ETLA
ELINKEINOELÄMÄN TUTKIMUSLAITOS
THE RESEARCH INSTITUTE OF THE FINNISH ECONOMY
Lönnrotinkatu 4 B 00120 Helsinki Finland Tel. 358-9-609 900
Telefax 358-9-601 753 World Wide Web: http://www.etla.fi/

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Terttu Luukkonen

VARIABILITY IN FORMS OF ORGANISATION IN BIOTECHNOLOGY FIRMS

Contact information:
Terttu Luukkonen, email: terttu.luukkonen, tel. +358 9 6099 0218

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ABSTRACT: This paper examines variability in forms of organisation, 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 different 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. Reasons for the variability are related to the stringency of the regulatory approval systems, technological risks, and the costs needed for building up full-scale manufacturing facilities thus influencing the choices of forms of organisation through the need for and access to funding. The paper will finally discuss the notion of networking as a separate form of organisation of economic activity and the extent of its applicability to biotechnology.

Key words: Biotechnology industry, network firm, organisational form

Contents

1. Introduction

In biotechnology, alliances and networks are generally noted to be essential and appear as 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). 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 biotechnology R&D. 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, business and networking strategies of biotechnological firms may differ. One may presume that this applies even more to other sectors of the application of biotechnology. Further, a lot 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 and the private venture funding sector is well developed, both offering alternative or complementary sources of funding for the new biotechnology firms. In a globalised world, access to partners and funding locally or nationally most probably is not a necessary condition for biotechnology firms to function. However, it can be presumed 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. It also pays attention to the fact that in the pharmaceuticals sector, firms have different forms of organisation based on their variable business strategies. 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. The paper will finally discuss the notion of networking as a form of governance and its applicability to biotechnology.

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. 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 (Powell et al., 1996; Pisano, 1991). The established firms on the other hand, 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 70s and the 80s in particular), was centred in a few places (Zucker, Darby and Armstrong, 1998). 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' decision 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 on French biotechnology firms, noted that among biotechnology firms, the frequency of alliances is related to business models. They classified new biotechnology firms, all SMEs, into two classes. First, companies with large research pro-

grammes which aim at broader markets and have high expectations of future growth and profits. 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 with human health products. Second, according to Mangematin et al (ibid.), 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, a need for alliances with bigger companies is limited, and it is a case of a vertically integrated firm.

In addition to business models, intellectual property rights systems have been noted to be important for networking and alliances (Arora and Gambardella, 1994). A division of intellectual labour - and thus cooperation 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, providing better protection than in other sectors (Levin et al., 1987). Another reason is the fact that the knowledge base can be articulated in universal categories thus facilitating the codification of knowledge in patenting (Arora and Gambardella, ibid.).

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 (ibid.) 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, presumably 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 for a lot of research 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 paper will pay attention to this distinction towards the end and will discuss the concept of a network company and some of the assumptions underlying it.

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. Here attention is paid particularly to forms of organisation, which means the reliance of the small biotechnology firm on vertical integration, versus networking in the organisation of the basic functions of a firm along the axis of research, product development, product approval, manufacturing, and marketing. The term of 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 presumed first that, in human health products, networking solutions are typical while in other segments, their prevalence varies. This study aims to understand the rationale for this 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 with which biotechnology SMEs make contracts about R&D or about out-licensing their IPRs provide an importance 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 pre- 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, a lot of the costs are borne by public institutes and public 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 a need for money, is the size of the potential markets and the costs related to building up large-scale manufacturing facilities.

The ease with which new firms can access money is dependent both on the institutional developments (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 for this variance and the size of the markets for the products of new biotechnology firms. The study will point to a strong relationship between these to show that with stringent regulatory systems and large markets the form of organisation will be a network firm, and with less stringent regulatory system and niche markets, the form of organisation is more mixed or vertically integrated. The study will pay attention 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: is it informal and based on social relationships and unwritten agreements or based on formal/written contracts? Research on biotechnology has generally shown that collaboration by new biotechnology companies with universities and other research organisations is extensive and that entrepreneurs in the new biotechnology firms often themselves come from universities and are located near academic institutions (cf e.g. Zucker et al., 1998a; Zucker et al., 1998b; Stephan et al., 2000). New biotechnology firms are dependent on the newest knowledge produced in academic settings, though their needs may differ.

3. Data

This study poses research questions which it attempts to answer drawing on a qualitative data set. The data consist of interviews carried out with 30 Finnish biotechnology firms (in the winter of 2003).[1] The firms were divided in five groups by main business segment and the size of each group was small. The segments were drug discovery (N=8), diagnostics (N=5), biomaterials (N=5), services (N=5), food and feed (N=3, but only two 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 are part of the 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 appendix table, not all firms are very new with a few founded in the 1980s.

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 face-to-face.

[1] The definition of biotechnology used was based on a survey with Finnish biotechnology firms ETLA carried out in the winter of 2002 (Hermans and Luukkonen, 2002). In the survey, the definition was practical, based on the data collection 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 all were among the surveyed firms.

4. Findings

The appendix table gives the basic findings by major application area. In each category, they are given in the order of the year of foundation of the firm.

4.1. Forward networking

(a) 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 through III, and intended or did out-license their IPRs to big pharmaceutical companies at 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 EUR. 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 to11 years, by applying new biotechnology this period has been claimed to have decreased to 4 to 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 downpayment and future royalties, since the SME has borne a larger share of the risks and expenses involved.[2] The decision 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-

[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.

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 five 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 organisation 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 concerned the number of innovative products in the pipe-line and/or the stages at which they intended to or already practiced the out-licensing of their products. According to 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 innova-

tions 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 smallish. Even an initial public offering does not necessarily secure a lot of funds, particularly not in a small market such as Finland. Further, the public financing window has been closed because of the ICT crisis since 2000-2001. A need for funding is currently regarded by the CEOs as the most acute problem of the sector in Finland. A need for funding was an important factor determining the stage at which products were out-licensed - and thus for the present and future revenues of 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., 2002). Some firms had started with expectations – which proved to be unrealistic – that they might able to obtain the resources to build up large-scale manufacturing facilities. The networking strategy has, in some cases, been the result of a painful learning process. Obtaining competent – major foreign – venture funding organisation as an investor at the beginning had helped some of the firms to build up 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.

(b) Diagnostic firms

Diagnostics is also related to pharmaceuticals through pharmaceutical therapy and diagnosis. Some of these firms produce tests or markers for research use, not just for medical therapeutic or industrial practice. Some firms are also involved in producing biosensors for e.g. environmental monitoring R&D activities. The business logic of 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 data set 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 thus vertically integrated firms, though one of the firms resorted to a partial network solution in manufacturing by subcontracting some of it.

In diagnostics there is no regulatory approval system and the product cycle is quick. 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 are based on older discoveries, originally published as scientific discoveries and not patented. This happened at a time when patenting was not practiced as widely as today.

(c) Biomaterials

Biomaterials are also used in the health care sector. Biomaterials are used in, e.g. orthopedic dental, and cranio-maxillofacial applications or other biomaterial 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, e.g., 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 customer firms 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 utilising its worldwide market networks.

One of the firms, which is 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 the 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 use of existing distributors in medical devices. The markets are for the largest part 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.

(d) Services

Since biotechnology is highly networked it offers many opportunities for service providers. The service firms in the interview data 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 done in university research 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 any more. 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 customers situated abroad. 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 newest techniques and methods either by informal contacts with university people or by contracting these 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.

(e) Other

<u>Food and feed</u>

In the appendix table there are only two companies under biotechnology related food products. These two are both 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.

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 (only 3 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, 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 for developing innovative products 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 had R&D collaboration with universities. 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 through the personal relations of its personnel monitors the developments in the research front. One of these two was a one-man consultancy, and in the other, university relations were founded 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 (cf. Powell, 1990) are needed to guarantee the intellectual property for the commercial utilisation of the invention. Zucker et al., (1998b) 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 founding 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 an Advisory Board/Medical Advisory Board of the company. These are used to provide input to the research programme of the firm and to help organise user trials or clinical testing of products. Being senior scientists, these members can influence purchasing policies in their home institutions and thus 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 provides two types of funding, direct support or loans to the company for its development projects or funding for company-university collaborative projects. The latter 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 appendix table.

5. Conclusions

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, while 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 system in the application segment 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. There were differences concerning the stage at which the inventions were out-licensed, and the decisions firms made about this were largely affected by the amount of resource they had available to further develop the products. The later they out-licensed, the more money they 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 of the bargaining power about control rights in alliances between small research firms and larger corporations, with the exception that control rights were not examines in this study (Lerner and Merges, 1998).

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 typi-

cally 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.

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 an 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 up the manufacturing facilities through venture funding. Hence, a firm would be more inclined to vertical integration. Several small firms outside drug discovery were developing products for niche markets and could build up 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, 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 companies are few and relatively small. The pharmaceutical companies with large enough resources to develop the new innovative products of small biotechnology firms further are typically large multinational companies. There are, however, some established national firms (food, chemicals, and pharmaceuticals) that have expanded to biotechnology and have promoted the development of the sector further by cutting off some of their activities in this sector. This has led to the establishment of small spin-off firms originating from the established firms, basing their activities on the innovations created and employing staff trained in these established firms.

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

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

	Stringency of the regulatory system	
	More stringent	Less stringent
Product markets Mass markets	Organisational form based on network firm: developing innovations and out-licensing IPRs E.g. drug discovery for common diseases	Vertically integrated firm E.g. industrial enzymes, animal feed (no examples in the data studied)
Niche markets	Mixed organisational form A based on developing innovations, out-licensing IPR & manufacturing, marketing 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; E.g. biomaterials, diagnostics, R&D and other services

In Table 1, the upper right hand box does not give an example from the studied material, 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 evidence purer cases 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. When the regulatory requirements are stringent and the markets are large, which presupposes building up 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.

Our findings also provide some evidence concerning the observation by Arora and Gambardella (1994) that intellectual property rights systems are important for networking and alliances. In the areas with least networked forms of organisation the patenting is less important than elsewhere. However, this can also be related to the stringency of the regulatory system concerning product approval, which means in practice 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 had it and a large proportion of their partners were domestic, many even from the local university. A lot of university collaboration, especially that related to knowledge sourcing, was informal and it was possible to trace it back to the old collegial networks, thus confirming 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, (1998b). 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.

5.3. 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 out-licensing 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 in this study, vertical integration was often resorted to in application segments outside drug discovery. Vertical integration vs. disintegration thus changed across different activity areas in which a firm was engaged, but also over time.

Overall, various degrees of network solutions, 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 the vehicle of 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 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. 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 author-

ity" (ibid., 300). Contracting and property rights form the normative basis of the market type of organisation while employment relations characterise that of the hierarchy (p. 300, ibid.).

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' in a sense of 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 means 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. (1998b). Our data suggest further that in forward collaboration 'market' arrangements, that is, contracts and licensing agreements, are central for organizing the relations between firms. Arora and Gambardella (1994) 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

[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.

built. It is 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.

Appendix. Characterisation of the interviewed firms by application segment

Drug discovery firms

Company	Year founded	Organisation form (based on actual or planned activities)	Venture Funding	University collab.	Patents or patent applications
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 sub-contractor; Marketing (division of markets 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
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 subcontract-ing to others; Marketing		Formal Informal	No
E	2000	R&D Services	Regional Venture Fund	Formal	No
Food and feed*					
A	1993	Manufacturing; Marketing through sub-contracting to distributors	Public Venture Fund Regional Venture Fund	Formal Informal	Yes
B	1997	Developing in-novations/out-licensing IPRs; Test manu-facturing through sub-contractors	National Venture Fund	Formal	Yes
Miscellaneous					
A instruments (US owner 10%)	1994	Manufacturing through sub-contractors; Marketing by the owner	Public Venture Fund	Informal	Yes
B Enzymes	1999	Developing in-novations/out-licensing IPRs		Formal	Yes
C Bioinformatics	2001	Manufacturing; Marketing; Services	National Venture Fund	Formal	Yes
D Drug delivery	2001	Developing in-novations/out-licensing IPRs; Manufacturing through sub-contracting; Marketing through a partner	National Venture Fund Public Venture Fund	Formal Informal	Yes

*Firm owned by a large firm has been left out.

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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