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New Entrants and Inherited Competence: The Evolution of the Irish Biotech Sector

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New Entrants and Inherited Competence - The Evolution of the Irish Biotech Sector

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Abstract

In this paper we use Klepper's (2008) theory of the evolution of industrial concentrations to study the role of entrepreneurial activity in the evolution of the Irish biotechnology sector. Specifically, we study the characteristics of new entrants, and the relationships between new entrants and existing private firms and higher education institutes. Two distinct evolutionary processes involving, on the one hand, the university spin-offs and on the other hand private sector spin-offs are observed to have shaped the Irish biotech industry's development. We also add to Klepper's (2008) theory by relating the theoretical concept of inherited company traits to a different typology of spin-offs – university spin-offs versus private sector spin-offs.

1. Introduction

Explanations of the emergence and subsequent development industrial clusters have become increasingly informed by evolutionary theory. This evolutionary perspective seeks to explain the clustering process in terms of the entry, growth, decline and exit of firms, and their locational behaviour (Boschma and Frenken, 2011). This economic evolution of firms facilitates the replication and selective transmission of firm-specific organisational routines, with spin-off firms and labour mobility being the primary vehicles for the transfer of increasingly modified routines (Nelson and Winter,1982; Teece et al.,1997). In this evolutionary characterization of the industrialisation process, spin-off firms enable clusters to be self-reproducing even in the absence of traditional Marshallian agglomeration economies, such as labour pooling, technological spillovers, and local access to specialised suppliers (Klepper, 2007; Boschma and Wenting, 2007).

This line of research focussing on the role of spin-off processes in cluster development has received a strong impulse from the work of Klepper (2008), who shows how organisational reproduction and inherited company traits can influence spin-off processes. Klepper's (2008) formal theoretical model of the evolution of industrial concentrations explains the process through which spin-off firms can lead to clustering in terms of these inherited company traits organisational reproduction: Firms differ innately in terms of their levels of competence, and the competence of firms is based on their pre-entry experience. Firms acquire their competence from firms in related industries and prior entrants into the new industry. In this way, clusters are characterised as emerging from a snowball process of spin-off formation. Spin-offs inherit a large part of their capabilities from their parent, which explains why successful firms tend to give birth to successful parents (Boschma and Frenken, 2011).

We believe that this theory can be usefully employed to understand the evolution of the Irish biotechnology industry. But we also add to the theory by relating the theoretical concept of inherited company traits to a different typology of spin-offs – university spin-offs versus private sector spin-offs. We argue that university spin-offs have high R&D competence but low innovation competence. Private sector spin-offs, on the other hand, have strong R&D competence and strong innovation experience. In the biotech industry this innovation competence is crucial. In fact, our detailed analysis of Irish biotech companies suggests that some Irish biotech private sector spin-offs are predominantly the organisers of innovation, with more limited technical R&D competence. Yet it is the innovation/business organisational competence, rather than technical R&D competence, that appears to be a prerequisite for strong firm performance.

The context for this study, the Irish bio-technology sector, is of interest for a number of reasons. First, the development of the biotechnology industry over the last two decades has not been a uniform process across countries. As discussed in Nosella et al. (2005) and Orsenigo (2001) among others, the biotechnology sectors of European countries (apart from UK) have developed at a much later stage than US. Second, over the period of this study, the business environment for research-orientated small dedicated biotech firms has varied in Ireland, with a significant increase in public research funding occurring in the period since 2000.

In this paper we analyse the evolution of the Irish biotech cluster. We identify two distinct evolutionary processes involving, on the one hand, the university spin-offs and on the other hand private sector spin-offs. We also analyse the performance of these two segments of the biotech industry over the last two decades. Given the large cohort of small firms operating in the Irish biotech industry, financial measures of firm performance are not available. Instead, we focus on a number of non-financial indicators, capturing the ability of firms to generate patentable research and to attract venture capital funding. Our analysis of the Irish biotech industry indicates that a similar quantity of university spin-offs and private sector spin-offs are present in the industry, and that both university and private sector spin-offs score well in term of patent generation. However, this may actually not tell us much about spin-off performance. An important indicator is success in attracting venture capital flows. In this respect, the private sector spin-offs far outperform the university spin-offs. We contend that this ability of private sector spin-offs to attract substantial venture capital stems from their superior organisational and industry experience.

This paper is structured as follows: Section 2 provides a brief overview of the development of theories of cluster evolution to incorporate spin-off processes and organisation reproduction. Section 3 details data sources and definitions. The evolution of the Irish biotech industry is described in detail in Section 4, while Section 5 discusses in detail the distinct development process of Irish Biotech companies of private sector origins compared to that of university origins. Finally, Section 6 concludes and sets out the policy implications of our findings.

2. Cluster evolution, spin-off processes, and organisation reproduction

Approaches to understanding the development of industrial clusters are increasingly informed by evolutionary thinking (Asheim, Cooke and Martin, 2006). The literature on regional and national innovation systems has been particularly influential (Cooke, 2001; Malerba 2003; Lundvall, 1992; Edquist, 2005). These evolutionary approaches to understanding cluster development are characterised by a focus on innovation and learning processes, a historical perspective and an emphasis on the role of institutions and networks. As regards the explanation for the actual clustering process, moving away from a narrow focus on external economies of scale and pecuniary externalities, the evolutionary approaches tend to focus on the role of proximity in stimulating information flow and knowledge spillovers. However, recent evolutionary scholarship suggests that such factors may actually play a limited role in driving industrial cluster processes, at least in the early stages, and call for a focus on spin-off processes (Boschma and Wenting, 2007; Ter Wal and Boschma, 2007).

An important contribution in this regard has been made by Klepper (2008 and 2010) who developed a formal model of the evolution of industrial concentrations driven by spin-off processes. The model has been applied to the US tyre industry in Buenstorf and Klepper (2009) and to Detroit's automobile industry and Silicon Valley's integrated circuits industry in Klepper (2010). The theory characterises industry evolution in terms of organisational reproduction and inherited company traits to explain how spin-off firms can lead to clustering. In this way, the theory emphasizes the internal spillovers and hereditary characteristics inherent in individual firms, rather than external spillovers accrued from close proximity to large concentrations of firms, as a driver of a given firm's long-term performance.

Specifically, Klepper (2008) argues that firms differ innately in terms of their levels of competence, and the competence of firms is based on their pre-entry experience. He identifies three types of entrants into a new industry based on their pre-entry experience: firstly, diversifiers, which are entrants that diversify from related industries; secondly, spin-offs, which are founded by employees from incumbent firms; and thirdly, start-ups, which are founded by employees of firms in related industries or other capitalists with no experience in the new industry. Klepper postulates that the spin-offs will have the highest degree of competence, based on organizational and industry experience. They can exploit knowledge about the new industry that their founders gained while working in the industry at their "parent" firms. They are expected to have inherited traits from these parents. Start-ups on the other hand are characterised by low competence, reflecting a lack of organisational and industry experience.

Thus a firm's pre-entry experience critically shapes its competence, and its performance then influences its competitiveness, its chance of survival and growth, and the rate at which it generates further spin-offs. Such spin-off processes are then an important factor in the explanation of industrial clustering processes because spin-offs tend to locate in relative proximity to their parent firm.

We can extend the application of Klepper's conceptualisation of firm competence, pre-entry experience and clustering processes, by distinguishing an important category of entrants in the biotech industry – university spin-offs. These university spin-offs account for a large share of new entrants in the biotech industry. In addition, the model can be refined by distinguishing two different types of competence. In this paper we distinguish two types of spin-off entrants based on their pre-entry experience - university and private sector spin-offs – and two types of knowledge and competence – R&D competence and innovation competence. Klepper loosely defines the concept of organisational knowledge and competence as a firm's "competence at doing R&D", its ability to "manage the R&D process" (Klepper, 2008), or its ability to "manage technological change" (Klepper, 2010). In this article we propose a more refined distinction between the competence at managing the narrow R&D process and the competence at managing the broader innovation process.

We suggest that the two competences are based on different combinations of knowledge, present in different intensities. In relation to the type of knowledge, a distinction has been made between know-why, know-how and know-who type knowledge (Asheim et al., 2011) Know-why knowledge relates to natural systems and the applications of scientific laws. Know-how type knowledge involved the technical skills, often of a tacit nature. Finally, know-who type knowledge involves knowledge about, for example, relevant business partners or sources of finance. Van Egeraat et al. (2009), based on their work on innovation processes and knowledge flows in the biotechnology industry, suggest adding a fourth, crucial, type of knowledge to the categorisation – industry/business knowledge. This includes knowledge of (unmet) market needs, the ability to connect particular inventions to market needs, knowledge about bringing products through clinical trials, knowledge of regulatory procedures, knowledge of raising finance, and so forth.

R&D competence involves a high level of know-why and know-how type knowledge, while know-who and industry/business knowledge play a less important role. The broader innovation process requires a different combination of knowledge. While know-why and know-how type knowledge remain important, bringing a new invention to market requires know-who and industry/business type knowledge. In the biotech industry this know-who/industry knowledge is crucial for success (Van Egeraat, et al. 2009).

We argue that university spin-offs have high R&D competence but low innovation competence. Private sector spin-offs on the other hand have strong R&D competence and strong innovation experience. Given the crucial role of know-who/industry knowledge and innovation competence, the inherited traits in this regard in the two industry segments are seen to be an important factor in the relative performance of the different segments and therefore in the development and evolution of the industry. Our analysis focuses on a number of non-financial indicators, capturing the ability of firms to generate patentable research and to attract venture capital funding. These non-financial indicators are then supplemented with qualitative data from interviews which explore the role of R&D competence, industry knowledge, and innovation competence in the development of the Irish biotech industry. The sources of these non-financial indicators, our population of Irish biotech firms, and our interview methodology are now discussed in more detail.

3. Data sources and definitions

Partly due to the lack of official statistics and partly due to the ambiguous nature of the definition it is difficult to determine the size of the Irish biotech industry. Our 'universe' of firms in the modern biotech industry in Ireland is based on existing survey material, the list of firms included on the 'Biotechnology Ireland' website (hosted by Enterprise Ireland), information from interviews with industry experts and internet searches. Our data collection began with an inventorization of biotech companies in Ireland. Following this, we compile a dataset based on a rigorous internet search of official company websites and media sources. This dataset contains information on the founders of each company; serial entrepreneurs, who form numerous companies; and spin-off companies. The database also identifies whether these spin-off companies emerged from existing private companies or universities. The date of establishment of all spin-offs and existing companies is also included in the dataset, allowing us to undertake an analysis of the evolution of the Irish biotech industry over time. We have endeavoured to verify the database through consultation with industry experts and with the information contained in the FAME business database.

This paper also analyses the stream of patent applications to emanate from Irish biotech companies from 1984 to 2008, based on patent data available from the Irish Patent Office (http://www.patentsoffice.ie/), US Patent and Trademark Office (http://www.uspto.gov/), and Esp@cenet, the European Patent Office (http://ep.espacenet.com/). This paper also utilises data on venture capital funding provided to Irish biotech firms over the period 2000-2010. This data is available from the Irish Venture Capital Association (www.ivca.ie) for the period 2007-2010. The data is available at firm-level across sectors, and the data

source also identifies the investors who provided the funding to each firm contained in the dataset. We have extended this data back as far as 2000 for the biotech industry, based on the data available from the Irish Times Archive.

To address the issues of the different types of knowledge and competence possessed by university spin-offs and private sector spin-offs within the Irish biotechnology industry, a set of interviews have been undertaken with key industry actors. Qualitative data on the role of different types of knowledge/competence and company strategies has been collected during interviews with ten biotech spin-off companies, as well as interviews with two venture capital companies, industrial development agencies and other industry experts. The ten biotech companies interviewed are representative of both university and private sector spin-offs.

Finally, it remains to clarify a number of definitional issues for the purposes of this paper. This paper focuses on the modern biotechnology industry. The "modern" refers to the post-genetic engineering era: that is, after scientists had developed the knowledge, techniques and tools to intervene directly at the gene level (Laage-Hellman et al., 2004). The definition of the modern biotechnology and the operationalization of such a definition are the subject of intense debate and controversy. A diversity of definitions exists. Some studies focus on particular industries while others argue that modern biotechnology should be regarded as a diverse set of knowledge bases and an enabling technology that has affected different industries (Brink, et al., 2004). OECD (2006) applies a combination of a single definition and a list based definition. Biotechnology is defined as the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or nonliving materials for the production of knowledge, goods and services'. It has been rightly pointed out that this would encompass not only most biomedical R&D and commercial activities that involve laboratory animals or humans, but also virtually all of agriculture, baking that uses yeasts, and the production of fermented beverages and foods, including beer and yogurt (Millar, 2007). In order to narrow the definition to *modern* biotechnology OECD (2006) employs a list based definition that includes various techniques and activities: synthesis, manipulation or sequencing of DNA, RNA or protein; cell and tissue culture and engineering; vaccines and immune stimulants; embryo manipulation; fermentation; using plants for cleanup of toxic wastes; gene therapy; bioinformatics, including the construction of databases; and nanobiotechnology. It is this OECD (2006) list-based definition of *modern* biotechnology that is used in this paper.

Regarding the term "spin-off", it should be noted that multiple definitions exist for the terms spin-off and spin-out (for a discussion see Myint et al., 2006) and the definitional issues are further confused by the fact that the meaning of the two terms tends to be inverted in Europe and the USA. Therefore, we only

use the term spin-off and apply a broad definition that covers a wide range of firms, including: (1) firms started as the result of a mother-organisation splitting off existing units or departments and the mother company holding (at least initially) equity stakes in the new firm and (2) firms formed by employees or groups of employees leaving an existing organisation to form an independent start-up firm. The parent entity can be a firm, a university or another organisation. In the second case the firm is only considered a spin-off if the employees received some form of assistance/support/stimulation from the parent organisation or if they are based on intellectual property/core capability developed during the employees' stay at the parent organisation.

4. The evolution of the Irish biotech sector in the context of the global industry

The development of the global biotechnology industry over the last two decades has not been a uniform process across countries. As discussed in Nosella et al. (2005) and Orsenigo (2001) among others, the biotechnology sectors of European countries (apart from UK) have developed at a much later stage than US due to differences in (i) the availability of financing for new firms (such as the absence of structured venture capital); (ii) the protection guaranteed by the patents system; (iii) the strength of university/industry relationship, and its implications for knowledge transfer; and (iv) the fragmentation and specialisation of research. In the aftermath of the US research programme known as the human genome project (HGP) of the early 1990s, a biotechnology industry organisational structure emerged which featured small dedicated biotech firms at the heart of a complex innovation network. Specifically, the post-genome era is characterised by knowledge accumulation no longer being driven by large international corporations, or small university start-ups in isolation. Rather, knowledge accumulation is now facilitated through a complex and interactive network of public research institutions, large international corporations, university start-ups and other research-orientated small biotech firms, and even consumer associations, Quéré (2004).

However, the business environment for these research-orientated small dedicated biotech firms has varied across European countries. Senker (2004), in a study of how country-specific characteristics have impacted biotech industry development in Austria, France, Germany, Greece, Ireland, Netherlands, Spain and the UK, found that differences in country-specific supply conditions and the existing national structure of production, such as the mix of domestic and foreign-owned firms; the level of biotech knowledge and skills; public policy for developing the science base; and cultural traditions in universities, can all lead to variations in the rate of small firm creation across national biotech sectors. What is more,

cross-country differences in demand for, and social acceptance of, emerging biotechnological applications can also impact upon the national pattern of biotech innovation. Of the eight European countries studied, the empirical analysis of Senker (2004) pointed to Germany, The Netherlands and the UK as having cultivated business environments rich in factors supportive of innovation (and free from factors which impede innovation) in the biotech industry. In the Irish case, while a long standing policy to support biotech innovation, technology transfer and small firm creation, as well as access to the EU market, were cited as positive factors, poor availability of finance capital and limited R&D skills were identified as negative factors.

The development of the 'modern' biotech sector in Ireland took off in earnest in the 1990s, although substantial employment growth only occurred in the 2000s due to the establishment of a number of foreign-owned biopharmaceutical manufacturing plants. Partly due to the lack of official statistics and the ambiguous nature of the definition, it is difficult to determine the size of the Irish biotechnology industry and its sub-sectors. Applying the OECD (2006) modern biotechnology definition, a recent inventorisation of the sector (Van Egeraat and Curran, 2010) counted 80 biotechnology firms (See Table 1). Biopharmaceuticals and bio diagnostics are the largest subsectors with 64 per cent of companies. The bio-pharma sub-sector is even more dominant than the table suggests since the majority of the indigenous biotechnology services companies are active in biopharmaceuticals. We have no exact data on employment numbers in each sub-sector but since the two sub-sectors include most of the large foreign-owned manufacturing plants, we know that virtually all employment is concentrated in these sub-sectors.

Table 1: Research-active biotechnology companies in Ireland

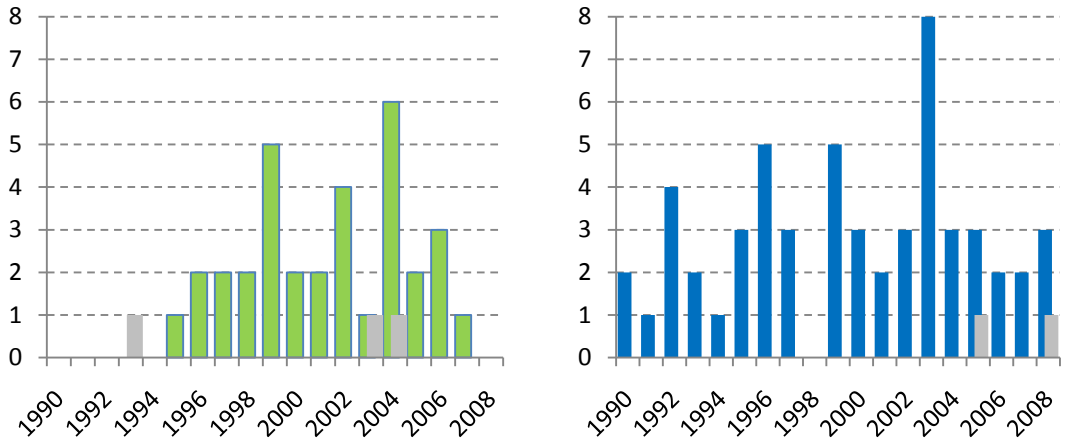
Dominant activity	**Indigenous companies**	**Foreign companies**	**Total**
Bio-pharma	17	16	33
Bio-diagnostics	16	5	21
Agri-pharma "green" biotech	3	7	10
Biotechnology services	10	-	10
Industrial "white" biotech, Aqua-marine "blue" biotech and unknown	6	-	6
Total	52	28	80

Source: Van Egeraat and Curran (2010)

Nearly all of the 28 foreign-owned companies are subsidiaries of multinationals with a strong manufacturing focus, although the biopharmaceutical manufacturing plants can have a substantial process development component (Van Egeraat et al., 2009). The sector counts 52 indigenous companies, mainly concentrated in bio-pharmaceuticals and bio-diagnostics. However, the majority of these firms are very small, early stage, start-up or campus companies. As regards company size the data are incomplete. What we know is that all but two of the indigenous companies are SMEs. It is estimated that the majority of indigenous companies on the list are micro-enterprises, employing less than 10 staff. Most of the 17 indigenous bio-pharmaceutical companies are still at an embryonic stage, operating out of university labs and less than a handful would have brought molecules beyond pre-clinical trials. Combining firm-level data available from the FAME database and reports from industry experts yields an estimate of total employment in the Irish biotech industry of just under 3,000 persons in 2009, of which approximately 10% are employed in university spin-offs. The remaining employees reside in firms of private sector origins (46% in private sector spin-offs and 44% in other private sector start-ups).

The remainder of this section focuses spin-off processes in the evolution of the Irish Biotech industry. Specifically, we distinguish between Irish biotech firms who have originated as university spin-offs and Irish biotech firms of private sector origins (both private sector spin-offs and private sector start-ups, as per Klepper (2008)). University spin-offs account for 35% of the firms in our dataset. The remaining firms originated in the private sector and are almost evenly split between private sector spin-offs (33%) and other private sector start-ups (31%). Figure 1 illustrates the chronology of university spin-off entrance and exit, as well as the entrance and exit of firms of private sector origins, over the period 1990-2008. It is apparent from Figure 1 that the incidence of biotech university spin-off begins circa 1995. Firms of private sector origins enter throughout the period 1990-2008, but occur with relatively more frequency in early 2000s. University spin-offs begin to enter from the mid-1990s onwards. The low incidence of exit observed in both university spin-offs and firms of private sector origins may be due to the fact that some biotech firms opt to remain dormant rather than exit the industry entirely in the hope that their research output may be acquired at a later stage.

Figure 1: University spin-off entrants and exits (left) and entrant and exits of private sector origins (right) 1990-2008

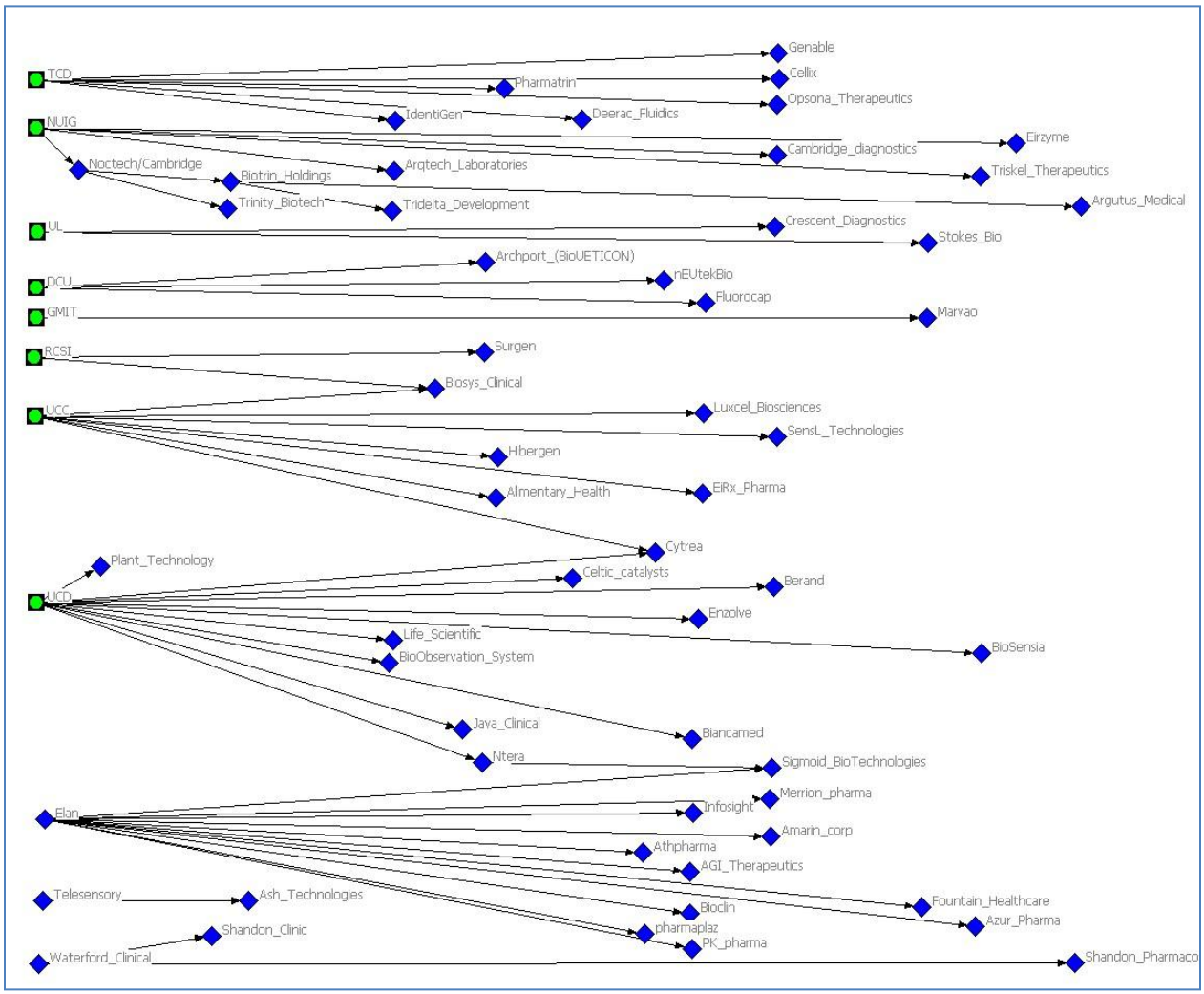


Source: *FAME database*

Notes: Entrants and exits above refer to the cohort of firms under observation in this study. Due to data constraints, acquisition by another biotech company is not counted as an exit in Figure 1.

Figure 2 presents a more detailed genealogy of Irish biotech spin-offs. University and private sector spin-off processes are largely separate processes, with only one spin-off identifiable as having both private sector and university origins. Subsequent waves of spin-offs have yet to emanate from those spin-offs created over the 1990-2008 period. University spin-offs occurred predominantly over the 1996-2004 period, and to a lesser extent over the 2005-2008 period. Elan is clearly the dominant source of private spin-offs, accounting for 12 spin-offs post-2001.

Figure 2: Chronology of Irish biotechnology Spin-offs, 1990-2008



Pre-1990	1991-1995	1996-2000	2001-2004	2005-2008

Note: **Universities denoted by circle-in-box; all companies denoted by diamond**

This paper therefore characterizes the development of the Irish biotech industry as comprising of two distinct evolutionary processes involving, on the one hand, a series of private sector spin-offs that can be traced back to the founding of Elan, Ireland's largest indigenous biotech multinational more than four decades ago and, on the other hand, a more recent process of university spin-offs which has emerged over the last decade.

Elan Corporation was launched in 1969, when Elan founder, Donald Panoz, moved to Ireland from the United States. He had formerly been the founder of a successful drug delivery firm, Mylan laboratories, in Pittsburgh. It has been suggested that his choice to set up Elan in Ireland was influenced by the favourable tax regime and less restrictive bureaucracy in place in Ireland.[1] Originally a specialist in drug delivery systems, Elan initially provided drug absorption control technology for antibiotics produced by other global pharmaceutical companies. By the early 1980s, Elan had secured contracts for the provision of absorption technology for 25 pharmaceutical products from 16 different pharmaceutical companies. While continuing this contracting work, Elan also further developed its own research and development capabilities, and in 1992 the company became the first to receive Food and Drug Agency (FDA) approval for the transdermal nicotine patch.

In the 1990s Elan's interests extended into the area of neuroscience and the company subsequently undertook the development of its own products for the treatment of Alzheimer's disease, Parkinson's disease, and multiple sclerosis.[2] To facilitate this product development, Elan embarked on an aggressive acquisitions strategy. At the same time, Elan began building a web of strategic partnerships, acquiring minority stakes in a number of companies that in turn paid the company licensing fees for its technology. However, Elan's stock market value collapsed in 2002 after the US Securities and Exchange Commission launched an investigation into the company's accounting practices. Elan responded by implementing a recovery plan which involved the divesting of a number of subsidiaries and licenses in an effort to drive down debt (*Irish Times*, 29 October 2010).

This divesture of biotechnology assets, accompanied by the departure of a substantial number of executives and scientists from Elan's Irish operations, has led to the emergence of a wave of Irish biotech

[1] See:http://www.fundinguniverse.com/company-histories/Elan-Corporation-PLC-Company-History.html.

[2] Elan's neuroscience drug discovery research is primarily carried out in the company's US-based laboratories. While Elan Corporation is headquartered in Dublin, Irish involvement has been largely confined to the development of drug delivery products in the Elan Drug Technologies unit in Athlone, Co. Westmeath. Elan also established a research group in Trinity College Dublin in 1990. In May 2011, US-based Alkermes agreed to purchase Elan Drug Technologies unit in a deal worth €960 million.

firms that were either spun off from Elan or formed by former Elan staff. During the two-year period between 2002 and 2004 alone, nine firms were spun off and another three firms followed between 2005 and 2008. Other Elan alumni have dispersed into existing biotech and pharmaceutical firms, as well as into legal and venture capital firms (Sheridan, 2008).

The interconnectedness of former Elan staff is a prominent feature of these spin-offs. One of the first spin-offs in 2003, AGI Therapeutics, which adapts molecular entities for the treatment of gastrointestinal conditions, was founded by former Elan executive, John Devane. He had previously been a founder of Athpharma in 2001, which was acquired in 2006 by another former Elan executive, Seamus Mulligan. Seamus Mulligan then transferred its assets into a new venture called Circ Pharma, where he was joined by another former Elan executive, Peter Thornton. Seamus Mulligan also established specialty pharmaceutical firm Azur Pharma, which is managed by a number of former Elan executives, (Daly, 2008). Peter Thornton is also a member of the board of Merrion Pharmaceutical. Established in 2004, this company acquired the oral drug delivery assets developed at Elan Biotechnology Research. In 2004 a management group led by Elan's former chief financial officer, Thomas Lynch, took over Amarin Corporation, following Lynch's purchase of Elan's stake in the firm (Sheridan, 2008).

In parallel with the wave of Elan spin-offs, since the mid-1990s, Ireland has witnessed a strong increase in university spin-offs. This development should be linked to a substantial public sector investment over the last 10 years which has significantly enhanced the biotech research performance of Irish universities. This funding injection has been timely, given the changing organisation of the global biotechnology industry in the post-genome era and the enhanced opportunities for small scale university spin-offs and dedicated biotech firms to explore new avenues of research, into which larger integrated firms are unable or unwilling to allocate resources. In 1998 the Irish government launched the Programme for Research in the Third-Level Institutions (PRTLI) and Science Foundation Ireland (SFI), which since its inception has invested €865 million (including exchequer and private matching funds) into strengthening national research capabilities via investment in human and physical infrastructure.[3] A biotech-related example of this public sector funding is the SFI's recent investment of €10million in the Regenerative Medicine Institute (REMEDI) based in NUI Galway (Ahlstrom, 2010).

A further effort aimed at cultivating university–industry linkages has been the establishment of seven Centres for Science, Engineering and Technology (CSET). One such CSET is the Biomedical Diagnostics

[3] See www.hea.ie for further details.

Institute (BDI), which brings together a partnership of five university institutions and six companies.[4] The BDI was founded in 2005 though SFI funding of €16.5 million and an additional €6.5 million provided by industry partners. The process of technology transfer within Irish universities has also evolved over the last decade. According to Geoghegan and Pontikakis (2008), a significant empowerment of Technology Transfer Offices of the Irish universities has occurred over the last decade, in tandem with a rapid realignment of university research activities. Figures 1 and 2 show how these policy initiatives paid off. The number of university spin-offs increased substantially since the mid-1990s with a peak in 2004.

To summarise, Elan's divestiture of biotechnology assets and product rights, as well as the dispersion of former Elan executives and researchers throughout the Irish biotech industry, fundamentally changed the trajectory of the Irish biotech industry. Prior to its restructuring (necessitated by an accounting scandal), Elan was characterized by industry analysts as being *"hermetically sealed from the rest of Ireland's indigenous life sciences industry"* and as operating *"on a different plane compared to the small-scale, undercapitalized ventures that otherwise constituted the sector"* (Sheridan, 2008). A second, distinct process shaping the Irish biotechnology sector over the last decade has been the large-scale public sector investment aimed at developing the biotechnology research capabilities university and university spin-offs. The next section will analyse the relative success of the spin-offs arising from the two processes.

5. Analysis of university and private sector new entrants

Having mapped the landscape and evolution of Irish biotech spin-offs, we now analyse the relative performance of the two segments of the biotech industry. In the absence of financial measures of firm performance we will start by comparing the number of spin-offs in both segments. We then compare the ability of university and private sector spin-offs to generate patentable research and their ability to attract private sector funding Finally, we explain the difference in relative performance of firms in the two segments as per Klepper (2008), in terms of inherited company traits. Notably we highlight the role of innovation competence in addition to R&D competence, as outlined in section 2

The cohort of university spin-offs and private sector spin-offs residing in the Irish biotech industry are of a similar population size. As discussed in Section 4, university spin-offs account for 35% of the firms in our dataset, while private sector spin-offs account for 33% (private sector start-ups as defined by Klepper

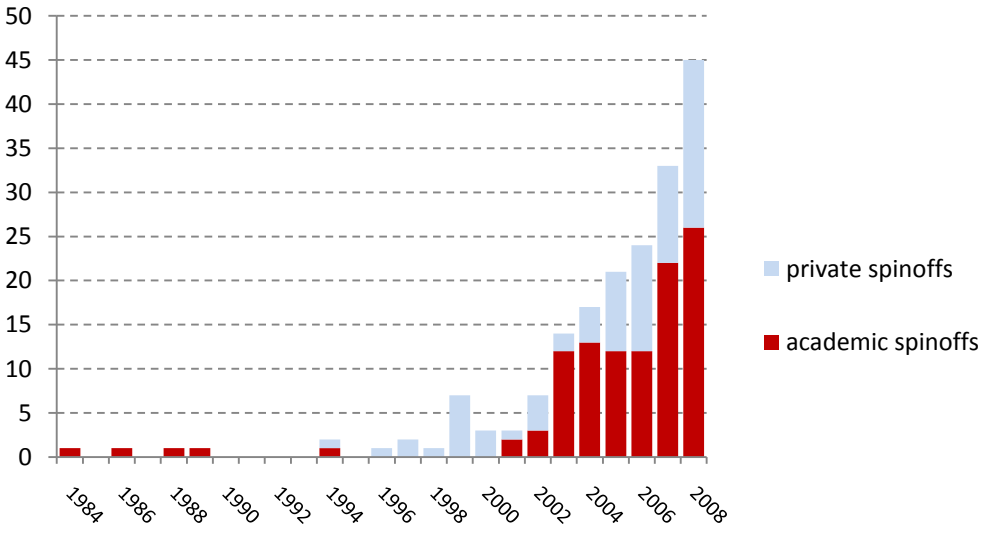
[4] For further information regarding the Biomedical Diagnostics Institute, see www.bdi.ie.

(2008) account for the remaining 31%). As illustrated in Figure 2 and discussed in the previous section, spin-off generation in both academia and the private sector has largely taken place from the mid-1990s onwards. While the number of spin-offs generated by academia has kept pace with that of the private sector, Irish university spin-offs are predominantly small dedicated research-orientated firms. As a consequence, university spin-offs account for a relatively smaller proportion of biotech sector employment. On basis of firm-level data available from the FAME database and reports from industry experts we estimate that the Irish biotech industry employed just under 3,000 persons in 2009, of which approximately 10% were employed in university spin-offs compare to 46% employed in private sector spin-offs (other private sector start-ups accounted for the remaining 44%).

It should be noted that a large presence of university spin-offs is not experienced across all European countries. Orsenigo (2001), in a study of the development of the Biotech industry in the Italian region of Lombardy, noted the lack of innovative biotech firms emerging at that time and attributed this, in part, to the lag in Italian molecular biology basic research relative to main European countries, in terms of absolute amounts of funding, organizational efficiency and overall quality of the research. Furthermore, a traditional separation existed between Italian academia and industry and the organizational deficiencies within universities which made it difficult to commercialize university research. Senker (2004) identifies the Spanish and French biotech industries as having a relatively low proportion of university spin-offs, with Germany, Austria, and Ireland possessing a greater proportion (over 20% of all biotech firms) of university spin-offs.

We now analyse the patent generation of both university spin-offs and private sector spin-offs over the period 1984-2008 (Figure 3). The strongest trend to emerge from Figure 3 is the marked take-off in Irish biotech patent applications from the early 2000s onwards. This pattern is evident among firms from both university and private sector spin-offs. University spin-offs accounted for 26% of Irish biotech patent applications over the entire 1984-2008 period. It is clear from Figure 3 that patents emanating from university spin-offs have shown a marked increase from 2000 onwards. This coincides with the substantial public sector investment over the last 10 years discussed in the previous section, which has significantly the biotech research performance of Irish universities. Private sector spin-offs accounted for 19% of Irish biotech patent applications over the entire 1984-2008 period. From Figure 3, it is clear that number of patent applications generated by private sector spin-offs increased notably from 2004 onwards. This reflects Elan's divesture of biotechnology assets and product rights, and the cohort of Elan-related spin-offs that emerged from this process.

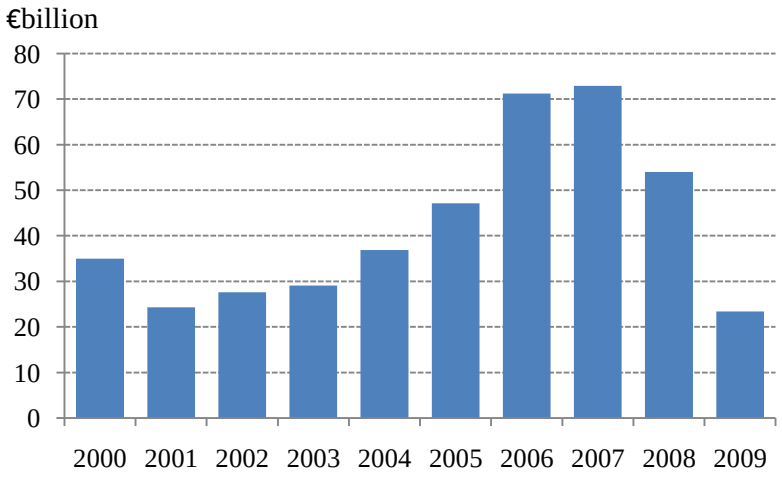
Figure 3: Irish Biotech industry patent applications, by company type (1984-2008)



Source: *Espace@net*

Both in terms of spin-off generation and generation of patentable research, Irish biotech firms originating from both the university and private sector perform well, and keep pace with each other, over the last two decades (particularly from 2000 onwards). Let us now compare the performance of the two segments in terms of their ability to attract private sector funding. The Irish biotech sector's development in recent years has been greatly shaped by the availability of private equity venture capital funding. As one would expect, the recent economic downturn has restricted the availability of venture capital. According to PWC (2010), the amount of venture capital raised in 2009 by biotech companies based in Europe was €800 million, the lowest figure since 2003. Figure 4 below illustrates the changing private equity environment in Europe over the 2000-2009 period.

Figure 4: Annual European Private Equity Investment, 2000-2009



Source: EVCA (2010)

Note: Private Equity comprises all stages of financing for unquoted companies: seed, start-up, expansion, replacement capital and buyouts. Venture capital is limited to the growth stages of a company, i.e. seed, start-up and expansion capital; EVCA (2010).

According to the European Venture Capital Association (EVCA), buyout and growth deals added up to 83% of the total investment value in 2009, with venture capital deals only accounting for the remainder. The top three industry sectors to attract private equity investment were life sciences with €3.6bn (15%), followed by communications with €3bn (13%) and consumer goods & retail with €3bn (13%). Venture capital was mainly driven by investments in the life sciences sector (28% of the total amount invested, and 21% of the total number of companies to receive funds); EVCA (2010). Despite the more restrictive funding environment in 2009, venture capital funding for Irish biotech companies appears to have remained resilient over the 2002-2009 period (see Table 2 below). Total venture capital investment in Ireland appears to have more than doubled since 2002, while the Irish proportion of venture capital secured by the Irish biotech industry has also experienced a marked increase since 2002.

Table 2: Irish biotech and total venture capital, 2002, 2008 and 2009

	2002	2008	2009
Biotech investment as a % of Total VC	1.87%	13.36%	30.69%

Source: PWC (2005), IVCA *Venture Capital Pulse*,2007-2009 www.ivca.ie **Note:** all monetary figures are given in current values. 2008 and 2009 Biotech investment refers to investment in the cohort of biotech firms under observation in this study.

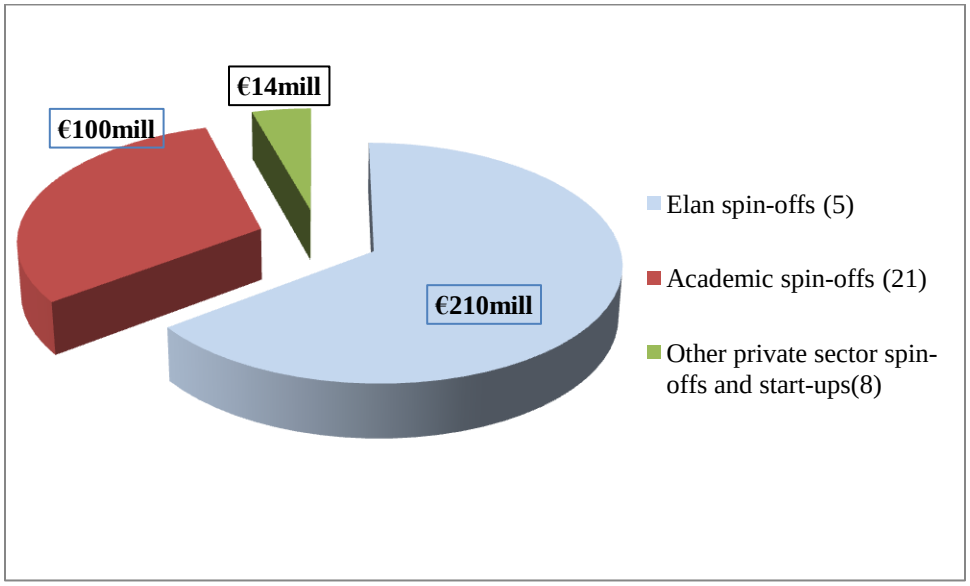
A breakdown of the venture capital invested in Irish biotech firms from 2000 to 2010 is provided in Figure 4. Private sector spin-offs were clearly the most successful in this regard, accounting for more than two thirds of all venture capital. Spin-off firms emanating from Elan have enjoyed notable success in attracting private sector investments. A mere five spin-offs from Elan have attracted more than twice as much venture capital funding as twenty-one university spin-offs over the period in question. Non-Elan private spin-offs and other private start-ups accounted for a mere 4% of venture capital funding, despite accounting for 31% of Irish biotech firms and 44% of Irish biotech employment. This is in keeping with Klepper's (2008) hypothesis that start-up companies are characterised by low competence, reflecting a lack of organisational and industry experience.

Table 3 provides a firm-level breakdown of these venture capital trends. Of the ten most successful Irish biotech firms in terms of attracting venture capital, five are Elan spin-offs. The data actually understates the extent of the relative success of the Elan spin-offs because some of these spin-offs have raised substantial funds as part of the initial public offering (IPO) process.

For example, Amarin had raised substantial private sector funding, prior to a securing a 70 million venture capital funding in 2009.[5] AGI Therapeutics raised €9.5m venture capital in 2004 and went on to raise a further €42.5 million in an IPO in Dublin and London in 2006. Azur Pharma was founded with private equity funding of $60 million in 2007 and the same year the company raised a further $50 million. Merrion Pharmaceuticals attracted €11m venture capital in the first two years of operation, a further €21 million during the period 2007-2010 as well as 5.6m at the time of the IPO.

[5] Much of the data in the remainder of this section are taken from a wide variety of official publications, newspaper articles and transcripts of interviews conducted with biotechnology companies and industry experts. In the interest of brevity and clarity of presentation, these sources are generally not cited. Further information can be obtained from the authors.

Figure 4: Irish Biotech Venture Capital funding, 2000-2010



Source: IVCA *Venture Capital Pulse*, 2007-20010 (www.ivca.ie); Irish Times Archive, 2000-2006. **Note:** Number of companies given in brackets; figures given in current values**.**

Table 3: Firm-level breakdown of venture capital flows, 2000-2010

Company	Origins	€'000
Amarin	Private sector (Elan)	85,900
Azur	Private sector (Elan)	75,000
Merrion pharma	Private sector (Elan)	33,500
Ntera	University (UCD)	28,000
Opsona Therapeutics	University (TCD)	22,900
Eirzyme	University (NUIG)	10,000
AGI	Private sector (Elan)	9,500
Biancamed	University (UCD)	7,550
Sensl Technologies	University (UCC)	6,445
Sigmoid Biotechnologies	Private sector (Elan)	6,420
Hibergen	University (UCC)	5,500
Beocare	Private sector (Beocare Corp.)	5,200
Biosensia	University (UCD)	3,900
Luxcel Biosciences	University (UCC)	3,000
Topchem	Private sector (-)	2,500
Cellix	University (TCD)	2,400
Vysera	Private sector (-)	2,200
Celtic Catalysts	University (UCD)	1,711
Argutus Medical	Private sector (Biotrin)	1,500
Pharmatrin	University (TCD)	1,500
Alimentary Health	University (UCC)	1,300
Genable	University (TCD)	1,100
Crescent Diagnostics	University (UL)	1,045
Stokes Bio	University (UL)	1,000
Neurocure	Private sector (BMR)	900
Marvao	University (GMIT)	850
Allegro (Deerac)	University (TCD)	800
Aerogen	Private sector (-)	750
Neutekbio	University (DCU)	650
Megazyme	Private sector (-)	650
Eirgen	Private sector (-)	500
Identigen	University (TCD)	500
Bioobservation	University (UCD)	120
Luxcel	University (UCC)	100

Source: IVCA *Venture Capital Pulse*, 2007-20010 (www.ivca.ie); Irish Times Archive, 2000-2006.

Thus, the venture capital data suggest that, as a segment, the private sector spin-offs have performed better than the university spin-offs. Also, those private sector start-ups that were not spin-offs appear to have performed particularly poorly. We content that this difference in performance should be linked to the different levels of organisational competence (Klepper, 2008) as defined in the theoretical section. The university spin-offs are typically founded, managed and directed by the university professor(s)

responsible for the invention/patent that lies at the basis of the new firm formation. Generally these academics have a large amount of know-why and know-how knowledge, supporting narrowly defined R&D competence. However, in general, know-who and industry/business knowledge are less developed. This knowledge is crucial for success in the biotech industry. *"The barrier to entry in our industry is not the technology, it is the regulatory environment. And the universities have no, nor should they have, any familiarity and finesse with the FDA"* (Interview VC firm). In spite of the often promising patents, many of these start-ups are slow to develop and are unable to attract the required finance. Many do not develop beyond the initial start-up stage and are eventually wound up or continue in a dormant form.

The private sector spin-offs, notably the Elan spin-offs, inherited strong technical R&D competence as well as a rich know-who and industry/business knowledge which forms the basis of their innovation competence. In some cases the technical R&D competence appears of secondary importance to innovation competence. This is because a substantial number of these spin-offs operate as "hollow companies" from an R&D perspective. They have a limited internal R&D infrastructure and focus on commercializing R&D, rather than on performing R&D (Interview, VC firm).

A good example of both the presence of innovation competence and the hollow business model is AGI Therapeutics, founded in 2003 by a group of former Elan executives. The CEO, John Devane, held a number of senior management positions with Elan, including VP of R&D, where he successfully directed the development and regulatory approval of a number of projects. AGI, employing four staff in 2010, operates a hundred per cent outsourcing model. The company adapts molecular entities for the treatment of gastrointestinal conditions. It acquires promising patents from external sources and brings these through clinical trials. However, all R&D, analytical services and clinical trial activity is outsourced.

Another example is specialty pharmaceutical firm Azur Pharma. The company was established in 2005 by three former Elan executives. The CEO had a 20-year tenure at Elan and had most recently been responsible for managing Elan's group-wide business and corporate development activities. The other two founders had acted as Vice President of Finance and Vice President of Strategic Planning at Elan. The management team was specifically designed for the commercial strategy of the company which is to identify, evaluate, selectively acquire and enhance the value of late stage development and FDA approved pharmaceutical products. Until this stage the company has only bought-in products that were already approved by the regulatory authorities and has conducted no R&D. Apart from the core management team, most of the employees are involved in sales functions.

The Merrion Pharmaceutical spin-off portrays a similar importance of innovation competence. Merrion was established in 2004 in the wake of Elan's divestment of its Biotechnology Research unit at Trinity College. A small group of biotech entrepreneurs acquired oral drug delivery patents developed at Elan Biotechnology Research. The chief executive had a background in toxicology but was working as vice president at a venture capital company. The Chief Operations Officer had a 20-year commercial background in business development and marketing at multinational pharmaceutical companies. Elan's Head of Product, Technology and Business Development joined the board of Directors. The management team swiftly built up a team of 25 employees to further develop and exploit the acquired IP. The company operates a semi-outsourcing model, retaining some in-house R&D capability but outsourcing important elements of the development activities. For example in the context of the in vivo pre-clinical studies, the actual administration of the drugs into the animals was conducted by a contractor in the US. In addition the company contracted-out a range of routine analytical services. Although the company is no longer involved in early stage research, it is important for the company to have access to knowledge and new developments in methodologies and techniques. For this the company uses consultancy services of a professor at one of the local universities.

6. Conclusions

The growth of the Irish biotech industry over the last two decades has been shaped by two distinct forces: (i) the rapid growth and subsequent restructuring of Elan; and (ii) the emergence of enhanced university research capabilities and university spin-offs as a source of basic research and patentable innovations. The co-existence of these two distinct industry catalysts, which appear to have been largely independent of one another, necessitates that the development of the Irish biotech industry must be understood in terms of two separate industry-shaping processes.

As per Klepper (2008), we find that a high competence parent (Elan) has borne high competence spin-offs, as indicated by the flow of venture capital in the industry. While the Irish biotech industry comprises of a similar number of university and private sector spin-offs, and these two cohorts have both generated increasing quantitiess of patentable research in recent years, we show that in one key respect – the attraction of investment funding - spin-offs from Ireland's most successful indigenous biotech firm, Elan, have enjoyed a superior performance relative to the spin-offs that emerged from Irish universities. For example, for the period 2000-2010 five Elan spin-offs attracted twice as much venture capital funding than the twenty-one university spin-offs in receipt of venture capital over this same period. We argue that innovation competence may be at least as important as technical R&D competence for spin-off success, and that the spin-off firms from Elan have inherited substantial business/industry knowledge and high innovation competence from a highly competent parent. We also find that private sector start-ups which were not spin-offs fared very poorly in terms of attracting venture capital, supporting Klepper's (2008) hypothesis that such start-up companies are characterised by low competence, reflecting a lack of organisational and industry experience. Taken as a whole, as per Klepper (2008) it appears that the level of inherited organisational competence present in an industry, which drives the evolution of an industry, is itself influenced by the origins of the firms within that industry. Specifically, it is the university/private sector origins that influence the innovation competence of these firms.

As discussed in Section 5, Elan itself can be considered to be, in the Klepper (2008) terminology, a high competence spin-off, as the founder left a parent company based in the United States, established his own company in an Irish location with few (if any) existing entrants, went on to become an industry leader, and in time spun off new high competence firms. This role played by inventor mobility as an important conduit for technological spillovers has been documented by Almeida and Kogut (1990) and Breschi and Lissoni (2002). Without wishing to draw comparisons between the Irish biotech industry and other far more established industrial concentrations, we note that Klepper (2010) identifies a similar initiation

process in both Detroit's automobile industry and Silicon Valley's integrated circuits industry. Indeed both Klepper (2008) and Buenstorf and Klepper (2010) point to the US automobile and tyre industries, respectively, as illustrations of how one firm can have a profound influence on the evolution of the geographic structure of an entire industry, in that it can catalyze the industrial concentration of that industry around a particular location.

A number of policy implications arise from our study of the Irish biotech industry, both of relevance in the Irish case and of broader application. The evolution of the Irish biotech industry serves as a reminder of the important role of divestments for new firm formation. The sudden divestment of biotechnology assets and product rights by an industry leader (Elan) can act as the catalyst for the creation of a wave of high competence spin-offs, which have given new impetus to the Irish biotech industry. Similar processes have been identified in relation to the Information Technology industry (for example, see Barry and van Egeraat, 2008).

The formative role of private sector spin-offs in industry evolution suggests that policymakers should at least pay as much attention to stimulating private sector spin-offs as to university spin-offs, and should be mindful of the proportion of industrial promotion agencies' resources that are directed to each of these cohorts. At the same time, we are not saying that investment in the science base and the promotion of university spin-offs is necessarily counterproductive. Our findings have identified a number of success stories in this field also. Rather, we are arguing for a greater focus on the commercial aspects of innovation in the science and industrial development promotion efforts of the state and its development agencies. For example, there may be scope to integrate more strongly an entrepreneurship and innovation stream into the science programs offered by the science courses of Irish universities. At a minimum, it seems prudent to include people with strong business and industry knowledge and innovation competence in the management team of university spin-offs at the earliest possible stage. This may need to be at a more hands-on level within the university spin-off than the current practice of including a person with business expertise of the board of directors.

The broader implication of our paper for policy is that government and government agencies should leverage the role of private sector spin-off processes and, within that, the role of high competence parents. However, this raises an age-old question for policymakers: is it possible to create high competence parents which will seed the development of new industries or should the focus be on creating the conditions in which high competence parent may emerge of their own accord?

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