompany the R&D projects that articulate the interest of public health<sup>202</sup>. Although the idea is in line RRI, the website has only one built from 2011 to 2014 project, clearly scope is extremely limited and does not guarantee an innovative process responsible.

Fifth, RRI proposes that innovative processes are transparent and accessible to the general population. As previously mentioned in this thesis, to be responsible, the results and problems of nano must be clear and understandable. The Argentine government, through the ANF carries out various initiatives in this direction, but they have proven insufficient to ensure a responsible process.

For example, the *Nanotechnology for Industry and Society* initiative holds regular meetings to link scientists with academic and industrial sectors, allowing it to share the opportunities offered by nanotechnology to improve products and processes, to increase competitiveness and to expand penetration market. It encourages scientists to articulate with business chambers, professional associations and government agencies interested in promoting new technologies. A positive aspect consists on that it is being carried out in various parts of the country and allows for the dissemination nanotechnology and its applications. The problem is that, judging by the respective programs of activities, has a *top-down* approach to the subject, does not have effective mechanisms to include society in the discussion and in the proposal of innovation.

Also, with the aim of publicizing the risks and impacts of nanotechnology, coordination efforts are made with regulatory agencies under the "Nano-sustainable" program, promoting contact between government agencies,

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<sup>201</sup> In particular, procedures that articulate the participation of various actors are established, in the field to allow inquiries regarding technical-scientific or regulatory issues. At the end of October 2012 there was only one project that entered the Faculty of Pharmacy and Biochemistry, University of Buenos Aires led by Professor Dr. Alejandro Sosnik. The initial target population are HIV-infected children, so it is a project with high social impact and constitutes an innovation as it is the first aqueous solution EFV developed for oral administration to children.

<sup>202</sup> See project entered in the webpage of ANMAT: [http://www.anmat.gov.ar/apoyo\\_innovacion/aprobados/NUEVA%20FORMULACION%20PEDIATRICA%20DE%20EFAVIRENZ%20Se%20plantea%20el%20estudio%20en%20un%20voluntario%20en%20Julio%20de%202011.asp](http://www.anmat.gov.ar/apoyo_innovacion/aprobados/NUEVA%20FORMULACION%20PEDIATRICA%20DE%20EFAVIRENZ%20Se%20plantea%20el%20estudio%20en%20un%20voluntario%20en%20Julio%20de%202011.asp) (consultado 10 diciembre 2014).

researchers and industry. While the proposal is interesting on the surface, in fact, they only spread international work and mention the work of the National Institute of Standardization (IRAM).

Another initiative was prompted FAN *Nano U*<sup>203</sup> program. This was proposed to make sensible university students about the importance of nanotechnology, challenges and implications in the field of labour and production. On the one hand, introductory activities will be held in different technical courses at universities across the country. On the other hand, a course is taught online, creating a space for interaction between participants and experts. The reality is that it only has a virtual course, which although interesting, it is clearly insufficient and too general on nanotechnology.

In line with the previous initiative, but with the aim to sensitize primary and secondary students, he boosted FAN *nanotechnologists for a Day*<sup>204</sup> program. The same is planned to disseminate and publicize nanotechnology in secondary level educational institutions in Argentina. Specifically, a contest where students must enter the world of nanotechnology and develop a working form is made aware of and sensitive. These initiatives are very good but isolated, not articulated with the network, so they do not allow extending it by including students and teachers in the process.

Finally, regarding the fifth principle, the State organized the First Conference on "Nanotechnology and Sustainability", organized by the ANF, under the auspices of leading companies in nanotechnology and national universities<sup>205</sup>, aimed to define an agenda linked the regulation of the sector which cover environmental aspects and human health (including the entire life cycle of products). It was pursued contribute to the development of regulatory standards and industry standards, while it sought to promote communication between government and industry researchers to strengthen the technical and scientific basis in order to develop new regulatory frameworks. For it is explicitly made reference to what has

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<sup>203</sup> <http://www.fan.org.ar/nanou/>

<sup>204</sup> <http://www.fan.org.ar/acciones/nanotecnologos-por-un-dia>

<sup>205</sup> View event details <http://www.mincyt.gov.ar/noticias/comenzaron-las-jornadas-nanotecnologia-y-sustentabilidad-nuevos-desafios-regulatorios-4690>

been done in this area both in Europe and in the United States. The presentations potential risks of nanotechnology on human health and the environment, and to propose some good practices in laboratories and in industry were analysed. Also in the round tables of the regulation the situation in Argentina was discussed and emphasized the importance of establishing a regulatory framework specific Argentine nanotechnology should be articulated with other international initiatives.

Finally, as a way of unifying the first five principles, RRI requires that nanotechnology is developed *with and for* the Argentina society. While the FAN incubated companies and makes direct actions to bring the industry to work for society, it does not give society participation in policy decisions, also it neither opens public debate, nor a critical analysis of ongoing developments, nor opinion of users is contemplated is performed<sup>206</sup>. This has drawn criticism from various sectors of society in Argentina. In response thereto and in order to involve the whole society in the governance process, the ANMAT created a public consultation process on the web<sup>207</sup>. But until October 2014 he was empty: no consultation projects entered, which clearly states that cash is not functioning.

As discussed in this section is clear that in Argentina there is now a *de facto* governance, built on a day-to-day business, government, researchers and society with conflicting interests. It is the action of the Argentine state which sets the context of the political debate and control dynamics with a techno-scientific *top-down* policy, as it has explained. Clearly not responsible for failing to fulfil the six RRI principles and is not sustainable.

#### **4.3.4 Proposals for a Sustainable Nanogovernance**

To propose a new nano sustainable governance for Argentina was crucial to understand the existing *de facto* governance, which was made explicit above. From the current sociotechnical network described, it is proposed to incorporate a

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<sup>206</sup> Moreover, while the government organizes events in various cities titled *Nanotechnology for the industry and society* (e.g. the event developed the August 22, 2014, entitled *Nanotechnology for Industry and Society in Rosario*), a detailed analysis reveals that the agenda are events where scientific experts spread mainly nanotechnology.

<sup>207</sup> It is a tool for both the general public and professionals and institutions that can review issues under the competence of the body (the tool is available at [http://opinion\\_publica.anmat.gov.ar/](http://opinion_publica.anmat.gov.ar/), retrieved December 10, 2014). In it, the user can consult the draft of interest and send your opinion to be analyzed.

*bottom-up* management to conceptualize society-material interaction<sup>208</sup>. Clearly, what is intended to regulate co-constitutes its governance process.

From the operational point of view, and for effective public policy, this thesis proposes to use quantitative tools developed in chapter three. The first allows, from the numbers of the public-private project in question, consider the uncertainty of the future benefit of an innovative project and that the State consider the advisability of carrying out or not. If you choose to carry it out, the second tool helps the Government to assess what is the most efficient way to do it. In general, and as developed in chapter three, what is proposed is to combine purchase contracts with commitment to cost-share funding to create hybrid contracts, in order to have the benefits that can give an initial sum to projects (*Push*) but also have an innovative project award for socially responsible way and achieved a solution to a public problem (*Pull*). Such tools allow state the main funder of the controversial article network and make efficient projects to extend and strengthen the socio-technical network, giving sustainability decisions.

In addition, to improve the dynamics of the nanogovernance constitution, it is required to change certain practices of the Argentine State that expand, from the scientific vision *for* society. Four strategies are proposed: (a) to incorporate the use of multi-criteria evaluation systems, (b) to achieve transparency of future scenarios knowing what we must do today (*Backcasting*), (c) to perform sensitivity analysis of the scenarios analysed and, finally, (d) to make a clear and precise mapping report of the various possible reference frames.

An interesting proposal that would promote citizen participation and that the State should intensify in the future is the creation of the ANMAT observatory by the disposition 907/2011 ANMAT(2011). It is an instrument that aims to articulate the government agency with the various health institutions and citizens. It seeks to identify social problems to guide the regulator through a participatory and inclusive

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<sup>208</sup> The political ecology analyzes the relations between the environment, politics and society, emphasizing inequality, hierarchical relationships and asymmetries of power in relationships. Some authors assume that capitalism is the root cause of environmental degradation (from the domination of nature) (Vogel, 1995). On the other hand, others politics contemplates in its many forms, incorporating civil resistance movements (Paulson *et al.*, 2003), individual relations and local cultural experiences (Peet and Watts, 1996; Bryant and Bailey, 1997). These perspectives see politics as a process of struggle from the bottom up, emphasizing the local.

system. Clearly this observatory democratizes the process of making the ANMAT<sup>209</sup> it actively involves the citizenry. To give voice to professionals, meetings are held<sup>210</sup> with associations representing a particular medical specialty where industry demands are identified and cooperation activities are developed.

In summary, currently the nano dynamic driven and regulated by the Argentine State is established from a top-down approach. While the State clearly has a nanotechnology policy that aims to support the production structure to social inclusion, no participation is given to different actors in the process, neither the possible future scenarios are anticipated nor there is place for a reflective-deliberative process that allows for sustainability. To be socially responsible, anticipation, reflection, discussion and confrontation are required, between different views and interpretations, to give sustainability, so as to go beyond the hegemonic perspective on what the problems are and what is the way forward<sup>211</sup>. It is important to accept (and publicize) that knowledge of the dangers is incomplete without forcing the concept of actuarial (or engineering) risk, adopting strategies that respond adaptively to the system and do not try to stabilize it.

## Chapter Conclusion

This chapter has argued that Argentina has not a sustainable nano-governance. While Argentina nanotech policy is geared towards productive innovation with social inclusion, it has a *top-down* government approach, excluding society from the decision process. There is a need for public policies that foster an anticipative, thoughtful, deliberative and responsive dynamic. Anticipation requires a detailed analysis of all future, economic and social or environmental impacts. Government funding should be accompanied by a multiple impact analysis of each of nanotech

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<sup>209</sup> The Observatory is structured in two levels. The first works directly with the actors, analyzing their vision and perspectives on every topic under discussion. Participatory diagnosis forums where citizens meet with officials to assess ANMAT action lines of the body are made.

<sup>210</sup> In the framework of the Observatory, the ANMAT and Argentina Association of Pharmacy and Industrial Biochemistry (SAFYBI) organized a specific seminar nanotechnology during the month of October 2012 where specific nano applications for the pharmaceutical industry were analyzed. They gathered at the event as researchers, technical, commercial, regulatory and general public directors. In particular, between national speakers highlighted Dr. Alejandro Sosnik (who, as noted, has a bill introduced in the ANMAT about HIV drug for children), Dr. Dante Beltramo (CONICET) and Dr. Eder Romero (who heads a research group at the University of Quilmes on nanomedicine).

<sup>211</sup> Thus multiple potential targets (and values) are recognized from a politicized perspective of sustainability.

projects. For example, in the case referred to the development of mosquito repellent clothing it is essential to examine in advance how this innovation could change labour relations in the economy and what will be its environmental impact.

Reflexivity requires an introspective analysis of the motivations and promotes honest discussions about what is known and what is not, on nanotechnology. It does not give rise to much debate. The government risk analysis is only based on international standards. This perspective can be effective in certain industrialized countries, but its application can be detrimental to Argentina society. More research is needed in the Argentine context in order to have a responsible public policy.

The release requires the inclusion of the perspectives of the stakeholders through open dialogue forums. The *top-down* approach only considers the government vision of nanotechnology. In this thesis it has been argued that it is important to give greater participation to the Congress and universities. Public interaction between agents with opposing views will help find a sustainable management that is socially efficient.

Receptivity encourages open and inclusive process of learning. In this sense, this thesis is the importance of developing databases updated with information on all kinds of nanotechnology projects (whether successful or not). This will allow researchers to learn from past experiences and propose best practices for the future.

In addressing the problem of nano sustainable governance, it has been taken into account that it is a discipline that combines basic science and technology, as a hybrid of both, poses a challenging dynamic. It is argued, therefore, that the specific features of industrial dynamics presented in chapter two has strong implications for regulation because they limit and intervene to shape the technology used. The key issue is that nanomaterials are not in general consumer products are intermediate goods that are used by other industries, which complicates the issue.

To achieve the goal of this chapter has presented the innovative dynamic nano described in the first three chapters as a socio-technical network in the process of incorporation. First, we analysed how nanotechnology actors coordinate



expectations innovating, shaping a complex and controversial dynamics, where researchers, companies, governments and NGOs interact in a network of relationships from positions often conflict with each other. Then the state role is problematized in the process of establishing the network and is interpreted as a distributed computing agency. Now, to understand how this dynamic is perceived by the community in various ways, various surveys that incorporate the voice of users were analysed. Then it has been critically analysed the North American and European models of regulation, arguing that only the precautionary principle is compatible with sustainable governance. It was argued that the nanomedicine market is a dynamic non-equilibrium system, in contrast to the orthodox approach hegemonic "market equilibrium", which allows a clear conclusion on the need for sustainable governance to account for the complexity of economic systems involved.

From the above, it was analysed the Argentinian case. Initially it described the public policy of the national government, which has prioritized technology and productive innovation in its action plan. Also it is shown in the public discourse a move from the old funding for basic science towards financing technologies applied to social and economic impact. This has been enrolled in the speech of the Minister of Innovation in 2012. Then four recent experiences of collective hybrids acting as agents of change, public-private partnerships with clear objectives to innovate in the context nano we analysed and plans. They are seeking to solve specific social and sensitive issues for society Argentina. Then the dynamic nano critically analysed in Argentina since the proposal of responsible innovation. While the government promotes this initiative, various problems and issues to resolve for a more responsible nanotechnology dynamic point.

## Conclusion

The term Nanotechnoscience denotes an investigation method in which scientific and technical practices converge, being an engineering way of making science. Researchers in this field work in a complex context between Quantum and Classical Theory, using eclectic principles for producing new materials. Even though Nanotechnoscience has disciplinary antecedents in Physics and Chemistry, it involves different laboratory practices. On the one hand, new lines of inquiry are being exponentially unfolded, following a divergent research dynamics, where new hypothesis are generated from established paradigms. On the other hand, new patterns of complementarity arise such as development processes, new ways of using existing infrastructure and the institutional cooperation among different types of actors.

This interaction amongst researchers, materials and devices in laboratories leads to a *nanotechnoscientific* practice. Human actors have different basic training. Hence they tend to select different theories when for solving a similar problem. However, all of them agree in choosing the same measuring instruments and the same computers programs. These devices have become a common reference in the scientific community and they have acquired great relevance in the dynamic of the practice itself. Furthermore, due to the need of scientific group members of getting government funds, the narratives about the past of similar technologies and the future expectations, play a major role for understanding interactions. This nanotechnoscientific practice spreads leading to a sociotechnical network articulated with its own dynamics. This resulting market has become a coordination mechanism through which the agents maximize their interests by establishing economic calculations and solving their disagreements defining prices according to their economic power.

This sociotechnoscientific network have promoted great expectations, and co-creates emergent risks in its own dynamic. Confronting with this incredible potential and its uncertain risks, policymakers have an important role to play in regulating this process. Firstly, they have to promote that companies work together with States, the scientific community and society, from the very beginning of the

innovation process. Secondly, they have to do the job under specific legal context, proposing actions aiming to reach an efficient sustainable governance of the industry. Given this problematic context, this doctoral thesis has argued (see chapter four) that it is necessary to build a *sustainable and a RRI responsible* process that co-creates a nanotechnology dynamic *with* and *for* the society. In addition, this chapter has argued that the application of this perspective to the *de facto* governance that is operating in the Argentinean nanotechnological field, would contribute to the development of a network constituted *with* and *for* society.

This nanotechnological dynamics could be traced in every sector of the economy, providing many solutions to social problems. One possible application would be to eradicate the global hunger, increasing the agricultural and farming productivity. Another contribution has been the use of nanoproducts in textiles, which has contributed to the development of new functionalities. Moreover, a variety of nano-innovations has been developed to create new and more efficient energy generation sources while achieving a reduction of pollution. The use of nanomembranes allows increasing the leaching methods effectiveness. Regarding to the pollution of the cities, nanotechnology has also offered more efficient ways to monitor air pollution. Moreover, nanomedicine has been a particularly rich field wherein variety of artefacts and products with high impact on human health have been developed. This is an interdisciplinary sector which has united biology, material science and engineering. Its impact has been noticeable on several medical fields such as diagnosis, drugs management, and regenerative medicine. It has been particularly emphasized the importance of nanotechnology when facing Alzheimer's disease and many problems related to diabetes.

This successful spread over variety of sectors has been forged by a sociotechnic network capable of claiming public and private funds for its research and production. This has opened up a public debate about the role of public policies in estimating costs of nanotechoscientific projects and, more importantly, to assess their potentials risks and social impacts. This thesis has examined the constitution processes and the dynamics of the nanotechnoscientific network and developed original valuation tools of its investment projects. To understand the constitution process of this network and its effects on several social areas, this thesis employed

the ANT perspective articulated with the *risk society* approach. In this way, it combined an observation of human and non-human interaction on the micro level with a theoretical interest in the organization of society. This nanotechnoscientific narrative and its social impact were examined, in such a way that it critically expanded traditional actuarial, financial and engineering approaches. Additionally, these investments in this sector have *sunk costs* and uncertain future benefits, hence, efficient valuation tools are needed for public management.

This thesis has shown that the nanotechnoscientific network is built every day by the interaction of agents with conflicting interests, which is why public policies are essential to promote a sustainable governance. Even though the complex nanodynamics emerged in post-industrialised countries, it has spread throughout emerging countries and it has acquired particular characteristics. This thesis scrutinised the Argentine context, where public institutions together with technological companies have configured a sociotechnical network which is rapidly expanding. Since 2006, the Argentinean government has been promoting the development of the nanotechnology market, encouraging public-private partnerships to produce a positive impact on different economic sectors. The State has promoted and funded several projects in key areas of scientific innovation which have promised to produce socially inclusive future benefits.

This thesis demarcated and articulated the concepts of *sustainable nanogovernance* and *RRI responsible* (section 4.2), and demonstrated that the Argentinean nanotechnology network is regulated by a *de facto* governance (section 4.3). Even though State's policies intervene the productive sector aiming at addressing social inclusion needs (*for the society*), the State has a *top-down* perspective on policy making that excludes society from the different stages of the decision-making process. In response to this finding, this thesis proposed the incorporation of a *bottom-up* public management approach that integrates the recognition of the centrality of the interactions between society and nature (materials) - allowing policy makers to work *with* society. On the one hand, this thesis contributes to unfold the complex layers and interactions that feature the nanotechnoscientific network by looking at the practice, the market, the associated risks, the State and the users, and the conflicting interests and expectations that are being mobilised in

its constitution. On the other hand, this thesis contributed to the theory of technological governance theory by integrating the socio-material perspective offered by ANT theory.

This thesis argued (section 4.3.3) that Argentina only relies on a *de facto* governance. To overcome this situation, this thesis formulated five proposals (section 4.3.4) that would contribute to move towards a sustainable governance and a responsible RRI. Firstly, it argued that it is necessary that the State evaluates research and investment projects incorporating variety of criteria addressing the complexities and layers the nanotechnoscientific practice and its effects involves. Secondly, it argued that it is important to imagine socially desirable future scenarios and perform backward induction analysis in order to define what it is necessary to do today (known in the specialised literature as *backcasting*). Thirdly, it argued that technicians have to consider users' perceptions, opinions and sensibility towards risks when defining their research and production processes and goals. This thesis also highlighted the need to produce clear reports and to map the different interpretative frameworks mobilised by different stakeholders. In addition to this, this thesis offered evaluative quantitative tools to assess nano investments and projects that could be used by policy makers and investors (see chapter three). This toolkit addresses conflicting interests and provides clues to make efficient decisions that would both expand and strengthen the network and contribute to social sustainability.

In order to have a nanodynamics sustainable and socially RRI responsible, this thesis also demonstrated that policymaking needs to be transformed. It has to abandon its underpinning conception of technology *for* society in favour of a new perspective of research *with and for* society – in line with the European approach to scientific, technological and social risks. In so doing, this thesis has deployed a critical analysis of the current regulatory frameworks operating in the US and in continental Europe (see section 4.2.1). In post-industrial Western countries, the neoclassical theory has been the hegemonic paradigm to understand economic investments and decisions. In this perspective, decisions must be oriented towards the establishment of an *equilibrium*. Hence, innovations should be regulated by the system in such ways that the equilibrium would be restored. This operates as an

imposition from above (from those with power) denying alternative ways to integrate the complex nanotechnology dynamics. This reinforces the power of dominant groups and silences society. To unpack policy making in the US and continental Europe, this thesis has drawn upon new narratives and made visible controversies and conflicting interests.

Nano regulatory frameworks have been exported by these economic zones and have been also borrowed by emergent countries such as Argentina. Both policy transfer and borrowing have neglected the complexities and interactions that configure the network in each country. As a critical response to these approaches, this thesis demonstrated that the nanodynamics is a historically and geographically situated process. Hence, policy making needs to recognise and address the particularities of regional, national and local scenarios. The traditional perspective on economic investments – that revolves around the notion of *equilibrium* and only offers actuarial assessment tools- was not only criticised in this thesis, but it has also been expanded including previously neglected social and environmental.

There are different perspectives on how to deal with this complexity. A dominant approach has argued that the State needs to statically regulate the nano dynamics. The metaphor of taking a picture of the nano dynamics in order to regulate captures the core of this conception. This thesis, on the contrary, proposed a constructive path analysis, wherein all agents take part in a collaborative network, which encompass reflexive and deliberative political processes (see section 4.1). Stakeholder groups (such as the already mentioned *Welcome Trust* in England, or the Nanotechnology Foundation in Argentina) have configured embryonic networks forging and disputing expectations about technology while also performing and constituting themselves. Different expectations have been converted into tradable goods, which has prompted innovators to legitimate their claims for state funding in Research and Technology and shaped the public debate on new technologies. Variety of interpretative frameworks confront in diverse scenarios in a continuous attempt to expand the sociotechnical network, generating dynamic political processes that are present not only in the bureaucratic, administrative and political structures of the state but also in wider society. In this context, this thesis described the nanodynamics unmasking relations and

transformational processes within the network, departing from analysis centred on the role of experts and of regulatory frameworks.

This thesis also argued that nanotechnology governance must be *sustainable*. In so doing, it critically explored the traditional approach on governance highlighting its static perspective. Moreover, even though the traditional definition of sustainability encompasses an interest on social impacts; it neglects the complex and uncertain constitution processes involved and the interactions between society and nature. It is argued that the traditional static approach should be overcome to achieve a dynamic sustainability. The static approach to economic decision making is still dominant both amongst companies and policy makers. This thesis, on the contrary, argued that only a governance that includes reflection, deliberation and confrontation of different points of view and interpretations could shape a sustainable nano dynamics.

To have a sustainable governance, this thesis argued that policymakers have to deal with *disturbances* with in-depth knowledge of their characteristics and deploy different responses to diverse scenarios. This thesis identified four potential scenarios and featured the corresponding optimal responses. Firstly, to deal with an internal disturbance of short duration, policy makers have to re-establish the lost equilibrium. Secondly, to deal with an external disturbance of short duration, policy makers need to be *resilient*. Thirdly, to address an internal disturbance of long duration, policy makers need to deploy *durable* strategies. Finally, to tackle an external disturbance of long duration; the efficient answer should be *robust*.

This analysis has forged the concept of sustainable dynamics, in line with the European perspective “*innovation and responsible research*” (RRI). This RRI approach emerged in 2011, strengthening The European Union’s ability to deal with the new social challenges that the nano sociotechnical network has brought about. This perspective has sought to align the innovation process and its expected benefits with the values, necessities and expectations of the European society. The European Union has demanded that the socioscientific network should be immersed in an anticipatory, reflexive, deliberative and receptive governance. *Anticipation* requires detailed studies of the economic, social and environmental

carried by nano investments, research and projects. In other words, state funding also has to be accompanied by a sophisticated social impact analysis. *Reflexivity* demands introversion about the motivations of launching new products on the market as well as honest debates around the available public information. *Deliberation* involves taking seriously users' points of view by engaging them in permanent dialogue. These public interactions between contradictories points of view will help to find new and more efficient ways to shape a sustainable and a responsible RRI management. Lastly, *receptivity* should be encouraged by creating open and inclusive learning situations focusing on the features, risks and challenges of the production of nanomaterials and products. This thesis highlighted the importance of developing updated databases containing information on every nanotechnological project.

The definition of *sustainable and RRI responsible governance* has required the articulation of diverse theoretical and methodological perspectives. This has allowed to unpack the nano dynamics in Argentina. Firstly, this study offered a better understanding of the nanotechnoscientific practice drawing upon ANT. This approach has made visible not only the sociotechnical network that underpins it but also its constitution process that takes place in the laboratory and in wider society. This thesis favoured the use of the term *Nanotechnoscience* due to its ability to capture the convergence of scientific and technical aspects of the investigation, expressing an engineering approach to science. Scientists, objects and materials interact defining a practice in laboratories. They are also part of an eclectic framework, where narratives of the past and of the future perform network interactions. This study, in line with its first specific objective, examined how laboratory practice is constituted through interactions amongst humans and devices.

Moreover, this thesis analysed nano-industrial dynamics as an extension of its scientific practice. It re-elaborated a market theory where interactions are co-produced alongside the generation of new risks. In so doing, this analysis focused on the design of markets and the role of experimentation, conceptualizing agents as collectives' hybrids with unequal economic power. Additionally, this thesis illustrates the application of this approach to the nano market through an



examination of the construction processes of nanocarriers market, tracing controversies amongst researchers who register patents, investors who seek for profitability, pharmaceuticals that try to impose its authority in the market, a State that tries to regulate them, doctors who obey protocols, and users who seek a cure of to an illness. This was carried out by scrutinising the transactions between hybrid agents (humans and artefacts), which interact in a constant process of co-creation. Moreover, this thesis depicted how agents' computing power is built, and how it reflects its own ability to impose prices. In this sense –responding to its second specific objective- it looked at how the laboratory practice is constituted as a sociotechnical network and a market.

The nano dynamics have co-constituted risks not only for human beings but also for the environment. Making visible these effects configured another contribution of this thesis, which critically studied the dominant approach to risk management. To unpack how the market works, it showed the associated risks of the production of five nanomaterials, demonstrating that experts need to engage with other bodies of knowledge if they want to assess the implementation and effects on the innovations. In so doing, it examined risk measurements in the production of five nanomaterials. Consequently, this thesis recommended that risk management methodologies should be changed in order to tackle current challenges.

This thesis also contributes to the field of knowledge production on Science, Technology and Society. As part of its explanatory framework, this analysis integrated not only actors' incentives but also mathematical models. In this way, this study payed attention not only to the complex features of the sociotechnical network but also to the construction of algorithms that would contribute to perform and extend it. In order to understand how actors make decisions, this study examined traditional investment valuation methodologies and highlighted their limits in uncertain and strategic contexts. It proposed the use of the *real option* methodology instead. In so doing, it offered four economic models that could be used by States to value incentives in the network. The first model formalised the valuation of combined investments, contemplating the development stages, and the uncertainty over raw material prices and life cycle. A second model allows valuating nanotechnological investment projects accounting for multiple sources

of uncertainty. The third model mathematically operationalized the precautionary principle. The last model includes the State intervention in the market. Subsidies can be granted at the beginning of the project (*push*), or can be promised if the project succeeds (*pull*). The elaboration of these models is linked to the fourth specific aim, which proposed elaborating evaluative tools of investment projects in the nanotechnological market of combined investments contemplating the required cooperation among the actors of the market, the market's uncertainty and the state regulations and incentives.

Although this thesis contributes to the understanding of the problematic of the governance process in Argentina, this research has not succeeded in answering all its guiding questions. Next, some of the remaining tasks will be identified and will serve as refined questions for future investigations.

This thesis, in line with its first specific objective, analysed different visions about nanotechnology, and described the constitution of a new discipline that works using an eclectic theoretical frame. In this perspective, the narratives of the past and future expectations perform the nanotechnoscientific practice as a *search regime*. Although it contributed to a better understanding of the nanotechnology practice, it is essential to broaden its scope by doing more intense qualitative research in laboratories in order to contrast these new findings with those of this thesis. This is crucial to interpret agents' interactions and the meanings attach to them. At the beginning of this investigation, the nano research centres were few with similar characteristics. However, during the last few years, the number of actors has rapidly increased as well as the heterogeneity amongst them.

With regard to the second specific aim, this thesis examined how the technoscientific practice has been extended through a construction process of a sociotechnical network and creating its own market. Departing from the nanodynamics transforming power, both the constitution of the nano conveyors market and the economic power asymmetries were explained. Moreover, this study described the process by which new companies were created and identified the valuation methodologies used to assess nano assets. In relation to this objective, it would be relevant to carry out qualitative research to further explore the

constitution of *spin-offs* in order to deepen the available knowledge on how companies are constituted in this sector. This kind of approach would offer relevant information that could inform policy making.

With regard to the third specific objective, although this thesis showed that the nano network simultaneously co-constitutes risks while performing itself, it would be valuable to deepen the analysis of the insurance companies' role, particularly in the Argentine context. These companies are the only ones that effectively moderate innovations, due to their awareness that risks involved in the production of a nanoproduct could potentially lead to their bankruptcy.

The fourth specific aim of this research guided the elaboration of an evaluation model of nanotechnological investment projects encompassing the required cooperation among the actors, the uncertainty in the market and the State regulations. Though four quantitative tools were successfully developed for orienting the public decision making process, it would be very useful to also develop an open source software. In this sense, another line of work could be the creation and implementation of a digital dashboard that articulates these four tools in such ways that could be used by a variety of users, such as policymakers, entrepreneurs, scientists and lay public.

The fifth specific aim of this thesis unpacked the role of the regulatory framework in the configuration of a market, focusing in particular on the role of the State. Even though the European regulatory framework was analysed, the future exploration of other normative matrixes would allow its critical assessment. To do so, it would be relevant to carry out comparative studies of different national public policies, especially in Latin-America to map alternative solutions that could improve, challenge or redefine the proposed sustainable and RRI responsible agenda.

The last specific objective of this study explored the nanotechnoscientific dynamic in Argentina and argued that it has a *de facto* governance. As a response to this scenario, it has been argued that a sustainable and RRI responsible governance should be promoted instead. Registers, translations and black boxes are analysed in the constitution process of the sociotechnical network in Argentina. Proposals of how this new network could be steered towards a nano sustainable governance

has also been made. However, the political scenario has recently changed. After the general elections held in November 2015, an opposition party coalition will be in office from December onwards. Despite ideological differences with the current political power in office, the elected government has announced that current Science and Technological policies would be continue. This changing scenario demands more research on the particularities that nano governance would assume under this new government.

Recent literature on standardization processes of the nanotechnological sector offers new lines of inquiry (Malsch *et al.*, 2015; Queipo *et al.*, 2015; Zi y Blind, 2015). Over the last few years, the European Community has focused on standardization processes as a key to successfully link research along with global market. Hence, it has launched the nanoSTAIR project. It has built a platform that contributes to convert scientific knowledge into industrial documents, name as *Standardization, Innovation and Research* (STAIR). Particularly, the purpose of the nanoSTAIR initiative has been the promotion of a sustainable process which helps to transfer academic knowledge into standards accepted at global level, which would contribute to increase the productivity of relevant European companies. This initiative has been welcomed by researchers and the market (López de Ipiña *et al.*, 2015). This development should guide new research that critically examines its relevance to the Argentinean context.

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## Apéndice

### Etapas del proyecto POTENCIAR

La primera etapa es el desarrollo de las obras de infraestructura. Esta etapa incluye los costos de acondicionamiento de las instalaciones en las que se desarrollan los productos. El sistema MPCVD se instala en el Instituto de Desarrollo Tecnológico para la Industria Química (INTEC), el mismo provee la capacidad de nanoencapsulado de dispositivos implantables en el cuerpo humano. Esta instalación requiere de un acondicionamiento de INTEC, así como también el acondicionamiento de diversas áreas de la UBA.

La segunda etapa contempla la adquisición de equipamiento. Primeramente, la compra del sistema MPCVD permite la elaboración del material principal que está presente en cada producto, el UNCD. Asimismo, para el recubrimiento de prótesis de caderas se necesita equipamiento, adquisición de literatura y revisión bibliográfica, el diseño y fabricación de dispositivos y máquinas de ensayo, el desarrollo de herramientas de cálculo y modelado, la instalación de máquinas y la puesta en marcha de las mismas. Dado que las prótesis de caderas son adquiridas a través del INVAP y es en este lugar donde se realizan los estudios tribológicos del producto creado, se necesita la adquisición de equipamiento para el laboratorio que esté ubicado en el lugar.

En la tercera etapa se propone lograr el diseño, fabricación y caracterización de microchip para liberación controlada de medicamentos. Para esto se utiliza las facilidades de laboratorio de micro-nanofabricación de ANL/INTEC. Allí se utiliza un Sputtering de magnetrón y CVD para hacer crecer un piezoléctrico que sirva para romper la membrana permitiendo la liberación del medicamento, así como para mejorar la biocompatibilidad del implante.

En la cuarta etapa se realizan las pruebas de funcionamiento de las prótesis y en especial las pruebas tribológicas<sup>212</sup> de las mismas. A través de estas pruebas se

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<sup>212</sup> La tribología es el estudio de la fricción, del desgaste y de la lubricación que tienen lugar durante el contacto entre superficies sólidas en movimiento.

estudia el comportamiento de recubrimientos de UNCD; esto forma parte del estudio de la tribología.

En la quinta etapa se realizan los estudios en laboratorios con animales como con células. Asimismo, se incluyen las aprobaciones de las entidades regulatorias, el diseño y generación de documentos y protocolos, los gastos en movilidad desde los centros de complementariedades. En el uso de nanopartículas para el desprendimiento de retina se procede, en esta etapa, a un completo y detallado diseño de protocolo según las normativas de: *International Conference on Harmonisation (ICH)*, *Good Clinical Practice (GCP)* y Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT). Se elabora el Manual de Investigador (este permite servir de guía y da a conocer cada uno de los procedimientos necesarios para la ejecución del proyecto), consentimiento informado (procedimiento médico formal, el cual tiene como objetivo el respeto hacia la libertad que tienen los pacientes como individuos), diseño de CRF, carpeta de investigador, carpeta regulatoria. Junto a todo esto se incluye la presentación en el ANMAT y Provincia de Buenos Aires la aprobación de pruebas clínicas Fase I y el sometimiento de la aprobación del protocolo según IRB del centro (comité de ética). Con respecto a la microválvula para el tratamiento de glaucoma, en esta etapa se deberían diseñar los estudios preclínicos.

Para esta etapa pre-clínica, es necesario conseguir nuevas fuentes de financiamiento, teniendo un dispositivo funcionando y validado exploratoriamente siguiendo las guías de la normativa vigente en los organismos regulatorios como la FDA (USA), los más estrictos. Llegado a este punto se puede interesar al capital privado y hacer eficiente la transferencia de acciones o licencia.

Los directivos del proyecto, al momento de presentarse al pedido de financiamiento público inicial, ya habían realizado varias reuniones con interesados (un inversor de riesgo extranjero, un inversor ángel nacional, una empresa farmacéutica nacional, una empresa de dispositivo farmacéutico nacional).

En el caso de dispositivos para la liberación de drogas los objetivos son los mismos en cuanto al tipo de dispositivo que se trate; en el caso de dispositivo de UNCD y silicio y el dispositivo de polímero se realizarán estudios in vivo, es decir estudios

en conejos en el laboratorio de la UBA para evaluar la eficacia de liberación de la droga, el efecto terapéutico y seguridad. En el recubrimiento de prótesis de caderas con UNCD se analiza la influencia de parámetros de fabricación en la reproducibilidad de resultados, el análisis de los parámetros de fabricación en la reproducibilidad de los resultados, la influencia de las tolerancias en los materiales, en las tolerancias dimensionales y otros parámetros de fabricación.

En la sexta etapa se realizan los estudios clínicos fase I. En esta etapa se tiene en cuenta las condiciones legales de protección intelectual de los productos desarrollados, diseño de documentos y contratos de conocimientos, gastos en cirugías y extracción de implantes, actividades clínicas (internaciones), estudios clínicos complementarios y calificación del personal para el desarrollo de esta etapa. Como ya fue aclarado el lugar del desarrollo de esta etapa es el Hospital Austral.

En el uso de nanopartículas para el desprendimiento de retina se pretende el desarrollo de la técnica quirúrgica. Para esto se realizan tareas de entrenamiento a grupos de profesionales, con la necesidad de capacitar a cirujanos con entrenamiento en la técnica, el reclutamiento de pacientes en los que se va a realizar la prueba, el seguimiento de los mismos, la elaboración de las estadísticas y el informe final. En la microválvula para el tratamiento de glaucoma se realizarían los estudios clínicos correspondientes. En relación a los dispositivos para el transporte de medicamentos se propone realizar estudios clínicos bajo las normas GCP, siguiendo los requisitos FDA y ANMAT. Asimismo, se llevan a cabo estudio de fase I en seres humanos para evaluar la eficacia y seguridad. El recubrimiento de prótesis de caderas con UNCD plantea la necesidad de probar el producto en personas para ver su eficacia.

Es necesario tener en cuenta que esta fase puede subdividirse en tres sub-fases: la fase A en la cual la prueba se realiza en un pequeño grupo de gente en general totalmente sana, básicamente para obtener el grado de toxicidad y seguridad que posee el producto en seres humanos. En la fase B es administrado a un grupo mayor de personas a los cuales se los considera como aquellos que necesitan el producto para una posterior recuperación, esto se hace para ver el grado de eficacia y la

información adicional en cuanto a seguridad que posee el mismo. En la etapa C la administración es masiva, por el hecho de encontrar un grado de eficacia definitivo y las posibles reacciones adversas. Una vez que se ha completado la fase clínica y se puede llegar a considerar que el producto podrá llegar a ser aprobada, se presentará ante el organismo necesario para su posterior aprobación.

Con esta subdivisión se realiza la aclaración de que tanto el uso de nanopartículas para el desprendimiento de retina como los dispositivos para la eliminación de medicamentos terminarán en la sub-etapa B, ya que los mismos no tienen la posibilidad de ser probados en forma masiva. Es decir que se patentan no como productos sino como proyectos, en cambio los otros dos productos si serán lanzados al mercado para ser comercializados.

La última etapa es la de patentamiento. El mismo se realiza por persona, como podrá observarse el recubrimiento de prótesis de caderas con UNCD y los dispositivos para la eliminación de medicamentos aun no tienen patente. Mientras que el uso de nanopartículas para el desprendimiento de retina y la microválvula para el tratamiento de glaucoma tienen en vías sus patentes. A partir de esta etapa se podrá considerar la existencia de una octava etapa relacionada al post-patentamiento.