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Selection and cluster evolution: A conceptual and empirical investigation using the case of Med-Tech

Markus Grillitsch
Lund University
CIRCLE
Markus.Grillitsch@CIRCLE.lu.se

Josephine Rekers
Lund University
CIRCLE
josephine.rekers@circle.lu.se

Abstract

An emerging body of work on industry evolution and cluster change points to various factors that shape the trajectory of industry clusters. Some are internal to the firm, industry, technology or the region, other triggers could be considered exogenous. While evolutionary approaches help us to understand the dynamics within a cluster, they are relatively silent with regards to the nature of selection. Selection is frequently conceptualised as market competition. However, firms are exposed to different forms of selection pressures. Moreover, the process of selection can change dramatically due to a variety of reasons such as regulatory changes or financial crises. In this paper, we investigate in depth how selection can be conceptualised in the context of economic geography. We argue that selection comes in different forms and we distinguish between formal and social selection. This has implications on other evolutionary mechanisms as well as the role of geography. Empirically, we analyse the med-tech sector in Scania, Sweden and show that firms operate in different selection environments and that different mechanisms are at work at various geographical scales. We further demonstrate how firms adapt to changes in their selection environments.

Jelcodes:R11,-

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Abstract

This paper contributes to the debate how and why clusters change. We investigate the role of selection in cluster evolution. Selection comes in different forms and we distinguish between formal and social selection. This has implications on other evolutionary mechanisms as well as the role of geography. Empirically, we analyse the med-tech sector in Scania, Sweden and show how changes in selection processes affect the evolution of the cluster by transforming the population of firms and firm adaptation.

Keywords: cluster, selection, evolution, industrial change, regulations, med-tech

JEL codes: B52, L16, O31, O33, R11

Introduction

This paper is concerned with the evolution of clusters. It contributes to the existing literature by conceptually developing and empirically examining the role of different forms of selection in explaining the evolution of clusters. Among the work on cluster change, the *cluster lifecycle* concept has received considerable attention (Bergman 2008; Maskell & Malmberg 2007; Menzel & Fornahl 2010; Ter Wal & Boschma 2011). According to this concept, clusters follow distinct development stages including emergence, growth, maturity and decline. However, this has been criticized for being too deterministic, as clusters do not necessarily follow a typical lifecycle. Martin and Sunley (2011) therefore propose an *adaptive cycle model* allowing for a variety of evolutionary trajectories, and Hassink (2010) finds that development trajectories are highly uncertain depending on a complex interplay between political-institutional and economic-structural factors. Additionally, Strambach (2010) suggests that there is a considerable degree of plasticity within a development path, which is used by firms in an attempt to employ their competencies in profitable market niches. This *path plasticity* can lead to the creation of new industries and clusters. Finally, the literature on *related variety* stipulates that the probability for cluster renewal increases if different but related industries co-locate in a region (Boschma & Iammarino 2009; Frenken et al. 2007). It is argued that the combination of different types of knowledge (Asheim & Coenen 2005; Martin & Moodysson 2013; Moodysson et al. 2008) is most conducive to foster innovation and thereby the renewal of clusters (Asheim et al. 2011; Grillitsch & Trippl 2013; Strambach & Klement 2012).

These contributions on cluster evolution point to various endogenous and exogenous factors shaping the trajectories of clusters such as firm competencies and networks, knowledge bases, institutions, technologies or markets. However, the evolutionary mechanism of selection has received little attention. In economic geography, selection is usually conceptualised as product market competition (Alchian 1950; Frenken & Boschma 2007; Friedman 1953; Nelson & Winter 1982). Firms that are successful in this competition, i.e. are selected, have a higher likelihood to be profitable and grow.

With the growth of the firm, the successful routines will be replicated through various mechanisms within the firm, through imitation by other firms, and by spin-offs. Another common interpretation in economic geography views regions as selection environments in which firms operate (Essletzbichler & Rigby 2007; 2010). Even if product markets are increasingly global, firms will face differences in the selection environment depending on their location because i) their access to recourses may differ, particularly to spatially-sticky resources such as tacit knowledge (Gertler 2003; Polanyi 1958), ii) institutions may impact business performance unequally by e.g. providing pecuniary incentives, business cultures and innovative milieus, or affecting the ease of doing business (Gertler 1995; Saxenian 1994); and iii) the resulting interdependencies, particularly untraded interdependencies, and relational assets (Amin 2002; Storper 1995). Geography, therefore, plays a role as the selection pressures for firms competing on the same product markets may differ depending on their location.

However, to reduce selection to market pressures can be problematic, and as Geels (2002, p. 1259) cautions: "Markets are simply assumed to be 'out there' […] the selection environment is wider than users and markets." Knudsen (2002) argues that conceptualising selection only as competition on product markets easily becomes tautological where "surviving firms are efficient because only the efficient survive." (Knudsen 2002, p. 446). Nelson and Winter (2002) suggests that market competition can only partially explain the evolution of industries. Also, the reduction of selection to market competition ignores other possible mechanisms of selection, e.g. before a product reaches the market; related to other markets such as labour and financial markets (Dosi & Nelson 1994); or related to selection where markets play a limited role such as the choice with whom knowledge is exchanged or who is selected as cooperation partner in innovation processes. Also, firms are subject to different forms of selection and we know little about the relative importance of and interdependencies between the different forms. Further, how geography relates to different forms of selection and what determines whether selection pressures are of rather local or global nature remains rather unexplored. Moreover, selection can change dramatically due to a variety of reasons

such as regulatory changes, financial crises or political conflicts. How changes in selection affect evolutionary dynamics in a particular cluster remains largely unexplored.

We address these research gaps by investigating how selection can be conceptualised in the context of economic geography. We argue that selection comes in different forms, which has implications on other evolutionary mechanisms and the importance of geography. Empirically, we analyse the med-tech sector in Scania, Sweden and show that i) firms operate in different selection environments and that ii) different selection mechanisms are at work iii) at various geographical scales. We therefore contribute by investigating one conceptual and one empirical research question:

- How can selection be conceptualized in the context of economic geography?
- To what extent, why and how does selection explain the evolution of the med-tech cluster in Scania, Sweden?

In section two, we focus on the first research question and propose a conceptualisation for selection in the context of economic geography. In section three, we present the empirical case study and describe in detail the selection environments relevant for med-tech firms. In section four, we analyse how changes in the selection environment have affected firm strategies. We conclude the paper with future research avenues.

Conceptualising selection in the context of economic geography

In our attempts to conceptualize selection in the context of economic geography, we took inspiration from the literature on Generalized Darwinism (Essletzbichler & Rigby 2010; Hodgson & Knudsen 2006; 2010; Knudsen 2004; Murmann 2003). This theoretical framework has the advantage of constructing a causal relationship between selection and other evolutionary mechanisms, notably variety creation, retention and replication. While taking inspiration from this literature, the aim in this section is to elaborate what role selection plays in explaining cluster evolution. In doing so, we unveil that there are different forms of selection and differentiate in two basic types, namely *formal*

and *social selection*. We will argue that these two basic types of selection have significant implications for other evolutionary mechanisms as well as for the importance of geography. We develop our argument by asking key questions in relation to the evolutionary mechanisms of selection, retention, replication and variety creation.

What are the selected entities? In the context of economic geography, the most commonly considered entities of selection are firms or individuals. Both are clearly identifiable entities that interact as a whole with their environment, enter or exit relevant populations (e.g. a sector, cluster or region), grow or decline. However, firms and individuals are not the only possible entities of selection. Products are also subject to selection, and moreover they are selected at multiple points. In a typical market place, products are selected by comparing quality and price. However, they are also selected prior to reaching the market place. For example, firms make selections about which products are kept on the market, which implies that non-profitable products can stay on the market (as long as the firm can subsidise the product from other sources). Likewise, regions and technologies are also possible entities to be selected. In contrast to firms and individuals, however, products, regions, and technologies lack agency on their own account. That is to say, despite inertia, firms and individuals can choose where to locate, in which industries to be active and which technologies to use. It is, thus, important to note that firms and individuals are thereby entities selected but can also act as selectors.

How are entities selected? Selection can be based on codified or non-codified criteria. The technical specifications of a simple product can be codified relatively easily. In science, knowledge is partly codified and publications may be a good proxy for the knowledge and capacities of researchers. Sometimes, however, it is more difficult or impossible to codify selection criteria in a way that adequately relates to the sought for properties. This may be the case for complex products or systems, for the tacit and context-specific knowledge required in for instance engineering or management, or where uncertainty is great like in innovation processes. Linked to the codification of

selection criteria is the formalisation of the selection procedure. A *formal selection* procedure requires codified selection criteria. The aim of a formal selection procedure is to "objectivise" the selection. This means that, in principle, the selection is independent of the selector and thus free of a possible bias of the selector. If the selection criteria are not codified, not codifiable, or codified in an ambiguous manner, formal selection procedures may be flawed. In other cases, where selection criteria are not codified or codifiable, the concept of *social selection* is highly relevant. This relates to the seminal work of Granovetter (1973; 1985; 2005) in which he shows that social ties and networks are crucial in labour markets. A formal selection based on for instance the CVs of applicants is constrained by the fact that many attributes influencing the potential performance of the applicant such as personality, social skills, or problem solving skills are not well captured by CVs. Such highly important but not codified properties can be unveiled through a history of interactions, either directly or indirectly through referral from trusted sources. Reputation, trust and history are fundamental in social selection. In a similar vein, the choice of collaboration partners depends on many subtle and non-tangible factors such as trustworthiness, "chemistry" between partners, or work routines. Hence, when criteria are not codified and selection processes not formalised, social selection will dominate.

What properties are retained? Suitable properties for retention require a certain degree of durability. Most commonly firm routines are considered as the retained properties in economic evolution (Alchian 1950; Nelson & Winter 1982). Firm routines correspond to behaviour learned over time that is engrained in a firm's organisational memory. This memory may consist of formal routines, i.e. guidelines and procedural books, but also encompasses tacit knowledge and behavioural patterns of individuals working in the firm. New recruits are trained and they learn through interaction with existing staff about behavioural patterns that comply with the routines of an organisation. "As a first approximation, therefore, firms may be expected to behave in the future according to the routines they have employed in the past." (Nelson & Winter 1982, p. 134). However, there are also other possible candidates for retention such as institutions of different types and

geographic scales. Institutions are "[t]he prevailing rule structure [that] provides incentives and constraints for individual actions" (Hodgson 2006, p. 6). Institutions are relatively stable, govern the interactions within the cluster and thus constitute a retaining force, which is also held responsible for the path-dependent development of many clusters (Hassink 2005; 2010; Maskell & Malmberg 2007; Trippl & Otto 2009). Additionally, the knowledge, skills and networks of individuals are suitable properties for retention and also product specifications can be retained. For instance, as shown later in the empirical section, if market access requires certification like in medical fields, the certified product will need to exactly retain its technical specifications when reproduced for market sales.

How are properties replicated? Replication mechanisms vary significantly and include learning at an individual, organisational and social level. At the *individual level*, the concept of interactive learning has received much attention in the literature (Lam 2000; Lundvall 1988; Malmberg & Maskell 2006; Nonaka & Takeuchi 1995; Polanyi 1958). Interactive learning is fundamental for transferring tacit knowledge or skills. Networks are transferred by processes of referrals, recommendations, or joint activities. In joint activities, two individuals can exchange contacts, arrange joint meetings with important contacts and thereby introduce each other. Furthermore, such joint meetings are usually accompanied with knowledge exchange about the history of previous interactions. Knowledge is exchanged about non-codified properties such as personality, knowledge and skills, trustworthiness, etc. At the *organisational level*, routines are considered to be the essential properties to be retained and replicated through various mechanisms. Within an organisation, replication usually works through organisational learning (Levitt & March 1988). When employees are hired, they undergo training programmes and learn interactively with their peers about organisational routines, systems in place, ways of communicating internally and externally, the organisational culture, as well as the informal and formal network structures within organisations. Within organisations, managerial selection also plays an important role (Knudsen 2002; Nelson & Winter 1982). Managers allocate resources between activities, teams, or approaches. This allocation will often depend on previous success. What has worked will receive more resources while resources will be withdrawn from areas

that were less successful. However, facing a highly uncertain environment, managers make choices based on their own experience, knowledge and beliefs, which often becomes a highly subjective exercise. Organisational routines can also be replicated outside an organisation through for instance spin-offs, imitation, joint ventures, collaborations, or take overs. At the *social level*, institutions have a durable impact on individuals' perceptions, intentions, interpretations and actions. When entering a social environment, individuals are confronted with the prevailing institutions. Through interactive learning and processes of socialisation, institutions are replicated (Hodgson 2006).

The above-mentioned mechanisms are particularly important for the replication of non-codified properties. Codification of knowledge, organisational routines or institutions allows for a more universal replication, independent of the entity holding the properties. Furthermore, standardisation is an important mechanism of replication. Firms need to comply with and/or participate in setting the standards to enter or stay in the market. Standards are usually specific as regards the technological design of a product or system. In order to comply with the standards, firms may need to implement certain standardised production technologies or quality control procedures. Standardisation allows for scaling up production but also marginalises alternative technologies. This typically leads to dominant designs in an industry, which is one of the theoretical foundations for the various lifecycle concepts (Bergman 2008; Klepper 1997; Menzel & Fornahl 2010; Storper & Walker 1989; Ter Wal & Boschma 2011). Incumbents can have a strong advantage through standardisation as it provides a protected market with raising barriers of entry and exit within which scale economies can be realised. The codification and standardisation of properties does not only allow for a more universal transfer of the properties but is also an important precondition for the application of *formal selection*.

What are the implications for variety creation? As regards variety creation, the advantage of *formal selection* is its openness towards all agents that fulfil the codified criteria. This implies that formal selection is in principle open to agents all over the world (assuming that location is not one of the

selection criteria). Also firms or individuals, who are not in any way linked to the selector, may enter the competition. On the other hand, formal selection is essentially a subset selection where a choice is made between several alternatives, i.e. reducing variety (Knudsen 2002; 2004). Formal selection sometimes also relates to an exchange on spot markets, i.e. the history of previous interactions plays a minor role. The quality of formal selection depends first on the extent to which the codified criteria are translated into adequate indicators for the sought-after properties. For instance, if largely intangible properties are sought after like context-relevant knowledge, work attitude or ethics, or personality, it may be possible to formulate the desired qualities, but it may be difficult to codify, measure and evaluate them. The quality of formal selection depends second on the level of uncertainty about the desired properties. Especially in fields like innovation, where uncertainty is high, a narrow formulation of criteria will exclude many possible alternatives that might be equally good or even better. On the other hand, a wide formulation of criteria implies that it becomes very difficult to select in an objective manner. In such cases, experts need to be asked to evaluate offers. Experts, however, are biased as they have developed a certain worldview, belong to epistemic communities or communities of practice and will therefore evaluate offers from this perspective. A third concern with formal selection is that participation in the competition requires knowledge about the selection procedures. Formal selection procedures can be very complicated and thus exclude a large number of agents who lack the procedural knowledge. Formal selection, therefore, seems to work well if i) there is little uncertainty about what is being selected, ii) if the selection criteria can be codified, and iii) if the sought for properties can be adequately measured. However, if these conditions are not met, which typically is the case in innovation related fields, formal selection is problematic and potentially impedes the creation of variety and evolutionary processes.

Social selection differs from formal selection in that the history of interactions plays a substantial role. The general assumption in social selection is that the entities to be selected will behave in the future in a similar way as they did in the past. In relation to individuals, this implies that intangible properties such as personality, work ethics or tacit forms of knowledge will be retained. As regards

organisations, it relates to the stability of firm routines. Through a history of interaction, knowledge is created about these intangible properties, which translates into reputation, credibility and trust. The ability to observe and interact in person is important in this process. Information about reputation, credibility and trustworthiness of entities to be selected, furthermore, circulates in informal networks. Informal networks relate closely to Granovetter's concept of social ties, which plays an important role not only in labour markets but also for pricing, productivity and innovation (Granovetter 2005). Furthermore, social selection has to be seen in the context of continued interactions where individuals or teams are selected for their knowledge, skills and networks, or organisations for their routines and capabilities. These largely intangible properties are retained and replicated through interactive learning processes among the selected entities.

Interactive learning processes are not only an important mechanism for replication but also a source for variety creation. Interactive learning will never lead to an identical transfer of these properties but will be appropriated in a given context, e.g. the previously acquired knowledge, skills and networks of an individual or the previously developed organisational routines or capabilities. Furthermore, interactive learning is not only a process of replication but results also in new knowledge. In consequence, the sought for intangible properties such as knowledge, skills and networks of individuals or the organisational routines and capabilities further develop contributing to the reputation, credibility and trustworthiness of the specific entities. This will then influence the likelihood of being selected in future creating a continuous process of selection, replication, and variety creation. However, social selection has a big downside when selection becomes too narrow, focussing only on strong ties, influenced possibly by vested interest and rent seeking. It seems that the acceptance of weak ties (Granovetter 1973) coupled with openness for newness and diversity, a sense of integrity, and business ethics are important preconditions for social selection to work well. If these conditions are met, theoretically, in the face of uncertainty, social selection and linked processes of retention and variety creation are assumed to play an important role in the evolution of

clusters as they drive the development of knowledge, networks and capabilities that are essential for innovation processes and the renewal of clusters.

What does this mean for economic geography? The importance of geographic proximity depends on the extent to which formal or social selection dominates. Formal selection, in principle, opens up competition to entities all over the world as long as they fulfil minimum criteria. Formal selection also does not necessarily imply a causal relationship between selection, replication and variety creation. Hence, it does not necessarily lead to spatially-bound learning processes. In contrast, geography plays an important role for social selection. Social selection is largely informed by experience from previous interactions. These interactions can be either directly between two agents or indirectly mediated through third parties. Social selection relies to an important extent on the reputation of agents or recommendations and referrals. These are circulated through informal networks implying that social ties are important for this type of selection. While informal networks or social ties are in principle possible over distance, geographic proximity and the possibility of regular face-to-face contacts facilitate such networks significantly. In social selection, entities are selected for largely non-codified properties. In order to appropriate non-codified properties, it is required to interact in person with the entity holding these properties. For example, in an innovation process, an individual might be selected largely for her tacit knowledge and networks. The tacit knowledge and network can only be brought to use through a contribution in person of this individual and in interaction with others involved in the innovation process. Hence, interactive learning is both a requirement and a result of social selection based on non-codified properties. Interactive learning largely depends on co-location, either permanently at the work place, or temporarily in for instance project groups (Amin & Cohendet 2005). While interactive learning over distance is possible, e.g. through project groups, it requires more time and efforts making it more costly and sometimes difficult to realise (Bathelt et al. 2004; Storper & Venables 2004). Geographic proximity plays, therefore, an important role for the replication of knowledge and networks through interactive learning (Lam 2000; Malmberg & Maskell 2006; Maskell & Malmberg 2007; Nonaka & Takeuchi

1995). Consequently, geographic proximity is important for social selection, the related replication mechanisms and thereby also variety creation. In contrast, formal selection, in principle, allows for competition independent of geographic proximity or social ties.

In summary, reducing selection to market competition, particularly product markets, turns a blind eye to other forms of selection. We suggest a broad distinction in formal and social selection. Formal selection works well if i) there is little uncertainty about what is being selected, if ii) the selection criteria can be codified, and if iii) the sought for properties can be adequately measured. As regards innovation processes, these criteria are usually not fulfilled. Since innovation is essential for the renewal and thus evolution of clusters, it can be assumed that social selection plays an important role. As selection changes, different entities (e.g. products, firms, or individuals) will be selected and different properties (knowledge, networks, habits, firm routines, or institutions) retained. Furthermore, firms and individuals are not only victims of selection but can also seize opportunities and change their behaviour as response to actual or expected changes in selection. Changes in selection will, consequently, have a powerful impact on the evolution of a cluster, i.e. the transformation of a cluster's population resulting from selection pressures as well as behavioural responses. Moreover, we have argued that geographic proximity plays and important role for social selection, while formal selection, in principle, opens up global competition. Therefore, changes in selection can have both local and global causes.

Case study: Selection and evolution of the MedTech cluster in Scania

This paper builds on an empirical case study of the Medical Technology (hereafter MedTech) sector in Scania, Southern Sweden. The MedTech sector, often considered part of the Life Science industries together with pharmaceutical and biotechnology sectors, includes firms producing low and high-tech products that aim to contribute to improving and extending people's lives, and thereby improving the efficacy and sustainability of healthcare systems (Eucomed 2013). MedTech is a rather heterogeneous sector in terms of product technologies, including low-tech products such as plasters,

assistive devices such as lifts and adjustable beds, as well as high-tech diagnostic kits, operating room ventilation systems and medical devices such as dialysis equipment and stent implants.

Sweden is said to have a "proud history in medical devices" built on innovations such as the gamma knife, dental implants, the implantable pacemaker and the dialysis machine (ActionMedTech 2007). Boasting consistent GDP contribution growth of 10% per year from 1999-2005 (ActionMedTech 2007), MedTech is considered a growth-industry in Sweden and internationally. Demographic shifts as well as increases in lifestyle and chronic diseases, suggest that the market for medical technologies will continue to grow in the coming years. Moreover, MedTech has become an increasingly important partner to the pharmaceutical and biotechnology sectors, providing essential technological inputs to integrated solutions and drug delivery systems. However, the growth of the industry is, as revealed by the economic crisis, dependent on investments in health: "On average across the EU, health spending per capita increased by 4.6% per year in real terms between 2000 and 2009, followed by a fall of 0.6% in 2010" (Eucomed 2013).

The MedTech industry, in contrast to the pharmaceutical industry, is dominated by small and medium sized companies. EUCOMED, an industry association at the European level, estimates that 95% of MedTech companies are SMEs, the majority of which are small and micro-sized companies (Eucomed 2013). In the southern region of Sweden, Scania, we observe a similar industrial structure. Here the group of approximately 135 MedTech firms includes larger firms such as Gambro, Getinge Group and Jolife, but consists primarily of small and medium sized companies. Industry data on what we consider to be 'core' MedTech activities, indicates that in 2008, 62% of the firms employed fewer than 10 people, and 15% employed more than 50. Total employment in this sector in the region is currently around 5000, and the number of firms has approximately doubled over the past two decades. However, this growth has peaked in the year 2000.

The empirical discussion that follows is based on desktop research, quantitative data analysis and original data collected using 16 semi-structured interviews in which we asked respondents about

their activities and experience in the sector, the changes they have observed in terms of technology, regulation, markets and regional assets, and their expectations for the future of the sector in Scania[i]. Our first round of interviews was conducted in February/March 2013, after which a second round followed in the Fall of 2013. Interviews had an average duration of around one hour, the shortest being 21 minutes and the longest 93 minutes. Six of these interviews were with supporting organizations such as industry associations, regional authorities and cluster organizations. Ten interviews were conducted with firms in the region of Scania, and they display a range in firm size (from one employee to over 4000 worldwide) and a range in therapeutic areas (from brain cooling technologies to image management software)[ii].

The process of data collection and analysis has been highly iterative, continuously moving between theoretical and empirical frameworks. Using "close dialogue" (Clark 1998), we worked backwards and forwards in a reflexive manner, setting received opinions against informed expectations and vice versa. This has also allowed for adjustments during the data collection process to probe emerging themes (Eisenhardt 1989).

Three selection environments

An emerging body of work on industry evolution and cluster change points to various factors that shape the trajectory of industry clusters. Some are internal to the firm, industry, technology or the region, other triggers could be considered exogenous. In order to identify drivers of change, we first identified what has actually changed in this industry. In our investigation of the MedTech industry in Scania, the most frequently cited changes in the industry over the last decade were i) increasing demands from regulatory agencies, ii) reduced access to clinical sites during product development, testing and validation; and iii) reduced access to sources of finance.

This led us to identify three environments en route to the ultimate marketplace where MedTech products are purchased by customers: the regulatory environment, clinical sites and financial markets. In this section, we illustrate that selection plays an important role in each of these

environments, that selection has changed qualitatively and has become increasingly tough, and that this has an important effect on the evolution of the cluster. If selection gets tougher (more discriminatory), then we expect the number of firms that meet selection criteria (and survive) to drop. Stated differently, when selection pressures increase, firms either i) fail to meet these requirements and exit; ii) increase their competence to meet the criteria, which they can do by hiring people with necessary skills (human resources) or by partnering with other firms that have the necessary experience (mergers and acquisitions); or iii) they switch in their selection environment. We describe each selection environment in detail, elaborate on the selection mechanisms, and describe the changes in the selection environment. We draw on our interview data to demonstrate how selection environments impact firm behaviour, and how they have been drivers of change for firm strategy, industrial structure and cluster dynamics.

Regulatory environment for medical technologies

Many MedTech products are used in, on or close to the patient, and their availability on the market is therefore controlled by a regulating body to ensure safety, a process similar to the one for pharmaceutical drugs. The European Commission's Medical Device Directive, originally adopted in the 1990s, ensures that "the design and manufacture of medical devices is subject to essential requirements concerning protection of the health and safety of patients and users of these devices" (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices). More than 500,000 types of medical devices are classified according to their risk profile, where responsibilities and evidence requirements are more strict for manufacturers of high risk devices (such as pacemakers) than they are for manufacturers of low risk devices (such as sticking plasters) (EC 2012b).

The existing EU legislation is under periodic review in order to keep up with technological and scientific progress and to ensure comparable interpretation and implementation of rules in different EU member states. Recent scandals, such as when the French manufacturer Poly Implant Prothese (PIP) was discovered of using unapproved non-medical grade silicone to make breast implants in

2011, drew a lot of attention in media and political arenas and generated criticism of existing regulatory frameworks. In the wake of this scandal, changes proposed by the European Commission have included reinforced rules for clinical investigations on devices, and increased requirements on clinical data for the pre-market and the continuous post-market assessment of medical devices (EC 2012a). Following negotiations between stakeholders, the European Parliament and the Council, an agreement is expected to be reached in 2014 with the new regulations coming into force in 2017-2019.

These proposals, more closely resembling the procedures in place for regulating pharmaceutical drugs (Coombes 2012), has elicited negative reactions from the MedTech industry: "Such an approach could lead to undue delays and higher costs for placing new devices on the market which […] would have an adverse effect on SMEs, which make up around 80% of the sector" (EC 2012a, p. 3). Moreover, industry associations, doctors and patients groups are voicing concern that increasing regulatory demands and complexity would stifle European innovation. In contrast to the European decentralized system, the US uses a centralized regulatory approach where the Center for Devices and Radiological Health (CDRH) within the FDA regulates the process by which medical devices gain approval for marketing (BCG 2012; McCulloch 2012). These two approval processes have different requirements and timelines, and taken on average, reports show that the same devices have been approved and made available to patients in Europe three or more years before devices are approved in the US (in the period 2000-2011) (BCG 2012; Eucomed 2013).

All our respondents expressed concern and frustration over the ways in which the regulatory environment has increased in complexity over the last decade. This has increased the cost of innovation (to meet regulatory requirements in terms of evidence and testing) and the time to get new products to the market and generate cashflow: "The regulatory burden gets heavier each day. You have to show that you comply with every new regulation that comes out as well…It is increasingly complex to navigate, especially for small firms" (14). These changes have had a deep

impact on an industry dominated by small and medium sized firms, who struggle the most to answer to these increasing demands for evidence and who face the highest barriers to participate in the setting of standards for what is considered safe and effective: “To be a part of this activity [standardization processes] is costly and difficult for small firms…the standards requirements will result in changes in the industrial structure, it’s a game only the large firms can participate in” (7). In other words, changes in regulatory environment clearly have an impact on innovation and the competitiveness of firms: “Imminent changes in regulation in the European Union will place more emphasis on clinical data, not just safety. This will slow down innovation, especially for SME’s” (2). The formalized regulatory environment, where products are increasingly approved (or selected) based on evidence of their safety and effectiveness, requires additional firm resources and competences.

These observations illuminate four important points: First, selection environments are industry-specific. Transferring selection procedures from the pharmaceutical industry (dominated by large firms) to the MedTech industry (consisting largely of small and medium-sized firms) is not unproblematic because firms in these two industries do not have the same resources and capabilities to answer to these selection requirements. Second, selection environments for the same industry can vary between different geographical areas, in this case between the European Union and the United States. This has had an impact on the time-to-market for a new product, and in turn the survival and competitiveness of firms that seek to bring this product to market. Third, these changes have a negative impact on variety creation. Changes to the regulatory environment have a detrimental effect on the activities of start-ups and SMEs in the MedTech sector and furthermore, large firms will be more selective in what innovation processes they pursue due to the increased risks and costs of bringing products to the market,. . Forth, the result of these changes in formal regulatory requirements is that this has increased the importance of a firm’s ability to access clinical and research sites (in order to develop, test and validate their new products), as well as their ability

to access finance in order to pay for these additional testing activities and the increased time it takes to get a product to the market and generate cash-flow.

These two selection environments, clinical sites and finance, are therefore of increasing importance. In contrast to the regulatory environment, (which can be characterized as formalized and increasingly so under proposed reforms), the clinical and financial environments present classic cases in which social selection mechanisms play an important role. Product developers and clinicians engage in interactive learning, exemplifying 'dui' modes of innovation where relationships based on trust and mutual understanding play an important role. Likewise, sources of finance such as venture capital are known to rely on information including past experience, reputation and networks in order to overcome uncertainty in investment decisions. However, as the following section illustrate, these selection environments have also undergone changes in the recent decade.

Access to clinical sites

Clinical and research sites are important to companies at different stages of the innovation process; from the idea or problem that prompts the development of a new solution, to product development, testing and validation, and ultimately to implementation or purchase. Some firms are set up together with the clinician who identified a 'need' or a technical problem. Many of these activities benefit from frequent interaction between industry and clinical sites and are therefore often 'local': "they [the university hospital] were the site of the original request and are still an active partner on product development, testing and demonstration…We are in contact a few times a month" (4). Geographic proximity offers the opportunity for frequent meetings and a shared cultural framework that eases interaction: "Local [hospital partner] makes it easier because you speak the same language, easy communication" (6). Additionally, geographic proximity and the concurrent social proximity support trust-based relationships: "Having the clinical site there is important, this is a network and trust-based relationships…doctors are important in product development" (9). In other words, clinical sites are important partners to industry during the innovation process, and due to

their nature of interaction, they are often in close proximity. This is also why large medical schools and academic hospitals are often anchoring organizations for life science clusters (Whittington et al. 2009).

During our interviews with MedTech firms in Scania however, it became clear that their access to such clinical and research sites has become more difficult over time in two ways. First, doctors have less time to interact with industry now than they did ten years ago: ”Doctors have less time to adopt, to fiddle around with new products to see what they can do with it” (7). The demands placed on doctors have increased with increasing pressures on the health care system to prioritize efficiency, which jeopardizes future collaborations as well: “it is difficult to find a doctor, it depends on the goodwill of the physician who now has much less time to spend on such projects… This is a problem, also because nurses are losing out on education from clinical trials” (11). Second, there have been marked changes in the organization, administration and management of hospitals in recent years: “The route to access clinical environments has changed, it used to be possible to access physicians and key opinion leaders from below, now hospitals have a different way of deciding on new projects and purchases. Big firms can navigate this route much more easily than small or new firms” (1). Whereas firms previously relied on their trust-based relationships with physicians that were built up over the span of careers and through professional networks, they now have to follow a much more formalized procedure and convince hospital administration of the value of their product-in-development.

In addition to these clinical site ‘supply’ changes – physicians having less time and decisions increasingly being made by hospital administration not by physicians – we observe an increase in ‘demand’ for interaction with clinical sites from industry. Hospitals are approached more frequently now than they were ten years ago, with requests to collaborate with industry: “Hospitals used to get approached with a few ideas per year, now with hundreds of new ideas. They now need evidence that says it’s a great product” (8). Hospitals therefore have to select which projects to participate in,

which has resulted in a (at least perceived) decrease in access: “Access to hospitals has become more difficult, doctors have less time, cost pressures. Now we need to show partners what’s in it for them” (13). The way to ’show’ this can take various forms such as written proposals and presentations, but this challenge seems especially acute at the larger, academic, prestigious hospitals: “The university hospital is too big, too arrogant, it takes too long and they want you to present at a costly breakfast meeting to make sure everyone is onboard” (7). This suggests that clinical sites vary in their procedures to select industry partners, where some rely on more formalized procedures than others. Additionally, we found some examples of firms that attempt to go around the new formalized selection procedure, so that they can continue to rely on their social network, reputation and trust-based relationships to get their products tested: “Our alternative strategies have included organizing after-work types of events, where people that work in clinical settings come and experiment with new products here, but it is dressed up as a social event” (13).

These statements illuminate three points. First, clinical sites are partners to firms throughout the innovation process and this partnership benefits from geographical proximity. Frequent face-to-face interaction and the development of trust-based relationships facilitated knowledge exchange and interactive learning. The presence and strength of these supporting organizations in the region is therefore an important ingredient to the competitiveness of the MedTech industry. From this follows our second point, namely that changes in this environment clearly will have an impact on the ability of firms to access these sites, and it therefore has an impact on their competitiveness. As pressures on the clinical environment have increased (from the political domain to be more efficient, and from increasing demand from the MedTech industry), their selection mechanisms are changing, and social networks and trust-based relationships have been increasingly replaced by more formalized criteria for selection based on various forms of evidence. Third, however, we observed that these pressures on selection do not affect each clinical site in the same way, where some (big, prestigious) hospitals have become much more formalized in their selection mechanisms than other (smaller, regional) hospitals. That is to say, clinical sites vary in their adaptation to external demands.

Access to finance

Finance is critical to the MedTech industry; it takes a long time from product development to sales and the costs associated with research and development are high. During our interviews, it became clear that access to finance is one of the biggest challenges that firms in this region face. Whereas financing was available in larger quantities and at earlier stages in the late 1990s, "those days are gone now" (16). Access to finance has become a bigger problem in the last five-ten years, and our respondents point to two main reasons. First, the availability of finance has decreased over the last decade, in part due to negative experiences in the past: "Scania is the non-capital region of Sweden, both in terms of absolute amounts of capital available and also the number of players. There used to be 10-12 players in the region, but most have left for different reasons. This leads to a negative spiral: fewer startups means decrease in scientific entrepreneurship, which means there are fewer projects which gives negative feedback to investors about activity in the region" (12). Venture capital has moved away from MedTech and to other, less risky, industries. However, within the MedTech sector it has also moved from early stage funding to late stage funding: "Now, VC seems to have stepped out of MedTech, much less money is being spent. Before they invested early in technology development, but got burnt on many projects in the past, now they invest much less and much later so risk is the responsibility of small firms" (9). Secondly, the availability of finance is a challenge because it has become more conditional, where investors require more 'evidence' of the value of the technology and the company, before deciding to invest: "Compared to five years ago, big companies scrutinize potential new acquisitions more now. This is due to a wave of acquisitions that did not turn out as profitable as hoped, and due to the financial crisis these companies have much less cash to work with as well. They are less willing to take risk, so these small companies are responsible for proving they are worthy of acquisition" (5). Indicators of such 'worth' take the form of scholarly publications and patents: "Up until 2000 it was easy to get money, since 2001 or so investors require patents" (15).

However, despite this seemingly 'formalization' of the procedure by which investors select which firms or technologies to invest in, there are countless references to the continued desire for social networks and trust-based relationships on behalf of both the investors and the receivers of financing: "Since the crisis in 2008 it is more difficult. Stockholm has ten times the VC we have here in Scania, and Danish investors didn't want to invest abroad, they don't feel safe" (15). Moreover, firms want more from their investors than mere capital in order to navigate the increasingly complex route to market: "Investors are prepared to give small amounts, in exchange for a part of the company. I don't want unintelligent financing, I need money connected to skills and strategy" (14). This suggests that although investment decisions are formalized on paper, there is a more informal and social procedure under the surface.

These findings echo some of the main developments we identified in the clinical environments, namely that the demand for access to this resource has increased, but the supply has decreased and become more restricted. First, finance is an important partner throughout the innovation process; some would say increasingly so as this is not only a source of financial capital but also a source of business knowledge, networks and experience. This type of relationship benefits from frequent interaction and trust, which is most likely to develop when partners are in close geographical proximity. Second, changes in the regional finance environment will therefore have an impact on the ability of firms to access these sources, and therefore have an impact on their competitiveness. External events such as the financial crisis, but also disappointing past investment experiences within this industry, have induced changes in the selection mechanism in finance whereby firms now are required to present evidence of value, rather than rely predominantly on social networks and reputations. Third, these pressures on selection mechanisms within traditional sources of finance are prompting the emergence of new, alternative sites that rely on alternative mechanisms. One example is the growing importance of the stock market for small listings, where companies will 'go public' and source capital from small individual investors. The growing pool of 'hobby' investors, supported by their increasing computer literacy and the improving user interface, has opened up this

alternative selection environment. Although still relatively small-scale, it is not unreasonable to assume that this environment and its mechanisms (regular reporting and communication with shareholders), will impact firm behaviour.

Cluster change: Selection and firm adaptation

Our argument in this paper is that important drivers of change in the MedTech industry in Scania over the past decade, have to do with selection. The interview data clearly show that the survival and competitiveness of firms in this industry is under increasing pressure due to changes in the regulatory environment where selection has become more discriminatory. The increased burden on firms to provide evidence of product safety and effectiveness subsequently placed increased pressure on clinical sites for firms to collect such data, and sources of finance for firms to pay for this testing period. The demand for access to these resources – clinical sites and finance – thereby increased. In part due to this increased demand, these two environments have also changed in terms of their selection mechanisms. Whereas these selection environments used to rely on social selection largely depending on networks and reputation that were built over the span of careers within the region, there are signals that clinical sites and sources of finance increasing rely on more formalized procedures. Hospitals select innovation projects based on their merits presented at open breakfast meetings, and investors select firms based on the patents and publications and grants already accrued. Moreover, these increasingly formalized procedures serve to document and justify selections to actors further removed from the actual experience of the innovation project. These developments can be seen advantageous to those (often large) firms that are able to participate in formalized environments such as standardization and public procurement, and who are not only restricted to the locations where they have established networks. This can also be seen as advantageous to hospitals, which hereby reduce the risk of 'lock-in' as they are not only tied to the quality of local suppliers for innovation development and procurement.

These changes, however, pose challenges to small, single-product and single-site firms such as the ones that form the bulk of this industry. These firms have relied heavily on interactive learning to develop and test their products, and their localized networks helped to overcome the inherent uncertainty that characterizes the MedTech industry. Our interviews with firms in the region of Scania point to several paths that firms have followed. The first is that firms exit the industry or die. Although our sample is biased towards survivors, a number of telling cases referred to by our respondents suggest that a substantial number of firms failed over the past five years. A second path is for firms to increase their competencies in order to meet the higher selection standards in the regulatory environment, as well as the clinical and financial environments. This strategy can take the form of partnering with another firm in a merger or getting acquired by a larger firm. This larger firm is likely to be American, and has resources and know-how to navigate the formal regulatory environments in both the US and the European Union. Another strategy for a firm to increase its competence is to hire people that have acquired experiences at larger and successful firms in the region: "I replaced more or less the entire team, let go of people that had been part of the company since the beginning and hired people with experience in big companies…These make the deliberate decision to work for a medium sized company instead. This complete overhaul was necessary to transition from operating in the 'inventor' market to the early adopter and into the mass market. The innovation phase is much more problem-solving focused, the mass market phase is about how to sell a product" (8).

The third strategy firms employ in order to cope with the increases in pressure and standards of selection (and the most interesting for the purpose of this paper), has to do with firm adaptation. Firms have responded to the above mentioned changes by by-passing formal selection, as for example illustrated by the after-work events organized for hospital staff, in lieu of the expensive official breakfast meetings. In addition, we can identify situations where firms have shifted between but also within selection environments. A number of firms shifted *between* selection environments, to a product market where the regulatory burden is less. In one case this involved a shift from human

health to animal health: “At that time, the veterinary market did not have the same requirements in terms of clinical trials and publications as the human market. Not yet, in any case. This will probably also change in the future” (10). Another involved a shift of geographic market: from Europe and North America to emerging economies: “The regulatory burden gets heavier each day…It is increasingly complicated to navigate, especially for small firms. Access to the US market, getting FDA approval costs a lot of money and time, small companies would rather go to China” (14). In other cases, firms shifted *within* a selection environment. As the findings on clinical environments showed, not all hospitals have implemented equally formal procedures to select development partners. This variety within selection environments creates opportunities for firm agency and strategy, where firms are able to shift partners from the prestigious hospital to a smaller site where trust-based relationships can still be built and maintained: “The University hospital is too big, the other, smaller hospital, although it probably lends less credibility to the product, was eager to collaborate” (7). We observe a similar ‘variety’ within the financial environment where pressures on selection mechanisms within traditional sources of finance are prompting the emergence of new, alternative sites that rely on alternative mechanisms such as small listings stock markets.

These cases indicate that firms (even small firms) are not merely passive receivers of regulations and standards set by large firms, lobby groups and governmental agencies. Firms adapt and change their behaviour as a response to actual or expected changes in selection environments, and they are actively selecting between a variety of selection environments; between different product markets, different clinical sites, different financial environments. Stated differently, changes in selection environments impact the evolution of clusters as a result of both selection and behavioural responses. Furthermore, this suggests that selection and variety are often intertwined, and in contrast to entities in the biological world, firms have agency and strategy. This means there is room for small firms, where they find slight variations in the selection environments and alternatives they can select themselves into.

Concluding remarks on selection and cluster evolution

This paper is devoted to selection, which – despite its essential role in evolutionary theory in general – has received limited attention in explaining the evolution of clusters. Selection comes in many forms. Some forms of selection are causally linked to other evolutionary mechanisms such as variety creation and retention while others are not. Selection differs in the degree of formalisation. Formal selection works well if i) there is little uncertainty about what is being selected, ii) if the selection criteria can be codified, and iii) if the sought-after properties can be adequately measured. If uncertainty is high and if non-codified properties such as tacit knowledge, expertise and networks are sought for, like in innovation processes – the main driver for variety creation in a cluster – formal selection has its limitations. In this case, social selection, building on networks and reputation, seems to play an important role.

From the case study, it becomes evident that firms in a cluster are subject to selection in different environments relating, in our case, to regulations for product certification, access to finance and access to clinical sites. The selection mechanisms clearly differ between these environments. The most formal selection environment, related to regulation for product certification, is least dependent on geographic proximity, thus opening competition globally. On the contrary, social selection has traditionally dominated access to finance and clinical sites. Geographic proximity has been important to build up social ties, reputation and trust, which are essential for social selection. We have also found evidence that selection environments have changed and that a change in one selection environment has an impact on other selection environments. For instance, selection as regards regulations for product certification has become tougher, increasing the pressure on the other two environments, access to finance and access to clinical sites. The demand for finance and clinical sites has increased while at the same time external factors, in particular the financial crisis, have put additional stress on these environments. Partly due to these factors, the selection mechanisms have become more formal and thus made it more difficult for SMEs in the cluster to access finance and clinical sites. These changes in selection environments have had fundamental effects on cluster

evolution. First, as selection becomes tougher fewer firms are selected and able to pursue innovation activities. Second, as selection mechanisms change other types of firms are selected. Third, firms adapt their behaviour and strategy as response to the changes in the selection environment. We have found evidence, for instance, that firms switch between selection environments (e.g. from human health to animal health) or within environments (e.g. from university hospitals to smaller hospitals).

Furthermore, cluster evolution results from the interplay between exogenous and endogenous factors. Exogenous factors frequently translate into changes in the selection environments of firms, which triggers strategic and behavioural responses of firms. This has important implications for innovation policy. One implication relates to the recognition that formal selection has limitations in evolutionary processes. Social selection and linked processes of retention and variety creation do play an important role in the evolution of clusters as they drive the development of knowledge, networks and capabilities that are essential for innovation processes. Creating opportunities for these evolutionary mechanisms to unfold should therefore find more consideration in innovation policy. Another implication is that policy can influence selection environments and particularly those where social selection plays a dominant role. In the investigated case, access to finance and access to clinical sites are essential for SMEs to innovate. In both cases, social selection used to dominate and while selection has become more formalised, we have indications for the continued importance of selection based on networks and reputation and of geographic proximity. These are “regional” selection environments that can be nurtured by policy makers creating competitive advantages for the local firms.

Selection, therefore, deserves more attention in research on cluster evolution. We found that firms, in our empirical case, perceived selection to be of fundamental importance. However, it remains an open question to what extent we can generalise our findings to other clusters and sectors. Does the conceptual framework and broad distinction in formal and social selection also help to understand

and explain other selection environments? Furthermore, we have found evidence for the interplay between changes in selection environments (exogenous factors) and changes in firm behaviour and strategy (endogenous factors). How does this interplay materialise in other contexts? What factors influence the (spatial) configuration of selection environments and to what extent do individuals and firms actively influence their selection environments? What are the policy implications? These are some of the questions that will be central as we try to improve our understanding of the interplay between the evolutionary mechanisms of selection, retention and variety creation and thereby cluster evolution.

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[i] The interview guide included three main sections. The first covered basic information about the firm and the respondent, and some of this information was already collected using publicly available data sources such as the firm website and media sources. This information was verified during the interview, and expanded on by asking how this had changed over the last five years. The second section covered questions concerning sources of change in the environment in which the firm carried out its innovation and business activities. Unless the respondent commented on the various themes unprovoked, we probed for their thoughts on technological development, regulatory changes, changes in the market, their relationships to other firms, globalization of the industry, and regional factors that played a role in the development of the firm and industry. The third section asked respondents for their perspective on changes in the industry more generally and their expectations for the (near) future. A selection of respondents, generally those with ten or more years of experience in the industry, were asked if they would be willing to participate in a follow-up interview a few months later to reflect on some of our findings. Following this first round, we initiated a second round of interviews in the Fall of 2013, where we focused our interview guide on sources of cluster change that were mentioned most frequently: changes in the regulatory environment, access to clinical sites and access to capital.

[ii] These firms were selected from a list of firms that were included in two or more of the MedTech industry "mapping initiatives" initiated by multiple organizations in the past few years, independently of one another (Swedish MedTech, Medicon Valley and Region Skåne). We stratified this list by therapeutic area and selected firms to include a range of sizes and locations.