

Pasi Tulkki, Anu Järvensivu, Anu Lyytinen
Coordinated by Gerd Schienstock

The emergence of Finnish Life Sciences industries

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Authors:

Prof. Dr. Gerd Schienstock is the Scientific Director of the Work Research Centre, University of Tampere. He is the co-ordinator of the Sitra's Research Program on the Finnish Innovation System.

Dr. Pasi Tulkki is a senior researcher in the Work Research Centre, University of Tampere. He also holds a docentship in the Universities of Tampere, Joensuu, and Lapland. Presently he is studying the regional innovation systems in a research project financed by the Academy of Finland.

Anu Järvensivu, M.Soc.Sc., worked as a researcher at the Work Research Centre, University of Tampere. Presently she works in a company specialised in personnel and knowledge management in industries.

Anu Lyytinen, M.Soc.Sc., is a researcher at the Work Research Centre, University of Tampere. She has been involved in the projects focusing on the national innovation systems in Finland and in some European countries.

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FOREWORD

This study was carried out as a part of the Research Programme on the Finnish Innovation System financed by Sitra, the Finnish National Fund for Research and Development. The national innovation system is defined as the system of organisations and actors whose interaction shapes the innovativeness of the national economy and society. The main goal of the research programme was to identify the future challenges of the Finnish innovation system. In a rapidly changing techno-economic environment, the Finnish innovation system cannot be expected to repeat its recent successes without continuous and effective development effort.

The research programme included 12 research projects that represented several scientific disciplines: sociology, economics, innovation research, psychology, jurisprudence, etc. The cross-disciplinary approach was chosen to gain many different, but complementary, perspectives on the structure and functioning of the innovation system. The close cooperation of scholars from different disciplines was aimed at creating an innovative research environment for the programme. A particular emphasis was laid on understanding the micro-level innovation processes and innovation networks. The research projects went beyond the traditional organisation- and institution-oriented studies of innovation systems in order to better understand the drivers and context of modern innovation processes. In the changed environment, innovation policies cannot be effective without a deep understanding of these processes and their environment. The results of the whole research programme were synthesised in the programme's final report *Transformation of the Finnish innovation system: A network approach* (Gerd Schienstock and Timo Hämmäläinen).

Sitra wants to thank all the researchers, policy makers and distinguished foreign experts that contributed to the success of the research programme. The results of the research programme provide plenty of challenges for further research and future innovation policies.

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1 | INTRODUCTION

The industrialised countries are in a process of transition from resource-based towards knowledge-based economies. It has become obvious that in the case of many industrialised countries, modernising their traditional industries is not a sufficient enough means to get them onto a new economic growth path. Instead, a successful transformation strategy of their economy must also include the development of new knowledge and major technological innovations as the basis for establishing new industries. Knowledge and competence are regarded as the most critical resource of firms and economies.

The newly developed, rapidly growing knowledge-intensive industries are to an increasing extent becoming the driving force of economic growth, social development, and employment in the industrialised countries, and the primary source of competitiveness on the world market. However, the development of these knowledge-intensive industries is not very well understood. Explanation is needed for the fact that in some countries, particular industries are growing much faster than in other countries. Obviously, national and regional specialisation is taking place, which can be explained by historical and institutional aspects.

There is another interesting aspect related to the newly developing knowledge-intensive industries. We can see two parallel developments: the increasing importance of the service component of manufacturing, on the one hand, and the increasing industrialisation on the other. Products now incorporate more and more (information) services but also services incorporate more products. As it is often hard to dissociate between products and services, we can easily come to the conclusion that the traditional distinction between the two becomes meaningless.

Finland's competitiveness increasingly depends on the development of knowledge-intensive industries. In order to understand the organisational and institutional factors influencing the process of knowledge creation and knowledge diffusion, a comparative research approach is needed. Here a twofold comparative approach is applied.

The innovation system approach

The diversity of social reality allows for research to adopt an open and unlimited approach. It is obvious that in research into the entities of social reality, it is somewhat useless and even impossible to construct the field of study in advance by theoretical definitions. Definitions and theories can arise only from the reflexive process between theoretical thinking and the collection and analysis of the empirical material. This kind of methodological approach is followed in this study as well.

This study focuses on the organisational and institutional structures in one industrial field of knowledge-intensive economy and on the effects these configurations have in the constellation of actors or agents, their functions, and activities. This study assumes that the actors' work contributes to the structures as much as the structural configurations of the field frame the agents. The relation between the actors and the field can be described as a double bond. This study, however, addresses the structures and organisational solutions in the industrial field of the Finnish Life Sciences industry. The analysis of the empirical material collected on the basis of the concept and theory of the idea-innovation chain (e.g. Hage 1999) proved the most useful.

The theory and concept of the idea-innovation chain assumes the innovation system approach. One approach type has been to look at systems of innovation from a national perspective. This kind of an approach studies innovations at the macro level. Innovations can also be studied at meso and micro levels. The former focuses the study on industrial branches and clusters, for example. The latter limits the research to one company or a small number of companies, or even in a single innovation. In this study, the focus is on the industrial branches or clusters, and it can be defined as a meso-level innovation system approach. (Nilsson et al. 2000.)

The most prominent researchers in developing the line of thought of the innovation system approach are Charles Edquist, Chris Freeman, Bengt-Åke Lundvall, and Richard Nelson. An innovation system consists of the organisations that influence the direction and speed of innovation and knowledge diffusion within the system. What is fundamental to the innovation system approach is the recognition that innovation processes are interactive activities in essence. Generally, firms draw considerably on interactions with other organisations, such as other firms, universities, research institutes, and public authorities.

The literature on the innovation system approach is a first bridge between traditional economic approaches and institutional literature. Specific institutions, such as the financial system, the training system, government support for research, and the legal system, influence the innovative capacity of a sector, partly by affecting those variables that economists identified as determinants of innovation: demand conditions, appropriability conditions, the absorptive capacity to use external knowledge; and the market structure. The innovation system approach

allows, however, to go beyond this market-oriented supply and demand schedule of determinants of innovation. A broader variety of determinants, such as the way of financing innovations and a more complex description of how institutions affect innovation are possible within an innovation system approach.

Along the idea-innovation chain, one can distinguish basic and applied research, experimental development followed by production and quality control, and finally, the commercialisation of the product. The first three elements in the chain are defined by the Frascati Manual (OECD 1994) as follows:

- *basic research* is defined as "experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view";
- *applied research* is defined as "original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective"; and
- *experimental development* is defined as "systematic work, drawing on existing knowledge gained from research and practical experience, that is directed to producing new materials, products and devices, to installing new processes, systems and services or to improving substantially those already produced or installed". R&D expenditures occur mainly at the first three steps of the chain. Patents are in the middle of the chain, sales at the end.

For the purposes of this study, the above definitions are too limited. Their point of view seems to be in the knowledge-intensive activities at universities and research institutes, but not in industrial fields. To have a more comprehensive outlook, it is necessary to anatomise the processes in industry more carefully. Hage and Hollingsworth (2000) have divided the research of the innovation processes into six research arenas: basic research, applied research, research on product development, research on manufacturing processes, research on quality control, and research on the commercialisation and marketing of products. As the matter of fact, each research arena is a functional arena with its own competence demands, modes of action, and specific outputs. In generating innovations, all these six arenas take part in the process. Vice versa this means that if one or some of the arenas are lacking in some industrial branch or in a country, a successful innovative process has to cast around for such an arena in other industrial branches or abroad.

Even though Hage and Hollingsworth discuss idea-innovation networks as some kind of meta-configuration of these arenas, this study uses the idea-innovation chain model. The approach can be argued by examining the situation in the knowledge-intensive industrial fields in Finland. A 'complete' network model can be used in an advanced industrial branch like the Finnish telecommunications industry, for example. All the functional arenas are present in the innovation processes of the sector. The situation is different in the case of Life Sciences

industry, however. Biotechnology is a new emerging technology, which is presently in the phase of composing its knowledge base. The activity in this field mainly consists of basic research and applied research, and the configuration process of the industrial field is still taking its first steps. Even though there are some allusions concerning the future structure, it is very difficult to predict what kind of industrial configuration will benefit the findings, innovations, and ideas of modern biotechnology research done in universities and research laboratories in the future. By using the idea-innovation-chain model, it is possible to place modern biotechnology and Life Sciences activities in an innovative industrial meta-configuration, and to compare the situation and configuration in the Finnish biotechnology with that in some European countries.

The networks of Life Sciences industries

In the 1990s, Finland has managed to make the IT industries the third stake for exports besides the old wood-processing industries and traditional metal industries. In 1970, the share of electronics was only 2 percent of exports; in 1997, it was already 25 percent. One expects Life Sciences industries to be a "fourth pillar" of Finnish exports industries in the future. According to some experts, biotechnology will most probably be the next expanding branch of the Finnish industries.

Three quarters of the Finnish Life Sciences industries consist of pharmaceutical industries with modern biotechnology. This report aims at outlining the situation and position of Finnish modern biotechnology. The study concentrates mainly on the existing innovations and biotechnological applications in industry; what is done, what is going on, and what the expectations of modern biotechnology in industry are.

Additionally, this report focuses on the organisational and social construction of the Finnish Life Sciences industries and modern biotechnology. Are they on their way to construct their own biotech cluster; if yes, why do the actors act in this way? Are they organising themselves into the existing clusters? Is Finnish modern biotechnology organising itself in both its own cluster and the existing industrial clusters, and why? We assume that the form and location of organising the biotech industry/industries has fundamental effects on the future development of the industrial branch. The ongoing "autonomous" organising into close linkages with pharmaceutical industries, for example, can close the gateways to other industrial areas.

Nowadays services play a vital role in advanced industrial economies. From the standpoint of information and knowledge, services are crucial because the service

sector is the major user, originator, and agent in transferring technological and non-technological innovations, playing a major role in creating, gathering, and diffusing organisational, institutional and social knowledge (Hauknes 1996). Along with the rising knowledge intensity of economies and informatisation of work, learning becomes the central element in the surviving of individuals, and firms and networks of innovators become the basis for accumulation of knowledge and creation of innovations.

According to Miles (1995; 1996; 1998), knowledge-intensive business services (KIBS) in particular, figure as high-tech and highly innovative, and they often form an integral part of innovative learning networks. What is characteristic of KIBS is that they rely on professional knowledge and tend to be leading users of IT in support of their activities. They produce services that in themselves are the primary sources of information or knowledge to their users (research, consulting, training, etc.), or they use their knowledge to produce services that are contributions to the customers' own knowledge development and information processing (communication, data processing, etc.). Their main clients are then other businesses (private and public sectors, entrepreneurs).

In this report, KIBS organisations are dealt with as institutional actors in the innovative network of modern-biotechnology-oriented pharmaceutical industry. The network of modern-biotechnology-oriented pharmaceutical industries is still small, compared with that of information and telecommunications industries, for example. On the other hand, because of this, it is easier to identify KIBS organisations in drug production than in any developed and large cluster.

On the threshold of a new biotechnology

Today, every tenth Life Sciences company in Europe is Finnish. The Finnish Life Sciences or biotechnological industry is ranked sixth in the European context. The strength areas of Finland in biotechnology are pharmaceuticals, biomaterials, diagnostics, and industrial enzymes. So far, the Finnish biotechnology is addressed mainly in research; the real growth in research expenditure in 1995–1997 was 16 percent annually (Kuusi 1999). The development of modern biotechnology has not been successful in other industrial branches, however. Although there are some furthering factors, there are also many obstacles and barriers in both society and industry that delay the implementation of modern biotechnology in the Finnish agro-food industry, for instance.

According to Ernst & Young (2000, 5–6), the total number of European biotech companies has increased over the year to 1 351. Much of the recent increase has

been concentrated in Germany, where the number of biotechnology companies has risen by over 150 percent in the past three years. In the number of biotechnology companies, Germany has passed the former leader, the United Kingdom.

The rapid development in Germany is based on the new approach to high-technology policy called The BioRegio Contest. In 1996, the Federal Ministry for Education and Research (BMBF) launched an initiative for the advancement of biotechnology. Unlike former programmes, the new one focused not on established enterprises but on small firms, and particularly on start-ups which were thought to be the most innovative. On the other hand, the new approach recognised the role of regional clusters. The BioRegio Contest meant that the BMBF invited eighteen regions to develop a regional network for advancement of biotechnological industries, particularly start-ups, and to establish a co-ordination agency. Three of the BioRegios were selected as model regions with extra funding. In an evaluation, the size of the BioRegio seems to be a very important factor. The BioRegios should have enough 'critical mass' to create new start-ups and new jobs. (Eichener 2000.)

On the background of the BioRegion policy lies the fact that, in the 1990s, Germany lost its leading position in innovation activities. Today, at the European Patent Office, there are three times more patents registered from the USA than from Germany. There are also four times more new pharmaceutical agents developed in the USA than in Germany. Today, even Japan and the United Kingdom produce more drugs than Germany. Also, in chemical industry, the number of European patents from the USA is twice as big as from Germany. (Schlüter et al. 1998.)

Also, the Dutch government has perceived a lack of innovative companies in the field of biotechnology. The '*Actieplan Life Sciences*' the Ministry of Economic Affairs introduced in 1999 contains the recipe and the financial budget for the preparation of successful biotech networks and innovative start-up firms. The plan is based on the fact that although the Netherlands has a strong and nationally oriented science base and a tradition of close co-operation between the academia and the industry, there are only very few small innovative companies working in the field of biotechnology. (Enzing 2000.)

If information and telecommunications technology can be characterised as a widely familiar/known and established new technology, modern biotechnology is just penetrating common awareness. Therefore, the social use and product applications of the new knowledge and technology are presently in the very first phase of their formation process. Actors from different institutional and business arenas, including consumers and lawmakers, try to find effective ways to act and define acceptable rules and limitations for the appliance of biotechnology in different social, scientific, and industrial fields.

2

MODERN BIOTECHNOLOGY: LINGUISTIC MEANINGS AND ECONOMIC SIGNIFICANCE

Biotechnology is often referred to as a new wave of technology. The OECD, for example, has defined biotechnology as a new developmental and leapfrogging "mega-technology". It is anticipated that, in the future, biotechnology will have the same effect on applications of "lower technologies" as information technology has today (OECD 1988). According to other scholars, biotechnology – especially genetic engineering – is not a new "mega-technology" but only a new form of information technology. Castells (1996, 30), for example, considers genetic engineering as a method which is "focused on decoding, manipulation, and eventual reprogramming of information codes of the living matter".

By the concept 'information technology' Castells usually refers to communication technologies, which are based on the flow of digital information. In the case of modern biotechnology and genetic engineering, Castells uses the concept in a way that refers in a larger sense to any technology that uses digital coding and computers. A third meaning that Castells gives to the concept is innovative work in general. According to Heiskala (2001, 38–39), the problem in Castells' analysis is that it is not linked to all of these three subjects. The problematic nature is manifested in the way he expands them. Castells moves from one subject and meaning to another without making a clear difference between them.

The battle of image: biotechnology or Life Sciences

Because of the rapid development of scientific methods and industrial applications, it is quite difficult to define and delimit the field of biotechnology. Broadly defined, biotechnology is exploitation of living organisms and their parts in the sense of creating products and services (Shan & Hamilton 1991; Shan & Walker 1994). In this sense, biotechnology has existed for thousands of years. We can, however, differentiate qualitative changes in the methods of biotechnology. Begun in the 1940s, the industrial utilisation of new biotechnological methods, such as fermentation and biocatalysis, for example, is called the second-generation biotechnology (Halme 1996, 7). By using the concept of modern biotechnology, one usually refers to the third-generation biotechnology. This new technological phase is based on the achievements of molecular biology, of which the most famous are the modification of the genetic structure of a living organism, and the exploitation of monoclonal antibodies (Kenney 1986; Senker 1998). According to the OECD, biotechnology is an application of natural and engineering sciences in biological processes with the aim of creating products and services (Faulkner & Senker 1995).

A group of leading Finnish biotechnology experts gives the following definition:

"Biotechnology concerns research, modification and application of substances and processes that have been discovered originally in living organisms. We can define biotechnology as technical application of knowledge arising from life sciences." (Lievonen 1999, 7.)

From one point of view, it is common to differentiate between traditional (first- and second-generation) biotechnology, which improves natural processes and modern (third-generation) biotechnology, which modifies natural products. In this framework, modern biotechnology as an industrial practice does have close linkages to genetic engineering, or manipulation, which involves taking genes from their normal location in one organism and either transferring them elsewhere or putting them back into the original organism in different combinations (ABA 1999).

Some scholars have counterpointed that, as a concept, modern biotechnology is much broader than mere genetic engineering. It includes, for example, the non-genetic methods of chemistry that are based on enzymes. A typology illustrating the domains of modern biotechnology can be constructed by reviewing its scientific base. From the 1970s on, when the breakthrough of modern biotechnology took place, different sciences began to merge under the conceptual umbrella of *Life Sciences* (OECD 1988). Within the concept of Life Sciences, fields of research can be realigned:

Core disciplines:

Biochemical engineering, biochemistry, chemistry, clinical medicine, molecular biology, organic chemistry, pharmacology, toxicology.

Other relevant fields:

Cell biology, cell culture, computer applications, electronic control, fermentation, genetics, haematology, membrane proteins, modelling active sites of enzymes and receptors, neurobiology, new screening methods, physiology, protein biochemistry, protein purification, protein structure, rDNA techniques, small molecular weight compounds, statistics, transgenic animals.

In fact, in the ongoing discourse, the concept of biotechnology has become so "elastic" that there are strong tendencies to give up using the whole word. Some experts characterise the concept as too constricting, and some doubted it of being too diffuse. Especially the representatives of large agro-food business companies suggest the implementation of the concept 'Life Science industries' instead of the concept 'biotechnological industries'. In fact, Ernst & Young have also replaced the concept of biotechnology by the concept of Life Sciences.

As a concept, Life Sciences' industries (or industries of Life Sciences) may attach the technological branch more to natural sciences, and thereby, to basic research and universities. In any case, some Finnish experts – mainly the representatives of small discovery companies – prefer the concept 'biotechnology' to the concept 'Life Science industries'. In these cases, the use of '*biotechnology*' is excusable, especially because of the stock exchange. Investors are casting around for new industrial frontiers and technological twilight zones, and it is easier for a company to be a participant of capital flows if it can introduce itself as a company of a brandnew technology. The existence of Nasdaq Biotechnology is a strong argument for using the concept 'biotechnology' in the future as well. From this point of view, a representative of one of the Finnish modern biotechnology microcompanies characterised biotechnology as "a part of the world to which everybody now wants to belong".

Constructing a biotechnology cluster

In Finland up to now, clustering of biotechnology has taken place mainly within existing industries, such as the agro-food industry, pharmaceutical industry, and wood processing and chemical pulp industry. However, there are ambitions to build up an independent national biotechnology cluster in Finland. One sign of

this aim is the founding of the Finnish Bioindustries (FIB) organisation. Currently, this association has 60 member companies from the chemical, food, pharmaceutical, and plant protection industries. Most of them are microenterprises located in the biotechnology research centres. Ernst & Young call these kinds of companies '*Entrepreneurial Life Science Companies*'. These ELISCOs use modern biological techniques to develop products or services to serve the needs of human health care or animal health, of agricultural productivity, of food processing, and of renewable resources in environmental affairs. The difference between the ELISCOs and the large multinational chemical, agrochemical, or pharmaceutical companies lies in the term 'entrepreneurial'. Another difference lies in the size: ELISCOs are small and medium-sized enterprises. The Finnish discussion has used the concept of '*discovery company*' to characterise the small innovative companies. From one point of view, one can say that the FIB is an organisation that clears social space and positions for newcomers – ELISCOs or discovery companies – in different industrial fields.

According to experts in biotechnology, the FIB is not a blanket organisation; it is estimated that there are 120 to 140 companies operating in the field of modern biotechnology in Finland (Ahola & Kuisma 1998, 7–10). Half of the FIB member companies work in the pharmaceutical or diagnostics industries. According to the FIB, the total number of the companies working in the field of modern biotechnology in agro-food industries is 24.

So far, the importance of modern biotechnology to the Finnish economy is still limited. In 1998, the turnover of the related industries was estimated to be EURm 1 249, which is only 1.1 percent of the total GNP. The employment rate of the Finnish modern biotechnological industry is also marginal. It employs 5 610 people, which is 1.3 percent of the employment in the entire industry, and 0.3 percent of total employment. About 4 000 people employed in the sector are working in the pharmaceutical industry, which is more than 70% of the workforce in this sector. Biotechnology-related employment in process industries, including agro-food industries and enzyme production industries, amounts to 1 400 people. And about one hundred people are working in knowledge-intensive business services (see e.g. Miles et al. 1995) in the field of biotechnology.

Up to now, modern biotechnology has had no significance in the Finnish exports statistics. In 1997, the value of exports of high-tech pharmaceuticals was only EURm 23.5, and the value of exports of high-tech chemicals was EURm 52.2. The combined value of exports of both high-tech industries was only 1.3% of the total high-tech exports in Finland. Exports of electronics and telecommunications, on the other hand, the strongest high-tech sector in Finland, had a value of EURm 3.800.

The distribution of venture capital investments represents another good indicator in addressing the importance of a particular industry. In Finland, the total value of venture capital investments in 1997 was EURm 984, of which two thirds were investments from the private sector. The venture capital investments in biotechnology were EURm 4.2, which is only 0.4% of total venture capital

investments in Finland. However, the investments in biotechnology are rapidly increasing. Last year, Sitra's investments in the sector alone were EURm 4.3, and the sum is increasing. Also, the private venture capital has activated, and we can estimate that the total venture capital investments have doubled in the last three years.

In any case, these figures show that a blanket biotechnology cluster is not looming in Finland in the near future. Kreiner and Schoulz have described this "pre-clusterical" situation of the biotechnological industries as follows:

"We refer to biotech as a field. It should be realised that it is a new and emergent field. It is neither clearly demarcated nor properly institutionalised. It includes a range of actors and companies from a variety of scientific disciplines, from different kinds of universities and research institutions, from different economic sectors [...], etc. In a loose sense, we may talk about a biotech community, since across all differences, all the competing classifications being applied and used, they identify themselves in certain situations and contexts as working in biotech." (Kreiner & Schoulz 1993.)

Whether biotechnology will ever become an industrial cluster of its own in Finland is controversial. So far, modern biotechnology is *de facto* a new method used by various industries in research, development and production, and in many different industrial clusters. Also, according to experts in Finnish technology research, modern biotechnology seems to be more a new technological method or paradigm than an independent industrial branch. As a new technological paradigm or method, it is the basis on which new technological applications develop. This basis, which is composed of research on natural sciences and the applications of the highest technology, can very well be called the arena for the knowledge of the Life Sciences (or the knowledge domain of biotechnology). New technological applications arisen from this arena or domain are then used in 'traditional clusters' or in industrial branches. In this respect, it is somehow comparable to information and telecommunications technologies. The complex nature of modern biotechnology makes it difficult to assess its economic impacts (Ahola & Kuisma 1998). Nevertheless, it is possible to identify the focus domains of modern biotechnology.

In Finland, modern biotechnology is also mainly applied in the pharmaceutical industry, in biomedicine, and in bioremediation, as in most European countries (TEKES 1998, 95). Exploitation of modern biotechnology in the agro-food industry and in the forest and chemical pulp industry is just taking off. Research and development work with biocatalysts and enzymes seems to produce some promising results (ibid. 95–96). Many of these biocatalysts can be used in the processes of the agro-food and the chemical pulp industries. The waste management industry in Finland is rather underdeveloped, although some applications based on modern biotechnology are currently researched.

For a long time, the scientific debate on the development of new technologies and new industries based upon them has been dominated by the controversy

between the 'knowledge or technology-push approach' and the 'market-pull approach'. Nowadays, there is widespread agreement that both these factors, newly created knowledge and the market, are important for the development of new technologies and industries. There is also, however, a third factor which must be mentioned here: the closeness of the existing knowledge stock within firms to the newly emerging knowledge. (Nelson & Winter 1982; Lovio 1993; Malerba 2000.)

Concerning knowledge or the technology aspect, not only the amount and the quality of research play an important role in Life Science industries but also the co-operation of knowledge producers (mainly universities) with industries is decisive, since successful innovation processes depend upon upon an inclusive and rapid knowledge flow between these two parts of the idea-innovation chain. Furthermore, companies need to have the absorptive capacity to be able to use the new knowledge produced at the university. Their knowledge stock must be compatible with the newly produced knowledge, as learning in companies is cumulative.

Regarding the market aspect, close co-operation between producers and users is crucially important for firms in order for them to be able to develop products for which the market demand exists. In this respect, small countries with closely networked small and medium-sized firms may even have some advantage; in the long run, however, the development of new technologies that can become the basis for new industries depends upon the access to international markets through global players.

In the following, we will discuss the extent to which the emerging biotechnology sector in Finland can rely on such favourable preconditions.

3 | NEW OUTLOOK IN THE PHARMACEUTICAL INDUSTRY

Changes in the Finnish pharmaceutical industries

In the Finnish industrial policy, biotechnology discourse is mainly associated with the pharmaceutical industry (e.g. Jalkanen 1998). The leading role of the pharmaceutical industry can be explained to some extent by the fact that the workforce in this sector is traditionally highly skilled with many academics having a degree in medicine or technical sciences and working in R&D departments. The fact that private ownership is dominating in this industry while in other biotechnology fields it is not may be seen as an important factor as well. Public opinion is also supportive; because of the careful clinical testing system and the regulations in medicine industries, people accept biotechnological solutions in drugs more easily than in other product branches (Jauho & Niva 1999).

The crisis of the pharmaceutical industry in the beginning of the 1990s may also have contributed to the dominance of medicine in Finnish biotechnology. Many companies in the industry changed their strategies and abandoned their biotechnological research and development activities and departments. As a consequence of this, many highly educated employees in companies' R&D laboratories lost their jobs and began to start their own small R&D firms. The founding of the new centres of expertise also supported the development; in these new centres, there was a proper support structure available for small R&D enterprises.

Today, the new university-affiliated bio-centres – or the centres of biotechnological expertise – have an important role to play in the research and development activities of the pharmaceutical industry. The BioCity centre in Turku, Biocenter in Oulu, and the A. I. Virtanen Institute in Kuopio all work in the field of medical and diagnostical research. They have strong linkages to pharmaceutical

industries, but they have also been accused of excessive diffusion of their limited resources. These centres of expertise take in a lot of small firms, spin-offs either from universities or larger pharmaceutical companies.

The founding of the centres of biotechnological expertise has changed the structure of the Finnish pharmaceutical industry significantly. Previously, there were only a few large national companies with their own research units. Nowadays, a network of small R&D-based firms situated in the university-affiliated biotech centres of expertise has become a key actor in this biotechnology sector. These enterprises can be divided into three different types. Firms belonging to the first type concentrate on research and development activities, the companies of the second type specialise in knowledge-intensive business services, and the companies of the third type can be characterised as technology-support-producing enterprises. Some global pharmaceutical companies also have smaller units in Finnish bio-centres and in Finland. In addition to enterprises, the Centres of Expertise also host university institutes and private research institutes.

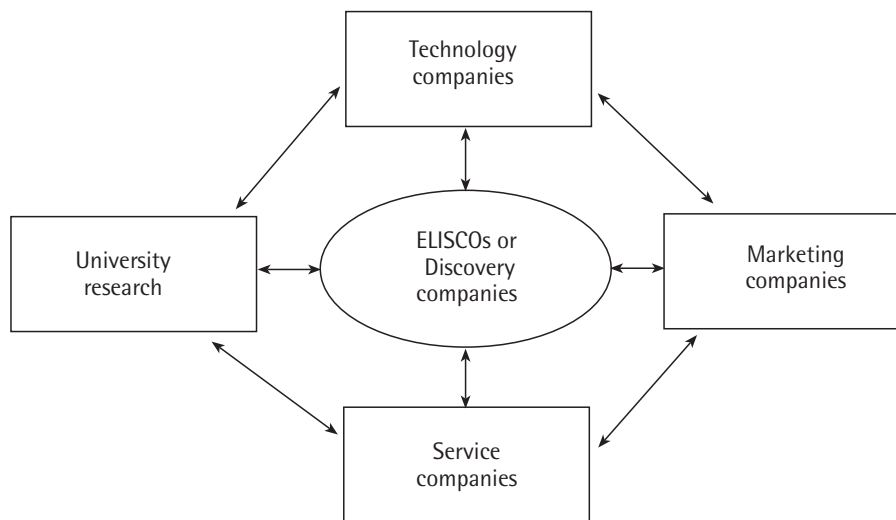


Figure 1. Pharmaceutical idea-innovation network in Finland. (Lammintausta 2000.)

The Turku area in the southwest of Finland has attracted a remarkable number of Finnish pharmaceutical companies. To further develop this industrial agglomeration, the city of Turku has made large investments in modern biotechnology. The reason for the heavy investments made by the city in biotechnology lies on the strong bases of medical industry in the area, but also in the fact that the city did not participate in the rapid development of the Finnish information and telecommunications technology.

Finnish pharmaceutical corporations are small, and that makes it difficult for them to hold their own on the global markets, however. Because of the limited scope of the national pharmaceutical industry, the most R&D-oriented companies in Finland look for co-operation with global corporations. After the economic crisis at the beginning of the 1990s, the Finnish pharmaceutical industry did not only restructure, but also a number of mergers and take-overs took place, and some companies went bankrupt.

The significance of pharmaceutical industries in Finland

An overview of Finnish pharmaceutical industries shows two main tendencies: first, two thirds of the sales is in the hands of eleven companies, and, second, only one of them is a totally Finnish company. The others are either subsidiaries of global companies or ex-Finnish companies bought by global companies. The crisis in the 1990s broke down the closed structure of the Finnish pharmaceutical industries and opened up the markets. In 1999, the total selling value of drugs was EURm 1 048, which is 3.8 percent of the total value added of Finnish industries, and 2.2 percent of the total value of the domestic trade.

	Sale EURm	Share (%)
Orion Group: Orion Pharma	203	19.4
Astra Zeneca Oy	68	6.5
Leira Oy/Schering AG	62	5.9
Suomen MSD Oy	61	5.8
Glaxo Wellcome Oy	56	5.3
Novartis Finland Oy	39	3.7
Pharmacia & Upjohn Oy	47	4.5
Pfizer Oy	34	3.3
Rhône-Poulenc Rorer Oy	27	2.6
Wyeth Lederle Finland	27	2.5
Novo Nordisk Farma Oy	26	2.5
Total	649	61.9

Table 1. The largest producers and marketers in Finland in 1999.

(Source: Lääketeollisuus ry. 2000.)

Modern-biotechnology-oriented pharmaceutical industry

The Orion Group is the leading Finnish company specialising in products for the health-care sector. Orion is now the only Finnish firm that operates across the entire pharmaceutical innovation chain. Earlier, another company, Leiras Oy, operated to an equal extent. But after 1996, when Schering AG acquired Leiras Oy, the basic research and development activities were reassigned to Germany. In 1999, the Orion Group's net sales were EURm 912, of which international operations accounted for EURm 330. Two thirds of the Orion Group's net sales come from the Finnish market, one quarter from the European markets and ten percent from the North American or other markets. The number of personnel in the continued operations was 5 172. In 1999, the Group's research and development expenditure was EURm 68, which is 7.4 percent of the total net sales of the corporation. The Orion Group is composed of four divisions: Orion Pharma, Oriola, Orion Diagnostica, and Noiro. Orion Pharma and Orion Diagnostica concentrate on products based on biotechnological research and development work.

In Finland, there are altogether 69 companies that are members of the association called the Pharma Industry Finland (PIF). Seven of them are also member companies in the Finnish Bioindustries (FIB) association. Ten FIB member companies working in the field of pharmaceuticals do not belong to the PIF. If we add to these ten the FIB members working in diagnostics, there are altogether 32 FIB member companies which operate in the pharmaceutical industry but do not belong to the Pharma Industry Finland. This reveals something about the orientation of the companies. Only a few pharmaceutical companies are interested in biotechnology in Finland. Among the non-interested companies, there are many subsidiaries to global companies which concentrate in marketing the products of their own parent company. Due to this, the latter are not interested in

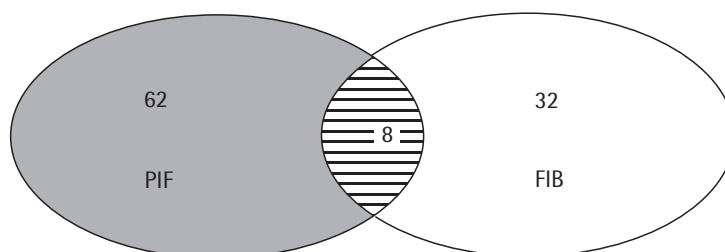


Figure 2. The member companies of the Pharma Industry Finland (PIF) and the Finnish Bioindustries (FIB) that operate in the pharmaceutical industries.

biotechnological research and development done in Finland. On the other hand, there is a large group of biotechnologically oriented small and microenterprises, which do not seem to find any larger benefits in belonging to the association of pharmaceutical industry. These enterprises rather identify themselves as members of their own 'biotechnology cluster'.

Orion Pharma

Orion Pharma is the research-oriented pharmaceuticals division in the core of the Orion Group health-care business operations. It is the largest division and it develops, manufactures, and markets pharmaceuticals. In the Nordic region, Orion Pharma operates with a comprehensive product portfolio of medications for most major human therapy categories, as well as animal health. With its 19% market share, Orion Pharma is the leading pharmaceutical company in Finland. Orion Pharma's subsidiaries in Germany, the UK and Ireland, Switzerland and France are focusing on a narrower selection of prescription drugs for selected therapy areas.

Original proprietary drugs account for an increasing share of Orion Pharma's net sales and boost the growth in international operations, with the new drug for the treatment of Parkinson's disease, *Comtess*, as the leading product. In 1999, its net sales were EURm 438, which is 48 percent of the Group's total net sales. Orion Pharma also accounts for 72 percent of the Group's operating profit and it employs 2 881 people. According to its own announcement, Orion Pharma aims at a global market position with its original drug innovations for chosen therapy areas.

The Orion Group has several drug-manufacturing plants in Finland, and one in Denmark. Today over one half of its total net sales comes from international operations. Orion Pharma's original preparations are marketed on international markets both by its own European subsidiaries and also through the sales networks of international pharmaceutical companies, which provide extensive and efficient channels for the worldwide distribution of Orion's proprietary innovations. In 1999, Orion Pharma co-operated with companies such as Novartis, R.P. Scherer Corporation, Abbott Laboratories, and Roberts Pharmaceutical Corporations.

The research and development expenses of Orion Pharma were EURm 62, which is 15 percent of its net sales of pharmaceutical preparations. A total of 787 people work on pharmaceutical R&D, which is more than a quarter of its personnel. Orion Pharma's research and development activity aims at proprietary drug innovations, with the focus on neurology, cardiac insufficiency, postmenopausal hormone replacement therapy, and asthma. Two of Orion Pharma's proprietary preparations received market authorisation in the United States, and two other products received their first national approvals as a basis for further EU registrations through a mutual recognition procedure.

In its innovation activities, Orion Pharma is very dependent on its environment. In the drug discovering process, the know-how and basic research that reside at universities is the basis on which the whole process is founded. The fundamental

results and ideas also come from universities and research centres. According to the experts at Orion Pharma, research in pharmaceutical companies can be characterised as applied research and development. Innovation processes advance in a network in which the service enterprises play an important role. From service companies Orion Pharma purchases toxicological analyses, pre-clinical and clinical studies, for instance. The innovation network of the company is not limited only to Finland. For example, in the area of toxicology, the companies at the required GLP level can be found in Great Britain and in the USA. The company also buys marketing from the specialised enterprises. The licenced partner companies play an important role in the network in the countries where Orion does not have marketing channels.

Orion Pharma co-operates with the pharmaceutical discovery companies working in the biotechnology centres in Turku and Kuopio. In Turku, its main partners are Hormos Medical Ltd and Juventia Pharma Ltd, and in Kuopio, Fincovary Ltd. The company co-operates with all the faculties of medicine and research centres in Finnish universities, most actively with the Universities of Helsinki and Kuopio. Orion Pharma also has linkages to the Institute of Biotechnology in Helsinki. It co-operates only to a minor extent with the University of Turku, and is developing its co-operation with the Universities of Tampere and Oulu. Orion Pharma has linkages to VTT Biotechnology, although the target areas of their activities do not overlap broadly.

Orion Diagnostica

The Orion Group has another division that works in the field of biotechnology, namely Orion Diagnostica. A great number of its products are based on the third-generation biotechnology. Orion Diagnostica is the smallest division in the Orion Group and its position is not so stable as that of Orion Pharma. While Orion Pharma has increased its net sales by one fifth from 1995 to 1999, the net sales of Orion Diagnostica have decreased by nearly 15 percent.

In 1999, the sales of this division totalled EURm 30, of which as much as 80 percent comes from international operations. Orion Diagnostica has its own marketing subsidiaries in all the Nordic countries. The net sales of these subsidiaries have increased and their profitability has improved owing to the rapid growth in the QuikRead CRP sales. Besides the Nordic countries, the major markets of the division are located in Western Europe, in the USA and in Japan. In 1999, the Chinese market showed the steadiest growth. In the same year, Orion Diagnostica employed 326 people.

Orion Diagnostica specialises in easy-to-use, reliable diagnostic tests and test systems. With its unique analyte discovery programme and comprehensive mastery of analyte technology, Orion Diagnostica aims to better its position in the selected areas of the global point-of-care (POC) market. The POC testing is one of the most rapidly growing areas in the *in-vitro* diagnostics market, as newer and simpler

techniques become available. For the patient, POC applications mean a better and quicker service. Overall health care costs can also be reduced through POC testing. Orion Diagnostica operates on a changing market with diagnostic applications for infectious diseases, C-reactive protein, hormones and bone markers as well as for hygiene testing. The main customer groups of the division are clinical laboratories at hospitals, health care centres and private practitioners.

Orion Diagnostica's co-operation and networking profile in the arenas of basic and applied research and in R&D activities differs from that of Orion Pharma. According to the representatives of the company, the most interesting centre of expertise is the one in Oulu. Although Orion Diagnostica co-operates with all biotechnology centres, the agenda and work of Oulu biotechnology centre fit best into the company's research and development practises. The company is interested in the small enterprises working in biotechnology centres, and it also has a unit in Oulu for monitoring these enterprises.

BioTie Therapies Ltd

In the 1990s, as a consequence of founding university-affiliated biotechnology centres, the most remarkable phenomenon in the Finnish pharmaceutical industry has been the mushrooming of small discovery companies or ELISCOs. Sitra and Tekes have been in the key financier role in promoting the new pharmaceutical entrepreneurship. These new drug discovery enterprises are usually located in the biotechnology centres. In the year 2000, BioTie Therapies was the first of them to go public. BioTie's mission is to convert high-impact scientific discoveries to pharmaceutical products. BioTie develops novel and patented biopharmaceutical drugs for global markets with unmet medical needs. BioTie's focus lies on inflammation, blood coagulation, thrombosis, and cancer.

Due to its nature as a discovery company in the field of pharmaceuticals, BioTie has until now produced hardly any profit and the cash flow of the company has been negative (EURm 6.8 in 2000). Generating a medical innovation is a long and very expensive process; pharmaceutical companies used to spend EURm 500 and 15 years to create a new drug. The mission of BioTie and the other small discovery companies is to work in the arenas of generating medical innovations, in the fields of basic and applied research, and in the research and development of new drugs. The idea of these companies is to sell the developed medicine preforms to large companies, which then develop it for the markets. The production concept of the discovery companies can in the near future be re-estimated; by combining IT- and genome-based technologies, some companies in the USA have produced new technological applications which may develop more effective medications in less time and for half the price. It is anticipated that these new technological solutions can shorten the development time of a new medicine to five years. This can mean less fruitful breeding ground for small medicine discovery companies in the future.

BioTie Therapies can be described as a spin-off company of a university. Its CEO is an ex-professor and there are more than 50 people working at the company. The personnel are very highly educated. Almost everyone holds an academic degree, and more than one fifth have obtained a PhD or equivalent. Today, Sitra owns 40 percent and private, institutional investors about 45 percent of the company's shares.

The network of BioTie is located in the academic world in Finland and abroad, on the one hand, and in the world of global pharmaceutical companies on the other. Its main partner in the academic world is naturally the University of Turku and its Faculty of Medicine, but the company co-operates with universities on quite a large scale. The company aims to conclude the licencing agreements with leading international pharmaceutical companies only when the product or the concept has been proved effective in its purpose of use (proof of concept). However, BioTie has concluded a production and development agreement with Boehringer-Ingelheim.

Hormos Medical Ltd

Hormos Medical Ltd is a biotechnology-oriented pharmaceutical company founded in 1997. It is engaged in discovery and development of compounds used in hormonal therapies. The business strategy of the company encompasses the development of drugs from discovery to clinical trials to licensing the drugs to global partners who carry out further development and marketing. Presently, the company is enlarging its operations into the research and development of functional food. Hormos Medical Ltd has two units that are located in biotechnology centres in Turku and Oulu. The company is a private enterprise with considerable funding by Sitra, and it has not yet gone public. Currently, it employs 51 people.

The CEO of the company is the chairman of the Medical Cluster, which is a community consisting of Finnish pharmaceutical companies, research and service units, and university researchers. The biotechnology centres and the most important financiers are also represented in the community. The Medical Cluster is a co-operation organisation, and it was founded in 1998. There are altogether 50 member organisations in the community. The Medical Cluster makes initiatives and attracts development projects which promote co-operation between companies, universities and hospitals, and the creation of new medical products and medical business activities.

According to its own definition, Hormos Medical Ltd is a virtual-type company, whose know-how is related to the synthesis and screening of novel molecules. It is closely connected to a university research network and collaborates with numerous academic research and development groups and contract research organisations. Its most important co-operation network is the network of academic research groups and enterprises in the BioCity technology centre in Turku. The company

also has close linkages to Medipolis Centre in Oulu and to A. I. Virtanen Institute in Kuopio.

From the viewpoint of corporate strategy, there is a certain kind of lack of globally marketing companies in Finland. Schering, which operates in Finland, is indeed a global company, but its product range is limited to a very specific product segment. The Orion Group has an important role on the Nordic market, where Hormos Medical Ltd co-operates with it. The companies also co-operate in R&D business. But on global markets, Hormos Medical Ltd seeks partners among the large pharmaceutical companies in Japan, in the USA and in Western Europe.

Expert services in drug production: their description and focus

In the pharmaceutical industry, the following can be classified as knowledge-intensive business services:

- pre-clinical research
- clinical research
- legal services and patenting
- business development and marketing services
- financial services

All these service functions are fairly accurately included in the industries that research literature considers as KIBS industries (cf. Miles 1995; Haukness 1996) and that, according to Kasanko and Tiilikka (1998), belong to the core industries on the basis of their knowledge intensiveness.

Pre-clinical research is conducted in various private and public laboratories. Some of the laboratories are separate small firms, some belong to large drug companies, and some are public. Some laboratories are housed by universities and science parks, for example. Pre-clinical services are needed when testing the qualities and effects of a drug preform and also when seeking to meet the requirements set by various authorities. Laboratories do not perform tests on people but may use guinea pigs. Researchers constitute a large share of their employees. Some of them work on basic research either for the laboratory as part of its product development, or for a department of a university. Pre-clinical laboratories' clientele consists of drug production firms and drug discovery firms as well as of food companies. The services rendered range from very standardised single tests to long-term product development worked on together with the client firm. Pre-clinical research services are primarily focused on the client firm's product

innovation.

In Finland, *clinical research* is organised into private or public laboratories, which have close relationships to universities. The reason why laboratories have been founded is that university researchers or departments have not been able to take on the assignments from private firms in addition to their other tasks. The laboratories have close relationships to university hospitals because they need both healthy and sick people to perform their basic task, which is to do empirical studies on the effects of different substances on people. These laboratories also provide certificates for authorities responsible for the pharmaceutical industry. Their clients are mainly drug firms but there are also new clients joining them, namely food companies. Clinical research clearly renders services for the client's product development activity. It is also strictly separated from pre-clinical research, and it seems that these research service types are rendered by different organisations. Therefore, this study addresses clinical and pre-clinical research separately through their own case organisations, although they as functions have many common features.

Legal services and patenting are extremely important to the firms in the pharmaceutical industry. The drug preforms that are being developed must be patented quickly, which is why legal services and patenting are needed even from the beginning of the drug discovery process. On the other hand, legal services are needed in order for the firms to be able to observe the various strict regulations of the field. These services are generally bought from private offices but large drug companies may also have their own legal experts. Law and patent offices often offer their services to a large clientele; they still often have their own experts that are specialised in certain industries. Legal services and patenting can be considered to focus above all on firms' product innovation activity.

Marketing and business development services are especially important to small firms that do not have these functions themselves. In addition, firms dealing with pharmaceuticals are often founded by scientifically or technologically oriented people, who are not interested in running an actual business or who do not possess the needed competence for it. There are various consulting services rendered both privately and publicly. They can be offered to several industries but some kind of specialisation is common. Typical development and consulting services are offered for the client firm's product marketing, personnel training and business operations, and business incubation, for example. Consulting services first focus on activity aiming at the client's organisatory and process innovations, although they can also have effects that direct the firm's product development.

Financial services are of great importance to drug production, since new firms' operations most often depend on external funding, which is provided by both public and private organisations. Risk investors usually offer their services to a large clientele. There are a few foundations specialised in a certain industry, however. We can consider the financial service to focus on the client's organisatory innovations, since the financier usually comes in when the firm is in some kind of

turning point (e.g. founding or expanding the firm). It may take part in the firm administration by being on the board or by offering different kinds of consulting services, such as consultation and contact making. On the other hand, financial services can focus directly on product development as project funding. Therefore, financial services focus, depending on the financier and the client, either on the client's organisatory or product innovations.

Case studies

Pre-clinical research: MCA-Tutkimuslaboratorio Oy

In this study, we chose MCA-Tutkimuslaboratorio to represent a case organisation rendering pre-clinical research services. It is a private laboratory operating in connection with a science park and in intermediate proximity of a university. Its business activity can be described as playing the roles of a knowledge provider, acquirer, combiner, and supplier. The laboratory is primarily a knowledge processor and knowledge carrier between client firms, university research, and authorities.

MCA-Tutkimuslaboratorio gets assignments in which the client working on drug discovery requests for an analysis of the compound it has discovered for further development of the product, on the one hand, and for fulfilling the rules and regulations set by the authorities on the other. The situation often is that client firms do not exactly know which product has to be tested and what kind of certificates they need. Therefore, one of the roles the laboratory plays is to inform the other actors in the pharmaceutical industry on the requirements of the authorities. On the one hand, the authorities need information about the situation in the "field" and about developed analysis methods of drug production to be able to keep the rules and regulations up-to-date. MCA delivers this information to the authorities and other state agencies.

MCA maintains extremely close relationships to the university. Its research and expert group includes people with posts at the university and it is physically located fairly near the university and the Faculty of Medicine, whose equipment it can use. On the other hand, the firm's premises are used by a group of university researchers under the supervision of the firm personnel. Some students complete their practical training period in the firm. MCA's product development is actually closely linked to the research conducted within the university. Correspondingly, knowledge also flows to other directions; that is, from the client to the authorities and to the university as well as from the authorities to the clients and to the university. In certain cases, the knowledge flow is limited by secrecy agreements, whose significance in the pharmaceutical industry is considerable.

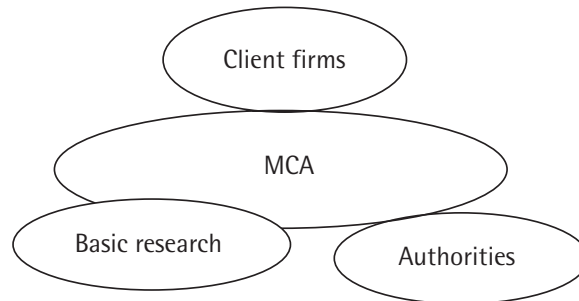


Figure 3. MCA's functional location in the interface of clients, basic research, and the authorities.

MCA-Tutkimuslaboratorio has clients not only in the Finnish pharmaceutical industry but also in foreign firms specialised in drug production and marketing, or in drug discovery. It also has clients in the food industry. The case firm obtains resources, in addition to the university, from other institutions of higher education, polytechnics, and vocational institutions. The firm employs trainees who may even stay in the firm after their practical training is over. If needed, it can rent equipment from the Science Park. The National Technology Agency, Tekes, and the Finnish National Fund for Research and Development, Sitra, belong to MCA's co-operation network in their capacity of a financier of development projects. These projects usually involve client firms as well. MCA has competitors among both foreign and Finnish laboratories and research institutions, and it co-operates with them a little in buying and client orientation. MCA has very few linkages to actors other than those related to biotechnology.

The knowledge of the firm is based on high biotechnological and medical expertise. Its personnel are extremely highly educated. Those acting in MCA's immediate network have a clearly noticeable, shared language, which is based on biotechnology, and more precisely, on its sub-area of medicine. The technological foundation of the network organisations is based on biotechnology. Their other knowledge foundation is also shared, since the central organisations' key persons usually have the same educational background and many have studied in the same faculty. We can say that the network actors are connected to each other by the faith they share in the success of biotechnology and medicine. MCA is strongly identified with its network formed mainly around drug production and research. The organisations of this immediate network have stable, long-term co-operation relationships.

There are, however, co-operation relationships of different levels in the laboratory's network. Its client relationships, for example, include three kinds of relationships looked at from the viewpoint of their trust levels and closeness:

1. Client relationship based on trust and personal acquaintance: MCA has a close relationship to a drug discovery firm. The managing directors have already known each other before the firms were set up, and the firms are co-operating in production and development on a long-term basis. According to the managing director of MCA, relationships this close cannot be maintained with several clients.
2. Client relationship controlled by written agreement: MCA signs secrecy agreements with large drug companies, based on which they then operate. Clientships with competing firms are then entirely possible.
3. Client relationship based on distrust: Some actors in the food industry have the firm perform single tests, "blind tests". Then MCA does not know what the tests are part of. This distrust can partly be explained by the fact that the food firms have been MCA's clients for a considerably shorter period of time than the pharmaceutical firms have. In addition, MCA identifies itself through its numerous linkages with drug production and research, which causes a certain degree of insecurity when working with food firms.

MCA's intermediate network is mostly located in the science park in which the firm operates. As the managing director puts it, inter-organisational relationships are good and working. Organisations can use each other's equipment, for example. They also co-operate somewhat in recruiting. When an organisation needs a new employee, it checks with other organisations if someone's contract is about to end. The organisations also use common recruiting databases. Some organisations have close product development co-operation, and the degree of solidarity in the network is high. For example, within the network, there are unwritten agreements on certain ways to do things.

Co-operation relationships are interpersonal, and therefore, extremely stable on the personal level: even if one of the key persons in the network changed jobs, co-operation with him/her would go on in the new organisation. MCA-Tutkimuslaboratorio's most central co-operation partners have been selected through personal long-term relationships. The same people play often many roles in the network, as knowledge providers through a professorship at the university, on the one hand, and as the laboratory's clients through being a managing director of a company on the other, for example. Several co-operation partners are also members of the same associations related to biotechnology or medicine as MCA is. The significance of personal relationships is also revealed in that the firms consider as problematic the downsizing taken place in the production and development departments of the Finnish drug and food production firms lately. As a firm dismissed some of its employees, it also lost the relationships created over a longer period of time, and co-operation became and remained more difficult for long, since the contact persons were not the same as before.

Clinical research: CRST (Turku)

The case organisation in pre-clinical research is Clinical Research Services, CRST, located in Turku. It is an actor in a network formed by the university, the university hospital, the authorities, and its clients. It can be characterised as the source, facilitator and carrier of information in the interface of these different institutions. In fact, the organisation is a part of the university in the sense that, for students working in the firm, their work constitutes a part of their studies, and that the same people work in the organisation and at the university departments. On the other hand, the organisation is part of hospital operations and it also gets clients through the hospital. Considering its clients, CRST enables a combination of university research and hospital operations in connection with clinical research. The hospital provides concrete resources, such as beds, testing material, and various kind of equipment, whereas the university houses the expertise needed in research. Contacts to the authorities are related to the fact that CRST performs expert tasks for the authorities and legislators. Correspondingly, it also tests substances and provides certificates for its clients to fulfill the official regulations.

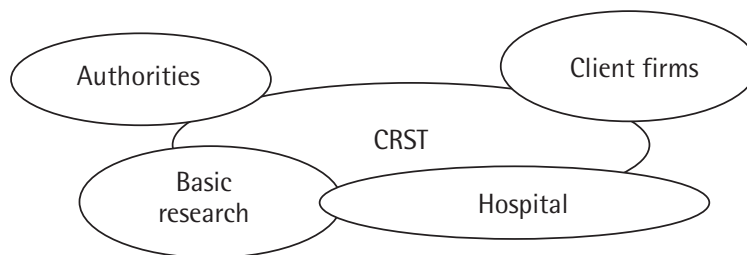


Figure 4. CRST's functional location in drug production in the interface of clients, authorities, university research, and hospital.

CRST's clients are both drug production firms and drug discovery firms, both in Finland and abroad. According to its plans, CRST is going to expand its clientele into food production. It has fairly many competitors, that is, organisations that offer the same kinds of services, but in reality, actual competition is scarce, since clientships are defined on the basis of long-term relationships. Laboratories of different industries co-operate to some extent in outsourcing and client orientation, for example. It is in contact with various financiers when dealing with development projects.

To summarise the structure of CRST's network, we can state that it is geographically large but industrywise narrow, since its operations are restricted to the pharmaceutical industry.

CRST's network has to some extent a shared knowledge foundation. The network actors mostly have a degree in biochemistry or in medicine. To be able to function efficiently in the network, it is necessary to master certain medical terms and terminology. The majority of CRST's personnel have an academic degree, among them some with a doctoral degree.

Both MCA and CRST make a certain difference concerning the food industry. The same manner of speaking can be heard when talking to the managing directors of firms focusing on drug discovery and production. It stresses the underdevelopment of food production and its incapability to exploit the methods and discoveries made in medicine. The interviews often contain comments according to which "the food industry is not doing well".

CRST identifies itself fairly strongly with drug production and research. The field in question has quite few Finnish actors; therefore, personal relationships have been created among the key persons within the country. Several key network actors know each other even from college. According to the managing director of CRST, the operations of the entire network are based on these relationships.

Co-operation is somewhat disturbed by cultural differences between actors: according to the managing director, CRST's operation methods are academically bureaucratic, whereas most of its clients act in a fast-paced private sector. This results in differences concerning modes of operation, which is followed by problems in communication as well.

CRST can be described as a project organisation. It forms a needed expert group around the ongoing projects. It has few but permanent employees, but in addition to that, it has strong relationships to university researchers and to specialists in medicine. These networks it uses to obtain the know-how needed for a project. A definite precondition is to know the important actors and to have the opportunity to hire them for projects, either by buying services from their firms or by exploiting the leave-of-absence system.

Legal services and patenting: Patent Firm

The case organisation rendering services in legal affairs and patenting will here be called Patent Firm. It is a firm specialised in patents that offers its services for firms in different industries. In addition to applying for patents and other kind of industrial property protection, the firm serves its clients by training personnel and providing information on patenting and on key actors related to research and development. The managing director of the Patent Firm considers knowing the actors of a certain area as its specific strength.

Patent Firm's main operations can be characterised as taking place in the interface of clients and the authorities. It informs its clients about regulations related to patents and inventions protected in registers and helps them protect their own inventions. This protection under the patent law is granted by the National Board of Patents and Registration of Finland. Correspondingly, patent

firms provide expert statements on the needs of the "field" for the organisation in question.

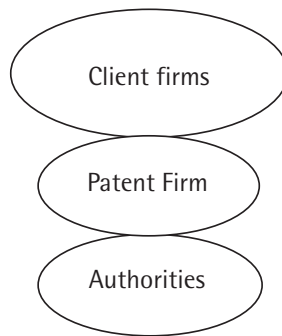


Figure 5. Patent Firm's functional location in the pharmaceutical industry in the interface of clients and the authorities.

In addition to a large clientele and various foreign and domestic authorities related to patents, Patent Firm's network also includes technology transfer organisations, advisory service centres for new business enterprises, translators, law offices, university researchers (usually through their firms) and other firms of the Group. It also co-operates loosely with other firms of the same field; that is, shares and guides clients according to the firm specialisation, and practices acquisitions.

Contrary to the organisation network described earlier, the Patent Firm's network does not focus on any particular industry but consists of significant actors from the patenting point of view. The network is larger than the other networks, but looser at the same time. Its most significant co-operation partners are the other firms of the Group, with whom knowledge is actively exchanged and who are turned to if additional expertise is needed

Although, in principle, Patent Firm offers its services to any industry, its employees are specialised in certain industries. For example, those who make biotechnological inventions constitute a great deal of the firm's clients. The firm has employees who have become highly competent in this area in the course of their education and earlier careers. These single employees thus share a language with their clients. Based on their earlier contacts, they also know people involved in drug discovery. The linkages are not as strong as at MCA and CRST, since they are linked to only a few employees, not to the entire firm or its managing director, for example.

Patent Firm is able to communicate in the language of drug production. But even more important to the firm's overall operations than that is the language of patents. Of the most important co-operation partners of the firm, the other firms

of the Group and the patent authorities speak that language. In addition, the clients at least understand it, and the firm actively seeks to teach its clients to learn more.

Patent Firm's relationships to the Group's other companies are close and they are distinctively trust-based. It also seeks to raise the trust level among its clients. It attempts to achieve a situation in which it could increasingly do business with clients without detailed agreements and in which clients would concentrate their business on one patent firm. In addition, the firm has a "designated" representative and assistant for each client. According to the managing director of Patent Firm, changes in the personnel of its co-operation partners cause problems. When we also take into account, for example, that the representative responsible for biotechnological inventions has earlier been involved in development activities in the pharmaceutical industry and that he/she already knows many clients, we can consider that the operations at some level are based on personal relationships.

At the firm level, relationships to single clients are not as close as to the previously described laboratories. There are different explanations to this. The operations of Patent Firm do not focus on the pharmaceutical industry in particular. Instead, it has numerous clients in different industries. The firm and its network speak numerous "languages" but the language of patents is its "native language". It does not master the language of drug production (or the languages spoken by any of its clients) as well as the case firms described earlier, even if some of its employees can communicate in the language in question.

The firm, however, has closer relationships to partners related to patents. For example, its employees have shared activities with the employees of other firms in the Group, such as training. They also communicate and exchange knowledge actively.

Marketing and business development services: Innomedica Ltd

Innomedica Ltd. practices marketing and business development, acquiring partners as its main service. Therefore, the firm has an extensive network since, according to its business idea, it has to focus on and invest in creating new relationships.

Innomedica's main task locates in its client interface. It seeks to bring mutually benefiting firms together by acting as a mediator until the clients have drawn up agreements. On the other hand, the firm is expanding its operations into bringing together client firms and various investors, who then will also become Innomedica's clients.

At the moment, Innomedica's clientele consists of actors linked to drug production. It is also planning on expanding into the sector exploiting biotechnology. The firm is now actively operating in a few countries and planning on getting new clients of biotechnology firms located abroad. Innomedica's other co-operation

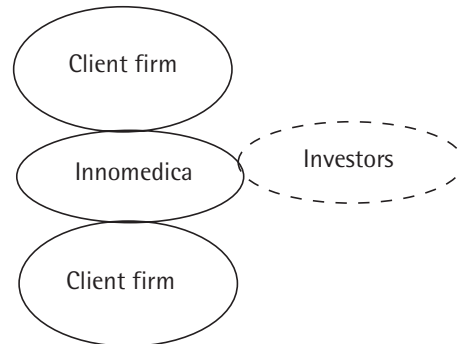


Figure 6. Innomedica's functional locations in drug production in the interface of various client firms and their financiers.

partners are science parks, various financiers, other consultancies and law offices, from which the firm buys services when its own legal resources are not sufficient enough. Of the linkages to universities, we can mention the docentship of the managing director.

Innomedica's operations cannot be considered to base on the same technology as those of its clients or of the network. At the moment, the firm's network is largely constructed around the actors in drug production. The firm has medical know-how and understanding of the need of biotechnology firms, biotechnological know-how, however, is not one of its most important core competences. In addition to employees with education in medicine, it has employees with other kind of education and backgrounds, many of whom with academic degrees.

We can say that Innomedica and its network share a language to some extent. Matters it takes care of with the most important clients concern internationalisation and network creation. Both client firms and investors need to believe in those future benefits that internationalisation and networking bring to business – especially to business related to drug production – in order for the client relationship to work.

The managing director of the firm has contacts to foreign and domestic drug production firms, which he created during his earlier career. Also, the other firm employees have been hired especially because of their personal networks. Personal relationships are the most important resource of the firm, although all of them are not very stable. It is enough that they can be "activated", if needed.

The firm thinks that its closest action network resides in the science park where it is located. This network includes actors that have already known each other through different contacts for a longer period of time. According to the managing director, drug production firms change but people do not.

The firm has varying kinds of relationships to its clients. Naturally, physical distance sets its limits: it keeps in touch with clients operating in the same building daily, whereas Japanese firms, for example, are contacted less often and

by different means. The assignments the firm gets are consultancy agreements; that is, co-operation has been defined as fixed-term.

Innomedica also chooses various service providers on the basis of personal relationships. The needed additional business and legal know-how is bought from "old friends", whose work and its quality can be trusted on the basis of earlier experiences. The firm seeks to limit outsourcing by additional recruiting, however.

At least at the moment, Innomedica identifies itself fairly strongly with drug production and development: the roots of its managing director are in the pharmaceutical industry, and the key network actors can be found in drug development and production. On the other hand, the firm stresses the consultative nature of its activities. In this way, it also identifies itself with business development consultancies.

All of the firm's activities are based on personal networks, central to which seems to be extensiveness, not intensiveness, although some network actors are clearly well known, which is considered something that makes business easier. On the other hand, the firm complains about the fact that favours are so important in its operations, which in the short run, of course, decreases its own spending.

Innomedica places a high value on formal contracts. It has an in-house lawyer, whose job is to draw up various contracts. The nature of its business requires strict secrecy agreements, although in its client relationships it aims at trust. In addition, its business goals are contracts that define co-operation between clients and guarantee the firm a certain share of the future profits.

Financial services: Aboa Venture Management Oy

Financial services are represented by Aboa Venture Management, a company that operates in investment. It is a company that administrates several different capital funds. It operates as a middleman through whom the money of the investors flows to the companies who are believed to yield profit on the investments, on the one hand, and the firms get an alternative for financing their operations on the other.

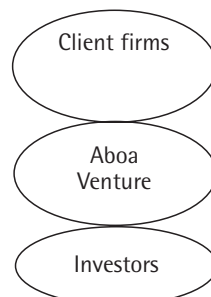


Figure 7. Aboa Venture's functional location in drug production in the interface of client firms and investors.

Aboa Venture has clients in different industries but firms specialised in medicine play an important role in its clientele. Its investors, in turn, consists of insurance companies, pension insurance companies, banks, other investor organisations, and private people.

An investment company considers extensive networks to be its competitive asset. It uses the networks also to market itself. Its network consists of actors in a certain geographical area in particular (e.g. science parks), but it also has linkages to nation-wide actors, such as the Finnish National Fund for Research and Development (Sitra) and the National Technology Agency (Tekes).

Aboa Venture's operations are not based directly on any particular technology. Its know-how rather consists of business economic knowledge, since the ability to evaluate the possibilities of the target firms is central to its activities. The firm's network includes organisations that need the same kind of knowledge, and this knowledge concerning potential growth companies does go around in the network. These actors can be considered to have a shared knowledge foundation and language based on education in economics.

Aboa Venture also communicates with its target firms mainly by using the language of economics. On the other hand, it has to understand to some extent technologies that possibly will be the basis of its business. For example, concerning drug discovery and production, it has to be stated that Aboa Venture does not possess know-how in biotechnology, since its employees lack the education in the field, although the pharmaceutical industry is its major investment sector. It does have know-how on the basis of which it can decide about investments in biotechnology firms as well. This know-how is mainly economic. Finding a common language can be difficult, since many small technology firms lack economic know-how and economic language skills in particular. In these cases, the anchorage of a KIBS organisation is narrow. Generally speaking, we can say that some of Aboa Venture's network actors "speak the same language", but it is difficult to find this kind of shared knowledge foundation or codes in the entire network.

Aboa Venture's network is extensive, but the relationships among its actors seem fairly loose. The firms that it chose to invest in are usually kept in touch with by taking part in board meetings as well by reporting and other kind of control. In some, above all new, small firms, the investor firm takes on a more consultative role; that is, gives advice to the client firm about issues it needs to take into account and practices that have been tried and found good. Its relationships to client firms or firms in which it could invest are fixed-term and last from three to six years.

The most intensive phase in the relationship between Aboa Venture and the company in which it is going to invest is the beginning of the relationship when the target company conducts a company analysis. In this phase, communication is intensive and attempts are made to solve issues raised as well as possible to back up the decision to invest. Both the investor and the target company want as

accurate and truthful a picture as possible of the aims and methods of the other party.

The investors who the company considers as its actual clients are kept in touch with on a loose basis, mainly through reports and client bulletins. The biggest investors take part in making decisions whether to invest; these meetings take place about once a month. According to the managing director of Aboa Venture, its investors have been very faithful. They stay along for a long time and also take part in the new funds of the company.

The interview did not reveal any personal relationships among various network actors. The nature of Aboa Venture's business operations does not necessarily require them. The relationships in Aboa Venture's network can primarily be considered as operational, loose relationships between different organisations, although they can in practice naturally be restored to interaction taking place between certain people.

Industry-specific and non-industry-specific KIBS organisations

The industry-specific and non-industry-specific case organisations' activities in the innovation system of the pharmaceutical industry differ from each other. Whether or not the organisation is industry-specific seems to have no impact on its participation in the client's product or organisatory innovations. Other differences can be found, instead.

Firstly, there are differences in the internal innovation activity of KIBS. The internal development activity of the industry-specific organisations seems fairly systematic. It is often founded on continuous research and academic qualification, in connection with which new analysis methods, for example, are developed to clients' needs. The business development services firm, in turn, seeks to systematically recruit employees who have good networks, keeping the developing of business operations in mind, since the business idea of the firm is based on extensive, functioning networks. Some of the industry-specific KIBS innovations can be considered as radical, since they are used to produce novel practices, new analysis methods, or novel co-operation forms, for example, for the industry. Many innovations are connected to particular, externally funded development projects. In the industry-specific KIBS, both product/service and process/organisatory innovations are made which spring from the needs and development trends of the pharmaceutical industry.

The non-industry-specific KIBS organisations' internal development activity largely corresponds to the general picture of expert service organisations' innovation activity suggested in research literature (e.g. Hauknes 1996; Piirainen et al. 2000). Actual innovation activity has not been arranged in the organisations; innovations are often based on learning on the job and are born in a network-like way in connection with client projects, most of them being incremental in character.

There are also differences in the ways in which the KIBS with various linkages to the industry participate in their client organisations' (and the entire pharmaceutical industry's) innovation activity. The industry-specific KIBS mainly participate directly in their client organisation's development activity, although taking into account the comprehensiveness of innovation activity, we need to remember that these KIBS naturally have indirect effects. Direct participation becomes possible above all through favourable conditions affecting the development of networking. A shared language and knowledge foundation together with strong relationships naturally increase intellectual capital as well as the probability of learning and innovating. Thanks to their close relationships, the industry-specific KIBS have plenty of possibilities to communicate with other actors in the pharmaceutical industry, and thereby, opportunities to exchange knowledge. The probability of knowledge exchange increases, not only by sharing a language but also by having linkages to and being identified with a common industry, which is ideal in raising the motivation to co-operate; interaction is experienced as productive, since interests are largely shared. The ability to combine knowledge also promotes learning by co-operating, which is characteristic of KIBS organisations. It can be assumed that this ability resides in the organisations specialised in the pharmaceutical industry to a great deal due to the high level of education of their personnel.

Co-operating with the industry-specific KIBS organisations affects the client's product, process, and organisational innovations. In addition, the case organisations bring about direct effects on all the following types of innovation: a business management consultancy on organisational process innovations, and laboratories on product and process innovations.

The non-industry-specific KIBS organisations, instead, usually influence their clients' innovation activity directly. There are fewer opportunities to knowledge exchange, since relationships are looser, motivation for shared learning may be weaker due to fewer shared interests, and the ability to combine the knowledge moving about in the pharmaceutical industry is weaker due to a different knowledge and technology foundation in the non-industry-specific KIBS. The knowledge in the non-industry-specific KIBS, instead, may be the significant factor directing the client's product development (patent firm) or functional specialisation (financier firm), but these KIBS rarely provide direct inputs in the development activities. They can still indirectly affect more than one type of innovation, acting as promoters, enablers and carriers of innovations.

The knowledge that an organisation transfers seems to be different depending on the industry specificity. The industry-specific KIBS operates on knowledge internal to an industry. It can be said to deepen this kind of knowledge among the actors of the network. The most essential knowledge that the non-industry-specific KIBS organisations have is not related to the core competence of the pharmaceutical network, or to how drugs are discovered, produced, and marketed. Instead, they seem to have their own core competences, which in this case are patenting and financing. The knowledge that the networks of these firms have is contentwise different from that in the networks of the industry-specific organisations. In addition, the non-industry-specific expert services seem to direct their activities in their network towards drug production firms as if they were diffusers of higher level knowledge untypical to the pharmaceutical industry, whereas the industry-specific KIBS act to provide the special, in-depth knowledge related to medicine. From this follows that the "anchorage", or interface, found in the client organisation for the knowledge transferred by KIBS varies by industry specificity. For the knowledge of the industry-specific KIBS there is a stronger, or larger and deeper, anchorage than for the knowledge of non-industry-specific organisations. A large anchorage here means a situation in which the client firm has comprehensive knowledge (e.g. in several functions or departments) that is related to knowledge brought in by a KIBS organisation; in other words, a large contact area. A deep anchorage here means a situation in which the needed knowledge is in-depth in nature, in other words, advanced and specialised (e.g. expertise in technology, even if just a few key persons had it in the organisation). Its existence leads to the fact that the ability of the client firm to receive and exploit the knowledge provided by an industry-specific KIBS organisation is better than when operating with a non-industry-specific KIBS organisation. Then the probability grows that the client learns and the innovations make progress in the industry-specific KIBS organisations' co-operation relationships.

In summary, we can conclude that the industry-specific knowledge-intensive services seem to be more important to the innovation system of the pharmaceutical industry than the non-industry-specific KIBS, if we look at the situation from a perspective of participating in producing innovations significant (radical) to drug discovery and production. On the other hand, we can state that if we think about larger entities than the pharmaceutical industry and industries applying biotechnology, we can see that the non-industry-specific KIBS play a considerably bigger role in transferring knowledge across the industry boundaries. In the case of these KIBS, the significance of regional innovation systems different in size (on regional innovation system, see in more detail e.g. Braczyk et al. 1998) is also probably greater than in the case of non-industry-specific ones. Geographically, the industry-specific KIBS seem to be actors in larger – even global – systems than the non-industry-specific ones, but only within one industry (pharmaceutical industry/life science). These conclusions should be further tested on more extensive data, however.

	Industry-specific KIBS	Non-industry-specific KIBS
Origin	"originated from a branch" (broken away from other companies and university): one reason for founding developing drug production services	origin does not have direct connection to pharmaceutical industry, various reasons for set-up and various histories
Age	new, five years at the maximum	varies by organisation
Public funding	some public funding available	only little public funding available
Core competence	one central sub-area on core competence expertise in drug production or medicine	no connections to pharmaceutical industry or any single field of science, but reflects firm's basic service (e.g. expertise in patenting process)
Organisation	hybrid: resembles private and public organisations, and on the other hand, service/production organisations ameba-like network: boundaries unclear, largely project-based operations	clear company form and organisation with visible boundaries no clear project dependency
Personnel's knowledge foundation	extensive academic education, post-graduate degrees central	emphasis on learning on the job, no education prepares directly to tasks
Internal innovation activity	related to drug production and its needs development projects product/service, process and organisatory innovations both incremental and radical innovations	above all innovations related to service process created in client work mostly incremental innovations
Participation in the client's innovation activity	participate directly in client's process or organisatory innovation activity	mostly indirect effects/direct development work aiming at client's product, process or organisatory innovation
Knowledge transferred in the network	special expertise in medicine or drug production, which deepens client's knowledge	own special knowledge and directly related knowledge learned from client fairly general level, enlarging client's knowledge
Plans concerning industry specificity	linkage to pharmaceutical industry is not questioned, expansion considered only within industries exploiting biotechnology	clientele discussed, may specialise or plan specialising in certain industries

Table 2. Characteristics of industry-specific and non-industry-specific KIBS organisations.

Shaping of pharmaceutical–industry–specific KIBS organisations

Of the case organisations, MCA (pre-clinical laboratory), CRST (clinical laboratory), and Innomedica (marketing and business development firm) belong to those KIBS organisations that have strong linkages to and are dependent on the pharmaceutical industry. These organisations' knowledge and know-how comes from drug discovery and production. In the case of all these, we can see expansion, either already started or planned, within industries exploiting biotechnology (life sciences). In practice, expansion has been carried out or planned chiefly towards food production. None of the organisations has planned on expanding into other than industries exploiting biotechnology.

There are many different levels of interaction relationships in the industry-specific KIBS organisations. For example, MCA was found to have a trust-based, solid development co-operation relationship, client relationships that were controlled by written agreements, and client relationships that were based on carefully limited knowledge exchange and expressed distrust. Based on these different relationships, we can see a clear connection between the amount and quality of interaction and learned methods of action. The less there has been interaction among the organisations, the less trust there is in the relationships, and the more controlled the interaction is. Careful control, in turn, is usually followed by scarce interaction compared to trust-based relationships. It is difficult to break the circle thus created; it is not always even necessary to break it, since in small organisations very many extremely close interaction relationships cannot even exist due to scarce resources.

A close interaction relationship in the case organisations seems to develop through long-term relationships of the organisations' key persons; they have often known each other for decades. They were first fellow students, later research fellows, and have after that continued co-operation through their own firms. It is also common that the key persons meet each other outside office hours in various association meetings, for example.

When taking into account that the field of Finnish drug production is fairly small and that earlier described close relationships among the key persons are typical, it can be stated that a kind of "closure" is prevailing in the field, which distinguishes members from non-members. In addition, the existence of a shared language and a shared scientific foundation creates a situation in which those who cannot speak the language are left out completely. Naturally, closure is also caused by strict, formal qualification requirements. It is difficult to work in the field, especially in management, without an academic degree, which in practice is mostly a doctoral degree in medicine.

The size, structure, and operation logic of the pharmaceutical industry reveal its degree of interdependency. The division of labour and specialisation in the industry has progressed fairly far, which is due to the amount of special knowledge and the number of costly equipment needed in the branch, and no doubt, to

financial policy favouring small firms. Due to the externalisation taken place in large firms and in universities, on the other hand, both small R&D firms and knowledge-intensive service providers have been set up in the field. This kind of development naturally increases the actors' interdependency. For example, the industry-specific KIBS are very dependent on their few main clients, although many also have clients abroad. In addition, KIBS organisations in the pharmaceutical industry are dependent on public activity, such as the institutions of higher education or financier institutions.

Non-industry-specific KIBS organisations from the viewpoint of drug production

There are two non-industry-specific but still very important KIBS organisations to the industry in question included in the data: the Patent Firm and Aboa Venture. They are not linked to any specific (industrial) branch, but they are able to act in several different fields. Both firms say that their clienteles cover all those needing the services in question, regardless of the industry. In practice, some kind of specialisation can be seen. Regarding both firms, biotech firms – drug firms in particular – constitute a significant clientele. One firm deals with specialisation in practice so that a few experts have special knowledge of the pharmaceutical industry and have even worked in the industry before. The other firm has not even made this big an investment; instead, the needed expertise has been gained through familiarising the employees with the central matters of the pharmaceutical industry.

If we look at how the firms have shaped over time, we can state that one of the firms is already fairly old, whereas the other one was founded at the beginning of the 1990s. Both have had time to establish their operation environments, however. The client relationships of one firm are quite long-term, which is also its aim. On the other hand, the operation pattern of the other case firm causes a situation in which its client relationships last only a few years, since it engages in relationships for a fixed period of time in the first place.

The firms emphasise the importance of knowing the actors of a certain geographical area as one of their competitive assets. In other words, according to the firm representatives, it is important to know the actors within the regional innovation system. Of these, the most important to the case firms are technology transfer organisations, representatives of various authorities, financiers, and other co-operation partners. The firms themselves hardly have any direct linkages to universities; direct linkages are created through firms owned by university researchers.

When analysing the interaction of non-industry-specific KIBS firms with other co-operation partners outside their own firm group, we can see that these firms do not have those extremely close co-operation relationships at all which are

common in industry-specific KIBS. Instead, loose relationships are typical. One of the firms, however, aims at developing closer and more trust-based client relationships.

The non-industry-specific KIBS firms are also fairly independent of the developments taking place in the branch. The drug production organisations are not their only clients, although they are of significance for both case firms at the moment. If needed, it is still possible for the firms with relatively small investments to redirect their business focuses, for example, by targeting services at some other industries. An extensive and loose network is helpful in preserving this possibility. Although these KIBS are not dependent on the actors and the development of the pharmaceutical industry, there is another kind of dependency towards another direction. Organisations acting within drug discovery and production are very dependent on the services that KIBS specialised in patents and financing provide. However, organisations have alternative ways to acquire these KIBS functions. Quite many various financing options and patent services are bought from abroad as well. Some firms also have their own patent experts.

If we think that there prevails a kind of closure in the pharmaceutical industry, we can state that non-industry-specific KIBS organisations are acting outside this closure. They do not belong to the actual "inner circle". Instead, they do have a some kind of recognised position within that circle; that is they are important co-operation partners, and through their chosen focuses, they get a kind of "guest pass" into the pharmaceutical industry. Thus they can to some extent act as knowledge transfer organisations between the industry and the society outside it. It needs to be noted, however, that these KIBS organisations' social capital and knowledge related to the pharmaceutical industry is fairly superficial if compared to the knowledge that actual pharmaceutical-industry-specific organisations have.

Interface-levelling KIBS in the field of drug production

In summary, after examining the networking of knowledge-intensive expert service organisations operating in the drug production sector, we can state that there are two kinds of KIBS organisations in the sector: KIBS that have strong linkages to the industry and KIBS that represent the public good. The former are extremely dependent on the development of the pharmaceutical or biotechnological industry. In practice, they do not have any linkages outside the sector. The latter in turn, safeguarded by their business ideas as well as by their wide and loose network formation, have a possibility to direct their operations and specialise in several industries.

The industry specificity of the knowledge-intensive business service organisations also determines their functions in the innovation system. Considering the industry-specific KIBS, we could talk about a one-industry innovation chain. This industry could be called the biotechnological industry, or to put it simply, the pharmaceutical industry; we should then remember that many so-called pharmaceutical-industry-specific KIBS have linkages to or at least plans to expand into the food branch or into related biotechnology-based industries. These KIBS have very few links to the rest of the innovation system, no direct linkages or effects in particular. The non-industry-specific KIBS organisations again operate in a larger network. Their significance is more general from the viewpoint of the regional innovation systems, for example.

The functions of the knowledge-intensive business services considering the innovation chain are often considered from the point of view of knowledge and its mobility. How new knowledge is created is also central to these processes. Considering the pharmaceutical-industry-specific KIBS organisations, we have already concluded that, from the viewpoint of the innovation system, they operate first and foremost by producing in-depth, industry-specific special knowledge: by creating new knowledge, by putting the already existing knowledge into a more easily understandable form, and by recombining it. The non-industry-specific KIBS organisations operate above all by disseminating their own knowledge and expertise in a larger innovation system in which this knowledge provided by KIBS is rarely available. In other words, there is more prepared surface in their network for the knowledge of industry-specific KIBS than for that of the non-industry-specific KIBS.

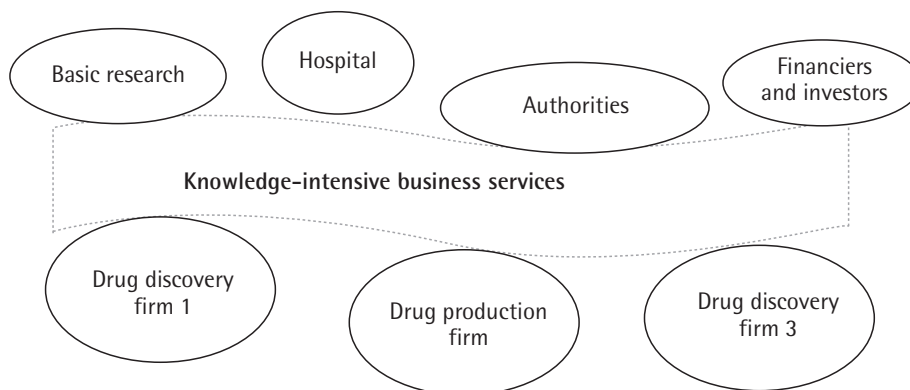


Figure 8. Expert services leveling various organisations/institutions interfaces.

Despite the differences, all the functions of KIBS organisations operating in the pharmaceutical industry can also be described coherently. Then the expert service organisations can above all be called the levellers of interfaces. The finding corroborates the earlier theories in which KIBS have been described as having bridging functions or gap-filling functions (see e.g. Bessant and Rush 1995; Bilderbeek et al. 1998; Miles et al. 1995; and Miles 1996).

The KIBS in the pharmaceutical industry above all level off interfaces that exist among the following actors: drug discovery firms, drug production firms, universities, hospitals, authorities, financiers, and investors. These actors can of course have direct contacts as well but a great deal of the efficient exchange of knowledge among them occurs through expert service organisations. The interfaces have been found very important from the point of view of operations and innovation activities, since the breaks usually result in a weak flow of information and a low level of trust when operating across the interface (e.g. Zucker et al. 1996; Ollus 1990). Therefore, KIBS as intermediating organisations in the interfaces may have an impact in promoting learning and innovations.

The organisation form of some KIBS playing the role of the leveller of interfaces reflects the role of the bridge builder. The organisation of pharmaceutical-industry-specific KIBS in the data can be described as a hybrid (cf. Oliver & Montgomery 2000). In a hybrid organisation, we can distinguish characteristics of a combination of production, service, and research in the same, usually very small organisation. They can be considered as organisations that deliver products or services but invest a lot in research and development at the same time. Likewise, we can find characteristics of both public and private sectors in these hybrids in the drug sector: their operations often get a considerable amount of funding from the public sector, which may benefit their client companies as well. On the other hand, hybrid organisations attempt to yield profit and act according to the conformities of normal business life. Also, the personnel policies and organisation cultures of hybrids can be seen to have characteristics of their "parent" organisation forms. The origin of a hybrid is often linked to both public and private instances and interests.

Legislation and regulations

The control over the pharmaceutical products and medical devices is concentrated under the administration of the National Agency for Medicines. The Agency works under the Ministry of Social Affairs and Health to maintain and promote the safe use of medicines, medical devices, and blood products. The National Agency for Medicines has three departments: the Pharmaceutical and Pharmacological Departments and the Department of General Affairs. Its other units are the

Secretariat for Marketing Authorisations, the Inspectorate, the Drug Information Centre, and the Medical Devices Centre.

The Pharmaceutical Department carries out and administers quality assessment related to applications for marketing authorisation of medicinal products and herbal remedies. It also evaluates pharmaceutical and chemical documentation. The post-marketing quality control of medicines and the research related to quality control activities also belongs to the department's sphere of responsibilities. It contributes to the complementing of the European Pharmacopeia.

The Pharmacological Department assesses the documentation related to applications for marketing authorisation of medicinal products and veterinary medicinal products. It carries out the evaluation of preclinical, toxicological, and clinical documentation information concerning medicinal products, matters concerning new indications. It performs clinical trials and GCP inspections. Also, the safety matters concerning herbal remedies and anthroposophical and homeopathic products belong to this department's sphere of responsibilities. It carries out and administers special marketing licences for non-registered medicinal products. Also, the department monitors laboratories and their biological and microbiological efficacy and the safety of their medicinal products. Its other spheres of responsibility are the GLP inspections of toxicological laboratories, medical and veterinary medical matters concerning mutual recognition procedures, and those facilitating meetings (MRFG and VMRFG). Also, the matters concerning members of the CPMP and CVMP belong to the department's agenda.

The Medical Devices Centre controls medical devices and their market. It also maintains the product control registers and implant registers. Also, the assessment of applications for clinical investigations of medical devices and supervision of marketing of medical devices belong to its sphere of responsibilities. The centre carries out and administers standardisation of medical devices in Finland.

The Secretariat for Marketing Authorisation handles the regulatory affairs concerning marketing authorisations and procedures (MRFG and VMRFG participation). It validates the marketing authorisation applications and co-ordinates the marketing authorisation procedures. The secretariat maintains the electronic database on national and European marketing authorisations. Also, administrative contacts with the EU Member States, EMEA, and the European Commission are on the secretariat's agenda. The Inspectorate of the National Agency for Medicines offers inspection services for pharmaceutical manufacturers, wholesale distributors, and pharmacies.

There is also a voluntary control system in marketing of medical products in Finland. Marketing of medicinal products is controlled by the law, and by the relevant authorities. The pharmaceutical industry also controls voluntarily marketing practices in accordance with a strict code of ethics. The Renewed Code for the Marketing of Medicinal Products came into force 1 Jan 2001. The principles behind this Code are based on legislation relating to medicinal products, consumers and competition and on the International Code of Advertising Practice and the provisions

introduced by the Council Directive 92/28/EEC on the advertising of medicinal products for human use.

All members of Pharma Industry Finland (PIF) have undertaken to comply with the Code for Marketing of Medicinal Products, which is monitored by the Supervisory Commission for the Marketing of Medicinal Products and by two Inspection Boards working under the Commission. Inspection Board I monitors all the marketing of medicinal products to the general public. It handles all magazine and newspaper advertisements of medicinal products four times a year during a two-week period. All radio and television commercials must be inspected in advance.

Inspection Board II monitors marketing activities directed towards health-care personnel. On request, Inspection Board II decides whether or not a product has been marketed contrary to the Code. On its own initiative, the Board may also deal with or issue statements concerning matters related to marketing in general. Both Inspection Boards consist of four permanent members and personal deputies and a secretary.

The Supervisory Commission deals with appeals against decisions taken by the Inspection Boards. If necessary, it deals with and issues statements concerning marketing principles and matters guiding the work of the Inspection Boards. The Supervisory Commission also appoints the members of the Inspection Boards. If a marketing practice is found to contravene the Code, the company concerned may be admonished or requested to discontinue the practice. A request to discontinue a marketing practice shall be made in cases in which a violation is not minor. The practice must then be discontinued immediately.

4 | MODERN BIOTECHNOLOGY IN OTHER INDUSTRIAL BRANCHES

Further explanations concerning the slow development and lack of innovations in the Finnish agro-food industry can be derived from the peculiarities in the development of Finnish society. Finland was an agricultural country until the late 1950s, while in other Nordic countries, the share of farmers fell short of 50% of the whole workforce as early as the beginning of the 20th century. Land reform, carried out after the Civil War in 1918, increased the number of farmers by 130 000 former crofters. At the same time, the size of farms correspondingly dwindled. After World War II, the Karelian immigrants and veterans were settled in 175 000 resettlement plots, under a political programme which again increased the number of farmers and delayed the "natural development" seen in more and earlier industrialised countries (Nyqvist, Ojanen & Tulkki 1991). In the following 25 years, the share of farmers decreased to 8% as Finland had to undertake the structural change in society and agriculture which had taken place 50 years earlier in the other Nordic countries. Nowadays, the number of farms in Finland totals 160 000, and the share of farmers is about 4% of the total workforce.

"The Agro-Food Industrial Complex"

The delayed social and economical transformation in Finland contributed to the high status of farmers in Finland. In Finnish agro-food industry, the farmers, their unions, and their co-operatives have represented the leading group in the techno-economic development. Most of the agro-food industrial mills, creameries, slaughterhouses, and food factories have been owned by the production co-operatives founded by farmers. The share of privately owned companies in the food industry is very limited and they are rather small by size.

The co-operatives have become national monopolies. Valio, a co-operative creamery, for example, was in the possession of 97% of the milk markets by the end of the 1970s. Correspondingly, the co-operative's market share in the meat industry was 53% and in the egg industry about one third (MTK 1976, 55–59). This "monopolar" structure in the Finnish agro-food industry, which prevented hard competition, has not been a supportive environment for any kind of innovative activities. Also, the fact that the industry was heavily subsidised became a hindrance for technological progress.

Before the Finnish EU membership and the opening of the markets in the 1990s, the structure of the Finnish agro-food industry can be described by the term "agro-food industrial complex" (Granberg 1979, 139–155). The "agro-food industrial complex" is an economical system consisting of the industries providing agriculture with material and technical equipment, the industries taking care of the agro-food raw material production and the industries taking care of the processing and delivery of the products. In this tightly coupled structure, the state and its finance, research, and educational organisations are entwined with farmers' organisations and co-operatives. Also, privately owned companies had to adapt themselves to the structure and strategies of the agro-food industrial complex. The fact that the whole education system for the agricultural sector was subordinated to the Ministry of Agriculture until the end of the 1960s is a further indicator of the closeness of the industrial and social field¹ (see Bourdieu & Wacquant 1992; Tulkki 1996, 17–20).

The structure of modern biotechnology-oriented agro-food industry

Today, the industrial field of modern-biotechnology-oriented agro-food industry is divided into two sub-fields. In the core of the field are the large institutional companies, such as Valio, Raisio, Danisco-Cultor, and Fazer. They all have a long history and strong traditions as key actors in the former national "agro-food industrial complex". On the one hand, the tradition based on national monopoly is a factor that has delayed the regeneration of these companies. On the other hand, the expansion and impact of the European and global markets has forced them to fast regeneration. Research and development activities in modern biotechnology

¹ Today all education in Finland is centralised under the governance of the Ministry of Education.

and Life Sciences are seen as a part of the regeneration process in these companies. However, most of the regeneration activities contribute to company's competitiveness in international markets. The former Finnish Cultor merged in 1999 with Danish Danisco, and the other large Finnish companies have concluded agreements of co-operation with global companies or are seeking partners among them.

Global integration can be a factor that can boost the position of research and development based on modern biotechnology in the Finnish agro-food industry. Until now, that kind of research and development has been – maybe not including Cultor's activities – in a very marginal position in the Finnish agro-food industry. On the other hand, expanding linkages to international, especially European markets can also delay the R&D based on modern biotechnology. On the European markets, the position of the consumers is stronger compared to that of Finnish consumers.

New innovative SMEs of modern biotechnology work in more peripheral positions in the field of Finnish agro-food industries. They lean on new university-affiliated biotechnology centres, and they – as well as the biotechnology centres – are forced to struggle for their position in the industrial field. From the point of view of the core actors, the position of these newcomers is not at all self-evident. The closed nature of the Finnish agro-food industrial field/industry has cramped the formation of the new start-ups of modern biotechnology, and guided the potential to the field of pharmaceutical industry. There are also some innovative, small and micro-agro-food companies acting in the field of Life Sciences in Finland, however. Some of them concentrate on research and development of new products; others on the technology needed in modern biotechnology-based R&D.

One can see the most rapid development in modern biotechnology research in the state-owned and state-aided research centres. The Agricultural Research Centre of Finland (MTI) and the Technical Research Centre of Finland (VTT) have both taken significant steps in the research and development of the Life Sciences. Also, the new biotechnology research centres take part in the progress. It seems that in Finland modern biotechnology in the field of the agro-food industry is located in basic research, but it has difficulties progressing along the innovation chain. No doubt, one reason for the difficulties is the existing, increasing market prevention of modern biotechnology in food production. The large agro-food companies are not so interested in changing the existing modern biotechnology knowledge into products.

Valio

The co-operative *Valio*, founded at the beginning of the century by co-operative dairies to export butter, plays an important role in the Finnish agro-food industry. The main issue in Valio laboratory's research in the 1920s was to hinder the process of rancid in butter during the exportation to England. The only Nobel Prize winner in sciences in Finland, A. I. Virtanen invented the so-called AIV salt,

which prolonged the durability of butter and other products. Virtanen also created his other inventions when he was working in the Valio laboratory, of which the AIV forage is most famous (Heikonen 1990, 136–141). Later on, Valio gave up its basic research-oriented R&D activities, as the company, due to its very strong position on the Finnish markets, was not pressured by national competitors to offer innovative products (Tulkki 1996, 277–280). Although the company concentrated its activities on the problems of the quality control of its products, the new trend did not undermine the position of Valio's research and development organisation.

Valio and the entire Finnish agro-food industry have been taken by surprise by the emerging innovation competition and the rapid development of modern biotechnology at the beginning of the 1990s, when the period of closed economy ended and Finland became a member of the EU. Although there were many research and development institutions and organisations in the field, the Finnish agro-food industry was lagging behind. The existence of these institutions, however, eased the adapting to the new circumstance. In the case of Valio, the existence of a strong research centre inside the company proved to be a strengthening factor. In the same time, when other companies in the Finnish agro-food industry have decreased their R&D organisations and staff, Valio acted differently. In 1999, Valio invested EURm 8.7 in its R&D activities. It is 0.7% of the company's net turnover. Valio also employed 120 persons in its R&D Centre. The main focus of Valio's research and development activities lies on the functional dairy products.

Today, Valio's research and development organisation has eight departments which concentrate on process technology, the development of its products, chemistry and microbiology, the quality of the products as well as on the international business on *Lactobacillus GG* (LGG), for example. The department of the research and production of souring agents employs a group concentrating on genetic technology.

During the 1990s, Valio has strongly been developing and marketing products with LGG under the Gefilus brand in Finland. Gefilus products include yoghurts, cultured buttermilks, pasteurised milk, a fermented whey drink, fruit drinks, and capsules as well. Today, products containing LGG are on the market in more than 20 countries around the world, under licence agreements from Valio. According to the representatives of the company, Valio has exploited the monitoring of the competitor companies. In the international business with products containing LGG, Valio has learned from the mistakes and failures Raisio has done in its Benecol business.

Valio is also the world leader in applying ultra-high temperature (UHT) technology to infant foods, which technology the company has developed in close co-operation with paediatricians. Several clinical studies have been carried out in order to improve the composition of its products. For nearly 20 years, Valio has also studied, experimented with, and put into practice lactose hydrolysis in a highly sophisticated and intensive manner. The company has developed tailor-made and patented solutions for the removal of lactose in different milk products.

These solutions include the use of many soluble enzymes; the Valio Hydrolysis Process in which immobilised enzyme technology is used and the Valio Chromatographic Process in which lactose is physically separated from milk.

In the near future, Valio will establish on markets a health-effective dairy product that decreases arterial hypertension as the very first company in Europe. The lactic acid bacteria used in the leaven milk drink, Evolus, chops the milk protein into peptides, which have a positive effect on arterial hypertension. The same kind of peptides can also be found in fish. According to the OECD's database of biotechnological field trials, two projects researching streptococcus bacterium are conducted in the Valio laboratories.

Despite the significant progress in producing new functional food products to markets, Valio as a company with its R&D organisations has frail co-operation with the new university-affiliated biotechnology centres. Traditionally, there have been students writing their theses employed by Valio's R&D organisation, and this practice continues. According to the representatives of Valio, the intellectual focus areas of the company and the Institute of Biotechnology in Helsinki University do not correspond. The institute concentrates on gene technology, but the company is interested in functional food production produced without genetic manipulation. Because of this, there are no linkages between the company and the institute. The same applies to the co-operation with other new technology centres. Valio's main partners in R&D are the Technical Research Centre of Finland (VTT) and the Agricultural Research Centre of Finland (MTT). Valio has also co-operated with universities abroad, with the University of Wageningen in Netherlands and with some universities in the U.S.A, for example.

Valio is engaged in processing and marketing milk, dairy products, and other food products over a total product range of 800 items. Eleven co-operative dairies own Valio Ltd and 17 000 dairy farms produce milk for the company. The Valio Group comprises the parent company Valio Ltd and its subsidiaries in Finland and abroad. The Group employs 4 300 people, a total of 3 800 of whom work for the parent company. The shareholder dairies co-operating with the Group employ about 370 people on average.

Valio Ltd's net sales stood at EUR 1.2 billion in 1998. The whole Valio Group net sales in 1999 amounted to EUR 1.25 billion, of which exports and foreign subsidiaries made up one third. The Group's most noteworthy subsidiaries are Valio Sverige AB in Sweden and Finlandia Cheese Inc. in the USA, among others. Fresh dairy products account for 38% of the Group's net sales, cheese for 32%, edible fats for 13%, milk- and whey-based powders 7%, ice creams 5%, and others 6%.

Raisio

Perhaps the best known functional food product of the Finnish agro-food industry is the Benecol plant stanol ester. It is an ingredient that lowers serum cholesterol levels. The problem that triggered this innovation was that of finding an application

for the surplus sitosterol of the chemical pulp industry of Kaukas Ltd. Consequently, Raisio Ltd developed the idea of using the surplus sitosterol in margarine and vegetable oil. In the so-called North Karelia project, researchers discovered Benecol's cholesterol-lowering character (Miettinen et al. 1999, 166).

Benecol, an innovation with great economic potential, has demonstrated many of the problems related to the long-term economic isolation of Finnish agro-food industries, however. Raisio Ltd had great problems in getting access to the US market, as it lacked the knowledge of the rules and procedures regulating the functionalistic food market in the country. Due to the lack of expertise, its competitors could bypass its R&D work on Benecol and develop their own similar products. In 2000, Raisio got into such economical difficulties that it was forced to cut down the R&D and production of Benecol.

Finnish farmers established the Raisio Group in 1939. Its first production unit was a flourmill, but over the years, the company has expanded into many other areas of agricultural product processing, and it can claim to be ahead in this field of knowledge. The Raisio Group's headquarters are in Raisio, a small town in the southwest of Finland. The Group employs almost 2 900 people, of which about 40% are based outside Finland. Today, Raisio has production units at over 40 locations in 17 countries. In 1999, the Group's total turnover was EURm 763 and its domestic turnover EURm 389. The parent company, Raisio Group plc, has been listed on Helsinki Stock Exchange since 1989, and international institutional investors and funds own over 50% of its shares.

The Raisio Group invested EURm 16 in research and development, which totals over 2 percent of its turnover in 1999. In the same year, it set up a Technology Development Board whose aim was to unite the Group's entire R&D resources and to divide into development units to cover the foods and chemicals sectors. It also aimed to carry out research and product development across divisional boundaries.

The Raisio Group exports margarine and malt products, wheat flour, pastas, cereal flakes, potato products, cat and dog food, feeds for fur animals, and farm feeds. The Chemical Division is Raisio's most international division, with production plants in 15 countries. It is a specialist supplier to the pulp and paper industry throughout the world. Raisio's exceptionally wide product range includes chemicals and equipment, extending from pulp making to the manufacture, coating, conversion, and recycling of paper.

Kemira Agro

According to the OECD's database of biotechnological field trials, Kemira Agro Ltd has a modern biotechnology project that studies the virus resistance of potatoes. Kemira Oyj is a holding company established by the State of Finland in 1920 with the objective of securing a national supply of fertilisers for Finnish farmers. Today Kemira Agro is Kemira Oyj's largest subsidiary company that accounts for about 40 percent of Kemira's turnover. Kemira Agro is comprised of three customer-

based business units: the largest one is the Agriculture Unit and the two others are the Horticulture and Process Chemicals Units, which will, however, be separated from Kemira Agro as part of its ownership arrangements.

Kemira Agro focuses on compound and nitrogen fertilisers. Its main products are crop and horticultural nutrients and process chemicals. In Finland, the fertiliser products are manufactured at three locations: Uusikaupunki, Siilinjärvi, and Kokkola. Its product range includes the granular compounds NPKs, NKs, PK, calcium ammonium nitrate, sulphate of potash, and horticultural fertilisers. In addition to Finland, Kemira Agro has production facilities in seven European countries and in the United Arab Emirates. The company has also strengthened its position in the Far and Middle East. In 1999, the turnover of Kemira Agro was EURm 1 015 and it employed 2 951 persons on average.

The research and development activities are an important part of Kemira Agro's business. The company has a research centre in Espoo, Finland. The Espoo Research Centre employs 140 people who are specialised in organic and inorganic chemistry, biological control, agricultural sciences, and chemical engineering. The main focus of Kemira Agro's R&D activities lies on new product development, search for solutions to environmental problems, and making more efficient use of applied nutrients. Co-operative research programmes contracted out within Europe and other market areas supplement the development work. The research unit co-operates with universities, research institutes, and advisory organisations throughout the world. In order to fulfil the need of turning science into practice to meet the demands of the domestic market, the Kotkaniemi experimental farm was established in 1961. Kemira Agro's R&D unit has also practical experience of agricultural research and development in the Baltic States, Russia, and the Ukraine. Last year, Kemira Agro spent about 1 percent of its net sales on research. In the future, an important research and development area will be the best practices from the manufacturing process to the use of the product on the farm, because of the demands of the new environmental legislation.

Danisco Finland Oy

After the opening of markets and Finland's EU membership, the Finnish agro-food industry has fallen into the situation of escalating change. One example of the fundamental nature of the changes is the course of events around the *Cultor Ltd.* The corporation employed 7 000 people in Finland. Cultor was both the largest producer of functional ingredients for the international food industry and the leading supplier of feed ingredients in the world. The company was also the leading producer of emulsifiers, functional systems, locust bean gum, fat replacers, butter flavourings, and the second largest producer of pectin in the world. Its product range also includes other textural ingredients, flavourings, enzymes, sweeteners, antioxidants, and other protectants, in the production of which Cultor was among leading suppliers in the world.

The development of the sweetener xylitol is one success story in applying biotechnology in the Finnish agro-food industry and Cultor. The research done in the Faculty of Dental Surgery at the University of Turku addressed the beneficial effects of xylitol to human teeth. Cultor Ltd. placed the xylitol of sugar in many of its products, which led to economical successes. In 1992, the R&D and the production of xylitol got the innovation reward of the Finnish National Fund for Research and Development (Sitra 25 Years, 10–12).

In March 1999, the company accepted the bid of a Danish corporation Danisco. In November 1999, Danisco listed as the first non-Finnish company on the HEX, Helsinki Stock Exchange's Main List of blue-chip companies. At first, Cultor continued to operate as Danisco Cultor in the ingredients sector of the Danisco concern, and then as Danisco Finland Oy. Most products of the new Danisco Finland Oy are produced using natural raw materials, such as vegetable oil, seaweed, citrus fruits, and seed from leguminous plants. The Danisco corporate strategy is to establish production plants close to key raw materials. Danisco is also developing and testing the GMO sugar beet in collaboration with DLF-Trifolium A/S and Monsanto Company.

The case of Cultor shows that even larger Finnish companies in the agro-food industrial sector have difficulties in holding their own on the globalising market. This may be due to the fact that, in biotechnology, huge investments in R&D have to be made to be able to compete globally. Nonetheless, Danisco has cut its R&D activities in Finland, and at least 15–20 percent of its researchers have been made redundant.

Fazer

Fazer is a family business established by Karl Fazer in 1891. Nowadays Fazer is an international group and an important actor in the confectionery and bakery industries and restaurant services, especially in the Nordic countries. The Fazer Group acts mainly in Finland, Sweden, and Estonia, and consists of its own business areas, such as Fazer Bakeries, Amica Restaurants, and Candyking. The Fazer confectionery and Swedish Cloetta Group merged in 2000. This agreement makes Fazer the principal owner of the largest confectionery company in the Nordic countries. Fazer also has a 30 percent minority holding in Fazer Biscuits Ltd.

In 1999, the Fazer Group employed 8 400 people, about 70% of them in Finland. The Group's turnover was EURm 831 and the domestic turnover EURm 515. The net sales of the Fazer's food industry sector (Fazer Bakery, Candyking) were EURm 328 and it employed 3 300 people. As many other companies in the Finnish food industry, Fazer is also interested in developing functional food products and in ensuring the high standard of quality.

The Fazer Group participates in national and international research projects. Its most important research results cover the health effects of rye. In Finland, Fazer concentrates on development activities. There are two experimental bakeries in

Finland, in Lahti and Vaarala. At the moment, Fazer's development activities employ over ten people and the company invests FIM 5–10 million on R&D activities annually. Fazer collaborates with universities and research centres. Its most important partners in co-operation are Universities of Helsinki, Kuopio and Turku, the Helsinki University of Technology, the Technical Research Centre of Finland (VTT) and the Agricultural Research Centre of Finland (MTT).

Fazer does not have a research centre of its own in Finland. Its research activities are acquired outside the company. For instance, the Department of Clinical Nutrition of the University of Kuopio has carried out the research project (1997–1998) "Wholemeal rye bread decreases serum total and LDL cholesterol in Finnish men with moderately elevated serum cholesterol" in co-operation with VTT Biotechnology. The results of the project showed that a substantial use of rye bread decreases the risk of heart and vascular diseases. The rye bread products used in the project were marketed by bakeries Fazer Oululainen and Vaasan Leipomot.

ELISCOs in agro-food sector: two examples of innovative micro firms

In Finnish biotechnology, the majority of ELISCOs work in pharmaceutical industries. There are quite few small innovative enterprises acting in agro-food production. However, the founding of biotechnology centres and centres of biotechnological expertise has promoted building up of this kind of companies. In agro-food industry, these enterprises are spin-offs from universities, and they are often located in regional technology centres. Usually these start-ups are partly owned by the Finnish National Fund for Research and Development (Sitra). Two thirds of the FIB member companies of this kind were founded in 1998 or later.

In Finland, there are – or have been – also units of global agro-food companies, such as Monsanto and Rhône-Poulenc Agro. These units are seeking and keeping up co-operation with Finnish companies, universities, and research centres. They are also monitoring the development of the Life Sciences and biotechnological R&D in Finland, and in some cases, they do R&D of their own. The development in Finland and in Europe has decreased the interest of the global companies in modern biotechnology in agro-food industries. Monsanto Oy, for example, has turned its focus totally into modern biotechnology research and development of Finnish pharmaceutical industries.

UniCrop Ltd is an innovative micro company founded in 1998. This enterprise, specialised in plant biotechnology, is located in the Helsinki Science Park Viikki. The main task in the work of UniCrop is research on the insect and disease resistance of crop. Also, the improvement in seed protein quality is in sight as well as foreign protein production in crop. At the moment, Sitra is holding 17 percent of the shares of the firm. UniCrop has a span directorship system, equal to that in some thriving Silicon Valley companies (e.g. Saxenian 1994); one director is

specialised in modern biotechnology research and the other in economics and management.

UniCrop is a typical spin-off enterprise in the Finnish academic environment. The financing by Sitra and the National Technology Agency (Tekes) have played a crucial role in its funding. At the moment, the company is in a so-called bridging phase; UniCrop Ltd is preparing for the entrance of external investors, which means that it is fattening its patent portfolio. This strategy means increasing the number of staff; today, there are about ten researchers in UniCrop, but the target is a staff of 50–60 researchers.

UniCrop's customers are large agro-food companies abroad. In the European environment, UniCrop is co-operating mainly with Danish companies. In the USA and Australia, its customers are large agro-chemical companies. According to the representatives of the enterprise, there is some co-operation with large Finnish agro-food companies, but not based on of commercial interests. Also, the co-operation among firms in the Helsinki Science Park is occasional and coincidental. The situation can be described as follows: "There is no natural chain among the entrepreneurs in Viikki, and there is no process of clustering".

FoodFiles Ltd. is an enterprise focused on clinical studies of foodstuffs. It also offers consultation in registration services for agro-food industry, literature reviews, and nutrient calculations. Founded in 1998, the firm defines itself as a contract research organisation (CRO). The firm has a turnover of one million Euro, and it has a staff of 13 employees. The firm is located in the Kuopio Technology Centre Teknia.

The business mission of FoodFiles lies in the increased demand for clinical studies in agro-food industries. It offers an answer to the changes in the business environment caused by the increased interest to the production of functional food. In many cases, the functional food products are so close to the field of pharmaceuticals by nature so that clinical research is imperative, perhaps even obligatory. FoodFiles Ltd offers its services to both larger agro-food and pharmaceutical companies as well as to small R&D enterprises. The majority of its customer companies are in Finland, but there are also some in Europe.

Progress in modern biotechnology: research centres

In addition to companies and enterprises, there are also other key actors in the modern biotechnology-oriented industrial field of Finnish agro-food industries. These are the state-owned and state-subsidised research centres. At the moment, one can even estimate that these research centres – not the production-biased

industry – are the front line actors in Finnish biotechnology. We can distinguish two principal types of research centres, the established ones and the newcomers. The established ones are the Agricultural Research Centre of Finland (MTT) and the Institute of Biotechnology Technical Research Centre (VTT). The new university-affiliated biotechnology centres belong to the latter group.

In historical retrospect, the established centres have for a long time been in the core of the industrial field and their relations and linkages to leading companies are broad and strong. So far, the position of the new biotechnology centres is on a more labile base. Lately, the whole agro-food sector in Finland is undergoing major changes, turning into research-based modern biotechnology. One can even anticipate that the radical change in the technological and knowledge base can create preconditions for re-constructing the configuration in the field of the Finnish agro-food industry.

The Agricultural Research Centre of Finland

The Agricultural Research Centre of Finland (MTT) promotes the competitiveness of the food industry, the liveliness of the countryside, and the pleasantness of the environment by producing R&D services. Results of research work are applied in order to lower production costs, improve the quality of foodstuffs, and decrease damages to the environment. MTT's history dates back to the year 1898 when the Institute of Agricultural Economics was founded. MTT was renamed in 1957, and it was moved to its current location in Jokioinen in the southwest of Finland in 1983. Presently, MTT employs approximately 300 researchers and other specialists, a fifth of whom have completed their doctorates. In total, MTT employs over 900 persons.

MTT is a research organisation operating under the authority of the Ministry of Agriculture and Forestry. The functional organisation of MTT includes a Board of Trustees, five field-related research organisations, one regional research unit, and four centralised service units. There are 19 research stations and experimental sites on various locations in different parts of Finland, the main research institute being situated in Jokioinen.

The centre is strongly focused on the research and development of foodstuffs. At the moment, the Agricultural Research Centre of Finland is planning on experimental production of genetically modified cheese and it has started the research of GMO animals. The primary goal of MTT's Food Research is to promote domestic food production and food processing in accordance with the principles of sustainable development. The consumers' wellbeing increases when safe and healthy food products are developed through research. The unit also generates analysing services related to food composition, nutritive value, and safety.

Several Finnish universities and state research organisations co-operate with MTT on scientific research projects. Other important co-operation partners include several foreign universities, research organisations operating in the fields of

agriculture and food industry, and international organisations. Among significant Finnish partners are agricultural advice organisations, businesses of the agricultural and food industries, and educational establishments. MTT's most important co-operation partners are the large Finnish agro-food companies and Finnish farmers. For example, MTT has worked in the research of lactic acid bacteria in the same area as Valio in its R&D on GEFILUS products. In its research and development work, MTT has used gene technology, but Valio has not. In this parallel research, both sides had a possibility to learn from each other. Also, the research and development work on cheese is done in MTT in co-operation with Valio.

Co-operation among MTT and the new biotechnology centres is occasional. According to the representatives of MTT, there is no division of tasks between the centres in their research and focus areas. This situation is perhaps caused by the equivocal position of the new centres in the agro-food industry. MTT's co-operation with universities is on a traditional basis: there are several students working on their theses in MTT's laboratories and there is scientific post-graduate education in the centre. Several academic dissertations have been completed in the departments of MTT. Its main partners are the Universities of Helsinki, Turku, Oulu, and Kuopio. MTT also co-operates with universities abroad. Besides the EU and other European countries, it has partners from the universities and research centres in the United States, Egypt, and China, for example.

A new, streamlined organisation was launched at MTT at the beginning of 1998. The new organisation reduced the number of field-related research units from ten to six. This regrouping did not decrease the volume of MTT's research activities nor did it cut out any of the existing locations. In 1999, MTT's budget amounted to EURm 37. Its activities continued to be financed primarily through the state budget, which accounted for 67% of the total financial income. Finance from joint-venture research projects accounted for 27% of funding, with customer financing providing the remaining 6%.

Biotechnology in the Technical Research Centre of Finland (VTT)

Beer is a product with long traditions in Finland. Lately, malt houses have focused on developing malting barley and on new malting technologies. The latest addition to barley breeding techniques uses genetic engineering. The first genetic barley in the world was created by the research group of the *Technical Research Centre of Finland (VTT)* in 1993 and was used in trials. The Finnish brewing industry has not been interested putting the new technology into use.

The GMO breeding technique is developed at the VTT Biotechnology, which is one of the twelve institutes of the Centre. VTT directs and develops its activities in close interaction with industry, research institutes, universities as well as government authorities responsible for co-ordinating technology policy and R&D financing.

VTT operates in accordance with Finland's technology, industrial, and energy policies, and play an active role in their formulation. In fulfilling its mission, the primary role of VTT's research institutes is to carry out research and development work, technology transfer, and testing. R&D is performed in the form of projects. VTT is a non-profit organisation and prices its commercial activities on the basis of economic principles.

VTT produces new applied technology in co-operation with domestic and foreign partners. The number of its employees is about 3 000 and its turnover about EURm 200. VTT serves over 5 000 domestic and foreign customers annually, and through creating and applying technology, it actively enhances the competitiveness of industry and other business sectors, and thus increases the welfare of society.

VTT Biotechnology was founded in the mid-1960s. The unit uses biotechnology and biological materials in its research and development work to develop innovative processes and products while promoting sustainable development and its industrial customers' competitiveness. Research and development work is carried out in interdisciplinary, joint projects with research partners in industry and at universities. The institute employs a total of 300 people and its turnover of the unit amounts to EURm 20.

VTT Biotechnology has worked in close co-operation with Primalco Ltd and Röhm Enzym Ltd., and Danisco, for instance, and it has stronger linkages to universities of technology than to MTT. As a matter of fact, its co-operation with universities is also quite close, especially with the Technical University of Helsinki, where biotechnological research began as early as the 1950s. The quality of its research is very high. At the beginning of 2000, one research group in the institute was promoted to the top research unit by the Academy of Finland.

Other actors in the field of biotechnology research

Other significant actors in modern agro-food industry's biotechnological R&D are the new Helsinki Science Park in Viikki, which employs about 1 000 researchers, the Kuopio Technology Centre Teknia Ltd., and the Development Company Foodwest in Seinäjoki. These new agro-food biotechnology centres of expertise are part of the new Finnish technology policy. The new biotechnology research centres operate in the core of the regional centres of expertise, which aim to establish larger and tighter linkages between universities and industries. Education, university research, knowledge-based industrial, small agro-food firms, and departments of larger companies are all operating in a close connection to each other in these centres.

The Helsinki Science Park houses the only Faculty of Agriculture and Forestry in Finland and the following other research institutes: the Institute of Biochemistry, the Institute of Microbiology, the Institute for Animal Physiology, the Institute for Environmental Research, the Institute for Pharmacy and the Institute of Biotechnology of the University of Helsinki (Kuusi 1999). The Helsinki Science Park on its way of becoming the most extensive concentration of biosciences in Europe.

Kuopio Technology Centre Teknia Ltd offers premises for enterprises in three buildings: in Tietoteknia, Bioteknia, and Microteknia 1. Bioteknia is specialised in biotechnological expertise. The University of Kuopio is working in the fields of health and environmental sciences, biotechnology, applied zoology, and veterinary medicine. Combined resources in these research areas are used in the agro-food-oriented research, which also has linkages to the structure of the surrounding business community. 'Agro-food biotechnology' in Kuopio takes the form of research on animal, fish, and plant biotechnology and on the nutritional value, health, and safety of foodstuffs. Notable examples of its development work include new berry species, farmed fish, and night milk containing a higher proportion of melatonin than normal. Research on animal biotechnology focuses on the production of transgenic animals as part of dairy product processing and the use of nuclear transfer techniques in animal breeding.

The Development Company Foodwest started in Seinäjoki in 1995. It is owned by 24 agro-food companies and 32 local municipalities and communities, among them the Central Union of Agricultural Producers and Forest Owners (MTK). A couple of years ago, Foodwest was elected a centre of expertise, and today it employs about 15 people. Today, in close connection with the Agricultural Research Centre of Finland, there is also a development company for agricultural production called Agropolis Ltd in Jokioinen, which is owned by local municipalities and other public authorities.

Legislation, regulations, and quality control

The National Food Administration in Finland is subordinate to the Ministry of Trade and Industry. It controls the production, import, serving, and sales of foodstuffs in Finland under the Food Act, the Public Health Act, and various EU directives. These laws and regulations fall within the sphere of the Ministry of Social Affairs and Health. The National Food Administration also carries out management tasks in its field for the Ministry of Agriculture and Forestry. At the practical level, local authorities control food with the assistance of the provincial state offices or regional state authorities.

The National Food Administration operates on the basis of performance targets set by the relevant ministries in order to achieve long-term goals and annual result objectives decided by the Parliament. The National Food Administration's primary customers in directing and developing control are the provincial state offices, local authorities, and the Customs. Its customers also include the relevant ministries, other authorities and organisations that have their say in food control,

food business and food consumption. The National Food Administration's quality objectives are aimed at ensuring good customer service.

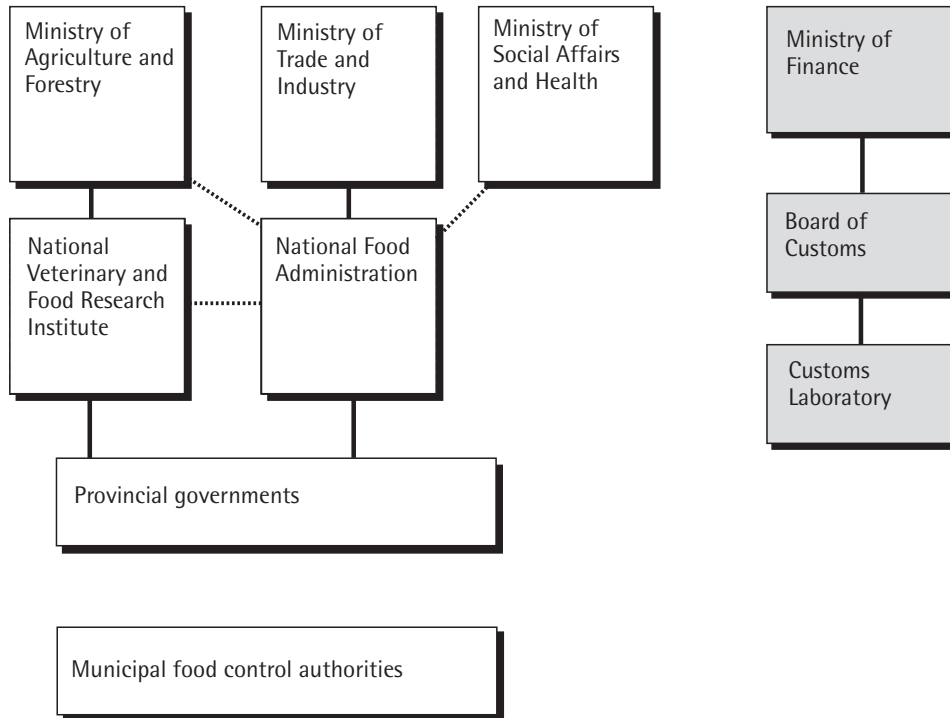


Figure 9. Food control in Finland.

Practical control takes mainly place in municipalities. The production, storage, sales, serving facilities and transport of food are controlled by inspection to ensure the compliance with food regulations. Samples are taken and analysed in municipal and state laboratories. The marketing of substandard products is prevented. Municipal officials direct and advise local businesses and provide information on food matters to citizens. Businesses also conduct in-house control to ensure food quality and compliance with regulations. In-house control is covered by legislation and monitored by authorities. Consumers can improve the quality of foodstuffs by remaining alert and reporting to municipal officials on any deficiencies they observe.

The National Food Administration's quality system

The National Food Administration has had a quality system since 1996. The system is based on ISO 9000 standards together with Finnish quality award criteria. The focus has been on setting priorities, improving efficiency, and expanding the use of computer technology in directing control.

So far, guidelines have been prepared under the SFS-ISO 9004-2 standard to cover such things as publishing and the monitoring of legislation and related information activities. Guidelines are now being drawn up for the handling of information received through the RAPEX system and for the procedures to be taken when the National Food Administration learns about foodstuffs which are not in compliance with regulations, when these are suspected of being on sale in single market trade or in Finland. Quality guidelines for internal information activities are being prepared at the moment.

The National Food Administration is responsible for developing and ensuring the high standard of food control in Finland. However, it does not have direct power over the provincial state offices or over the local authorities, which are largely self-governing under the Finnish law. Instead, it issues recommendations and strives to motivate other authorities to utilise quality systems in their own work. In 1997, a working group was set up to study the flow of information between the provincial state offices, local authorities, and the National Food Administration, and to prepare a model which can be incorporated into quality systems. The working group included representatives from each control level.

Control over gene technology

In 1999, the Finnish Parliament enforced the Gene Technology Act (377/1995) and the Council of State the Gene Technology Statute (821/1995). The Act ordered that the Board for Gene Technology be constituted. In 2000, the Act (490/2000) and the Statute (491/2000) governing the regulations contributing modern biotechnology were reformed and adjusted by their definitions. The amendment did not affect the position and functions of the Board substantially. In addition to being a national authority in Finland, the Board functions as a competent authority towards the European Community. It processes notifications concerning the use and release of genetically modified organisms as defined in the directive 90/219/EEC and its amendments 98/81/EEC and 90/220/EEC, and reacts to them within its authority to make legally binding decisions.

The Board aims to promote the safe and ethically acceptable use of gene technology and to prevent and avert any harm gene technology may inflict on human health, animals, property, or the environment. Its priorities include processing notifications, issuing instructions and regulations, acting as a registration authority, preparing opinions and recommendations, monitoring, restricting, or prohibiting

the use of potentially dangerous organisms, and imposing administrative sanctions to ensure that its provisions are complied with.

The Board consists of a chairman, a vice-chairman and five members, who represent the Ministry of Trade and Industry, the Ministry of Agriculture and Forestry, the Ministry of Social Affairs and Health, and the Ministry of the Environment. Ethical expertise must also be represented on the Board. The Council of State appoints the Board for a five-year period.

Genetically modified foodstuffs and the genetically modified components of the foodstuffs belong to the sphere of influence of the EU's Novel Food Directive (258/97/EY). In their case, the acting authority is the Board of Novel Food. The Board is located at the Ministry of Trade and Industry, and its duty is to evaluate the novel food products aimed to Finnish markets. The Board also evaluates the applications in other countries.

The Advisory Board of Biotechnology

The Advisory Board of Biotechnology is a consultative administrative body appointed by the Council of State. The work of the Advisory Board is based on the Gene Technology Statute (821/1995) and its mandate is for three years. The Advisory Board has 36 members and deputy members representing the research organisations; the key authorities; and the agricultural, industrial, merchant and consumer organisations. Also, the animal and environmental organisations are represented in the Advisory Board.

Among the Advisory Board's main tasks is to boost the co-operation of the state authorities and other actors in the field of biotechnology. It also monitors the international co-operation and research considering the development of the modern biotechnology. One of its important tasks is to promote research and education in biotechnology. The ethical questions concerning biotechnology also belong to the Advisory Board.

The Advisory Board takes part in the preparation of the lawmaking concerning biotechnology. It gives information and announcements to the Parliament and other legislative authorities. The Advisory Board also informs the public about gene technology in seminars and through the media. The Advisory Board also publishes a journal called '*Geenitekniikka tänään*' [Gene Technology Today].

The wood-processing industries

In Finland, the production and exports of chemical pulp, which ultimately is a semi-manufactured product and raw material to paper industry, have been comparatively large. The manufacturing of chemical pulp is a representative example of mass production. For a long time, one problem of the Finnish wood-processing industry has been the low degree of horizontal process integration. This is the result of the Finnish so-called smallholding policy; two thirds of the Finnish forests are nowadays privately owned by farmers or testamentary heirs of ex-farmers, one quarter belongs to the state, and only eight percent to corporations.

Due to this situation, a dichotomy emerged in the production chain of wood-processing industry, which has drawn a clear dividing line between corporations, on the one hand, and farmers on the other. Both interest groups formed their own economic and commercial organisations. In the 1960s, the situation had already developed into a "double-closure" (Murphy 1988) and opposite national cartels. Not surprisingly, the research and development interests of the two key actors also diverged into two different directions. The wood-processing industry was mainly interested in research and development of end products and processes inside the factories. Correspondingly, the farmers' or wood growers', as they are called in this connection, interest focused on the betterment of the productivity of forests. In general, biotechnologically oriented research had a larger indent on wood growers' side, and not so much in the corporations' side. However, wood growers' interest in intensifying forestry's yield by biotechnological applications was not very strong. Because of the fact that Finland is rich in forests, wood growers were mainly interested in improving forestry work.

The productivity of Finnish forests was already defined as an issue of national survival (Kuisma 1993, 104–120; see also Michelsen 1999; Tulkki 1996) very early. Besides the Finnish wood grower organisations, the state has been active in forestry research and development. The great interest of the state in the wood-processing industry is somehow self-evident, as some forty years ago 70% of Finnish exports came from this industry. Due to the polarised situation in the Finnish wood-processing industry, the state has placed itself into a kind of an umbrella position. It established a broader vision in which both the interests of the corporations and of the farmers can be argued.

Actors and the network of Finnish forest industry

Today, there are three globally acting corporations in the Finnish forest industry. The *UPM-Kymmene Group* is the biggest measured by turnover, *Stora Enso* is one of leading forest industry companies in the world; and *Metsä-Serla Oyj* is the sixth largest forest industry and paper-producing company in Europe. The large

forest industry companies, however, seem to be less active in promoting biotechnology innovations, while companies in the chemical pulp industries, being part of the forest cluster, seem to be much more engaged in research in modern biotechnology.

Developed by the Technical Research Centre of Finland at its biotechnology laboratory, the most famous biotechnological innovation in the chemical pulp industry is an enzyme-aided process for bleaching cellulose pulp (Miettinen et al. 1999, 61–88). In this process, hemicellulases are used in order to avoid using chlorine chemicals. The first pulp mill designed for complete chlorine-free bleaching was built at Oy Metsä-Rauma Ab and started in 1996. Ahlström is the leading company in Finland in developing new processes and machinery for pulp and paper manufactory, in which the environmental aspect is considered.

The structure of the biotechnology innovation network in forest industries differs significantly from the one in pharmaceutical industries. There are different research organisations functioning in the forefront and in the end of the production chain. The chemical pulp and paper companies and the Central Laboratory KCL co-operate in research and development of the enzymes with companies like Raisio Chemicals, Primalco, and Genencor International. The latter two co-operate with VTT Biotechnology, which has close linkages to university research. In the forefront of the production chain, there are actors working on improvements in productivity of forests, such as Forest Centres and the Finnish Forest Research Institute METLA.

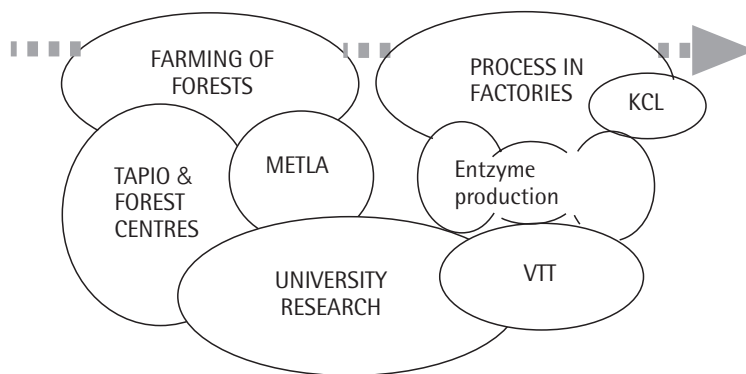


Figure 10. The biotechnology network in Finnish forest industries.

Biotechnology research in the forest sector

Established in 1917, the Finnish Forest Research Institute (METLA) is an independent research organisation subordinated to the Ministry of Agriculture and Forestry. This central forest research organisation has a staff of 700 people, of whom 200

are research officers in the research centres located in Helsinki and Vantaa. METLA also has eight research units in different parts of the country. METLA has strong traditions in research and development activities based on traditional biotechnology. Applications of modern biotechnology have often been delayed, mainly because of the problematic proprietorship of Finnish forests. Wood production based on applications of modern biotechnology would be easier to realise in a large and market-oriented forest industry than under the conditions of disintegrated forest smallholding. Despite these difficulties, six research projects based on modern biotechnology and forest genetics are currently conducted at METLA.

Concerning corporations, the most interesting institutional actor has been the above-mentioned Central Laboratory KCL, which concentrates on the quality control of the end products of chemical pulp and paper industry mills. But lately the interest of the laboratory has grown from mere quality control to larger R&D activities, including also research on biotechnology. The state research organisation, the Technical Research Centre of Finland (VTT) with its biotechnological laboratory is another important actor that has close linkages to corporations. Although most of the biotechnological projects of METLA, VTT, and other institutional actors are financed by the Wood Wisdom Programme, modern biotechnology is in a marginal role in the whole programme entity.

The radical changes at the beginning of 1990s broke the customary notion of the juxtaposition of wood-processing corporations and wood grower organisations. In the new atmosphere, the wood-processing industries were considered as an uninterrupted production chain from forestry to consumption. According to the Technology Development Centre of Finland, the greatest future challenge for the wood-processing industry is "to integrate forest economy and forest research to be a constant part of the research of products of wood-processing industries. This means comprehension and governance of the linkages between the wood raw material quality and the end product quality" (TEKES 1998, 115–116). Research in the Bio and Food Technology Unit of the Technical Research Centre of Finland goes in this direction; it applies biotechnology in the wood-processing industry in several research and development projects. The research on wood material, for example, aims at increasing biological stability and hindering the raw material from dyeing.

5 | POLICIES PROMOTING BIOTECHNOLOGICAL INDUSTRIES

At least in Europe, it is widely believed, especially in modern biotechnology, that a flexible innovation network plays significant role in generating new knowledge and innovations and in exploiting them for commercial purposes. In technology policy programmes, the focus had been in regional closeness, because it is also believed that intensive social exchange relations are necessary in generating innovations (e.g. Audretsch & Stephan 1996). This theoretical assumption is used in many countries' technology policy to justify the construction of regional biotechnology clusters. Finnish technology policy has also followed the main stream: in the 1990s, almost twenty new centres of expertise were founded in the country; six of them presently working in modern biotechnology. Finland has followed the 'Silicon Valley model' (see e.g. Saxenian 1994): in the core of all these new centres, there is a university, or at least a branch unit of a university. The work in new centres is concentrated in large new buildings called technology centres, in the case of biotechnology, biotechnology centres.

Centres of biotechnological expertise

The Ministry of Education established the first national research programme on biotechnology in 1987. The aim of the programme was to develop four powerful centres of biotechnological expertise by 1992. These new centres were planned to be affiliated with those Finnish universities which were assessed as having the capacity and resources to develop this new field of scientific research. The centres of biotechnological expertise were set up in Helsinki, Turku, Kuopio, and Oulu. By the end of the five-year period, the Ministry of Education made an evaluation

aiming at identifying needs to further develop biotechnology and molecular biology. The Ministry decided to continue the programme until the end of 1996. Later on, the period of the programme was extended until 2000 (Jäppinen & Pulkkinen 1999, 10–13).

Besides the Ministry of Education, the Ministry of Trade and Industry, the Ministry of Agriculture and Forestry, and the Ministry of Social Affairs and Health also took part in the financing of the biotechnological research programme. The four centres of biotechnological expertise became part of the Finnish network of the centres of expertise. Nowadays, this network consists of 17 centres of expertise, of which seven are large and have an established status. Four centres have been working for some time, six are new and rather small ones (Saarinen 1999, 32). The new centres of expertise in Seinäjoki, Lahti, and Pori are located in regions without a local university but are linked to large regional polytechnics and local annexes of universities.

As can be seen from the following table, research and development in biotechnology is nowadays also conducted in the centres of Tampere and Seinäjoki besides the traditional centres in Helsinki, Oulu, Kuopio, and Turku. In Finland, the centre of expertise programme is intended to become the core of a newly developing regional policy. The strong relationship between the state's regional financing and the centre of expertise programme has led to "an excess demand" for new centres. Therefore, the policy has been criticised for its excessive decentralisation of limited R&D resources. The consequence of this is that there will not be any new centres of expertise set up in the field of biotechnology in the near future (Kekkonen & Nybergh 1999, 18–20).

Centres of Expertise offer local companies business services and forge links between regional enterprises and local universities or – in some cases – local polytechnics. They are presumed to be sources of knowledge for regional economies. They have an important role to play in the transfer of technology from high-tech centres in Finland and abroad to their own regions. They are also expected to generate new forms of business and to support the foundation of new enterprises, and they are expected to create a stimulating environment for the techno-organisational modernisation of the existing companies. The university or polytechnic affiliation of the centres – the basic philosophy of the Centre of Expertise Programme – can stimulate and support regional development in the high-tech sector, in biotechnology, for example (Jäppinen & Pulkkinen 1999).

In case there is no university located close to the centre of expertise, a regional polytechnic may, as the only base and core of local industrial network, begin to imitate the university's function. In research, this phenomenon is called the 'academic drift' in polytechnics (Pratt & Burges 1974). It has contributed to the fact that the end of the 1980s discharged the whole polytechnic system in the UK and polytechnics were transformed into universities. In Finland, in the regions without a local university, polytechnics may well become the base and core of local industrial network, which was also the case in the UK (Beck, Giddens & Lash 1995). The fact that in Finland the polytechnics are claiming the right to award

post-graduate degrees and to get the state's research financing reveals something about the direction of the development (e.g. Tulkki 1999a).

The so-called declarations of Sorbonne and Bologna have boosted the development of integration in European higher education systems, both in the national and European levels. In Germany, for example, these tendencies can nowadays be seen; the *Fachhochschulen* are just starting their *Magister* programmes and preparing themselves for *Doctor* education in the near future. This may promote the development towards the integrated higher education system also in Finland. The German dual model has been the ruling paragon for the new Finnish system (Tulkki 1999a).

	Large and established	Medium-sized and stable	New
Centres of biotechnology expertise	Turku: BioCity Ltd Oulu: Biocenter Oulu Ltd Tampere: Finn-Medi Research Ltd	Kuopio: Science Park Ltd	Helsinki: Science Park Ltd Seinäjoki: Foodwest Ltd
with focus on agro-food biotechnology	Turku: BioCity Ltd Oulu: Biocenter Oulu Ltd	Kuopio: Science Park Ltd (Bioteknia II)	Helsinki Science Park Ltd Seinäjoki: Foodwest Ltd

Table 3. The centres of biotechnological expertise in Finland.

There is a division of labour between the Finnish centres of biotechnological expertise. Four biocentres, Oulu, Turku, Tampere, and Kuopio focus on medical research and co-operation with the pharmaceutical industry. The Helsinki Science Park and Foodwest in Seinäjoki focus on co-operation with the agro-food industry. The situation is not clear, however. There is biotechnological research and development oriented to agro-food industry in the biotechnology centres of Kuopio, Oulu, and Turku.

The dominant status of the pharmaceutical industry in the field of Finnish biotechnology can partly be explained by the fact that this was the focus area of the "old" or the first centres of expertise. As those centres that concentrate on R&D in the agro-food field have been established only lately, this area is still lagging behind in its economic development. For instance, Foodwest, an only recently established science park, has not been able to promote new knowledge-based enterprises so far. However, there are a lot of "old" agro-food companies and units of large companies in the region.

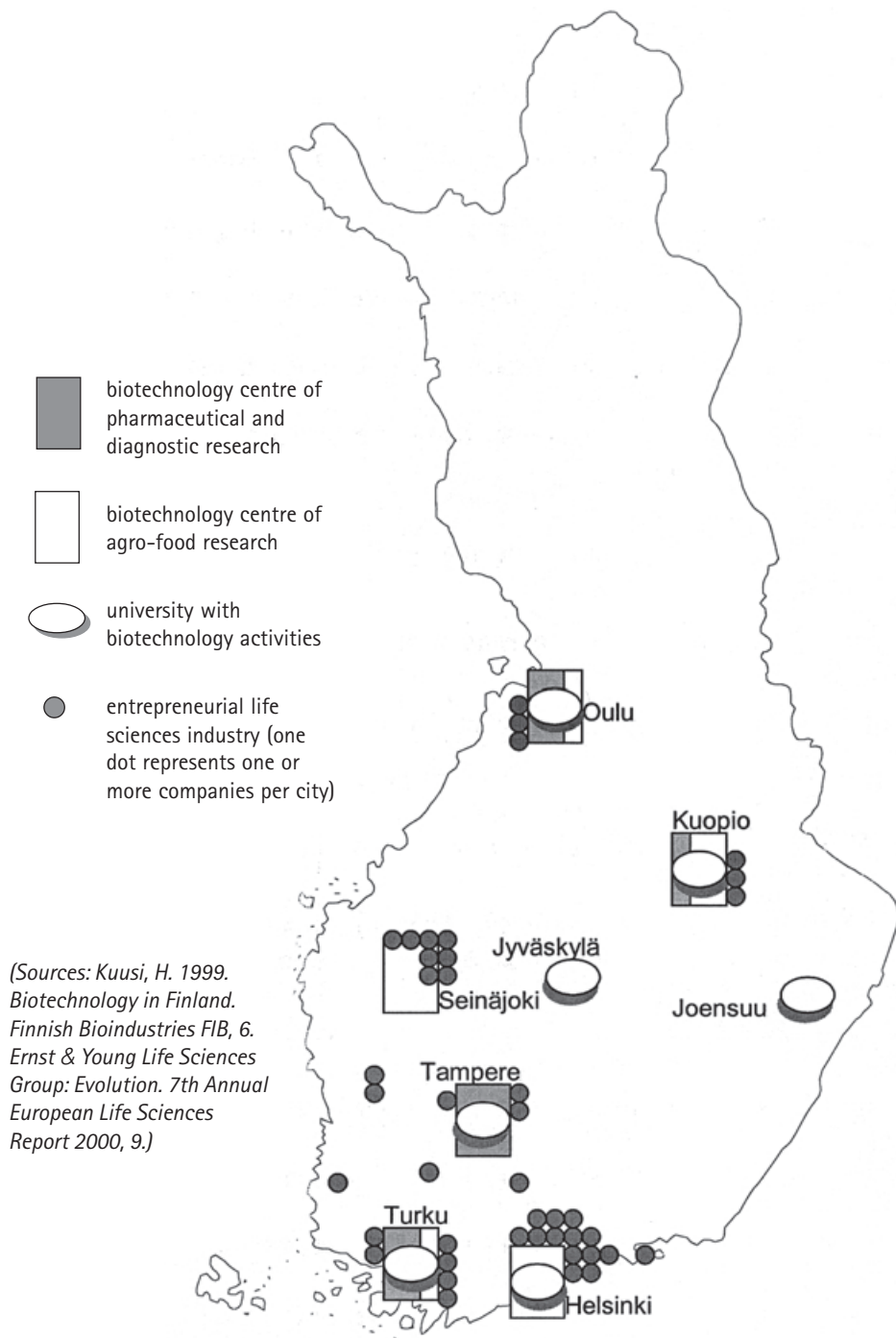


Figure 11. Universities, centres of expertise, and location of biotechnology business firms in 1999.

Education in biotechnology

As a traditionally technology-importing country, Finland has experience in transferring and implementing foreign innovative technologies into her own industries. Education was always seen as an important factor in this process of "borrowing new technology", as a successful technology transfer depends upon the skills and competencies needed to use and understand new knowledge, methods, and instruments. For example, the fact that Finnish engineers were educated in Germany and that Finnish engineers working in Germany and the USA helped the Finnish industries to accommodate to the electro-technical revolution of production in the beginning of the 20th century (Tulkki 1996, 327–332). Finnish engineer education also played a remarkable role in the success story of Nokia and the Finnish information and telecommunications industries (Tulkki 1999b, 33–66).

The Finnish example also indicates the great importance of the flexibility of the educational institutions and the whole educational system under the conditions of the new knowledge-based economy. The Finnish educational administration and the educational institutes have answered rapidly and effectively to the challenge of developing the new knowledge-based economy. The growth rate of education in Finnish universities and polytechnics has not only ensured the existence of the skilled labour force in high-tech companies but also attracted global companies to locate their R&D departments in Finland. Siemens, LM Ericsson, and many other companies capitalise on the results and the knowledge of the Finnish engineer education and the know-how of the Finnish IT industry in their many R&D units located in Finland (see e.g. Tieke 1999, 11–14). It seems that equal development is aspiring modern biotechnology as well. The increased higher education also decreases prejudice against modern biotechnology. Thus education can promote the markets for the products of modern biotechnology (Tulkki 2001).

According to the representatives of companies and research centres, there is a lack of educated labour force in Finnish biotechnology, which is in many cases defined as a main factor delaying the development of the field. Some companies, even innovative micro firms, have been forced to recruit experts from abroad, and some large companies explain their cuts in R&D functions in Finland by the lack of skilled and highly qualified employees.

Modern biotechnology relies a great deal on formal education, as – according to Lundvall (1999) – knowledge in this field is highly codified (see also OECD 1996, 14–15; Hatchuel & Weil 1995). From this point of view, the use of the concept of Life Sciences is justified: the knowledge basis of modern biotechnology is highly scientific by nature. This is reflected in the fact that Finland has certainly invested a lot in education in the field of biotechnology in the recent 15 years (Rannikko & Tulkki 1999).

Bio-engineers have been educated at the Helsinki University of Technology since the mid-1980s. In 1998, a special master's programme in biotechnology was

established at the University of Turku. Each year 20 students begin their bio-master studies instructed jointly by the Faculty of Medicine and the Faculty of Mathematics and Science. The training programme trains the students for the commissions of expertise in pharmaceutical and in food industries. In the first and second year, the students study chemistry, biochemistry, cell and development biology, molecular biology, genetics, and human biology. Students start their studies in business administration and economics also in the first year of their studies. One idea and goal of the training programme is to promote new entrepreneurship into the field. After the second year, the student can choose between the orientation study in the pharmaceutical route or the food development route. It is assumed that students write at least a part of their master's theses in biotech companies or laboratories. (Väänänen 1999, 44–47.)

In 2000, sixty new students started their studies in a new training programme in biotechnology at the University of Kuopio. The programme consists of three main subjects: animal biotechnology, plant- and agro-biotechnology, and nutritive and food biotechnology. At the University of Kuopio, the main research and education focuses of animal biotechnology are genetically modified mammals and fish. In plant- and agro-biotechnology, the focuses lie on increasing the productivity of crop, the prevention of plant pests, and environmental biotechnology. In nutritive and food biotechnology, the focus is on health-advancing attributes of food. (Lindqvist 1999, 41–43.)

In the Science Park of Viikki in Helsinki, about 3 000 students study different subjects in biotechnology or Life Sciences (Halme 1996). Also, Finnish polytechnics offer training programmes in biotechnology. The number of biotech students is not yet comparable with the number of engineering students, for instance. At the moment, at the university level, about 500 students start their studies in biotechnology; while about 5 500 start their engineering education, almost one third of them in information and telecommunications technologies. It has been debated, however, whether the number of the students in biotechnology education is too high.

The complexity and multidisciplinary nature of modern biotechnology makes it very difficult to distinguish the students whose education is directed to modern biotechnology in agro-food industries. The figure below illustrates the training programmes picked up from the broad spectrum of Life Sciences, the linkages of which with agro-food business are obvious. The table shows that the total number of the students passing the entrance examinations of universities in the agro-food biotechnology did not increase in the 1990s. Instead, the number of new biotechnology students in universities has been rather stable. In polytechnics, the intake of new biotechnology students was 267 in 1999, which is only 0.8 percent of the total student places. These numbers mean that no additional investments in the basic degree education in agro-food biotechnology can be found there. When considering education in biotechnology, one should remember the fact that the focus in modern biotechnology is on the pharmaceutical industry. Also, the focus of education is on the faculties of medicine.

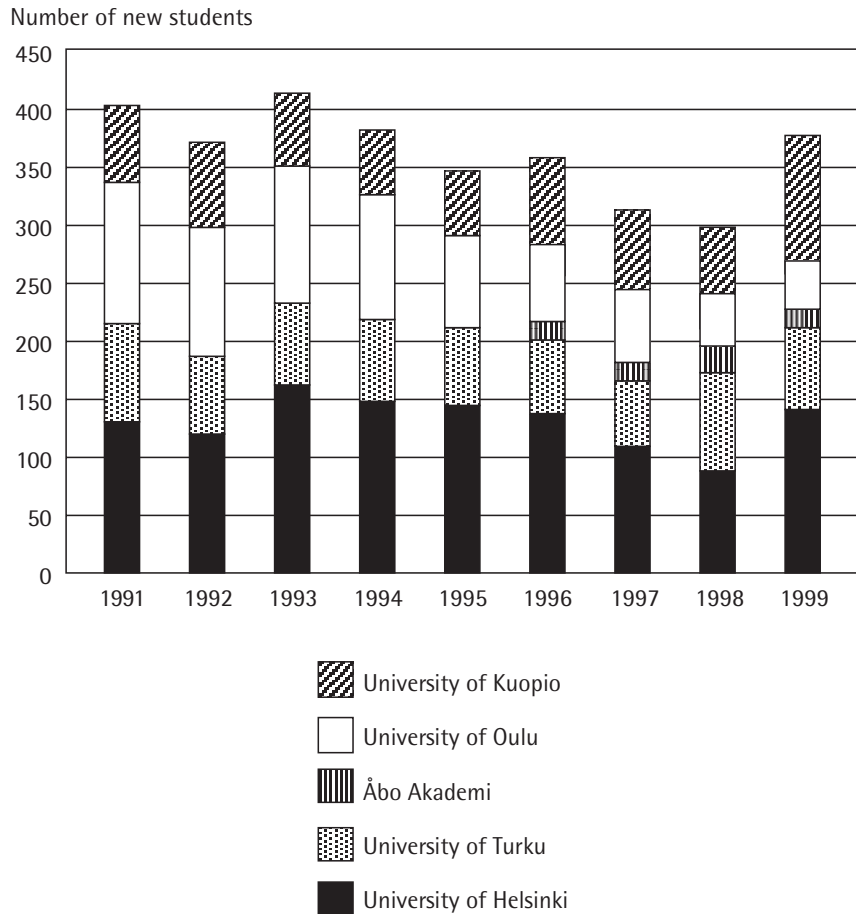


Figure 12. The intake of students in biotechnology in Finnish universities in 1991–1999.

The figures change when we turn to postgraduate education. Fourteen graduate schools have been established at Finnish universities supporting research in various areas of biotechnology (Makarov 1999, 21–23). Five of them are situated in Helsinki, four in Turku, two in Kuopio, and one in Oulu, Tampere and Joensuu. The location of graduate schools tells us something about the anticipated location of Finnish biotechnological industries; the appreciable regions of the future biotech industries seem to be the Helsinki region and Turku region. The graduate schools are mainly integrated into regional biotechnology centres of expertise. As can be seen in the table below, most of the graduate schools are operating in the areas of medicine. In Finland, the educational investments in biotechnology are largely directed to postgraduate degrees and in medical sciences, which is the choice made not only within educational but also within research policy.

University	Graduate Schools
University of Helsinki	<ul style="list-style-type: none"> • The Biomedical Graduate School • The Graduate School in Neurobiology • The Finnish Graduate School on Applied Bioscience • The Graduate School in Biotechnology • Viikki Graduate School in in Biosciences
University of Turku	<ul style="list-style-type: none"> • The Graduate School of Biomedical • The Finnish Graduate School in Musculo-Skeletal Problems • Biological Interactions Graduate School
Åbo Akademi (Turku)	<ul style="list-style-type: none"> • The Graduate School of Informational and Structural Biology
University of Oulu	<ul style="list-style-type: none"> • Biocenter Oulu Graduate School
University of Joensuu	<ul style="list-style-type: none"> • The Graduate School in Forest Sciences
University of Kuopio	<ul style="list-style-type: none"> • A.I. Virtanen Graduate School

Table 4. The graduate schools of biotechnology in Finland.

Financing

Research and development in biotechnology is highly dependent on state funding. As has been mentioned earlier, only 0.4% of private venture capital investments were directed to biotechnology in 1997. As a capital-needy country, the state and public finance plays an important role in the Finnish venture capital markets. Different parts of the idea-innovation chain are financed by different institutions. The Academy of Finland is supporting scientific basic research in universities and research centres. The Technology Development Centre (Tekes) aims to applied research and product development by supporting the co-operative activities between university research and companies. The role of the Finnish National Fund for Research and Development (Sitra) is to support promising start-up enterprises. Later on, new knowledge-intensive companies will be expected to get their financing from the capital markets.

Tekes has invested EURm 90 in the fields of chemistry and biotechnology, which accounts for 27% of its total investments. The Academy of Finland and Tekes invest about EURm 3.4 yearly in research on biosciences and biotechnology as part of the Centres of Excellence Programme. In addition, they have also invested EURm 0.7 in Biocentrum Helsinki, Biocenter Turku, and BioCity Turku. This means that 40% of the aggregated financial support of the Academy of Finland and Tekes is directed to biotechnology. The National Programme for Research on

Biotechnology, started in 1988, invests about EURm 13.5 yearly in biotechnology (Vihko & Pauli 1999). Since the state financed Finnish biotechnology quite extensively in the 1990s, some criticism has been raised about the results of this massive investment.

There have been two research programmes going on, financed jointly by Tekes and the Academy of Finland: the Genome Research Programme and the Cell Biology Research Programme. The Genome Research Programme focuses on gene regulation, studying interactions between several genes and gene products, gene transfers and knockouts as well as gene therapy. The budget of this six-year programme amounted to EURm 15 in six years. Within this programme in the period 1995–2000, the Academy of Finland financed a number of projects: in 1995–1997, it invested in EURm 6 in twenty projects, and in 1998–2000, it invested EURm 4 in fifteen projects. In addition, Tekes invested EURm 1 in five projects in 1998. The Cell Biology Research Programme studies mechanisms of cell division and differentiation, biogenesis of cell organelles, and intracellular trafficking as well as signal transduction. The programme started in 1998 and will continue until the end of 2001. Its budget amounts to EURm 5.4. Within this programme, the Academy of Finland has financed 19 projects by EURm 4; Tekes has financed 4 projects with EURm 1 from 1998 to 1999.

In 1993, the Ministry of Education established a new centres-of-excellence policy by ordering the Finnish Higher Education Evaluation Council to choose ten units and institutes as 'top units' (Ketonen & Nyyssölä 1996, 68–73). This policy of establishing centres of excellence has become the core of the Academy of Finland's policy (Vihko & Pauli 1999, 15). It expects that their new policy can lead to a strong concentration of research and innovative power. Currently, 6% of the Academy's funding is directed to the Centres of Excellence Programme. In 2000, a total of 26 new Centres of Excellence were established, nine of which are operating in the field of modern biotechnology and biosciences (*ibid.* 14). The Academy of Finland also financed research in modern biotechnology within its basic research programmes. In 1999, the Research Programme for the Biology of Structures started and, in 2000, a Research Programme for Biological Functions was being planned on.

The Academy of Finland is also financing the Research Programme in Molecular Epidemiology and Evolution. The primary areas of this programme are population genetics, concerned particularly with the evolution of genes, the adaptation of organisms to extreme conditions, genetic epidemiology and the Finnish genetic heritage, and environmental molecular genetics, including genetic factors predisposing to disease.

Tekes started a five-year Biotechnology Development Programme in 1988. It consisted of five areas important to Finnish industry: biotechnology for the pulp and paper industries, bio-process engineering, plant biotechnology, animal cell technology, and biologically active molecules. Tekes also has an agro-food biotech programme named 'The Innovation in Foods Programme'. It aims at supporting the production of more competitive foods through research. The goal of the programme is to ensure the production of increasingly top-quality products by improving the

standards of food technology and related research in Finland. The programme started in 1997 and continued until 2000. The budget of the four-year programme was over FIM 200 million (EURm 33,7 million). All significant Finnish agro-food companies participated in the programme.

At the beginning of the year 2001, Tekes launched the technology programme 'Medicine 2000'. The programme addresses biomedicine, medicine development and pharmaceutical development, and it will end in the year 2006. The Academy of Finland is financing the programme jointly with Tekes. The total budget of the programme amounts to EURm 102 to 151, of which Tekes' share is more than 90 percent. The Academy of Finland will invest EURm 3.4 in the programme for the first three years of research. Besides Tekes and the Academy of Finland, Sitra, Finnish Bioindustries (FIB) and a large group of pharmaceutical biotechnology enterprises and researchers have also taken part in the planning of the programme. In March 2001, Tekes launched 39 and the Academy of Finland 11 new research projects, the total funding of which amount to EURm 10.

In 1991, the Finnish National Fund for Research and Development (Sitra), with the aim of financially supporting new start-ups, invested EUR 67 000 in biotechnology, which was only 1.2 percent of its total investments. Eight years later, Sitra's investments in biotechnology amounted to EURm 6 million. Today biotechnology is the strongest supported industrial branch in Sitra's portfolio. All in all, Sitra has invested in eleven biotech companies; today, the share of its biotech investments accounts for as many as 9.5 percent of its total investments. In 1997, two special funds, Sitra Bioventures Ky and Sitra Bio Fund Management Ltd, were started with a capital of EURm 25.2.

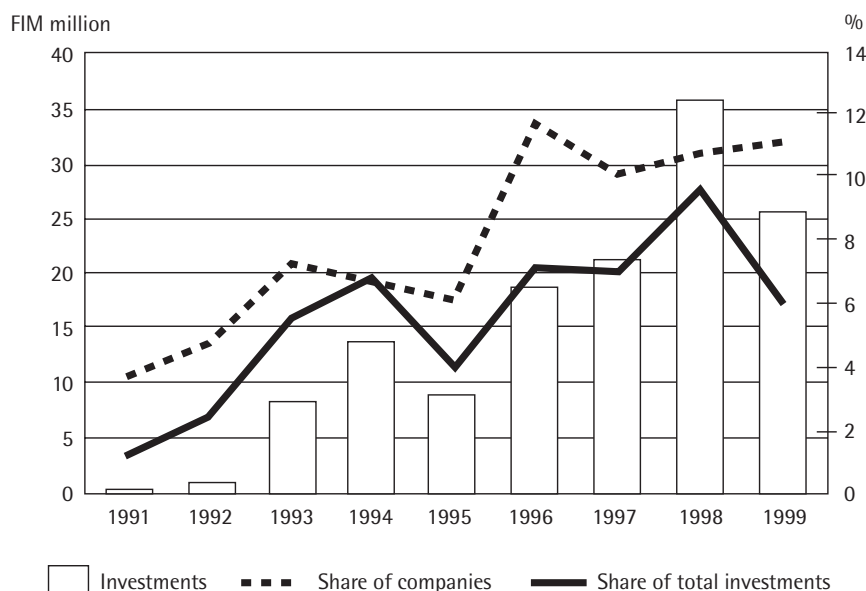


Figure 13. Investments of Finnish National Fund for Research and Development (Sitra) in biotechnology 1991–1998.

6 | SOME INTERNATIONAL COMPARISONS

One, or perhaps the most important, key ratio describing the innovativeness of a country's Life Sciences industries is the number of the Entrepreneurial Life Science Companies. This key ratio describes the degree of networking in the industrial branch. This approach assumes that the highly knowledge-intensive ELISCOs play the central role and are the key factors in innovation processes. ELISCOs work as knowledge transporters and knowledge refiners among universities and research institutes, on the one hand, and among large business companies on the other. The quantity of ELISCOs describes the intensiveness of a country's Life Sciences industries. If we compare four countries, Netherlands, Germany, Austria, and Finland to each other, we can easily see that the leading biotechnology country among them is Germany. The number of German ELISCOs has increased very rapidly since 1997. The trend in Finland has also been increasing, but not at such a speed as in Germany. In the Netherlands, the development seems to have bogged down. In Austria, the ELISCOs have totally disappeared in the year 2000.

In the following, we address mainly the development and situation of German biotechnology. Its rapid development in Germany in the late 1990s is based on the federal government's activity in generating biotechnology business networks in the country and on the existence of large, global-sized pharmaceutical companies.

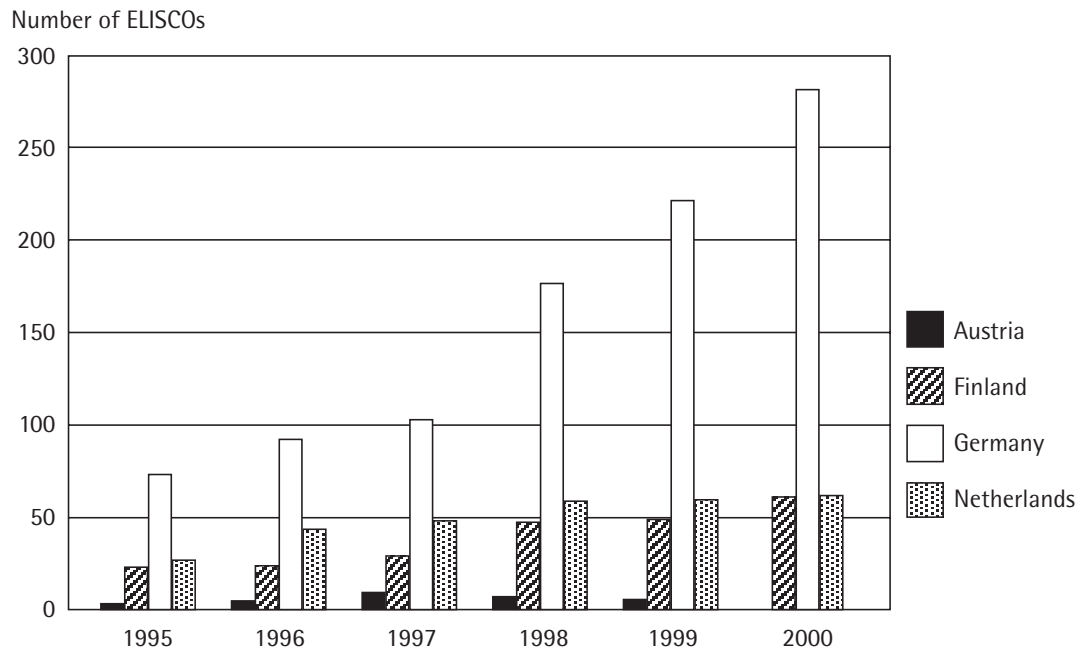


Figure 14. The number of ELISCOs in Austria, Finland, Germany, and the Netherlands in the years 1995–2000. (Ernst & Young: Biotechnological industry Annual Reports 1995–2000.)

The German federal government has not used the traditional regional policy tools and modes of action. It has supported the most promising regional business concentrations with the aim of promoting fast development of biotechnology innovativeness. Unlike in Germany, in the Netherlands the development of ELISCOs has been delayed, although the biotechnology sector of the country has been among the most promising ones. Perhaps the most delaying factor is tight 'sectoralism'. In the Netherlands, for example, biotechnology-oriented education is diffused under the governance of several ministries, which makes it difficult to produce cohesive policy in promoting new cross-industrial networks under the conditions of diffuse state administration.

Modern biotechnology in Germany²

In the second half of the 1990s, the German biotech industry developed from a latecomer into the most dynamic sector of its kind in Europe. In terms of commercialisation of scientific knowledge, Germany surpassed Great Britain, which has Europe's largest Life Sciences industry. In 1999, Germany's Life Sciences start-ups attracted a total venture capital sum of EURm 260, the highest amount of the early stage financing in Europe. With the establishment of 279 start-up companies in this sector between 1995 and 1999, Germany scored most formations of new biotechnology companies in the EU member states, beating Britain, France, Sweden, the Netherlands, and Finland into the following places (Deutscher Bundestag 2000; Ernst & Young 2000 14–17).

The Life Sciences sector in Germany is highly regionally clustered. Companies have been established around eighteen different locations. However, most companies as well as research organisations are situated in the three leading biotech clusters in Munich, Berlin, and the Rhine-Neckar area around Heidelberg. This decentralised structure of the industry is mainly the result of an ambitious federal initiative, the BioRegio programme, which started in 1996 and has led to the formation of eighteen BioRegionen, which went into a competition for federal funds. Two of today's three most dynamic clusters, Munich and Heidelberg, have already succeeded in the BioRegio competition, while the third region, the Berlin area, has been able to catch up in recent years.

Germany's industry is clearly focused on pharmaceutical biotechnology. Especially those Life Sciences start-up companies that are characterised by a highly innovative and science-based business strategy concentrate on the development of therapeutic products, platform technologies, and diagnostic products. Most of them are also engaged in contract research for large pharmaceutical companies. By far fewer companies of this kind, however, focus on plant and food biotechnology, animal health products, transgenic animals, or environmental biotechnology. According to experts, the dominant position of pharmaceutical biotechnology in Germany can be explained by at least two facts. First, since modern therapeutic products are able to generate significant revenues, companies engaged in pharmaceutical biotechnology can more easily apply for venture capital. Second, since public opinion is especially concerned about genetically modified plants and food, there is far less political support, and therefore, only limited public R&D funds available for these sectors.

² This chapter is based on Robert Kaiser and Edgar Grande's paper "The Emergence of the German Biotech Industry in the 1990s: the Role of the National Innovation System and its Specifications at Regional Level". Report is part of the work programme of the TSER project "National Systems of Innovation and Networks in the Idea-Innovation Chain in Science-based Industries", Munich, March 2001. Presented in the TSER-NIS Workshop in Florence, March 17–18, 2001.

Actors in the German pharmaceutical biotech industry

Traditionally, Germany has a strong and long-established pharmaceutical industry primarily consisting of three large integrated chemical-pharmaceutical companies. They are Bayer, BASF, and Hoechst, which is now part of Aventis. There are also seven medium-sized companies acting in the field, Boehringer Ingelheim, which now belongs to Hoffmann-La Roche, Boehringer Mannheim, Chemische Werke Hüls, Degussa, Henkel, Merck, Schering, and Wacker Chemie. Until the 1990s, these companies clearly dominated the German Life Sciences industry, and they still invest the most in biotech research and development both in terms of expenditures and employees. Until 1995, only few start-up companies entered this market. Initially, the newcomers focused on contract research and contract production for the Life Sciences industry and were active in the development of platform technologies. However, they were not engaged in R&D for modern therapeutics or diagnostics at that time (cf. European Commission 2000 DE-28).

This situation has been changing significantly since 1995, when the federal government, after reforming the regulatory framework, set up a new programme aimed at promoting the commercialisation of scientific knowledge in biotechnology. As a result of this new BioRegio programme, many start-up companies were founded as spin-offs from public research organisations, especially the non-university research institutes. The yearly Ernst & Young '*German Biotech Report*' gives a detailed overview of the rapid industrial expansion in the German biotechnology sector. This analysis measures the growth of the industry by defining three different types of corporate actors:

- *Category I: Entrepreneurial Life Science Companies (ELISCOs)*: small or medium-sized companies which exclusively concentrate on the commercialisation of modern biotechnology. They are highly innovative and follow a typical business strategy to develop therapeutics in co-operation with traditional big-pharmaceutical companies. Scientists and entrepreneurs normally set up their management. In view of financing, they rely heavily on venture capital and therefore have to aim at a listing at specialised high-technology stock exchanges.
- *Category II: Extended Core Companies*: small or medium-sized companies which are engaged in the development of products or processes in biotechnology, but realise less than 50 percent of their revenues with biotech products or related services and supplies.
- *Category III: Big Companies*: Life-Science corporations with more than 500 employees. They either invest significantly in biotechnology R&D or their revenues in biotechnology products or services amount to at least EURm 10.

The number of ELISCOs has increased steadily since 1995. Their growth rate is higher than that of Category II extended core companies, while the number of large pharmaceutical firms remained constant. The highest growth rate in the establishment of biotech start-ups occurred between 1996 and 1997. Since then, the number of new company formations has slightly been decreasing, which could be seen as a sign that the sector has entered a phase of consolidation. All in all, the increase of ELISCOs on the German market is mainly the result of spin-offs from research organisations as well as a consequence of the establishment of joint ventures between large pharmaceutical companies and research organisations. To a lesser extent, some extended core companies switched into a business strategy which qualified them as ELISCOs. Besides that, ELISCOs also have the highest growth rates in terms of employment, revenues, and R&D expenditures. However, they are also confronted with increasing deficits, whereas only extended cores and large pharmaceutical companies were able to make profits.

The German biotech industry is regionally clustered and located mostly around those four cities in which the federal government established national research centres for genetics in the 1980s: Munich, Berlin, Heidelberg, and Cologne. Despite the fact that the BioRegio contest motivated the commercialisation of scientific knowledge in biotechnology at eighteen different locations in Germany, these four areas are the only ones developing most dynamically. Moreover, the example of the biotechnology business region Berlin-Brandenburg shows that at least one cluster was able to catch up even if it did not succeed in that contest. As a result, looking at the level of the sixteen federal states in Germany, most biotech companies are today situated in Bavaria, Baden-Wuerttemberg, North-Rhine Westphalia, and Berlin. Hessen was able to enter the phalanx of the leading clusters because of the existence of a relatively large number of extended core companies. However, in terms of the number of ELISCOs, Hessen is significantly behind the Berlin-Brandenburg area.

Besides regional concentration, there is a strong tendency in the pharmaceutical biotechnology sector towards focusing on a limited number of medical indications. This applies especially to the group of ELISCOs, which are engaged in drug development. It seems obvious that companies in this sector associate the high risk of drug development with a concentration on those disease areas that have the highest potential market volume. Most product candidates introduced by German ELISCOs in preclinical research or clinical trials are developed for the treatment of cancer, infections, and cardio-vascular disorder. Therapeutics is currently developed for indications concerning metabolism, pain, or allergy only little.

Business models and business strategies of German pharmaceutical biotech companies

Roughly speaking, there is a typical business model for most of the biotech companies that are active in the pharmaceutical branch of the sector. It can be

described as the development of a firm from a technology supplier to a drug developing company. Normally, biotech start-ups enter the market as spin-offs from academic research, commercialising first a certain platform technology or tool. In case a company decides to enter drug development, it will seek strategic alliances or joint ventures with large pharmaceutical companies in order to develop the drug candidate in co-operation and thus sharing the financial risks during the R&D phase. The ultimate goal, however, is to reach a position in which the firm can set up individual drug development programmes financed by internal cash flow, which originates from licences for their technology or royalty payments out of co-operative drug development programmes.

This business model copies the example of successful U.S. biotech companies, such as Amgen or Biogen, which were able to develop into biotech-driven pharmaceutical firms. Apart from the fact that this business model has proved to be successful in the U.S., it is quite obvious that the market itself prompts many companies to shift from a platform technology supplier into a drug developing company. For pure technology suppliers attracting external capital is going to be more and more difficult since investors are more interested in companies which have the potential to develop a blockbuster therapeutic. Moreover, there is already pricing pressure of some technology services like the identification of targets.

However, there are some companies in the German Life Sciences sector that are doing well in some market niches. Quiagen, for example, is a world-market leader for a certain purification system, whereas LION Bioscience is a bioinformatics specialist which develops high-performance systems for the identification and validation of targets. Other companies concentrate or have a strong position in new fields of biotechnology, such as biomaterials.

Regardless of whether a biotech company is engaged in drug discovery and development or whether it is focusing on platform technologies, partnerships and alliances primarily with established pharmaceutical firms are equally important. On the one hand, those partnerships are essential to generate revenues to stabilise the internal cash flow, to create resources for in-house R&D programs, and to reduce the dependency on venture capitalists. On the other hand, being selected by a large pharmaceutical company as a partner in drug development or as a supplier for certain services or technologies underlines that the biotechnology company has gained ground in competition with important national and international companies. In that way, these alliances are an integral part of the activity and strategy of the biotech business.

Since 1998, many German ELISCOs have been able to enter a strategic alliance or partnership with established pharmaceutical companies. The number of agreements increased by nearly one hundred percent between 1998 and 1999. Apart from that increase in partnerships, a new tendency occurred in the biotech sector through the emergence of intra-biotech alliances, which provide the opportunity for all partners to expand their portfolio of products and services. Moreover, in 2000, some German Life Sciences companies, such as *Medigene* and *GPC Biotech*, took over British or U.S. biotech companies in order to gain access to

the industry's lead markets and to get special knowledge – that is, in bioinformatics – into the firm, which was not available or hardly obtainable on the German market.

There are only few examples of acquisitions of German pharmaceutical biotechnology companies by large pharmaceutical firms up to now. One of the rare cases concerned *Novartis*, which purchased the *Grandis Biotech GmbH*, a company developing human hormones, in May 1999. On the one hand, this indicates that traditional pharmaceutical companies tend to licence certain products or technologies from biotech companies but are not interested in incorporating those companies into their firm. On the other hand, it is likely that large pharmaceutical companies have little incentive to heavily invest in Germany's ELISCOs as long as they have only a limited portfolio of products, services, or technologies. Moreover, one has to bear in mind that many of the leading German biotechnology companies have a relatively high stock-market valuation, which makes acquisitions expensive.

Regional activities

The federal states contribute to the R&D infrastructure primarily by financing the university system, both as institutional funding as well as by co-funding R&D programmes of the German Research Council. Both activities amount to a total annual budget of about EURm 17 895, of which about 40% can be regarded as R&D related expenditures. Additionally, many federal states have implemented various programmes aimed at promoting research and development in biotechnology or fostering the commercialisation of biotechnology through initiatives especially designed for the establishment of start-up companies or the development of small and medium-sized firms.

Subnational programs which apply to the biotech industries as well as to other science-based industries exist for the implementation of innovative products or production processes, for the establishment of R&D networks between companies and research organisations, for co-financing of employment of experts in innovation management, for assistance with patenting of products and processes, for the stabilisation of internal cash-flow of innovative companies, and for the establishment of research organisations which have an orientation towards application of knowledge within the industry:

- The state of *Bavaria* promotes the implementation of innovative products and production processes through its investment agency "Bayern Kapital". Investments are made as dormant co-financing with private venture capital providers. The maximum amount of investments in the biotech sector is EURm 2.6.
- The state of *Berlin* supports small and medium-sized companies in R&D projects, which are conducted in co-operation with universities or non-

university research organisations. Projects are funded to a maximum of 50 percent of the total costs.

- The state of *Berlin* co-finances labour costs for the employment of experts in innovation management in small and medium-sized companies. The subsidy is given for 12 months and amounts to 40 percent of the total labour costs.
- The state of *Brandenburg* supports small and medium-sized companies in patenting their products or production processes. Subsidies are available to a maximum of EUR 205 000.
- The state of *Schleswig-Holstein* provides financial assistance through its public venture capital agency for the stabilisation of the internal cash flow of companies, which are engaged in high-technology areas or environmental technologies.
- The state of *Thuringia* finances the establishment of research organisations, which focus on the application of knowledge within the industry. Funds are available for the labour costs of scientists, for the development of the infrastructure or for the expansion of activities.

Remarks on the Dutch biotechnology³

In the Netherlands, the number on ELISCOs has become fixed at about 50 in the late 1990s. Analogous growth seen in Germany – or in Finland – has not been seen there. According to the Holland Biotech Association and the Nature Biotech Directory, there are altogether some 140 companies acting in the field of biotechnology. About one third of these belong to the categories of consultancy or public institutes or organisations. They are typical knowledge-intensive business service (KIBS) organisations, and they – according to definitions used in this study – do not belong to category of Life Sciences or of biotechnology companies. In practice one can assume that there are 60 to 80 biotechnology companies in the Netherlands presently.

The Dutch Life Sciences business, unlike the corresponding German one in Germany, for example, is addressed in great quantity in Dutch agro-food industries. Most of the 'non-ELISCO' companies are large agro-food companies which have not actively generated innovative networks around them. According to the national

³ This chapter is based on Herman Oosterwijk's paper presented in the TSER-NIS Workshop in Florence, Italy, on March 17-18, 2001

experts of the Dutch modern biotechnology innovation system, the close and direct co-operation between universities and industries is on cutting edge. On the other hand, the statistics on innovation in Europe (2001, 75) reveal that only 29 percent of the innovators co-operated in the Netherlands in 1996. In Austria, the corresponding share was 23 percent, in Germany 23 percent, but in Finland as great as 71 percent.

The largest field of interest in the Dutch biotechnology business is human health care and animal health. Four companies out of ten are working on this area. The second largest are the fields of agro-food industry and plant breeding. Together they form as large field of interest as the arena for human health care and animal health. The environmental industry and the fine chemicals industry both have a ten-percent share of the biotechnology business. The total number of industrial and academic scientists involved in biotechnology is estimated at 4 000, in addition to which about 300 companies in the Netherlands conduct biotechnological research, involving between 2 000 and 2 500 people. This includes companies as well as research institutes.

In the Dutch pharmaceutical industries, the number of jobs is declining, due to globalisation and mergers and an unfavourable investment climate in comparison to other countries. The share of employees in research and development activities increased from 14 percent in 1994 to 23 percent in 1996. Because the costs of R&D investments have increased, the activity of Dutch pharmaceutical industries is more and more centralised.

The Netherlands has its roots deep in biotechnological research. The Department of Agricultural Research (DLO) and the Institute of Applied Technological Research (TNO), both publicly funded research organisations, are strongly involved in biotech research, and so are universities. There are strong links between these publicly funded institutes and universities. As a result of this co-operation, the DLO is today integrated with Wageningen University for Agriculture. There are, however, some problems in the Dutch education system. The universities and other institutes do not seem to be able to produce enough broadly educated biotechnology researchers and experts. This can be a result of the disjointedness of the Dutch education system. For example, the Ministry of Agriculture governs the whole system of education in agriculture, from upper secondary vocational schools to universities.

Besides education and administration, the social configuration of the actors in the field of Life Sciences industries is also fragmented. Consequently, there are three associations for biotechnology in the Netherlands. The pharmaceutical branch was traditionally organised in *Nefarma*, but the organisation did not devote much or better special attention to developments in biotechnology or developments related to biotechnology. Due to its lack of interest in the special properties of biotechnological drug research and production, *Biofarmind* was founded. The association has brought together specialised biotechnology companies that are active in pharmaceuticals. The large Life Sciences companies are not welcome in this association consisting of about twenty members. Biofarmind strongly

concentrates on rules and regulations. It has gained access to the Ministry of Health Care and is an important advocate for biotechnology companies' interests. The oldest association especially for biotechnology is *Niaba*. Compared to Biofarmind, Niaba has a broader scope and also includes, in addition to pharmaceuticals, chemicals, food and feed, seeds, and the environment. Niaba has about 60 members, among them big, established companies. Whereas Biofarmind is much more involved in advocating and negotiating over biotechnology matters with governmental bodies, and thus paving the way for biotechnology research, Niaba is much more involved in playing the public opinion. According to experts, there is an atmosphere of animosity between associations. They all claim the right to exist, but regard the given situation as fragmented and waste of influence, vulnerable in political strategy and "games".

There is a lack of innovative companies in the field of biotechnology in the Netherlands. The Dutch government has perceived this absence in the national biotechnology innovation system, and it has introduced the '*Actieplan Life Sciences*' that the Ministry of Economic Affairs introduced in 1999. It contains the recipe and the financial budget for the preparation of successful biotech networks and innovative start-up firms. The plan is based on the fact that although the Netherlands has a strong and nationally oriented science base and a tradition of close co-operation between the academia and the industry, there are still very few small innovative companies working in the field of biotechnology.

7 | CONCLUSIONS AND POLICY RECOMMENDATIONS

Modern biotechnology, or Life Sciences, does not mean one single industrial branch or cluster. It is rather a domain of scientific and technological knowledge, or a new technological paradigm, which the concept refers to. The fact that industrial applications based on modern biotechnology are used in many different industrial branches may reconstruct the industrial structure in the future. It is not exclusionary that an industrial cluster of its own may be composed on the basis of modern biotechnology and Life Sciences. But today we can describe biotechnology as a generic technology used in many industrial branches (Bartholomew 1997). The situation of modern biotechnology, or Life Sciences, within different Finnish industrial sectors can be described as follows: in the case of pharmaceutical industries, there is a network with several ELISCOs but a missing centre. Correspondingly, in other industrial sectors there are centres, but almost without ELISCOs and networks.

The increased needs for clinical testing in producing functional foodstuffs refer implicitly to the process of rapprochement between agro-food industry and pharmaceutical industry. This "medicinalisation" of food production is a process that will unify – or at least provide an opportunity to unify – the working and the institutional environment of the pharmaceutical industry and the most advanced agro-food industry. Today, the leading Finnish functional food producers, Valio and Raisio, are tightening co-operation between each other in the R&D, production, and marketing of the most advanced products they have. This development can generate, or start the generation of, the longed-for co-ordinating centre for the Finnish Life Sciences business networks. Even today, for example, some of the KIBS organisations specialised in pre-clinical and clinical research work in both industrial branches.

In Finland, like in most European countries, the leading edge of modern biotechnology is in pharmaceutical industry. There are three main reasons for this kind of configuration. First, the customers are more critical about the modern

biotechnological applications in food production than in drug production. People trust that the legislation and regulations concerning the pharmaceutical industry can guarantee safe medicaments but they do not trust that the same happens in the case of food production. This pressure from markets is the main factor in promoting "medicinalisation" of the food production. Second, the knowledge of modern biotechnology is not only highly codified but also theoretically of high standard. The labour force in the pharmaceutical industry is very highly qualified, a great number of employees have a PhD or an equal degree, which is not the situation in agro-food industries, for example. Third, the pharmaceutical industry has a long tradition in research and exploitation of scientific knowledge.

We can describe the situation in Finland as follows: the activities in biotechnology concentrate on the initial parts of the idea-innovation chain. There is a lot of research and development projects and there is a lot of education, but there is lack of products. From the point of view of the learning economy, we can describe the Finnish situation by saying that today there is a lot of learning in the knowledge arenas of biotechnology and Life Sciences. The work of the biotechnology companies and research centres has promoted the Finnish industries' capability to keep up with the development of the modern biotechnology research and development. It has also created (and is creating) the necessary knowledge base for learning. The activity of public finance organisations has also been successful in a more practical way: according to an OECD research (2000, 102), the growth rate of biotechnology patents in Finland in 1992–1999 has been over the EU average.

From this point of view, there seems to be no need to change the selected policy. The new training programmes and graduate schools generate the knowledge and know-how needed in the field of biotechnology. The companies' and research centres' work produce the necessary skills and tacit knowledge. However, it seems that the national borders are too narrow for the modern biotechnology. The smallness of the Finnish biotechnological firms is a problem. Small companies face serious problems, as product innovation and improvement in operating efficiency come to depend increasingly on the use of biotechnology. In order to be able to develop the absorptive capacity necessary for applying biotechnological knowledge, companies have to set up respective research capacities. This is a major problem for small companies, as can also be demonstrated by the small amount of private R&D investment of Finnish firms in biotechnology. However, Finnish firms are starting to co-operate and merge not only with European but also with US companies to overcome the disadvantage of being small.

One can pitch for greatness – and the role of the national network coordinator – also by amalgamating the existing national level powers and action, for example in the way Valio and Raisio are now conducting their co-operation. As the pulp and paper industry includes some global players, the sector is not affected by this problem. As some huge mergers have already taken place in this sector, Finnish pulp and paper companies may well be able to hold their own in the biotechnology era. Perhaps one bountiful direction of developing work is to focus

modern biotechnology more on the field of forest industry. In the Netherlands, there are good results and experiences in the modern biotechnology-based research and development of cuten flowers. This work in flower production, which is not as regulated as food production, for example, has promoted biotechnological and genetic engineering skills and know-how, which can be used in other industrial branches.

Today, the research and development of new drugs takes about 15 years and is very expensive, costing half a billion Euro. These numbers make it very clear why the network of small companies is not enough for constructing the modern biotechnology-based industry. According to studies, the success of the biotechnology company networks depends on large, global companies' participation in the co-operation (e.g. Prevezer 1998, 154; Saviotti 1998). A successful innovative biotechnology network can, in the long run, be constructed only around global companies. Successful experiences of the German BioRegio programme also refer to this kind of a 'networking co-ordinated by a centre' model. It is possible that the high standard and qualification of the Finnish biotechnology labour force can attract some large companies to set up their research and development units in the country. On the other hand, it can be achievable and reasonable to promote such a biotechnology business pool – or even a merged company – out of existing companies from different industrial branches.

The further development of the biotechnology sector in Finland depends on whether the emerging research infrastructure will soon lead to the building up of a significant number of manufacturing plants. In overall terms, the business environment in Finland seems to be less supportive for investment in and use of biotechnology than in the USA and some other parts of Europe. However, there are also some supportive factors. There seems to be widespread agreement that biotechnology could become the fourth pillar of the Finnish exports sector, indicated by the massive public investment in research. Furthermore, the Finns in general are very open to technological development and their attitudes to biotechnology seem to be less negative than those in other European countries. And last but not least, Finnish universities are known for their openness to close co-operation with industry. The centres of expertise seem to create a supportive environment for close university-industry co-operation.

There are also important factors that can hinder the further development of the biotechnology sector in Finland. First, there seems to be a serious shortage of highly qualified scientific staff in the sector, which the government is aiming to overcome by investments in the education infrastructure. There is, however, a demand for qualified engineers in the IT sector as well. Whether in the competition over human resources the biotechnology sector will be able to hold its own will have to be seen. However, there is a lack of students oriented in mathematics and natural sciences in their matriculation examination.

However, there seem to be 'signs in the air' that the Life Sciences studies are on their way to beat the IT engineering studies in popularity. In the USA, graduate enrolment in engineering programmes is down to 15 percent in the year 2000. The

popularity of biomedical studies has increased correspondingly. According to researchers, this is a consequence of students' being used to "following the money".

A major disadvantage is the smallness of the Finnish market. Therefore, companies in Finland have to be globally oriented already from the beginning. However, as some examples demonstrate, the small Finnish biotechnological firms, particularly in the agro-food and pharmaceutical sectors, often lack the management capacity to establish themselves on the foreign and particularly on the most important US market. The companies operating at the national or even at the European level only may soon face serious problems because they lack sufficient awareness of and access to new biotechnological knowledge. Concerning regulatory aspects, Finnish firms suffer the same fate as other European firms. The European regulatory framework seems to have a not so encouraging effect on the competitiveness of European firms.

From our point of view, one of the main directions of the development of biotechnology centres and other research and development institutions seems to be the question of co-ordination. Today there are six Centres of Expertise with a focus on biotechnology in Finland, and at least three "older" institutions. The work of these centres and in these centres is based mainly on public funding, but the share of private venture capital is increasing. Nevertheless, there seems to be a need for a horizontal co-ordination of the work of these centres. Certainly, there are a lot of "policy lines" and administrative bodies, but the co-ordination between them progresses with difficulty. Perhaps because of this, there is a lot of overlapping work done in biotechnology centres. Horizontal co-ordination is needed for directing the biotechnology centres into the areas of their own and into the strong areas of their industrial environment.

Suomenkielinen tiivistelmä

SUOMEN LIFE SCIENCES- TEOLLISUUDEN MUODOSTUMINEN

Life Sciences -teollisuus Suomessa ja Euroopassa

Manuel Castellsin mukaan uusi biotekniikka on todennäköisesti digitaalisen informaatiotekniikan jälkeen seuraava teknologinen läpimurto, ehkäpä uusi teollinen paradigma. Castells näyttäisi nyttemmin yhtyvän OECD:n piirissä jo 1980-luvulla esitettyihin arvioihin uudesta biotekniikasta ja geeniteknologiasta teollista kehitystä voimakkaasti eteenpäin vievänä uutena 'mega-teknologiana'. Aiemminhan Castells tarkasteli Life Sciences -teknologiaa ja geeniteknologiaa vain eräänä informaatioteknologian muotona, joka piisirujen sijasta kohdistaa huomionsa elävän materiaalin ohjelmointiin, uudelleenohjelmointiin ja informaatiokoodeihin (Castells 1996, 30).

Suomessa uuden biotekniikan tarjoamat mahdollisuudet on havaittu eurooppalaisittain suhteellisen varhain. Suomen Opetusministeriö käynnisti yhdessä muiden ministeriöiden kanssa jo 1980-luvun lopulla biotekniikan osaamiskeskusohjelman, joka laajeten ja kehittyen jatkuu edelleen. Ohjelma on edistänyt uusien innovatiivisten Life Sciences -yritysten ja alueellisten osaamisverkostojen syntyä. Tulokset ovat olleet vakuuttavia. Suomeen on kehittynyt viisi merkittävää Life Sciences -osaamiskeskusta, Turkuun, Ouluun, Kuopioon, Helsinkiin ja Seinäjoelle. Lisäksi on pienempiä alan osaamiskeskittyviä eri puolilla maata. Vuosituhannen

vaihteessa joka kymmenes Life Science -yritys Euroopassa on suomalainen ja Suomen bioteknologinen teollisuus on sijoitettu kuudennelle sijalle eurooppalaisissa vertailuissa. Suomalaisen bioteknologian vahvuusalueet löytyvät lääketeollisuudesta, biomateriaalien tuottamisesta, diagnostiikasta ja teollisuuden entsyymien tuotannosta. Suomessa, kuten muuallakin maailmassa, merkittävimmät edistysaskeleet uudessa biotekniikassa on otettu lääketeollisuudessa ja Life Sciences -teollisuuden kehäänkärki onkin löydettävissä tältä alueelta. Muilla teollisuuden aloilla menestys ei ole ollut vastaavaa.

Suomessa toimii 140 yritystä, jotka toiminnassaan hyödyntävät Life Sciences -alan tutkimusten tuloksia. Näistä eräät ovat perinteisiä suuria yrityksiä, kuten Orion ja Raisio, mutta valtaosa yrityksistä on ns. ELISCO:ja (*Entrepreneurial Life Science Company*). ELISCO:t ovat kooltaan pieniä ja yrittäjävetoisia yhtiöitä, minkä katsotaan erottavan ne vakiintuneista suuryrityksistä. Uuden bioteknologian kentällä toimii myös koko joukko ns. tietointensiivisiä yrityspalveluyrityksiä eli KIBS:ejä (*Knowledge-Intensive Business Services*), jotka tuottavat ELISCO:jen ja suurten yritysten tarvitsemia palveluita kliinisen ja prekliinisen testauksen, lakiasioiden ja patentoinnin, markkinoinnin ja yrityskehityksen sekä rahoituksen alueilla. Alan yrityksiä kokoaa yhteen niiden edunvalvonta- ja yhteistoimintajärjestö Suomen Bioteollisuus. Lääketeollisuuden alalla toimivia ELISCO:ja yhdistää Suomen lääkeklusteri -yhdistys.

Ernst & Young konsulttiyhtiö on viime vuosikymmenen alusta lähtien julkaissut vuosittain Euroopan bioteknologian ja Life Sciences -teollisuuden tilaa ja kehitystä kuvaavan raportin. Tällä hetkellä Euroopassa toimii noin 1 400 alan yritystä. Viime vuosikymmenen alkupuolella yritysten määrä kasvoi voimakkaasti Isossa Britanniassa, Hollannissa ja Ranskassa. Myös Etelä-Ruotsiin on kehittynyt merkittävä Life Sciences -keskittymä. Vuosikymmenen loppupuolella voimakkain kasvu näyttää siirtyneen Saksaan, jossa biotekniikkayritysten määrä on lisääntynyt 150 prosentilla viimeksi kuluneiden kolmen vuoden aikana. Saksa onkin ohittanut yritysten määrässä aiemmin Euroopan kärkitilaa pitäneen Iso Britannian.

Saksan menestyksen taustalla on Liittotasavallan Koulutus- ja tiedeministeriön (BMBF) vuonna 1996 käynnistämä BioRegio-ohjelma. Ohjelman taustalla on Saksan jälkeenjääneisyys uuden bioteknologian alueella. Tutkimuksissa havaittiin, että vaikka Saksalla on vahva perinne lääketeollisuudessa, tuottaa Yhdysvallat kolme kertaa enemmän patentteja. 1990-luvulla myös Japani ja Iso Britannia ovat ohittaneet Saksan lääkkeiden tuotannossa. Ohjelma poikkeaa perinteisestä saksalaisesta teollisuuspoliittisesta ohjelmasta siinä, että sen kohteena eivät ole vakiintuneet kemian- ja lääketeollisuuden suuryritykset. Ohjelman tavoitteena on generoida pienten, innovatiivisten yritysten perustamista ja niiden verkottumista. Ohjelma siis tunnistaa sekä innovatiivisten pienyritysten tarpeen uuden bioteknologian kehityksessä että alueellisten yritysverkostojen merkityksen toiminnassa. Tässä ohjelma hyödyntää muiden maiden, mm. Suomen, kokemuksia. Liittotasavaltaan luotiin ohjelman kautta 18 biotekniikka-alueita (*BioRegio*), joista kolme valittiin lisärahoituksen kohteiksi menestyvinä mallialueina. Saksa kykeni hyödyntämään mui-

den maiden kokemuksia myös siinä, että BioRegio-ohjelma kohdistettiin heti alusta uuden bioteknologian edistämiseen lääketieteellisyydessä.

Hollannissa uuden biotekniikan tutkimustuloksia alettiin soveltaa teollisuudessa huomattavasti aiemmin, jo 1980-luvulla. Varhainen liikkeellelähtö on kostautunut uuden teknologian suuntaamisongelmina. Hollannissa kehittämistoiminnan keskiössä ovat olleet maatalous- ja elintarviketeollisuus ja suuret ylikansalliset alan yritykset. Kuluttajien reaktiot ja vastustus on kuitenkin ollut tekijä, joka on rajoittanut ja estänyt uuden biotekniikan soveltamista erityisesti elintarviketeollisuudessa. Juuri tästä syystä uusi biotekniikka on maailmalla, kuten myös Suomessa, löytänyt hedelmällisimmät sovellutusalueensa lääketieteellisyydestä. Kuluttajat luottavat lääketieteellisuuden kontrolli- ja testausjärjestelmiin enemmän kuin elintarviketeollisuuden vastaaviin. Hollannissa parhaita tuloksia uuden biotekniikan soveltamisessa onkin saatu geneettisesti muunneltujen leikkokukkien tuotannon alueella.

Hollannin ongelmana on toiminnan keskittyminen maatalous- ja elintarviketeollisuuden suuryrityksiin. Niiden ympärillä ei toimi riittävän laajaa pienten ja innovatiivisten biotekniikkayritysten verkostoa. Maan hallitus käynnistikin vuonna 1999 *'Actieplan Life Sciences'* -ohjelman, jonka tavoitteena on generoida innovatiivisten pienyritysten ja yritysverkostojen syntymistä. Ongelmia on aiheuttanut myös hallinnon sektoroituneisuus. Hollannin maatalousministeriö hallinnoi ja ohjaa lähes tulkoon kaikkea maatalous- ja elintarviketeollisuuden alan liittyvää julkisen vallan toimintaa, myöskin koulutusta. Maassa toimii muusta koulutuksesta erillään maatalousyliopistojen, maatalousammattikorkeakoulujen ja maatalousammattikoulujen järjestelmä. Tämän sektorisidonnaisen systeemin katsotaan useissa hollantilais-tutkimuksissa rajoittavan liikaa teollista osaamista. Life Sciences -teollisuus alana näyttäisi kehittyvän useampien olemassa olevien teollisuudenalojen perustalta ja edellyttävän nämä kaikki alat kattavaa ja niiden perinteisen osaamisen ylittävää osaamista.

Tutkimuskohde ja menetelmät

Käsillä olevan tutkimuksen kohteena on Life Sciences -teollisuus Suomessa. Tuo teollisuus pohjautuu uusimmille tieteellisille löydöksille ja havainnoille sekä uudentyyppiseen teknologiaan. Tästä syystä on perusteltua väittää Life Sciences -teollisuuden olevan vielä ilmeisen varhaisen kehitysvaiheessa. Tieteellisten menetelmien ja teollisten sovellutusten nopeasta kehityksestä johtuen on hyvin vaikea määrittellä ja käsitteellisesti rajata uutta bioteknologiaa tai Life Sciences -teollisuutta. Laajasti bioteknologialla tarkoitetaan elävien organismien hyödyntämistä teollisten tuotteiden ja palveluiden tuottamisessa. Uudella bioteknologialla kuitenkin viitataan alan viimeisimpään kehitysvaiheeseen eli nk. kolmannen suku-

polven bioteknologiaan. Tämä uusi vaihe perustuu molekyylibiologian alueella saavutettuihin tuloksiin, jotka mahdollistavat mm. elävän olion geneettisen rakenteen muokkauksen ja muuntelun sekä monokloonisten vasta-aineiden hyödyntämisen. On kuitenkin erittäin tärkeää huomata, etteivät geenimanipulaatio ja geeniteknikka ole 'kaikki' uudessa bioteknologiassa. Mukaan mahtuu myös koko joukko molekyylibiologian uusimpia tutkimustuloksia hyödyntäviä 'perinteisempiä' menetelmiä ja suuntauksia, mm. terveysvaikutteisten ravintoaineiden ja teollisuuden entsyymien kehittäminen ja tuottaminen. OECD:n mukaan bioteknologia on ala, jossa luonnontieteet käyvät yksiin teknillisten (insinööri-)tieteiden kanssa uusien tuotteiden ja palveluiden tuottamisessa.

Uuden bioteknologian kehittyminen on vaikuttanut tiedemaailmaan kokoomalla eri tieteenaloja Life Sciences -sateenvarjon alle. Tämä kehitys käynnistyi jo 1970-luvulla. Life Sciences -tieteiden ytimessä ovat sellaiset tieteet kuten biokemiallinen tekniikka, biokemia, kemia, kliininen lääketiede, molekyylibiologia, orgaaninen kemia, farmakologia ja toksikologia. Lisäksi Life Sciences -tiedekonsortioon luetaan melkoinen joukko relevantteja tieteenaloja solubiologiasta tilastotieteeseen. Itse asiassa bioteknologian tiedeperustan muotoutumisen prosessi on niin moniaineksinen, että se on muuttanut koko biotekniikan käsitteen epämääräiseksi. Alan piirissä onkin voimakkaita pyrkimyksiä luopua koko käsitteestä. Bioteknologian sijaan esitetään tässäkin tutkimuksessa käytettyä Life Sciences -käsitettä. Mm. Ernst & Young -yhtiö, joka tekee vuosiraporttinsa EU:n komission toimeksiantosta, on luopunut biotekniikka-sanasta. Vuoden 2000 raportin otsikko on "*Evolution. Ernst & Young's Seventh Annual European Life Sciences Report*".

Suomen teollisuudessa uutta bioteknologiaa sovelletaan olemassa olevien teollisuudenalojen piirissä; ennen muuta lääketeollisuudessa, mutta myös elintarvike-, kemian ja puunjalostusteollisuudessa. On kuitenkin olemassa pyrkimyksiä muusta teollisesta toiminnasta erottuvan itsenäisen Life Sciences -klusterin rakentamiseen. Erityisesti tämän suuntaisia pyrkimyksiä on ollut havaittavissa ELISCO:jen piirissä. Life Sciences -teollisuuden taloudellinen merkitys on kuitenkin vielä perin rajallinen. Esimerkiksi vuonna 1998 alaan kytköksissä olevan teollisuuden liikevaihto oli 7 426 miljoonaa markkaa, mikä on vain 1.1 prosenttia bruttokansantuotteesta. Life Sciences -teollisuus työllistää 5 600 henkeä eli vain 1.3 prosenttia teollisuuden työvoimasta. Reilu kaksi kolmannesta alan työntekijöistä työskentelee uutta biotekniikka soveltavissa lääkeyrityksissä. Life Sciences -teollisuuden marginaalisen aseman ei kuitenkaan tule antaa hämätä; 1970-luvulla elektroniikkateollisuuden osuus Suomen viennistä oli sekin vain pari prosenttia.

Tukeutuen Kreinerin ja Schoultzin (1993) määrittelyyn Suomen Life Sciences -teollisuuden voi sanoa olevan eräänlaisessa 'esi-klusteroitumisen' tilassa. Life Sciences -teollisuutta onkin helpompi tutkimuksellisesti lähestyä muodostuvana teollisena kenttänä, jonka rajat, instituutiot, toimintatavat, tietoperusta jne. ovat edelleen yksiselitteisesti määrittelemättä. Tästä syystä on myöskin mahdollista määritellä uusi bioteknologia teknologiseksi metodiksi tai paradigmaksi, jota sovelletaan olemassa olevien teollisuudenalojen puitteissa ilman, että Life Sciences -perusta koskaan generoisi itsenäistä teollisuudenalaa tai klusteria.

Käsillä oleva tutkimus lähestyy kohdettaan innovaatiojärjestelmätutkimuksen systeemisestä näkökulmasta. Sosiaalisen todellisuuden moniulotteisuus toki edellyttää tutkimukselta ennalta rajoittamatonta ja avointa lähestymistä, eikä kohteen moniulotteisuutta tule teoreettisin määritelmän himmentää. Onnistuneet tieteelliset määrittelyt ja teoriat nousevatkin empiirisestä tutkimuksesta ja sen tulosten käsitteellisestä reflektoinnista. Systeeminen lähestymistapa, jota käsillä oleva tutkimus soveltaa, on rakennettu juuri näin: empiirisen tutkimuksen tulokset ovat jatkuvasti muotoilleet teoreettista viitekehystä.

Tämä tutkimus on kohdistettu erään tietointensiivisen teollisen kentän, Life Sciences -teollisuuden, organisoitumiseen ja sen institutionaalisiin rakenteisiin. Rakenteita on kuitenkin mahdollista lähestyä vain yhteydessä teollisen kentän toimijoihin ja näiden muodostamiin konfiguraatioihin kentällä. Tutkimuksen kuluessa kävi selväksi, että kokonaisuuden kannalta selkein lopputulos on mahdollista saada aikaan konstruoimalla Life Sciences -teollisuuden kentän innovaatiojärjestelmä teollisuudenalakohtaisiksi idea-innovaatioketjuiksi. Esimerkiksi innovatiivisen verkoston malli ei olisi vastannut todellista tilannetta tutkittavan teollisuuden piirissä. Idea-innovaatioketjun ajatellaan koostuvan kuudesta funktionaalisesta alueesta, joiden kaikkien edellytetään osallistuvan menestyksekkäiden innovaatioiden tuottamiseen. Näitä alueita ovat perustutkimus, soveltava tutkimus, tutkimus ja tuotekehitys, tuotanto, laaduntarkastus ja markkinointi.

Innovaatiojärjestelmätutkimuksen systeemisen lähestymistavan tunnetuimpia edustajia ovat Charles Edquist, Chris Freeman, Bengt-Åke Lundvall ja Richard Nelson. Heidän käyttämiensä määrittelyjen mukaan innovaatiojärjestelmä koostuu niistä organisaatioista ja instituutioista, jotka vaikuttavat innovaatiotoiminnan kiihdyttämisen ja tiedon diffuusion suuntaisesti systeemissä. Perustavanlaatuisista innovaatiojärjestelmätutkimukselle on innovaation käsittäminen ennen kaikkea vuorovaikutteisen toiminnan tulokseksi. Innovaatioita etsiessään yritykset ja yliopistot, tutkimuslaitokset ja markkinointiyhtiöt jne. vaihtavat keskenään tietoja, taitoja ja osaamista. Tämä vuorovaikutteinen toimintatapa puolestaan näyttää generoivan alueellisia ja alakohtaisia innovatiivisia verkostoja. Innovaatiojärjestelmätutkimuksen systeemistä lähestymistapaa on mahdollista soveltaa sekä makro-, meso- että mikrotasolla. Makrotason tarkastelujen kohteena ovat kansalliset tai globaalit järjestelmät, mesotason tarkastelut kohdistuvat teollisuuden alaan tai klusteriin ja mikrotason tarkastelut yksittäiseen yritykseen tai jopa yksittäiseen innovaatioon. Käsillä oleva tutkimus liikkuu mesotasolla, ja sen kohteena on uuden bioteknologian soveltaminen *suomalaisilla* eri teollisuudenaloilla.

Innovaatiojärjestelmätutkimuksen systeeminen lähestymistapa rakentaa siltaa perinteisen taloustieteen ja sosiologisen instituutiotutkimuksen välille. Sellaiset sosiaaliset instituutiot, kuten rahoitusjärjestelmä, koulutusjärjestelmä, tutkimusjärjestelmä ja teollisuuden tukijärjestelmä vaikuttavat teollisuuden alan innovaatiokapasiteettiin. Näin tarkastelu ei rajoitu yksikertaiseen "teknologinen työntö–markkinoiden veto" -näkökulmaan, vaan voi avata innovaatioprosessien sosiaalisen maailman koko rikkautessaan. Tutkimus etsii vastauksia kysymykseen suomalaisen Life Sciences -teollisuuden kentän rakenteesta. Onko sen perustalla muo-

dostumassa kokonaan uusi teollinen klusteri vai tapahtuuko toiminta myös tulevaisuudessa toisistaan eroavien teollisuudenalojen puitteissa. Tulevan organisoitumisen muoto aivan ilmeisesti vaikuttaa uuden bioteknologian sovellutuksia hyödyntävän teollisuuden menetykseen niin kansallisesti kuin kansainvälisestikin.

Uusi biotekniikka lääketeollisuudessa

Suomalaisessa teollisuuspolitiikassa Life Sciences -teollisuus identifioidaan yleensä lääketeollisuuteen. Tämä johtuu monestakin tekijästä, joista keskeisimpiä ovat työntekijöiden koulutustaso, yritystoiminnan luonne ja kuluttajien näkökulma. Lääkeyrityksissä työskentelevien koulutustaso on perinteisesti ollut teollisuuden yleiseen kuvaan verrattuna poikkeuksellisen korkea. Läketeollisuus ja erityisesti sen tutkimus- ja tuotekehitystoiminta on työllistänyt paljon paitsi akateemisen loppututkimuksen suorittaneita myös tohtoritason tutkijoita. Yksityinen omistus pohja on myös edistänyt alan profiloitumista. Läketeuotannon vakiintuneet huolelliset ja perusteelliset testausjärjestelmät puolestaan ovat vakuuttaneet kuluttajat tuotteiden turvallisuudesta, mistä johtuen uuden biotekniikan ja geeniteknologian soveltaminen on lääketeollisuuden piirissä ollut helpompaa verrattuna muihin teollisuuden aloihin.

Yritystoiminta lääketuotannon ytimessä

Suomen lääketeollisuus ajautui kriisiin 1990-luvun alkupuolella. Kriisin vaikutukset ovat olleet kahtalaisia. Toisaalla talouden avautuminen horjutti kansallisten suuren lääkeyritysten asemaa. Seurauksena oli toiminnan lopettamisia, uudelleen suuntaamisia ja sulautumisia kansainvälisiin suuryhtiöihin. Orion säilytti ainoana suomalaisena yhtiönä asemansa kentällä. Tässä hetkellä sen osuus Suomen lääke-markkinoista on noin viidennes. Yhdentoista johtavan Suomen markkinoilla toimivan yhtiön joukossa se onkin ainoa suomalainen. Leiras sulautui Shering AG:n suomalaiseksi markkinointiyritykseksi ja Farnos muutti tuotantosuuntansa lääkkeistä teknisiin välineisiin. Toisaalla lääketeollisuuden kriisi vauhditti ELISCO:jen syntymistä. Supistukset ja lakkauttamiset suomalaisten lääkeyhtiöiden tutkimus- ja tuotekehitysosastoilla ulkoistivat korkeasti koulutettua ja osaavaa työvoimaa, joka nopeasti hakeutui yliopistojen yhteyteen perustettuihin biotekniikkakeskukseen ja perusti sinne omia innovatiivisia pienyrityksiään.

Merkittäviä tukipalveluiden organisoijia lääkekehityksen ja tuotannon kentällä ovatkin 1990-luvulla olleet teknologiakeskukset. Suomen Teknologiakeskusten Liittoon kuuluu 19 jäsentä, joista 7:n osaamisalaksi on määritelty bioteknologia. Teknologiakeskukset ovat yhtiöitä, jotka hallinnoivat, ylläpitävät ja kehittävät tekno-

logiakeskusyhteisöä, sen toimintaa ja toiminnan edellytyksiä, kuten laitteistoja ja toimitiloja. Teknologiakeskuksilla on usein myös merkittävä alueellinen rooli. Ne ovat mukana alueensa yritystoiminnan kehittämisessä, muun muassa osaamiskeskusohjelmien kautta. Monet lääketoimialan uusista yrityksistä ja organisaatioista sijaitsevat teknologiakeskuksissa ja saavat näiden kautta keskeisiä resursseja. Teknologiakeskuksia sinällään voidaan myös pitää yrityspalvelujen tarjoajina: osa palveluista voidaan katsoa osaamisintensiiviksi, kuten yrityshautomotoiminta, mutta osa palveluista ei lukeudu osaamisintensiivisiin palveluihin, esimerkkinä tilahallinto.

Tällä hetkellä suomalainen lääketeollisuus on noin sadan yrityksen muodostama teollisuudenala. Suomen Lääketeollisuuden liittoon (Pharma Industry Finland PIF) kuuluu kaikkiaan 69 jäsenyritystä, joista seitsemän on jäsenenä myös Suomen Bioteollisuusliitossa (Finnish Bioindustries FIB). Lisäksi viimeksi mainitun liiton jäsenistä 32 toimii lääketeollisuudessa kuulumatta PIF:n jäsenyyteen. Tämä kertoo melkoisesti suomalaisen lääketeollisuuden orientaatiosta; vain vähemmistö lääketeollisuusyrityksistä on suuntautunut uuden biotekniikan hyödyntämiseen. Toisaalta ei-kiinnostumattomien yritysten joukossa on monia globaalien lääkeyritysten suomalaisia tytäryhtiöitä. Toisella puolen toimii joukko uuteen biotekniikkaan suuntautuneita ELISCO:ja, jotka aivan ilmeisesti eivät pidä hyödyllisenä kuulumista PIF:n jäsenyyteen. Nämä yritykset identifioivatkin itsensä kansallisen 'biotekniikkaklusterin' kautta.

ELISCO:t suuntautuvat uusien lääkkeiden keksimiseen, mistä syystä ne usein käyttävät itsestään keksintöyrityksen (*discovery company*) nimeä. Lääkkeen ideointi alkaa yleensä yliopiston perustutkimuksesta, joka itsessään ei välttämättä tähtää uuden lääkeaineen kehittämiseen. Yliopistojen läheisyyteen (erityisesti Turkuun, Helsinkiin, Ouluun ja Kuopioon) on 1990-luvulla syntynyt pieniä lääkekeksintöyrityksiä. Nämä ELISCO:t etsivät perustutkimuksesta ideoita, joille ne olettavat markkina-arvoa uusien lääkkeiden kehittämisessä. Nämä yritykset toimivat erittäin kiinteässä yhteistyössä yliopiston tutkijoiden kanssa, minkä yhteyden on kansainvälisissä arvioissa todettu olevan Suomessa poikkeuksellisen tiivistä ja innovaatioita edistävää. Usein ELISCO:n perustaja tai joku perustajista onkin kokenut tutkija. Lääkekeksintöihin suuntautuneessa ELISCO:ssa tutkimus- ja kehittämistoiminta on yrityksen ydintoimintona. Tällaisilla yrityksillä ei esimerkiksi ole välttämättä lainkaan liikevaihtoa, sillä ne alkavat tuottaa vasta kun jokin niiden kehittämä ja patentoima lääke on saatu valmiiksi ja markkinoille.

Vastaavaa tutkimus- ja kehitystoimintaa harjoitetaan toki myös perinteisissä isoissa lääkeyrityksissä yhtenä niiden toiminnoista. Kustannuspaineiden helpottamiseksi ja innovaatioiden nopeuttamiseksi suuret lääkeyritykset ovat kuitenkin nyttemmin ulkoistaneet tutkimus- ja kehitystoimintaansa. Uuden lääkeaineen tuottaminen markkinoille maksaa noin 3 000 miljoonaa markkaa ja prosessi yleensä kestää noin viisitoista vuotta. Yhdysvaltalaisen ELISCO:jen ja teknologiayhtiöiden yhteistoiminta näyttäisi kuitenkin olevan tuottamassa geeni- ja informaatioteknologiaan perustuvia sovellutuksia, jotka lyhentävät uuden lääkeaineen kehitystyö-

hön tarvittavan ajan ja pienentävät samalla kustannuksia noin puoleen nykyisestä tasostaan.

Suomalaisilla ELISCO:illa eli keksintöyrityksillä on harvoin omaa 'tavaratuotantoa', yleensä sitä on korkeintaan koemielessä. Idea-innovaatioketjussa suuret lääkeyritykset ovat keskittyneet lääkkeiden tuottamiseen ja markkinointiin. Systemissä ELISCO:t keskittyvät innovaatioiden käyntiin saattamiseen, esimerkiksi 30 prosenttiin koko tuotteistamisprosessista. ELISCO:t, jotka yleensä ovat solmineet yhteistoimintasopimuksen jonkin suuren ja yleensä kansainvälisen markkinointiyhtiön kanssa, myyvät tuottamansa "puolivalmiit innovaatiot" tai lääkeaihiot näille. Suuret yhtiöt huolehtivat prosessin loppuun saattamisesta ja uusien lääkkeiden toimittamisesta apteekin hyllyille. Tarkastelemalla suomalaisen lääketeollisuuden toimintaa idea-innovaatioketjun näkökulmasta havaitaan, että kansallisissa puitteissa toiminta keskittyy ketjun alkupäähän, perus- ja soveltavaan tutkimukseen sekä tutkimukseen ja tuotekehitykseen. Asetelma on toki hedelmällinen ajatellen Life Sciences -teollisuuden tietoperustan ja osaamisen luomista Suomeen, mutta se sisältää myös omat vaaramomenttinsa. Ketjun loppupään tuotantoon ja markkinointiin suuntautuneet osa-alueet sijaitsevat yleensä Suomen ulkopuolella. Näin on mahdollista, että tieto, osaaminen ja myös taloudelliset hyödyt valuvat maan ulkopuolelle.

Modernia biotekniikkaa hyödyntävän lääketeollisuuden osalla pätee sama mikä yleensä pätee Life Sciences -teollisuudessa. Menetyksen saavuttamiseksi on välttämätöntä, että innovatiiviset yritysverkostot kiinnittyvät toimintaa ylläpitävään keskuksen, joka on yleensä globaalin kokoluokan tuotantoon ja markkinointiin suuntautunut yritys. Selitys tälle "hierarkiakeskeiselle verkostoitumiselle" löytyy toiminnan kustannuksista ja aikajänteestä. Lääkkeiden, kuten muidenkin uuden bioteknologian tuotteiden, kehittäminen on tavattoman kallista ja aikaa vievää toimintaa. Innovaatioiden tuotteistaminen ei näillä aloilla käy päinsä käden käänteessä. ELISCO:jen rahoitusperusta on usein siksi epävarma, ettei niiden voi olettaa ylipäätään olevan olemassa 15 tai 20 vuotta, mikä usein on tuotteistamiseen kuluva aika. Suomen uuteen biotekniikkaan perustuvassa lääketeollisuudessa tällainen kokoava ja koordinoiva keskus kuitenkin puuttuu. Tilannetta voisi kuvata verkostona ilman keskusta.

Osaamisintensiiviset yrityspalvelut lääketeollisuudessa

ELISCO:jen syntyminen suomalaiseen lääketeollisuuteen on lisännyt osaamisintensiivisten yrityspalveluiden kysyntää alalla. Hedelmällisin tapa määritellä nämä palvelut (Knowledge-Intensive Business Services KIBS) on lähestyä niitä neljän keskeisen toisiaan täydentävän näkökulman kautta. Tässä lähestymistavassa (Miles ym. 1995; Haukness 1996) osaamisintensiiviset yrityspalvelut ymmärretään organisaatioiksi, jotka

- perustavat toimintansa merkittävästi asiantuntijaosaamiseen,
- joko tuottavat palveluja (mm. tutkimus, konsultointi, koulutus tms.), jotka itsessään ovat primaarisia tiedon lähteitä tai osaamista käyttäjilleen (esim. raportit, mittaukset, asiantuntijalausunnat),
- tai käyttävät osaamistaan tuottaakseen palveluja (mm. erilaiset suunnittelupalvelut), jotka ovat panoksia asiakkaiden omaan osaamisen kehittämiseen sekä tiedon ja informaation tuotantoprosesseihin ja prosessointiin (viestintä- ja informaatiojärjestelmät tms.) ja
- tuottavat palveluja pääasiallisesti toisille yrityksille tai julkisen sektorin organisaatioille.

Edellinen määritelmä on hyvin väljä eikä siinä oteta selkeää kantaa sen keskeisiin osiin, kuten osaamisen tai palvelun käsitteisiin. Esimerkiksi palveluista puhuttaessa on hyvä huomata, että palveluilla tarkoitetaan ensisijaisesti toimintoja. Palvelutoiminnot voivat olla organisoituneina yhtä hyvin suurten tuotantoyritysten osastoiksi tai tiimeiksi kuin itsenäisiksi yrityksiksi tai yritysrajat ylittäviksi projektikohtaisiksi asiantuntijatiimeiksi. Palvelutoiminnot voivat myös sisältyä fyysisiin tai elektronisiin tuotteisiin tai sisältää tällaisia tuotteita osana palveluprosessia. Samoin myös teollisuusyritysten tuottamissa lopputuotteissa on sitoutuneena suuri määrä palvelua. (Vrt. myös Soete 1996.)

Tässä tutkimuksessa käsitellään yhden (teollisuus)toimialan, lääketoimialan, käyttämiä osaamisintensiivisiä yrityspalveluja. Sen sijaan KIBS-organisaatioiden ei ajatella muodostavan omaa toimialaansa eikä niitä lähestytä myöskään perinteisesti palvelutoimialoittain. Menettelyn tarkoituksena on etsiä lääketuotannolle merkittävät asiantuntijapalvelut sitoutumatta toimialapohjaiseen lähestymistapaan palvelujen osalta. Tällöin tutkimuksessa lähdetään liikkeelle nimenomaan palvelutoimintojen käsitteestä. Käytännössä tämä on tarkoittanut sitä, että palveluja ei esimerkiksi ole etsitty Tilastokeskuksen yritysrekisteristä. Sen käyttö lääketuotannon palvelujen kartoittamisessa ei ole hedelmällistä ensinnäkään siksi, että tilastot laahaavat jäljessä, kun taas lääketuotanto on parhaillaan voimakkaan kehityksen vaiheessa. Tästä seuraa, että suuri osa yrityksistä puuttuu saatavilla olevista tilastoista tai niiden tiedot ovat vanhentuneita. Toiseksi lääketuotanto voimakkaasti tutkimukseen sitoutuneena toimialana on organisoitunut monilta osin julkiselta tai puolijulkiselta pohjalta, mikä tarkoittaa käytännössä sitä, että tietyt merkittävät palveluntarjoajat puuttuvat yritystilastoista. Palvelutoiminnot on tässä tutkimuksessa pyritty kartoittamaan niin sanotusti kentältä tutkimalla erilaisia dokumentteja sekä kyselemällä ja haastatteleamalla avainhenkilöiksi havaittuja asiantuntijoita. Merkittäviä palveluja on etsitty myös yksinkertaisesti kysymällä tuotantoketjun yrityksiltä, mitkä (asiantuntija)palvelut niissä koetaan tärkeiksi.

Innovaatiolla tarkoitetaan laajasti määriteltynä hyödyllistä uuden luomista eli uutta ideaa, käytäntöä, tuotetta, palvelua tai muuta lopputulosta, ennen muuta innovaatioissa on kyse rajojen ylittämisestä. Osaamisintensiivisiä yrityspalveluja pidetään erittäin innovatiivisina, mikä seuraa edellä esitetystä tavallisimmasta tutki-

muksellisesta lähestymistavasta, jossa KIBS-organisaatiot määritellään pitkälti uuden tiedon ja osaamisen tuottamisen kautta. KIBS:ien onkin todettu muodostavan keskeisen osan innovaatiojärjestelmiä tai oppimisverkostoja. Asiantuntijapalveluille on luonteenaista, että ne käyttävät hyväkseen uusinta teknologiaa ja tieteellistä tietoa. Niiden palveluprosessit sisältävät yleensä suuren määrän erikoistietoa, jota palveluorganisaatio hankkii, kehittää itse ja välittää edelleen asiakaskuntaansa. Jotta asiakasyritys voi käyttää KIBS-organisaation palveluksia ja saada niistä täyden hyödyn, sillä itselläänkin pitää olla jonkin verran samaa tietoa eli ikään kuin "ankkuroitumisalusta", johon KIBS-organisaation tuoma tieto voi tarttua.

Asiantuntijapalvelun ja sen asiakkaan vuorovaikutussuhteen tuloksena syntyy runsaasti oppimiskokemuksia, joista puolestaan voi kehittyä erilaisia innovaatioita. Tutkimuskirjallisuudessa eritellään usein rooleja, joissa KIBS-organisaatio voi toimia suhteessa asiakasyrityksessä tapahtuvaan oppimiseen ja innovointiin. KIBS-organisaatio voi ensinnäkin olla asiakkaan innovaatioiden *edistäjä* tai *mahdollistaja* tukieessaan asiakasta sen innovaatioprosessissa. Toiseksi sitä voidaan luonnehtia innovaatioiden *välittäjäksi* tai *kantajaksi* sen siirtäessä toisaalla kehitettyjä innovaatioita uusille asiakkaille. Kolmanneksi KIBS voi olla myös innovaation *lähde* osallistuessaan merkittäväällä tavalla asiakkaan innovaatioprosesseihin. Osaamisintensiiviset yrityspalvelut ovat lääketuotannossa edellä kuvattua lääkeideasta markkinoille saatetuksi innovaatioksi (=lääkkeeksi) kulkevaa idea-innovaatioketjua tukevia toimintoja. Näitä toimintoja voidaan löytää jossain määrin myös isojen lääketuotantoyritysten sisältä, mutta suurin osa tukipalveluista on organisoitunut omiksi yrityksikseen tai puolijulkisiksi organisaatioiksi. Ketjua tukevia palveluja löytyy luonnollisesti myös teknologian ja materiaalien toimittajista, mutta etupäässä nämä toimittajat voidaan laskea tyypillisiksi alihankkijoiksi tai yrityksiksi, joiden ketjuun tuoma lisäarvo on enemmän tuote kuin palvelu. Näiden toimittajien osaamisintensiivisyys voi tuki olla hyvinkin korkea, mutta osaamisintensiivisinä *palveluina* niitä ei voida pitää.

Varsinaisiksi osaamisintensiivisiksi yrityspalveluiksi voidaan lääketuotannon alalta luokitella seuraavat:

- prekliininen tutkimus,
- kliininen tutkimus,
- lakiasia- ja patenttipalvelut,
- yritystoiminnan kehittämis- ja markkinointipalvelut,
- rahoituspalvelut.

Edellä esitetyt viisi lääketuotannolle keskeistä osaamisintensiivistä yrityspalvelutoimintoa voidaan jakaa edellä käsiteltyjen innovaatiotyyppien mukaisesti toisaalta niihin, joilla on ensisijaisia vaikutuksia asiakkaan tuoteinnovaatioihin, joissa lopputuloksena on uusi tai parannettu tuote, ja toisaalta niihin, joiden vaikutukset kohdistuvat asiakasorganisaatioon itseensä tai siellä tapahtuviin prosesseihin. On kuitenkin muistettava näiden eri innovaatiotyyppien keskinäiset yhteydet: käsiteltävillä palvelutoiminnoilla on yleensä vaikutuksia sekä tuote- että prosessi- ja

organisatorisiin innovaatioihin. Nämä vaikutukset voivat olla suoria tai epäsuoria.

Prekliinistä tutkimusta tehdään erilaisissa yksityisissä ja julkisissa laboratorioissa. Osa laboratorioista on erillisiä pieniä yrityksiä, osa kuuluu isoihin lääkeyrityksiin ja osa toimii julkisella pohjalla. Laboratorioita löytyy esimerkiksi yliopistojen ja teknologiakeskusten yhteydestä. Prekliinisiä palveluja tarvitaan testattaessa uusien lääkeaihioiden ominaisuuksia ja vaikutuksia sekä toisaalta pyrittäessä täyttämään erilaisten viranomaisten vaatimuksia. Laboratoriot eivät testaa kemikaalien vaikutuksia ihmisissä, mutta saattavat käyttää koe-eläimiä. Niiden työntekijöissä on paljon tutkijoita, joista osa tekee myös perustutkimusta joko laboratorion nimiin osana sen tuotekehitystä tai yliopiston laitoksen palveluksessa. Prekliinistä tutkimusta tekevien laboratorioiden asiakaskunta koostuu sekä lääketuotanto- että lääkekehitysyrityksistä ja lisäksi elintarvikeyrityksistä. Tarjotut palvelut vaihtelevat hyvin standardoiduista yksittäisistä testeistä yhdessä asiakasyrityksen kanssa tehtävään pitkäaikaiseen tuotekehittelyyn. Prekliinisen tutkimuksen palvelut kohdistuvat ensisijaisesti asiakasyrityksen tuoteinnovaatiotoimintaan.

Kliininen tutkimus on Suomessa organisoitunut yksityisiksi tai julkisiksi laboratorioiksi, joilla on läheiset suhteet yliopistoihin. Laboratorioita on perustettu, koska yksittäiset yliopiston tutkijat tai ainelaitokset eivät muiden tehtäviensä ohella voi toteuttaa yksityisten yritysten toimeksiantoja. Laboratorioilla on kiinteät suhteet yliopistollisiin sairaaloihin, koska ne tarvitsevat sekä terveitä että sairastuneita ihmisiä suorittaakseen perustehtävänsä; eri aineiden vaikutusten empiirinen tutkiminen ihmisessä. Myös nämä laboratoriot kirjoittavat todistuksia lääkealaa valvoville viranomaisille. Asiakkaina on pääasiassa lääkeyrityksiä, mutta elintarvikeyritykset uutena asiakaskuntana ovat tulossa mukaan. Kliininen tutkimus tuottaa palveluja selkeästi asiakkaan tuotekehitykselle. Kliininen tutkimus erotetaan lääkealan toimijoiden keskuudessa tiukasti prekliinisestä tutkimuksesta ja näyttää myös siltä, että näitä tutkimuspalvelutyyppjä tekevät eri organisaatiot.

Laki- ja patenttipalvelut ovat erittäin tärkeitä lääkealan yrityksille. Kehitteillä olevat lääkeaihiot pitää saada nopeasti patentoitua, minkä vuoksi laki- ja patenttipalveluja tarvitaan aivan lääkekehittelyn alusta asti. Toisaalta lakiasianpalveluja tarvitaan erilaisten tarkkojen säädösten noudattamiseen. Nämä palvelut ostetaan yleensä yksityisiltä yrityksiltä, mutta isoissa lääkeyrityksissä saattaa olla myös omia lakiasiantuntijoita. Laki- ja patenttitoimistot tarjoavat useimmiten palvelujaan laajalle asiakaskunnalle, mutta usein niiden sisältä löytyy tietyille toimialoille erikoistuneita henkilöitä. Laki- ja patenttipalveluiden voidaan katsoa kohdistuvan ennen muuta yrityksen tuoteinnovaatiotoimintaan.

Markkinointi- ja liiketoiminnan kehittämispalvelut ovat erityisen tärkeitä uusille pienille yrityksille, joissa näitä toimintoja ei ole yrityksen sisällä. Lisäksi lääkealan yrityksiä perustavat usein tieteellisesti tai teknisesti orientoituneet ihmiset, joita varsinainen liiketoiminta ei joko kiinnosta tai sitten heiltä ei löydy tarvittavaa osaamista. Erilaisia konsultointipalveluja tuotetaan sekä julkisesti että yksityisesti. Niitä voidaan tarjota useille toimialoille, mutta jonkinlainen erikoistuminen on myös tavallista. Tyypillisiä kehittämis-/konsultointipalveluja ovat asiakkaan tuotteen markkinointipalvelut, yrityksen toiminnan ja henkilöstön kehittäminen sekä

yrityshautomotoiminta. Konsultointipalvelut kohdistuvat ensi kädessä asiakkaan organisatorisiin ja prosessi-innovaatioihin tähtäävään toimintaan, vaikka niillä voi olla myös tuotekehitystä suuntaavia vaikutuksia.

Rahoituspalvelujen merkitys lääketuotannolle on suuri, sillä uudet yritykset toimivat useimmiten ainakin osittain ulkopuolisen rahoituksen varassa. Rahoitusta järjestävät sekä julkiset että yksityiset organisaatiot. Riskirahoittajat tarjoavat yleensä palvelujaan laajalle asiakaskunnalle. Jonkin verran on kuitenkin olemassa tietyille alalle erikoistuneitakin rahastoja. Rahoituspalvelun voidaan katsoa kohdistuvan asiakkaan organisatorisiin innovaatioihin, sillä yleensä rahoittaja tulee mukaan jonkinlaisessa yrityksen murrosvaiheessa (esim. perustaminen, laajentaminen). Se saattaa osallistua yrityksen hallintoon hallitustyöskentelyn kautta tai tarjoamalla erilaisia konsultatiivisia palveluja, kuten neuvontaa ja kontaktointia. Toisaalta rahoitus voi kohdistua myös suoraan tuotekehittelyyn projektirahoituksena. Näin ollen rahoituspalvelut kohdistuvat rahoittajasta ja asiakkaasta riippuen joko asiakkaan organisatorisiin tai tuote-innovaatioihin.

Lääketoimialan KIBS-organisaatiot toimivat ennen muuta erilaisten rajapintojen tasoittajina. Toimialatasoisia tiedonkulun ja luottamuksen katkoskohtia eli rajapintoja voidaan löytää lääkeyritysten ja yliopistojen väliltä, yritysten ja sairaaloiden väliltä, yritysten ja rahoittajien väliltä, yritysten ja viranomaisten väliltä sekä eri lääkeyritysten väliltä. Jonkin verran KIBS:it toimivat myös esimerkiksi sairaaloiden ja yliopistojen sekä yliopistojen ja viranomaisten välillä. Näin ollen KIBS:it tuottavat palveluja yksityisten yritysten lisäksi merkittävälle joukolle muita toimijoita. Eri toimijoiden välillä on toki suoriakin kontakteja, mutta monesti rajapinnalle sijoittuva KIBS-organisaatio toimii kommunikaation tehostajana ja tiedon siirtäjänä.

Lääketoimialalta löytyy kahdenlaisia KIBS:ejä, joiden roolit alan innovaatiojärjestelmässä ovat jossain määrin erilaiset: *Toimialaspesifit KIBS:it* – joita voidaan myös nimittää toimialaan tiukasti sitoutuneiksi tai toimialariippuvaisiksi – ovat tiukasti sidoksissa lääkealaan ja niitä voidaan kuvata toimialan erikoistiedon syventäjiksi, kun taas *toimialaan erikoistumattomien (ei-toimialaspesifien) KIBS-organisaatioiden* verkostot koostuvat löyhemmistä ja yhtä toimialaa selvästi laajemmalle ulottuvista sidoksista ja niiden voidaan sanoa laajentavan lääkealan toimijoiden tietoperustaa lähinnä liiketoimintaan, siihen liittyviin säännöksiin ja toiminnan kehittämiseen liittyvällä tiedolla. Aineiston toimialaspesifien KIBS-organisaatioiden tieto näyttävää ankkuroituvan muiden KIBS:ien tuomaa tietoa tiukemmin asiakasyrityksen tietopääomaan. Ne toimivat kutakuinkin yksinomaan Life Sciences -teollisuudessa. Myös niiden sisäinen innovaatiotoiminta näyttää olevan strukturoidumpaa ja lääketuotannolle erityistarpeet huomioivampaa kuin toimialaan erikoistumattomien KIBS-organisaatioiden. Näin ollen on selvää, että niiden vaikutukset lääketuotannolle ovat myös suurempia kuin ei-toimialaspesifien. Ei-toimialaspesifit KIBS:it toimivat myös muilla toimialoilla. Kuitenkin on huomioitava, että myös ei-toimialaspesifien KIBS:ien palvelutoiminnot ovat erittäin tärkeitä lääketuotannolle.

Uusi biotekniikka muilla teollisuuden aloilla Suomessa

Suomen elintarviketeollisuuden kentän keskeisiä toimijoita ovat aiemmin kansallisten monopolien asemaan kohonneet suuryritykset, joista useat ovat osuustoyhtiöiden omistusjärjestelyjen kautta kytketty maataloustuotannon tuotantoketjun muihin toimijoihin. Aiemmassa tutkimuksessa tähän kattavaan ja sulkeumatyypiseen rakenteeseen on viitattu maatalous-teollisen kompleksin käsitteellä. Tutkimusten mukaan tämä yksinapainen rakenne on paitsi estänyt aidon kilpailutilanteen muodostumista myös hidastanut ja estänyt teollisuudenalan kehitystä ja uusien innovaatioiden syntyä. 1990-luvun muutokset, ennen muuta Suomen talouden avautuminen kansainväliselle kilpailulle, ovat muuttaneet yritysten toimintaympäristöä siinä määrin, että niiden on ollut enemmän tai vähemmän pakko muuttaa toimintatapaansa. Myös elintarviketeollisuuden 1990-lukua ovat tahdittaneet kriisit ja yritysfaussit.

Perinteisen elintarviketeollisuuden toimintaa on tukenut valtion rahoittama tutkimuksen ja kehitystoiminnan organisaatorakenne, jonka keskeisiä toimijoita ovat Maatalouden tutkimuskeskus ja Valtion teknillinen tutkimuskeskus. 1990-luvulla ne molemmat ovat ottaneet merkittäviä askeleita uuden bioteknologian alueella. MTT on mm. kehittänyt juustoja ja muita geneettisesti muunneltuja elintarviketuotteita, ja VTT:n bioteknologian yksikkö mm. GMO-hiivan. Nämä tuotteet eivät ole kuluttajien epäluulojen takia koskaan päätyneet yritysten tuotantolinjoille ja kaappoihin, mutta niiden synnyttämisen prosessilla on ollut suuri merkitys Life Sciences -teollisuuden kansallisen tietopohjan luomisessa ja vahvistamisessa. Molemmat tutkimuslaitokset toimivat tiiviissä yhteistyössä suomalaisten ja ulkomaisten yliopistojen kanssa ja niiden käytettävissä on erittäin korkeasti koulutettu ja osaava henkilökunta.

Menestyksekkäintä bioteknologinen tutkimus ja tuotekehitys on ollut funktionaalisten elintarvikkeiden alueella. Niitä ja niiden tuottamista ei tule missään tapauksessa sekoittaa geeniteknologiaan. Niiden kehittämisessä ja tuotannossa on kyse uuden bioteknologisen tutkimuksen avaamien mahdollisuuksien hyödyntämisestä perinteisen elintarvikkeiden tutkimuksen ja tuotekehityksen alueella. Tunnetumpia terveysvaikutteisia elintarvikkeita ovat Xylitol, Rasion Benecol sekä Valion Gefilus ja Evolus. Mielenkiintoisesti takaiskut ja menestykset funktionaalisten elintarvikkeiden tuotannossa näyttävät edistävän perinteisten elintarviketeollisuuden yhtiöiden yhteistoimintaa. Suomalaisen elintarviketeollisuuden kansainvälisen kilpailukyvyn kannalta onkin tärkeää, että voimia ja osaamista kootaan nykyistä enemmän yhteen innovatiiviseksi verkostoksi yritysperusteisen erillisyyden sijaan.

1990-luvun loppua kohden, erityisesti maataloustuotteiden kehittämiseen suuntautuneiden biokeskusten perustamisen jälkeen myös elintarviketeollisuuden piiriin on syntynyt ELISCO:ja. Tärkein biokeskus tällä alalla on Helsingissä sijaitseva Viikin keskus. Elintarviketeollisuuden ELISCO:jen määrä on kuitenkin perin vähäinen verrattuna lääketeollisuuden ELISCO-verkoston yritysten määrään. Jossakin mielessä on kuitenkin perusteltua kuvata elintarviketeollisuuden kenttää kaksina-paisena systeeminä, jonka hallitsevan kohtion muodostavat perinteiset elintarviketeollisuuden yritykset ja niiden tukioorganisaatiot ja toisen, edelliseen verrattuna paljon heiveröisemmän, kohtion uudet ELISCO:t ja niiden toimintaa tukevat organisaatiot. Kaksina-paisen kentän mallia puolustaa sekin seikka, että perinteisten elintarviketuotantoyhtiöiden ja uusien bioteknologiakeskusten ja ELISCO:jen yhteistoiminta on kangerrellut monessa tapauksessa. Bioteknologiakeskusten elintarviketuotantoon suuntautuneet ELISCO:t toimivat lääketeollisuuden vastaavien tapaan, eli ne etsivät yliopistojen perustutkimuksesta kiinnostavia ideoita, joita ne jalostavat innovaatioiksi. Näitä innovaatioita ei kuitenkaan pyritä itse tuotteistamaan, vaan ne myydään aihioina tuotantoa ja markkinointia harjoittaville yrityksille.

Uuden bioteknologian paikka elintarviketeollisuuden idea-innovaatioketjussa sijaitsee korostuneesti ketjun alkupäässä; maassamme harjoitetaan suhteellisen laajasti Life Sciences -perusteista tutkimustoimintaa yliopistoissa ja tutkimuslaitoksissa. Toiminnan tulokset kuitenkin perin harvoin löytävät tiensä tuotteiksi. Innovaatiojärjestelmätutkimuksen näkökulmasta katsottuna elintarviketeollisuuden tilanne Suomessa muistuttaa jossain määrin Hollannin vastaavaa. Teollista kenttää hallitsee joukko pitkät perinteet omaavia suuria yrityksiä, mutta alalta puuttuu innovatiivisten pienyritysten verkosto. Tämänkaltaisen tilanne on innovaatiiovetoisessa taloudessa vähintäänkin yhtä ongelmallinen kuin lääketeollisuuden tilanne, jossa on verkosto vailla kansallista keskusta. Tilanne toki on paranemaan päin, varsinkin uusien maatalouteen ja elintarviketeollisuuteen suuntautuneiden biokeskusten perustamisen jälkeen.

Puunjalostusteollisuuden piirissä tilanne on hyvin samantapainen. Metsäntutkimuslaitoksella on ollut ja on käynnissä koko joukko uuden bioteknologian tutkimushankkeita, joilla mm. pyritään parantamaan metsän tuottavuutta. Tutkimustulosten jalostaminen innovaatioiksi ja niiden tuotteistaminen on kuitenkin vähäistä, ellei peräti olematonta. Toki joitakin menestyksekkäitä bioteknologisia innovaatioita on tuotteistettu, mm. selluloosan valkaisuissa. Alan tutkimustoiminnan painopiste ei kuitenkaan ole Life Sciences -aloilla, vaan perinteisemmällä alueella. Uusia innovatiivisia ELISCO:ja ei metsäteollisuuden alalle ole vielä syntynyt, mikä johtuu paljolti siitä, ettei yksikään uusista biokeskuksista keskeisesti suuntaudu metsäteollisuuteen.

Johtopäätöksiä: Menestyksellistä politiikkaa on syytä kehittää

Opetusministeriö käynnisti bioteknologian ensimmäisen kansallisen tutkimusohjelman vuonna 1987. Life Sciences -teollisuuden vauhdittamisen asioissa Suomi on ollut liikkeellä varhaisessa vaiheessa, esimerkiksi Saksaan verrattuna maallamme on kymmenen vuoden etumatka. Tutkimusohjelma edellytti neljän bioteknologia-keskuksen perustamista ja tällaiset keskuskeskukset perustettiin Helsinkiin, Turkuun, Kuopioon ja Ouluun. Vuonna 1992 ohjelma arvioitiin menestyksekkääksi ja sitä päätettiin jatkaa vuoteen 1996 saakka. Sitten ohjelmaa on päätetty jatkaa edelleen. Paitsi Opetusministeriö, ohjelman rahoitukseen ovat osallistuneet myös Kauppa- ja teollisuusministeriö, Maa- ja metsätalousministeriö sekä Sosiaali- ja terveystieteiden ministeriö. Se tosiseikka, että tällä hetkellä joka kymmenes Life Sciences -yritys Euroopassa on suomalainen ja että Suomen uusi biotekniikka on rankattu kuudennelle sijalle eurooppalaisessa kontekstissa, kertoo paitsi biotekniikan tutkimusohjelman saavuttamasta menestyksestä myös siitä, että julkisen vallan toimin on todellakin mahdollista synnyttää ja vauhdittaa uutta innovatiivista yritystoimintaa.

Life Sciences -teollisuuden innovaatiojärjestelmä Suomessa on kokonaisuus, jossa yritysten ohella tärkeitä toimijoita ovat biotekniikan osaamis- ja teknologiakeskukset, yliopistot ja korkeakoulut sekä sellaiset rahoitusinstituutiot kuten Suomen Akatemia, Tekes ja Suomen itsenäisyyden juhluvuoden rahasto Sitra. Suomalaista Life Sciences -teollisuutta on kutakuinkin mahdoton tarkastella irrallaan innovaatiojärjestelmän kokonaisuudesta, olletikin jos tavoitteena on kokonaisuuden ymmärtäminen. Tällä hetkellä maassamme toimii jo seitsemän osaamis- ja teknologiakeskusta, jotka ilmoittavat toimivansa uuden bioteknologian alueella. Tämä lienee aluepoliittisesti perusteltua, innovaatioiden tuottamisen näkökulmasta se sen sijaan on ongelmallista. Useat tutkimukset ovat osoittaneet menestyksekkään innovatiivisen verkoston edellyttävän paitsi alueellista keskittymistä myös riittävän suurta "osaamismassaa". Osaamisen liiallinen maantieteellinen hajottaminen voi ajan mittaan osoittautua kehitystä hidastavaksi tekijäksi. Yhtäkaikki, saksalaisen BioRegio-ohjelman toteutuksesta toki voi ottaa oppia ja keskittää rahoitusta tulevaisuudessa keskustusten saavuttaman menestyksen perusteella.

Toimeliaisuuden sijoittuminen idea-innovaatioketjun alkupäähän kertoo siitä, että Suomessa ollaan edelleen luomassa tietoperustaa Life Sciences -teollisuudelle. Keskeisellä sijalla tietoperustan luomisessa ovat paitsi yliopistojen koulutus ja suomalaisyritysten tutkimus- ja kehitystoiminta myös tutkijoiden työskentely ulkomaisissa yliopistoissa ja tutkimuslaitoksissa sekä yrityksissä. Lundvallin (1999) mukaan uuden bioteknologian osaaminen on hyvin riippuvainen yliopistojen tarjoamasta muodollisesta ja teoreettisesta koulutuksesta. Tästä yliopistojen tarjoaman tiedon keskeisyydestä alalla johtuu myös se, että Life Sciences -tieto on luonteel-

taan hyvin pitkälle kodifioitua. Tästä näkökulmasta tarkasteltuna suomalainen politiikka on oikeilla jäljillä investoidessaan paljon bioteknologian koulutukseen niin maisteri- kuin tohtoritasollakin. Life Sciences -alojen koulutuksen ehkä tärkein ongelma liittyy riittävän motivoituneiden ja osaavien opiskelijoiden rekrytoimiseen koulutusohjelmiin. Life Sciences -alat nimittäin joutuvat kilpailemaan informaatio- ja telekommunikaation koulutusalojen kanssa samoista opiskelijoista eli lukion pitkän matematiikan kurssin suorittaneista. Tulevaisuudessa näiden osaamisresurssien riittävyys voikin osoittautua kehitystä hidastavaksi pullonkaulaksi. Toisaalta kokemukset Yhdysvalloista kertovat opiskelijoiden kiinnostuksen muutamana viime vuoden aikana kääntyneen IT-aloilta biotekniikkaan.

Suomen Akatemia ja Tekes ovat vuodesta 1988 lähtien toteuttaneet useita Life Sciences -alojen ja teollisuuden tutkimusohjelmia. Esimerkiksi vuoden 2001 alusta Tekes käynnisti Lääke 2000 -tutkimusohjelman, joka jatkuu aina vuoteen 2006 saakka. Ohjelman kokonaisbudjetti on 600–900 miljoonaa markkaa, josta Tekesin osuus on yhdeksän kymmenesosaa. Akatemia rahoittaa ohjelmaa ensimmäisinä kolme vuotena 20 miljoonalla markalla. Sitran rahoituksessa Life Sciences -teollisuus on noussut eniten rahoitetuksi teollisuudenalaksi. Suomalainen Life Sciences -teollisuus onkin vielä varsin riippuvainen julkisin varoin toimivasta rahoituksesta. Esimerkiksi vuonna 1997 vain 0,4 prosenttia yksityisistä riskisijoituksista Suomessa ohjautui uuteen bioteknologiaan. Alalle syntyneiden uusien yritysten määrä ja ensimmäisten listautuminen pörssiin kertovat kuitenkin siitä, että panostus alalle on ollut kannattavaa.

Suomalaisen Life Sciences -teollisuuden yleiskuva tällä hetkellä on sellainen, että alan menestyksekkäimmällä loholla eli lääketeollisuudessa on olemassa innovatiivisten ELISCO:jen verkosto, mutta ei kansallista koordinoivaa ja toimintaa kannattelevaa keskusta. Muiden teollisuudenalojen, erityisesti elintarviketeollisuuden piirissä tilanne on päinvastainen, niillä on olemassa useampiakin suuryrityksiä, mutta perin heiveröiset innovatiivisten ELISCO:jen verkostot. Prevezerin (1998) ja Saviottin (1998) mukaan menestyksekkään Life Sciences -teollisuuden syntyminen kuitenkin edellyttää paitsi innovatiivisia pienten ja keskisuurten yritysten verkostoja myös näiden verkostojen kiinnittymistä toimintaa kannattelevaan keskuksen, joka yleensä on globaalin luokan suuryritys. Tämä vaatimus perustuu innovaatio-toiminnan poikkeukselliseen pitkäsyklisyyteen ja kalleuteen biotekniikassa. Tässä Life Sciences -teollisuus poikkeaa esimerkiksi IT-alasta. Toisaalta kansallisen keskuksen olemassaolo turvaa Life Sciences -teollisuuden osaamisen ja hyötyjen pysymisen Suomessa.

On mahdollista, että kansallinen keskus voi muodostua olemassa olevien suuremman kokoluokan yritysten Life Sciences -toiminnan verkottumisen ja yhteistoiminnan tiivistymisen kautta. Tähän suuntaan viittaavia tendenssejä toki löytyy, esimerkiksi Valion ja Raision yhteistoiminnasta funktionaalisten elintarvikkeiden tuotannon alalla tai elintarviketuotannon "medisinalisaatiosta". Viimeksi mainitulla tarkoitetaan funktionaalisten elintarvikkeiden terveysvaikutusten kliinisen testaamisen aiheuttamaa kehitystä, jonka seurauksena elintarviketeollisuuden eräät osat ja lääketeollisuuden toimintaympäristö ja toimintatavat alkavat lähentyä toisiaan.

Ilmiö on toki tunnistettu teollisuudessa; eräät lääketieteellisuuden ELISCO:t ovat laajentamassa toimintaansa terveysvaikutteisten elintarvikkeiden alueelle, ja eräät kliiniseen ja prekliiniseen testaukseen erikoistuneet KIBS:it toimivat molempien teollisuudenalojen piirissä. Kansallinen keskus on näin mahdollista toteuttaa yritysten jonkinasteisen sulautumisen kautta. Tämä tie kansallisen keskuksen luomiseksi on kuitenkin ilmeisen vaivalloinen ja hidas. Aivan ilmeisesti nopeampia tuloksia on saavutettavissa jo nyt olemassa olevan rakenteen kehittämisen kautta. Esimerkiksi Suomen bioteknologiakeskusten toimintaa on mahdollista kehittää siihen suuntaan, että ne yhdessä kantavat vastuun osaamisen ja innovatiivisen toiminnan hyötyjen ohjaamisesta Suomeen.

References

- ABA (1999) 'What is genetic engineering?' No. 2, Australian Biotechnology Association Ltd, online-edition: <http://www.aba.asn.au>.
- Ahola, E. & Kuisma, M. (1998) 'The Biotechnological sector in Finland: From laboratory to an expropriator of promises' [Biotekniikkasektori Suomessa: Laboratoriosta lupausten lunastajaksi], TEKES: Technology Development Centre Finland, *Technology Review* 61/98.
- Audretsch, D. B. & Stephan P. E. (1996) 'Company-scientist location links: The case of biotechnology', *American Economic Review* 86, 3: 641–652.
- Bartholomew, S. (1997) 'National systems of biotechnology innovation: Complex interdependence in the global system', *Journal on International Business Studies* 28, 2: 241–267.
- Beck, U. & Giddens, A. & Lash, S. (1995) *Reflexive modernization. Politics, tradition and esthetics in the modern social order*, Cambridge: Polity Press.
- Bessant, J. & Rush, H. (1995) 'Building bridges for innovation: the role of consultants in technology transfer', *Research Policy* 24, 97–114.
- Bilderbeek, R., den Hertog, P., Marklund, G. & Miles, I. (1998) 'Services in innovation: Knowledge-Intensive Business Services (KIBS) as co-producers of innovation', SI4S Synthesis Paper, STEP Group.
- Bourdieu, P. & Wacquant, L. J. D. (1992) *Innovation to reflexive sociology*. Chicago: The University of Chicago Press Chicago. <http://www.step.no>
- Braczyk, H.-J., Cooke P. & Heidenreich, M. (eds.) (1998) *Regional innovation systems*, London: UCL Press.
- Castells, M. (1996) *The information age: Economy, society and culture*, Volume I: The rise of the network society, Oxford: Blackwell.
- Deutscher Bundestag (2000) "Zur Situation der Biotechnologie in Deutschland", Antwort der Bundesregierung auf die Kleine Anfrage der Abgeordneten Annette Widmann-Mauz, Wolfgang Lohmann (Lüdenscheid), Dr. Wolf Bauer, weiterer Abgeordneter und der Fraktion der CDU/CSU, BT-Drs. 14/3969, August 2, 2000.
- Edquist, C. (ed.) (1997) *Systems of innovation. Technologies, institutions and organisations*, London: Pinter.
- Enzing, C. (2000) *Dutch cluster policy and the character of regional concentration of biotech firms*, paper presented at the workshop 'Comparing the Development of Biotechnology Clusters', in Stuttgart, Germany, 27–28 January 2000. The Centre of Technology Assessment in Baden-Württemberg.
- Ernst & Young International (1999) *Communicating value. European Life Sciences 99, Sixth Annual Report*, London.
- Ernst & Young (2000) *Evolution. Ernst & Young's Seventh Annual European Life Sciences Report 2000*, London: Ernst & Young: Life Sciences Group.
- Ernst & Young (2000) *Gründerzeit. Zweiter Deutscher Biotechnologie-Report 2000*, Stuttgart.
- EU (1997) *The Europeans and modern biotechnology. EUROBAROMETER 46.1*, European Commission: Science, Research, Development, Brussels-Luxembourg.
- European Commission (2000) *Inventory of public biotechnology R&D programmes in Europe, Volume 2: National Reports*, Luxembourg.
- EuroStat (2001) *Statistics on Innovation in Europe. Data 1996–1997*. European Commission, Luxembourg.
- Faulkner, W. & Senker, J. (1995) *Knowledge frontiers – Public sector research and industrial innovation in biotechnology. Engineering ceramics and parallel computing*, Oxford: Clarendon Press.

- Finnish Bioindustries (2000) *Index of biotechnology companies, organisations and science centres in Finland*.
- Granberg, L. (1979) 'The Location of Agriculture' ['Maatalouden asema'], in Kosonen et al. (eds.) *The Finnish Capitalism [Suomalainen kapitalismi]*, Helsinki: Love Kirjat.
- Hage, J. & Hollingsworth, J. R. (2000) *Idea-innovation networks: a strategy for integrating organizational and institutional analysis*. Unpublished paper.
- Halme, K. (1996) *Biotechnology as a branch of new enterprises*. [Bioteknikka uusien yritysten toimialana], VTT: Reports 24/96, Helsinki.
- Hatchuel, A. & Weil, B. (1995) *Experts in organisations: A knowledge-based perspective on organizational change*, Berlin-New York: Walter de Gruyter.
- Haukness, J. (1996) *Innovation in the service economy*, Oslo: STEP Group.
- Heikonen, M. (1990) *AIV - Keksintöjen aika*, Helsinki: Kirjayhtymä..
- Heiskala, R. (2001) 'Informationaalinen vallankumous, verkko ja kulttuurinen identiteetti. Manuel Castellsin Informaation ajan käsitteistön kritiikki', *T & E -tiede & edistys*, Vol 26, No 1:34–44.
- Jalkanen, M. (1998) 'From academic networking to new bioindustries', in *High Technology Finland 1999*, Helsinki-Forsaa, Finnish Academies of Technology and The Finnish Foreign Trade Association, 20–21.
- Jauho, M. & Niva, M. (1999) *A risk or a future's commitment [Riski vai tulevaisuuden lupaus. Geeniteknikkaa elintarviketuotannossa koskevat käsitykset ja julkinen keskustelu]*, Kuluttajatutkimuskeskus, Julkaisuja 5/1999.
- Jäppinen, A. & Pulkkinen, M. (1999) 'Biotechnology as a focus domain in research' [Bioteknikka tutkimuksen painopistealana], *Yliopistotieto* 3/99, 10–13.
- Kasanko, M. & Tiilikka, J. (1999) *Osaamisintensiivisen palvelusektorin kehitys Suomessa*, Helsingin Kauppakorkeakoulu, Liiketaloustieteellinen tutkimuslaitos, Julkaisuja B 148.
- Kekkonen, T. & Nybergh, P. (1999) 'Biotechnology as a breeding ground of new technology' [Bioteknikka uuden teknologian kasvualustana], *Yliopistotieto* 3/99, 18–20.
- Kenney, M. (1986) *Biotechnology; university-industrial complex*, New Haven, Connecticut: Yale University Press.
- Ketonen, K. & Nyyssölä, K. (1996) *Policy of award, [Palkitsemisen politiikka]* University of Turku, Research Unit for the Sociology of Education, Reports 39, Turku.
- Kreiner, K. & Schoultz, M. (1993) 'Informal collaboration in R&D. The formation of networks across organisations', *Organisation Studies* 14/2.
- Kuisma, M. (1993) *The land of wood processing industries. Finland, forests and the international system 1620–1920 [Metsäteollisuuden maa. Suomi, metsät ja kansainvälinen järjestelmä 1620–1920]*, The Historical Association of Finland and The Association Finnish Wood-Processing Industries, Helsinki: Gummerus.
- Kuusi, H. (1999) *Biotechnology: A promising high-tech sector in Finland*, <http://www.finbio.net/nature-fin.htm>.
- Lievonen, J. (1999) *Technical opportunities in biotechnology*, Technical Research Centre of Finland (VTT), Group of Technology Studies, Working Papers 43/99.
- Lindqvist, O. V. (1999) 'The university of Kuopio invests in education of biotechnology', *Yliopistotieto* 3/99.
- Lovio, R. (1993) *Evolution of firm communities in new industries, the case of Finnish electronics industry*, The Helsinki School of Economics and Business Administration, Helsinki.
- Lundvall, B-Å. (1999) 'Understanding the role of education in the learning economy: The contribution of economics', in CER/CD (99)10 *Knowledge Management in the Learning Society*, Paris: OECD.
- Makarov, M. (1999) 'Tutkijakoulutuksella tuloksiin', Ministry of Education, *Yliopistotieto* 3/99.
- Michelsen, K-E. (1999) *The fifth estate, [Viides sääty]* The Historical Association of Finland and the Association of Technical Academics, Helsinki: Gummerus.
- Miettinen, R., Lehenkari, J., Hasu, M. & Hyvönen, J. (1999) *Osaaminen ja uuden luominen innovaatioverkossa*, Helsinki: SITRA.

- Miles, I. (1996) *Innovation in services: Services in innovation*, Manchester Statistical Society, 20th February 1996.
- Miles, I. (1998) 'Services in national innovation systems: From traditional services to knowledge-intensive business services', paper prepared for international seminar: Challenges of the Finnish Innovation System, Helsinki, November 1998.
- Miles, I. & Kastrinos, N. with Flanagan, K., Bilderbeek & den Hertog, P. with Huntink, W. & Boumnan, M. (1995) *Knowledge-Intensive Business Services. Users, carriers and sources of innovation*, in European Innovation Monitoring System (EIMS), EIMS Publication Nr. 15.
- MTK (1976) *Price formation of agricultural products and farmers' commercial co-operation*, [Maataloustuotteiden hinnanmuodotus ja maanviljelijöiden kaupallinen yhteistoiminta] The Central Union of Agricultural Producers in Finland (MTK), Publications Nr. 10. Tapiola.
- Murphy, R. (1988) *Social closure. The theory of monopolisation and exclusion.*, Oxford: Clarendon Press.
- Nelson, R. & Winter, S. (1992) *An evolutionary theory on innovation*, Cambridge Ma: Harvard University Press.
- Nilsson, A., Pettersson, I. & Sandström, A. (2000) *A study of the Swedish biotechnology innovation system using bibliometry*, Swedish National Board for Industrial and Technical Development – NUTEK: Innovation Policy Studies, Working Paper, Stockholm.
- Nyqvist, L., Ojanen, M. & Tulkki, P. (1991) *Pitäjänkierrosta perusturvaan*, Helsinki.: Kirjayhtymä.
- OECD (1988) *Biotechnology and the changing role of government*, Paris.
- OECD (1996) *The OECD jobs strategy: Technology, productivity and job creation*, Vol. 4: Analytical Report. Paris: OECD.
- OECD (2000) *Science, technology and industry outlook 2000*, Paris: OECD.
- Oliver A. L. & Montgomery, K. (2000) 'Creating a hybrid organizational form from parental blueprints: The emergence and evolution of knowledge firms', *Human Relations* 53, 1: 33–55.
- Ollus, M. et al. (1990) *Joustava tuotanto ja verkostotalous. Tekniikan, talouden ja yhteiskunnan vuorovaikutus 1990-luvulla*, [Flexible production and network economy. Interaction of technology, economy and society in the 1990s], Sitra 109, Helsinki.
- Piirainen, T., Järvensivu A. & Kautonen, M. (2000) 'Asiantuntemus kasvualana. Tuotteistaminen, innovaatiotoiminta ja kansainvälistyminen Pirkanmaan osaamisintensiivisissä yrityspalveluyrityksissä', julkaisematon loppuraportti, Tampereen Teknologikeskus Oy.
- Pratt, J. & Burgess, T. (1974) *Polytechnics: A report*, Pitman. Bath.
- Prevezer, M. (1998) 'Clustering in biotechnology in the USA', in Swann, P., Prevezer, M. & Stout, D. (eds.) *The dynamics of industrial clustering: International comparisons in computing and biotechnology.*, New York: Oxford University Press.
- Rannikko, E. & Tulkki, P. (1999) 'Innovations and the field of biotechnology. A study of BioCity', unpublished manuscript, Turku.
- Saarinen, N. T. (1999) Finnish science parks benefit companies and investors, in *High Technology Finland 1999*, 32.
- Shan, W. & Hamilton, W. (1991) 'Country-specific advantage and international co-operation', *Strategic Management Journal* 12, 6: 419–432.
- Shan, W. & Walker, G. (1994) 'Interfirm co-operation and start-up innovation in the biotechnological industry', *Strategic Management Journal* 15, 5: 387–394.
- Saviotti, P. P. (1998) 'Industrial structure and the dynamics of knowledge creation in biotechnology', in Senker, J. (ed.) *Biotechnology and competitive advantage; Europe's Firms and the US challenge*, Edward Elgar Publishing Ltd.
- Saxenian, A. L. (1994) *Regional advantage. Culture and competition in Silicon Valley and Reute 128*, Cambridge (Mass.) & London: Harvard University Press.
- Schienstock, G. & Tulkki, P. (2000) 'The fourth pillar? An assessment of the situation of the Finnish biotechnology', *Small Business Economics, An International Journal* 17, 1–2, Kluwer Academic Publishers.

- Senker, J. (1998) 'Biotechnology: the external environment', in Senker, J. (ed.) *Biotechnology and competitive advantage; Europe's firms and the US challenge*, Edward Elgar Publishing Ltd.
- SITRA 25 years: *Bridging the research and the economy* [Tutkimuksen ja talouden sillanrakentaja], The Finnish National Fund for Research and Development 1967–1992, Helsinki.
- TEKES (1998) *Technology and future*, [Teknologia ja tulevaisuus] Technology Development Centre Finland, Technology Review.
- TIEKE (1999) *IT cluster Finland review*, TIEKE Information Technology Development Centre, Helsinki.
- Tulkki, P. (1996) *State service or work in industry? Engineer education as a social phenomenon 1802–1939*, University of Turku: Research Unit for the Sociology of Education, Report 38, Turku.
- Tulkki, P. (1999a) 'Korkeakoulutus ja tulevaisuuden työelämän haasteet', in *Tekniikan oppia ja teollista osaamista*, Satakunnan ammattikorkeakoulu, Tekniikan Porin yksikkö, Helsinki: Edita, 187–201.
- Tulkki, P. (1999a) 'The birth of engineer education in Finland', *European Journal of Engineering Education*, Vol 24 Nr 1 March 1999, SEFI: Paris-London, 83–94.
- Tulkki, P. (1999b) 'Two types of engineers in a slowly industrialising Finland', *History and Technology* 16, 1: 33–66, Paris-London: Harwood Academic Publishers, The Gordon and Breach Publishing Group.
- Tulkki, P. (2001) 'Finnish way to the information society: Expanding engineer education', *European Journal of Engineering Education* 26, 1. A Taylor & Francis Journal, SEFI: Paris-London. (forthcoming)
- Vihko, R. & Pauli, A. (1999) 'Centres of excellence in bio sciences – The role of the Academy of Finland in financing bio sciences' [Biotieteiden huippuyksiköt – Suomen Akatemian rooli biotieteiden rahoituksessa], *Yliopistotieto* 3: 14–17.
- Väänänen, K. (1999) 'Masters of the health biosciences from the university of Turku', *Yliopistotieto* 3/99.
- Zucker, L. G., Darby, M. R., Brewer M. B. & Peng, Y. (1996) 'Collaboration structure and information dilemmas in biotechnology. Organizational boundaries and trust production', in Kramer, R. M. & Tyler, T. R. (eds.) *Trust in organizations. Frontiers of theory and research*, 90–113.

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