Financing Knowledge, Appropriating Value. Two faces of Biopharmaceutical Innovation.

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Abstract

This dissertation elaborates on two aspects that characterise the early stages of the innovation process in biotechnology: the financing of basic knowledge and the appropriation of value for commercial purposes.

The rise of biotechnology industry and the expanding role of academia in the market arena, have brought important changes to the division of innovative labour between public and private actors. Prior research of knowledge transfer has focused primarily on academic entrepreneurship and a large pressure has been placed on universities to commercialise research discoveries. This dissertation takes a different look at the way the innovation process unfolds, focusing on the scientific founders of European biotechnology companies that originate new drugs and tracing back the scientific pathways that characterise the transformation of 'R' into 'D'.

Consisting of three published essays, this doctoral work brings together the literature on knowledge transfer, scientific human capital and scientific entrepreneurship. It starts with a systematic revision of the literature, exploring the mechanisms of knowledge transfer between academia and industry. On the identified transport mechanisms, it frames a new taxonomy which defines 'channels' and 'processes' of knowledge transfer based on levels of individual involvement. Furthermore, starting from publications, patents and IPO documents by biotech founders, a bibliometric analysis and regression model are developed to identify the scientific origins of biopharmaceutical discoveries and the extents by which these are appropriated for economic use.

The essays of this thesis show that the knowledge base upon which biotechnology start-ups are established is created by actors with heterogeneous scientific and career backgrounds across academia and industry. Public institutions back up the creation of valuable inventions by financing most of the basic research conducted by scientists before they start their own biotech start-ups. Furthermore, work experience at university increases the chances that biotech companies appropriate the intellectual property rights of academic inventions. In contrast, spending their careers in the private sector brings scientists to disclose their inventions to their private employers. As a result, these findings contribute to understanding the dynamics behind the private ownership landscape of academic patents in Europe.

In conclusion, through an innovative methodology centred on the scientific founders of biotech start-ups, this thesis provides new evidence to understand the critical roles that public and private organisations play at the early stage of the innovation process. This research has the potential to inform the debate on whether and how risks and rewards of investments in innovation can be aligned with contributors to the innovation process.

Keywords: knowledge creation, value appropriation, innovation, scientific entrepreneurship.

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PART I

Preface

The appropriation of knowledge and its valorisation has become a key characteristic of the modern pharmaceutical and biotechnology industries. Since the advent of the biomedical era, many compounds travel through both public and private sectors while changing hands multiple times (Pisano, 2006). Innovation hinges on the coordinated efforts of governments, universities, biotechnology and established life sciences firms involved in multi-lateral interactions and overlapping networks. The convergence on shared means relies, on the one side, on the shift from the traditional mission of educating students which universities have broadened to include the patenting and commercialisation of research discoveries; and on the other side, on the transformation of knowledge into commodities as the core of the biotechnology sector (Bok, 2009; Cohen, Nelson and Walsh, 2002; Perkmann *et al.*, 2013; D'Este and Patel, 2007; Wang *et al.,* 2015; Etzkowitz and Leydesdorff, 2000). Biotechnology firms, by capitalising on their networks in the academic community, play the role of assisting the development and the transfer of university-originated science to firms with in-house commercialisation capabilities (Stuart, Ozdemir and Ding, 2007). Pharma companies, in addition to the still-important in-house knowledge generation, observe this technological development on a global scale and acquire promising substances and technologies from smaller biotech companies or from academic research institutes so as to minimise their own risk (Zeller, 2003).

Despite theoretical discussions about 'open' innovation and innovation 'eco-systems' placing an emphasis upon the collective character of the innovation process, the fundamental fact that innovation is inherently an uncertain, cumulative and collective

process that unfolds over a long time makes it very difficult to track the genesis and the development of an idea into a marketed product. Even more challenging is the estimation of the risks and expected financial returns. In the dominant view, a key assumption is that fundamental knowledge is often created by publicly funded research and then acquired by companies through securing the ownership of intellectual property rights (Zeller, 2007; Angell, 2005). This role is usually played by biotechnology companies that position themselves between a) the organisations embarking on the risks of investments in knowledge creation, and b) the pharmaceutical companies selecting and developing the most promising candidates into viable commercial products (Powell, 1998).

In the last decade, highly priced medicines and budgetary constraints from public health payers have raised questions such as whether the risks of value creation and the benefits from value extraction are fairly distributed among players in the innovation field (Lazonick and Mazzucato, 2013). Traditionally, the economic answers around drug pricing and innovation were centred on two main assumptions (Roy, 2017), the primary discourse being that prices are justified based on the cost of drug research and development (DiMasi, Grabowski and Hansen, 2016). Under this logic, monopoly pricing is necessary to pay for the lengthy and failure-ridden process of successfully bringing a new therapy to market. This position has been backed up mostly by the work of the 'Tufts Center for Drug and Development', which has produced periodic estimations of the costs of research and development, arriving at a figure of US2.6$ billion per newly approved molecule in 2015 (DiMasi, Grabowski and Hansen, 2016). A second narrative that gained consensus among scholars and actors in the pharmaceutical industry, is centred around the so-called value-based pricing strategy. Within this view, higher prices reflect improved patient health outcomes and adverted

medical expenses, and therefore the definition of what constitutes value is based on cost-benefit research in health economics (Gregson *et al.*, 2005). The benefits of new interventions involve measurement against a standard of care and a certain 'willingness to pay' which is a monetary threshold set by public health systems.

In recent times, both positions have been criticised on methodological standpoints, omissions and budgetary concerns (Reinhardt, 2015). For example, some authors have shown that the total marketing expenditure by pharma companies was higher than that incurred for research and development (Gagnon and Lexchin, 2008; Swanson, 2015). Also, scepticism has been shown towards the methodological challenge of measuring health outcomes in monetary terms (Knapp and Mangalore, 2007; Nord, Daniels and Kamlet, 2009), and furthermore, the assumption that single patients are willing to pay more for better health outcomes places the responsibility of valuing innovative medicines on the ultimate buyer: the public health systems.

Overall, it seems that the structural characteristics of production have been overshadowed in both the current theoretical and empirical debates on innovation. In fact, a separation has occurred at an academic level, with industrial economists focusing on market dynamics, such as whether a productivity crisis follows a decrease in the numbers of newly approved drugs, and health economists paying more attention to the estimation of health statuses and prices via health technology assessment analyses. Therefore, the nexus between value creation and value extraction has been partially left uncovered and the debate has remained somewhat silent on questions of who bears the risks of knowledge creation behind the development of new drugs, as well as how value spurring from investments in blue-sky research is appropriated for economic use.

As we will discuss in our theoretical chapter, this phenomenon has been largely studied by the literature on knowledge and technology transfer. In this context, the economic studies of science have mostly followed the trajectories of academics involved in commercialisation activities and university links with the industry. Much attention has been given to the analysis of academic spin-offs and academic patenting. Rather than attend to university-industry relations from the perspective of academic entrepreneurs and university spin-offs, this dissertation takes a different vantage point. It centres on the scientific founders of the biotechnology companies that originate new drugs, and tracks back the origins of the knowledge that leads to innovation. Furthermore, this work takes an innovative approach to the underlying phenomena by employing bibliometric and documentary data.

Previous analyses have centred on the notion that the monetised transfer of knowledge and technologies is to a large extent based on intellectual property rights (Zeller, 2007). In fact, intellectual property titles are used to enable firms in knowledge-based industries to limit the uncontrolled diffusion of their products and to artificially create scarcity so to legitimise the exclusion of other companies from the use of knowledge (May, 1998; Sell and May, 2001). Furthermore, through the assignation of intellectual property rights, biotech start-ups acquire the inventions generated earlier by their research teams. Therefore, being that most of the biotech firms have no product at the time of founding and are often started by university scientists, publications as well as patents have become a valid bibliometric indicator of the usefulness and transferability of research outputs (Lissoni, 2012; Meyer, 2000). Moreover, some empirical studies on scientific human capital have demonstrated the varying performance impact of a mix of scientists in terms of their orientation towards publishing and patenting (Dietz and Bozeman, 2005; Bozeman and Corley, 2004). For example, the importance of star

scientists, who show above average scientific performance and individual-level capabilities which become important extensions of the firm-level dynamic capabilities (Zucker and Darby, 2006b; Zucker and Darby, 1998).

Yet, despite the potential for employing bibliometric sources of data, the existing body of literature has rarely led to these being incorporated into the structural analysis of the innovation process. Furthermore, few attempts have been made to consider heterogeneity among scientists who contribute to the creation of biotechnology enterprises and to investigate how this heterogeneity affects firms' creation and appropriation strategies.

Main scope and contribution

The main argument of this dissertation is presented by unfolding the key elements in the economics of health, innovation and entrepreneurship, and overall to build an account of the relationship between science and technology. The intention here is to provide a logical flow and coherent overall story of how knowledge transforms into value and is directed for economic use. The empirical corpus of this thesis aims to respond to two specific research questions: What is the financial contribution to the knowledge which leads to the development of new pharmaceuticals? How is knowledge transferred and value appropriated?

The dissertation focuses on some distinct aspects of the early stages of innovation which reflect in those employed in the three papers composing this work. The aim was to maintain a set of original objectives in each paper so that the papers would relate but not overlap. However, although the three essays represent an integrated and coherent whole, a few repetitions are unavoidable, as the same themes and ideas are developed and considered from different perspectives.

In first instance (Essay One), I reduce the ambiguity of university-industry relations by investigating the extant literature on the mechanisms of knowledge transfer. The results of this work define a gap in the literature, based on which I frame a new taxonomy centred on the concept of individual involvement and give direction to future research.

The second empirical paper (Essay Two) explores the process of knowledge creation through the publications authored by scientists involved in the foundation of biotech start-ups in the United Kingdom. The analysis takes advantage of the information contained in the acknowledgment section of the publications made by the scientific founders so as to highlight the financial contribution given to the science behind the origination of new companies which originate drugs.

Lastly, the third empirical paper (Essay Three) investigates how knowledge is appropriated for economic use. Here, the scientific human capital of European biotech founders is analysed based on the biographical information contained in IPO prospectuses. Research and career trajectories are then integrated into a regression model to estimate how they affect the assignation of intellectual property rights.

This work provides evidence of the fundamental role played by public institutions financing the early and riskiest stages of innovation. I highlight that the value associated with early-stage invention is appropriated by the private sector through the assignation of intellectual property rights. Moreover, I show the incentives for scientists to assign property titles to the companies they help start, as a conduit to capitalise on their previous research and discoveries.

Overall, the findings of this doctoral thesis can be used to map out a range of solutions that might be necessary to bring about change in the way that early innovation is

financed and the access to new interventions is provided. My hope is that by raising this set of enquiries, through this dissertation I can contribute to the larger effort already underway in moving biomedical innovation closer to human needs.

Thesis outline

This dissertation unfolds in four chapters. The first chapter details the theoretical landscape. Here, the focus is on building an analytical toolkit from the economics of innovation, entrepreneurship and health that accompany me in my investigation. This chapter illustrates and links the different theoretical lenses used in the three essays. The second chapter defines the rationales specific to each of the essays. Research questions and objectives are also stated and justified. In Chapter 3, I present the philosophical assumptions and map out the research strategy and methodology. Chapter 4 outline the main contributions by the three essays. The chapter includes a documentation of the contributions and limitations of the study, as well as potential research projects that my findings may provoke and reflections at policy level.

Part II of this thesis contains the essays written in the form of scientific publications. The published versions of the first two works are reported, whereas the last paper is presented in the form by which to has been accepted for peer review and currently is at the second round of peer revision.

CHAPTER 1: Theory

According to definition by Kerlinger (1966), theory is "a set of interrelated constructs, definitions and propositions that presents a systematic view of phenomena by specifying relations among variables, with a purpose of explaining and predicting phenomena".

This chapter presents and discusses the main changes in the innovation landscape and theories linking the contributions by the three essays composing this thesis. The focus is on the role that scientific entrepreneurship plays as a conduit for the transfer of knowledge from non-economic to economic domains. To this end, I take a systemic approach to the orchestration of different theories in the economics of knowledge, innovation and entrepreneurship.

Institutional Background

The emergence of biotechnology marked a fundamental change in the way in which science moves from the laboratory to the market and it represents a prototypical example of the changing patterns of specialisation in inventive activity.

Biotechnology has a 'science-push' origin which dates back to the pioneering work of Watson and Crick, who discovered the structure of DNA as a double helix in the early 1950s (Watson and Crick, 1953). However, it was the development of recombinant DNA techniques by Herbert Boyer at UCSF and Stanley Cohen at Stanford in 1972, and the subsequent foundation of Genentech in 1976 to exploit these techniques which heralded the dawn of a new industry (Wakeman, 2008). Since then, the division of

innovative labour within the pharmaceutical industry has experienced profound modifications driven by both institutional and technical changes.

Earlier in the 1960s and 1970s, the industry had been characterised by distinctive roles played by upstream not-for-profit organizations specialised in curiosity-driven basic research and downstream, for-profit companies involved in applied research (Cockburn, Iain, 2005). Upstream organisations usually took the form of taxpayer-supported government labs, universities, research institutes and teaching hospitals. Not-for-profit researchers concentrated largely on fundamental science and were driven by extensive publication activity and peer-reviewed competition in order to establish priority and reputation, as well as the securing of grants required to fund their research (Whitley, 2000). Downstream pharmaceutical firms were mature organisations, originated within the 19th-century chemical industry. These firms were characterised by strong in-house capabilities ranging from drug discovery, through clinical development and regulatory affairs, to manufacturing and marketing (Cockburn, Iain M., 2004).

Despite this vertical structure, many drug companies invested significant resources in ‘blue sky’ basic research, and many academic researchers had close financial and contractual links with drug producers either through individual consulting arrangements or institutional research grants and partnership. Despite these caveats, the industry was still characterized by a clear distinction between upstream open science conducted in realm of academia, and a downstream commercial sector dominated by large and highly integrated pharmaceutical firms (Cockburn, 2005; Kahin and Foray, 2006).

Since the early 1980s, the industry structure has become considerably more complex. In the late 1970s biotech enterprises started to emerge as an intermediate sector between academic research institutions and the so-called 'big pharma'. These new biotechnology companies straddled the historical for profit/not for profit divide. Although they were, profit-oriented organizations, biotech also had much tighter links to non-profit research institutions, with close personal, geographical, cultural and contractual ties to universities, research institutes and government labs (Cockburn, 2005).

A significant role in the founding of biotech firms was played by university scientists. In many instances, biotech companies were founded to exploit discoveries made by professors or groups of academic scientists (Arora and Gambardella, 1995). For this reason, biotech major assets consisted of the knowledge embodied in their founders and researchers (Pisano, 2006; Zucker and Darby, 2006a). Steven (2008) notes that it was not until the 1970s that scientific entrepreneurs began to occupy a central place in the entrepreneurial landscape by keeping one foot in the world of academia and another in the world of business.

These new biotech companies forced some important adjustments to university-industry relations. By taking over a certain amount of research activity from both upstream and downstream entities, biotech heralded a new partnering mode of research with large incumbent firms relying heavily on their research tools and candidate molecules (Cockburn, 2005). Cockburn (2005) refer to this as a "vertical dis-integration" (p. 7), and report a number of interlinked economic and legal forces that may have caused it. In particular, one of the main reasons was the developments in law and administrative practices that brought much of molecular biology within the ambit of the patent system.

Among the legal and economic changes, the passage of the Bayh-Dole Act in 1980, which in the US enabled and encouraged the commercialisation of publicly funded research, played a particularly important role (Grimaldi *et al.,* 2011; Mowery and Sampat, 2004; Mowery *et al.,* 2001). After the Bayh-Dole Act, academic researchers were granted permission to file for patents and to issue licenses for intellectual property rights to other parties. As a consequence, despite Mowery and Sampat (2004) charting the continuously increasing participation of US universities in the national patenting system since 1963, the entry rate of small firms is reported to have soared during the 1980s. Moreover, while biotechnology companies have become important participants in basic biomedical research, universities and other non-profit entities have increased their levels of participation in the patent system. In this way, market-based competition started determining the overall rate and direction of technological progress.

Despite their innovative mission, the great majority of biotechnology firms never managed to develop into fully integrated drug developers (Jensen, 2011). Typically, biotech enterprises were lacking capabilities in the later stages of the drug innovation process. Large pharmaceutical firms, conversely, found themselves in the opposite situation, i.e. whilst having trouble in adopting new biotechnology methods, they developed strong capabilities in the later stages of the innovation process. In this context, universities also controlled assets and skills that were to some extent complementary to those of both the biotech and the large firms (Jensen, 2011; Arora and Gambardella, 1995).

In sum, because 'big pharma' and biotech firms controlled assets that were largely complementary, systematic collaborations between them arose (Arora and Gambardella, 1990). This created a stronger division of labour where, on the one side,

small biotechnology firms together with academia specialised in drug discovery, and large pharmaceutical firms on the development and marketing of drugs (Arora and Gambardella, 1994). As a result, the growth of the industry has hinged upon network-like relationships based on extensive collaborations and a division of labour between these agents. In particular, given the tight relation between academic and biotechnology organizations that characterize the transformation of 'R' in 'D', any investigation cannot avoid to look at the combination of roles and actions undertaken by these actors at the early stage of the innovation process.

Theoretical Background

Nowadays, the research behind drug discovery is associated with a high level of knowledge complexity. Sources of knowledge are diverse and are derived from a wide variety of scientific fields and technological competencies. Generating and embodying new knowledge in products or processes is often conditional on the ability to access and then make sense of a significant variety of complementary research inputs (Allarakhia and Walsh, 2011). In the last decades, there has been a shift in the way innovation is conceived by authors in the economic arena. On the one side, at firm level, many scholars point out that the characteristics of the biopharmaceutical sector have helped pioneer the open innovation paradigm (Hughes and Wareham, 2010; Chiaroni, Chiesa and Frattini, 2011). At institutional level, there has been a move from the linear model to innovation systems.

Open innovation

The paradigm of open innovation has received substantial attention from scholars since its conceptualization by Chesbrough, Henry William (2003) as a counterpoint to

the traditional ‘closed innovation’ view. The open approach suggests that innovative outputs generate more easily in contexts with more openness towards external sources of knowledge. This openness encourages the fluidity of knowledge and information flows between firms (Ferreira and Teixeira, 2019; Chesbrough, Henry, Vanhaverbeke and West, 2006). Open networks have been found to be particularly beneficial in providing opportunities for knowledge creation through enhanced opportunities for ‘spill-over’ effects or by increasing the likelihood of knowledge leaking through open network channels (Owen-Smith and Powell, 2004; Murray, 2002).

The open business model requires the definition of a series of activities or value chain that will lead to a new product or service. Under the open paradigm, value creation is said to arise from multiple sources, and relates to strategic network theory and cooperative strategies (Dyer and Singh, 1998). Secondly, open strategies require that firms have one or more unique assets within the value chain allowing the firm to enjoy a competitive advantage and so capture a portion of that value (Chesbrough, Henry, Lettl and Ritter, 2018).

Previous scholars showed that for a successful adoption of open innovation strategies, firms need to develop a number of open networking capabilities such as absorptive, multiplicative and relational capacity to deal with suppliers, customers, higher education institutions, and competitors (Gassmann, Enkel and Chesbrough, 2010; Perkmann and Walsh, 2007; Huston and Sakkab, 2006). In fact, the further firms open their boundaries, the further they become both interdependent and embedded within complex networks of interactions. Therefore, the emergence of the open innovation approach implies a system perspective which is “made up of components, linkages between the components, and dynamics” (Afuah and Tucci, 2003), (p.3).

The open paradigm has deeply influenced our thinking about the essential importance of firms' internal and external knowledge environments, in contrast to the earlier focus on firms as 'black boxes' of closed relationships. Moreover, the mobility of trained workforces a more prepared transmission of information by data innovation has extended the event and the pertinence of overflows among firms and their outer surroundings.

Innovation systems

Innovation models have also followed the trend towards interactivity and openness which has characterised the industry in recent times. As such, there has been a shift from the linear model, where investments in science were assumed automatically to result in technical innovation, to a network mode of resource allocation which involves individuals, firms and institutions engaging in preferential and supportive actions. The conceptualization of the linear model of innovation is attributed to (Bush, 1945). The linear approach asserts that first there is basic research produced by universities, which gradually diffuses out into society and the economy. Incumbent firms then absorb the commercially relevant elements of university research and develop them into knowledge applications and innovation. In this way, within the frame of linear innovation, the relationship between knowledge and innovation is sequential in nature. With the evolution of industrial contexts, the linear model of innovation has become challenged by non-linear models, in which basic research and innovation are coupled together not in a 'first-then', but in an 'as well as' and parallelised relationship (Carayannis and Campbell,2012).

The changes in the relationship between 'science' and 'business', both within the firm and also between industrial and institutional environments, have been studied in the literature on the systems of innovation. The concept was introduced as 'Innovation

Systems' by the evolutionary economist Bergt-Åke Lundvall to emphasise the interactions between firms, organisations and policymakers (Freeman, 1995; Lundvall, Bengt-Ake and Dosi, 1988; Lundvall, Bengt-Åke, 2010). Based on the joint work of Lundvall, Freeman and Nelson, it became 'Systems of Innovation' (Dosi, 1999; Nelson, R. R., 1993; Lundvall and Dosi, 1988). The system approach is about the determinants of innovations, not about their consequences. The two main areas of application and contribution for systems of innovation literature concern the regional/national development, and the public policy for science, technology and innovation (Boschma, 2004; Edquist, 2001). Studies about systems of innovation usually refer either to one specific 'territorial level' (e.g. 'national systems of innovation') or to one specific technology or industrial branch (e.g. 'sectoral systems of innovation'). However, due to the processes of political decentralisation, globalisation, and some paradigmatic changes in certain technological fields such as biotechnology, the borders of such systems have blurred.

Nowadays, more of the functions at financial and policy levels are located across various territorial and sectoral levels. As a result, innovation systems have undergone a process of reconfiguration and there has been a substantial change in the role attributed to certain organisations in the systems. In particular, in the context of the Triple Helix literature, the role of universities was highlighted as a locus of national knowledge-intensive networks.

Traditionally, the role of academia centred on teaching and producing basic research, without any interest in the practical use of knowledge and innovation. This model of university-based knowledge production is known as 'Mode 1' (Gibbons, 1994). In the last decade, Etzkowitz and Leydesdorff (2000), emphasised the core role of universities as a central model for knowledge production and innovation, where three

"helices" – identified as academia (universities), industry (business), and state (government) – intertwine and thereby create a national innovation system. Etzkowitz and Leydesdorff (2000) refer to "university-industry government relations" and networks, putting a particular emphasis on "trilateral networks and hybrid organizations".

In the Triple Helix model, universities are deemed to have a third mission, defined as the transition from educating individuals to shaping organisations. This 'third mission' idea was first presented as an expansion of the scholarly world to other market-arranged advancements and information move (Sánchez-Barrioluengo, 2014; Chen and Lin, 2017). As a consequence, universities are now viewed as engines of economic growth through a recognition of the strategic role of science (Hussler, Muller and Rondé, 2010). Universities are recognized in a position of being engaged through knowledge transfer in societal and economic growth activities. Universities have therefore become much more oriented to the commercialisation of research, and consequently, academia is witnessing a functional shift from basic to applied research (Perkmann and Walsh, 2007). Powell and Owen-Smith (1998) go as far as to argue that the separation of the scientist in the academic world and the technologist in the private arena no longer holds in the life sciences.

Theoretical Framework

The changes at institutional and theoretical levels have made difficult, from a research perspective, the tracking of innovative ideas and conversion into technological knowledge and innovation. The new pharmaceutical reality is, in fact, still characterised by high risk and appropriability issues, and research activities are dominated by high levels of uncertainty in terms of both generating knowledge and

then applying this knowledge to downstream activities. Scholarships in innovation and entrepreneurship have made significant strides in examining how the macro-knowledge context relates to the micro-underpinnings of new firm formation. In this context, the role that scientific human capital plays is an essential element for competitive success.

Based on these premises, in the next paragraph, we present the theoretical framework in which the three essays of this doctoral work have been framed. I illustrate the main elements of the knowledge spill-over theory of entrepreneurship, which is the main theory linking the three empirical works. Furthermore, I present the main features of two other connected disciplines – scientific and technical human capital, and scientific entrepreneurship. Based on these, I identify the research gap and the rationales to formulate my research questions.

Knowledge Spillover Theory of Entrepreneurship

Entrepreneurship scholarship is focused on the process by which individuals discover and act on entrepreneurial opportunity. According to (Shane, Scott and Venkataraman, 2000), (p.218), the field of entrepreneurship is concerned with "the sources of opportunities; the process of discovery, evaluation, and exploitation of opportunities; and the set of individuals who discover, evaluate, and exploit them". For long time, the literature has focused on the characteristics specific to individuals in order to explain the ability to either exploit or create entrepreneurial opportunities. Traditional theories have considered entrepreneurial opportunity as exogenous, and then implied that the likelihood of becoming an entrepreneur was attributable solely to differences in the propensities, proclivities and inclinations of the individual entrepreneur.

Initiated by Audtrescth in 1995, the Knowledge Spillover Theory of Entrepreneurship (KSTE) takes a different starting point (Audretsch, 1995). Rather than on individuals,

the focus is on the organisational context as a source of knowledge creation and entrepreneurial opportunity. In particular, the KSTE theorises how and why knowledge spills over, and in what manner entrepreneurship acts as the mechanism by which knowledge evolves into economic knowledge within a given framework. Interestingly for the purpose of this thesis, the theory highlights that entrepreneurial opportunity is derived from the creation of knowledge that has not been fully appropriated within the incumbent organisation from which that knowledge originated, for example the university. Thus, the entrepreneurial activity of scientific founders is seen as the conduit facilitating the spill over of that knowledge into the market arena (Audretsch and Link, 2019; Audretsch and Keilbach, 2007).

The KSTE brings together contemporary theories and thoughts of entrepreneurship with prevailing theories of economic growth. This theory poses on the scholars who highlighted the characteristics of knowledge as distinct from the 'normal' economic goods. As Arrow (1962) emphasised, the first aspect of the knowledge concept involves its *non-excludability*, which means the inability to exclude others from accessing and using that knowledge. The second element refers to the *non-exhaustibility* of knowledge, meaning that its use by one party does not preclude others from using that same knowledge. The third point refers to the high degree of *uncertainty*, which makes it difficult, if not impossible, for firms to assign an expected value to various outcomes. Furthermore, knowledge is not a given or a free good at everyone's disposal, and thus only a few people know about a particular scarcity or a new invention, (Hayek, 2007; Katz and Shapiro, 1985; Stiglitz, 1999). Taken together, these characteristics increase the propensity for knowledge to spill over from the firm or the organisation in which it was created to other third parties who can access that knowledge for a cost less than its value.

The way in which knowledge spills over between organisations has attracted the attentions of many scholars. In particular, this has been central for the development of endogenous growth theories (Romer, 1986; Lucas Jr, 1993). Compared to exogenous models such as the Solow model, endogenous models make explicit that knowledge is a key factor of production, along with the traditional factors such as capital and labour (Solow, 1956). However, the assumption in the endogenous model of growth by Romer (1986) is that spill over from investment in new knowledge results automatically in commercialisation. In particular, the Romer model refers to the geographical location and proximity to other firms as a source of purposeful investment in R&D. In contrast, the premise of the KSTE theory is that the spill over of knowledge from its source is impeded by the so-called 'knowledge filter' (Acs *et al.*, 2004; Audretsch and Keilbach, 2007).

Since new ideas and knowledge are characterised by uncertainty, the knowledge filter is the reason why they may not be pursued and instead remain uncommercialised by incumbent organisations. Alvarez (2003) distinguishes between decision-making under uncertainty (which is typically associated with organisational inertia) and decisions taken under risk (which instead enables the incumbent firm to calculate expected outcomes along with a probability distribution associated with those outcomes) (Alvarez and Barney, 2005; Alvarez, 2003). At an institutional level, regulations and legal restrictions may likewise account for a portion of knowledge filter. However, the aspects most often regarded as the source contributing to the knowledge filter are the Arrowian conditions inherent in the knowledge concept such as uncertainty, asymmetries, and high costs of transaction (Ahmetoglu *et al.,* 2017).

Therefore, the KSTE argues that due to the presence of the knowledge filter, investments in science and research do not automatically spill over into the market.

Consequently, the knowledge filter is the reason why investments in R&D do not automatically influence economic growth and employment generation as hypothesised by endogenous growth models. There is, of course, a correlation between investments and economic growth, although Audtresch (2008) argue that this is not maintained at lower levels of aggregation (Audretsch and Keilbach, 2008). The so-called 'European Paradox' represents an empirical case for the knowledge filter, as it refers to the existence of economic stagnation even in countries in which investments in education and research are high (Audretsch, 2009; Audretsch and Keilbach, 2008). No systematic relationship has been revealed between R&D expenditure and GDP-growth, whereas a positive relationship between entrepreneurship and subsequent economic growth has been found, and traditional theories have failed to disentangle the reasons why small firms with low investment in knowledge creation are able to generate innovative output (Wennekers and Thurik, 1999; Braunerhjelm *et al.*, 2010). In sum, what has been regarded as the *missing link* in endogenous models, and that the KSTE has explained, is a failure to incorporate one of the most crucial elements in the growth process: the transmission of knowledge through entrepreneurship (Braunerhjelm *et al.*, 2010).

In the KSTE, a higher level of entrepreneurial activity corresponds to a greater portion of ideas flowing through the filter and being transformed into economic knowledge. Also, by promoting a shift from the firm level to the contextual level in which scientists becomes entrepreneurs, the KSTE provides an answer to the so-called 'appropriability problem'.

In the traditional economic approach, the issue revolves around how firms investing in knowledge creation can best appropriate the economic return from that investment (Arrow, 1962). The KSTE takes a different perspective, which involves the

transformational function of humans, rather than the firms, constituting an economy. Therefore, from the perspective of the KSTE, the question of appropriability has become: "How can scientists with a given endowment of new knowledge best appropriate the returns from that knowledge?" (Audretsch, Aldridge and Oettl, 2009) (p.174). The answer provided by the KSTE theory is that through entrepreneurship, scientists are able to appropriate returns from knowledge and the ideas that they have created within the incumbent organisations, which also financed such process of knowledge creation. Levin and Stephan (1991) suggest that this appropriation also depends on both the career trajectory as well as the lifecycle of the scientist. Scientist lifecycle models suggest that early in their careers scientists invest in human capital in order to build reputation (Levin and Stephan, 1991). More specifically, the appropriability question confronting academic scientists can be investigated by taking the perspective of two important streams of research: the literature on scientific and technical human capital, and that of scientific entrepreneurship.

Scientific and technical human capital

Theorists define scientific and technical human capital (S&T human capital) as the "sum of scientific, technical and social knowledge, skills and resources embodied in a particular individual" (Bozeman and Corley, 2004), (p.599). It includes both human capital endowments, such as formal education and training included in human capital models (Schultz, 1963; Becker, 1962) as well as the social relations and network ties analysed by social capital theories (Coleman, 1988; Bourdieu, Pierre and Wacquant, 1992; Bourdieu, P., 1986). Despite this separate approach, scholars have struggled to disentangle the practice of science from the career of growth of scientists. Therefore S&T human capital comprises of the overall skills, knowledge, and social relations needed to participate in science.

Scientific human capital primarily consists of the scientists and inventors within a firm. Skilled and talented knowledge workers are critical determinants of innovation (Merton, 1973; Nelson, K. and Nelson, 2002). However, with the birth of science-intensive industries, an increasing number of scientists from academia began actively contributing to technological activities within firms. In addition, firms began attracting scientists to join their organisations, offering incentives to publish their research findings and to collaborate with leading academic scientists (Helfat *et al.,* 2009). Therefore, following the evolution of the biotechnology sector and links within universities, the careers of scientists co-evolved to reflect the changes occurring in models of R&D, as well as the new norms in the legislative landscape.

Traditionally, an academic researcher worked at a university or independent research laboratory (Partha and David, 1994). Particularly in the early stage of their career, the goal for an academic scientist was to establish the priority of a discovery through publications in scientific journals. Recognition by peers and paper citations were other factors motivating researchers in their tenure stage (Merton, 1957). With maturity, scientists sought to appropriate the economic value of such knowledge, and therefore the decision to commercialise might depend on the value of the reputation they had built (Levin and Stephan, 1991).

With the advent of the knowledge economy and the transition to networked processes of innovation, the traditional aspects of the academic profession have also changed. For example, often academic inventors now patent their research before openly presenting it to the public at large, through publications (Boardman, 2008; Boardman and Ponomariov, 2009). Firms also seek to collaborate with research universities by adopting open science strategies. In order to resolve the differences between scientific objectives and industrial goals, corporations have developed different models of R&D

organisation and human resource strategies. A major challenge for many high-technology firms and institutions has been the development of collaborative structures to engage academic and industrial scientists in joint knowledge production (Bozeman and Corley, 2004). Universities have contributed to closing this gap by providing access to research and development facilities, enhancing the production of knowledge that facilitate the understanding of practical issues, and providing services which ensure the assimilation of new technologies. Overall, the nature of academic and industrial work has coevolved along with changes to innovation models, such as the move from a technology push to a market pull, and a network of collaborative activities between organisations of different kinds (Rothwell, 1992; Liyanage, Greenfield and Don, 1999).

Scholars such as Henderson and Cockburn (1994); Zucker, Darby and Armstrong (1998) focused their attention on the study of firms' ties to the scientific network and the way these influence companies economic performance, and technological progress. Ties and modes for spill-overs were categorised in three main types: publication and co-authorship; proximity to star scientists; and movement of scientists. With regard to the first type, scholars in this field have argued that, especially in periods characterised by shifts in the technological paradigm, such as the rise of biotechnology, publications are a crucial to make this transition successful (Arora and Gambardella, 1994; Liebeskind *et al.*, 1996; Henderson and Cockburn, 1994). Moreover, Zucker and Darby (1998) argue that ties to science arise largely through the proximity and participation of 'star scientists'. Star were scientists with exceptional scientific records as defined based on the number of publications and gene discoveries. The relevance of firms ties with Stars was supported by the degree of success of such firms, which was demonstrated to be largely dependent on the

involvement of these scientists. Lastly, a third tie is characterised by the movement of human capital. Partha and David (1994) assert that the "export of scientists and engineering from the academy to industrial research is potentially the most important and salutary among the mechanisms available for effecting knowledge transfers" (p.511).

Furthermore, the S&T literature has contributed to our understanding of the impact of involvement in science on technical productivity. In this context, Murray showed that science and technology networks co-evolve and overlap through a number of avenues, such as co-publishing and citation, co-patenting, consulting, advising, movement of human capital from academia to industry, proximity to 'star' scientists, licensing and company founding (Murray, 2002). Furthermore, Breschi and Catalini (2010) explored the co-evolution of science and technology and found that author-inventors who bridge the boundaries between science and technology domains are crucial for allowing connectivity. Furthermore, Gittelman and Kogut (2003) show the importance to biotech companies of ties with open science through boundary-spanning '. In this context, bibliometric and social network analyses are used to study, respectively, the science–technology overlap (Murray, 2002) and the evolution of scientific collaboration between scientific and technological communities (Barabâsi *et al.*, 2002). In these contributions, the different actors and groups that shape new technologies may belong to scientific and/or technological communities, while being affiliated to organisations which can be positioned in the triple helix of university–industry–government relations (Blosch and Preece, 2000). Therefore, by focusing on actors it is possible to move from people to their corresponding groups, organisations and the triple helix. Scientific entrepreneurship constitutes an essential determinant in the emergence of a system of innovation and represents the key element in connecting

the distinct but overlapping roles of individuals, firms and institutions in the pharmaceutical industry.

Scientific entrepreneurship

The features of biotechnology as a scientific field can be related to those of scientific entrepreneurs. Concepts such as 'scientific entrepreneurship' or 'entrepreneurial scientist' have not been commonly used in the scientific literature. An early account of this phenomenon was provided by Ben-David (1971) in the context of American universities and the process of 'professionalisation' of scientists. Specifically, David relates the concept of scientific entrepreneurship to academic scientists conducting professional, large-scale research with graduate students, including paid-for research (Oliver, 2004). The birth of academic entrepreneurship has mirrored the increasing integration of science with different sectors of the economy (Lacetera, 2009b). In the course of this change, academic entrepreneurs act as a link between the worlds of academia and private enterprise (Lacetera, 2009a).

The approaches followed by scholars can be categorised under three main theoretical approaches which also confirm the extensiveness of the definitions in use. The first prevailing view stems from the idea of business creation by academics (Wright *et al.*, 2009; Shane, Scott Andrew, 2004). Some authors have included in this category companies created from the intellectual property generated inside universities, irrespective of whether the entrepreneur was an academic employee (Hayter, 2011). A second approach is provided within the context of the literature on knowledge transfer. (D'Este, Mahdi and Neely, 2010) describe an academic entrepreneur in the following way: "The literature on university-industry technology transfer defines an academic entrepreneur as a university scientist who engages in the commercialisation of the result of his/her research, largely by patenting and/or setting up a business"

(p.2). From this standpoint, the authors included the contacts that academics have with business entities that are the basis of monetary value creation. 'Hard activities', such as patenting, licensing and spin-off formation, as well as 'soft activities' such as publishing, grant seeking and contract research, are included under this commercial definition (Cantaragiu, 2012; Philpott *et al.,* 2011). Furthermore, an interesting line of inquiry was developed by Zucker in relation to 'star' scientists who work collaboratively with firms' scientists (Zucker and Darby, 1998). The third theoretical approach to scientific entrepreneurship employs value-based definitions and entails a broader view of entrepreneurship as the creation of societal value. Under this framework, the scientific entrepreneurship concept refers to scientists who acknowledge the commercial value of their discoveries and act to legitimise and commoditise their findings, thereby enabling commercialisation (Oliver, 2004). In this approach, a key feature of the entrepreneurial scientist is their claim for patent rights over academic research in order to licence rights to future use by third parties (Oliver and Liebeskind, 2003).

In the scientific literature, the terms 'academic entrepreneur' and 'academic entrepreneurship' are treated and theorised in different ways. Traditionally, academic entrepreneurship was intended as 'university spin-off' or an institutional transfer of research or technology aimed to start new ventures (Shane, 2004). According to Beckman and Cherwitz (2009), academic entrepreneurship can be defined as an 'intellectual enterprise' created by universities that cooperate with local communities to create new values or ideas. Shane (2004) explains the five advantages of an academic entrepreneurship spin-off: (1) to "encourage economic development," (2) to "enhance the commercialization of university technologies," (3) "spin-offs help

universities with their mission," (4) "spin-offs are high potential companies," (5) "creating spin-offs is more profitable than licensing to established companies."

Due to the characteristic of 'producing knowledge', the definition of academic entrepreneurship is close to that of 'academic firm', which sees an academic entrepreneur operating simultaneously as intellectual actor and as entrepreneurial actor (Campbell and Guttel, 2005). Therefore, an 'academic entrepreneur' is defined as an occupational profile for an actor who is scientifically active and at the same time working as an entrepreneur. Based within an integrated network of academic and business organizations, an academic entrepreneur distinguishes for an entrepreneurial thinking and actions and the creation of earnings and profit through self-employment. By bridging the science and business domains, academic entrepreneur creates economic value the utilisation of knowledge. By playing this role, academic entrepreneurs derive direct utility from research activities that precede the completion of a project and the monetary returns from its commercialisation (Lacetera, 2009).

In conclusion, with the development of new models of innovation the academic entrepreneur increasingly becomes a central actor in facilitating a cooperative and targeted exchange of knowledge and technologies between the academic world and the world of private enterprise. In this context, the academic entrepreneur also symbolises the modernisation of universities and the transformation of scientific into market-driven society.

CHAPTER 2: Rationales and Research Questions

The variety of theoretical arguments landscaping this work suggest that a clear perspective and definitions of the main arguments contained in the three essays of this thesis should be stated. A first element is the definition of scientific entrepreneurs, which in the context of my essays are also called 'scientific founders'.

According to the knowledge and technology transfer literature, this thesis adopts a broad approach to the analysis of scientific entrepreneurship. In the context of the empirical essays, the focus is not on the motives that lead scientists to become entrepreneurs, but rather on the means by which knowledge is transferred from scientific to commercial domains. As illustrated in the theoretical chapter, I take the view of KTSE theory, which sees the entrepreneur as a conduit facilitating the spill over and commercialisation of knowledge which hasn't been fully appropriated by the organisation which created it.

Based on these premises, I define scientific founders or entrepreneurs as:

Scientists, with heterogeneous career trajectories within academia and/or industry, engaging in the commercialisation of research that hasn't been appropriated nor used by the organisation(s) from which it originated.

The proposed definition is based on KSTE theory by viewing entrepreneurship as a conduit to the transfer of knowledge which hasn't been converted, yet, into product. I bring together the literatures on scientific and technical human capital by highlighting the heterogeneous pathways followed by scientific founders across networks of organisations. This point is relevant because it provides a shift in the way that

knowledge transfer can be studied, as compared to the predominant view by extant scholars. In fact, the approach adopted in this thesis is to identify scientific entrepreneurs from their organisations, and not vice versa.

Based on these premises, in both Essays 1 and 2 I take biotechnology companies as a starting point from which I trace the identity of the scientists who contributed to their foundation. This element represents an innovative approach to the study of the knowledge transfer phenomena. In the extant empirical literature, much attention has centred on academics who start spin-off companies and, more generally, on the multiple ways in which universities become involved in activities shared with actors at an industrial level. This thesis takes a different perspective, focusing instead on biotechnology ventures that create new drugs (Essays 2 and 3) and achieve IPOs (Essay 3). Based on these, I trace back the identities of the scientists whose innovative ideas have flowed into correspondingly innovative products.

Rationale for Essay One

Previous chapters have revealed a variety of theoretical and institutional lenses that can be adopted to study the phenomenon of how science is transformed into products, as well as the role that scientific entrepreneurs play in such complex processes. The Knowledge Transfer literature suggests that there are several other aspects of academic life which can be classified as entrepreneurial activities. The lenses offered by the KT approach allow the appreciation of a broader dynamism with respect to academic engagement in different entrepreneurial activities than simple spin-off creation (Franzoni and Lissoni, 2009; Jain, George and Maltarich, 2009). It has been highlighted that academic involvement in knowledge transfer activities is a precondition for subsequent spin-off creation (Tijssen, 2006), and furthermore (D'Este

and Patel, 2007) found that other knowledge-transfer activities are equally, or even more, important than company creation, both in terms of frequency and economic impact.

Based on these findings, KT provides the missing link between the theories illustrated in the previous chapters and the empirical examinations which will follow in Essays 2 and 3. Knowledge transfer is defined as movement of know-how, technical knowledge, or technology from one organizational setting to another (Roessner, 2002). In Essay One, I investigate the nature of knowledge, and the relational context of sources and recipients involved in transfer activities. These elements are revised with the specific aim of clarifying what drives the adoption of different transfer modes of knowledge transfer and to converge on shared elements.

Essay One – Research questions

The main research questions guiding my review are:

1. What determines the movement of knowledge between university and industry?
2. What are the characteristics of the transport mechanism?

Objective: To gain a better understanding of academia–industry interactions and to explore the conduit of knowledge transfer to bring innovation to market.

Rationale for Essay Two

In the previous chapters I highlighted the complex set of relationships guiding the efforts of scientists and organisations, and the seizing of entrepreneurial opportunities to capitalise on research discoveries. It was shown that the extent of public-private interaction in drug development has been accompanied by several institutional changes in the innovation process and the distribution of innovative work between

university, government and industry in the last decades. Furthermore, at a theoretical level, KSTE theory has offered a relevant point of view in understanding how knowledge spills from universities to the private sector, thanks to the entrepreneurial initiatives of scientists. In this context, it was evident that a core element was the knowledge which was not appropriated within the organisation from which it originated. Secondly, it was recognised that due to the presence of the knowledge filter, investments in R&D do not automatically result in innovation. Despite this, a relevant quantity of resources is spent every year at global level, to foster and support innovative activities of universities and the transfer of potential innovative ideas to companies. Yet elements such as the financial aspects related to the transfer of knowledge and the financing of basic science have been studied to a lesser degree, both at theoretical and empirical levels. Furthermore, most of the scientific production has looked at the use of governmental funding from a macroeconomic perspective.

Recently, in light of the key role played by universities and governments in the production of basic research, new questions have been raised about the rates of return from public spending to support blue-sky research. Budgetary concerns and high prices of medicines have fuelled proposals to recoup profits from government-funded drugs and to avoid taxpayers having to pay twice – first with taxes for publicly funded research, and then through monopoly of prices or restricted access (Sampat and Lichtenberg, 2011; Alperovitz and Daly, 2009). Based on these premises, in Essay Two, I explore the relation between funding inputs and research outputs by centring on the scientific production of scientists and founders of biotech firms, taking advantage of the acknowledgment sections of the publications by the scientific founders of biotechnology companies in UK.

In accordance with the lenses adopted by this thesis, which focus on the role played by individuals in the transfer of knowledge between academia and industry, in Essay Two I contribute to the debate by providing a new perspective on the finance in innovation. Here, rather than analysing research budget top-down, I trace back to the financial origin of innovative ideas, as disclosed within the literature realized before the involvement of scientists in entrepreneurial activities. In doing so, the main scope was to shed light on the financial contributions given to science that go on to be successfully developed into pharmaceutical products.

Essay Two – Research questions

1. What is the nature of the financial support acknowledged in the publications by biotech founders?
2. What is the distribution of funding organisations across countries and disciplines?
3. To what extent does funded research have a higher impact in terms of article citations?

Objective: To analyse the nature and the scope of the financial contribution acknowledged by scientists involved in the foundation of biotechnology companies which lead to biopharmaceutical discoveries.

Rationale for Essay Three

Founders of biotechnology companies are the focal element of many theoretical and empirical instances. At the individual level, scientific founders act at the interface between science and commerce. At the organisational level, the biotechnology companies, built upon the founders' scientific backgrounds, act as intermediaries between university research and the commercial arena.

KSTE highlights the critical role played by scientists who engage in entrepreneurial activities and function as a conduit for unappropriated knowledge to transfer from scientific to commercial domains. On the other side, the elements from the scientific and technical human capital literatures, pointed out the variety and heterogeneity of career trajectories which characterize the scientist professional life cycle. The knowledge transfer literature rationalized these theoretical underpinnings by shifting the attention to the channels and processes by which knowledge is transferred and contemporarily transformed into innovation (Essay One). Lastly, the potential for the use of publication data was highlighted as a mean to analyse the financial aspects related to the creation of knowledge by scientists (Essay Two).

In this final work the elements by previous literature, including the previous essays of this thesis, are employed to investigate another aspect of the relation between the "R" and "D": the appropriability issue. To this end, I take advantage of the patent documents filled by the biotechnology founders in order to investigate the relation between founders' scientific human capital and patent ownership.

Essay Three – Research questions:

1. What is the scientific human capital upon which European biotechnology firms are created?
2. To what extent is the assignation of intellectual property rights sensitive to:
    1. the inventor professional career;
    2. scientific experience; and
    3. patent characteristics?

Objective: To analyse the career trajectories and research backgrounds of scientific biotechnology founders, and to explore how these affect the assignation of intellectual property rights and thereby the appropriation of knowledge.

CHAPTER 3: Methods and Philosophy

Research philosophy

As noted by Johnson (2006), researchers need to be aware of the philosophical commitments they make through their choice of research strategy because they may influence not only our understanding but also what we are investigating. Paradigms may be defined as the worldviews or belief systems that guide researchers (Guba and Lincoln, 1994). From the second half of the nineteenth century, two major approaches to the study of reality have become predominant, and form part of an ideological conflict which is still ongoing: the positivist/empiricist approach versus the constructivist/phenomenological orientation. The positivist paradigm forms the basis of quantitative methods, while the constructivist paradigm underpins qualitative methods (Guba and Lincoln, 1994). The qualitative-quantitative divide plays out at different levels, with various peculiarities in terms of epistemological issues, ontological concerns and the role of theory (Bell, Bryman and Harley, 2018). The quantitative approach implicitly assumes the existence of an objective world, independent from our thought, a '*res extensa'* standing autonomously from human reasoning, or '*res cogitans'* (Mariani, 2011). The object of research is, thus, 'discovered' through a deductive approach towards data, which are collected in order to test hypotheses on the basis of previous theoretical reasoning. In contrast, qualitative research emphasises an inductive process, drawing generalisable inferences (theories) from observations. Here the focus is on the understanding (Weber, 2009) of human behaviour as distinct from the subject of the natural sciences. This requires a different logic to be applied in order to reflect the distinctiveness of humans as the subject matter of research. Drawing on Creswell and Poth (2016), in

Table 1 I provide brief a summary of the philosophical assumptions characterising two main paradigms.

	Positivist Paradigm	**Phenomenological Paradigm**
Ontology (nature of reality)	Reality is objective and singular. Social phenomena exist independently of social actors.	Reality is subjective as seen by participants in a study. The world is socially constructed and can only understood by examining the perceptions of the human actors, (Collis and Hussey, 2013).
Epistemology (the relationship of the knower to the knowledge)	Focus on causality and generalisation. The researchers are independent from that which is being researched.	Observable phenomena and subjective meaning provide acceptable knowledge.
Axiology (role of values in enquiry)	Independent and objective stance. Positivist scholars believe that the object they are studying is unaffected by their research activities.	Researchers are bound to their values that help determining what are recognised as facts and the interpretations which are drawn from them (Collis and Hussey, 2013).
Generalisation	Time- and context-free generalisations are possible.	Time- and context-free generalisations are not possible.
Causal Linkages	There are real causes that are temporally precedent to, or simultaneous with, effects.	It is impossible to distinguish causes from effects.
Logic	Deductive logic: from the general to the particular, and emphasis on *a priori* hypotheses (or theories).	Inductive logic: from the particular to the general, and emphasis on 'grounded' theories.

Table 1: Philosophical Assumptions

Despite all this, the distinction between the two paradigms is not as straightforward as it might seem. Boundaries between philosophical assumptions are not markedly defined, and such labelling (deduction/positivism, induction/interpretivism) can be misleading (Saunders, Lewis and Thornhill, 2009).

Thus, according to Tashakkori and Teddlie (2010), in this dissertation I believe the importance and predominance of the research question over the paradigm. This pragmatic position postulates the predominance of the research question over the

epistemology, ontology and axiology I adopt, as one may be in turn more appropriate than the other for answering particular questions.

Therefore, from my research questions, it is noticeable how the philosophy behind the present study is mainly driven by a *positivist* orientation toward a *deductive* investigation, and thus the study is based on a quantitative approach. In fact, my hypotheses have been previously settled in order to give justifications and fundamentals through what is discovered. The assumptions will be first tested on a conceptual basis and then empirically validated in order to obtain an objective and 'credible' result where cause-effect relationships are made clear and generalisations are made possible.

The ontological assumptions I make about the world I investigate are towards objectivism. The position that I assume towards reality, conceives it as an external entity separated from social actors. In fact, the analyses do not include the researcher's perceptions or those of individuals. Even though the process of knowledge transformation at the origin of the innovation process takes place individually, my believe is that there exists a social phenomenon and their meanings have an existence that is independent of social actors (Bell, Bryman and Harley, 2018). Furthermore, the epistemological position of this dissertation is towards positivism; only phenomena that we can observe will be considered as credible data. Facts (rather than impressions) constitute the observable social reality (Saunders, Lewis and Thornhill, 2009). Lastly, my emphasis is on gathering quantifiable observations to enable statistical analysis and 'free-values' considerations. Thus, my axiological assumption entails the researcher to be independent from an objective stance.

Research approach

This study follows a mainly quantitative approach in which theories and hypotheses will be tested throughout a research strategy. As proposed by Saunders *et al*. (2009), I have first delineated a proposition, as a result of the literature review, about the relationship between some concepts and variables. More precisely, I believe in a positive relation between publicly funded scientific research and the creation of start-ups and spinoffs in the biotechnology sector. Secondly, I have expressed my hypothesis in operational terms and further details on the measurement of each variable will be provided in the data collection paragraph. In particular, I believe in the existence of a link between the scientific background of the founders of such companies, and their public support and scientific achievements. Thirdly, I adopt a strategy, as I will illustrate in the following paragraph, to respond to each operational question and hypothesis. Finally, I examine the outcome of my research, either to confirm the hypotheses or to indicate the need for a modification to the theory.

Research strategy

According to Saunders *et al.* (2009), the research strategy is the "general plan of how you will go about answering the research questions" (p.74). For Ritchie *et al.* (2013), the relationship between research design, theory and data collection is reiterative, and each phase should inform and be informed by the others. Therefore, the literature review operates as a strategic plan that logically turns the original research questions into empirical projects. The purpose of my study is to establish and explain the causal relations between variables and concepts. The strategy adopted here could be described as ‘explanatory’, since purpose of enquiry may change over time, and consequently, the study could also be termed descripto-explanatory, as a result of the

fact that I took advantage of previously available data to infer and test the validity of certain theoretical assumptions, such as those of KSTE theory. In particular, the research makes use of documents, previous literature, reports and administrative documents, so that the nature of the answer to our research question could be constrained by the nature of the information collected. In terms of methodology choice, multiple methods were employed for data collection. In particular, different sources and collection techniques were combined from previously published studies (see data collection paragraph). Another relevant aspect to mention is that this study is not aimed at representing the development or change of the phenomena over time. However, I am aware that my understanding will be necessarily time-constrained. The structure of the industry, the regulatory framework and the economic outlook will certainly determine some of my conclusions, even though it was my intention to use those empirical observations only as a confirmation of previous theoretical hypothesis.

Sampling

The quantitative research paradigm emphasises the importance of generalisability and reliability (Henn, Weinstein and Foard, 2005). The aim is to apply the relationship obtained between variables to the general, i.e. the population. For these reasons, the sampling procedure is an essential part of quantitative research. One approach to identify appropriate samples is to start from the whole population and then specify the study group to work with. The researcher should pay special attention to presenting information about the characteristics of the sample, and include details on sampling strategies which would enable others to repeat the research (Henn, Weinstein and Foard, 2005). In the context of my empirical examinations, a specific sampling strategy was employed to ensure the generalisability, reliability and repeatability of

the research findings.

In both essays, a deductive strategy to sampling was employed. The starting point was represented by a population made of biotechnology companies headquartered in the UK (Essay Two) and in Europe (Essay Three) which had created at least one drug development project. Drug originator companies were defined as "when the drug is conceptualized, discovered and initially developed and the intellectual rights originate" (GlobalData, 2020).

Samples employed in Essays two and three were identified from the electronic database by GlobalData PLC, a digital company providing data and analysis for consumer, technology and healthcare businesses. The GlobalData database comprises of information on companies' pipelines with a focused and comprehensive coverage of the drugs in development. The samples were narrowed down by applying a series of criteria which helped to identify the relevant units of observation. In Essay Two, an initial selection criterion was that the UK-based biotech firm had received Venture Capital (VC) support. This condition was applied because the purpose of the essay was to analyse the early stage of the pharmaceutical R&D. In fact, contributions by venture capitals are considered key for the early development of promising drugs. The access to VC financial tools was employed in the essay as a signal of successful and promising development of inventions into innovative products.

In contrast, in Essay Three, the sampling criteria was centred on biotech firms which reached the Initial Public Offering (IPO) stage. An IPO can provide an entrepreneurial firm with critical resources for its future expansion, and therefore IPO is regarded as one of the most important stages in the life of an entrepreneurial firm. Furthermore, IPO represents the first and most important 'liquidity event' (Daily *et al.,* 2003).

Typically, the founders and early-stage investors use IPOs to appropriate a proportion of wealth associated with the venture (Bruton, Chahine and Filatotchev, 2009). In this analysis, the objective was to analyse and connect the process of knowledge creation (as represented by the data on the publications made by the biotech founders) with the appropriation of intellectual property rights through patents assignation. To this end, the IPO criteria served to further identify a successful stage within the R&D process. IPO documents also served as a source for biographical information, and were used to define the founders' careers trajectories.

Data collection and analysis

For the purpose of the three studies, data was collected with a cross-sectional design format applied to the different contexts of analysis. A multiple-stage approach to the collection of the relevant information was employed.

Essay One

Systematic reviews are essential tools for summarising the extant literature accurately and reliably. The Cochrane library defines systematic reviews as the "attempts to collate all empirical evidence that fits pre-specified eligibility criteria to answer a specific research question" (Oxman and Guyatt, 1993; Lasserson, Thomas and Higgins, 2019), (p. XXIII) . The key element of systematic reviews, compared to narrative approaches is that "systematic methods are selected to minimise bias, thus providing reliable findings from which conclusions can be drawn and decisions made" (Liberati *et al.*, 2009), (p.e2). The systematic approach has its origins in the medical sciences. In healthcare, scientific evidence plays a key role in informing decision-making about the organisation and the delivery of health and social care, and

significant strides were made in the attempt to improve the quality of the review process by synthesising research in a systematic, transparent and reproducible manner (Tranfield and Mouchel, 2002; Wolf, Shea and Albanese, 2001; Tranfield, Denyer and Smart, 2003). In 2005, a group of 29 review authors, methodologists, clinicians, medical editors and consumers developed the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) statement (Moher *et al.,* 2009). PRISMA is composed of a 27-item checklist and a four-phase flow diagram used to enhance the selection of relevant studies and the reporting. PRISMA represents a way in which authors can ensure the transparent and complete reporting of systematic reviews and meta-analyses (Liberati *et al.,* 2009). In contrast, in management research, the literature review process tends to be conducted mostly through narrative approaches. Tranfield, Denyer and Smart (2003) proposed applying specific principles of the systematic review methodology used in the medical sciences to management research. In the authors' view, there was the need to counteract authorial biases by making explicit the values and assumptions underpinning a review.

The guidelines suggested by Tranfield, Denyer and Smart (2003) and the PRISMA diagram have been combined in Essay One. Furthermore, in order to get to a synthesis of these two approaches, the investigation was operationalised based on the work of (Di Maddaloni and Davis, 2017). Overall, my data collection strategy consisted of three levels, through a deductive approach representing the knowledge areas relevant for investigation. A first level (domain) was identified from the literature on university-industry relations, intended as the broad range of activities involving universities and industry within the economic system. A second level (phenomenon) was that of knowledge and technology transfer. A third and final level of analysis was that of the mechanisms of knowledge transfer, meaning the ways in which knowledge

moves across organisations. Overall, this top-down approach served the purpose of pinpointing the theoretical elements guiding my review.

Relevant data was collected by employing a set of specific keywords, which had been previously tested and approved through discussion with senior academic supervisors and further developed into Boolean operators (Stage 1). In Stage 2 analysis, a set of selection criteria was rationalised, including the choice of databases (ISI, Web of Science), the year span (1980–2018) and the language of the articles (English). Next, a quality appraisal was conducted in order to further narrow down the publications reflecting high academic standards. The quality of publication data then was assessed through a two-step analysis (Stage 3). The first quality criteria were reflected by the number of yearly citations. Following Crossan and Apaydin (2010) research, we identified high-impact publications which showed at least five citations per year, using 2018 as the base year. Previous scholars have used the number of citations as an indicator of impact and performance, as well as an indicator of research excellence for an individual publication (Waltman and van Eck, 2013; Hicks *et al.*, 2015). A further advantage of using citation-based indicators is that they are objective measures which reflect evaluation by subsequent researchers (Van Raan, 2004). The second quality criterion related to journal ranking. This was verified against CABS Journal Guide, the standard of reference for journals in the fields of innovation and business management. Stage 4 consisted of a content analysis of the publications (Mok, Shen and Yang, 2015). Titles and abstracts were included based on deductively formed themes with specific reference to the employed keywords. In this context, my attention was focused on identification and therefore included conceptual analysis of the knowledge transfer channels. I did not take in consideration articles which were focused exclusively on the technological aspects of knowledge from an empirical

point of view. The screening was conducted based on visual examination of titles, abstracts and texts. To avoid bias, two investigators performed a blind reading of the materials, and any disagreement or risk of bias was resolved through discussion with the supervisory team and I. Overall, the results of the selection process were included into the PRISMA chart, and the number of articles included and excluded at each stage of analysis was reported.

Essay Two

In Essays 2 and 3, I follow a bibliometric approach to data collection and analysis, involving the publications and patents authored/invented by the scientific founders of the biotech companies. Specifically in Essay Two, the database Beaurhurst contains key information on high-growth companies that have secured equity fundraising in UK, and this is accessed in order to retrieve the biographical information related to the founding scientists (full name, role, previous affiliation). Furthermore, in Essay Two a literature search was conducted in order to identify relevant publications made by the scientific founders. Two methods were employed for data retrieval, both focusing on the scientific production published before the year of company incorporation. The first data collection method (Method 1) identified the most relevant publications in terms of number of citations. As highlighted in Essay One, citations were employed as a measure for impact, and therefore the ten most cited articles were downloaded in order to capture the publications with the highest scientific relevance. A second research query (Method 2) was made by associating the founders' identity with the information regarding the products in the company pipeline. Specifically, information such as therapy area, molecule type and mechanism of actions were included in the literature search. The objective was to identify the most relevant article per author

according to the company science. In other words, the intent was to identify the key publication containing the scientific discovery upon which the company was created. In this way, I tried to identify the link between the scientific production made before the company foundation and the applied science conducted thereafter, as highlighted by the company drugs pipeline. Overall, the two data collection strategies allowed me to include the most influential publications in the founders' backgrounds (Method 1), as well as the research made in the areas that were then carried out within the founded enterprise and utilised as the basis for drug development (Method 2).

Data analysis required the harmonisation of biographical information and disambiguation of author names to match author and as well as funder identity in publication data. Previous scholars highlighted that manual inspection to disambiguate authors can be very effective for small populations of scientists (D'Angelo, Giuffrida and Abramo, 2011), and therefore in Essay Two I took a manual approach to name disambiguation, which also involved a blind reading of the bibliometric material with the members of my supervisory team. This was required since several authors share the same name, but also one author might express his/her name in different ways. To this end, the Web of Science database provided a grouping option which allowed for the identification of specific authors and their publications. In Web of Science, author records are generated by a proprietary algorithm that identifies and weighs shared data elements such as author names, institution names, and citing and cited author relationships (source: Web of Science).

Secondly, as the objective of the essay was to analyse the financial disclosure of acknowledgment sections, name disambiguation was required to correctly identify funders. The extraction, coding and interpretation of funding data was conducted

manually. Once the relevant funding information for a given publication was identified, the full name of the organisation was retrieved, and a thesaurus of the various names and acronyms of funding agencies was created. During a second stage, data names were cleansed and associated with country code and type, such as whether the funder was a non-profit organisation, a governmental body, charity, university or private financer.

Finally, authors 'affiliations were also coded and categorised. Affiliations were retrieved from the [C1] author address field in the Web of Science database. The [C1] field provides address information separately for each author, and lists more than one address per author where this occurs. Based on this information, the coding was undertaken semi-manually following (Hottenrott and Lawson, 2017). A search algorithm containing word elements such as "univ", "hosp", "ltd" was applied using Microsoft Excel. All entries were then checked, and organisation names were searched online to assign institution types (universities, hospitals or companies respectively).

Essay Three

Three main sources of data were considered in Essay Three: IPO documents, publications, and patents. IPO documents are considered a reliable source of information as they offer a unique opportunity to study the amount and type of voluntary disclosures to the capital market. IPO prospectuses are likely to be highly accurate because companies are liable for any misleading or inaccurate information (Daily *et al.,* 2003). Under the regulations from the US Security and Exchange Commission (SEC), key information needs to be disclosed through certain documents within IPO prospectuses. Similarly, AIM Rule 26 obliges companies to disclose

information on the pre-IPO ownership structure, and such information must be made available to view free of charge.

First, IPO prospectuses were downloaded from companies' websites under the investor relations section, as required by the AIM Rule 26. In cases where it proved difficult to identify the bibliographic information of the founders, IPO material was integrated by searching for biographical information of the company Founders on crunchbase.com, as well as in the Beaurhurst dataset and companies' websites. In order to characterise scientific founders' career trajectories, two co-authors independently scanned, collected, and performed a blind reading of the biographical material. Based on this biographical information, three distinct career trajectories were defined:

1. The industrial trajectory describes scientists who, subsequent to receiving training, have mainly spent their careers working in the drug industry, as well as scientists who have been employed by non-pharmaceutical firms.

2. The academic trajectory includes scientists with stated academic positions or experience in research organisations.

3. The mixed trajectory describes scientists who have worked in both industry and the academic research sector.

Secondly, patent data in which the founders figured as 'inventors' was downloaded. For this purpose, patents were retrieved from 'The Lens' suite (https://www.lens.org/lens/), an integrated initiative by CAMBIA comprising patents registered within the European Patent Office's (DOCDB) bibliographic data, the United States Patent Office (USPTO) database, data from the World Intellectual Property Organization (WIPO-PCT), and Australian patents. The main advantage of

using ‘The Lens’ suite is that inventor names are linked with social web directories (LinkedIn and ORCID), making it easy to further check on founders’ professional and scientific backgrounds.

As a result, patents granted between 1980 and 2019 were included in the sample, but pending patent applications were excluded. Linked to patents, ‘The Lens’ suite also provides references to non-patent literature (NPL). NPL refers to the scientific literature cited by patent documents, and is commonly used as a proxy for knowledge flow between different organisations. Therefore, the NPL included in the patent documents by the scientific founders was also downloaded.

Next, publication data authored by scientific founders was retrieved from ‘The Lens’ suite. A similar data collection strategy as in Essay One was applied. Specifically, articles published in peer-reviewed scientific journals between 1970 and 2019 were included. Meeting abstracts, commentaries and reviews were, however, discarded. Name disambiguation and data cleansing was conducted. The names of the scientists were carefully screened in order to match with those appearing in the patent documents and the publications.

Based on patent and publication data, scientists were categorised based on their propensity towards publishing and patenting (Stokes, 2011; Hess and Rothaermel, 2011; Baba, Shichijo and Sedita, 2009; Subramanian, Lim and Soh, 2013). Specifically, the average number of patents and publications per year was calculated based on the years during which each scientist had been active (i.e. the number of years between the first and the last publication/patent). The scientific production of each scientist was then compared to the mean number of patents/publications of the sample. Accordingly, scientific profiles were defined as follows:

1. Pasteur bridging scientists were those with above-average per-year patenting and publication records.

2. Edison scientists were defined by above-average patenting records but below-average annual publication records.

3. Star non-patenting scientists were those with above-average yearly publication records but below-average annual patents.

Lastly, patent assignees were categorised based on Eurostat's project on Data Production Methods for Harmonised Patent Statistics (Callaert *et al.,* 2011). In particular, the assignee names containing business designations or not-for-profit entity names were checked. Assignees were coded as 'CORP' when the name contained a corporate designation. When the name of a university or research centre was found, patents were coded as 'ACA'. Assignment to governmental bodies and public research institutes was coded as 'PRO'. Unassigned patents were those assigned not to organisations but to individuals (Callaert *et al.,* 2011).

CHAPTER 4: Contributions and Discussion

In this chapter, I outline the general content and the contributions of the three essays which represent the main body of my doctoral work. The comprehensive description of the outcomes and discussion of results are described in detail in the three manuscripts, (Part II).

The essays were written following the editorial requirements of highly ranked academic journals. Two essays were published after a rigorous peer review process. The third is currently under a second round of review.

Main Contributions

This research offers the opportunity to explore some important aspects of the innovation process in biotechnology, including the creation of basic knowledge and its appropriation for commercial use.

These arguments have characterised the scientific debate on innovation for decades. Most previous analyses focused on the transfer of knowledge and technology from university to industry. The literature on scientific and technical human capital investigates the dynamics of academic communities and the engagement of firms in the norms of science. Entrepreneurial perspectives are typically used to analyse the behaviour of academic entrepreneurs, technology transfer offices and spin-offs, as well as the changing roles that universities play in the economy. To our knowledge this is the first attempt to bring these perspectives together. As a result, this research is genuinely multidisciplinary. The innovativation that characterises this doctoral research is the focus on biotechnology founders and the role they play as conduits for

the transformation of knowledge into practice. My works traces back to the origins of innovation, while maintaining an external look at the ‘transformation’, rather than the ‘transfer’, of knowledge embedded in such individuals.

A first contribution stems from the systematic revision of the literature (Essay One). Here the variety and the relation between knowledge transfer mechanisms was investigated. Knowledge transfer mechanisms were characterised by different degrees of formalisation, relational involvement, direction and time. Determinants of these mechanisms were found in the characteristics of knowledge, individuals, organisations and disciplines. As a result, a new taxonomy was framed which distinguishes between channels and processes of knowledge transfer. Channels are linear configurations which allow the transfer of codifiable content, such as publications and patents. Processes are defined as multidimensional spaces that reflect different degrees of relational involvement, such as the entrepreneurial activity of scientists.

Based on this taxonomy, the second essay focuses on publication by biotech founders. The objective was to investigate the nature of the funding given to basic knowledge embedded in these scientific entrepreneurs. Rather than focusing on research budgets top-down, the paper develops a bottom-up approach based on the acknowledgment sections of key publications by biotech founders. As a result, the study highlights the contributions given to science that have transformed into business. As a result, the paper evidences that public institutions finance a substantial part of the knowledge published by the scientific founders of biotechnology enterprises.

The third essay investigates the direction given to the knowledge produced by biotech founders and financed by public institutions. The observation is made on the patents, the channels through which valuable inventions are protected and rights to use are

assigned. The work makes multiple contributions. First, it adds further elements that characterise the career trajectories of scientists who found biotechnology companies. It highlights that scientific human capital behind biotech companies is heterogeneous, and this demonstrates the value of adopting a broader view, rather than being restricted to academic publishing and patenting. Second, the analysis of patent assignation provides important elements in understanding the patent ownership landscape in Europe. Previous analyses of academic patenting claim the presence of private ownership model in Europe and associated this with factors such as a professor's privilege with regard to different institutional schemes. This work uncovers an important element, that in the most part corporate ownership can be explained through the assignation of IPR to start-up companies. Third, the results of my regression model show that academics have stronger incentives than scientists with careers spent in the industry, to capitalise on the discoveries made by assigning the patent property to their own start-ups. By contrast, the study finds that corporate scientists have stronger links with their employers as they show stronger likelihood of assigning to them the inventions they patent.

Overall, based on the combined outcomes of the three essays, this thesis shows that public institutions back up the creation of valuable inventions by financing the knowledge produced by academic scientists. Academics capitalise on their experience at university by assigning the majority of patents to their own start-ups. In this light, the papers presented here support the argument that the risks that characterise knowledge creation and the rewards connected with the appropriation of economic value should be shared between public and private actors.

	Title	Status	Research Questions	Objective	Main Outcomes	Contribution
Essay One	Channels and processes of knowledge transfer: how does knowledge move between university and industry?	Published in *Science and Public Policy* (2019)	1. What determines the movement of knowledge between university and industry? 2. What are the characteristics of the transport mechanism?	To gain a better understanding of academia–industry interactions and to explore the conduits of knowledge transfer.	Determinants for the adoption of knowledge transfer mechanisms were: knowledge, individuals, organisations and disciplines. Knowledge transfer mechanisms can be classified based on degrees of formalisation, relational involvement, direction and time. Overall, knowledge content, embedded in individuals or processes within organisations, is the main component which drives the adoption of knowledge transfer mechanisms.	A new taxonomy was proposed. I define 'channels' as media through which encoded knowledge is transferred uni-directionally. 'Processes' are social configurations in which coded and encoded knowledge is shared (multi-directional) with an increasing level of relational involvement.
Essay Two	Public-private contribution to biopharmaceutical discoveries: a bibliometric analysis of biomedical research in UK.	Published in *Scientometrics* (2019)	1. What is the nature of the financial support acknowledged in the publications by biotech founders? 2. What is the distribution of funding organisations across countries and disciplines? 3. To what extent does funded research have a higher impact in terms of article citations?	To analyse the nature and scope of the financial contribution acknowledged in publications by scientists involved in the foundation of biotechnology companies.	The support from public institutions was reported by the majority of publications. Most scientists were affiliate with public institutions.	Public institutions play a major role in the financing of basic knowledge produced by academic scientists who are also founders of drug-originating biotechnology companies.

Essay Three	R versus D, from knowledge creation to value appropriation: ownership of patents filed by European biotechnology founders.	Under review- second round by *Technovation*	1. What is the scientific human capital upon which European biotechnology firms are created? 2. To what extent is the assignation of intellectual property rights sensitive to: 2.1. the inventor's professional career; 2.2. scientific experience; and 2.3. patent characteristics?	To analyse the career trajectories and research backgrounds of biotech founders and by what means these affect the assignation of intellectual property rights and thereby the appropriation of knowledge.	Biotech founders show heterogeneous career backgrounds across academia and industry. Patents are assigned, in the main, to their own start-ups. Academic founders show stronger incentives to transfer their inventions to the start-ups than industrial scientists. Industrial scientists have stronger ties with their employer than academics with university.	Biotech founders capitalise on their research and professional backgrounds by assigning the IPRs of their inventions to their own start-ups.

Table 2: Main results and contributions by the three essays

Limitations

As with all forms of empirical research, this work is recognised to have some limitations. Overall, the critical elements that should be considered when interpreting the results of this research concern the methodology applied for the identification of scientists involved in company' creation and the relative publications and patents. Certainly, the bibliometric approach adopted in the studies represents a strength of this work, for its ability to track the development of individual innovators and the transformation of their knowledge into products. As I have largely illustrated in the previous chapters, no attempts were made by scholars to investigate the innovation process starting from its final product. At the same time, due to the lack of previous evidence in employing a similar approach, the approach itself is also a study limitation. Several efforts were required to standardise data collection procedures and to retrieve the relevant information without compromising the validity of the results.

In this context, a specific limitation concerns the process of identifying the scientific founders of biotech companies. Biographies and information on their accounts were not always available from the companies' websites or from institutional sources and online databases. This was particularly true when the scientists had multiple appointments with public and private organisations (mixed career scientists). Therefore, to avoid errors, data on biotech founders was retrieved from different sources (see chapter 3, p.41), and then triangulated. Also, more than one researcher was involved in the double blind reading of the retrieved material and disagreements among the team members were solved through discussion. Overall, a conservative approach was followed, in that when the information was not sufficient to correctly characterise the identity of the founders, these were dropped from the analysis. Once founders' identities were clarified and included, a second limitation was the process

of name disambiguation to associate publications and patents with each of the founders. To this end, I relied on data sources, disposing of automised systems for author disambiguation, such as ‘Web of Science’ and ‘Lens’. Also, the triangulation of different data sources allowed control for bias.

In conclusion, despite the subjectivity of the author and the supervisors being reduced to a minimum, the observed sample of biotech companies and founders suffers from the standardised procedures and exclusion criteria adopted to avoid selection bias. For example, the choice of including drug originating companies certainly allows for the observation of companies started with the sole purpose of developing ideas and technologies into products. At the same time, the decision made in the Essay Three to focus on biotech companies that reached IPO underlines the relevance of this choice for the purpose of tracking the genesis of ideas and their transformation into drug compounds. These choices were also consistent with the need to create standardised procedures to discover the origins of innovations. By contrast, through this approach biotech companies that failed or did not reach a successful stage of venture financing as well as those licensing out their inventions to other enterprises, were left out of the analyses. Overall, in the light of these limitations, future researchers may consider extending this thesis and drive more empirical investigations on the topic to strengthen the validity of the bottom-up approach for analysing innovations as delineated in this dissertation book. I propose some lines of research in the next paragraph.

Future Research

Overall, this research aims to contribute to the debate of how to achieve a fair distribution of risks and rewards between actors at different stages of the innovation process. Previous scholars, such as Lazonick and Mazzucato (2013), have made

substantial contributions to this field by highlighting the 'risk-reward nexus' that seeks to analyse the ways in which risks and rewards can be aligned with contributors to the innovation process. In line with the contributions by these scholars, my work highlights the collective aspect of knowledge creation and tracks the contribution of actors of different kinds to the innovation process in biotechnology. Future research in this field should pay attention to factors that have limited the analysis performed here, and should extend the purposes of the investigation to aspects that my research has not fully addressed. For example, scholars may find interesting the application of my bottom-up approach to track the genesis of innovations in fields other than biotechnology. Authors may perform qualitative research on biotech founders to investigate further the extent to which scientists seek to capitalise on their academic research by starting biotech companies. Qualitative research would be also useful for the purpose of confirm the validity of bibliometric data associated with founders' identities, and could provide a standardised procedure that can be replicated in different fields. Furthermore, another aspect I deem relevant of attention by future scholars is the study of the collaborative efforts of scientific founders. Understanding to what extent authors affiliated to the same institution face incentives to bypass formal institutional channels, such as TTOs, could be an interesting perspective from which to look at the network of individual relations that characterise the transfer of knowledge to the private sector. Lastly, the approach undertaken in this thesis opens the way for future analyses to clarify and measure the risks undertaken by actors positioned at the early stages of the R&D process. This, perhaps, is the major challenge for future research developments, as the quantification and assessment of risks is made difficult by the inherent uncertain characteristics of innovation. However, a bottom-up approach to the analysis of risks undertaken by organisations that finance single

research initiatives and scientists may be an alternative strategy to the top-down analysis of research budgets.

In conclusion, this book advocates a wide and dynamic approach to how value is created. Contributions in this field are relevant for advancing evidence needed for price negotiations between manufacturers and public payers. Therefore, my research calls for more efforts towards understanding and supporting equitable and accessible ways to provide innovation.

Policy Reflections

By highlighting the dynamics behind the division of labour in the biopharmaceutical industry, this thesis provides new evidence that may influence the policy debate on innovation. Based on the results of my essays, I claim that the debate on the distribution of risks and rewards between the actors on the innovation process should recognize not only the roles of public and private organizations, but also that of key individual actors, such as the entrepreneurial scientists.

My reflections are inspired by those of previous scholars such as Mazzucato and Lazonick who pointed out that the collective, cumulative and uncertain aspects of the innovation process make possible a disconnect between who bears the risks and who gets the returns from the investments in R&D (Lazonick and Mazzucato, 2013). In the entrepreneurial theories of the State by Mazzucato, the public sector co-creates, and not just fixes, the market (Mazzucato, 2011). Public institutions shape the innovation process without limiting their role to the upstream investments in R&D, but actively contributing to the success of innovating companies and products such as those in the tech and pharmaceutical industries. By acknowledging the State plays a key role as

risk-taker, the entrepreneurial theories justify the reap of a share of the financial rewards and, thus, the use of instruments to appropriate returns. This approach is opposite to the traditional view of market failures in which the State fixes the market dysfunctions and gets the returns of a societal nature, such as job creation, economic growth and positive fiscal impact (Laplane and Mazzucato, 2020).

By maintaining the view of the Entrepreneurial State, my essays demonstrate that a way in which the public sector co-creates, and shapes biotechnological innovation outputs is through investments in scientific and human capital of key bridging scientists. My research points out that public institutions bear a high risk which is that of investing in the training, and formation of scientists and operating as the embryonal context in which the knowledge is created. Therefore, by pointing out the dynamics behind the movement of scientists along the innovation process, my works point out the need to combine the individual with the organizational levels when designing policies to align the risk-reward nexus.

In my research I show that scientists position themselves along the innovation process so as to appropriate and maximise a portion of the value they contribute to create through their discoveries. On the one side, in Essay Two, I point out that a great portion of their discoveries are co-created by universities and public institutions that also support research projects financially. On the other side, in Essay Three, I show that university scientists have strong propensities to maximise their rewards by assigning the intellectual property of patents to the biotech companies they start their own. In sum, my research highlights that the ‘Entrepreneurial State’ is made by ‘Entrepreneurial Universities’ which are in turn made by ‘Entrepreneurial Scientists’. Therefore, in the logic that aims to assess the risks and the rewards of the public and

private organizations in the innovation process, it is necessary to look also at the risk-reward nexus that involves each of these levels.

Adopting an individual perspective can be relevant for the design of appropriate fixes to the innovation process. From a macro perspective, Mazzucato propose several instruments to ensure the State with the possibility to get a fair share of rewards, the so-called 'socialization of rewards" (Laplane and Mazzucato, 2020). Examples of instruments are profit sharing via royalties on sales or equity, or conditionality instruments such as the pricing of final goods as well as the use of mission-oriented public finance. One field of application is the control over drug pricing. In the US, some authors have discussed the use of "march-in-rights" as provisioned by the Bayh-Dole Act, and never used by governments (Arno and Davis, 2000; Alperovitz and Daly, 2009). By contrast, other scholars have pointed out that using control pricing would discourage private investment to bring early discoveries to the marketplace (Thomas, 2016; Treasure, 2016).

In the European context, finding appropriate policy measures to adopt is made harder by the fact that legal prescriptions in the kind of the Bayh-Dole Act are not adopted uniformly and the presence of "professor privilege" regulations still characterises many of the national patent contexts. However, the role of public authorities in the negotiation of prices and access to medicines, under the "value-based" pricing approach, constitute an important space to implement a risk-reward narrative in the European landscape. From the perspective of health systems facing budgetary concerns and the contemporary soring price of some pharmaceuticals, it is important to re-establish a symbiotic relation between the risk takers organizations and the individuals who appropriate the economic rewards.

Bibliometric data employed in this thesis offers a unique lens to highlight a small, yet relevant aspect of this phenomenon, through the explanatory potential of micro-level analysis conducted on individual innovators. Therefore, enhancing the availability of financial information behind knowledge creation, such as the disclosure of financial contributions in publications and patents documents, is key for the future development of models for risk assessment at individual levels. A better understanding of these dynamics may help bring new evidence that may influence the negotiation of fair prices and contribute to the debate on how risks and rewards can be fairly distributed among all the actors, and the organizations, in the innovation process.

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PART II

Highlights of the Essays:

Essay One – Title: Channels and processes of knowledge transfer: how does knowledge move between university and industry?

Authors: Gianluca Fabiano, Andrea Marcellusi, Giampiero Favato

Affiliation: Institute for Leadership and Management in Health, Kingston University, London, UK.

Published in: *Science and Public Policy*, Volume 47, Issue 2, April 2020, Pages 256–270, https://doi.org/10.1093/scipol/scaa002

Journal ranking: 2 stars ABS, **Impact Factor:** 1.730 (2019)

Abstract:

The role of knowledge and technology transfer between academia and the industry has received increasing attention in the analysis of innovation. This paper aims to explore the scientific literature concerning knowledge transport mechanisms and describe how the topic was organized by previous studies and terminologies applied. A systematic review was conducted in which the content of recent contributions best fitting these intensions was analysed. The characteristics of knowledge, individuals, organizations and disciplines were found to be the main determinants in the adoption of transfer mechanisms. These were classified in terms of formalization, relational involvement, direction and time. On the revealed multi-dimensionality of knowledge transfer and complementarity between transfer activities we framed a new taxonomy distinguishing between channels and processes. Future research may deepen these factors, such as the economic aspects driving the adoption of transfer mechanisms informing decisions on the funding of innovation.

Keywords: university-industry; knowledge transfer; innovation

Essay Two – Title: Public-private contribution to biopharmaceutical discoveries: a bibliometric analysis of biomedical research in UK.

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Published in: Scientometrics 124, 153–168 (2020). https://doi.org/10.1007/s11192-020-03429-1

Journal ranking: 2 stars ABS, **Impact Factor:** 2.867 (2019)

Abstract:

Basic research creates new knowledge that fuels technological advances. However, budgetary concerns and escalating R&D prices are challenging organizations to show returns from investments in scientific research. Few attempts are made to analyse research that leads to pharmaceutical innovation. In particular, the financial contribution of public and private organizations to the riskiest stage of biomedical discovery has remained unclear and partially unexplored.

This study is a first attempt to shed light on the financial support to basic research by public and private sectors using publications data. We conducted an exploratory analysis of funding acknowledgments (FA) on publications authored by the founding scientists of 91 'drug originator' companies in United Kingdom. The nature and distribution of the support acknowledged to the research conducted before the company creation was analysed and the impact of publications and type of support were statistically tested.

We found the majority of publications acknowledged public institutions, whereas, commercial organisations were likely to support those with privately affiliated authors. Based on these findings, we discussed the need to foster collaborative

research and to set adequate incentives for shared risks and benefits from investments in knowledge creation.

Keywords: basic research, drug discovery, innovation, funding acknowledgment

Essay Three – Title: R versus D, from knowledge creation to value appropriation: Ownership of patents filed by European biotechnology founders

Authors: Gianluca Fabiano, Andrea Marcellusi, Giampiero Favato

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Under Review – second round: Technovation

Journal ranking: 3 stars ABS, **Impact Factor:** 5.729 (2019)

Abstract:

Biotechnology firms are often created on the premise of commercializing the results of research carried out by scientists with heterogeneous careers and research trajectories. Patents filed by company founders provide accessible information on the appropriation of knowledge through the assignment of intellectual property rights (IPR).

In this study, we developed a novel database of patents and publications by the founders of European drug-originating biotech companies that reached IPO between 2013 and 2018. The founders' scientific human capital was analysed. Moreover, we developed a regression model to estimate whether the founders' career trajectories, previous publications and patent characteristics affected the likelihood of the use of a university versus an industry patent ownership model.

Our findings suggest that founders' scientific human capital influences the way knowledge is captured for economic use. Compared to patents filed by industrial inventors, those filed by academics are more likely to be assigned to the inventor's own start-up company or to universities and public research organizations (PROs) than to be appropriated by private organizations other than the one founded by the inventor. Patent data, when not restricted to university members, provide a very comprehensive picture of the knowledge transfer activities. This lens encourages fundamental questions about biopharmaceutical innovation regarding issues such as whether risks and returns are appropriately shared between actors in the public and private sectors.

Keywords: patent ownership; scientific founders; knowledge technology transfer; European biotechnology

JEL classification codes: L38, L33, O31, O32, O34

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Appendix

Table 1: Examples of identification of career trajectory

Academic trajectory
"Professor James Lorens is the co-founder of BerGenBio, serves as the company's Senior Scientific Advisor and is also a Professor at the Department of Biomedicine at the University of Bergen. On completing his postdoctoral research studies at Stanford University he joined Rigel Inc., a San Francisco based biotechnology company, as a founding scientist and research director. Prof. Lorens has managed several large scientific collaborations in cancer research and development with major pharmaceutical and biotechnology companies".
"Prof. Riedemann received his medical training at Freiburg, Germany, and Stanford University, USA. He performed basic science research at The University of Michigan in the field of complement immunology and inflammation for several years and then completed his board certification in General Surgery at Hannover Medical School, where he still holds a Professorship in Experimental Surgery.".
Industrial trajectory
"Dr Love was a senior scientist at Ciba Geigy/Novartis focused on novel drug delivery technologies and involved in the development of the world's leading eye-care pharmaceutical, Visudyne. In 1997, Dr Love founded Destiny Pharma and he is the co-inventor of the XF drug platform. Dr Love was a founding member of the BEAM Alliance, an EU SME group focused on promoting antimicrobial drug development [...]" - Ph.D. in Drug Delivery University of Wales.
"After gaining a PhD in pharmacology from the University of Dijon, Philippe Genne began his scientific career as a project leader at Debiopharm where he oversaw a clinical development program related to multi-drug resistance inhibitors. He also worked as a research associate at Glaxo-Welcome." - PhD in pharmacology from the University of Dijon.
Mixed trajectory
"Pascale Fouqueray joined Merck KGaA in 2000 from Paris VII University, where she was Assistant Professor of physiology. At Merck KGaA, Dr. Fouqueray's activities were centered on metabolism, with a particular focus on diabetes and obesity but also including lipids and uric acid metabolism. Dr. Fouqueray was responsible for the clinical development of compounds for the treatment of diabetes and gout disease, working on strategies to define and reach proof-of- concept and investigate mechanisms of action"- PhD from the University of Paris XI.
"Daniel Obrecht, Ph.D., spent 11 years at the Central Research Laboratories of Roche Basel. In his previous position he was Head of the Combinatorial Chemistry Group. Dr. Daniel Obrecht obtained his Ph.D. in Chemistry from the University of Zurich in 1985 under the supervision of Prof. H. Heimgartner, after which he was associated with Prof. R. E. Ireland at Caltech as a postdoctoral fellow for 2 years".

Table 2: Correlation matri

		Inventor Professional Trajectory	No. previous patents	No. previous publications	Applicability	Backward citations	Forward citations	No. assignees	No. inventors	NPL Citations
Inventor Professional Trajectory	Pearson Correlation	1	0.017	-0.053	.133**	-0.062	-0.060	-.113**	-0.031	-.092**
	Sig. (2-tailed)		0.597	0.127	0.000	0.059	0.069	0.001	0.345	0.005
No. previous patents	Pearson Correlation	0.017	1	.093**	0.036	.121**	-0.024	.132**	.217**	0.052
	Sig. (2-tailed)	0.597		0.007	0.293	0.000	0.465	0.000	0.000	0.114
No. previous publications	Pearson Correlation	-0.053	.093**	1	.136**	-0.010	-.095**	.094**	-0.022	-0.007
	Sig. (2-tailed)	0.127	0.007		0.000	0.781	0.006	0.006	0.525	0.850
Applicability	Pearson Correlation	.133**	0.036	.136**	1	0.024	-0.035	-.079*	-0.040	-0.023
	Sig. (2-tailed)	0.000	0.293	0.000		0.491	0.310	0.022	0.250	0.506
Backward citations	Pearson Correlation	-0.062	.121**	-0.010	0.024	1	.287**	0.048	0.039	.692**
	Sig. (2-tailed)	0.059	0.000	0.781	0.491		0.000	0.140	0.232	0.000
Forward citations	Pearson Correlation	-0.060	-0.024	-.095**	-0.035	.287**	1	-0.047	-0.032	.287**
	Sig. (2-tailed)	0.069	0.465	0.006	0.310	0.000		0.152	0.327	0.000
No. assignees	Pearson Correlation	-.113**	.132**	.094**	-.079*	0.048	-0.047	1	.127**	0.030
	Sig. (2-tailed)	0.001	0.000	0.006	0.022	0.140	0.152		0.000	0.361
No. inventors	Pearson Correlation	-0.031	.217**	-0.022	-0.040	0.039	-0.032	.127**	1	0.047
	Sig. (2-tailed)	0.345	0.000	0.525	0.250	0.232	0.327	0.000		0.151
NPL Citations	Pearson Correlation	-.092**	0.052	-0.007	-0.023	.692**	.287**	0.030	0.047	1
	Sig. (2-tailed)	0.005	0.114	0.850	0.506	0.000	0.000	0.361	0.151	