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Stem Cells as a Driver of the Knowledge Economy: Progress and Challenges Facing Scotland

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Stem Cells as a Driver of the Knowledge Economy:

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Abstract

Regional science and innovation policies have diffused rapidly through OECD countries and regions, partly stimulated by evolutionary theories of learning and innovation, which hold that the regional institutional environment can play a role in stimulating innovation. The concept that became known as regional systems of innovation has received attention from both theorists and policy makers. This paper evaluates this concept using Scotland as a case study.

The Scottish experience supports critics' views against those of theorists of regional innovation systems for two reasons. First, the systems of innovation are bounded by knowledge and technology, but less by geography. Second, markets tend to limit the potential of regional-driven knowledge to foster local development. The Scottish case highlights the difficulties of pursuing regional science and innovation policies in the era of globalization.

Keywords: Regenerative medicine, Translational research, Regional systems of innovation, Network, Regional development, Local governance

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Paper Outline

1. Introduction

Regional science and innovation policies diffused rapidly through OECD countries and regions in the 1990s and 2000s, partly stimulated by evolutionary theories of learning and innovation, which hold that the regional institutional environment can play a role in stimulating innovation and development (Morgan 2004: 18). The concept that became known as regional systems of innovation has received attention from both theorists and policy makers.

Recognizing the insufficiency, as a whole, of the traditional "hands-off" approach towards industrial policy in the UK, Scotland introduced its own regional science and innovation policies (Asheim 2004, Cooke 2004). Ever since the new strategy was launched by Scottish Enterprise in 1999, support for life sciences and biotechnology has become a priority in economic and industrial policy discourse in Scotland (Leibovitz 2004: 1138, Rosiello 2008: 497). The modern life sciences and biotechnology industry is widely considered to be the most science-driven of the "knowledge economy" industries (Cooke 2004).

Since 2004, stem cell research in particular has attracted strategic policy attention in Scotland for two main reasons.[1] First, Scotland's renowned science base in stem cell research is considered to constitute a key driver of regional development. Second, regenerative medicine (RM)[2] that uses stem cell technology is now regarded as a major source of innovation in healthcare in the twenty-first century.

Arguments against the concept of regional systems of innovation, however, emerged in the 2000s. For instance, Bathelt (2003) argues for the importance of establishing external-local linkages over local networking. He stresses that these linkages require public institutional and infrastructure support, and he cautions against recent regional innovation and development policies that are predisposed toward local networking.

This paper, therefore, evaluates the concept of regional systems of innovation using Scotland as a case study. Section 2 summarizes arguments both for and against the concept of regional systems of innovation. The methodology used to assess the relevance of this concept is discussed in Section 3. Section 4 provides an overview of the Scottish stem cell science base and its industrial application during the early days of the development of the RM industry. Section 5 examines carefully the degree to which the Scottish Stem Cell Initiative, which is an attempt by Scottish Enterprise to establish a more robust regional innovation system, has contributed to fostering regional innovation and development since 2004. Section 6 discusses the empirical results, and Section 7 presents the conclusion.

2. Theoretical Framework

2.1 Regional systems of innovation

Philip Cooke was one of the first people to promote the idea of regional innovation systems in the 1990s. The origins of this concept lie in two main bodies of theory and research (Cooke 1998, Cooke et al. 1997). The first field of research is systems of innovation research. The second field is regional science and economic geography, which is concerned with the locational distribution and policy impacts of regional high-technology industry, technology parks, innovation networks, and innovation programs.

During the 1990s, the question of systemic innovation was posed by those interested in innovation as a national process[3]. "The national systems of innovation (NSI) literature made enormous strides in defining innovation, correcting the perceived wisdom about innovation processes by showing them to interactive, non linear, and introducing the important concept of 'institutional learning' into this more systemic analysis of innovation" (Cooke 1998: 24).

Philip Cooke questioned the appropriateness of the national level as a starting point for the analysis of innovation processes (Cooke et al. 1997: 476). The development of post-Fordist supply chain relationships among firms and their contribution to cluster formation, to some extent concentrated in regions, "opened up the way to explore the extent to which innovation processes at regional level could be defined as systemic" (Cooke 1998: 24).

More recently, Cooke specified conditions and criteria to promote innovation at the regional level and divided them into infrastructural and superstructural characteristics (Cooke 2001). Infrastructural characteristics include regional financial competence (both private and public finance), regional public budgetary competence for mobilizing regional innovation potential, and the competence regional authorities have for controlling or influencing investments in hard and soft infrastructures. Superstructural characteristics include the degree of embeddedness of the region, which is defined in terms of the extent to which a social community operates in terms of shared norms of co-operation, trustful interaction, and untraded interdependence (Cooke 2001: 960).

Philip Cooke emphasized the importance of regional public governance systems because they were considered essential to trigger development in most OECD countries and regions in which Entrepreneurial Regional Innovation Systems were underdeveloped (Cooke 2004). These include some of the most dynamic US regions, such as Silicon Valley. Sharing the same view, Asheim

(2004) promoted the idea of regional networked innovations systems [4] that try to increase innovation capacity and collaboration at the regional level through public policy instruments. [5]

2.2 Critics against the concept of regional systems of innovation

Bathelt (2003) provided the first critical discussion of the concept of regional innovation systems. He argues that the "systems" notion can be easily misunderstood when used in a regional context because economic value chains extend across regional borders and because decisive institutional conditions are regulated at the national level (Bathelt 2003: 771). Furthermore, Bathelt et al. (2004: 40) argue that access to new technology does not result from only local and regional interaction but is often acquired through strategic partnerships of inter-regional and international reach. Their policy implication is, therefore, not so much the promotion of local networking as the building of trans-local or global channels of communication.

Even within economic geography (from which the concept of regional innovation systems originated) itself, some theorists have begun to question the prominent role that physical proximity is assumed to play in shaping the special distribution of innovation activity (Morgan 2004: 3). The "communities of practice" concept [6] now lies at the heart of a new debate on economic geography. This debate questions whether organizational proximity can be a substitute for geographical proximity as a means of producing and diffusing tacit knowledge (Morgan 2004, Asheim and Gertler 2005).

Moreover, although implicitly, some empirical studies such as Garnsey and Cannon-Brooks (1993) have shown how market dynamics limit the potential for regional knowledge-driven innovation to foster local development. According to their study, Cambridge high-technology firms are drawn into global innovative activity and serve international development without making major contributions to local and national economies (Garnsey and Cannon-Brooks 1993: 200).

Works such as those of Krugman (1995) and Porter (1990), while emphasizing the importance of locality, place high regard on market dynamics and inter-firm networks rather than on public governance issues in the process of innovation (Humphrey and Schmitz 2002: 1026). The conditions and criteria outlined by Cooke (2001) to promote innovation at the regional level ignore the market.

3. Methodology

3.1 Scottish stem cell framework

Scotland has been known for its strong science base and commercialization activities in the field of stem cell science and technology since the beginning of the 1990s. In the 2000s, however, Scotland embarked on constructing a more robust regional innovation system to foster local innovation and development. In the mid-2000s, Scottish Enterprise launched new initiatives specifically designed for the life sciences sector; among these initiatives, stem cell technology and translational medicine were prioritized (Scottish Enterprise 2007). Ever since then, the focus on achieving critical mass through the concentration of efforts on key technologies such as stem cell technology has become characteristic of the Scottish life science innovation system (Bergqvist 2008: 110).

Table 1 summarizes the Scottish stem cell framework that Scottish Enterprise initiated in 2004, which consists of five key programs. The first is the establishment of the Scottish Center for

Regenerative Medicine (SCRM). The SCRM is the first center not only in the UK but also in Europe in which the full spectrum of research—from basic mechanisms of stem cell regulations, via translational studies to provide the basis for new therapies, to clinical trials with stem cells and their derivatives—is covered (Livesey et al. 2008: 19). The SCRM is being built as part of a vision that Scotland will become a world center of excellence in regenerative medicine and stem cells.

The SCRM project is complemented by two other programs: the introduction of a translational research fund and financial support to establish Roslin Cells Ltd. This company was founded by Roslin Institute in 2006 with financial support from Scottish Enterprise and others [7] to create a Scottish capacity for the production of clinical grade stem cells. Roslin Cells will be housed in SCRM with the completion of its building in 2010/2011. SCRM is unique not only because of its scale but also because of the interdisciplinary nature of the research conducted at it. SCRM carries out both **basic** and **translational** research alongside **production** to clinical trials scale, so there is a close interaction between biologists, engineers, and clinicians.

The fourth program is the Stem Cell Technology Program launched by the Intermediary Technology Institute (ITI) Life Sciences in 2007. ITI Life Sciences was established in 2003 and was funded by Scottish Enterprise to create and commercialize new, market-driven technologies and to stimulate business growth in Scotland (Scottish Enterprise 2008: 9). The three-year, £9.5 million stem cell technology R&D program, funded by Scottish Enterprise through the ITI Life Sciences, aimed at overcoming two key technical hurdles in order to extensively use stem cells for drug discovery, to control the way in which a stem cell differentiates into another cell type, and to develop a robust process for producing large numbers of stable differentiated cells. [8]

The fifth program is the establishment of the Scottish Stem Cell Network (SSCN) with a clear strategy of what needs to be done to maintain Scotland as the preferred location for developing and delivering economic and healthcare benefits from stem cell research.[9] This program aims to accelerate interdisciplinary contact and collaboration between scientists and clinicians from both academia and industry through a wide program of informal meetings and workshops. An important part of SSCN activities is the provision of factual information on stem cell research and public engagement in informed discussion. SSCN is now seen as an example of international best practice in network development.

3.2 Before-and-after comparison approach

The innovations systems approach focuses on policy instruments and measures to create capabilities for innovation and to enhance innovation processes (Rosiello and Orsenigo 2008, Lacasa et al. 2004). Although it is difficult to find a direct causality between policy measures and outcomes, this paper examines the extent to which Scotland has achieved its objectives. In this paper, capabilities for innovation and innovation process in the Scottish stem cell sector are compared before and after the introduction of the Scottish Stem Cell Initiative in 2004.

More specifically, using a framework developed by Senker et al. (2001),[10] four main networks within which the relevant institutions and organizations are embedded and their inter-relationships across these networks are identified and examined before and after the introduction of the policies. The main networks considered in the framework are as follows: 1) the knowledge and skills base, 2) the network of actors involved in industrial application and development, 3) the network of actors providing financial resources for industrial development, and 4) the demand conditions, including the users of biotechnology-based products and social acceptance of innovative products.

3.3 Data collection

Data on the Scottish stem cell sector were obtained through interviews as well as through information available publicly. First of all, a total of 26 respondents representing 18 organizations and institutions were interviewed. These include Scottish public agencies (including Scottish Enterprise, Translational Medicine Research Institute, ITI Life Sciences, and Scottish Development International), organizations at the University of Edinburgh (including the Scottish Center for Regenerative Medicine, Institute for Stem Cell Research, Institute of Cell Biology, Edinburgh Research and Innovation Ltd., and Roslin Institute), and stem cell or stem cell related companies located in Scotland (including Roslin Cells Ltd., Cellartis AB in Dundee and Gothenburg, CXR Biosciences, Invitrogen, Ilyine Ltd., and two companies located in Cambridge: Pfizer and Two BC Ltd.) The organizations and institutions selected are key factors that influence innovation in the Scottish stem cell sector.

Information on the Scottish stem cell sector was also obtained through a variety of different sources such as 1) the various issues of *SSCN News*; 2) the homepages of organizations such as Scottish Enterprise, SSCN, public research institutes and universities in Scotland, and both Scottish and foreign stem cell companies; 3) patent data available publicly through databases such as those of the World Intellectual Property Organization (WIPO), the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and Annex 5 in the UK Stem Cell Initiative (2005); 4) Companies House (the official UK government register of UK companies); 5) proprietary database of drugs in the pipeline and companies involved in their development: *the PharmaProjects v.5.2 on the Web*; and 6) the world's largest abstract and citation database of peer-reviewed literature: SCOPUS.

4. Scottish Stem Cell Science and Industrial Application in the Early Days

4.1 Prominence of Scotland in stem cell science and patenting activities

The UK has a history of discovery in stem cell research and hosts world-class academic researchers in developmental and reproductive biology. This is especially true of Scotland, which has been well known as an important life sciences hub, with a particular specialization in stem cells, since the early days. For instance, the UK Stem Cell Initiative (2005) cited three landmark achievements in UK stem cell research, among which two were conducted in Scotland: the first cloning of a mammal at the Roslin Institute in 1997 and the first identification of the stem cell "immortality gene" at the Institute of Stem Cell Research in the University of Edinburgh in 2003.

The UK Stem Cell Initiative (2005) also highly ranked both Roslin Institute and the University of Edinburgh as organizations that were most prolific in the UK in generating patents from stem cell research between 1993 and 2004. The former was ranked as the first and the latter as the sixth.

4.2 Roslin Institute

Roslin Institute was established as a wholly owned but independent institute of the British Biotechnology and Biological Research Council.[11] Roslin Institute attracted enormous interest from both the world's scientific community and the popular press when the lamb, "Dolly," was created from an adult mammary cell through the nuclear transfer technique in 1997. Although Dolly attracted much attention, a key practical breakthrough in nuclear transfer had been made at the institute in 1995 when two live lambs from an established cell line were produced (Megan and

Morag).[12] The invention was covered by two patent applications[13] filed by and in the name of the Institute in 1995.

Roslin Institute attempted to exploit the nuclear transfer technology commercially in two important, but different, ways.[14] The first was through a simple licensing agreement. The other was through the establishment of a new company. First, a simple licensing deal was made between Roslin Institute and PPL Therapeutics, the best known of the Roslin spin-out companies. PPL Therapeutics became famous worldwide along with the Institute because it had cooperated with the Institute both technically and financially during the production of “Dolly.” The license agreement covered the production of therapeutic proteins in ruminant livestock and rabbits and the modification of milk composition for nutraceutical applications.

A new company called Roslin Bio-med was established in April 1998 to develop the Roslin Institute’s nuclear transfer technology for applications in medicine. The Roslin Bio-Med agreement with Roslin Institute provided an exclusive license to use the Institute’s nuclear transfer technology for bio medical applications of genetically modified livestock and other animals, including applications in xenotransplantation.[15] The agreement setting up Roslin Bio-Med included a commitment of £6 million from 3i, a European venture capital company, for the first three years.

Having recognized that there were wider applications for nuclear transfer, the announcement in November 1998 that putative human embryonic stem (hES) cells had been produced in research funded by the Geron Corporation in California in US allowed Roslin Institute to combine its own technology with that of Geron to develop novel approaches to cell based therapies.[16] Negotiations between the parties involved concluded in the acquisition of Roslin BioMed by Geron, involving a commitment of £12.5 million of additional funding to the Roslin Institute over the next six years and an opportunity to contribute to the development of human cell therapy. The new company was named Geron Bio-Med. The Roslin Institute retained a significant portion of Geron shares and had a financial interest in the exploitation of new intellectual property. In return, Geron received an exclusive license to Roslin Institute's nuclear transfer technology in all areas of use except for human reproductive cloning and applications previously licensed to PPL Therapeutics.[17]

Despite the good reputation that the Roslin Institute has as a result of its contribution to science and its being an ideal model for a public research institute in terms of commercialization activities, the advancement of stem cell science and business has not been smooth at all times. First of all, PPL Therapeutics had to sell its Virginia subsidiary in the US to the University of Pittsburgh in 2003 just to stay afloat. In the following year, PPL Therapeutics left the stock market altogether (Wilmut and Highfield 2006: 147). Investors lost confidence in a firm that had produced so many remarkable scientific papers but that had made so little money (Meek 2002).

The collaboration between Roslin Institute and Geron was not always smooth. The initial focus of Geron Bio-Med was on developing a method to efficiently generate pluripotent stem cells from adult human tissues that would be genetically matched to the tissue donor. The work was being carried out in the laboratories of Roslin Institute. Several years later, however, Geron withdrew its funding for the initial research projects at Roslin (Wilmut and Highfield 2006: 142) and the intellectual property portfolio covering nuclear transfer in animals was subsequently conveyed to another US biotech company.[18]

4.3 University of Edinburgh

Scotland also became famous in the field of stem cell science because of the work carried out by Professor Austin Smith at the University of Edinburgh between 1990 and 2006, prior to his move to the Welcome Trust Centre for Stem Cell Research, University of Cambridge as its Director. After having been at the Centre for Genome Research as a Group Leader for six years, Professor Smith was appointed Director of the Centre in 1996; under his leadership, the Centre became the first Institute of Stem Cell Research in the UK.[19] He pioneered key advances in the field of human embryonic stem cell research.

A new company called Stem Cell Sciences was founded in 1994 to commercialize the joint research of Professor Austin Smith at the Institute for Stem Cell Research and Professor Peter Mountford at Monash University in Melbourne, Australia. The company was founded based on proprietary platform technologies that allow the isolation, growth, and manipulation of stem cells. Stem Cell Sciences was driven by the wish to provide widespread clinical benefits from human embryonic stem cell therapy.

More than 20 patents were filed based on the stem cell research of Professor Austin Smith prior to his move to the University of Cambridge in 2006, out of which at least 10 were granted to the University of Edinburgh.[20] Under a deal signed in 1994 between the University and Stem Cell Sciences, the company was granted exclusive access to those proprietary platform technologies.[21]

The thriving stem cell research at the University of Edinburgh that took place when Professor Austin Smith was there did not immediately lead to the same level of commercial activities as that at Roslin Institute because the company was born as an Australian company in 1994 and its headquarters was established in Australia. Only a decade later (at the end of 2003), the Australian Stem Cell Sciences relocated its headquarters from Melbourne to Edinburgh.[22]

Moreover, although Stem Cell Sciences was the only company given a license to exploit key stem cell technologies commercially, it moved from Scotland to Cambridge in 2006 and was bought by a US-based stem cell company in 2009 (Rowley and Martin 2009: 33).

4.4 Getting the science right is not enough

Numerous studies, including those of Leibovitz (2004) and Henderson et al. (1999), emphasize the role of universities or public research institutes in promoting science-based industries such biotechnology. The two aforementioned Scottish examples, Roslin Institute and the University of Edinburgh, however, seem to demonstrate how it is difficult to trigger sustainable industrial growth based on thriving science alone. First, the earlier experience of Scotland is a counter example of the relationship between science, technology, and innovation in a linear and unidirectional way: In other words, scientific and technological changes cannot be seen as exogenous factors that automatically give birth to the inventions that act as the driving force of industrial and economic growth (Fransman 2001: 264).

The Scottish experience also demonstrates that both knowledge creation and exploitation unfold on a global scale, at least in the case of stem cell science and technology. As Senker (2004) argues, the innovation system is bounded by knowledge and technology, but not by geography.

5. Scottish Stem Cell Science and Industrial Application after the Mid-2000s

5.1 Toward translational research

A clear improvement in the innovation process seems to lie in the way in which the various Scottish stem cell programs mentioned about are institutionally designed. Figure1 shows how the five Scottish stem cell programs listed in Table 1 can fit into a comprehensive framework of biotechnology innovation developed by Senker et al. (2001).

First of all, several new institutions are set up in such a way that the early joint engagement of scientists, clinicians, and engineers in research and development (R&D) is possible for the development of cell therapy products (Figure 1). The establishment of the SCRM in 2006 brought scientists who were previously members of the Institute for Stem Cell Research, University of Edinburgh, together with the clinical groups within the University's Medical School under one roof and enabled collaboration between the two groups in translational research to develop cell therapy products in such clinical fields as liver, brain, and blood (see Figure 2 for the interdisciplinary nature of translational research). Two-way knowledge flow between two groups is regarded as absolutely essential for the successful launching of stem cell therapies (Martin et al. 2009). In addition, the development funding gap is now bridged through the Scottish Enterprise translational research fund (Figure 1).

At the SCRM, the early engagement of cell engineers and manufacturers in clinical and translational research has also become easy because Roslin Cells is housed there. Since its establishment in 2006, Roslin Cells has grown to become one of the world leaders in the isolation of new clinical grade undifferentiated stem cells for use in research and therapy; it now employs around 25 people. The company also helped the establishment of Roslin Cellab Ltd., a stem cell biology services company, in 2008. The chief scientific officer at Roslin Cells, Dr. Paul De Sousa, is also a senior research fellow at the SCRM. He plays a key role in bridging the gap between academia and industry.

High manufacturing cost and the lack of clinical demand were two most important structural barriers to the success of cell therapy (Martin et al. 2009: 37) not only in Scotland but also in the UK. The Scottish stem cell research framework has been addressing and trying to remove these barriers to improve the innovation processes and to enhance capabilities of the Scottish stem cell sector.

5.2 Stem cells as a research tool

ITI Life Sciences was among the first to identify the market need for a plentiful supply of hES cells, which are capable of unlimited self-renewal and can become any other type of cell. The Institute judged, based on the detailed market research conducted in the mid-2000s, that hES cells would be extremely valuable to pharmaceutical companies as tools for research in the near term. These cells would enable pharmaceutical companies to test new drug candidates for efficacy and toxicity in biological and disease-relevant human cells, although the introduction of widespread stem cell therapies is unlikely to become a reality within the next ten years. [2] [3]

The novelty of the ITI stem cell R&D program also lies in its institutional design. First of all, the program was conducted on a global platform in an internationally open and collaborative environment. ITI formed an R&D consortium with Swedish company Cellartis AB, one of the most advanced stem cell companies and the largest provider of ethically derived hES lines, and three Scottish Universities (University of Glasgow, University of Dundee, and Heriot Watt University). Figure 3 illustrates the close industry-academia collaboration between them. Cross-border joint R&D was facilitated by Cellartis AB establishing a new R&D and production division in Dundee, Scotland with financial support from the Scottish government. While Cellartis' significant know-how in growing, handling, and maintaining hES cells was transferred from Cellartis AB to researchers at the universities, another novel, new scale-up technology[24] was developed through the collaborative R&D between the four key actors.

The ITI stem cell technology program is also unique because Cellartis AB was not only the initial provider of a key proprietary technology[25] but also the first company that demanded and licensed the new proprietary, scale-up technology from ITI Life Sciences in 2009.[26] As Figure 1 shows, the ITI program is designed in such as way that the four key factors that influence biotechnology innovation are well-connected right from the initiation of the program.

ITI Life Sciences crossed a major milestone with its first license deal with Cellartis for the Stem Cell Technology program in 2009. ITI will receive royalties on the sale of products created using this technology. Since the technology is licensed out on a non-exclusive basis, ITI still holds ownership over the manner in which its technology is further exploited commercially, either through the establishment of a new company or through the conclusion of licensing deals with other companies.

5.3 Development of an informal network system through SSCN

Although it is difficult to quantify its exact contribution, SSCN has played an important role in enhancing the innovation process in Scotland through the establishment of an informal network system. Since its establishment, with a wide program of meetings and workshops through Scotland, SSCN has engaged with scientific, clinical, and other communities to accelerate interdisciplinary contact and collaboration.[27] As a matter of fact, increasing Scottish interest in stem cell research and its commercial applications has been observed in the trend of SSCN membership. Not only has the number of SSCN members increased from 200 in 2003 to over 1000 in 2009, but the activities have also been supported widely across sectors, from academia, industry, and the public sector, to charity, the press, and the other general public (see Figure 4).

The development of an informal network system may enhance the innovation process for various reasons. One reason is provided by sociologists, who argue that knowledge can be socially organized and embedded in particular local networks (Martin et al. 2008: 3). A shared sense of community created through the development of an informal network system is required in the stem cell sector in particular because the groups involved in the industry consist of otherwise highly distantiated heterogeneous groups. SSCN is expected to form what Martin et al. (2008) call "communities of promise."[28]

Second, an increasingly large number of studies[29] point to the enormous potential that informal ties have in making a significant contribution to innovation. For instance, Powell et al. (1996) found that, in the life sciences, beneath most formal ties lies a sea of informal ties. Longhi and Keeble (2000: 49) found that high-technology small and medium enterprises (SMEs) characteristically use collaborative networking via both informal and formal partnerships with other firms and universities, which is lacking among conventional SMEs.

An interview conducted on December 15, 2010 with a stem cell scientist at the Institute for Stem Cell Research, Edinburgh, clearly indicates the importance of informal meetings, such as the one organized by SSCN, especially in the explorative stage of research. Another researcher at the same Institute pointed out the important role that SSCN plays in bridging the gap between academia and the industry.[30] SSCN sometimes serves the community as a kind of "knowledge broker."

5.4 Toward development of multiple nodes of network

As Youite and Shapira (2008: 1192) note, leading regions for innovation are often those with multiple nodes of research strength, including universities, government laboratories, non-profit research organizations, and private-sector R&D units.[31] Although Scotland is well known for the strength of its basic science, industrial R&D activities have not been very prominent (Asheim 2004: 20). The Scottish Stem Cell Initiative seems to be playing a role in triggering the catch-up process.

An example is Geron's investment in Scotland. Geron is the world leader in the development of human embryonic stem-cell-based therapeutics, with its spinal cord injury treatment poised to be the first product to enter clinical development. Since the establishment of the SCRM, Geron has been engaged in three preclinical development projects at the Centre using three hESC-derived cell types: hepatocytes for the treatment of liver failure and for use in cell-based assays in drug development, chondrocytes in the development of the treatment of osteoarthritis, and osteoblasts for use in the treatment of musculoskeletal disorders.[32] This indicates that the SCRC possesses the potential to become one of the important development centers of novel cell therapy products.

Another example is the role that Cellartis AB plays as the gatekeeper between Scotland and global major industrial players in the field of stem cells. Since 2004, Cellartis AB has successfully concluded a series of R&D collaborative agreements with global players such as GE Healthcare (2004), Tanabe Seiyaku Co. Ltd. (2004), Invitrogen (2006), AstraZeneca (2006, 2009), Pfizer (2008), and Novo Nordisk (2008), in addition to ITI Life Sciences.[33] The division in Scotland, Cellartis AB in Dundee, has been collaborating on an R&D project with Novo Nordisk, the Hagedorn Research Institute, and Lund University for the development of a future cure for diabetes, together with Cellartis AB in Gothenburg.[34]

Scotland has strongly expressed the intention to become a world-leading research and commercial center in the field of stem cell research; this has started to materialize in the form of inward investment from UK companies located outside Scotland. After ReNeuron, a leading Surrey-based stem cell company, received regulatory approval to conduct a first-in-man clinical trial of its stem cell therapy for ischemic stroke in 2009, the company made two announcements that were particularly important for Scotland. [3 5] The first was that ReNeuron would conduct the ground-breaking phase one trial at Glasgow's Southern General Hospital. The other was that ReNeuron had chosen Angel Biotechnology, a biopharmaceutical contract manufacturer located in Scotland, as a partner to produce very advanced biological therapies such as high quality stem cells for clinical usage. These two announcements will place Scotland at the forefront of important developments in cell therapy in the UK.

5.5 Commercialization challenges that Scotland faces

Despite the substantial progress that Scotland has made so far in light of the systems of innovation and attracting a global attention, it faces significant challenges. The key challenge is the weak local pool of commercialization.

Alongside prominent foreign and UK companies such as Geron, Cellartis AB, and ReNeuron, indigenous Scottish stem cell firms have started to emerge. Table 2 lists stem cell companies located in Scotland by their position in the value chain of the RM and stem cell industry. So far, these new Scottish companies, however, have not taken on the stem cell research created by Scottish Universities per se, but have just diversified and/or expanded the focus of business to include the stem cell sector, with their core competencies already built up within the company. The current business model of Scottish firms, therefore, is in sharp contrast to the early days of the development of life sciences, in which a number of new companies were immediately spun out to commercially exploit the frontier research. The differences are examined more carefully below.

CXR Biosciences, a spin-out company from Dundee University, established in 2001 and one of the most successful biotech companies in Scotland, has been growing into an established profitable business by collaborating with companies around the world. It was established in order to develop new technology platforms that will transform the way the metabolism and safety liabilities of molecules evaluate.[36] As part of its objectives only, CXR Biosciences became engaged in the development of the stem-cell-based technology platform in collaboration with Geron. Moreover, commercial exploitation of the technology did not follow immediately.[37] CXR Biosciences instead now intends to advance the use of stem cells as a tool in other fields, such as cosmetics, by joining an EU-funded project.[38]

AvantiCell Science[39] specializes in cell-based analysis for use in drug discovery and development. Since its incorporation in 2006, AvantiCell Science has sought to position itself as a leading-edge provider of cell culture technology. Founding investment was supported from the outset by sales revenue, which has doubled year-on-year. A modest amount of the Scottish Enterprise Co-investment Fund has enabled company consolidation; assays of the company have increasingly been based on human stem cells. However, cell-based analysis based on physiologically relevant cells is increasingly being recognized to have application beyond the field of drug discovery. As such, AvantiCell Science is now progressively adapting its assay platforms for application in the evaluation of natural products, including traditional medicines and nanosafety testing.

Antoxis[40] was founded in March 2005 as a spin-out company from the University of Aberdeen and the University of Glasgow. It was founded to commercially exploit proprietary platform technologies surrounding the design of novel, cell-targeted antioxidants following a successful Scottish Enterprise Proof of Concept Program (POC).[41] Antoxis broadened its traditional drug development model to include regenerative medicine because of Scotland's focus on life sciences, and regenerative medicine in particular. A supportive environment in Scotland and the availability of and accessibility to local expertise has allowed the company to expand the scope of its business to include the development of compounds specifically in relation to regenerative medicine.

ImmunoSolv[42] was also founded in 2005 as a spin-out company, specializing in antibody-based strategies for the detection and manipulation of dead and dying cells, from the University of Edinburgh, with funding aid from the Scottish Enterprise Proof-of-Concept Program. Again, the application of their core antibody technology to the field of stem cells and regenerative medicine recently advanced because of Scotland's focus on life sciences, and regenerative medicine in particular.

In addition to the core biotech firms mentioned above, several service providing Scottish firms have started to emerge in Scotland in the field of stem cell business, such as Angel Biotechnology, which was discussed in Section 5.4, Stem Cell Services, and Pharma Cells. Instead of developing their core technologies and owning intellectual property, they all concentrate on providing services in response to customer needs in this field.

A close examination of Scottish companies currently engaged in the stem cell business shows that except for Roslin Cells and Roslin Cellab, none of the Scottish indigenous companies are directly engaged in the commercial exploitation of the fruits of stem cell research at Scottish

Universities. They were already in profitable business before foraying into the field of stem cells. Besides, although the resources increasingly available at Scottish Universities are in the therapeutic area, the real business opportunities found by these local firms tend to exist beyond them.

Regions have to invest in the important field of science and technology because it is necessary to stay abreast of what is happening on the biotechnology frontier (Senker 1994). However, the evolution of Scottish local stem cells companies seems to demonstrate that the local pull of commercializing stem cell research in Scottish Universities is currently weak. Scotland may need to capitalize on the newly emerging trend of investment in the stem cell and RM field by global players to a great extent.[4 3] The commercialization challenges of Scottish stem cell science still loom large.

6. Discussion: Applicability of the Concept of Regional Systems of Innovation

A careful examination of the Scottish experience seems to support critics against the concept of regional innovation systems. First, systems of innovation seem to be bounded by knowledge and technology, but not by geography. As shown in the paper, stem cell technologies developed by Scotland have been exploited commercially outside Scotland since the early days of their development. Besides, since the mid-2000s, Scottish Enterprise itself has tried to build the capabilities of stem cell technology, forming an R&D consortium with Cellartis AB, a foreign stem cell company, at its core (Figure 3). Cellartis AB has played an important role as both technological gatekeeper and geographical boundary spanner in the field of stem cell science and technology in the development of the Scottish RM industry.

Second, market dynamics tend to limit the potential of regional knowledge-driven innovation to foster local development. It is true that Scottish research capabilities remain high and their intellectual resources continue to be abundantly available in the biotechnology sector, particularly in the field of stem cell science and technology. However, so far, it is mainly foreign or extra-regional players that capitalize on these intellectual resources and technological capabilities. Scottish local and indigenous firms have not yet exploited them commercially to any great extent. In other words, Scottish universities and research institutes tend to serve international development without leading any substantial regional development.

Philip Cooke and others outlined the conditions and criteria necessary to promote innovation at the regional level. However, these conditions and criteria ignore the market. Although it is not wrong to emphasize the importance of establishing regional innovation infrastructure, these supportive institutional networks cannot be a substitute for the local corporate sector (Morgan 2004: 17–18). Even if local and indigenous firms lack knowledge of possible market and technological opportunities, global players may possess this knowledge and exploit Scottish intellectual assets commercially in this era of globalization. This seems to be happening in Scotland. Foreign firms are taking the most initiative in commercializing the high value potential of stem cell technologies, whereas Scottish companies seem to be restricted to the lower value chain activities so far.

7. Conclusion

This paper evaluated the concept of regional innovation systems using Scotland as a case study. The systems of innovation approach teaches us the importance of innovation in economic development, the systemic nature of the innovation process, and the significance of the linkage of technological dynamics with social, organizational, and institutional features. The Scottish experience, however, seems to raise an important question about setting geographical boundaries in innovation systems in science-driven industries such as biotechnology. The processes of both knowledge creation and exploitation are unfolding on a global scale. In other words, economic value chains extend widely across regional borders. Public policy therefore needs to tap into an external pool of knowledge and establish new relations with distant firms and institutions rather than just foster local networking; this is of utmost importance in promoting innovation at the regional level.

The Scottish experience also demonstrates the difficulty of designing or planning a regional innovation system by outlining conditions and criteria in the field of biotechnology in general and in stem cell technology in particular. Market dynamics tend to limit the potential of regional knowledge-driven innovation to foster local development. In the absence of a dynamic local corporate sector, research capabilities and intellectual assets that are regionally available tend to be exploited mainly by global players, without resulting in substantial local innovation and economic development. The Scottish case may indicate the need to target regional innovation policies in technologies that have local market pull and to not target those technologies where commercialization tends to take place at the global level.

Table 1 Scottish Stem Cell Framework

Program	Funding	Financier	Period
Center for Regenerative Medicine	£59 M	SE[2],/UoE[3]/ SFC[4]/Gov[5]	To be completed in 2010
Roslin Cells Ltd	£3.9M	SE/SNBTS[6]/UoE/Roslin[7]	
Translational research fund	£5M	SE	Started in 2006, 5-year fund
ITI[1] Stem Cells Program	£9.5M	ITI (SE)	2007-2009
Scottish Stem Cell Network	£1.85M	SE	2004-2013 (ten years)

Notes: [1] The Intermediary Technology Institute

[2] Scottish Enterprise

[3] University of Edinburgh

[4] Scottish Funding Council

[5] The Scottish Executive

[6] Scottish National Blood Transfusion Service

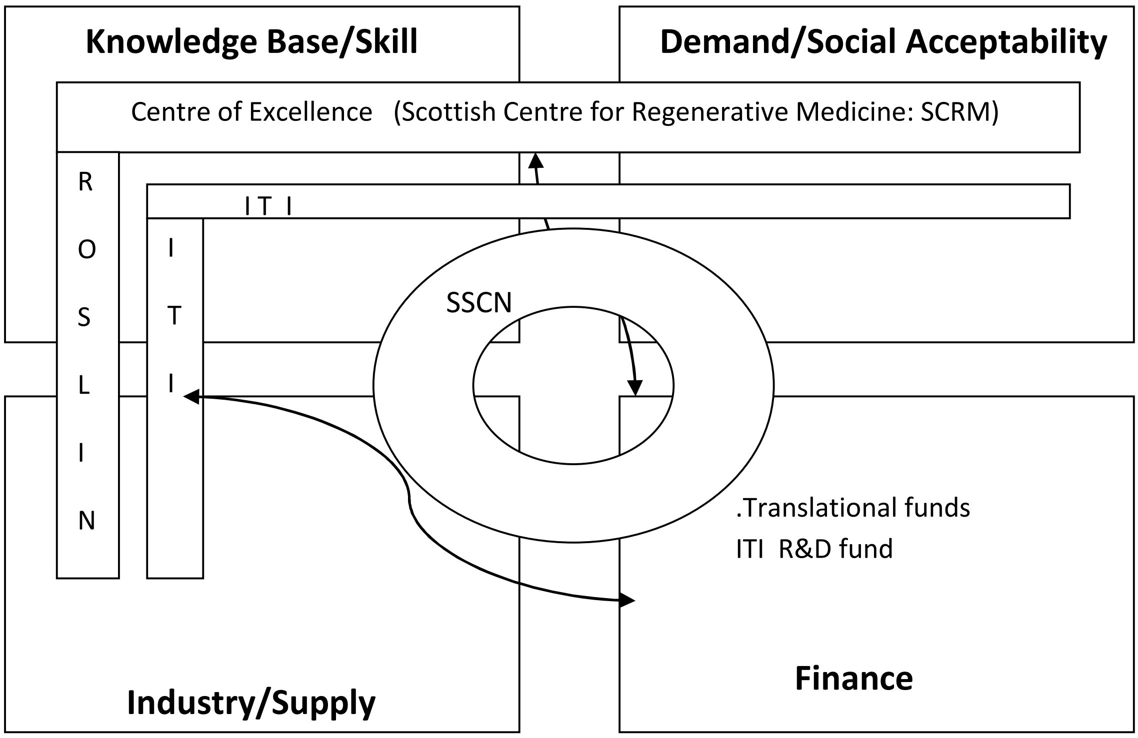
[7] Roslin Foundation

Sources: ① The author's interview at Scottish Enterprise in Edinburgh on December 3, 2009

② Scottish Enterprise (2007), p. 28

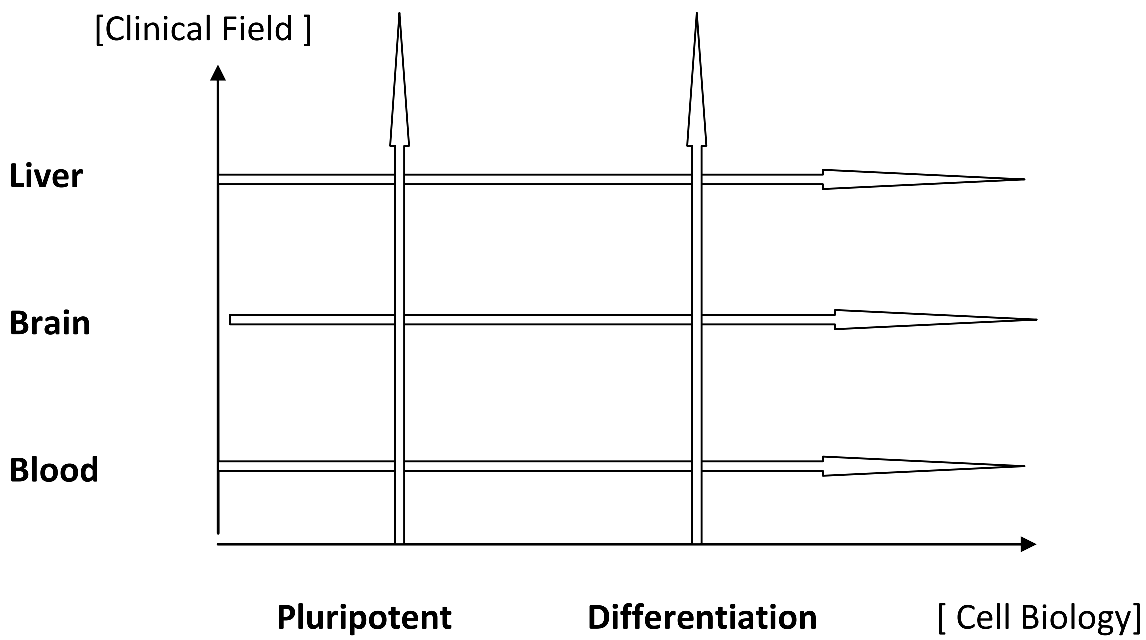
③"Financial assistance and other support for the Life sciences sector: Scottish Enterprise", available at <http://www.scottish-enterprise.com/your-sector/life-sciences-sector/lifesciences-support.aspx>, last accessed August 23, 2010.

Figure 1 Scottish Stem Cell Initiative within a Framework of Biotechnology Innovation



Source: the author's construction based mainly on information provided by Scottish Enterprise.

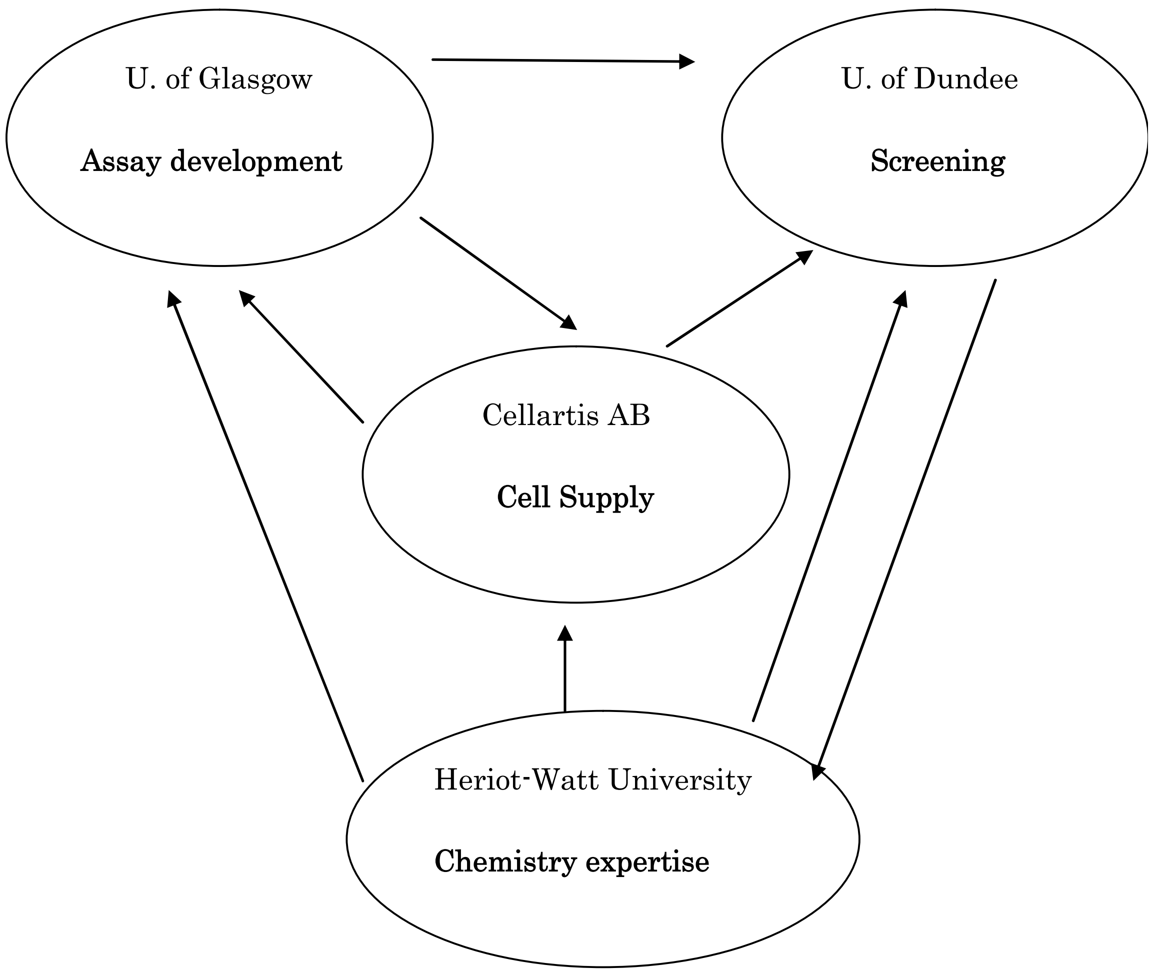
Figure 2   Importance of Interdisciplinary Approach in Translational Research



Source: the Author's construction based on information provided by Professor Ian Wilmut on March 15, 2010.

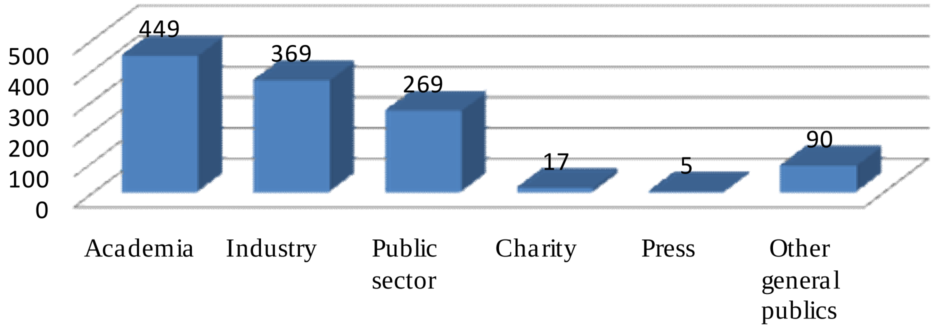
Figure 3 Flow of Knowledge and Materials through Stem Cell Technologies

Program of ITI Life Sciences among Four Collaborators



Source: the author's construction based on information provided by Dr. Mikael Englund at Cellartis AB in Dundee on March 23, 2010

Figure 4 Sector Distribution of SSCN Members, 2009



Source: SSCN

Table 2 Stem Cell Companies in Scotland [1] by their Position in the Value Chain

< LOW ---TECHNOLOGICAL AND MARKET UNCERTAINTIES--- HIGH >

Stem cell service providers			Stem cells as a tool for research			Application of stem cells as a tool for the drug discovery and toxicology			Regenerative medicine including cell therapies [2]		
Company name	Year of establishment	Number of employees	Company name	Year of establishment	Number of employees	Company name	Year of establishment	Number of employees	Company name	Year of establishment	Number of employees
FOREIGN FIRMS											
			Cellartis AB [3]	2001	63 (13)	Cellartis AB [3]	2001	63 (13)	Cellartis AB [3]	2001	63 (13)
						Geron Bio-Med	1999	0-5	Geron Bio-Med	1999	0-5
SCOTTISH FIRMS											
Roslin Cellab [4]	2008	5	Roslin Cells [4]	2006	25	Avanticell Science	2006	6-24	Antoxis	2005	0-5
Angel Biotechnology [5]	2000	17				CXR Bioscience [6]	2001	36	immunoSolv [7]	2005	0-5
Stem Cell Services	2006	6-24									
Pharmacells	2008	0-5									

Notes and sources:

1 Such foreign companies as invitrogen, Millipore, and BioReliance are not included in the table, although they have various relatively large-scale operations in Scotland and the companies themselves are engaged in stem cell business, because the extent to which Scottish operations are involved in stem cell business is unknown.

2 Regenerative medicine includes both stem cell-based therapies and small molecules that direct the differentiation of cells in vivo.

3 Information is based on the interview conducted at Cellartis AB in Gothenburg on May 28, 2009.
The number of employees in parenthesis is for Cellartis AB in Dundee only.
Cellartis AB is involved in three segments of the value chain in collaboration with both industrial and academic partners.

4 Employment figures are based on information collacted at Roslin Cells on March 24, 2010.

5 The employment figure is based on *Annual Report 2008* , available at <http://www.angelbio.com>, last accessed January 7, 2010.

6 The employment figure is based on information available at<http://www.cxrbiosciences.com/page/CXR_Biosciences_Home_7.html, last accessed January 10, 2010.

7 The 'old' immunoSolv before the merger with Grampian BioConsultants

8 The information of other companies for the number of employees and the year of establishment was obtained from <http://www.scottish-enterprise.com/your-sector/life-sciences-sector/life-sciences-sourcebook.aspx>.

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[1] This is based on information provided at Scottish Enterprise in Edinburgh on December 3, 2009.

[2] RM is defined as medicine that "replaces or regenerates human cells, tissues or organs to restore or establish normal function," according to Neil Harris (2009), "Regenerative Medicine

– Glossary PAS 84: 2008," A supplement of *Regenerative Medicine* 4 (4). Its ability to replace or repair damaged cells and tissues using innovative technologies (including stem cells) has the potential of providing a lifetime cure for many current medical needs such as diabetes, blindness, coronary failure, stroke, spinal trauma, and burns. The coverage of RM is broad and includes not only stem-cell-based but also non-stem-cell-based therapies and products. With the rapid and new development of stem cell research, however, Martin et al. (2009) have identified a shift in focus over the last decade to stem cell technology as a dominant feature of the RM industry.

[3] See, for instance, Lundvall (1992), Nelson (1993), and Edquist (1997).

[4] Cooke (2004) uses the terminology called an institutional regional innovation system instead.

[5] See also Asheim and Gertler (2005).

[6] Communities of practice are defined as groups of workers informally bound together by shared experience, expertise, and commitment to a joint enterprise (Asheim and Gertler 2005: 308).

[7] See Table 1.

[8] Information is available at <http://itilifesciences.com>, last accessed November 30, 2009.

[9] See "SSCN Annual Review: 2008.7" in *SSCN News* Issue 7 Spring 2008.

[10] See also Lacasa et al. (2004).

[11] Information is available at http://www.roslin.ed.ac.uk, last accessed January 20, 2010.

[12] See *Annual Report 96/97* of the Roslin Institute.

[13] PCT/GB96/02099, entitled *Quiescent cell populations for nuclear transfer*, and PCT/GB96/02098, entitled *Unactivated oocytes as cytoplast recipients for nuclear transfer*. See Fransman (2001: 270) for details.

[14] See *Annual Report 97/98* of the Roslin Institute.

[15] The agreement between Roslin Bio-med and the Institute does not include the modification of milk composition in ruminants and rabbits because it is the subject of a separate license to PPL Therapeutics (*Annual Report* 97/98 of the Roslin Institute).

[16] Three key technologies were involved: two technologies (human pluripotent stem cells, and telomerase) from Geron and one technology (nuclear transfer) from the Roslin Institute (Annual Report 98/99 of the Roslin Institute).

[17] See *Annual Report 98/99* of the Roslin Institute for details of the deal between the Roslin Institute and Geron in setting up Geron Bio-Med.

[18] http://www.geron.com/, last accessed January 20, 2010.

[19] http://www.cscr.cam.ac.uk/research/smith/smith.html, last accessed February 23, 2010.

[20] This is based on the information provided by Edinburgh Research and Innovation Ltd. at the University of Edinburgh on January 14, 2010.

[21] This is based on the information provided by Edinburgh Research and Innovation Ltd. at the University of Edinburgh on January 14, 2010.

[22] Information is available at <http://www.scotlandistheplace.co.uk/stitp/298.2.1357.html,>, last accessed January 19, 2010.

[23] See *SSCN NEWS* Issue 9 Autumn 2008, pp. 8–9.

[24] At least one patent (WO/2009/147400, Stem cell culture media and methods) has been successfully filed to protect the technology by ITI Life Licenses, by January 19, 2010.

[25] Cellartis AB possesses a proprietary technology (WO/2003/055992, A method for the establishment of a pluripotent human blastocyst-derived stem cell line).

[26] See a news release titled "ITI Life Sciences achieves major milestone with first license deal with Cellartis for Stem Cell Technology programme," available at <http://cellartis.com/index.php/february-4th-2009>, last accessed on June 10, 2010.

[27] See "SSCN Annual Review 2008:7"in *SSCN NEWS* Issue 7 Spring 2008.

[28] It is important to note that SSCN membership is open to foreigners.

[29] For instance, Powell et al. (1996), Powell and Grodal (2005), Longhi and Keeble (2000), and Lazer and Friedman (2007).

[30] See *SSCN NEWS* Issue 5 Autumn 2007, p. 11.

[31] See also Huggins and Kitagawa (2009).

[32] See information available at< http//geron.com/partners/bio-med.aspx>, last accessed January 20, 2010.

[33] This is information provided by Dr. Johan Hyllner, Cellartis AB, in Gothenburg on May 28, 2009 and Jens et al. (2009).

[34] This is information based on an interview made with Dr. Mikael Englund, Cellartis AB, in Dundee on March 23, 2010

[35] See, for instance, *SSCN NEWS* Issue 12 Summer 2009, p. 6.

[36] See *SSCN NEWS* Issue 2 Autumn 2006, pp. 6–7.

[37] This is based on an interview with Dr. Tom Shepherd, CEO of CXR Biosciences, conducted on January 13, 2010.

[38] Information is available at <http://www.cxrbiosciences.com/>, last accessed June 10, 2010.

[39] See *SSCN NEWS* Issue 15 Spring 2010, p. 9

[40] See *SSCN NEWS* Issue 13 Autumn 2009, pp. 8–9.

[41] Scottish Enterprise Proof of Concept program is a unique Scottish initiative, now adopted by other countries. The Proof of Concept Programme supports the pre-commercialization of leading-edge technologies emerging from Scotland's universities, research institutes, and NHS Boards.

[42] Information is available at http://www.immunosolv.com/AboutUs.htm, last accessed January 10, 2010, and at *SSCN NEWS* Issue 11 Spring 2009, pp. 6–7.

[43] See Smith (2009) for the details with respect to the emerging trend of investment in the stem cell business by global players.