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Variability in organisational forms of biotechnology firms☆

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Abstract

This paper examines the variability of organisational forms in terms of forward and backward networking versus vertical integration in biotechnology SMEs. The study examines forms of organisation in a set of firms across application segments. The forms of organisation vary by application segment in biotechnology, but differences are not clear-cut, and a firm can apply different forms to different application segments in its activities. The reasons for this variability are related to the stringency of the regulatory approval systems, technological risks, and the costs of building full-scale manufacturing facilities which influence funding needs and thus also the choice of organisational form. The paper finally discusses the notion of networking as a separate form of organisation of economic activity and the extent of its applicability to biotechnology.

Keywords: Organisational forms; Biotechnology firms; Network company

1. Introduction

In the field of biotechnology, alliances and networks are essential and appear to be a key factor for the survival and growth of new biotechnology firms (e.g., Powell et al., 1999; Niosi, 2003). Established firms invest in biotechnology R&D in specialist small firms through R&D contracts, equity investments and joint ventures (Powell, 1990; Sharp and Senker, 1999). In exchange for their support, they obtain exclusive or shared rights to specific technologies or products that emerge from the new biotechnology firms' R&D programmes. The latter obtain funding for R&D, and both funding and expertise for manufacturing and marketing their products. These arrangements have been so frequent and intensive that they have even been regarded as a new organisational form (a network company as contrasted with markets and hierarchies; see Powell, 1990; Powell et al., 1996; Mangematin et al., 2003), or as a hybrid governance form (Williamson, 1991).

Nonetheless, Pisano (1991) noted a reverse trend towards forward vertical integration by new biotechnology firms into manufacturing and marketing, and backward integration by established firms into

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biotechnology R&D (see also Senker and Sharp, 1997). According to Pisano, at the same time, organisational structures to source or commercialise technology have become more diverse and hybrid.

A lot of previous research in biotechnology has concentrated on pharmaceuticals-related biotechnology, which is the earliest and probably still the most typical application sector of new biotechnology. However, even in pharmaceuticals-related application areas, the business and networking strategies of biotechnology firms may differ. One may presume that this applies even more to other biotechnology application areas. Further, much of the research on biotechnology firms has been carried out in the USA, where biotechnology was commercialised earlier than in Europe. US circumstances differ from those in small European countries, not only because the biotechnology business sector is more mature there, but also because there are large established firms in the various application areas of biotechnology with resources for networking with small biotechnology firms. Moreover, the private venture funding sector is well developed in the US, offering both alternative and complementary sources of funding for the new biotechnology firms. In a globalised world, access to partners and funding, either locally or nationally, most probably is not a necessary condition for biotechnology firms to function. However, it is likely to be a facilitating framework condition.

This paper examines the extent to which networking and vertical integration in new biotechnology firms differs in different application areas and compares firms in and outside the pharmaceuticals sector. The viewpoint of the paper is that of a new firm. The paper focuses on the factors that influence the observed diversity. The empirical research material comes from a small European country where new biotechnology firms are a much more recent phenomenon than in the USA, giving rise to more varied circumstances under which these firms hope to survive and grow. Private venture funding is also scarcer. Further, the paper will discuss the notion of networking as a form of governance and its applicability to biotechnology.

Finally, the question of organisational form adopted by new biotechnology firms is of policy relevance. Different organisational forms can influence the growth prospects of biotechnology firms and the potential returns to investments in R&D, which in many countries are heavily dependent on public money. This is the case in, e.g., Finland where, since the late 1980s, research funding agencies have invested large sums of public money in biotechnology R&D, motivated by great expectations concerning a new growth sector. Whether these expectations are realistic will be touched upon at the end of this paper.

2. Networking and forms of organisation

There exist a host of studies on networking or alliances in biotechnology (e.g., Pisano, 1991; Liebeskind et al., 1996; Audretsch and Stephan, 1996; Zucker and Darby, 1996; Niosi, 2003; Mangematin et al., 2003;). Being strongly science-based, biotechnology firms have emerged as research spin-offs from academic or established industrial firms. Entrepreneurs in the new biotechnology firms often come from universities, and the firms are located near academic institutions, with which they collaborate intensively (e.g., Zucker et al., 1998a, 1998b; Stephan et al., 2000). Further, new firms lack funding for R&D that is needed for developing their inventions into products or processes. They lack resources and capabilities in manufacturing, clinical testing, regulatory processes and distribution/marketing, while incumbent firms can offer these capabilities (Powell et al., 1996; Pisano, 1991; Senker and Sharp, 1997). In Teece's terms (1986), it is a question of large and small firms having complementary assets. The established firms lack competencies in biotechnology R&D, a lot of which is tacit, and which in the earliest phase of the development of the field (in the 1970s and the 1980s, in particular), was centred in a few places (Zucker et al., 1998a; Sharp and Senker, 1999). Small firms are also regarded as more flexible, that is, able to react to new challenges and more innovative in new areas. Technological uncertainty has, further, played a role in the established firms' decisions to contract out for R&D in biotechnology (Sharp, 1985; Pisano, 1991). These observations have led to the notion of small biotechnology firms being exemplars of network firms.

This picture has recently been further elaborated by, e.g., Mangematin et al. (2003) who, drawing on data from French biotechnology firms, noted that the frequency of alliances among biotechnology firms is related to business models. They classified all new biotechnology firms, SMEs, into two classes. The first

group comprises companies which have large research programmes aiming at broader markets and have high expectations of future growth and profits. The authors show that these companies typically enter into contracts with big industrial groups. In a study of Canadian firms, Niosi (2003) noted that this business strategy is more often characteristic of a firm aiming at human health products. The second group, according to Mangematin et al. (2003), are biotechnology SMEs which run small projects, target small and segmented markets, often domestic, and make incremental innovations, manufacturing their own products and marketing them. In the latter case, the need for alliances with bigger companies is limited, and the organisational structure is typically that of a vertically integrated firm.

In addition to business models, intellectual property rights systems have been noted to be important for networking and alliances (Teece, 1986; Arora and Gambardella, 1994). A division of intellectual labour—and thus co-operation within a network—relies on strong intellectual property rights. A clear division of intellectual labour between small and large firms can be observed in the pharmaceutical industry, where patent protection is more effective than in other sectors (Levin et al., 1987). Another reason explaining strong property rights is the fact that the knowledge base can be articulated in universal categories, thus facilitating the codification of knowledge in patenting (Arora and Gambardella, 1994). Also Teece (1986) has noted that, in addition to the efficacy of legal mechanisms of protection, the nature of technology (product versus process and tacit versus codified) is an important dimension for appropriability and related to vertical integration versus disintegration. With effective property rights protection, codified knowledge and product innovation firms are more likely to be vertically disintegrated.

It thus emerges from previous research that there is variation in the extent of forward collaboration versus vertical integration in new biotechnology SMEs. This is related to the business models of the firms, and probably to the application segment of biotechnology with human health and pharmaceuticals firms being more inclined towards alliances and collaborative arrangements. However, Mangematin et al. (2003) argue that firms in the same application segment may choose different strategies.

Further, the intellectual property rights systems are related to the extent of networking and alliances, creating the conditions under which a system with extensive division of labour and alliances can evolve. It can be presumed that extensive division of labour further reinforces the intellectual property rights protection and induces firms to patent.

Networking, alliances and co-operation have been used interchangeably in the above analysis, as is the case in many studies on biotechnology. Different types of co-operative relations, such as those based fully on informal agreements versus those based on formal contracts, differ in their nature and function. The final sections of this paper will pay attention to this distinction and will discuss the concept of a network company and some of the assumptions underlying it.

2.1. Research questions

The paper assumes that instead of two distinct business strategies or models, as defined by Mangematin et al. (2003), there is more variability among biotechnology firms. Particular attention is paid here to forms of organisation, which means the reliance of the small biotechnology firm on vertical integration versus networking in its research, product development, product approval, manufacturing, and marketing activities. The term forward networking here means collaborative solutions with other companies in manufacturing and/or marketing while backward networking means collaboration with a university or a research institute in R&D.

This paper examines reasons for the observed variability in forward networking versus vertical integration. It is assumed first that networking solutions are typically used in human health products, while in other segments their prevalence varies. This study aims to test this assumption and to understand the rationale for variation. As the above references imply, one of the factors potentially influencing the decision concerns a need for and access to resources, especially money. Large companies which biotechnology SMEs make R&D contracts with or license their IPRs out to provide an important source of funding needed for the R&D processes of the SMEs. Alternative or additional sources are provided by public or private venture funding organisations, or, in the case of very early research stages, public R&D funding organisations. According to Lerner and Merges (1998), in pharmaceuticals, however, alliances with large firms have become the single largest source of financing for biotechnology firms.

It can be further presumed that the amount of money a new biotechnology SME needs is primarily related to the stringency of the regulatory systems for accepting new products in the markets. They are most stringent—and the process longest—in human health products, where it may take 10–15 years from the discovery of a new medicinal molecule to the introduction of a product into the market. Technological risks are high since a new product may fail in its presumed effects at each stage of the preclinical or clinical trials—or in the worst case, after market entry (for unexpected side-effects, etc.). The overall high costs of developing new medicines and the high risks can explain the prevalence of forward co-operative solutions in human health products where small firms cannot obtain the resources needed. According to Sharp (1985), this uncertainty and risk makes large firms more inclined to contract out biotechnology R&D to small firms. Especially in the early research phase, many of the costs are borne by public institutes and funding agencies. It means that the overall costs and risks in biotechnology are shared by a larger number of organisations. A second reason, presumably affecting the need for money, is the size of the potential markets and the costs related to building large-scale manufacturing facilities.

The ease with which new firms can access money is dependent both on the institutional framework (availability of public and private risk funding) and the innovations of the firm and its scientific and business networks. Though important, these are not the actual research focus in this study.

This study examines the extent to which business rationales and forms of organisation differ across application segments and sectors, and pays attention to the role of the approval or regulatory systems explaining this variance and the size of the markets for the products of new biotechnology firms. Attention will be paid to the importance of IPR protection, and particularly, the tendency of firms to patent, in each type of business strategy. An important aspect of the IPR strategies is the way in which a company has organised its backward co-operation, that is, co-operation with academic and other research organisations; whether it is informal and based on social relationships and unwritten agreements or based on formal/written contracts.

3. Data

This study attempts to answer research questions drawing on a qualitative dataset. The data consist of interviews carried out with 29 Finnish biotechnology firms in the winter of 2003.[1] The firms were divided into five small groups by main business segment. The segments were drug discovery ($N = 8$), diagnostics ($N = 5$), biomaterials ($N = 5$), services ($N = 5$), food and feed ($N = 3$, but only 2 are analysed in this paper), and others ($N = 4$), which is a miscellaneous group. Not all firms were small or medium-sized according to the standard definitions. Five firms had a large parent abroad—owned partially or fully—by companies in the USA or the UK. These firms are included, since the ownership arrangements in most cases incorporate forward networking strategies and the parent is involved in financing and marketing arrangements of the biotechnology subsidiary. One firm is a division of a larger multinational company and represents the expansion of an established firm into biotechnology. It is not included in the analysis of this paper, and thus, the number of analysed firms is 29.

Most firms are co-owned by founders, investors and venture funding organisations. As can be seen in the table in Appendix A, not all firms are very new with a few founded in the 1980s.

4. Findings by application segment

The table in Appendix A gives the basic findings as stylised facts by major application area. In each category, they are given in the order of the year of

[1] The definition of biotechnology used was based on a survey of Finnish biotechnology firms carried out by ETLA in the winter of 2002 (Hermans and Luukkonen, 2002). In the survey, the definition was practical, based on the data collected by the Finnish Bioindustries Association; in practice, the various biocentre directors had often made the definition while responding to enquires about recently founded companies. All the interviewed firms were among the surveyed firms.

The interviewees were in most cases the CEOs of the companies. In one company, both the CEO and the research director were interviewed, while one person was interviewed for two companies, since he was simultaneously the CEO of two small firms. In another company, a co-founder and board member were interviewed. With the exception of two telephone interviews, all the others were carried out in person.

foundation of the firm. The third column (functions of the firm) is the basis on which the classification of the firms into vertically integrated versus disintegrated has been made. If the column notes that the firm has manufacturing and marketing functions, it means that it is a vertically integrated firm, while a mention that it only has a function of 'developing innovations/out-licensing IPRs' means that it is a vertically disintegrated firm. Other characterisations mean a mixed firm.

4.1. Forward networking

4.1.1. Drug discovery firms

Drug discovery firms are a clear group mostly based on forward alliances, highly contractual relations, and having the least forward vertical integration. All the firms engaged in drug discovery developed medicinal products into clinical trials I–III, and intended to or actually did out-license their IPRs to big pharmaceutical companies during one of the trial phases. The big pharmaceutical companies would be in charge of the last and most expensive phases of the drug discovery process, and manufacturing and marketing. Safety and toxicological tests inclusive, the total expense of developing a new medicinal product presently is assessed to be in the order of € 500 million. The technological risks are great. There are different estimations of risks of failure, but one of the interviewed CEOs presented an estimation that only 1–5 of 100 original pharmaceutical discoveries will eventually lead to a new medicinal product. According to the same source, because of the improvements in the discovery process, thanks to the application of biotechnology, the risks have decreased to 1 in every 10 discoveries turning out successful. While traditional drug development takes from 7 to 11 years, by applying new biotechnology this period has been claimed to have decreased to 4–8 years (Powell, 1996).

According to the interviews, the later a biotechnology SME out-licenses the IPR to a product innovation, the more it gets as down payment and future royalties, since the SME has borne a larger share of the risks and expenses involved.[2] The decision of when to sell is dependent on how cash-stripped the SME is. The drug discovery companies mostly wanted to out-license, if possible, in trial phase II, though this was not always possible. Some were/are able to develop their products up to trial phase III, when they can earn larger revenues at the time of making the contract and as potential, future royalties. One of the firms with ample foreign venture funding aimed at a strategy to out-license in different phases, thus securing a steady short-term income while, at the same time, securing larger, potential longer-term income.

As a result of the tightening of the financial markets, one of the SMEs had recently made a co-operation contract with a big pharmaceutical company on R&D in the discovery phase. The big pharmaceutical companies will finance the R&D and will be the owner of the IPR for a potential invention. It will pay further compensation to the small biotechnology firm if the research leads to a discovery. This kind of contract will secure short-term funding for the activities of the firm while being less advantageous in the longer term.

Only one of the pure drug discovery firms intended to manufacture and market one of its products. It was a question of a medicinal product for a specific niche market with worldwide demand estimated to be quite small in the beginning. Specialised treatment in which this drug is used will be provided only in very few hospitals in the world and thus marketing would not require a great effort. The firm planned to manufacture the product during the first 5 years after its approval and to out-license the rights at a later stage. This means that the firm saw its role mainly as a drug discovery firm.

There were two firms that, in addition to drug discovery, were engaged in other types of activities; diagnostics, services, and chemicals. These firms had a clear distinction in their business strategies concerning the different types of activity: in drug discovery, they intended to or were engaged in out-licensing their product innovations. By contrast, in diagnostic tests or chemicals, they manufactured—one through a subcontractor—and marketed the product, and one of them was engaged in services. In the latter application segment, the organisational form was thus that of a vertically integrated firm.

A summary of the above is thus that, with the exception of niche drugs for very small markets, the drug discovery business is about developing and out-licensing product innovations. The variation between the firms

[2] This is in accord with the finding by Lerner and Merges (1998) that financial constraints drive R&D firms to cede control rights in a buyer's market and that alliances, signed in early stages of R&D projects, give less control for the R&D firm.

concerned the number of innovative products in the pipeline and/or the stages at which they intended to or already out-licensed their products. According to these firms, the best insurance against risks was to have several inventions/products at different stages when out-licensed, thus securing a mix of resources in the short and long term. However, this was not always possible for reasons related to access to funding. Thus, the business of out-licensing product innovations is based on a highly developed division of labour among various firms and networking.

All the drug discovery firms had had access to some venture funding, private or public, national, regional or foreign, and some had had a few funding rounds. Nevertheless, this was seldom sufficient for the envisaged development process. The sums secured were in most cases relatively small. Even an initial public offering does not necessarily secure a great deal of funding, particularly not in a small market such as Finland. Further, the public financing window has been closed because of the downturn in the capital market since 2001. The need for funding is currently regarded by the CEOs as the most acute problem of the sector in Finland. This need was an important factor determining the stage at which products were out-licensed—and thus for the present and future revenues of the firms.

It is to be noted that the present forms of organisation in terms of forward collaboration/networking have not necessarily stayed unchanged (cf. Mangematin et al., 2003). Some firms had started with expectations—which proved to be unrealistic—that they might be able to obtain the resources to build large-scale manufacturing facilities. The networking strategy has, in some cases, been the result of a painful learning process. Obtaining a competent—mostly foreign—venture funding organisation as an investor in the beginning helped some of the firms to build a viable business strategy at the outset. Even though all firms had obtained some venture funding, most had not been as fortunate—or rather had not had the networks to obtain such funding and/or had not had equally attractive inventions to offer.

4.1.2. Diagnostic firms

Diagnostics is also related to pharmaceuticals through pharmaceutical therapy and diagnosis. Firms may produce ingredients of monoclonal antibodies such as purified protein or antigens, or further, they may produce tests or markers that are key components of tests. Some of the firms produce these for therapeutic use, some also for research, not just for medical therapy or industrial uses. Firms are also involved in producing biosensors for, e.g., environmental monitoring R&D activities. The business logic of the firms engaged in diagnostics by and large differs from that in drug discovery firms, with no major differences in the strategies of firms across different diagnostic segments.

The diagnostic firms in the interviewed dataset were engaged in developing, manufacturing and marketing raw materials, such as antibodies or reagents for diagnostic tests, or the tests themselves. A major part of their customers are foreign companies. Some firms used distributors in their specific market segment. Two of the firms provided or had provided services in the early phase of their activities since these offer a quick cash flow. All the firms were vertically integrated firms, though one of the firms resorted to a partial network solution by subcontracting some of its manufacturing activity.

In diagnostics, there is no regulatory approval system and it is possible for firms to introduce new products as soon as they have developed them and set up systems to make them. A young firm may obtain revenues from the start and is far less in a need of external funding. Only two of the five firms had obtained venture funding, national, regional or public; one as capital to start the firm, and the other to develop new products, yet in the former case, the sums were very small. Overall, the required funding to start and develop business is much smaller than in drug discovery.

All the firms had patented their processes or test techniques. In diagnostics, however, not everything is being patented. Specific tests (test kits) are typically patented, but antibodies which are used as a raw material for making tests are not. Since these firms typically are engaged in producing both, they have patented only some of the knowhow related to their innovations. These companies often also used trademarks to protect their intellectual property. It is also true that many of the basic methods used in diagnostics, such as the methods to make monoclonal antibodies, are based on discoveries originally published as scientific discoveries and not patented (in the 1970s). This happened at a time when patenting was not practiced as widely as today. The competitive advantage for the firm is its tacit knowledge concerning the practical working methods of, e.g.,

how to extract antibodies and markers most effectively and with the intended impact. Even though firms may in principle be aware of the basic methods, their ability to make the end product varies. Firms may be able to license out their products, such as cell lines, without having patented them, facilitated by having mastered the technique effectively.

4.1.3. Biomaterials

Biomaterials are also used in the health care sector. Biomaterials are used in, e.g., orthopedic dental and cranio-maxillofacial applications or other solutions for musculoskeletal reconstruction and temporary stenting (implants). Biomaterials often replace older materials, such as metal plates, used in surgery. New and developing application areas are, for example, drug delivery and tissue engineering.

In terms of networking versus vertical integration, biomaterials is between drug discovery and diagnostics: four out of the five biomaterials firms aim at product innovations and out-licensing the IPRs. However, the main activity of the four firms is to manufacture their products, and in three of the five firms, also to market them.

Some biomaterials firms use distributors in the specific segment. This has the benefit that these have former customers and existing markets. Often the same distributors offer both conventional and new products (e.g., biomaterials versus metal plates for surgery) to their customers. Especially in the case of niche markets for specific products, professional groups, conferences, fairs, Internet-based advertising, training, and direct marketing to potential customers have been used. Marketing efforts are facilitated by the fact that the customers consist of hospitals and medical personnel. In one company, a foreign parent was in charge of marketing by utilising its worldwide market networks.

One of the firms involved in developing innovations and out-licensing the IPRs is a holding company, founded to commercialise research results of university researchers in the biomaterials field, and is thus not fully comparable to the rest. Another firm, not involved in marketing, is owned by a US firm, which markets the products. One of the firms also intends to do business in manufacturing for other companies under their brand name either using their design or its own design. All except the holding company had received venture funding. One had had an IPO in New York.

In biomaterials, the product approval process is much shorter than that in human drugs, though it depends somewhat on the application. The most stringent requirements concern biomaterials which are used inside the human body as contrasted with outside uses (such as on teeth). The US Federal Drug Administration requires clinical tests, but these do not follow the procedures set for human drugs. In European countries, there is a certification process by specific notified bodies after which the product can be given CE approval and be marketed in the European Union. Many countries outside the EU accept the European certification.

The overall development of biomaterials products from discovery to market launch is shorter and less expensive than in drug discovery, enabling small biotechnology firms to integrate manufacturing. Marketing is also within their reach through the use of existing distributors in medical devices. The markets are for the most part located abroad. One of the firms has a group of test users in various countries. These test the product before the actual market launch and suggest improvements before a major launch. Patenting is important and all firms do so. Patents are usually taken on materials, techniques, and/or work processes.

4.1.4. Services

Since biotechnology is highly networked, it offers many opportunities for service providers. The service firms interviewed were engaged either in consulting or in R&D services. One firm was a vertically integrated firm, since it manufactured diagnostics components for its customer firms. Most of the customers of the service firms were other biotechnology (diagnostics, food) or pharmaceuticals firms. One of the service firms subcontracted special analyses to other R&D service firms. None of the service firms had patented their knowhow, since it was based on publicly available knowledge and on their own acquaintance with processes, though some had plans to patent potential new methods to be developed in the company. New methods development is, however, mainly researched in universities in connection with basic research on, e.g., health issues and the diagnostics of various diseases. New methods development information is normally published in connection with the publication of the original discoveries and thus cannot be patented. Marketing is typically part of the everyday business of a service firm and cannot be contracted out. Service

firms differ from other firms in that often their major customers are in Finland, while firms in other types of business mainly cater to foreign customers. However, one R&D service firm in a narrow subject area had the majority of its customers abroad. Local demand for its services is too limited to offer a viable business model.

The special advantage of service firms is their ability to apply specific—yet generally known—methods in an effective way, and also the fact that they have the required instruments and trained personnel at hand. A lot of service provision is based on tacit knowledge. These firms learn to apply the latest techniques and methods through either informal contacts with university staff or by contracting them formally to teach their personnel.

Only two of the firms had obtained some venture funding as founding capital. Service firms accrue income from their services and, despite being young, they do not need large investments to pursue their business activity.

4.1.5. Other

4.1.5.1. Food and feed. The table in Appendix A lists only two companies under biotechnology-related food products. These two both operate in functional food production. A service firm is also in the functional food field. One of the two food firms carries out R&D to make product innovations in the functional food field and its business strategy is to out-license the discoveries. It does, however, take the development up to the production stage and is therefore in need of venture funding to finance the process. The other firm is in a very narrow niche market for functional food, and has created a production organisation and markets its products through a distributor. Both have patented their basic inventions.

In functional food, the approval system varies from country to country. There is no joint European legislation on the matter. The way health-related claims are treated in product approval differs among the European states and between Europe and the USA. It is easy for companies to launch new food products; however, substantiation of health claims may prove much more difficult. This is also a market which has widely different potential demand in different countries, since conceptions concerning food are culturally conditioned and health concerns vary. It is not so much a question of acceptability, as in genetically modified food, but of an interest in and market demand for health food products.

4.1.5.2. Miscellaneous. The last group includes, as the name indicates, a set of firms in many business areas: an instrument manufacturer (in surface chemistry instrumentation for pharmaceutical drug screening, research and environmental monitoring), genetic protein modification and engineering, bioinformatics, and drug delivery. The firms have somewhat different strategies varying from developing innovations (and out-licensing) to full vertical integration of various functions.

The instrumentation firm has a US owner which is in charge of its marketing (a leading provider of drug discovery, genetic screening, and chemical analysis tools and instrumentation). The volume of the specific instrument production is not large and the SME is able to organise it through subcontractors. By contrast, the SME involved in industrial enzymes (genetic protein modification and engineering) is very small (with a staff of only three people) and only involved in developing innovations on a small scale. It has adopted this business strategy knowing that any other strategy would require a major input of venture funding, which it is not in the position to obtain on acceptable conditions. The bioinformatics firm is fully integrated and, in addition to innovation development and marketing, is engaged in services. The development of software and its marketing does not require major financial investments, and therefore an integrated form of organisation is possible.

Finally is the drug delivery firm. Since it does not develop the molecules itself, but the delivery technology, the process of developing innovative products and taking them to market does not take as long as with a drug discovery firm. Still, the products have to be tested clinically. The firm is networked in many ways, i.e., it has a portfolio of ties to specific partners for certain activities (Powell, 1998): with university researchers for more fundamental questions, with a research institute on questions related to measurements and production technology, with a partner firm on medical molecules to be delivered, with a supplier on manufacturing the device, and finally, with a partner firm on marketing. As a part of the strategy, it considers the possibility of licensing out the IPRs for its basic innovation at a later stage.

4.2. Backward networking

Since backward networking, in practice, collaboration with universities, did not differ in different application segments, this question is treated jointly for all segments. With the exception of one firm, all the firms collaborated with universities in R&D. The exception was a consultancy firm for the commercialisation of biotechnology innovations in a particular foreign market, a very specific business idea having a niche market. Again, only two firms relied on informal networking without any formal arrangements. In practice, informal relations mean that the company monitors the developments on the research front through the personal relations of its personnel. One of these two was a one-man consultancy, and in the other university relations were established on the fact that the CEO owner was also a university professor and through the research activities of his colleagues and students was able to survey the developments. Once he found something interesting, he started to develop the ideas into practical applications within the company. As to the rest, the relations were formal, or both formal and informal.

This is in accord with the findings of Liebeskind et al. (1996) that the sourcing of new knowledge in biotechnology firms takes place through social networks. However, once there are research findings that have potential commercial value, the firm makes formal contracts for the further development of the findings into products. Thus, market arrangements are needed to guarantee the intellectual property for the commercial utilisation of the invention. Zucker et al. (1998a) noted that because biotechnology discoveries are characterised by natural excludability, scientists who make these discoveries do not give away the fruits of their intellectual labour to firms, but instead enter into contractual arrangements with them.

According to this study, contracts are typically about patenting and the utilisation of product innovations. Product development is most often done in the company. Usually, the ownership of the utilisation of the invention is transferred to the company. The latter pays the patenting fees and makes an agreement with university researchers on the division of potential future royalties, sometimes also paying a fee immediately. Another form of formal collaboration consists of contracting out specific studies or analyses to university institutes. In some cases, a company has a network of researchers who have agreed to offer their inventions with commercial potential to the company for commercialisation. These networks are informal, though they may also consist of the group of researchers who were actively engaged in establishing the firm. In all cases, the companies seek to secure the IPRs to the inventions (either through ownership or exclusive licensing rights) which they wish to develop further into commercial products.

There are also networks of university researchers with a formal function as members of an Advisory Board/Medical Advisory Board of the company. They provide input to the research programme of the firm and help organise user trials or clinical testing of products. Being senior scientists, these members can influence purchasing policies in their home institutions and thus can be helpful in the eventual marketing of the end product. The Boards typically consist of both Finnish and foreign members. Alongside scientific publications and patenting, Advisory Boards are of significance in signalling to venture funding companies the potential (scientific) value of the company and its products.

Several companies had obtained R&D funding from the National Technology Agency (Tekes) at some point in the past. Tekes does not provide risk funding like Sitra, a public venture fund, mentioned in the table in Appendix A. Tekes provides two types of R&D funding: direct support or offers loans to the company for its development projects or funding for company–university collaborative projects. It does not assume equity in firms even though it may offer equity loans to young firms. Company–university collaborative projects are typically coordinated by university (research institute) researchers, and provide companies with an opportunity to "peek" at the research front. Because of the public funding, these consortia have formal contracts and provide some of the formal relationships which appear in the table in Appendix A.

5. Factors affecting the organisational form

5.1. Forward collaboration versus vertical integration

In accord with Pisano (1991), the organisational structures in small biotechnology firms have become diverse and hybrid. Many forms of organisation co-exist in small biotechnology firms (cf. Mangematin

et al., 2003). These forms seem to be related to the application segments of the firms. In drug discovery, the forms of organisation were mostly based on network solutions, i.e., alliances with large pharmaceutical firms which develop the new products further. In the other application segments, the degrees of networking versus vertical integration varied, though firms in diagnostics, biomaterials, and services were largely vertically integrated. Several firms used partly integrated, partly network solutions.

The study pointed to co-variance between the regulatory approval systems in the application segment, the effectiveness of the property rights protection regimes, and form of organisation or strategy of a small biotechnology firm. The strictness of the regulatory system influences the overall costs of commercialising inventions and thus affects the decisions of firms to choose forward co-operation instead of vertical integration. The costs of fulfilling the requirements of the regulatory approval are highest in human health products, and consequently, all the drug discovery firms had adopted the business strategy of developing innovations and out-licensing the IPRs to their inventions to big pharmaceutical companies. An important precondition for this is a tight appropriability regime, that is, the innovators can benefit from their innovation through strong protection and the innovations can be codified in patents (Teece, 1986).

With regard to firm strategy, there were differences concerning the stage at which the inventions were out-licensed, and the decisions firms made about this were largely affected by how cash-stripped the firms were to further develop the products. The later these were out-licensed, the more money the firm obtained or were to obtain for successful final products. Financial constraints may thus weaken the relative bargaining power of small biotechnology firms and drive them to agree to less advantageous deals. This finding is close to what has been written on bargaining power and its effect on control rights in alliances between small research firms and larger corporations, with the exception that control rights were not examined in this study (Lerner and Merges, 1998). The firms did actually make money on property rights (patents), since the property right regime was tight and the rights well protected by patents.

In other application areas, even though these were often related to the pharmaceuticals sector, e.g., diagnostics and biomaterials, the business strategies were different from those in drug discovery. In studies on biotechnology, the pharmaceuticals sector is typically treated as one block, and it is an important finding of this study that this is not the case. Firms in areas other than drug discovery did not have to plan for an equally long and costly trial process before they could obtain product approval. Consequently, these firms typically built their business around a strategy according to which they intended to manufacture their products themselves. These firms aimed at niche markets, or alternatively, at conquering a small portion of big and highly competitive markets. The typical solution was an integrated firm where the firm adopted not only manufacturing but, in most cases, also marketing. There were, however, also mixed cases in which some of the functions had been subcontracted. In these application areas, the appropriability regimes are not quite as tight and they vary by the application sector. Following Teece (1986), if an innovation requires an extensive amount of tacit knowledge and specialised assets, such as in manufacturing, the firm can take time to build its own facilities and does not necessarily need to contract out the function. An important difference with regard to drug discovery is also the fact that even if a firm did contract out some functions, such as manufacturing or marketing, it maintained control of the different functions, while in drug discovery the incumbent large firms were responsible for the integration function and the small innovating firm obtained a front payment and potential future royalties for the innovation. The firm in charge of the integration function is the one that will reap most of the potential future returns.

The importance of the application segment was highlighted by the fact that companies that were both in drug discovery and in diagnostics (chemicals, services) applied different strategies for these two areas. In drug discovery, firms followed the strategies of other drug discovery firms, and in diagnostics, the pattern of more integrated firms.

On the basis of the study, it can also be inferred that the resources needed for and the ease of building large-scale manufacturing facilities were related to the choice of organisational form. When a product was oriented to very specific niche markets, in which volumes are not large, a company could more easily acquire the resources needed for building the manufacturing facilities through venture funding. Hence, a firm would

be more inclined to adopt vertical integration. Several small firms outside drug discovery were developing products for niche markets and could build their manufacturing facilities. In human drugs, the type of markets varied, but many of the products under development were aimed at diseases with a large potential market. The typical pattern was not to manufacture products but to license out the IPRs to the innovations. One drug discovery company planned to take a niche market drug up to the final product stage. Its plans were based on the availability of foreign venture funding and of future income to be obtained from out-licensing the IPRs in clinical phase III. This was deemed possible because the volumes of sales in this very specific drug would be very small.

When compared with studies carried out in other countries (such as those by Mangematin et al. (2003) and Niosi (2003)), the findings of this study may be specific to a small country in a couple of respects. Aside from a few service segments, the domestic markets are so small that most firms need to look for clients abroad. Irrespective of their business strategies, they have to be export-oriented. Further, in pharmaceuticals the domestic incumbents are few in number and relatively small. The pharmaceutical companies with sufficient resources to develop the new innovative products of small biotechnology firms are typically large multinational companies. However, some established national firms (food, chemicals, and pharmaceuticals) did expand into biotechnology in the 1980s, but due to the recession of the early 1990s or for other reasons, ended some of their activities in this sector. This led to the establishment of small spin-off firms originating from the established firms, whose activities are based on the innovations created and who employ staff trained in these established firms. These incumbents have not, however, made contracts with small innovative biotechnology firms for R&D development or other functions, and are thus not benefiting from, or contributing to, the creation of network externalities.

Table 1 illustrates how companies in different application segments are situated in terms of the stringency of the regulatory system and the size of their markets and subsequent need to build appropriate facilities.

Table 1 does not give an example of a company from the studied material with less stringent property rights and mass markets, since there were none. However, it provides a couple of potential examples. Table 1 summarises the fact that there is variety in the degrees of vertical integration and network solutions and that firms with large markets with both stringent and less stringent regulatory systems take on only one organisational form while firms with small, niche markets have mixed forms of organisation. The strategies can be linked to both the demand for and the availability of funding as well as the tightness of the property rights regimes. When the regulatory requirements are stringent and the markets are large, which encourages building large-scale facilities, the need for resources is great. Even though most studied firms had obtained venture funding in one form or another, it was in most cases very small, with the foreign venture funding firms providing the largest and the regional ones the smallest sums. The limited resources of the domestic venture funding organisations constitute yet another feature specific to the Finnish context.

The stringency of the regulatory system seems to coincide with the tightness of the appropriability

Table 1
Forms of organisation by stringency of the regulatory system and market size

Product markets	Stringency of the regulatory system	
	More stringent	Less stringent
Mass markets	Organisational form based on *network firm*: developing innovations and out-licensing IPRs *Strong property rights regime*, e.g., drug discovery for common diseases	*Vertically integrated firm*, e.g., industrial enzymes, animal feed *From medium to strong property rights regime* (no examples in the data)
Niche markets	*Mixed organisational form A* based on developing innovations, out-licensing IPR and manufacturing, marketing *Strong property rights regime*, e.g., drugs for niche markets (brain tumours, etc.)	*Mixed organisational form B* based on vertical integration; with some firms having partial forward network solutions *From weak to medium strong property rights regime*, e.g., biomaterials, diagnostics, R&D and other services

regimes, which suggests their co-development. This can be understood in a way that if the resources invested in the product approval process are large, securing IPRs becomes more important than when this is not the case. We clearly need more research on IPR systems and their functions in the various application segments in biotechnology.

5.2. Backward collaboration

The study confirmed previous findings about the prevalence of university collaboration for small biotechnology firms. Practically all companies collaborated and a large proportion of their partners were domestic, many even from a local university. A lot of the university collaboration, especially that related to knowledge sourcing, was informal and it was possible to trace it back to old collegial networks. Thus, this confirms the findings of Liebeskind et al. (1996) that for new biotechnology firms, social networks are vitally important for knowledge sourcing. The informal networks were, however, the basis on which more formal contracts were negotiated. Formal contracting turned out to be of vital importance for an undisputed attribution of the ownership of immaterial rights or the right to commercialise findings, which is in accord with the findings of Zucker et al. (1998a). Irrespective of whether the firm intended to manufacture the final product itself or to out-license the IPRs, securing the immaterial rights to the firm was the basis for any further business transactions.

6. What is a network company?

In the foregoing analysis, the meanings of networking have been manifold: searching for new knowledge at universities through informal contacts, making formal R&D contracts, subcontracting manufacturing or marketing, subcontracting analyses/services, and outlicensing IPRs to an innovation with varying degrees of R&D collaboration. It is common to all of them that some of the phases of the process from discovery through product development and manufacturing to marketing and the various processes in between have been contracted out or done in agreement with another organisational entity. It is thus a question of vertical disintegration. An alternative organisational arrangement is a vertically integrated firm which is in charge of all these functions. In the biotechnology firms examined in this study, vertical integration was often resorted to in application segments outside drug discovery. Vertical integration versus disintegration thus changed across different activity areas in which a firm was engaged, but also over time.

Overall, various degrees of network solutions, or in the words of Powell (1998), “a portfolio of ties to specific partners for certain activities”, abounded. However, practically all the individual ties studied were bilateral, though a single company had many bilateral ties or relations, usually based on formal contracts, with a variety of partners. The only examples of multilateral ties in the data were groups of researchers who founded a particular firm or made an informal agreement to use it as a vehicle for commercialising their inventions. Our study proposes that among small firms in biotechnology these ties are mainly vertical in contrast to horizontal ones and between two partners at a time rather than multilateral. The situation is probably very different in other sectors such as ICT where standardisation requires the formation of horizontal collaboration and forums consisting of multiple partners.

In the research literature, the term ‘network’ has been used in yet another way, namely as an alternative to the dichotomy of markets and hierarchies as forms of economic organisation. According to Williamson (1991), the network is a hybrid form within the market-hierarchy continuum, while Powell (1990) proposed that networks constitute a third form of economic organisation, one which emphasises “reciprocal patterns of communication and exchange” (p. 300). Trust created in such reciprocal relationships is an important means of avoiding opportunism inherent in uncertain contracts. According to Powell, networks constitute organisational forms that are “more social—that is, more dependent on relationships, mutual interests, and reputation—as well as less guided by a formal structure of authority” (Powell, 1990, p. 300). Contracting and property rights form the normative basis of the market type of organisation while employment relations characterise that of the hierarchy (Powell, 1990, p. 300).

In further research on biotechnology, Liebeskind et al. (1996) used the term of social network relationships for relationships similar to those Powell analysed. The importance of informal networks in social and economic activity overall and trust created in such

networks has attracted a lot of attention in recent years and has been coined social capital.[3]

Powell's schematic presentation of the three forms of economic organisation of course exaggerates and highlights the essential features in each. In practice, these features do not appear in pure forms, but in varying mixes. Thus, when interpreting Powell's term 'network' as less formal structures in relationships, as social relationships, or as contrasted with markets or hierarchies, our data among SMEs in biotechnology show that, aside from knowledge sourcing, where social networks are the principal pattern of organisation—also confirmed by Liebeskind et al. (1996)—'market' arrangements are dominant in other contexts. 'Market' arrangements here mean being regulated by formal contracts. Even in university collaboration 'market' arrangements become the rule when the commercial value of new findings becomes apparent. This has been noted also by Powell et al. (1996) and Zucker et al. (1998a). Our data suggest further that in forward collaboration 'market' arrangements, that is, contracts and licensing agreements, are central for organising the relations between firms. In accord with this, Arora and Gambardella (1994) have argued that network types of governance structures cannot do without property rights and the mediation of contracting.

The findings of this study and earlier research thus suggest that in collaboration among firms and universities and in firm-to-firm relationships, contractual and formal relationships are an important foundation for commercial activities. We may, however, presume that in collaboration and alliances that are controlled by formal contracts, informal social relationships constitute the foundation on which formal contracts and joint work is built. It is important to emphasise that a minimum degree of trust is needed for concluding contracts. Informal social relationships are, however, a feature that is present in varying degrees, but the purely non-contractual organisation of a network is a rarity in biotechnology. Thus, in Powell's sense, a 'network' company is an ideal type, and as such, rarely to be found in reality, at least in biotechnology, where, because of long lead times, uncertainty and high risks, securing the immaterial rights plays such an important role in the provision of value for the business.

[3] Social capital has been equated with social networks and trust, and the normative rules and mutual expectations underlying collaboration in social networks (Ruuskanen, 2001). Dasgupta (2002) considers social capital as a system of interpersonal networks (p. 35), which are a means to create trust needed in cooperation. Social capital is needed to build up feasible co-operative relations and it is further reinforced in co-operation.

7. Conclusions

This study examined the forms of organisation of small biotechnology firms in terms of their vertical integration versus disintegration. It found that when the application area had a stringent regulatory (product approval) system, as in human drugs, and the products were aimed at large markets, the form of organisation tended to be a network firm. With less stringent regulatory systems and niche markets, the form of organisation was more mixed or vertically integrated. The data used in this study were based on a limited sample of firms interviewed, and thus we may pose the question of the extent to which the findings are robust and hold true for different samples of firms or for firms in different stages of maturity.

First, the study is explorative and its findings are tentative and need to be confirmed in other studies. Second, it is to be noticed that, when faced with a given situation, firms may indeed adopt different strategies. This is evidenced by the finding that there was variation in the organisational form in the situation of less stringent regulatory system and niche markets. Nevertheless, the constraints imposed on the firms by their need of resources to develop their products and build the facilities clearly affect their choices of organisational forms. Still, we may presume that a lot of what has been said is valid particularly for firms in their early stages of development. Their needs for resources are most pressing at this stage when many of them still do not make revenues, or if they do, these are not sufficient for their product development needs. We may assume that in areas other than drug development, the more mature the firm, the more often vertical integration is adopted as an organisational form. Drug development will probably remain a field in which few biotechnology firms will grow into big vertically integrated firms simply because of the enormous costs this would entail and due to extremely heavy competition in the worldwide pharmaceutical market.

These findings have some policy implications. A network firm not involved in manufacturing or market-

ing will not have the same potential for quick growth as a vertically integrated firm, since it will not reap all the potential economic returns to its innovations, if and when these turn out to be successful in the markets (particularly if it is not in charge of the integration function). Further, if the network firm is an important organisational form of firms in a high technology area such as biotechnology, the location of the partner firms influences where major economic returns will accrue. When the majority of these firms are located abroad, as may be the case for a small country, major economic returns will go elsewhere. As expressed by Teece, this highlights "the importance to innovating nations of maintaining competence and competitiveness in the assets which complement technological innovation, manufacturing being a case in point" (Teece, 1986, p. 304). If manufacturing and marketing assets are situated outside the country, its economy may not benefit from investments in R&D as much as in the opposite case. This may turn out to be the case for Finland, where, since the late 1980s, research funding agencies have invested vast sums of public money in biotechnology R&D and the commercialisation of research results, with few economic returns so far (see Luukkonen and Palmberg, 2004). It is true that the sector as a whole, even in other countries, is still in its early stages of maturity, but the possibilities to capture economic returns may differ from country to country. Finland lacks major industrial firms ready to take on the large-scale industrialisation of biotechnology innovations, and small biotechnology firms are looking for partners in other countries. This situation questions the basic assumptions underlying the past policies in supporting and promoting the area, and it may turn out that the expectations, on which the policies have been built, turn out to be unrealistic.

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Appendix A. Characterisation of the interviewed firms by application segment

Company	Year founded	Functions the firm has adopted (based on actual or planned activities)	Venture funding source	Nature of university collaboration	Patents or patent applications
Drug discovery firms					
A (drugs, diagnostics, services)	1984	Developing innovations/out-licensing IPRs; manufacturing; marketing; services	National Venture Fund; Regional Venture Fund	Formal	Yes
B (UK owner)	1993	Developing innovations/out-licensing IPRs; manufacturing; marketing	Foreign Venture Fund; National Venture Fund	Formal	Yes
C (animal drugs animal vaccines)	1994	Developing innovations/out-licensing IPRs		Formal; informal	Yes
D (drugs, chemicals, diagnostics) (US owner)	1996	Developing innovations/out-licensing IPRs; manufacturing through a subcontractor; marketing (markets divided geographically with owner)	National Venture Fund; Public Venture Fund; Foreign Venture Fund	Formal	Yes
E	1996	Developing innovations/out-licensing IPRs	National Venture Fund; Public Venture Fund; IPO	Formal	Yes
F	1997	Developing innovations/out-licensing IPRs	Public Venture Fund; National Venture Fund; Regional Fund; Foreign Venture Fund	Formal; informal	Yes
G	1997	Developing innovations/out-licensing IPRs	Public Venture Fund; National Venture Fund; Regional Venture Fund; Foreign Venture Fund	Formal	Yes
H	1998	Developing innovations/out-licensing IPRs; manufacturing semi-finished products for other firms	Public Venture Fund; National Venture Fund	Formal	Yes

Appendix A (*Continued*)

Company	Year founded	Functions the firm has adopted (based on actual or planned activities)	Venture funding source	Nature of university collaboration	Patents or patent applications
Diagnostic firms					
A	1985	Manufacturing; marketing		Formal; informal	Yes
B	1990	Manufacturing; marketing; import; services			Yes
C	1994	Manufacturing; marketing		Formal	Yes
D	1996	Manufacturing, partly through subcontractors; marketing; services	Regional Venture Fund	Formal; informal	Yes
E (US owner)	1996	Manufacturing; marketing	National Venture Fund; Public Venture Fund	Formal	Yes
Biomaterials firms					
A (US owner)	1985	Developing innovations/out-licensing IPRs; manufacturing; owner markets	Public Venture Fund; IPO	Formal	Yes
B	1995	Developing innovations/out-licensing IPRs			Yes
C	1996	Developing innovations/out-licensing IPRs; manufacturing; marketing	Public Venture Fund	Formal	Yes
D	1997	Manufacturing; marketing	National Venture Fund; Regional Venture Fund; Foreign Venture Fund	Formal; informal	Yes
E	1999	Developing innovations/out-licensing IPRs; manufacturing (in future also brand manufacturing to others); marketing	National Venture Fund; Foreign Venture Fund	Formal	Yes
Services					
A	1995	Consulting; services		Informal	No
B	1997	Consulting; services			No
C	1998	R&D services	Public Venture Fund	Formal; informal	No
D	2000	Services; manufacturing; also subcontracting to others; marketing		Formal; informal	No
E	2000	R&D services	Regional Venture Fund	Formal	No
Food and feed					
A	1993	Manufacturing; marketing through subcontracting to distributors	Public Venture Fund; Regional Venture Fund	Formal; informal	Yes
B	1997	Developing innovations/out-licensing IPRs; test manufacturing through subcontractors	National Venture Fund	Formal	Yes
Miscellaneous					
A (instruments) (US owner 10%)	1994	Manufacturing through subcontractors; marketing by the owner	Public Venture Fund	Informal	Yes
B (enzymes)	1999	Developing innovations/out-licensing IPRs		Formal	Yes
C (bioinformatics)	2001	Manufacturing; marketing; services	National Venture Fund	Formal	Yes
D (drug delivery)	2001	Developing innovations/out-licensing IPRs; manufacturing through subcontracting; marketing through a partner	National Venture Fund; Public Venture Fund	Formal; informal	Yes

National Venture Fund = private venture fund operating nationally; Regional Venture Fund = private venture fund operating regionally; Public Venture Fund = public venture funding organisation operating nationally, in practice, Sitra. Sitra is an independent public fund under the responsibility of the Finnish Parliament. Its operations are mainly financed through income from endowment investments and project finance. Sitra has an important role in the development of business based on knowledge and know-how. Public equity investment for the start-up and early stages of companies is concentrated in Sitra. Foreign Venture Fund = private venture fund based abroad. A firm may obtain funding from several funds belonging to a class. In that case, it is only mentioned once.

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