Innovation through Biotechnology in Healthcare and Food & Drink Companies in Ireland

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by

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DECLARATION

The present thesis "Innovation Through Biotechnology in Healthcare and Food and Drink Companies in Ireland" is based on the work of Deirdre Mullen, post graduate research student at the Dublin Business School, Dublin City University, during the period November 1988 - September 1990. The research was carried out under the supervision of Professor Peter Chisnall, Head of Management Division, Dublin Business School, Dublin City University.

Deirdre Mullen

Signature of Research Student

Signature of Supervisor

To my Parents

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ABSTRACT

This study was carried out to synthesize qualitative research data on innovation strategies of Healthcare, and Food and Drink companies in Ireland involved in biotechnology research and development in Ireland, for the purpose of determining in a pragmatic manner the level of activity and types of innovation strategies pursued.

Several types of innovation strategies through biotechnology have been identified. These strategies vary according to company type, company size and industry sector. Furthermore, those companies which represent a potential of considerable creativity in the innovation of products through biotechnology in Ireland have been identified.

Thus, the medium involvement long-term planners identified in this study represent a source of entrepreneurial potential for the commercialisation of biotechnology in Ireland.

Policy makers must investigate the implication of this for further biotechnology development in Ireland.

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CHAPTER 1: RESEARCH STUDY OUTLINE

1.1 INTRODUCTION

This section of the present thesis outlines the research problem and the thesis outline. The section also includes a discussion on the importance of the two industrial sectors chosen as the focus of the study in the context of the Irish economy. The operational definition of certain terms employed during the present research study are outlined also.

1.2 THE RESEARCH PROBLEM

This study involves an examination of the innovation strategies associated with companies involved in the development of a research field. The research field selected for the study is biotechnology. In the history of its development, the technology has passed through two major "paradigm" shifts of which the most recent, associated with the developments in genetic engineering methods, or "third-generation" biotechnology, is still unfolding.

The development of biotechnology appears to be characterised by considerable science-push. The breakthroughs which provide the

core of this new technological trajectory originated in research undertaken within academia. Moreover, prior to this point, the key underpinning discipline in this area of endeavour - molecular biology, had not made its mark on industrial research and development efforts. This suggested that an examination of innovation strategies in the new biotechnology might provide an insight into other new science-based technological fields.

As an innovation or set of innovations, technologies can be seen as having two distinct kinds of development paths. On the one hand, there is the trajectory of the innovation process itself; the path from basic science or fundamental invention, through systematic application and early development to more specific and advanced development. What characterises the biotechnologies is the compression of this internal innovation chain - the time from basic discovery to advanced development, has grown shorter and shorter especially in the last decade.

On the other hand, there is the diffusion process by which innovations are spread into the economy. Biotechnology appears to be a new attempt to integrate these processes. Therefore, it is the infusion of scientific knowledge into the manufacturing process by which marketable products are made out of biological

phenomena that represents the challenge and enormous potential of biotechnology.

Industry plays the pivotal role in transforming new biotechnology into an economic force and it is assumed that present industrial involvement and strategies are an indication of future economic developments. Therefore, to gain insight into these strategies it is suggested that organisational studies of companies involved in the technology are appropriate.

From preliminary research as part of the present study it was established that industrial biotechnology in Ireland is mainly in the Healthcare and Food & Drink industry sectors (See Section 7.4). These two sectors are very diverse, not only in the nature of their products but also in their industrial structure.

The Healthcare sector is mainly comprised of foreign owned subsidiaries of international companies, while the Food & Drink sector is mainly made up of indigenous companies.

The present study focuses on these two Irish industrial sectors.

Due to the differences associated with these two sectors it is suggested that an examination of the innovation strategies through biotechnology in each of these sectors might provide an interesting comparison of the innovation strategies of new high-technology based companies and established low-technology based companies operating in the same generic field - biotechnology.

Finally, the new opportunities emerging in the area of biotechnology promise to be quite pervasive in economic impact suggesting that the commercialisation of the particular "nascent" technology will be of quite general interest. This study is an attempt to synthesize qualitative research data on innovation strategies of Healthcare and Food & Drink companies involved in biotechnology research and development in Ireland, for the purpose of determining, in a pragmatic manner, the level of activity and types of innovation strategies pursued by those companies involved in the technology.

Within this overall objective of the research, the study has a number of specific aims:

(1) To establish those Healthcare and Food & Drink companies in Ireland involved in biotechnology research and development as a means towards innovation.

(2) To establish reasons for developing biotechnology activities.

(3) To determine the innovation strategies through biotechnology of Healthcare and Food & Drink companies in Ireland actively involved in biotechnology research and development.

1.3 LIMITATIONS OF THE STUDY.

A limitation is a factor that may or will affect the study in an important way. The potential limitations of the present study include the following:

(1) The willingness of individual companies to respond to the enquiry of the study. In this respect, every possible effort was made to make individual companies respond to the research enquiry. During the preliminary stage of the research study, it was necessary to establish those companies in Ireland involved in biotechnology research and development. However, a limitation of the study is that 18% of the sample population were not willing to respond to such

enquiry and thus are not included in the research results. (See Section 8.2)

(2) The ability of respondents to answer research enquiries: This potential limitation was overcome by directing enquiries at individuals within the companies studied who were deemed capable of providing accurate information. (See Section 7.3)

(3) The willingness of respondents to respond accurately is a limitation of the study which is not under the control of the researcher. However, every possible effort was made by the researcher to make the respondent aware of the importance of accurate information for the success of the research study.

(4) The study is limited to Healthcare and Food & Drink companies in Ireland, to keep the sample size manageable considering the time and resources available to the researcher. However, focusing the research enquiry on these two industry sectors can be justified in several ways including:

(A) These two sectors represent those sectors in which present and future applications of biotechnology developments have major impact (See Section 4.4);

(B) These two sectors are very important in the context of the Irish economy. The Food & Drink industry employs 26% of the Irish workforce. Exports in 1989 of food & drink were worth over two billion pounds or 24% of total exports. It is thus a very important sector and one in which biotechnology can play an important role. The Healthcare sector is also important for Ireland and has undergone considerable growth in recent years. As part of Irish industrial policy, the Industrial Development Authority (IDA) has implemented a policy of attracting foreign manufacturing industry to Ireland, including Healthcare companies. Ireland now has 110 Healthcare company plants, including 10 of the world's top 15 pharmaceutical companies. Ireland is now the 10th largest exporter of pharmaceuticals in the world. Within the Healthcare industry in Ireland there has been a particularly encouraging growth in the Medical Diagnostics area. Several indigenous companies operate in this sector. Thus the Healthcare sector is very important to the Irish economy and one in which biotechnology can play an important role.

(C) Furthermore, as indicated in Section 1.1, by focusing the present research on the innovation strategies through biotechnology in each of these sectors, a comparison of the innovation strategies of new high-technology based companies and established low-technology based companies operating in the same generic research field could be made.

1.4 DEFINITION OF OPERATIONAL TERMS

(1) BIOTECHNOLOGY

The question of definition with regard to biotechnology has been difficult. However, these are the principles which have been followed and the terms which have been used with regard to biotechnology:

Classical biotechnology is thousands of years old. During the last several decades numerous scientific and technological advances have turned biotechnology into an increasingly efficient set of techniques, referred to as Modern biotechnology. Since the late 1970s, the discovery particularly of recombinant DNA techniques and cell fusion has led to a radical acceleration of progress and to

a multiplication of both tools and applications. This is referred to as New biotechnology.

Classical, Modern and New biotechnology is not a distinct sector, but a broad enabling technology which affects many industrial sectors. It is not in contradiction with this that this study also uses the terms Biotechnology Industry or Biotechnology Companies. These refer to the industrial enterprises which carry out the bulk of industrial research and development in "Modern biotechnology" and "New biotechnology", irrespective of the sector of activity. Whenever a precise definition of biotechnology was required, particularly during preliminary research and depth interviews (see Section 7.5) with industrial companies, the adapted OECD (1982) definition was employed: "Biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services. This term is understood to exclude bio-medicine and agriculture, excepting those areas which now involve the application of cellular or molecular biology."

(2) INNOVATION

Difficulties were similarly encountered in defining innovation in the present research study. However, innovation was taken to refer to

new product and/or new process developments, either new to the market or new to the company, (See also section 2.2).

1.5 THESIS OUTLINE

This thesis is organised into eight sections. The present section focuses on the research problem of the present study, specific research questions to be investigated, limitations of the study and definition of operational terms employed during the research employed in the study.

Section 2 draws on literature concerning industrial technological innovation, the economic role of research and development and turns to some of the prospective long-term economic impacts of technology, including impacts on trade and competitiveness. Particular reference is made to the technology research field selected for the present study, that is, biotechnology.

Section 3 focuses on the literature concerning strategic management and the innovating firm, in particular corporate

strategy and innovation strategy and also on characteristics of successful technological innovation in the firm.

Section 4 and 5 outline the technological context of the study. Section 4 is largely descriptive, providing essential background information. It starts with a short history of the evolution of biotechnology and focuses on current and future perspectives. The global biotechnology situation is briefly discussed. Specific issues related to the development of biotechnology and its commercial application are discussed including finance, patent protection and public attitudes and acceptance of the technology - these issues being important when considering the commercialisation of new products or processes through biotechnology.

Section 5 discusses the future diffusion of biotechnology through the economy and particularly the probable time-scales and consequences. Parallels are drawn with the diffusion of the electronic computer and of electric power. This part also discusses biotechnology as a techno-economic paradigm accompanied by many changes including structural adjustments in the sectors affected by biotechnology. Finally, Section 5 reviews prospective employment impacts of biotechnology.

Section 6 focuses on Ireland and innovation, the evolution of Irish Science and Technology and the Government Policy for Innovation through Biotechnology in Ireland.

Section 7 describes the research design of the study, focusing on the general research method, the research population and specific procedures employed.

Section 8 presents the findings and conclusions resulting from the present research study.

CHAPTER 2: TECHNOLOGICAL INNOVATION IN THE ECONOMY

2.1 INTRODUCTION

This section of the present thesis draws on literature concerning industrial technological innovation; including models of the innovation process. The section also includes a discusssion on the economic role of research and development as a means towards innovation and turns to some of the prospective long term economic impacts of technological change, including impacts on trade and competitiveness, foreign direct investment and the process of globalisation.

Particular reference is made to the technology research field selected for the present study, that is biotechnology.

2.2 INDUSTRIAL INNOVATION

The establishment of research and development laboratories by industrial concerns must be understood in the context of the competitive pressures operating in the economic environment to innovate, through the introduction of new products or production

processes which have been described in the works of Karl Marx and Joseph Schumpeter, as well as many others.

Broadly, these pressures hinge on the necessity for companies to maximise profits. This endeavour may involve an attempt to secure, however briefly, competitive advantage through for example, increased market share or accumulated technological capacity.

For the individual firm, it is clear that failure to innovate results in commercial suicide:

> *... no firm ever yields returns indefinitely if only run according to unchanged plan.*[1]

Similarly on the macroeconomic level,

> *... without technological innovation, economic progress would cease in the long run and in this sense we are justified in regarding it as primary.*[2]

In order to understand the role of science and technology in the innovation process it is necessary to clarify some of the terms used.

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[1] Schumpeter, 1950
[2] Freeman, 1974

Strictly speaking the term technical or industrial innovation is more generally used to connote changes in technique, involving

> *the introduction and spread of new and improved products and processes in the economy.*[3]

In this study, technological innovation in those firms operating in certain sectors of Irish industry involved in biotechnology research and development is considered. Therefore the broad definition of Christopher Freeman of the Science Policy Research Unit of the University of Sussex, seems an appropriate definition to adopt.

> *The process of innovation is the first commercial introduction of new techniques. Inventions which are both introduced and updated into the regular system of production and provision of services are technical innovations.*[4]

This definition embraces the techno-commercial activities which result in either the successful market adoption of a new or improved product of the firm, or the adoption of a new or improved process within the firm.

Interpretation of this definition suggests that the product or process innovation may be new at the level of the firm but not necessarily at

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[3]Freeman, 1974
[4]Freeman, 1974

the global or industrial level, and also that both radical and incremental innovations are included in the definition. With this definition of technological innovation and the innovation process it is necessary to enlarge on a number of aspects including the following;

(1) Much differentiation has been made in the literature between product and process innovation. This is especially true of the work of Abernathy and Utterback (1978) who use the "learning curve" concept to emphasise the changing profile of the mix of product and process innovation over the life-cycle of the product. Interestingly, the term "output" is often used instead of the "product" as the firms output may in fact be a service or a process in the case of non-manufacturing industry. Equally, technological innovation may lead to the development of new and more efficient processes for the production of new or existing products.

(2) The interpretation of technological innovation allows the scope for distinction between "radical" innovation and "incremental" innovation. Numerous studies of industrial innovation have revealed that "technological innovation" is to

a large extent based on the cumulative effect of small incremental innovation.[5]

However, innovations embodying large advances in knowledge although less common, are of great commercial importance. Such radical innovations have a pattern of diffusing through the economy by a process of largely imitative activity in which the original elements are adopted and re-adopted by more and more firms. Such imitative activity accounts for a good proportion of incremental innovation.

(3) Innovation is more than technological research and development. It can and does involve technological R & D as well as market R & D. However, the acquisition of licensing rights for a technological product and process or the adoption of a technological capability would be other valid routes to innovation. Similarly innovation is more than simply engineering design. It represents in scope the range of activities relevant to the commercialisation process from the recognition of new technological opportunities or latent market demands, through various stages of maturity, until commercial success is realised.

[5]Marquis, 1981

(4) Technological innovation need not necessarily involve so-called high technology or technology-intensive products. It can occur equally at "low" or "medium" technology levels. It can and does occur to the same extent in traditional well established sectors, such as the food and drink sector, as in newer sectors such as electronics. Wherever it occurs, technological innovation will result in raising the technological level and capability of the firm, whether the level be initially high or low.

In practice, it is difficult to describe the multidimensional dynamics of the innovation process. The process is a complex socio-economic one for which many representations or models exist, the majority referring to the industrial innovation process. Many studies based their measurements of innovation at firm level on simple indicators of key characteristics and trends. The adequacy of such indicators is a factor not to be ignored in deriving conclusions from such studies. For example, R & D expenditures as a percentage of sales is one such indicator frequently used both at macro and micro level. This indicator ought to be used with care in considering innovation since innovation involves much more than R & D.

While the problems involved in developing realistic models of the innovation process are both broad and complex, Robbins, Burke and Milliken (1977) have shown how useful these models can be when developed. They can be used in several ways, including the following:

* To help predict performance of a system when it is subjected to a set of various environmental conditions or stimuli, such as different forms of government intervention or changes in government politics.

* To analyse the functions of a system when various changes are made in its components.

* To gain knowledge for decision making and problem solving.

* To contribute towards the optimisation of the design of the system by experimenting with various changes in its parameters.

While crude models or descriptions of the innovations process involve simplifications of reality, they nevertheless portray several important features of the real system. The complexity and

usefulness of models of the innovation process has grown with increased understanding of the innovation process.

Most models can be divided into broad groups as follows:-

GENERALISED MODELS

This group includes a societal model followed, for comparison purposes, by models of innovation in the public and private sectors.

MODELS OF TECHNOLOGICAL INNOVATION IN MANUFACTURING INDUSTRY

These models range from basic linear models, through more complex non-linear models to those which place greater emphasis on human and environmental factors.

2.3 GENERALISED MODELS OF THE INNOVATION PROCESS

Perhaps the earliest generalised model of the innovative process was developed by Hornig who defined innovation as the process by which knowledge is generated and applied to the operations of society.[6] By this definition, therefore, innovation is more than discovery, more than invention, even more than engineering drawings. Until the know-how is incorporated into the operations of society, society does not benefit.

On the evidence of studies of a large number of innovative organisations, Hornig suggests a broad based model of the innovation process. He describes the process as an interactive one between three functionally different, interrelated "suborganisations", these include:

(1) Organisations that recognise the needs and desires to be satisfied, set goals and allocate the necessary resources i.e. management and decision-making organisation whether it be government, industry or components of either.

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[6]Hornig, 1978

(2) Organisations that educate people to staff the enterprise, generate scientific knowledge and new technology.

(3) Organisations which apply the new technology to society's operations or use the technical knowledge in the formulation of policy.

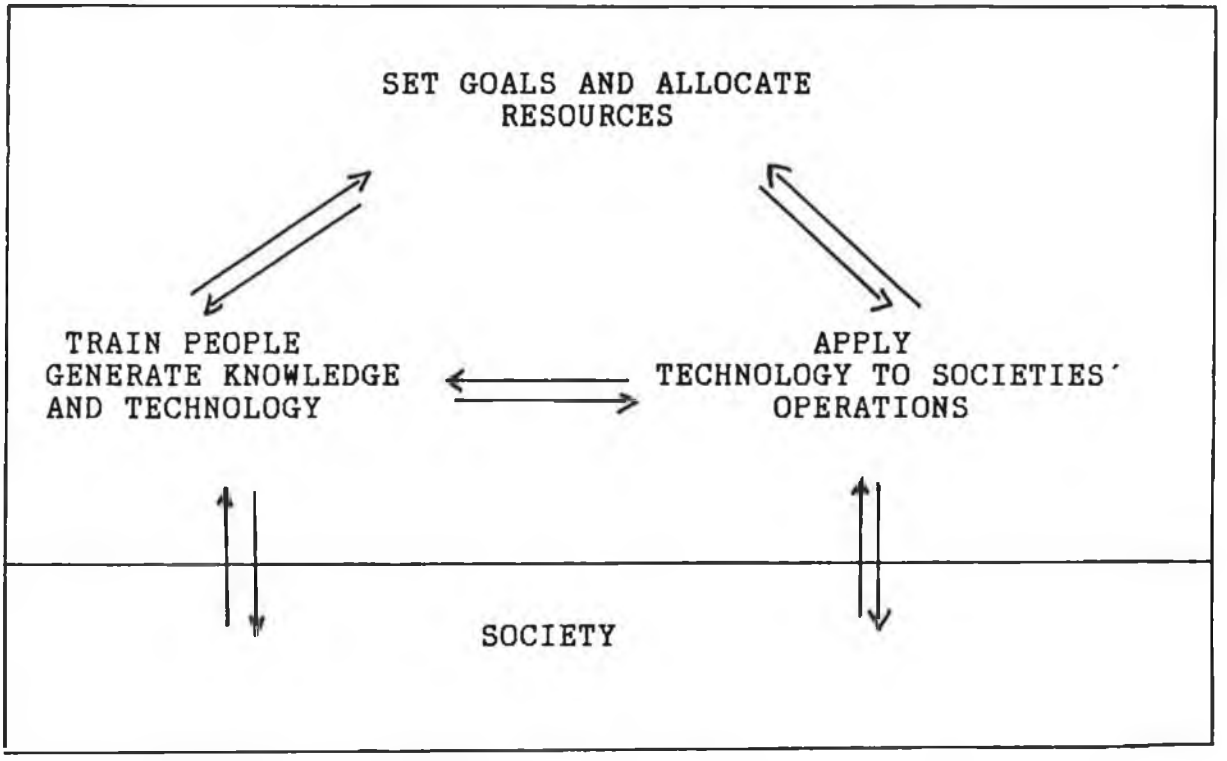
In the highly "interactive process" of innovative activity, Hornig's description of the necessary close interaction is shown diagrammatically in Figure 1.

Usually all three functions are found to some degree in each performing organisation and all three must interact to some degree with the outside world (society), as well as with each other.

While Hornig's model is still the most popular generalised model of the innovation process, some further work has been carried out on the identification of the significant differences between the nature of the innovation process in the public sector, and its nature in the private sector.

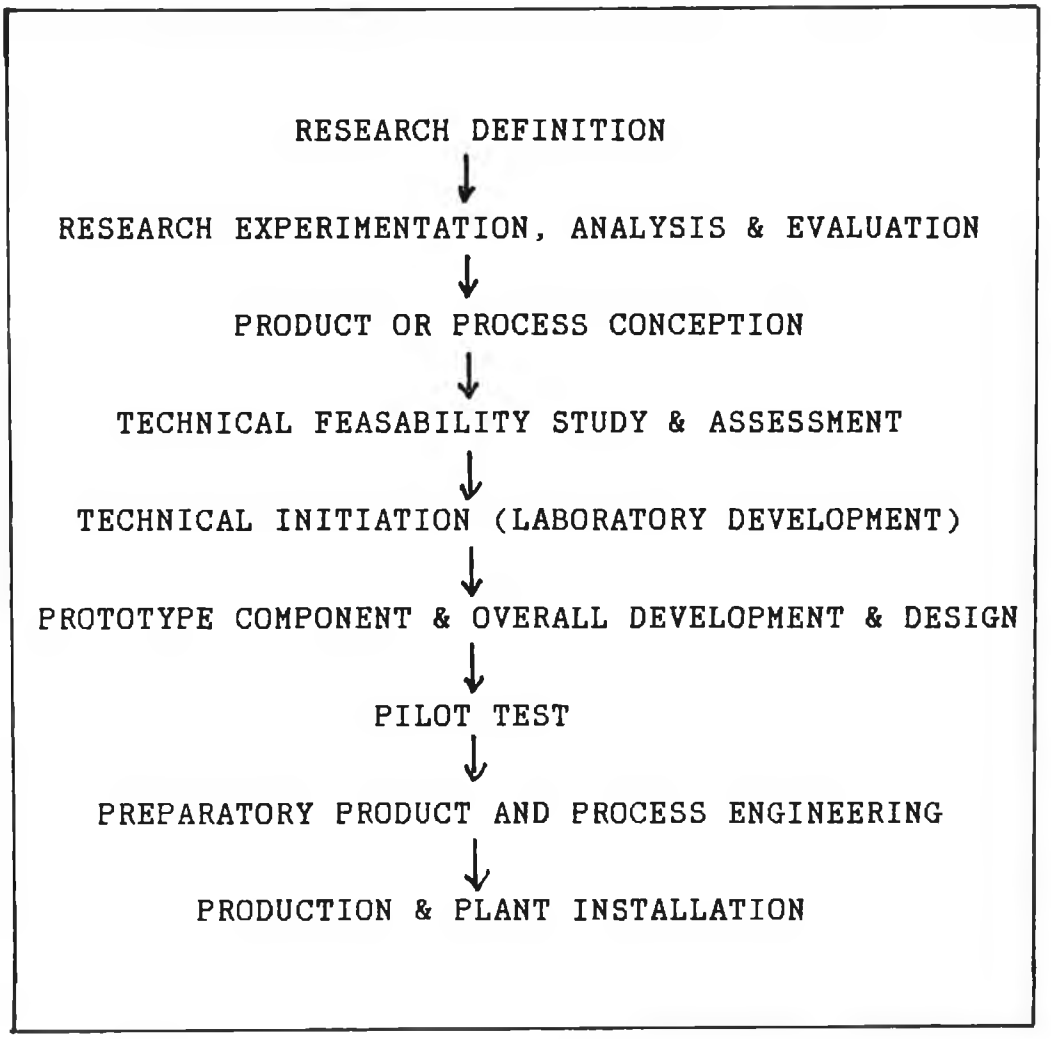
Of interest to the present study is the private sector generalised model of the innovation process, developed by Robbins et al.

FIGURE 1 HORNIG'S GENERALISED MODEL OF THE INNOVATION PROCESS (1978)



Source: Hornig, D., (1978), "Health of the Scientific and Technical Enterprise - An Advisory Report" NTIS Publication, Washington, D.C.

FIGURE 2 ROBBINS ET AL (1977) PRIVATE SECTOR GENERALIZED MODEL OF THE INNOVATION PROCESS



Source: Robbins, M.D. et al, (1977), The Technological Innovation Process in the Private Sector, Westview Press, Boulder, Colorado.

which, having nine sequential stages described in Figure 2, has a technology-push orientation.[7]

In addition to the technological stages described in Figure 2, Robbins also states that environmental factors affect the flow of innovation throughout its progression.

These factors may be internal or external to the firm, and they may have either a positive or negative effect on innovation.

Five categories of institutional factors have been identified as having major impacts on the success or failure of an innovative idea.[8]

(A) Marketing and Market - Related Factors

(B) Regulatory and Standard Setting Factors

(C) Capital Related Factors

(D) Human Resources - Related Factors, including management, organisation, and staffing.

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[7]Robbins et al., 1977
[8]Robbins et al., 1977

(E) Technology Related Factors.

2.4 MODELS OF TECHNOLOGICAL INNOVATION IN MANUFACTURING INDUSTRY

Leaving aside the more generalised models of the innovation process discussed in Section 2.3, this section will discuss a number of models of technological innovation in manufacturing industry, ranging from the basic linear model type, to the more complex models involving human and environmental factors.

Basic linear models of "technology-push" and "demand/need - pull" type have been proposed by many researchers.

The Organisation for Economic Co-operation and Development[9] propose a linear model described in Figure 3. This model describes only product innovation but states that process innovation is analogous. Not showing a market input in the earlier stages of the process, this model could be considered a "technology-push" type model as described in Section 3.8.

[9]OECD, 1978

A further linear model of technological innovation in manufacturing industry has been suggested by Haeffner to describe

> *... a piece of systematic innovation work.*[10]

Having six stages, Haeffner argues, starting backwards, that it is reasonable that full scale industrial exploitation should be preceded by a sales testing period. This implies that at least a pilot part production is already underway. Before a pilot plant is decided on, the product, process or method has passed a stage of development that might be called an objective or mission oriented industrial research and development phase.

This must be preceded by an idea generating phase. The argument to support the phase described as "specification of innovation needs", is made on the basis that about three quarters of successful innovations need to be stimulated while the rest might be characterised as recognition of a technical opportunity. This model represented in Figure 4, could therefore be regarded as a "demand/need - pull" type model (see Section 3.8) as it starts with the identification of a market need.

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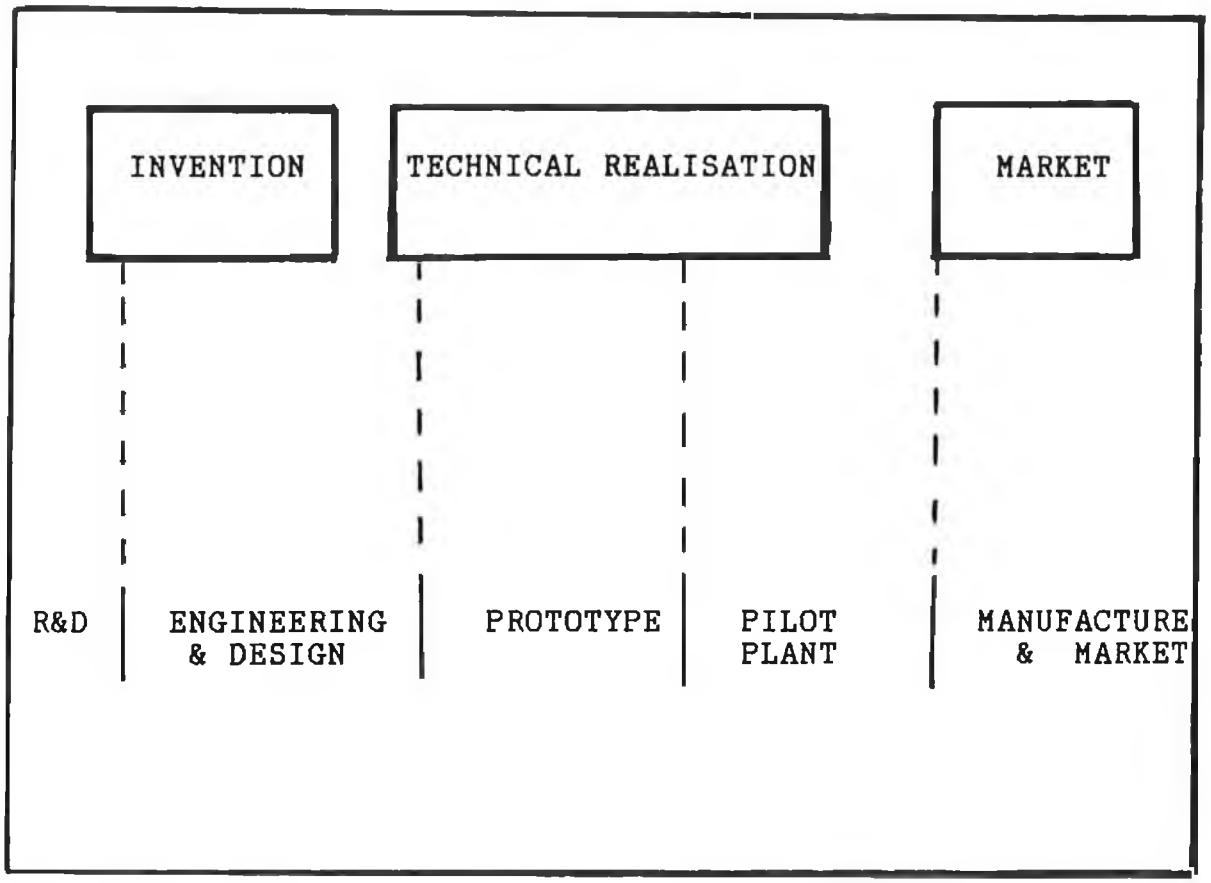
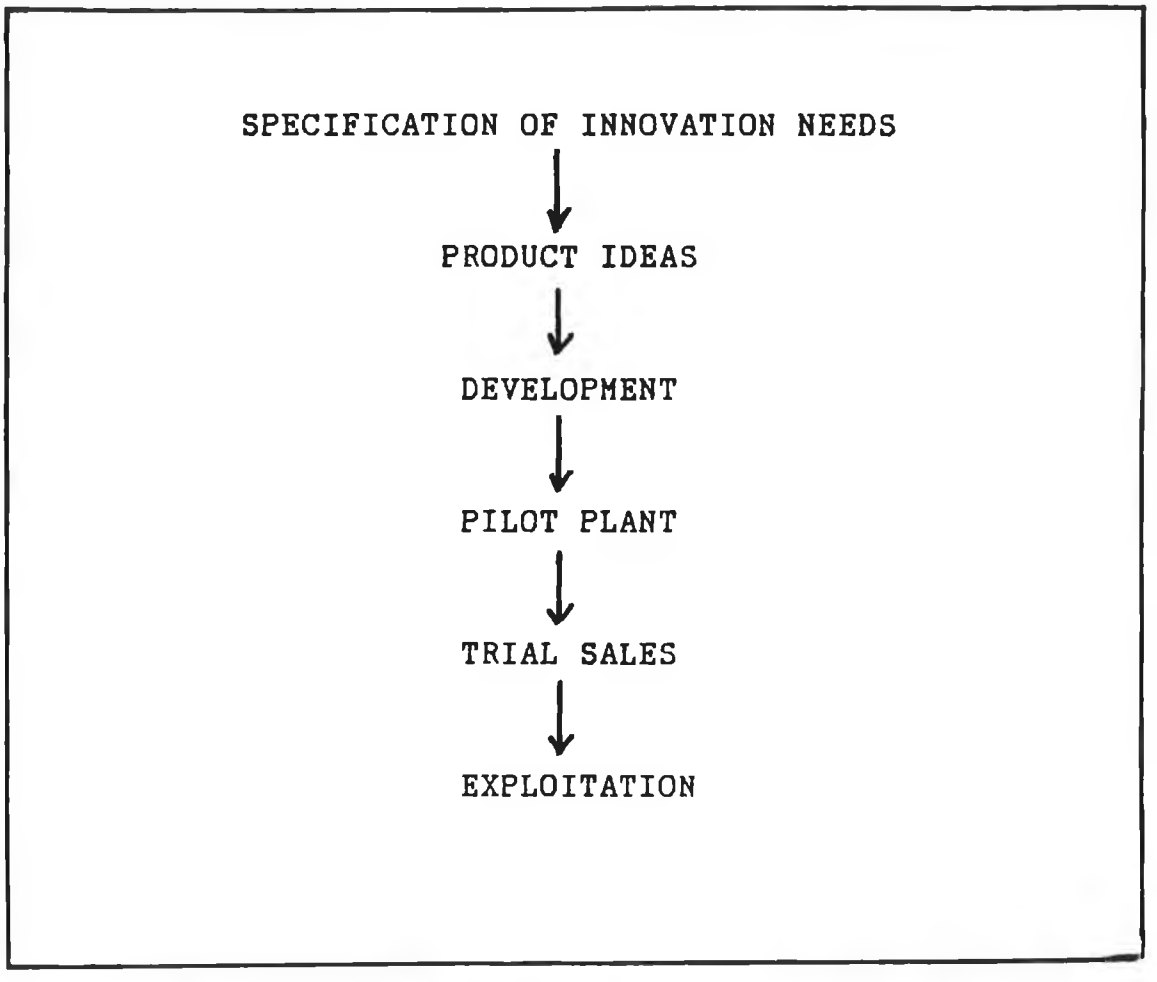
[10]Haeffner 1979

FIGURE 3 OECD (1978) GENERALISED LINEAR MODEL OF THE INNOVATION PROCESS IN MANUFACTURING INDUSTRY



Source: OECD, (1978), "Policies for the Stimulation of Industrial Innovation", Volume 1, Analytical Report, Paris, 1978.

FIGURE 4 HAEFFNER'S LINEAR MODEL OF THE INNOVATION PROCESS IN MANUFACTURING INDUSTRY (1979)



Source: Haeffner, A.E., (1979), "Innovation Strategies for Industrial Corporations and for Satisfying National Needs", The Mac Millan Press, London.

One of the important additional features of this model is the explicit inclusion of five natural decision states, a choice between specified innovation requirements; decision to develop a product; decision to proceed with development work; decision to proceed with trial production and trial sales, and decision as to complete exploitation.

More complex models of the innovation process recognise the need for both technical and market input to the generation of ideas for successful innovations and the role of a "feedback" or iterative process.

In his description of the innovative process Marquis (1981) demonstrates the ongoing interaction between technical knowledge and market needs at all stages of the process. It also shows feedback between stages which is a good reflection of what actually happens in practice in most industrial sectors. The model shows a distinct departure from the linear thinking of the earlier models. For further discussion of Marquis' model of the innovation process and a diagrammatic representation of the model see section 3.8, Figure 9.

Finally, the changing character of innovation and its changing role in corporate advance is discussed in this section.

Seeking to understand the variables that determine successful innovation strategies, Abernathy and Utterback (1978) focus on three stages in the evolution of a successful enterprise: its period of flexibility, in which the enterprise seeks to capitalize on its advantages where they offer greatest advantages; its intermediate years in which major products are used more widely; its full maturity, when prosperity is assured by leadership in several principal products and technologies.

The above authors examined different types of innovations and their relationships by looking at the successive steps in the development of a line of business which is described as follows:

> *The business starts through the origination of one or more product innovations. These are usually stimulated by users' needs through frequent interaction with users of innovation. Exploitation of the product's potential in different applications follows. Rising production volume may lead to the need for innovation in the production process. Demands for greater sophistication, uniformity, and lower cost in the product create an ongoing demand for the development and improvement of both product and process.*[11]

This means that product and process design become more and more closely interdependent as a line of business develops.

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[11] Abernathy and Utterback, 1978

As a result of this interdependence, Abernathy and Utterback (1978) suggest that a shift from radical to evolutionary product innovation will occur. This shift is accompanied by heightened price competition and increased emphasis on process innovation.

Thus, changes in innovative pattern, production processes and scale, and kind of production capacity will all occur together in a consistent predictable way.

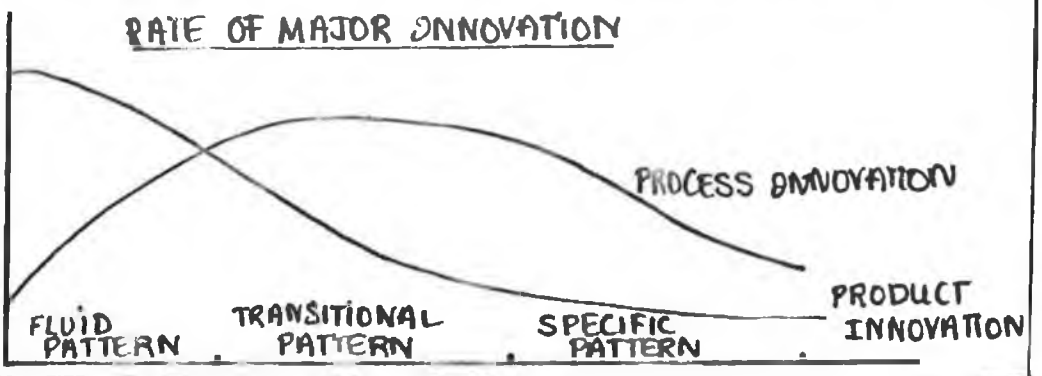
Abernathy and Utterback (1978) propose a mode of industrial innovation which indicates the changing character of innovation and its changing role in corporate advance. See Figure 5.

Obviously, this model has important implications in the study of innovation strategies as the innovation strategy of a firm will change as the firm's business develops.

2.5 THE ECONOMIC ROLE OF RESEARCH AND DEVELOPMENT

That innovation is not wholly incremental and that major breakthroughs in knowledge are sometimes critical, reflects the

FIGURE 5 : ABERNATHY AND UTTERBACK'S MODEL OF THE INNOVATION PROCESS AND ITS CHANGING ROLE IN CORPORATE ADVANCE (1978).



COMPETITIVE EMPHASIS ON :	Functional Product Performance	Product Variation	Cost Reduction
INNOVATION STIMULATED BY :	Information on user's needs and technical inputs	Opportunities created by expanding technical capability	Pressure to reduce cost and improve quality
PREDOMINANT TYPE OF INNOVATION	Frequent major changes in products	Major Process changes Required by Rising Volume	Incremental for product and process, with cumulative improvement in productivity + quality
PRODUCT LINE	Diverse, often incl. custom designs	Includes at least one product design stable enough to have significant production volume	Mostly undifferentiated standard product
PRODUCTION PROCESSES	Flexible + inefficient major change easily made	Becoming more rigid with changes occurring in major steps.	Efficient, Capital intensive + rigid cost of change is high.
MATERIALS	Inputs are limited to generally available materials	Specialized material may be demanded from suppliers	Specialized materials will be demanded; if not available, vertical integration.
PLANT	Small scale, located near user or source of technology	General purpose with specialized sections	Large scale, highly specific to particular product's.
ORGANIZATION CONTROL IS :	Informal and Entrepreneurial	Through liason relationships, project + task force	Through emphasis on structure + goals.

Source : Abernathy, W. J. and Utterback, J. M., "Patterns of Industrial Innovation", Technology Review, July, 1978, P. 40.

relative autonomy of technological development or change, and economic forces.

This theme is implicit in most attempts to characterise the evolution of technological fields, including that by Granberg and Stankiewicz (1978).

The development of a technological field begins with the recognition of the potential of some range of phenomena, such as processes, effects and properties, for serving some specialised function. The phenomena in question may or may not be newly discovered. The essential point is that they have not previously been used for the given purpose.

Once the generic idea or technical concept of such phenomena and their utilisation has emerged, it initiates a process which consists of the reorganisation of existing knowledge and the generation of new problems for solution.[12]

Within the ideal type proposed by Granberg and Stankiewicz, the early development of a technological field is characterised by systematic research and development, and the emergence of a

[12]Graberg and Stankiewicz, 1978

core group of researchers, interested in and committed to the solution of problems raised by the technical concept, followed by the utilisation of these solutions through innovation and its eventual decline as the number of research problems lessens.

It is clear in a general sense that companies need to utilise available resources of scientific and technological knowledge if they are to sustain innovative activity. Furthermore, by privately funding research and development activities, companies add to the total stock of knowledge as well as simply drawing on that which is publicly available.

Studies of innovation reveal that, averaging across a range of industries, some 60% of the knowledge applied by companies in innovation is derived from their in-house research and development efforts.[13] [14]

This appears to contradict the concept of technology being a general stock of knowledge from which companies draw, prevalent in much classical economics' treatment of the subject. The reason

[13] Robbins et al., 1977
[14] Freeman, 1974

for this probably lies in the very targeted nature of innovative efforts necessitated by the economic pressure to compete for markets.

Specificity is crucial to commercial success at the level of product differentiation. It is also an essential prerequisite if firms are to appropriate the knowledge embodied in a given innovation and so secure commercial success in a competitive market. As Pavitt remarks,

> *... most of the knowledge applied by firms in innovations is not general purpose and easily transmitted and reproduced, but appropriate for specific applications and appropriated by specific firms.*[15]

Furthermore it is revealed that on average some three quarters of industrial research and development expenditure is accounted for by development work.[16] It is in this area that the specificity issue especially obtains, and that information or knowledge is least transmissible.

Nevertheless, at the research end of industrial research and development, where inventive activity is perhaps most crucial, there are also benefits accruing from a firm's decision to invest. When

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[15]Pavitt, 1987
[16]Abernathy and Utterback, 1978

research is focussed in the selective fashion highlighted by Dosi (1982), there is scope for ordered progress:

> *... inventions usually result from a systematic attack on a problem.*[17]

Furthermore, companies investing in both research and development are better able to exercise control over their innovative efforts, and to ensure that these efforts are not wasted. This has been very elegantly argued by Dosi in a theoretical contribution in which he characterises industrial research and development (taken together) as a search activity, and suggests a theory of knowledge as

> *capability for efficient search*[18]

He further argues that the stronger the knowledge base a company is able to draw on, the greater its ability to make rational decisions about where to search, and thus, the greater the returns on its investment in R & D. In short,

> *... basic research ... enhances the productivity of applied research and development.*[19]

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[17] Dosi, 1982
[18] Dosi, 1982
[19] Dosi, 1982

Industrial R & D often generates new knowledge as well as new techniques, which itself is relevant to the next round of search. Rosenberg (1976) has shown that companies do not generally possess knowledge of all the possible lines of investigation and further, that companies are in any case constrained in their choices about which alternatives to pursue, by the state of their existing knowledge and skills. For further discussion on this topic see Section 3.6.

In a similar vein, Moweny (1981) has argued that the cumulative nature of industrial innovative R & D does not generally cover high risk and complex projects.

Concerning the selection of new technological paths, it has been suggested that the greater the discontinuity of capability involved in moving from an existing technological area to a new one, the greater the risk and uncertainty and the greater the reticence.[20] Furthermore, the benefits of investing in relatively more open-ended research activities are not always as apparent as are those of undertaking development work.

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[20]Dosi, 1982

Recognition of the general importance of technological advance to economic progress provides the major economic justification for the public funding of R & D and especially of fundamental research.

Three possible economic benefits of science, in general, have been investigated.[21] First the long term benefits of providing knowledge to industrial innovation; Second, the technological benefit of "spin-off" to industry; finally, the benefits accruing through the training of skilled personnel, who are then employed in R & D in industry. Of these benefits, Irvine and Martin suggest that the third is the most tangible and may well have the greatest impact.

From studies of industrial innovation[22] [23] private companies ten to "underinvest" in basic science and research. Reasons for such underinvestment may be associated first with the risk factor, and second with the question of appropriability, that is, how relevant the basic research is with regard to potential commercial applications of products or processes; the results of basic research are generally long term and unpredictable and are not usually in a form which can be easily "appropriated".

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[21] Irvine and Martin, 1980
[22] Freeman, 1974
[23] Robbins et al., 1977

For these reasons, it could be suggested that money spent on basic research undertaken in academic and other non-commercial institutions is more productive, the fundamental objective of these institutions being the advance of knowledge. Hence, governments are obliged to commit resources to basic knowledge in a particular technological area, and in effect, undertake to support the longer term interests of industry by conducting more speculative search operations on its part.[24]

Furthermore, it has been argued that because of the burden of R & D expenditures on smaller companies, government support of science and technology is one way of countering the monopolistic trends of larger firms. As Dosi remarks,

> *If we want to maintain our enterprise economy, basic research must be a matter of conscious social policy.*[25]

It could be argued therefore, that there is an economic basis for the division of labour between academia and industry with respect to research and development activities.

The extent to which industry is likely to do university-type science is limited by the breadth of knowledge involved and by the inevitably

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[24]Faulkner, 1986
[25]Dosi, 1982

long term nature of any returns from it. Similarly, universities lacking the competitive pressure to innovate are unlikely to undertake any sizeable development work. Thus the two institutions perform complementary roles proportionate with their institutional objectives. It can be further suggested that the promotion of academic - industry linkages in a particular research area would further facilitate innovation by merging the complementary roles of each organisation.

Thus on the micro-economic level, public sector R & D represents a source of knowledge which firms may access with ranging degrees of success. What matters in the competitive market is the marginal advantage captured by adding in-house knowledge to public knowledge.

2.6 TECHNOLOGY, COMPETITIVENESS AND COMPARATIVE ADVANTAGE

For the economist, the rationale of international business lies in the theory of comparative advantage, the same theory which in effect lies at the heart of all economic specialisation. Countries, like

individuals, are well advised to concentrate on those things they do best, and, as far as they can, buy other things from someone else who will accept their products in payment. The theory of comparative advantage was developed more than a century ago by David Ricardo, John Stuart Mill and other English followers of Adam Smith. The theory of comparative advantage is a closely reasoned doctrine which, when properly stated is unassailable.[26]

In a dynamic, innovation-driven economy, comparative advantage is hard to distinguish from competitiveness as expressed itself by the price, quality and novelty of products. At certain periods, competitiveness is in fact, strongly determined by the type of competition which Schumpeter defined as,

> *... competition from the new commodity, the new technology, the new source of supply, the new type of organisation ... competition which commands a decisive cost or quality advantage and which strikes not at the margins of the profits and the outputs of the existing firms (and possibly even entire economies) but at their foundations and their very lives.*[27]

After having been virtually ignored by mainstream and neo-classical international trade economists for many decades, there has been initial recognition of this Schumpeterian approach by the leading trade economists.

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[26] Samuelson, 1948
[27] Schumpeter, 1943

As stated by Johnson,

> *... innovative capacity should be viewed as a basic source of difference in comparative advantage and technological change as a chronic disturber of existing patterns of comparative advantage.*[28]

These "chronic disturber" effects of technology may occur in two main ways[29], (OECD 1989).

(1) By modifying trade flows as a result of the marketing either of totally new products or of products or of new, better and differently sourced substitutes, whether they are material inputs to industry or products for final consumption, and;

(2) By creating new gaps between countries, or suddenly widening gaps which were previously being reduced as a result of international transfers or technology.

A closer examination of the trade modifying effects of technology shows that these can occur through four main channels or mechanisms:[30]

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[28] Johnson, 1975
[29] OECD, 1989
[30] OECD 1989

(A) The creation of new trade (either along existing overall international trade patterns or with a recognisable change in patterns) through the marketing through exports of totally new products. Stress is placed here on the words <u>through exports</u> to indicate that in the area of high technology (Eg.. R & D intensive) industries, the world-wide marketing of new products may take place through delocated manufacture and the foreign operations of multinational enterprises (MNES) and have little effect on trade flows per se.

(B) Shifts in the structure of trade, marked by the reduction, and at some stage possibly the outright disappearance of particular trade flows, resulting from the creation of entirely new substitutes for previous products.

(C) Shifts in the structure of trade, again marked by the reduction of particular trade flows, resulting from the introduction of new production processes which change major factor proportions (Eg.. capital/labour ratios) and reduce trade flows based on an abundant cheap labour type of comparative advantage.

(D) Shifts in the structure of trade, also involving a reduction in the level of trade flows, which stem from the reduction of

material inputs to production as a consequence of a number of parallel and/or related processes of economisation and substitution.

This fourth process which is of particular importance in modern biotechnology has been overlooked for a long time but has recently been studied fairly systematically by trade experts and international organisations in relation to fall in developing countries' exports of primary metals and agricultural raw products.[31]

The results of such studies has given support to what a number of economists and technologists now designate as,

> *a generally neglected dimension of long term structural change which can be characterised as a "dematerialisation" of production that is, a shift in the composition of demand in industrialised countries away from the products of the more intensely raw material - consuming industries and a diminution in the intensity of raw material use in existing manufacturing industries.*[32]

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[31] UNCTAD, 1986
[32] UNCTAD, 1986

2.7 INNOVATION CAPABILITIES, TRADE IMPACTS AND THE ABILITY TO SHAPE NEW TECHNOLOGICAL PARADIGMS

If the distinction proposed by Freeman and Perez (1986) between (i) incremental innovations; (ii) radical innovations; (iii) technological revolutions and (iv) historical transitions to new technological paradigms is accepted, the three latter types of innovation may all be expected to have trade creating, substituting or displacing impacts. However, even incremental innovations will influence the process of dematerialisation (see Section 5.1). In periods of technological revolution or historical change in basic paradigms, the impacts on trade are likely to be accelerated, possibly with dramatic effects on the production and export of given products.

The extent and nature of such impacts on international trade patterns and country specializations will depend on a number of factors: the scale and speed with which new output related to radical or revolutionary technologies is marketed; the level of development, wide and narrow trade specialization and industrial sophistication of national economies, and also of course on the overall economic climate in which the trade impacts take place.

The trajectories of new technologies are rarely "natural" (Eg.. in the sense of being commanded essentially by endogenous scientific and technological factors). Economic and social factors are of paramount importance in shaping trajectories and determining the way in which the new techno-industrial paradigms emerge.[33]

The process is one of selection through the play of economic, political and social factors, at the basis of which lies of course a sufficient degree of indigenous, technological and industrial capacity to be able to participate in this selection process.

Countries, industries and firms with strong scientific and technological capacities may be predicted to be on the initiating end of such processes or at least to have a reasonable hope of adjusting to them successfully, through investments in R & D, innovation, and related shifts in industrial specialisation. As previous history has shown, on the contrary,

> *... countries with weak scientific and technological capabilities will often be on the receiving end of such processes and may consequently be forced to bear the full brunt of adjustment through painful changes in exchange rates, employment and real incomes.*[34]

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[33] Piore & Sabel, 1984
[34] Chesnais, 1986

2.8 TECHNOLOGY, FOREIGN DIRECT INVESTMENT AND THE PROCESS OF GLOBALISATION

The commercialisation of products through exports is only one of the several ways in which firms can exploit the temporary monopoly-advantages and firm-specific assets stemming from technological lead times and unique experience with new technologies. Such advantages are more and more often exploited through foreign direct investment and the international network of delocated production units based on transnational or multinational enterprises or corporations.

A number of factors lie behind this development in particular:

(A) The large range of factors which place a premium on delocated production inside foreign economies, inter alia non-tariff, and regulatory barriers to trade (some of which may take the form of government regulations regarding health and safety) but also proximity to scientific and technical skills; and

(B) The special imperatives of ogliopolistic competition in industries where concentration has developed and where firms must be present on a fairly large scale inside the home markets of major competitors in order to wage competition successfully.

In industries where R & D costs are high, market niches for new products in the early stages of innovation are small and hence cash flows from innovation investment are low in relation to R & D and start-up investment. These factors, coupled with the imperatives of rapid commercialisation may often push firms to accentuate their multinational production and marketing strategies at the expense of exports. A generally considerably less advantageous form of recouping R & D costs and reaping benefits from innovation is through foreign licensing and/or establishment of joint ventures and other interfirm technological and industrial co-operation agreements. This course is one which small innovative firms or else larger firms with lower levels of multinationalisation may be forced to adopt because they do not possess the complete range of assets required to reap the profits stemming from their innovations.

Delocated production and the emergence of global competition on a world level in markets with a small number of competitors, have

two major implications for the level and pattern of foreign trade and the international competitiveness of national economies.[35]

(i) Delocated production resulting from foreign investment will tend to replace trade flows.

(ii) Firms will choose their competitive strategies on the basis of considerations pertaining to world markets and the global relationships with their main competitors.[36]

They will forego national or even regional, for example, European, considerations when shaping their strategies, thus complicating the attempts made by governments to formulate and apply policies aimed at enhancing national or regional competitiveness.

2.9 BIOTECHNOLOGY, TRADE AND COMPETITIVENESS

The concern by governments with future competitiveness in biotechnology, as well as with the effects of biotechnology on the

[35]OECD, 1989
[36]Porter, 1986

overall competitiveness of domestic economies and on the scale of technology driven structural adjustment is well-founded and legitimate.[37]

Biotechnology has all the requisites necessary to usher in a set of technical and organisational paradigms in many industrial areas, including healthcare and agriculture. Consequently, biotechnology also has the requisites of the type of competition described by Schumpeter (1943) (see Section 3.2); it will create trade, but it will also have strong trade displacement effects.[38]

Other studies have already suggested that in the case of biotechnology, a number of factors

> *... preclude a traditional analysis of international competitiveness.*[39]

The first factor relates quite simply to the impossibility at present of measuring and comparing performances.

OECD work has shown that competitiveness is as much, and in new industries and technologies generally more, a question of quality and novelty than of price. In such industries, indicators of

[37] OECD, 1989
[38] OECD, 1989
[39] Office of Technology Assessment, OTA, Washington D.C. 1984

relative cost (Eg.. wage levels) and price simply do not represent meaningful proxies of competitiveness.[40]

Competitiveness has to be measured through foreign trade data and derived calculations, for example, shares in world exports, ratios of foreign penetration of domestic markets at the most disaggregated level possible. In the case of biotechnology, and in particular new biotechnology, the level of production and sales simply do not permit any such measurement.

The second point made by the 1984 O.T.A. report regarding competitiveness is of greater analytical interest, and may be more durable in its influence on the way competitiveness among industrialized countries will shape up to biotechnology.

> *Even with many more products on the market, a traditional competitive analysis might not be appropriate because an economic analysis of competitiveness usually addresses a specific industrial sector. The set of techniques that constitute biotechnology, however, are potentially applicable to many industrial sectors.*[41]

Even if biotechnology seems, at present, a less pervasive generic technology than for example, microelectronics (see Section 5.3), its range is potentially very wide. One aspect of the highly ubiquitous

[40]Dosi, 1983, paper prepared for the 1983 OECD workshop on Technological Indicators and the Measurement of Performance in International Trade.
[41]OTA, 1984

nature of biotechnology, and the array of techniques it calls on, is that it offers in the long term, unique opportunities for creating totally new products, opening up totally new markets for which there exists at present no competition and so no issue of competitiveness.

A further novel feature of competitiveness in biotechnology is the fact that the contours of competition are shaped by previous processes of technological accumulation, industrial concentration and multinationalisation. Biotechnology has begun to grow not exclusively, but to a considerable extent within the framework of already strongly concentrated and highly globalised industries such as pharmaceuticals, chemicals and multinationalised food processing.

In conditions where profitable market niches are still small and current cash flows insufficient to meet high R & D outlays, the pressure on firms to establish their strategies for the world-wide sourcing of scientific and technological resources and the global marketing of products is particularly strong (see Section 2.8). Firms may tend, perhaps more than in some other areas, to "go it their own way", without putting great expectations in national policies for competitiveness.

These particular features have a number of implications for trade and competitiveness within OECD countries[42], inter alia the fact:

(1) That initially at least, firms and countries will probably, to a fairly significant extent, seek to use biotechnology as a way of consolidating and enhancing their "comparative advantage" (in pharmaceuticals, agriculture, food processing etc.) based on technological accumulation undertaken in earlier phases of industrial development.

(2) That there is less risk, in the longer term at least, for "picking the winner" strategies by firms as by governments to create trade tensions and trade issues, since they are less likely than in the case of automobiles for example, to be concentrated on exactly the same products, and to occur in slow growth markets. It is true that today companies are pursuing the same few product developments principally in pharmaceuticals and that the race of firms to be first to commercialise these products on a world scale lies behind some major patent disputes and behind the trend of increasing secretiveness in R & D.[43]

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[42]OECD, 1989
[43]OECD, 1989

However, it has been suggested that a prospective analysis of competitiveness and its related issues must emphasis that the present situation is necessarily temporary, that the number of new products arriving on the market are expected to increase fast in the coming years, and that the range of totally new or old, but hitherto, not addressed individual and collective needs which could be catered for, is potentially so large that if the needs were to be recognised and met, the market could be a very open and large one.[44]

(3) That for an OECD country today, being competitive in biotechnology has still essentially the meaning of taking the necessary steps to prepare for the future, to avoid being on the receiving end of the process of "creative destruction"[45], and to participate as fully as it can in the scientific and industrial development of biotechnology, and so in the new commercial opportunities it will offer, and

(4) That large firms possessing an advantage in biotechnology may tend to establish their own competitive strategies without waiting for governments to act and without necessarily welcoming government plans.

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[44]OECD, 1989
[45]Schumpeter, 1943

For reasons explained in this discussion, the use of the term "competitiveness" in biotechnology is, for the time being at least, somewhat different in its use from the context of many other technologies and industries. This does not mean however that countries can overlook the scientific and technological lead-times in terms of the time required to train the appropriate scientific and technical labour power, build the appropriate R & D infrastructures, and create the appropriate conditions for transferring the new technologies to industry.

A wide range of factors may have an effect on competitiveness, most notably the industrial base and the industry research interface along with technical manpower.

However complex the support base for competitiveness may be in relation to a technology such as biotechnology, and a given set of industries, such as those involved in biotechnology, ultimately competitiveness is dependent on the efficiency of the industrial base, and the competitive capacity of the final link in the chain, namely firms.

Furthermore, the fact that the new biotechnology is of particular importance in industrial sectors shaped by earlier processes of concentration and multinationalisation, raises a number of

important issues for competitiveness in a national context. Two issues are of particular importance: the place of small firms in the industrial base and the possibilities offered to multinational enterprises of locating a part of their own firm-specific industrial and technological base outside their home country

Chesnais (1966) described the industrial structure which is emerging as a result of new biotechnology developments as "decentralised concentration". This structure, as well as the limited markets and high R & D expenditures encourage companies - big and small - to look for arrangements which make sure that possible returns on investment are not jeopardised, including in some cases , an international division of markets. Furthermore, "decentralised concentration" based on large companies, has helped the transformation of biotechnology know-how into products, and has familiarised companies with new patterns of research-oriented enterprise.[46]

Chesnais (1966) further argues that "decentralised concentration" places large firms n the principal form of industrial organisation through which the industry - research interface can be organised with a view to competitiveness. A number of implications stem from

[46]OECD, 1989

this, notably the fact that the course of biotechnology's future technological trajectories are likely to be traced principally by the strategies and earlier lines of development of those firms.

Furthermore the OECD (1989) report on biotechnology suggests that building the industrial base for national competitiveness in biotechnology around large well-established pharmaceutical, speciality chemical or food processing firms raises other issues for governments which derive from the multinational character of many of these firms, and the global nature of their research strategies.

Thus, it has been suggested that decentralised concentration will most likely remain an important form of industrial organisation for new biotechnology developments because it is the most appropriate solution for large research problems.[47]

However in the long term it does not have to remain the only form of industrial organisation on which biotechnology is based. In order to exploit the markets which the ubiquity of biological phenomena could create, the entrepreneurial potential of numerous, more traditional small and medium sized companies could be better mobilised.

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[47] OECD., 1989

The capability of small and medium sized companies to react quickly in regional markets and market niches, is an asset for the diffusion of biotechnology. Large companies may ignore such markets or leave them aside for cost reasons.

Furthermore, the OECD (1989) suggests that a precondition of faster diffusion of biotechnology is an improvement of the biotechnological qualification of traditional small and medium sized companies. Moreover, these companies may have to acquire more competence in large-scale marketing because many biotechnology products become profitable only if the national market segments of various countries are added together to form larger market and it is suggested that new instruments of economic policy and organisations may be able to assist the small and medium sized companies in this respect.[48]

[48]OECD, 1989

CHAPTER 3: TECHNOLOGICAL INNOVATION AND STRATEGIC MANAGEMENT

3.1 INTRODUCTION

This section of the present thesis focuses on the literature concerning strategic management and the innnovating firm, in particular corporate strategy and innovation strategy.

The importance of technology stategy as part of a firm's innovation strategy is discussed, including technology strategy alternatives.

The determinants of innovative success and characteristics of successful technological innovation in the firms is illuminated.

This section also discusses corporate culture and its effect on innovation. Finally, the concept of technological discontinuities and institutional continues is briefly discussed.

3.2 STRATEGIC MANAGEMENT IN THE INNOVATING FIRM

In the 1980s, research into technology and the firm has been strongly stimulated through a variety of initiatives by the

Organisation for Economic Co-operation and Development (OECD), Economic and Social Research Council (ESRC), and other research councils. Given the pressures to make academic research more obviously relevant to practical problems this is hardly surprising.

It is widely recognised that in industrialised countries both competitiveness of firms and more general welfare depend critically on the ability to keep up with the world frontier in innovative products and processes, and in their underlying technologies.

The best indicator of this recognition is what business firms actually do. Hence, the increased interest in the 1980s amongst management scholars, consultants and practitioners in the role of technology in such matters as corporate strategy, operations management, global competition, new product development and the like.

Although the importance of technological change has been acknowledged by the earlier writers it was Schumpeter (1950) who stressed the central importance of innovation in competition amongst firms, in the evolution of industrial structures, and in processes of economic development; and who gave us the most

useful definition of innovation, comprising not just of new products and processes, but also of new forms of organisation, new markets and new sources of raw materials.

Schumpeter also made the distinction between administrative management of what is well known and entrepreneurship which is the creation and the implementation of the new. He believed that entrepreneurship depends on super-normal individuals with exceptional intelligence and energy, and that innovation is an act of will rather than intellect.

However, although Schumpeter had a theory of innovation and entrepreneurship, he never developed a theory of the innovating firm. He had little to say about the sources of innovation, and the importance of continuous incremental innovations or improvements. More specifically, he had little to say about the organisational and other characteristics of the major sources of technical change in established firms - that are large in some industries and small in others - and that maintain their existence over long periods by continuously changing their products, processes and markets.

As Freeman (1987) has concluded,

the task ... is to develop a theory of the firm which ... does not assume as its foundation either hyper-rationality of individual; of entrepreneurs or groups, nor yet supernormal intelligence and energy.

3.3 CORPORATE STRATEGY AND INNOVATION RESEARCH AS BUILDING BLOCKS TO NEW PRODUCT STRATEGY RESEARCH

While the research in corporate strategy and innovation is extensive, the subject of new product strategy as a specific research topic lacks both conceptual modelling and methods for empirical testing. Nevertheless, as synopsised below, the existing strategy and innovation research points to a large number of important variables that, taken together with the new product strategy, affect the firm's performance.

The goals and business implementation tactics that emerge from corporate strategy have a direct bearing on new product decisions. Accordingly, from a research prospective, the study of new project strategy should find a home in the corporate strategy literature.

Abell (1980) has described the complex interrelationships between defining business missions, developing functional strategies and

allocating resources to implement strategies. Porter (1980) conceives the process of defining business activities in terms of differentiation, where the firm identifies specific market opportunities that are defined by the customer requirements and competitive analysis.

Lorange and Vancil (1977) focus on the process of strategic planning itself and present formal mechanisms for integrating planning that occurs at different levels of the organisation. Techniques for corporate planning and business portfolio management are a logical outgrowth of this research. However, new product strategy is treated as a tangential issue to this research and is commonly viewed as the outcome of market segmentation and other forms of market planning. It has further been suggested that the technology factor in new product activities, which would appear equally important as the target markets of new products, is the "orphaned child" of strategy research.

It is certainly there, but nobody knows what to do with it.[49]

[49]Meyer and Roberts, 1986

A second vein of strategy research is empirical in nature. This research has focussed on the relationship between patterns of business diversification and organisational structure.

Chandler (1986) defined the hypothesis that structure follows strategy, and supported it by tracking the developments within 70 large corporations over a 20 year period. Rumelt (1974) expanded upon Chandler's thesis with another sample of large corporations, demonstrating that corporations with related business units outperformed those with wider business diversity. Roberts and Berry (1985) most recently reviewed the research on diversification strategy at the level of a firm's portfolio of businesses. But that research does not seem to extend downward to the product level.

The technological resources of the firm and their utilization also have a direct bearing on new product strategy. The forecasting of technological change has been explored in some depth, both at the general level[50] [51] and in terms of contrasting rates of product versus process innovation over time.[52]

Petrov (1982) describes how a firm may profile its technologies in a fashion similar to standard portfolio management techniques, using

[50] Martino, 1969
[51] Fusfield, 1970
[52] Utterback and Abernathy, 1975

two parameters of technological "attractiveness" and "relative technological position" of technology units identified in the firm. Gluck and Foster (1975) indicate conceptually how this profiling approach can be applied to competitive analysis at the product level. Thus technology strategy research has many interesting components.

Innovation research provides a broader foundation for the basis of new product strategy. Research in this area has been both diverse and substantial. The subset most applicable to current research interests are the empirical studies of the sources of innovation. While research in this area has examined a broad range of innovation - facilitating factors, the outcomes are often presented in the context of the roles of "market/need-pull versus "technology push" in effective innovation.[53] [54] [55] Those factors deemed important for new product successes by these researchers have included a clear understanding of user needs, strong marketing investments, active new product champions and sponsors, and the flow of relevant technical information into the organisation from external sources (for further discussion on the determinants of innovative success, see Section 3.8).

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[53] Myers and Marquis, 1969
[54] Langrish et al., 1972
[55] Rothwell et al., 1974

Since the sample of the present study includes a number of small to medium sized technology based enterprises, (see Section 8), prior entrepreneurship research may also be of background utility. The "need to achieve" identified by Mc. Lelland (1961) as the primary motivating force affecting entrepreneurs was further examined by Wainer and Rubin (1969) as a factor affecting performance of the young technology-based corporation.

Similarly, the role of prior business experience in successful technical entrepreneurship is examined in Cooper (1970) and Bruno (1977).

Roberts (1968) has identified a range of factors associated with success and failure of technology-based start-ups, including the presence of a diversified management team, the implementation of proactive rather than opportunistic marketing programs, and a high degree of technology transfer from former places of employment. However, none of these entrepreneurial studies has concentrated on product strategy issues.

Research that has specifically targeted new product strategy has usually focussed on multi-company samples of individual products or paired product comparisons.

Calantone and Cooper (1981), for example, reported on 195 new product cases from 103 firms, finding 18 cluster dimensions that related to individual product success.

Marquis (1969) and Rothwell et al. (1974) cited above, and Cooper (1979) reported similar analyses on large samples of single products. But by their very nature studies of single product successes and/or failures within a company cannot empirically explicate the firm's historical new product strategy.

To overcome the above problem Meyer and Roberts (1986) report on a method for relating the degree of "newness" within a firm's portfolio of products and the firm's economic success. Research on small-technology based companies was conducted. A two-dimensional "technology newness - market newness" grid is prepared for the product set of each firm, based on the conditions existent at the time of each product's development. Alternative weighting schemes are used to generate a "newness index" for each firm. The degree of strategic focus is shown to relate directly to corporate growth in that small firms with more restricted degrees of technological and market change in their successive products outperform companies with wide diversity.

The evidence from Meyer and Roberts' (1986) research suggests, that some product "newness" is better than no "newness" and that more technological change can be effectively employed in small company product strategy than market change.

The above research studies are useful for a study of innovation strategies and they indicate the need to focus both on past and future innovation strategies in order to assess the current position of companies, operating in a particular technology area, such as biotechnology.

3.4 CORPORATE STRATEGY AND TECHNOLOGICAL STRATEGY

Technology is a core asset and a major resource of competitive advantage. In the present period of rapid technological change, firms therefore need to consider technology strategy. A technology strategy involves an understanding within a firm, manifest among senior management, but diffused throughout the entire organisation, of the importance or potential of technology for the firm's competitive position, how in the future that potential is to be

realised and how this compliments the other aspects of strategy in the firm such as finance, marketing and personnel.

Technology strategy involves complex decisions. Foremost amongst these are decisions concerning choice between alternative new technologies, the criteria by which they are embodied into new products and processes and the deployment of resources that will allow their successful implementation, development and diffusion in the firm and its output.

The extraordinary range and potential uses of contemporary technology have important consequences for industrial and commercial firms. The industrial and organisational turbulence engendered by technological change and increasing international competitive pressures, provides threats and opportunities for firms. Therefore, an effective strategic approach to technology allows firms to cope better with these changes, and will reduce the threats and insecurities facing firms and their employees.

3.5 THE IMPORTANCE OF TECHNOLOGY STRATEGY

According to Dodgson (1989) the main issues which bear on the importance of corporate strategy for technology include:

(1) The need to cope with technological uncertainty, complexity and the discontinuous nature of technological development.

(2) The need for technology to be viewed in a global context.

(3) The need to attain "complementaries" internally between different elements of overall corporate strategy, and externally between companies' strategies.

(4) The failure of existing strategies which do not integrate technology satisfactorily.

(5) Public technology policies.

Each of these main issues which support the importance of corporate strategy for technology will now be examined.

(1) TECHNOLOGICAL UNCERTAINTY AND COMPLEXITY

The new technologies pervade both new and traditional industries. Electronics, for example, has a number of industrial branches in its own right, but significantly affects whole economies through its diffusion into wide ranging applications from manufacturing systems to telecommunications. Biotechnology has also found application across a wide variety of industries, from Healthcare to Food Processing (see Section 4.5).

Some agree that technological development is increasingly discontinuous and that product life cycles are shortening and that this has profound consequences for companies' technology strategies.[56] There are however, different interpretations of just how profound these consequences will be for firms.

Tushman and Anderson (1987) in their study of the cement, airline and microcomputer businesses argue that technological change is characterised by periods of continuous incremental change punctuated by more radical discontinuous periods. These periods of more rapid change can be "competence-enhancing", usually derived from, and beneficial to existing firms, or "competence

[56]Urban, Hauser, Dholakia, 1987

destroying" , usually exogenously sourced, and threatening to existing firms.

Pavitt (1987) contends that the formation of research and development laboratories in large firms is in part a means of internalising technological discontinuities and thereby ensuring institutional stability.

Whatever the source of technological breakthrough, it is companies with wider ranging R & D expertise that are more likely to recognise the significance and potential of both incremental and radical technological developments.

> *Broad R & D competences and skills are a method of dealing with discontinuities and turbulence; a way of technology-watching and keeping options open.*[57]

The new technologies are enormously complex. Complexity results from the convergence of technologies between, for example, computers and communications technology to produce integrated digital networks or microelectronics and biotechnology to produce novel drug delivery systems.

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[57]Dodgson, 1989

Pavitt et al. (1989), conjecture that one of the reasons for their finding that companies show greater diversification in their technological activities than in output is because of the complex nature of contemporary technological interdependencies. The sheer complexity of technological systems indicates the inclusion of technology among corporate concerns.

Strategic decisions need to be made on how to deal with this complexity; on how to match or better the opportunities is provides to existing or potential competitors.

Decisions on acquisition and collaboration as a means of dealing with technological complexity are an important component in technology strategy also.[58]

Technology strategy is important, therefore, to see firms through periods of technological turbulence and uncertainty and to deal with the high complexity and cost of technology.

(2) GLOBALISATION

Developing and marketing new technology are essentially international activities. The new pervasive or "generic" technologies

[58]Thomas and Miles, 1988

such as information technology and biotechnology are world-wide phenomena.

There are numerous examples of public policies and private corporations' strategies reflecting recognition of comparative technological advantages on a global scale.

The Japanese "Fifth Generation Computer Project" catalysed information technologies world-wide.[59] Monsanto, a US biotech company invests heavily in biotechnology research at Oxford University.[60]

The evidence presented in this study reflects the international nature of both corporate technological development and of governmental policy responses to technological challenges. There are very real differences in the strategic competences of, for example, Irish, UK, and Japanese corporations and within the same countries, marked differences in the abilities of ministries to foster and direct technology strategies. Nonetheless, there are more similarities than differences in the manifestly world-wide pressures influencing private and public strategies for technological

[59]Arnold and Guy, 1986
[60]Dodgson, 1989

development. For this reason, it is considered necessary to consider the situation with regard to biotechnology as a technological development in a multinational context, from the US, Japan and the rest of Europe including Ireland (see Section 4.6).

International intercorporate collaboration extends beyond sharing the heavy financial and intellectual burden of R & D in systems such as biotechnology, and includes manufacturing and marketing.

For Japanese corporations, the concept of globalisation of markets is paramount.[61] Furthermore, Baba (1989) argues that direct foreign investment in manufacturing plants is a similarly crucial component of strategy.

(3) COMPLEMENTARITIES

Technology strategy is important as it needs to complement overall company strategy: encompassing business, marketing, manufacturing, personnel, investment and financial strategy. Project SAPPHO showed that successful innovative firms matched their technological developments with complementary marketing,

[61] Porter, 1987

advertising and manufacturing efforts.[62] The SAPPHO project also showed that successful innovators made use of external technology and scientific advice. Teece (1987) similarly refers to the importance of "complementary assets" (marketing expertise, distribution networks) in realising full returns from technological innovation. He also highlights the importance of accessing external technological expertise.

For a company to have an effective strategy for innovation, all the aspects of the innovation process have to be considered, and strategies for change merged into a cohesive and coherent whole. Baba (1989) also emphasises the need for a successful technology strategy to encompass both product and process innovations.

External complementarities are also required. An example of this point is the biotechnology industry in the US, where Hamilton (1986) found a widespread use of external links between firms, and these links were a significant part of the firm's technology strategy.

Firms increasingly collaborate in their technological efforts. Joint-ventures and "strategic alliances" designed to merge firms' specific

[62]Rothwell et al., 1974

technological competences are now a feature in a number of industries including biotechnology.[63] [64] [65] [66]

Therefore, the contention is that contemporary technology extends the boundaries of the firm. It becomes essential to relate to the behaviour of firms in complementary horizontal and vertical activities, as the new technologies provide wider opportunities for those firms to affect competitiveness.

To overcome the problems of complexity, high cost and high risk, activities previously proprietorial to individual firms such as R & D and manufacturing may become shared between a number of firms.

As Dodgson (1989) states,

> *The necessary sacrifice of autonomy in the generation and diffusion of technology involves a strategy of sharing control in order to retain it. Without participation in multilateral technological arrangements, even the most advanced companies may lose their leadership positions.*

(4) FAILURE OF EXISTING STRATEGIES

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[63] Hobday, 1986
[64] Hladik, 1985
[65] Mowery, 1987
[66] Faulkner, 1986

Recent turbulence in world markets and extensive currency fluctuations compound and accentuate corporate uncertainty in existing strategies for growth and profitability. This added to the growing evidence which questions the strategic efficacy of recent acquisition booms, necessarily focuses attention on the importance and potential of key elements of corporations' assets, most particularly on technology and innovation. Dodgson (1989) suggests that the reasons why technology demands greater strategic consideration are compounded by the failure of past corporate strategies. Furthermore, Dodgson cites corporate obsession with acquisition as the method for achieving growth, and short-termism in corporate investment as two of the major factors which have in the past discriminated against the formulation of coherent technology strategies, at least in the US and UK.

The long-term nature of technology strategies is apparent. Corporate ventures and new business developments can take up to ten years to become profitable.[67]

Industrial clubs take many years to fuse cohesively.[68] Building the entrepreneurial ethos into large organisations, and providing the management structures and reward systems to stimulate product

[67] Littler and Sweeting, 1984
[68] Sharp and Shearman, 1987

champions and project leaders is a lengthy process.[69] Doz and Prahalad (1987) in their study of sixteen large multinational companies found that a change in strategy, once formulated, takes between three and ten years to implement.

Nevertheless, long-term commitments are required for the development of a particular technology and resulting innovation.

(5) PUBLIC TECHNOLOGY POLICY

Heightened international industrial competition has focussed attention on the sources of comparative industrial advantage, in particular, technological development. As the recent work by Patel and Pavitt (1987) shows, the behaviour of a limited number of key companies can determine the technological trajectory and economic competitiveness of industrial sectors in a company.

Public technology policy plays a major role in influencing and encouraging the extended boundaries of firms. There are nowadays few industrialised economies which do not have policies designed to encourage and support the growth of high-technology small firms.

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[69] Burgelman and Sayles, 1986

Porter (1987) has argued for the very important influence of governments' use of political pressures on global strategies:

> *The political imperative is to concentrate activities in some industries where governments provide strong export incentives and locational subsidies.*[70]

Sharp (1987) shows how ESPRIT (European Scientific Programme for Research in Information Technology) has played a seminal role within Europe in changing attitudes and strategies amongst Europe's top electronics firms. She argues that it has acted as a catalyst for the process of rationalisation now underway.

It is also important to understand the role played by firms in framing public policies. ESPRIT was formulated on the basis of representations by firms. It is essential for firms to represent a coherent argument on the need for public support, such as the Senior Advisory Group on Biotechnology's efforts with regard to biotechnology public policies in Europe (see Section 4.6.3).

A strategic view of the necessity and nature of government intervention in technology development improves industry's case for support.

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[70]Porter, 1987, p.43

Public research institutes are, of course, important sources of technology and technological support for industry. Some argue a convergence of technology with the science base.[71] [72] It becomes essential for companies not only to access scientific information and technologies from new sources, but also to learn how to transfer and integrate knowledge from these previously separate sources. There are now a plethora of public programmes and intermediary organisations and industrial firms.[73] Among those relevant to biotechnology are the ECLAIR, FLAIR, BAP and COMETT programmes which focus on biological sciences. Whether such efforts result in successful technological developments will depend on the strategies for technological receptiveness within firms.

3.6 TECHNOLOGY STRATEGY ALTERNATIVES

Technology strategy consists of the portfolio of choices and plans that enables the firm to respond effectively to technological threats and opportunities.

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[71] Narin and Noma, 1985
[72] Dosi, 1988
[73] Rothwell, Dodgson and Lowe, 1988

In formulating its technology strategy the firm must make choices in at least the following six areas.[74]

(1) Selection, specialisation and embodiment of the technology

(2) Level of technological competence

(3) Sources of technology

(4) Research and Development investment level

(5) Competitive timing

(6) Research and Development organisation and policies.

Since the technology strategy appropriate for an individual firm clearly depends on the corporate strategy of the firm, an examination of corporate strategy alternatives in high-technology industries is required.

For the purpose of this study four alternative strategies in high technology industries will be considered. The strategies discussed are based on a framework of strategies in high technology industry

[74]Maidique et al., 1988

suggested by Maidique and Patch (1988) adapted from Ansoff and Steward (1967).

(A) FIRST-TO-MARKET OR LEADER STRATEGY

Such a strategy aims to get the product to the market before the competition. It provides the advantages of a temporary monopoly in exploiting a new technology during the period proceeding the adoption of the new technology by competitors. Such a strategy normally requires a strong commitment to applied research and development in order to achieve a position of technological leadership.

SECOND-TO-MARKET STRATEGY

This strategy involves entry early into the growth stage of the life cycle and quick imitation of innovations pioneered by competitors. This strategy generally requires a strong and nimble development and engineering capability with little attention to applied or basic research.

Marketing strategies will generally be more on winning customers away from the technological innovator, with less emphasis on

primary demand generation as compared to the first-to-market strategy.

Such strategies also try to learn from the innovator's mistakes so as to develop an improved, more reliable product that may include advanced features, while avoiding those innovations or features which prove to be market failures.

(C) LATE-TO-MARKET STRATEGY

Such a strategy achieves a relative cost advantage over competitors through economies of scale, through process and product design modifications to reduce costs and through overhead minimisation and operating cost control.

To achieve a low-cost position requires product and process engineering skills. Entry into the market is generally in the growth stage or later to allow market volume to grow to the point where significant economies of scale can be achieved.

(D) MARKET SEGMENTATION OR SPECIALIST STRATEGY

This strategy focuses on serving small pockets of demand with special applications of the basic technology. Entry typically occurs in the early or growth stage of the product life cycle, but may also occur at later stages as the market is segmented further.

This specialist strategy requires a strong capability in applied engineering, a well as flexibility in the manufacturing area. Large size or mass production competence is not required for this strategy, and may even be a handicap, since the scheduling and control requirements for a large number of special applications can be exceedingly complex.

The essence of the late-to-market strategies is a reduced emphasis on basic and applied research and a resulting reduction in the risk associated with the R & D investment of the firm. Of course these defensive strategies do not absolve the firm of technological risk - risk of technological obsolescence in particular.

These strategies are also characterised by the increased investment (at least in relative terms) in various dimensions of the marketing and production activities of the firm, investments which carry their own risk.

For firms selecting a given technology area, for specialisation, the early-market strategies require a higher level of competence in the technology, reflected in proximity to the state of the art in the particular technology and increased emphasis on basic research, while the second to market strategy would employ relatively more emphasis on developmental engineering.

The relation between strategy and technology policy can also feed back in the other direction from a technological policy to strategy. A high level of competence achieved through the commitment of substantial resources to basic and applied research can lead to discoveries of new products or processes which can provide an opportunity to lead competitors in introducing a product, although the firm might view itself as pursuing a second-to-market strategy in general.

For each of the strategies discussed, there are natural implications for the capabilities required of the different functional areas within the business. Typical functional requirements associated with each strategy are represented in Figure 10.

As suggested already the appropriate technological policies for an individual firm depend largely on the strategy adopted by the firm. The appropriate strategy depends, in turn, on the competitive

FIGURE 10 : TYPICAL FUNCTIONAL REQUIREMENTS OF ALTERNATIVE STRATEGIES.

STRATEGY	R + D	MANUFACTURING	MARKETING	FINANCE	ORGANIZATION	TIMING
First to market	Requires state of the art R & D.	Emphasis on pilot and medium-scale manufacturing	Emphasis on stimulating primary demand.	Requires access to risk capital.	Flexibility rather than efficiency Encourage risk taking	Early entry inaugurates the PLC.
Second to market	Requires flexible responsive advanced R + D	Requires agility in setting up manufacturing medium scale.	Must differentiate the product; stimulate secondary demand.	Requires rapid commitment of medium / large amounts of capital	Combine elements of flexibility and efficiency	Entry early in the growth stage of PLC.
Late to market	Requires skills in Process development and Cost Effective product	Requires efficient Large Scale Production	must minimize selling and distribution costs	Require access to capital in large amounts	Emphasis on efficiency; Procedures rigidly enforced.	Entry during late growth or early maturity
Market Segmentation	Requires ability in applications Custom Engineering and Advanced Design	Requires flexibility on short to medium runs	must identify and reach favourable segments	Access to capital in medium or large amounts	Flexibility and Control required in serving different customers requirements	During growth Stage

Source : Maidique, M.A. and Patch, P. (1988), "Corporate Strategy and Technological Policy", Readings in the Management of Innovation.

opportunities and threats faced by the firm and on the objectives of the firm.

3.7 DIMENSIONS OF TECHNOLOGICAL POLICY

The following section discusses how individual dimensions of technological policy may vary with the strategy adopted by the firm. Building on the six dimensions of technology policy mentioned already one can examine the following dimensions of policy:

* Technology Selection or Specialisation

* Level of Technology Competence

* Sources of Technological Enquiry

* Research and Development Investment Level

* Competitive Timing

* Research and Development Organisation and Policies

(1) TECHNOLOGY SELECTION OR SPECIALIZATION

Obviously the selection of the technology or particular area of a given technology in which the firm will specialise is of paramount importance for the technology-intensive firm.

For the smaller firm, technology specialisation may be simply determined by the skills of the founders, while for the larger firm, existing technological resources will heavily influence the firm's choice with respect to technological specialisation.

The appropriate choice of technologies is an issue of particular importance for firms adopting the first-to-market strategy since they must adopt the technology to their product needs earlier in the development of the technology. However, the choices of a second-to-market firm trying to identify which of the technologies adopted by the first-to-market firms will prove successful, or of late-to-market firms trying to determine when to adopt a new technology for larger-scale development are not necessarily easier.

(2) LEVEL OF TECHNOLOGICAL COMPETENCE

There are two factors to be considered by the firm in deciding the level of competence to attain in a given technology, namely proximity to the state of the art in the technology and relative emphasis on basic research, applied research and developmental engineering.

The following discussion focuses on each of these dimensions individually;

(A) PROXIMITY TO TECHNOLOGICAL STATE OF THE ART

Proximity to the state of the art is an important dimension of the nature of the technology commitment of a firm, and is closely related to the timing-to-market aspect of its strategy. It in turn, has important implications for the planning and control environment of the firm and for the research versus development mix within the R & D function of the business.

The first-to-market strategy often employs high proximity to, or development of, the state of the art. This often implies a significant emphasis on applied research.

The second-to-market strategy also requires proximity to the state of the art, although the emphasis shifts from original

development to a monitoring function, followed by imitation developmental engineering.

The market segmentation and late-to-market strategies are typically a substantial distance from the state of the art, but are characterised by nimbleness in adopting new developments.

Proximity to the state of the art results in lower stability in the relevant technology for the firm and reduces predictability as to the direction in which the technology will change.

Thus strategies relying on mass production of products incorporating proven technologies are generally less susceptible to such rapid and unpredictable shifts. However, such competitors may find it more difficult to shift to new technology when it becomes economic to do so, since they are heavily committed to their technology through plant and equipment investment. Known competitors employing the same basic technology are unlikely to initiate rapid changes in technology.

For these reasons, radical change usually comes from outside the industry or from smaller more flexible competitors in the industry.

The lack of stability and predictability associated with state of the art strategies implies greater difficulty in controlling and greater need for freedom and flexibility in the R & D function.

By way of contrast, the second-to-market and market segmentation strategies are more development intensive. Development intensive organisations are characterised by well-defined design specifications, highly directive supervision and structured sequencing of tasks and development responsibilities.[75]

(B) RELATIVE EMPHASIS ON BASIC RESEARCH, APPLIED RESEARCH AND DEVELOPMENTAL ENGINEERING

Basic research, applied research and developmental engineering differ with regard to the required creativity, risk, expenditure level and return on investment.

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[75]Urban and Hauser, 1987

They also differ in the sophistication of technical personnel required, the appropriate organisational environment and the types of control procedures which can be adopted. Thus the choice, with regard to the R & D emphasis of the firm affects its risk profile and organisational structure.

Since increased emphasis on being near the state of the art and on fast response to technological opportunities, has implications for the balance between fundamental research, applied research and developmental engineering, these strategic choices also affect the risk profile of the firm and its appropriate organisational structure. As suggested already the strategic choice with regard to the state of the art has direct implications for R & D emphasis.

The commitment to developing the state of the art in a given technology generally implies a commitment to applied research due to the fact that most basic research in a given technology is carried out in government and university laboratories and independent research contractors.

A commitment to meeting the state of the art through a second-to-market strategy implies at a minimum, a commitment to a strong developmental engineering

capability and perhaps a limited capability to applied research so as to monitor and capitalise on new technology quickly, once it has been developed and brought successfully to the market.

(3) SOURCES OF TECHNOLOGICAL CAPABILITY

Although an internal R & D unit is a common source of technological capability for the firm, companies in many industries are increasing their search for new technology development outside the firm.[76]

Neuno and Oosterwald (1988) discuss technological alliances and draw a distinction between pre-competitive and competitive alliances. In the case of the former, the effort is far away from the industrial or commercial phase of development. A competitive alliance is where the companies involved in the alliance are competitors or the result of the alliance will provide two competing companies with a common component or product which will be integrated in their competing product(s).

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[76] James, 1985

A number of strategic alliances are illustrated by Beckers (1989) primarily as tools for technology transfer. These include licensing agreements, acquisitions, R & D cooperations and joint ventures.

Such strategic alliances can be an important alternative source of technology know-how, particularly for firms adopting a follower strategy, although some first-to-market firms could use it to good advantage.[77]

The reasons for forming a strategic alliance are many. Many companies form alliances due to the costs of development coupled with market and technological uncertainties.[78]

James (1985) not only cites the high development costs but also the long pay-back period as a motive for forming strategic alliances. Furthermore, it is not only small companies who need the financial support and technological input that strategic alliances offer, even large companies use such tools for technology transfer and "pooling of resources".

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[77] Maidique and Patch, 1988
[78] Neuno and Oosterwald, 1988

Finally, it should be noted that a strategic fit is vital for strategic alliances and the short-term and long-term benefits of such efforts must be considered for the individual firm to benefit.[79] [80]

(4) RESEARCH AND DEVELOPMENT INVESTMENT LEVEL

Setting the aggregate level of investment in equipment and staff that is committed to understanding, development and application of the selected technologies is a fundamental decision for the firm participating in a given technology.

The firm that attempts to be first-to-market consistently needs to make a substantial R & D investment. This investment should be balanced between applied research and developmental engineering.

The second-to-market generally makes a smaller investment and emphasises product development and technology monitoring.

The investment made by the late-to-market firm is typically smaller, yet, though these firms may make substantial investment in process engineering.

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[79] Porter and Fuller, 1985
[80] Doz, 1988

Firms following a market segmentation strategy even if they adhere to early-to-market policies may require a lower R & D investment, for the fundamental technology may be developed by firms following broader market policies.[81]

(5) COMPETITIVE TIMING

A firm may wish to lead its competitors to market taking risks with regard to technological development and market acceptance to gain a competitive advantage such as a larger market share.

Alternatively, the firm may prefer to allow other competitors to take those risks and rely on superior marketing or manufacturing capabilities to respond with a more attractive or less expensive product later in the life cycle of the product. In so doing, the firm takes the marketing and financial risks associated with these strategies.

The issue of timing is particularly important for the execution of a second-to-market strategy. Given that customers normally experience some costs and inhibitions switching suppliers, earlier entry leaves a larger portion of the potential market available for penetration without having to overcome these switching costs. And

[81] Maidique and Patch, 1988

of course, the competition for this market intensifies as more competitors bring their entries to the market.

(6) RESEARCH AND DEVELOPMENT ORGANISATION AND POLICIES

Maidique and Patch (1988) suggest that firms entering into a new technology early generally depend more on technological experts than firms that enter late. Such dependence may involve extraordinarily high levels of compensation for such experts and the establishment, if their scale of operations permits, of well equipped central R & D laboratories.

On the other hand, it is suggested that those firms emphasising competition through new technology later on in the technology life cycle experience ample availability of technical personnel with the requisite skills in the new technology.

For this reason, such firms are much less likely to adjust corporate-wide policies of the firm to satisfy the needs of the technical staff.

Thus the cumulative and differentiated nature of technological developments in firms suggest that the choices about the content of technological strategy, normally presented in the literature -

broad-front versus specialised, product versus process and leader versus follower, do not take into account the enormous variety between firms in sources of technological opportunities, and in the rate of their development.[82] In particular, the innovative opportunities open to a firm are strongly conditioned by a firm's size and by its core business.[83]

Thus, innovating small firms are typically specialised in their technological strategies, concentrating on product innovation in specific producer goods, such as scientific instruments, specialised chemicals or reagents. The key strategic tasks are finding and maintaining a stable product niche, and benefiting systematically from user experience.

Large innovating small firms, on the other hand, are typically broad front in their technological activities, and divisionalised in their organisation. The key technological strengths can be based on research and development laboratories, or in the design and operation of complex production technology (typically in mass production and continuous process industries, and increasingly in the design and operations of complex information processing technology).

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[82] von Hippel, 1988
[83] Pavitt et al., 1989

In research and development based technologies, the key strategic opportunities are horizontal diversification into new product markets. The key strategic problems are those of mobilising complementary assets to enter new product markets, for example, obtaining marketing knowledge when a pharmaceutical firm moves into pesticides.

In production-based technologies, the key strategic opportunities are in the progressive integration of radical technological advances into products and production systems, and in diversification upstream into potentially magnificent production inputs. The key strategic tasks are ensuring diffusion of best practice technology within the firm, and choices about the degree of appropriation of production technology.

Thus, firms do not have a completely free hand about whether or not to be broad front or specialised, product or process oriented. Similarly, they do not have a completely free choice about being a leader or a follower.

In many areas, especially with nascent technologies, it is not clear before the event who is in the race, where the starting and finishing lines are, and even what the race is about.

Even when it is, firms may start out wishing to be a leader, and end up being a follower.

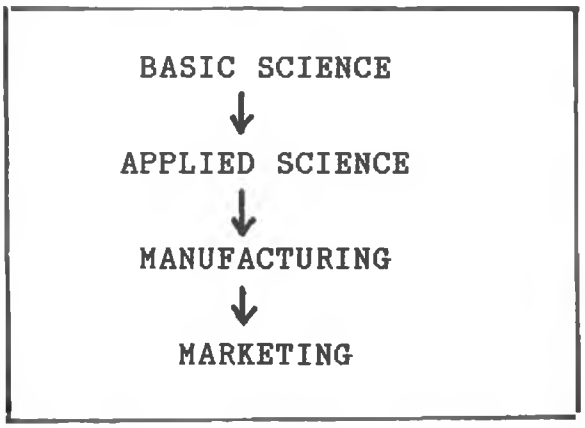
Teece (1986) has shown that while there are some advantages in being first, particularly when there are strong regimes of property rights or cumulative learning, it is sometimes advantageous to be second, particularly when product configurations are not fully fixed, so that followers can learn from the mistakes of leaders who find themselves without the required range of complementary assets.

Given the cumulative nature of technological development, technological choices in the firm also depend critically both on the time horizons chosen and on management's abilities to anticipate future cumulative paths of technological development, and their commercial significance.

3.8 THE DETERMINANTS OF INNOVATIVE SUCCESS

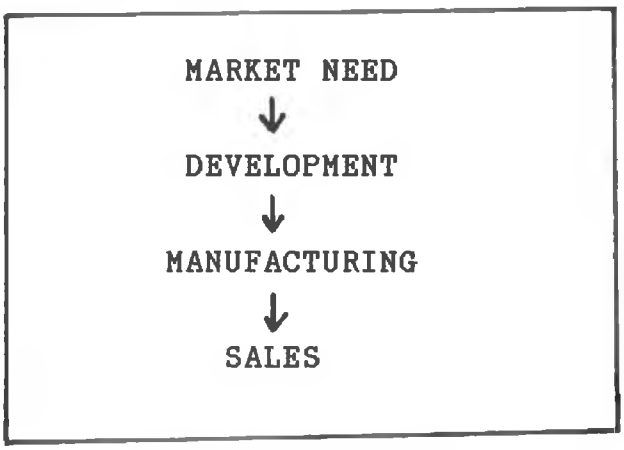
There has been considerable debate amongst economists over the actual significance of advances in science and technology to industrial innovation. To an extent this debate parallels that

FIGURE 6 TECHNOLOGY-PUSH MODEL OF INNOVATION



Source: Rothwell, R. (1983), "The Role of Design in Product and Process Change", Design Studies, 4(3).

FIGURE 7 NEED-PULL MODEL OF INNOVATION



Source: Rothwell, R. (1983), "The Role of Design in Product and Process Change", Design Studies, 4(3).

concerning the history of science with certain contributors placing the emphasis on market forces and others on technology as determinants of innovative activity.

Early models of the innovative process emphasised the casual role of scientific and technological advance and were generally linear. These can be summarised in a simple form in Figure 6 which represents the so-called "technology-push" model of innovation. According to this model, discoveries in basic science lead eventually to industrial technological developments which in turn lead to a flow of new products and processes onto the market place.

This model implies a more or less passive role for the user, and the market place is simply a receptacle for the results of research and development, and technological endeavours. Therefore, the basic premise underlying the model is that "more R & D" is equivalent to "more innovation".

From the mid-sixties onwards the role of market forces as a determinant of innovative success began to be emphasised. Strong support for the "demand - pull" theory was provided by Schmookler's exhaustive indicator-based study, in which he

showed that patenting activity has tended to lag behind investment activity.[84]

Subsequent analyses of specific innovation suggested that on average, 75% of all successful innovations were primarily due to market demand.[85 86 87]

Such research was interpreted into the linear "need-pull" model of innovation, represented in Figure 7. According to this model, innovations arise as the result of perceived and often clearly articulated needs.

In a critical review of Schmookler's work and research of specific innovation undertaken in other studies, Mowery and Rosenberg challenge the case:

> *The notion that market demand forces "govern" the innovation process is simply not demonstrated by the empirical analyses which have claimed to support that conclusion.*[88]

The authors highlight the conceptual vagueness surrounding much of this work and believe a number of methodological biases in such

[84] Schmookler, 1966
[85] Langrish et al., 1972
[86] Baker et al., 1980
[87] Utterback, 1974
[88] Mowery and Rosenberg, 1979

FIGURE 8 SUMMARY OF FINDINGS ON SOURCE OF STIMULATION FOR INNOVATION IN EIGHT EMPIRICAL STUDIES

STUDY	PROPORTION OF INNOVATIONS FROM MARKET, MISSION OR PRODUCTION NEEDS %	PROPORTION OF INNOVATIONS FROM TECHNICAL OPPORTUNITIES %
Baker et al	77	23
Canter & Williams	73	27
Goldhar & Sherwin	69	31
Langrish et al	66	34
Myers & Marquis	78	22
Tannebaum et al	90	10
Utterback	75	25

Source: Utterback, (1974), "Innovation in Industry and the Diffusion of Technology", Science, Volume 83, No.15, February.

studies afford such criticism. The authors point out the danger of generalising from empirical work which often deals with different aspects of the innovation process and different industrial sectors.

In many respects, the debate is a dead one; obviously both market and technical opportunities are necessary for success in innovation, neither is sufficient. This is confirmed in the research of Utterback (1974) who reviewed eight studies of innovation, which provided evidence of the sources of stimulation of innovation.

Their results shown in Figure 8, clearly show that both need and technology stimulated innovations exist, and that those from market mission or production needs dominate. However, as suggested by Mowery and Rosenberg (1979) the extent to which they predominate is questioned.

It does not follow for example, that because it has been suggested that successful innovators tend to have identified needs that companies should, or indeed are able to simply ascertain needs at the outset of the innovation process in order to ensure that their investment will be profitable. First as Langrish et al. (1972) noted in their study of 84 successful innovations, innovations often end up satisfying needs that are different from those originally intended.

Secondly, there is the problem of defining the "need" precisely. For instance, a consumer may have a need for a particular product, which will be defined in terms of a set of specifications. The problem is in eliciting this set of specifications, which of course the consumer itself may not be able to do articulately.

Thirdly, the priority that the customer gives to its needs and the manner in which these are defined may alter as a result of changed macroeconomic conditions, customer's specific financial circumstances, technological innovations and the introduction of new products between the formulation of the innovation's specifications and its launch on the market.

Fourthly, the "correct" identification of product specifications is not straightforward either. Marketing research techniques will tend to focus on securing information on what customers feel they want now rather than in the future, with the result that the product eventually developed will satisfy what was wanted yesterday.[89]

A final point, which is extremely important when considering innovation through the application of technology, is that technology itself can generate demand, for as it develops, the technology can open up opportunities for new products that were previously

[89]Rosenbloom and Abernathy, 1980

unanticipated. Where the technology is advancing rapidly, as in the case of biotechnology, the scope for a thorough ex-ante exploration of preferences and specifications may be extremely limited.

Under such conditions, instinct, judgement and an empathy with the market are suggested as vital ingredients for innovative success.[90]

Such ingredients may be sadly lacking in those firms accustomed to administering a large-scale operation selling to the mass market.

In the case of radical innovation employing new technology, where the eventual product specifications are likely to be imprecise at the outset, traditional marketing research techniques are unlikely to supply a meaningful working brief, while the results from many of the "management science" techniques are little more than academic given the uncertain nature of much of the data that are available.

In the case of the development of new businesses founded on new technology and sometimes, although not inevitably so, aimed at new types of customers, an adaptive, entrepreneurial approach

[90] Littler and Sweeting, 1985

based on close liaison with the market may be more appropriate for successful innovation.

Therefore, it should be noted that neither demand nor science and technology may be taken as given: both are constantly changing, and furthermore, may be directly influenced by the activities of innovators themselves through their research and development and marketing efforts.[91]

Furthermore, balance depends on equilibrium, and maintaining this equilibrium is a rather delicate process. It should be noted that marketing is about satisfying the consumer's need at a profit, and that successful marketing is supplying consumers needs using the particular advantages of the company, one of which may be technology. As Twiss (1980) explains, the challenge

> *... is not only one of innovation, but of managing technological innovation for profit.*

Twiss cites an OECD (1971) study which reviewed several research projects on the stimulus for innovation. This states that between 25% and 33% of the ideas originate within research and development, but that their importance may be greater than their

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[91] Rothwell, 1977

proportion suggests, since they tend to lead to additional need oriented programmes. Thus it should be noted that basic research has a role to play, particularly for the "big changes".

An article by James P. Casey (1976) describes a case history of high fructose corn syrup (isoglucose) and concludes that the Japanese benefited most from this innovation because of a lack of basic R & D in the USA. He states that "R & D is capable of bringing about dramatic and far reaching changes in a mature industry", in this case, the food industry. Twiss (1984) reasons that,

> *... at the more basic research end of the process we have the terrible paradox of irrelevance. We really have no clear idea about how to decide what subjects of research are not irrelevant to what it is we are trying to do ... The most important technological changes have come almost always out of the wrong line of research and out of the wrong technology ... the big changes are by definition, big changes, and are not contained in the previously understood knowledge.*

The point here is that innovation is closely related to creativity and it arises by the linking together of previously unconnected lines of thought. Hence, a major objection to the application of formal planning to research and development is that many of the most important technological innovations originate in a random fashion. Chance plays an important role and the literature often alludes to

serendipity, the process of making happy and unexpected discoveries by accident.

Creativity does not lend itself to planning. Ideas often seem to appear spontaneously or through serendipitous discovery arising from the observation of an unplanned event and noting its significance, as in the discovery of penicillin by Flemming.

Furthermore, creativity is not only required for the original concept of an innovation. There is ample scope for the application of creativity, although of a lower order, at every stage of development.

It is also argued that the technologist's spirit of inquiry, particularly when he/she is working towards the research end of the R & D spectrum, must be given some satisfaction. Provision should be made to devote some of the technologist's effort to working on projects which may not appear immediately relevant to the company's needs.

The argument runs that without this freedom to follow certain personal interests, the laboratory would become uncreative and it would be difficult to attract or retain high calibre technologists. Some managers would support provision of personal research on

these grounds alone, irrespective of the possibility of any commercial return. These considerations however, arise mainly in large laboratories where applied research forms a high proportion of the total activity.[92]

Furthermore, Twiss (1980) suggests that the existence of serendipity and personal research does not destroy the rationale for planning if the planning system is sufficiently flexible to accept some activities not directed towards clearly identified ends. He argues that this can be accommodated by the recognition that a company which is investing heavily in technology, relative to other business operations, is in reality engages in two businesses which include:

* The primary business defined by its corporate objectives which is directed towards satisfaction of identified market needs.

* A secondary technological business which is generating technology of a commercial value but often unrelated to the corporate objectives. This value will normally be realised only by selling the technology itself, although in exceptional circumstances it may warrant full development of a product

[92]Twiss, 1980

and the establishment of a separate manufacturing and marketing operation as a diversification.

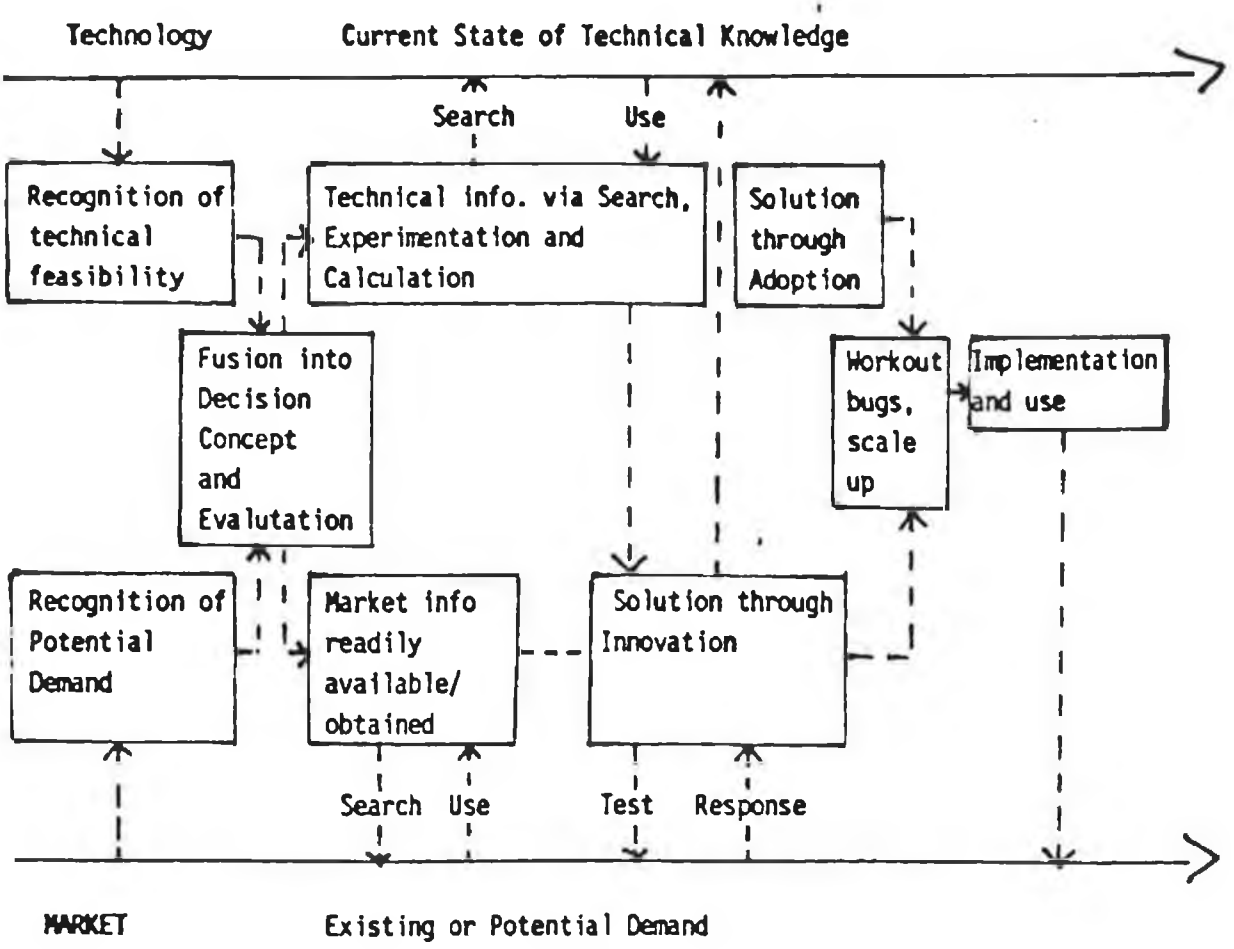
Having discussed the concept of technology-push and market-pull, and having identified that these two components of innovation are closely interlinked and that both should be present of an innovation to be successful, a more representative model of the innovation process is given by Marquis (1981).

This model recognises that the starting point for successful innovations requires the interaction of market demand and the technical resources available at a particular time. This model suggests that innovation can be regarded as a logically sequential, though not necessarily continuous process, that can be divided into a series of functionally separate but interacting and interdependent stages (see Figure 9).

What is significant about this model is the linking together of the firm to the broader scientific and technical community and to the market place.

What is crucial, therefore to the eventual success or otherwise of an innovation is the action of Schumpeter's entrepreneurs, who must

FIGURE 9 MARQUIS'S INNOVATION PROCESS MODEL (1981)



Source: Adapted from Marquis D., (1981), "The anatomy of Successful Innovations" in Corporate Strategy and Product Innovation, ed. Rothberg R. 2nd edition, Collier MacMillan Publishers, London, p.14.

find ways of "coupling" technological capability to market needs and opportunities at the earliest possible stage.

Testimony to the crucial importance of this coupling process was provided by the SAPPHO project undertaken in two phases at the Science Policy Research Unit.[93] It avoided some of the pitfalls of earlier innovation studies by investigating pairs of innovations, one successful and one failed. Altogether some forty three pairs were drawn from the chemical process and scientific instruments industries. Project workers measured 122 features of the firms involved which led them to identify five main areas of competence differentiating the successful from the failed innovators.

These were, better understanding of user needs; more attention paid to marketing and publicity; efficient performance of development; more use of outside technology and scientific advice and greater authority given to the individual within the firm responsible for the innovation.[94]

Such conclusions were upheld in a later review of the literature undertaken by Roy Rothwell of the S.P.R.U. team. Furthermore, in

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[93]Rothwell et al., 1974
[94]Rothwell et al., 1974

all of the studies covered, emphasis was placed on the role of "good communications and effective collaborations" including that with external research establishments.[95]

Empirical work in the field thus attests to the importance of scientific and technological knowledge to innovation success. Crucially, it also indicates that this knowledge comes both from in-house R & D efforts and from the external research infrastructure.

3.9 CHARACTERISTICS OF SUCCESSFUL TECHNOLOGICAL INNOVATION IN THE FIRM

Innovation research has come to robust conclusions about the factors associated with successful innovations. In addition to the quality of technical work, these include strong horizontal linkages amongst functional departments, with outside users and with other sources of relevant technical expertise; building on existing competences and skills; learning from experience; (a) responsible manager(s) with expertise in all the functional activities involved; accessing complementary non-technological assets.

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[95]Rothwell et al., 1977

Given the high uncertainties involved in technological innovation, trial and error are inevitable in the development and implementation of innovation. In fact, the major importance of development, as opposed to research activities in industrial laboratories can be considered a systematic form of trial and error.

In addition, the ability to learn from experience whether internally (learning by doing), or from suppliers, customers and competitors (learning by using, learning by failing, reverse engineering is of major importance in the management of innovation.[96]

Individuals' capacities to learn from their experience depend not only on their personalities but on their training. Comparative and empirical research has demonstrated the importance of training for the effective exploitation of technology.[97] [98] Particularly in the large firm, learning is also a collective activity requiring frequent communication amongst specialists and functions.

Since knowledge accumulated through experience is also partly tacit, and the tasks to which such knowledge is applied are complex and loosely structured, personal contact and discussions

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[96] Pavitt, 1987
[97] Pratten, 1976
[98] Prals, 1987

are the most frequent and effective means of communication and learning.

Many authors have argued that technological expertise is a pre-requisite to the adoption of a technology strategy.[99] [100] [101]

Approaches to technology strategy focus on the importance of accumulated skills within firms. There are advantages for firms building on existing competences and skills. While radical changes in strategic direction are attainable, they are more likely to be successful and more easily realisable if they focus on the competences and know-how existing within the firm.[102]

However, the significance of accumulated technological competences has been questioned by Hobday (1986). He cites the examples of new start-up companies in the semi-conductor industry in Europe, and the prevalence of strategic alliances, as examples of opportunities provided to firms without established technological strength.

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[99] Porter, 1983
[100] Pavitt, 1987
[101] Maidique and Patch, 1988
[102] Nelson and Winter, 1982

The importance of such developments and their potential in more than limited market niches has yet to be seen.[103]

Nonetheless, Hobday's observations are important. It is not purely accumulated technological competences that provide the basis for successful diversification, but it is also accumulated management skills, market knowledge and the experience within organisations which allows the firm meet changing market requirements.

The importance of successful innovation of collaboration and interaction amongst the various functions within a firm, particularly research and development, production, marketing and finance is well known.[104] [105]

Several authors have asserted that technology strategy cannot be considered in isolation from the other facets of corporate activity, including those mentioned already.

Successful technological innovation, be it in semi-conductors, chemicals, foodstuffs or new materials depends on the ability of

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[103] Dodgson, 1989
[104] Rothwell et al., 1974
[105] Cooper, 1980

firms to access non-technological, complementary assets, and to use them effectively.[106]

Senker and Brady (1989) address one particularly important complementary asset, the skills of the people developing and using the technology. These authors suggest that just as technology needs to be considered strategically, so too does human resource development.

The complexity and composite nature of technology along with the high cost and risk associated with its development has led to technological collaboration between firms, and between firms and infrastructure scientific organisations.

The ability to access and integrate external sources of knowledge helps to overcome the problems cited above. Furthermore, as discussed in Section 2.6, it can overcome skill deficiencies and provides a potential source of comparative competitive advantage. The process of accessing and integrating such externalities involves several key functions including considerable management skills, identification of skill deficiencies, effective decision making in choosing partners and careful monitoring of the effects of such collaborations. Obviously, such skills are put to best use in the

[106]Dodgson, 1989

pursuit of technology central to a firm's future direction and development, that is collaboration needs to be viewed strategically.

These research results show that further analysis of the processes of technological innovation and characteristics of successful technological strategies in the firm need to go beyond purely political interactions between functional and professional groups, to include learning from experience, communication from within and amongst firms' functional elements, and with the outside world of suppliers, users and competitors, building on existing competences and skills and accessing non-technological complementary assets.

The following section attempts to show that these characteristics have major implications for theory and action related to the content of technological strategy, to the processes through which they are developed and implemented, and to organisational continuity in the face of technological discontinuity.

First of all it is necessary to consider corporate strategy of the firm as it has implications for technological strategy.

Company structure and company strategy play a major role in the formation of technological strategy. Sharp (1987) argues that

recent initiatives in European technological cooperation in ESPRIT have taken off rapidly precisely because they involved chief executives rather than solely R & D directors.

However, as outlined in the previous discussion the results of past research show that technology strategy cannot be described solely in terms of negotiation between professional and functional units in the firm. In the market system, the ability to satisfy the user's needs better than the alternatives on offer is the ultimate measure of success and profitability, and consequent the allocation of resources, power and prestige within the firm.

3.10 SETTING STRATEGY AND DIRECTION FOR INNOVATION: THE NEW PRODUCT DEVELOPMENT STRATEGY STATEMENT

The new product development strategy statement is essential in setting the direction for innovation within the firm. The essential elements of this statement are the specification of the product - market scope to become involved in, and identification of the basic

strategies to be used for growing within that product - market scope.[107] [108]

In attempting to specify the product - market scope element of the new product development strategy the firm should adopt a definition of the future business the firm wishes to be involved in. In defining future business several important criteria should be satisfied.[109]

(A) Future business should be linked to the present product - market scope by a clearly definable common thread.[110] However, Ansoff (1969) clearly argues that the linkage can be with product characteristics, distribution capability or underlying technology as long as the firm has distinctive competency in these areas.

(B) Definition of the product - market scope should be as specific as possible to impact on the organisation.

(C) The product - market scope definition should be adapted constantly to recognise changing environmental conditions.

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[107] Day, 1988
[108] Booz, Allen and Hamilton, 1982
[109] Day, 1988
[110] Day, 1988

(D) The firm's resources and competencies must be compatible with the product - market scope definition.

(E) The product - market scope should reflect the exploitation of the firm's strengths and competencies that are not possessed as fully by the competition.

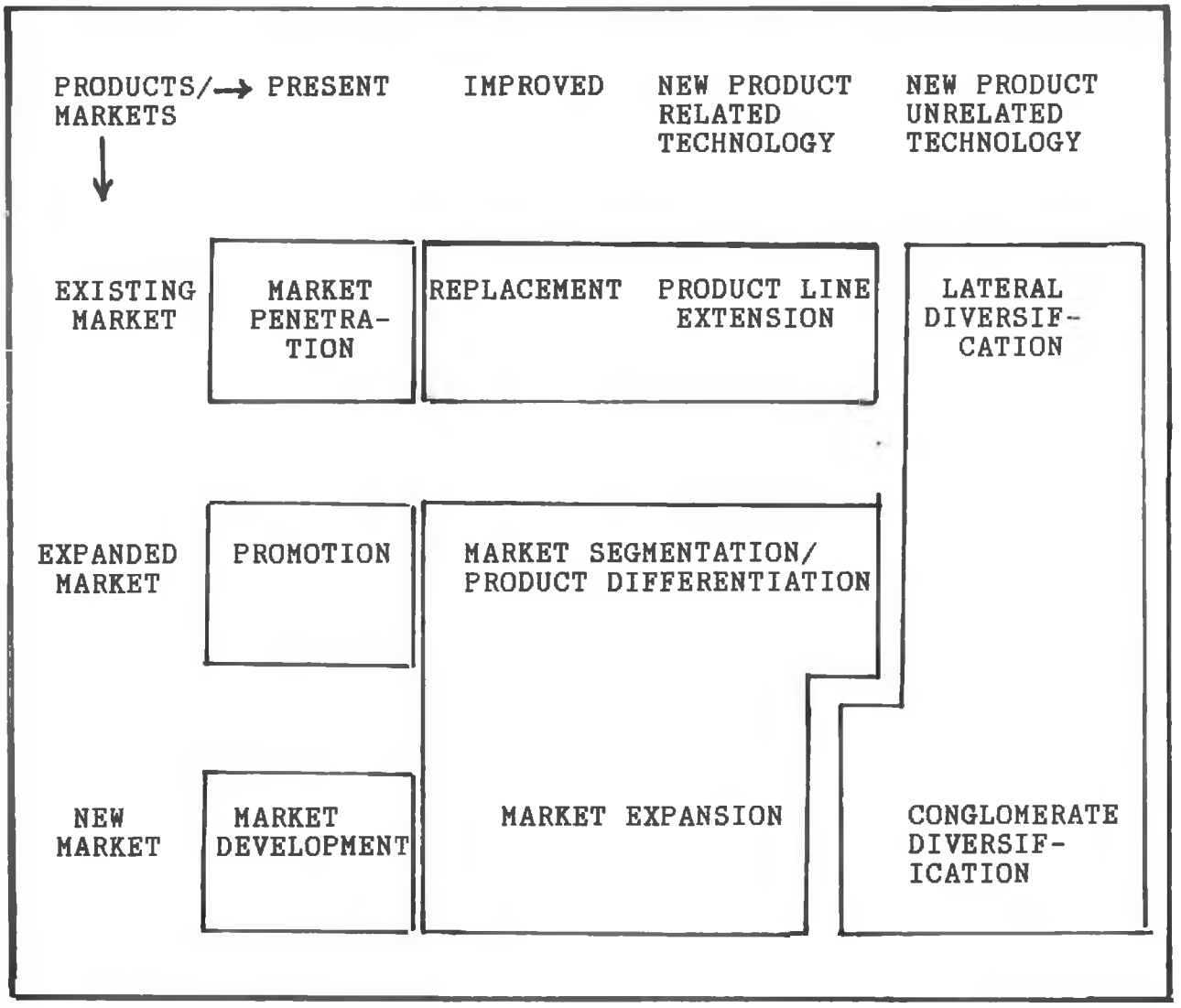
At the broad level of a new product development strategy, the basic issues are the strategies to be used for growing within the chosen product - market scope, and the emphasis on innovation versus imitation. There are almost an infinite number of possibilities for growth strategies. The basic alternatives are summarised in Figure 11.

These strategies are by no means mutually exclusive, indeed various combinations can be pursued simultaneously in order to realise identified opportunities.

Furthermore, most of the strategies can be pursued either by internal development or acquisition and coupled with vertical diversification.

An equally crucial basic strategy choice is the degree of emphasis on innovation versus imitation. The conscious decision to lead or

FIGURE 11 GROWTH STRATEGY ALTERNATIVES



Source: Kollat, D.T., Blackwell, R.D. and Robeson, J.F.; "Strategic Marketing", N.Y., Holt, Rinehart and Winston, 1972, pp. 21-23.

follow pervades all aspects of the firm. Some of the important differences that result can be seen from the various strategic orientations to high technology markets discussed by Ansoff and Steward (1967).

Briefly, these strategic orientations involve a strategy based on strong R & D, technical leadership and risk-taking which attempts to be first-to-market with the results of its technology. Secondly, a strategy based on strong development resources and the ability to act quickly as the market starts its growth phase. "Applications Engineering"[111] involves a strategy of production modification to meet the needs of particular customers in mature markets. Finally, "me-too" strategies involve competition through superior manufacturing efficiency and cost control.

[111] Ansoff and Steward, 1967

3.11 INNOVATION AND CORPORATE CULTURE

An innovative programme should be carried out in an environment conducive to new products and guided by corporate objectives.[112] [113] The final component of an innovation strategy is a set of guide-lines that drives the corporate culture required to execute the innovation strategy.

Once the type of innovation required to meet the strategic objectives have been identified, an environment must be created to support the development of such innovation. Environmental elements include management style, organisation structure, management responsibility and support from top management.

In creating a supportive environment it is crucial that product opportunities be matched to the elements listed in Figure 12. For example, generally riskier ventures or those with a longer pay-back period such as the development and launching of new product lines, or new-to-the-world, innovative products, require a more entrepreneurial management approach. A highly creative venture team, headed by a general manager eager to take substantial risks and strongly supported by top management, would be appropriate.

[112] Booz, Allen and Hamilton 1982
[113] Kuczmarski and Silver, 1982

FIGURE 12 NEW PRODUCT PROCESS ENVIRONMENT

NEW PRODUCT OPPORTUNITY	ORGANIZATION STRUCTURE	MANAGEMENT STYLE	RESPONSIBILITY	TOP MANAGEMENT SUPPORT
NEW PRODUCT	VENTURE	ENTREPREN-EURIAL	GENERAL	HIGH
ADDITIONS TO EXISTING LINES	MARKETING &/OR R&D	COLLEGIAL		
REPOSITION/ COST REDUCTIONS	FUNCTIONAL	MANAGERIAL	FUNCTIONAL MANAGER	MODERATE

Source: Kuczmarski, T.D. and Silver, S.J., "Strategy: The Key to Successful New Product Development", Management Review, July, 1982, p. 40.

It should also be noted that innovation opportunities change over time, and companies must change their environments accordingly. Companies should periodically and systematically evaluate the innovation strategy and the organisational environment to avoid the problems that result from a mismatch.

Many authors have suggested that approaches to innovation strategy and organisational environment should be tailored to support emerging innovation objectives.[114]

3.12 TECHNOLOGICAL DISCONTINUITIES AND INSTITUTIONAL CONTINUITIES

With the present wave of radical technological change in microelectronics, information technology and biotechnology, considerable emphasis is being placed on management theory and practice on the notion of "technological discontinuities", implying a radical increase in the rate of technical change, and a marked shift in its associated skills and required organisational forms.[115]

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[114] Booz, Allen and Hamilton 1982
[115] Tushman and Anderson, 1987

It is often argued that technological discontinuities are associated with the emergence of new small firms to exploit them, given conservatism, obsolescence and bureaucracy in established large firms.

However, research has indicated that some of the most revolutionary business applications of several technologies including semi-conductor, microelectronic and information technology, are to be found not only in new technology-based firms, but also amongst the longest established, largest and most conservative of firms. Two factors may help explain why technological discontinuous can co-exist with institutional continuities.

First, large established firms normally have specialised and professionalised R & D laboratories and other technical functions with accumulated skills and experience in orchestrating and integrating inputs from a wide variety of scientific and technical disciplines. They are therefore experienced in hiring and integrating professionals from promising new areas.

Examples from the past included the hiring of computer experts by IBM[116] whilst today strenuous efforts are being made by the large

[116]Katz and Philips, 1982

chemical firms to understand and assimilate biotechnology advances.[117]

The second reason was identified by Schumpeter in his later writings.[118] Large firms have both considerable resources and oligopolistic power. The opportunity to explore the implications of technological discontinuities with core competences within the firm, through learning and incremental change, before deciding whether or not to move into commercialisation. One observable feature of innovating firms is precisely that they develop technological capabilities beyond those strictly related to their current output.

[117] Faulkner, 1986
[118] Schumpeter, 1950

CHAPTER 4: BIOTECHNOLOGY AND INNOVATION

4.1 INTRODUCTION

This section of the present thesis involves a largely descriptive outline of the technological context of the present study, that is, biotechnology. This outline is presented to provide essential background information regarding biotechnology for the reader. It starts with a short history of the evolution of biotechnology and focuses on current and future perspectives. The global biotechnology situation is briefly discussed. Furthermore, specific issues related to the development of biotechnology and its commercial applications are discussed; including public attitutes and acceptance of the technology; finance and patent protection. Such a discussion is essential when considering the commercialisation of new products or processes through biotechnology.

4.2 BIOTECHNOLOGY

Biotechnology is a generic technology, a somewhat formless body of knowledge and experience about particular groups of production process, with applications in a wide range of different

industries. As a consequence of its very nature, available definitions of biotechnology tend to be indistinct. The following are amongst the most frequently cited; taken together they indicate the multidisciplinary nature of the technology:

> *The application of biological organisms, systems or processes to manufacturing and service industries.*[119]

> *Any technique that uses living organisms (or parts of organisms) to make or modify product, to improve plants or animals or to develop microorganisms for specific uses.*[120]

> *The integrated use if biochemistry, microbiology and engineering sciences in order to achieve industrial technological application of the capabilities of microorganisms, cultured tissue cells or parts thereof.*[121]

Thus biotechnology may be taken to refer to the industrial use of biological agents, especially microbial, plant or animal cells. Unfortunately, the term biotechnology has, at least in popular usage, become synonymous with "genetic engineering". This usage is misleading in the genetic engineering is only one of the techniques involved in the technology. Furthermore it ignores the extent of existing industrial capability in biotechnology and the long history underlying recent scientific and engineering advances.

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[119] A.C.A.R.D., 1980
[120] Office of Technology Assessment, 1984
[121] European Federation of Biotechnology, 1981

4.3 THE HISTORICAL EVOLUTION OF BIOTECHNOLOGY

Biotechnology may be characterised as having three generations historically.[122] The first generation dates from pre-history to the 1940s and incorporates the traditional uses of microorganisms by fermentation to produce food, drink and energy. This historical period of biotechnology is characterised by minimal scientific and engineering inputs.

With the discovery of penicillin, and the consequent use of natural microorganisms to produce therapeutic or chemical agents, the technology entered its second generation of evolution. The "second generation" of biotechnology which lasted until the 1970s was based on the integrated application of industrial microbiology, biochemistry and chemical engineering. This period is characterised by the organisation of scientific and engineering inputs to industrial scale processes.

The "third generation" of biotechnology had its origins in the discovery by Cohen and Boyer in 1973 of restriction enzymes which enabled the deoxyribonucleic acid (DNA) chain to be cut,

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[122] A.C.A.R.D., 1980

inserted and accepted by a foreign host. This period in the evolution of the technology is characterised by the production of novel genetic combinations and is based on the applications of molecular biology and the use of genetic engineering techniques.

During the past years there has been a growing realisation that new biotechnology, resulting from developments during the third generation of the technology's evolution, represents the third and probably the most dynamic technological revolution of the 20th century, preceded only by nuclear energy and information technology. Among the fundamental aspects of this revolution are;

a) The development of recombinant DNA technology based on the powers of gene cloning and splicing which allow for the production of large quantities of DNA and for the expression of DNA towards the production of rare proteins.

b) Hybridoma technology allowing for the fusion of specific antibody - producing spleen cells with myeloma cells to produce large quantities of pure antibodies, and,

c) Instrumentation for the microsequencing of proteins and DNA and for the synthesis of oligonucleotides and peptides.

These and other powerful technologies based on earlier fundamental research, carried out during the second generation of the technology's evolution, will have an increasing impact on the world's major problems of disease, malnutrition, energy availability and environmental deterioration.

4.4 CURRENT AND FUTURE PERSPECTIVES: MAJOR SECTORS OF APPLICATION

The only way to indicate the importance of biotechnology products at present and in the future (actual or potential) is by sales or production figures. However, precise data on current sales and production have until presently been extremely scarce and fragmentary.[123]

In contrast however, global market forecasts for biotechnology products have been numerous. It should be noted however that the reliability and relevance of such forecasts should be considered. Furthermore, factors such as the rate of diffusion of biotechnology, including environmental and public acceptance of biotechnology products and the future general economic situation

[123] United Nations Centre on Transnational Corporations, 1988

will effect the development of biotechnology and also determine the potential markets for innovative products and processes arising from this technology. A further discussion of such factors are considered in Section 5.

Nonetheless, global market forecasts for biotechnology continue to be performed. Table 1, compares results of eleven reports provided by different industries during the 1980-90 period. This shows an extremely wide range of forecasts with an order of magnitude separating the least optimistic forecast of 9 billion dollars for the year 2,000 from the most optimistic which was over 100 billion dollars.

It has been suggested from these and other OECD (1989) figures that the most current commercial applications of biotechnology are in the chemical, pharmaceutical and instrumentation/electronic sectors, because the technical hurdles have been more rapidly overcome.

Commercial applications in food and agriculture will develop more slowly until the mid 1990s because significant technical hurdles must still be overcome.[124]

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[124]Senior Advisory Group on Biotechnology, 1990

TABLE 1: FORECASTS ON SIZE OF WORLDWIDE MARKETS FOR BIOTECHNOLOGY DERIVED PRODUCTS (IN MILLIONS OF DOLLARS)*

Report	Year	Pharamaceut. & Healthcare	Chemicals Processing	Agriculture & Food	Energy	Total
Business Communication Company	1990	12,300	270	430	-	13,000
Robert S. First Company	1985	1,400	250	-	-	-
	2000	43,000	8,200	-	-	-
Genex Corporation	1990	-	-	-	-	10,000
International Resources Development	1990	-	-	-	-	3,000
International Planning Information (UK)	1990	-	-	-	-	4,500
	2000	-	-	-	-	9,000
Arthur D. Little	1990	-	-	4,000	-	-
	2000	23,000	-	-	-	-
Policy Research Corporation	2000	10,000	-	75,000	-	-
Predicasts, Inc.	1985	1,120	-	6,200		
	1995	18,600	-	101,000		
T.A. Sheets & Company	1990	2,900	5,100	-	9,400	-
	2000	9,100	10,600	21,300	16,400	69,000
Strategic Inc.	1990	5,000	-	4,500	-	-
	2000	-	-	9,500	-	-
US Congress Office of Technology Assesment/ Genex Corp.	2000	-	-	-	-	14,600

*High Technology Institute, Profits and Outlook: Biotechnology, US Dept. of Commerce, International Trade Administration / Genex Corporation, Washington DC, 1984

4.5 MAJOR SECTORS OF APPLICATION FOR BIOTECHNOLOGY

4.5.1 PHARMACEUTICALS (DRUGS AND HUMAN HEALTHCARE)

The new biotechnology has clearly had its earliest and greatest impact on the pharmaceutical and healthcare industry. Already, products of this industry have emerged in the form of insulin, produced by bacteria for use in the treatment of diabetes, several interferons for the treatment of cancer and leukemia, human growth hormone for the treatment of pituitary dwarfs, tissue plasminogen activators used for the dissolution of blood cells clots and a hepatitis B sub-unit vaccine.

Other important new products are the many (hundreds in fact) of diagnostic tests uniquely capable of detecting diseases including chimeric, that is humanised, monoclonal antibodies, some of which will also be used in therapy.

The general trend with regard to biotechnology application in the pharmaceuticals sector will be towards disease diagnosis (immunological tests, gene probes, biosensors etc.) and prevention (vaccines) rather than cure, although this will require the continual generation of new knowledge related to the etiology and pathobiology of disease.[125]

Acquired Immune Deficiency Syndrome (AIDS) has dramatically influenced society and become a problem of sever proportions. New biotechnology has already facilitated the understanding of the disease, by the generation of monoclonal antibodies, DNA probes and genetic structural analysis, thereby enhancing the ability to detect the virus. Simultaneously, numerous approaches to dealing with the disease have been initiated utilising biotechnology products. Vaccines, viral inhibitors and immune modulators are being actively pursued and hopefully will provide a solution before the end of the century.

The drug industry is suffering badly from the spiralling cost of R & D. A drug can cost up to $125 million to bring to the market and that figure may have trebled by the end of the century.[126] Meanwhile, the number of prescriptions is not growing and

[125]OECD, 1989
[126]Johnson, 1990

governments are increasingly exerting price pressure to cut their public health bills. The outcome is necessarily a reduction in the number of new therapeutics that are launched. In this atmosphere, pharmaceutical companies are increasingly joining in crucial alliances to ensure that expensively developed new drugs are launched without any significant competition. They are also turning to chirality as the possible solution to their problems.

Many compounds have what are called centres of chirality. Around these centres the attached molecules can be arranged in two ways. Even though the two versions are the same compound, they can have different biochemical effects in the body. The two versions or isomers are referred to as dextro (D) or levo (L) depending on the direction in which they rotate polarised light.

Usually, only one version exists naturally. Only the D-isomer of thalidomide, the anti-morning sickness drug prescribed in the 1960s, caused the toxic effects seen. The other isomer was not toxic, but was an effective therapeutic.

Although only one isomer may be necessary or effective in treating a patient, drugs are often a mix of isomers because synthetic methods produce both types and separation can be difficult and expensive. Many drugs on the market contain this "isomeric

ballast" which at best, is ineffective and wasteful of manufacturing efficiency and, at worst, may be toxic to the patient as seen in the case of thalidomide.

While no country is banning racemic (mixture of the two isomer forms) drugs, drug companies in Europe and Japan must now produce evidence that racemates on the market have advantages over the single pure isomers.

In the U.S., the FDA (Food and Drink Administration) looks as if it is heading in the same direction. The results of this will be that companies will be forced to carry out extensive and very costly testing of the different isomers of compounds on the market.

However, the fast spawning separation technology and the increasing availability of isomeric intermediaries or chiral pathways may, in turn, lead to an increase in drug specificity.

Specificity will lead to a drop in drug volumes according to Dr. Balling, director of sales and new product development for DSM chemicals,

There will be fewer billion dollar drugs but these new isomers will be very, very marketable, because of their specificity and their safety profile.[127]

Marketing a racemic pharmaceutical already on the market, in its isomeric form can also be one way to extend a patent or revamp an old drug. Schering has done this with its beta blocker product, Labetalol. Schering is now marketing the single isomeric form of this product as Dilevalol and claims it significantly reduces postural hypertension or dizziness on rising, a side-effect of beta blockers, including Lebetalol.[128]

However, in some racemates the isomers actually potentiate each other's action and this two can be marketed as a bonus.

Hence, biotechnology influences the development of chiral intermediates by providing stereo-selective biocatalysts and facilitating speedier and more effective separation of racemates. Furthermore, it has been predicted that by the year 2000 chiral chemistry will be the major element of new intermediates for drugs being launched[129] and biotechnology has certainly a role to play in this development work.

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[127]Johnson, 1990
[128]Ibid, 1990
[129]Johnson, 1990

Finally, an entirely new challenge has arisen to deal with the delivery of protein/peptide drugs and therapeutics. These large molecule drugs cannot be absorbed orally without being degraded, and injection of large molecules has also proved problematic and occasionally followed by side effects. Delivery problems, including for vaccines, have led to delays compared with the expectations of a few years ago. Consequently, drug delivery technologies, both for humans and for animals have become a major area of interest, mobilising already several dozen specialised companies. New and novel approaches for drug deliveries will be required and will draw heavily upon the advanced, physical, chemical and modern biological tools mentioned previously.

Modern technology therefore has the potential to change the technology paradigm of healthcare and the pharmaceutical industry, to improve cost control of healthcare and to enormously enhance the quality of human life.

4.5.2 AGRICULTURE AND FORESTRY

Agriculture is one of the largest economic sectors throughout the world and one where the stakes of new biotechnology are very

great. In the fields of plant and animal agriculture, biotechnology may improve food production by increasing the growth rates and growth efficiency of animals. Transformation technologies have the potential to create plants resistant to diseases, insects, herbicides, and plants capable of surviving in environmentally harsh climates. Genetically engineered microbial organisms to control plant pests and influence nutrient uptake are also under development.

A key area of agriculture is already benefiting from biotechnology-generated products is the livestock industry. Field trials have indicated that bovine somatotrophin (BST) a naturally occurring protein in cows, can be supplemented with biotechnology-derived somatotrophin to increase milk production and improve feed efficiency leading to more milk for the same amount of feed. New and improved vaccines are being produced for foot and mouth diseases, scours, shipping fever and other diseases of domesticated animals.

The understanding and use of retroviruses for the creation of transgenic animals is advancing and may provide a means by which animals will be born resistant to various diseases.

In animal reproduction, sex-specific semen may well enhance the business of embryo transfers by producing a greater concentration of embryos of the desired sex, although this has also led to concerns that sex-specific semen could be used in human reproduction. Research focussing on reproductive hormones, such as luteinising hormones, folicle-stimulating hormones and gonadotrophin-releasing hormones will both benefit animals and produce many spin-offs for various aspects of human fertility.

In many of the above described developments, fundamental molecular biology, with particular emphasis on receptor biology and the regulation of hormone/receptor systems, will be pursued. As anticipated for the pharmaceutical industry, this transition will ultimately lead to the development of organic molecules that replace or augment the first generation of biotechnology-based animal products.

Lastly, an area of rapidly developing interest is the use of animals as bioreactors to produce rare proteins. For example, the tissue plasminogen activator gene has been engineered to create transgenic mice that produce and secrete tPA into the mammary glands. By simply milking the animal, the product can be isolated and purified. Similar studies are being conducted with larger

mammals. However, the economics of manufacturing rDNA products by this means has yet to be established.

4.5.3 FOOD AND FEEDS

Many aspects of the food and feeds industry could benefit from biotechnological advances made in plants and animals, as described in Section 4.5. Significant quality changes can be anticipated in food products derived from these sources.

Biotechnologically-derived and improved enzymes for food processing, such as bovine chymosin (rennin) used in milk clotting, have already undergone first generation developments. The further modification of these enzymes through protein engineering may lead to the potential industrial production of foods under conditions that are more efficient and cost effective. This area holds great potential for the food processing industry.

The genetic modification of food using genetically engineered lactic acid bacteria represents yet another area for growth and opportunities. These bacteria find utility in the production of

thickening agents, natural food preservatives and enhancers of flavour development. These bacteria also represent a safe production host for the manufacture of a variety of food grade products such as chymosin for the manufacture of cheese.

Significant advances can be expected in other food grade microorganisms, such as yeasts (for example, for low calorie beer), bacteria, and fungi. The use of these organisms for the production of important food technology enzymes and in various fermentation processes will be beneficial.

Clearly, the food products derived from the applications of fermentation technology, enzymology, and food microbiology will benefit from advances in basic biology and biotechnology.

4.5.4 CHEMICALS - SPECIALITY AND COMMODITY

Many important industries are actively using fermentation to produce industrial chemicals. They range from gluconates, lactic

acid, citric acid, antibiotics, steroids, amino acids to a wide variety of enzymes.

Amino acids will be among those products benefiting most from advances in genetic engineering, host strain modification and improvements in the bioengineering sciences, such as fermentation, reactor design etc.

The major trend in those instances will be the application of fundamental genetic engineering to cost reduction in the production of a variety of amino acids, such as phenylalanine, aspartic acid and lysine.

Biotransformation, which may include fermentation but is somewhat more specific and sophisticated may find increasing use in the modification of modules. Biotransformation is the modification of organic substrates using enzymes and other biological systems. It is likely that chemists will use enzymes for synthesis instead of classical organic reagents.

Advantages of such approaches would include reduction of side products, thereby minimising pollution problems and maximising yields. It should be noted that enzymes used in organic reactions

will help the chemist in the laboratory and may well see commercial application in more sophisticated and high value products.

Protein engineering will provide a major tool for the improvement and development of industrial enzymes, an opportunity which is already actively pursued by industry. Examples will include enzymes with greater stability, unique physical properties and novel applications.

Regarding feedstocks for biotechnology applications, it is likely that sucrose, starch, methanol, paraffins and lignocellulose will be potential replacements for the commodity chemicals currently produced from petroleum. However with current oil prices, one should not expect a significant impact of biotechnology on commodity chemicals in the next decade.[130]

4.5.5 ENVIRONMENT

While much has been written about the environmental uses of biotechnology, including about biofilters which play an increasingly

[130]OECD, 1989

beneficial role in waste-treatment plants, many commercial developments for pollution control and waste-treatment will be slow in the next decade.[131]

Important future applications for biotechnology in the environment will include the area of waste water purification, groundwater contamination and the recycling of important chemical materials such as sulphur. Progressing this area will be economically influenced by the coupling of reactor design and chemical engineering principles with the genetic modification of appropriate microbes.

Bacteria will be engineered to enhance the metabolism of sequester-specific toxic wastes. While naturally occurring bacteria have abilities to degrade a variety of specific chemical agents, modern genetic engineering and selection tools will be able to enhance the abilities of these microbes to be more efficient and cost effective.[132]

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[131] OECD, 1989
[132] OECD, 1989

4.6 GLOBAL BIOTECHNOLOGY

Developing and marketing contemporary technology are essentially international activities. The new pervasive technologies, information technology, new materials and biotechnology are world-wide phenomena. There are numerous examples of public policies and private firms' strategies reflecting recognition of comparative technological advantages on a global scale. In recognition of the economic importance of biotechnology many nations of the world are becoming increasingly involved in the new era of technology.

This section of the present report examines the level of international involvement in biotechnology, considering such issues as development origin, public policies and the major industrial sectors involved in biotechnology in individual countries. The discussion focuses on these issues relating to the US, Japan and Europe.

The centre of commercial biotechnology activity as measured by small enterprise creation and corporate investment is clearly the United States (see Section 4.6.1). US commercial biotechnology is a result of the country's strong climate support for biotechnology and the fact that American investment culture and incentive

schemes remain innately more attractive for risk capital, especially start-up venture capital.

Furthermore, the United States has been the principal beneficiary of recent commercial investment in biotechnology, both start-ups and major investments. It is interesting that European investors represent a significant share of biotechnology investment in the US. Furthermore, virtually all US-source start-up investment in 1989 remained in the US. Japanese investment patterns reflect a strategy of global technology sourcing with regard to biotechnology, (see Table 2).

Intellectual property rights, and particularly patents, are a direct indicator of effective research and development activity. Even more important they secure the future economic benefits of R & D and commercial investments (see also Section 4.7.3 for a further discussion on intellectual property rights). It is interesting that far fewer biotechnology patents are being granted around the world to European inventors than to American or Japanese inventors, 19% versus 41% and 36% respectively of patents recently documented (see Table 3). Furthermore, European-owned patents account for far less of total biotechnology patents granted in each competing region than the US and Japanese-owned patents, that is,

TABLE 2 COMMERCIAL BIOTECHNOLOGY INVESTMENTS IN 1989

TO EUROPE	FROM EUROPE	FROM USA	FROM JAPAN	FROM OTHERS
Start Up	FM Innovation Immunology Ltd. Biocon. Genset Duclos Fermentech Serono (Spain) Scottish Beef Dev. Bioresearch Ireland Knoll. MOC Tech		PGS British Biotechnology AGC	
Corporate	Inov Elf Biotech. Inv. Finbiotec. ICI	Johnson & Johnson Smith Kline G.D. Searle	Chugai Japan Tobacco	
TO USA				
Start Up	Genentech Cultor Kodak Bissendorf Peptide Inestar Separex DNA Plant Tech. Cytel Karo Bio	Integr. Gen. Genzyme. Ingene Viragen. Xoma La Jolla Pharma Cy. Oncogenetics CT Biosciences Metabolic Biosys. Epicor. Transgene Receptech Athena Neurosciences Affymax. Mimesys Cent. for Innov. Techn. Delphi Biovent. Biolistics. Genecor Bioscience. Epicor Agridiagnostics Infergene	Native Plants Inc. Mycogen	
Corporate	Wacker-Chemie Hoffmann-La-Roche BASF. Schering Bayer Organics Intern.	State Farm Fritzsche Dodge Ji. D. Blech Boston University Delco. Upjohn Paine Webber Equity Tr. IO Publishing D.M. Blair. Mercon Labs Calgene. Gen-Probe Cartel Aquisitions	Kaken Chugai Kubota Sumitomo Chemicals Japan Tobacco	USSR Acad. of Sciences Institut Merieux (Can.)
TO JAPAN				
Start Up			Daiichi Seed Plantech Sumitomo Metal Bionks MT Science Co. Ltd.	
Corporate			Toray. Mitsubishi Izaki Glico Sumitomo. Mitsui Sanyo Chemical Dowa Mining Nippon Roche	
TO OTHERS				
Start Up	Connaught (Canada) Unipharm (USSR) Biotech. Austr.	Un. Biot. Lab (China) Cibran (Brazil)		Gene Shears (Austr.) Pacific Biotech. (Austr.) Vepex (Hungary) Unicorn Biotech. (India) Hong Kong Inst. Biotech.
Corporate				Cortecs (Austr.) Wheat Pool (Canada) Apotex (Canada)

Source: Senior Advisory Group on Biotechnology Report 1990, SAGB, Brussels.

irrespective of the features of the local patent environment (see Table 3).

Europe falls behind America and Japan in securing proprietary rights for biotechnology for a number of reasons, but primarily due to the fact that unlike the US and Japan, Europe remains ambivalent about patents for biotechnology;

(1) Europe has not yet reconciled its traditional system of Plant Variety Rights with the need for strong biotechnology patent law.

(2) European law currently excludes patents for plant and animal varieties.

(3) The ethical acceptability of patenting living organisms has yet to be resolved in Europe via open political debate and resolution.

(4) Biotechnology inventors are seeking patents first where the entrepreneurial opportunities are perceived to be greatest, that is, in Japan and the United States.

TABLE 3

ACQUISITION OF INTELLECTUAL PROPERTY RIGHTS - RECENT BIOTECHNOLOGY PATENTS GRANTED

Patent issued in	Origin of Patent Holder			
	Europe	USA	Japan	Total issued
EUROPE (EPO) * (1985) (1)	123 (29%)	215 (50%)	92 (21%)	430 (12 mths.)
USA (1988) (2)	500 (26%)	950 (51%)	420 (23%)	1,870 (6 mths.) estimate 3,700 (12 mths.)
JAPAN (1988)	239 (10%)	454 (20%)	1,599 (70%)	2,292 (12 mths.)
TOTALS	862	1,619	2,111	4,592

* EPO = EUROPEAN PATENT OFFICE

SOURCES: (1)BREVETTI, PULAZZINI, BIOTEC; JUNE 1988
(2)BIOTECHNOLOGY BACKLOG OF PATENT APPLICATIONS, (US GENERAL ACCOUNTING OFFICE, APRIL 1989)
(3) WORLD PATENT INDEX, DERWENT PUBLICATIONS

Public support for biotechnology research obviously influences a country's development with regard to this new technology. Public support of basic scientific research is a catalyst of growing importance for cycles of technology-driven economic growth. In competitive terms, the political and financial weight of governments in pre-competitive scientific research is an increasingly decisive factor in strategic commercial development by the public sector.

Furthermore, for these reasons an analysis of public support for biotechnology is required. Public funding of biotechnology within the European community in 1989 was 79% of the total US funding, representing a shortfall of half a billion ECU.

Furthermore, federal government biotechnology funding in the US represented 95% of total US funding of 2,379 billion ECU.

European Community level support in 1989 amounted to 50 million ECU, 2.6% of total European public support of 1, 857 billion ECU.

Japanese public funding of biotechnology R & D appears low at 283 million ECU in 1989, however it must be noted that R & D investment in Japan is undertaken largely by the private sector. But virtually all of this effort is organised and co-ordinated by M.I.T.I. at the pre-competitive stage (see Section 4.6).

Table 4 summarises public support for biotechnology research and development spending and its impact in terms of related spin-off research and development.

It is recognised that European Community member states have world class centres for expertise in biotechnology. Nevertheless, public funding for biotechnology research within the community is fragmented amongst member states and for this reason is likely to be less efficient than federal support and co-ordination in the US and Japan.

The following section considers the level of international support and involvement in biotechnology, considering such issues as development origin, public policies and major industrial sectors involved in biotechnology in the following countries.

* United States

* Japan

* Europe (Great Britain, West Germany France, The Netherlands and Ireland)

TABLE 4

PUBLIC SUPPORT FOR BIOTECHNOLOGY RESEARCH
R & D SPENDING AND IMPACT

(ALL FIGURES IN BILLION ECU)

	RELATED SPIN-OFF R & D				
	Direct publicy funded biotechnology	Instruments	Databases	Computer hard/soft ware	Reagents
EUROPEAN COMMUNITY EEC MEMBER STATES TOTAL	0.050 ('89) 1.807 ('89) 1.857 ('89)	0.041	0.004	0.060	0.001
USA FEDERAL STATES TOTAL	2,250 ('88) 0.129 2, 379	0.205	0.010	0.190	0.010
JAPAN	0.283 ('89)	0.122	0.001	0.300	0.060
AUSTRALIA	0.070 ('89)	NA	NA	NA	NA
CANADA	0.160 ('88)	NA	NA	NA	NA

SOURCES:

EUROPEAN COMMISSION, DG XII

CHEMICAL ENGINEERING - PROGRESS, DEC. '89
P.27-32

COMLINE COMPUTERS, AUG. '89

COMLINE BIOTECHNOLOGY & MEDICINE, FEB. '89

4.6.1 UNITED STATES OF AMERICA

The US is world leader in genetic engineering, immunology and molecular biology. Its superiority is founded upon its research institutes and universities and the intellectual base therein (including some eminent scientists attracted from abroad). In fact, the new era of biotechnology has its roots in the pioneering work of two prominent American scientists, Dr. Stanley Cohen of Stanford and Dr. Herbert Boyer of the University of California. These scientists were responsible for the new enabling technique of recombinant DNA technology.

Historically, the US has maintained a technological advantage in biotechnology projects compared to Japanese and European efforts. This lead has been a result of many factors. In relation to Japanese efforts, the superiority of American developments in biotechnology is partly based on the late entry of Japan to the field. Furthermore, during the 1970s, genetic engineering was fraught with ethical and philosophical controversies, even though there were no commercial applications for recombinant DNA. As a result, the US banned genetic engineering research from 1976 - 1978 until the National Institute for Health formulated specific guide-lines.

However, the ban in Japan lasted far longer which delayed their entry into the field until 1980.

At the national level, the US indicated its support for technology-government ties through such legislation as the Stevenson-Wydier Technology Act of 1980.[133] This legislation served to stimulate technology transfer between industries.[134]

Furthermore, a major influence on the US biotechnology industry's development has been the level of state funding of research. For example, in 1982, this support accounted for about $380 million in health, $35 million in agriculture, $52 million in science and $36 million in energy/biomass research, thus the total government spending for this period amounted to some $510 million.[135]

The US succeeded in translating its intellectual base into commercial practices. Since the early 1970s more than 300 small companies have been founded to work with the new technologies of genetic engineering, monoclonal antibody production and protein engineering. In addition many major corporations in the US have sought entry into biotechnology. Hundreds of new

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[133]Dutton, 1989
[134]US congress, 1985
[135]O.T.A., 1984, p309

companies have been founded to interact with the biotechnology firms, supplying reagents, equipment and serving a variety of other ancillary functions.[136]

Braun suggests that the boom of specialist biotechnology companies was to a large extent fostered by

a) the cultural entrepreneurial spirit of open market competition,

b) the availability of venture capital, and,

c) tax laws which encouraged personal investment through tax write-offs.

An interesting aspect of the development origins and evolution of biotechnology in the US is the shift in founders of biotechnology companies. Dibner (1987) reports that there has been a shift in founders of biotechnology companies from academic backgrounds from 52% to 18.5%, while those of industrial background have risen from 25% to 66% during the period 1982-1987. This shift is attributed to the following factors:

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[136]Braun, 1987

(1) The movement from basic research to product development, manufacturing and marketing.

(2) The awakening of non-academic entrepreneurs to the potential of biotechnology, and,

(3) More involvement of established industries in biotechnology as indicated in Table 5 by the level of R & D investments in biotechnology. (It should be noted that more recent information on R & D biotechnology budgets of US companies is not available, probably due to the increased secrecy of these companies).

There is a definite bias in the US towards pharmaceutical and agriculture biotechnology as reflected by the proportion of American biotechnology firms engaged in different areas of research; 62% pharmaceutical and 28% animal and 24% plant culture.[137] This bias may be partially due to the perception of biotechnology as a cheap route to pharmaceuticals, and may also be a reflection of the federal funding directed towards these research areas as outlined earlier.

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[137]OTA, 1984

TABLE 5

R & D BIOTECHNOLOGY BUDGETS FROM LEADING U.S. COM-

COMPANY		$M
SCHERING PLOUGH	(pharmaceuticals)	60
ELI-LILLY	(pharmaceuticals)	60
MONSANTO	(chemicals)	62
DU PONT	(chemicals)	120
GENENTECH	(New Biotech Co.)	32
CETUS	(New Biotech Co.)	26
GENEX	(New Biotech Co.)	8.3
BIOGEN	(New Biotech Co.)	8.7
HYBRITECH	(New Biotech Co.)	6.0

SOURCE: OFFICE OF TECHNOLOGY REPORT, 1984
"GENETIC TECHNOLOGY: A NEW FRONTIER
WESTVIEW PRESS / CROOM HELM, P.74

However, American firms involved in biotechnology research are predominantly small companies which market one or two products, in the hope that profits will finance further research and new products. Of the 300 companies involved in biotechnology, only a few have accomplished the goal of independent, profitable operation.

One of the main difficulties with bringing a biotechnology product to market is extremely high development costs. While it costs only $10,000 to develop a new monoclonal antibody, it costs millions to test and market the product.[138]

In 1985, the Food and Drug Administration first approved a biotechnology product which synthesized a human growth hormone. Sales of $90 million of the drug by the company Genentech produced 1987 earnings of $5 million[139]

With this commercial success, Genentech and other biotechnology firms were extremely successful in raising capital to finance long-term projects. As recently as 1987, raising money beyond the start-up phase was not difficult, particularly in the stock market. As a result of the popularity of biotechnology stock in the mid 80s,

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[138]Lunzer, 1988
[139]Hamilton, 1988

several US firms grew large enough and were profitable enough to finance growth internally.

Unfortunately, because of high risk, biotechnology stocks are more volatile than most others. One analyst summed up biotechnology's position very simply:

Biotech stocks exaggerate market conditions.[140]

Continuing investor pessimism has effectively closed the public equity markets for initial and secondary stock offerings to finance operations beyond their venture capital or private funding beginnings.

As a result of investors' pessimism in biotechnology stocks, joint ventures and biotechnology alliances have suddenly become popular for US companies suffering from cash shortages. Cash-rich limited partners who invest in biotechnology R & D hope to receive a high rate of return in royalties when the products finally get to the market. However, recent tax law changes have dictated an important qualification for R & D partnerships to be profitable; the biotech firm must be close to bringing a product to market.

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[140]Lunzer, 1988

Therefore, limited partnerships are realistic only for the larger biotech companies who have already finished most of the testing on the product.

For small firms in the early development stages, there are currently two common ways of financing operations:

(A) Performing contract R & D for larger companies.

(B) Making marketing agreements with large pharmaceutical or biotechnology houses giving away some or all rights to products.

These strategic linkages serve to strengthen the position of the leading firms in biotechnology and makes it very difficult for small firms to realise supernormal profits. Thus in the US, the competition for finance will continue to favour the large biotechnology houses.[141]

[141] Lunzer, 1988

4.6.2 JAPAN

Biotechnology is one of the fields, along with microelectronics and superconductivity in which Japan's rapid transition from a major purchaser of technology to a major developer of it can be seen most clearly.

In the case of biotechnology, all the necessary factors are there for Japan to excel. Both the government and the corporate sector are flush with cash and are looking aggressively for new industrial developments which will sustain the momentum of the country's strong economic growth.

Most leading industrial companies are now internationally competitive in their fields and can no longer hope to improve their positions by buying technologies from abroad. Thus they are willing to invest heavily in research and development of new products on their own.

In some cases, they also appear to be acquiring foreign companies with a view to speeding the process. The purchase in 1989 by Yamanouchi Pharmaceutical of the US health products group Shaklee for $395 million is thought to have been made in part to

improve the Japanese groups position in biotechnology research.[142]

By nature, the Japanese are also willing to take a long view, an approach which coincides perfectly with the profile of biotechnology where successful commercial applications are not expected to be numerous for at least another decade.

Perhaps most importantly, the Japanese people are embarrassed about their image as copiers and are eager to shed it. Tt has been said that there is something approaching a national campaign in Japan at the moment to promote creativity and innovation, and investment in biotechnology research is one of the main beneficiaries.[143]

In terms of commercial production, the earliest developments in Japan were in pharmaceuticals. Competition emerged about two years ago among companies to commercialise hepatitis B vaccines to treat the disease hepatitis B, a disease which is more common in Japan than elsewhere.

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[142]Rodger, 1989
[143]Rodger, 1989

More recently, the focus of biotechnological product development has switched to agriculture with new companies bringing out new type of flowers and vegetables applying tissue culture. A couple of years ago a lot of publicity as generated around the development of seedless watermelons and something called a pomato, but now more serious products are emerging!

For example in April 1989 Sapporo Breweries set up a joint venture in Peking that will use a clone proliferation technique to raise masses of low priced orchid seedlings for import and sale to Japanese horticulturalists.

Similarly, Japan Tobacco, the dominant tobacco industry in Japan, paid $6 million for an 8.7% stake in Plant Genetic Systems, a Belgian company active in the genetic engineering of plants. It claims to have pioneered field research in making plants resistant to specific insect predators.[144]

The following section of this discussion on Japanese developments in biotechnology will focus on specific public policies and private sector involvement with regard to biotechnology, to illuminate the environment in which this nascent technology has and is developing.

[144]Rodger, 1989

The patenting of recombinant DNA procedures by US scientists in 1980 led to immediate interest in Japan, particularly since its ban in genetic engineering had just expired. Japan's biotechnology interest is consistent with its overall goals in science and technology. Given Japan's limited natural resource base and its dependence on other countries or food, energy and raw materials, the Japanese government viewed biotechnology as a means of strengthening its economic position during the 1980s, if progress could be made quickly.[145]

The research development corporation of Japan (J.R.D.C.), established in 1961, has been actively working on the development of technology with a gradual shift in focus from production processes and large scale efficiency to prevention of pollution, technology for social gains, energy-conserving technologies and high technology.

Another agency which fosters biotechnology is the Science and Technology Agency. Its involvement began in 1981 with a $25 million grant for recombinant DNA research.[146] Its research team composed of Seiko, Fuji, Hitachi, Toyo Soda and Mitsui Knowledge Industry, developed the first biorobot to automate the task of

[145]Rodger, 1989
[146]Tatsuno, 1986

analysing DNA cultures. This has led to much faster progress in deciphering genetic data than in the US. In fact, it has been stated that,

> *There is no question that the Japanese are ahead in automating DNA sequencing.*[147]

The advent of commercial biotechnology in 1980 nearly coincided with the creation of a new organisation called the Exploratory Research for Advanced Technology program (E.R.A.T.O.). Its purpose is to promote basic research in leading techniques through a unique structure. The program features key individuals who are named as project leaders or directors and are usually young researchers from varied technical backgrounds. According to the president of the J.R.C.S., Nobuhisa Akabane, the E.R.A.T.O. program has proven far more successful that expectations, and is one of the world's most advanced pure research programs.[148]

Progress in biotechnology was spearheaded by Japan's Ministry of International Trade and Industry (M.I.T.I.), along with thirteen other industries targeted for basic research and product development, in 1981.

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[147] Wall Street Journal, 1987
[148] Akabane, 1986

In 1981, M.I.T.I. budgeted $150 million to Japan's first biotechnology project.[149] Over the next two years, M.I.T.I. organised fourteen companies to carry out research in recombinant DNA and bioreactors for industrial and medical applications.

One year later, M.I.T.I. formed the Office of Biotechnology to fund and provide information for the 150 companies which were then involved in biotechnology research.

Continuing to support biotechnology at the national level, the M.I.T.I. established a "Key Technology Centre" in biotechnology in 1985. The centres allow two or more Japanese countries to set up joint venture companies whereby 70% of R & D is funded by the centre.

Japan's real strength however, lies in its company sector. Significant numbers of Japanese companies have shown awareness and involvement in biotechnological activities. A survey by M.I.T.I. in 1982 which involved 200 corporations revealed that 157 had a R & D programme involving biotechnology. Furthermore, certain companies were devoting significant resources in this area. For example, the managing director of Mitsubishi Chemical Industries Ltd. reports that 40% of the

[149] Tatsuno, 1986

company's $233 million R & D budget is devoted to biotechnology.[150]

Like most of Japan's large corporations, Mitsubishi can afford to spend large amounts of cash from profitable divisions to develop biotechnology products which have payback projections far in the future.

It appears that Japanese companies are well-positioned in the certain and long term biotechnology market. One indication of this is that Japanese biotechnology firms have not been as adversely affected as US firms in the aftermath of the downturn of financial markets in October, 1987.[151]

Hence the pattern of development of biotechnology in Japan differs considerably to that witnessed in the US. In Japan, the technology is developed and exploited by the largest corporations with the integration of government support. In the US open market, competition has driven development resulting in a rash of entrepreneurial "start-up" companies involved in biotechnology research. These new biotechnology companies have served as

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[150] Wall Street Journal, 1987
[151] Dutton, 1989

research bases for established larger companies to become involved in the technology.

Japan's forte with regard to biotechnology is in the area of fermentation. This strength combined with industrial foresight has given Japan the lead in the world amino acid market and considerable strengths in other fine chemical and enzyme areas.

Japan's commitment to biotechnology is expected to yield dividends and compensate richly for the country's lack of natural resources.

Biotechnology trade associations in Japan expect biotechnology to account for 11% of the country's G.N.P. by the year 2,000.[152]

4.6.3 EUROPE

As a whole, Europe's intellectual base for biotechnology is quite strong. The major disadvantages facing Europe are those of internal language and trade barriers, which at present contribute to

[152] Smith 1988

the fragmentation to the industry. However, the advent of the Single European Act may help contribute to the development of science research and technological development, including biotechnology, through the eliminating of trade barriers and the dissemination and optimisation of the results of activities in community research and development. This aspect of biotechnology development will be discussed further in this section.

At this stage it is considered appropriate to consider the industrial production and trade impacts of biotechnology on European Sectors in which the future commercial impacts of biotechnology will be most significant.

Estimates based on European Community/GATT statistics suggest that with regard to industrial production sections in which the future commercial impacts of biotechnology will be most significant (agriculture/food, pharmaceuticals/healthcare and chemicals), today account for over 21% of total European Community industrial production in these five sectors, higher than in the US or Japan[153] (see Table 6).

[153]SAGB Report, 1990

TABLE 6

INDUSTRIAL OUTPUT
EUROPEAN COMMUNITY INDUSTRIAL PRODUCTION IN SEVERAL SECTORS (AS% OF EC TOTAL)

	Agriculture	Chemicals	Pharms.	Health	Food	Total 5 Sectors
% of EC total	4.5%	6%	3%	NA	8%	21.5
ECU (bn)	157.5	210	105	_	280	752.5

SOURCE: SAGB Report, 1990
SAGB Estimates based on European Community/ GATT Statistics

To add to this the market sectors most affected by biotechnology developments account for almost 30% of community exports with the rest of the world (see Table 7).

Although the organisation which provides such estimates is reputable, these estimates must be created with caution. Nonetheless, they attempt to set the context with regard to biotechnology and European industrial sectors in which the future impacts of the technology will be most significant.

The European Community has adopted several initiatives in biotechnology designed to achieve a cohesive European market. In 1978, the European Federation of Biotechnology (EFB) was formed. Furthermore in 1981, the Concentration Unit for Biotechnology in Europe (CUBE) began a relationship with the EFB, to effectively monitor and co-ordinate European biotechnology activities.

The European Commission put together a community strategy for biotechnology in 1983 partly as a result of the FAST program (Forecasting and Assessment of Science and Technology) and also various contributions which the EFB and CUBE made.

TABLE 7

EUROPEAN TRADE
EUROPEAN COMMUNITY EXPORTS WITH THE REST OF THE WORLD, IN SEVERAL SECTORS
(AS PERCENTAGE OF TOTAL EC EXPORTS)

	Agriculture	Chemicals	Pharms.	Health	Food	Total 5 Sectors
% of EC total	3%	14%	1.5%	NA	11%	29.5
ECU (bn)	13.5	63	6.75	–	49.5	132.75

SOURCE: SAGB Report, 1990
SAGB Estimates based on European Community/ GATT Statistics

The 1983 European Community Strategy for Biotechnology is outlined in Figure 13.

Training was certainly seen as a major part of the 1983 community strategy. As a result, training and research programmes in biotechnology have continued and are expanding.

Since 1983, CUBE have focussed on development and demonstration projects which has led to the establishment of such programs as FLAIR, which focuses on food technologies, and ECLAIR regarding agro-industrial technologies. There has certainly been an expansion of the research programs in biotechnology throughout Europe.

The library of the Royal Netherlands Academy of Arts and Sciences recently prepared a permanent inventory of publicly funded biotechnology research projects in the European communities, as part of a BIOREP database.

During the period 1981-89 data was collected on the number of projects and institutes involved in publicly funded biotechnology research projects of each member state. The data obtained were tested against the selection guide-lines employed or inclusion of scientific papers and patents in Derwent Biotechnology abstracts,

FIGURE 13 THE 1983 COMMUNITY STRATEGY FOR BIOTECHNOLOGY IN EUROPE

The 1983 Community Strategy for Biotechnology in Europe

1. **RESEARCH AND TRAINING**
   - "CONTEXTUAL" BIO-INFORMATICS
     CULTURE COLLECTIONS
   - BASIC BIOTECHNOLOGY 16 AREAS
2. **CONCERTATION OF ACTIONS AND POLICIES (CUBE)**
3. **FEEDSTOCK PRICES**
   - SUGAR, STARCH REGIMES
4. **REGULATORY REGIMES**
   - FOOD, FEED, CHEMICALS, PHARMACEUTICALS, ENVIRONMENT, rDNA
5. **INTELLECTUAL PROPERTY RIGHTS**
   - PATENTS, PLANT VARIETY, TECHNOLOGY TRANSFER
6. **DEMONSTRATION PROJECTS**
   - AGRO-INDUSTRIAL

Source: Cantley, M.F.,(1989), "Manpower & Training Needs for Biotechnolgy in Europe in the 1990s", Report of a Working Party Meeting at Delft University of Technology, Netherlands, 1989.

Derwent Publications Ltd., and against the following definition of biotechnology:

> *Biotechnology comprises the integrated use of biochemistry, molecular genetics, microbiology and process technology to arrive at practical application at the possibilities of microorganisms, cell cultures or part thereof.*

It is important to note that in the BIOREP database, classic biotechnology, for example, brewing, as well as fundamental research, mostly molecular sciences research relevant for biotechnology, has been included.

The number of projects and institutes in each member state is tabulated in Table 8. The number of records in the BIOREP database does not give any indication on the coverage because of the level of aggregation of the information values. For example, the 506 German records which are generally taken up in the database as themes with often very extensive abstracts describing the various projects, from the information and coverage points of view may be regarded to be equivalent to the 2180 British records.

TABLE 8

THE NUMBER OF PROJECTS AND INSTITUTES INVOLVED IN BIOTECHNOLOGY RESEARCH IN EACH EUROPEAN COMMUNITY MEMBER STATE

MEMBER STATE	PROJECTS	INSTITUTES
BELGIUM	374	127
DENMARK	168	77
BRITAIN	2,108	521
GERMANY	506	286
SPAIN	33	20
FRANCE		*
GREECE		**
IRELAND	261	43
ITALY	225	151
LUXEMBOURG	1	1
NETHERLANDS	407	184
PORTUGAL	70	40
CEC (BAP)***	245	213
TOTAL	4, 480	1,663

* Involved in 46 BAP projects
** Involved in 5 BAP projects
*** BAP:Biotechnology Research Programme

SOURCE: BIOREP DATABASE; LIBRARY OF THE ROYAL ACADEMY OF ARTS AND SCIENCES, (JANUARY, 1990)

All data in 1989/1990 are now available on line on the host ECHO. Additionally a printed directory is also available.[154] Plans to develop the starting databases have been formulated and set down in a proposal for the Commission of the European Communities (period 1991 -93). Such plans include attempts to complete the technical and organisational infrastructure and to improve it, where necessary. Routines will be developed to guarantee completeness of the data and the user-friendliness of the on-line directory will be raised. Furthermore, preparations for a new program are being made, part of which will include examination for the possibilities for extension of the information in order to raise its attractiveness for management and biocommerce.[155]

For a starting database the use of BIOREP is satisfactory and makes a significant contribution to bioinformatics for the following reasons;

(1) The data have a high intrinsic value. This is indicated by the fact the BIOREP, although still far from being up-to-date and complete, provided keys for collaboration in formulating proposals in the framework of the new BRIDGE

[154]BIOREP-Permanent Inventory of Biotechnology Research Projects in the European Community (Library of the Royal Netherlands Academy of Arts and Sciences) (1989)
[155]Personal communication, confidential source

biotechnology program of DG XII; people did in fact find research which was unknown to them.[156]

(2) Because biotechnology is multidisciplinary and has applications in many fields, the potential number of users is high.

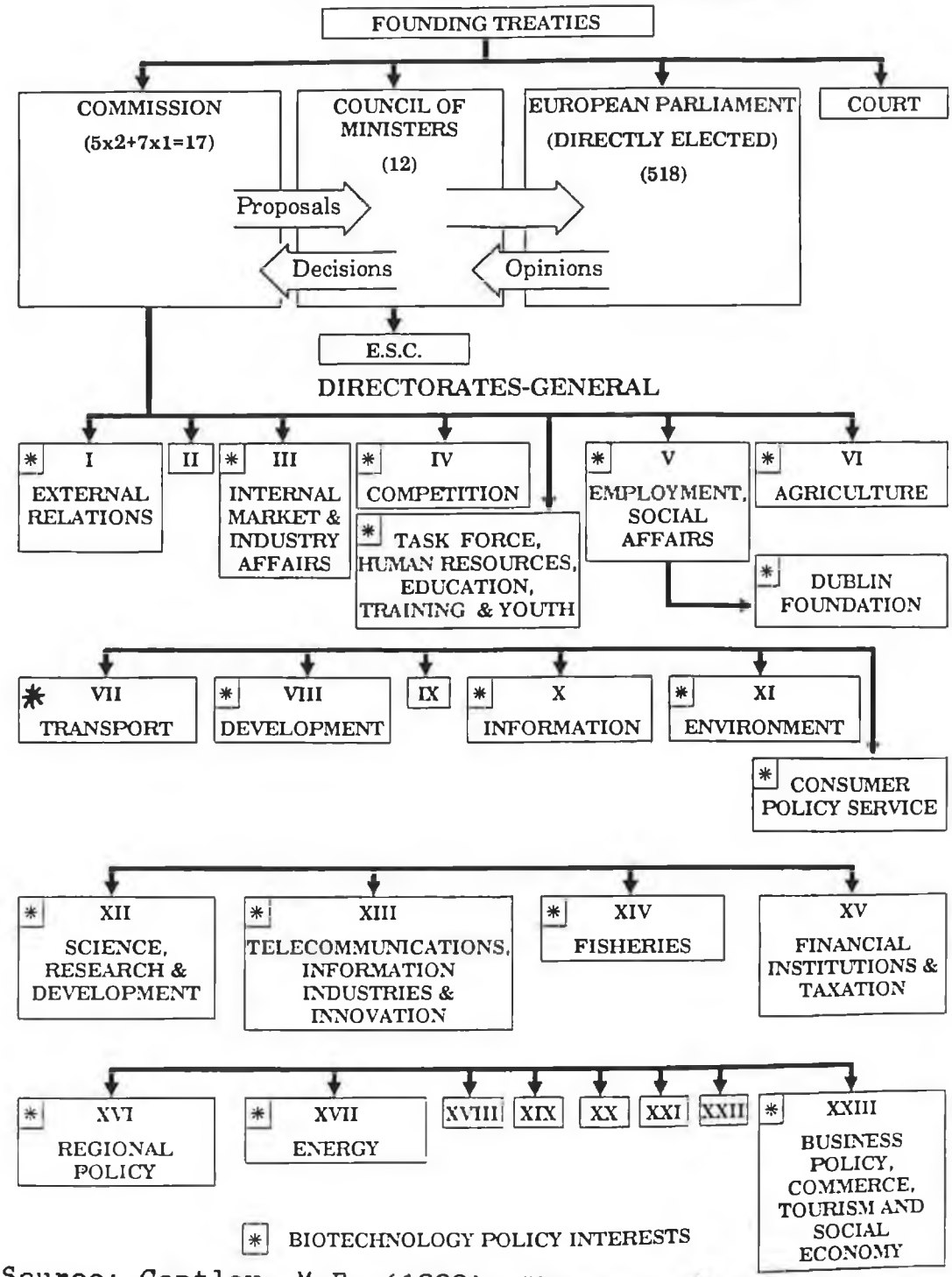
(3) It serves as a welcome addition to the already available commercial systems such as BioCommerce Data, BIKE (Biotechnology Information Knot for Europe), and a key player in the future biotechnology information infrastructure for which a strategy has to be developed.

With regard to the gradual awakening of the significance of biotechnology by many areas of the European commission, the organigram outlined in Figure 14 emphasises the large and growing number of services that are becoming involved in biotechnology.

The Single European Act, 1987, has also happened since FAST and the 1983 Community Strategy for Biotechnology in Europe. It is of major interest to the scientific community. It spells out in very "hard-nosed" terms that research is given much more attention in

[156]Lalieu, 1990

FIGURE 14 BIOTECHNOLOGY POLICY INTERESTS OF THE COMMUNITY INSTITUTIONS AND THE DIRECTORATE GENERALS OF THE EUROPEAN COMMISSION



Source: Cantley, M.F. (1989): "Manpower & Training Needs for Biotechnology in Europe in the 1990's", Report of a European Working Party on Education in Biotechnology.
Delft University of Technology, Netherlands.

order to strengthen the scientific basis of Europe's international industrial competitiveness. Article 130F, paragraph 3, expresses the connection between R & D effort, the implementation of the common market and all other common policies, thus providing horizontal cross-linkage (see Figure 15).

Further to these developments with regard to European biotechnology, the European Biotechnology Co-Ordination Group (EBCG) was created in 1985. It now has about seven national and eight sectoral associations. The Senior Advisory Group for Biotechnology was since created in June 1989.

The Senior Advisory Group for Biotechnology (SAGB) includes members of the European Chemical Industry Federation (ECFI) and several of the large multinational companies in Europe, including ICI plc, Unilever plc, Sandoz Pharma Ltd., Ferruzi Group, Rhône Poulac, Hoechst AG and Monsanto Europe S.A.

The SAGB provides a senior industrial forum for debating policy issues affecting biotechnology in the European Community in an effort to promote a supportive climate for biotechnology in Europe.

As with any new and advancing technology, biotechnology raises important issues for a broad range of interest groups. Of concern to all is protection of humankind and its environment. Secondly, the rapid development and spreading use of biotechnology inevitably creates important economic and industrial policy issues for Europe. The nature of biotechnology is such that social and ethical issues also need to be addressed.

The SAGB recognises that the intrinsic nature of the biotechnology issue must determine how community policy making is conducted. The SAGB outlines priorities and actions for each of the issues discussed above.[157] It should be noted that the SAGB explicitly excludes the modification of the human germ line from its meaning of "biotechnology", and confirms that none of its member countries is working in that area. The proposals as to how the European Community should deal with biotechnology policy issues, suggested by the SAGB are discussed as follows:

(1) PROTECTION OF HUMANKIND AND ITS ENVIRONMENT

According to the SAGB this issue requires a community regulatory system based on the three scientific criteria of **safety**, **quality** and

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[157] SAGB Report, 1990

efficacy, and objective assessment of the highest possible standard. It believes that political involvement must comprise:

* The legislation necessary to establish the appropriate community-level regulating processes;

* On-going community level review and surveillance to ensure effective functioning of these processes.

(2) ECONOMIC AND INDUSTRIAL POLICY ISSUES RAISED BY BIOTECHNOLOGY

The SAGB believes that where these issues are community-wide in scope, they must be addressed by the political processes by which community citizens decide what is in their common interest, subject always to the judicial processes by which the individual's community rights are protected.

(3) SOCIAL AND ETHICAL ISSUES

The SAGB believes that such issues are equally contentious and feel that Europe's processes and institutions are therefore the proper venue for debate and resolution.

According to SAGB members the most immediate European Biotechnology policy priority is to ensure that the community's regulatory framework for human and environmental safety is science-based, co-ordinated, and not overlapping or contradictory and that community regulation does not compromise long term European biotechnology competitiveness.

Finally the SAGB promotes broad community-wide debate on social and ethical issues relating to biotechnology. Furthermore, its members fully encourage broad understanding of scientific principles, practices and goals as a basis for responsible choice. The SAGB also endorses the decision of member states' research ministers taken in December 1989 to mandate a process of continuing debate and reporting on ethical aspects of the community-funded program for research on the human genome. This may provide an appropriate venue for other issues as well.

More recently a series of Irish initiatives designed to promote European Biotechnology research were announced by the Minister of State for Science at an international conference on biotechnology (Ahlstrom, 1990). These initiatives will be put to the Council of Science Ministers in Luxembourg in late 1990. Initiatives such as these have resulted from increased recognition of the danger of losing key scientists and researchers because of the

strongly restricted controls being placed on the development of biotechnology in Europe.

It has also been suggested that such restrictions also put European industry at a competitive disadvantage compared to the US or Japanese companies.[158]

It has been suggested that future European tax revenues derived from competitive biotechnology will rise in direct proportion to the European added value contained in future products and processes of biotechnology. The SAGB indicates that the key generator of tax revenue will nevertheless be the downstream industrial and commercial activity following on from research and development, because R & D is generally accorded tax incentives, precisely to encourage the downstream activity in nearby locations.[159]

Finally, a great deal of European public money in the form of R & D support and R & D tax incentives, has and will continue to be invested in biotechnology R & D. The only way Europe can ultimately reap the future tax dividend from this public investment is to develop taxable, downstream industry. Otherwise this public

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[158] Ahlstrom, 1990
[159] SAGB Report, 1990

investment will produce no public wealth. The European Community objectives for biotechnology in Europe in the 1990s is summarised in Figure 16.

The following part of this discussion will focus on the development of biotechnology in several European Community member states and reflects the on-going commitment, both by governments and individual firms to the new technology, despite European opposition from several quarters. The countries considered include:

* Great Britain
* West Germany
* France
* The Netherlands
* Ireland

FIGURE 16 BIOTECHNOLOGY IN EUROPE IN THE 1990s
EUROPEAN COMMUNITY OBJECTIVES

BIOTECHNOLOGY IN EUROPE IN THE 1990s: COMMUNITY OBJECTIVES

Overall, continuing, long-term goal:

- THE BENEFICIAL APPLICATION OF BIOTECHNOLOGY TO THE MAINTENANCE AND IMPROVEMENT OF HEALTH AND WELLBEING, LOCAL ENVIRONMENTS, AND THE GLOBAL ECOSYSTEM

Major policies with specific implication for biotechnology:

- COMPETITIVENESS AND INNOVATION IN THE BIO-INDUSTRIES, WITH PARTICULAR REFERENCE TO THE FORMATION AND GROWTH OF SMALL AND MEDIUM-SIZED ENTERPRISES
- HARMONISED INTERNAL MARKET (REGULATIONS, PATENTS, STANDARDS), TAKING INTERNATIONAL DIMENSIONS INTO ACCOUNT
- RESEARCH (BASIC, PRE-COMPETITIVE AND INFRASTRUCTURE), DEVELOPMENT AND TRAINING
- INTERNATIONAL COLLABORATION (SCIENTIFIC, TECHNOLOGICAL AND INDUSTRIAL)

Other current priorities for biotechnology:

- EUROPEAN BIOTECHNOLOGY INFORMATION POLICY (FOR INFRASTRUCTURE AND COMPETITIVENESS)
- COMMUNICATION : PUBLIC, CONSUMERS, POLITICAL LEADERS AND LEGISLATORS

Source: European Commission, Brussels (1990).

4.6.4 GREAT BRITAIN

Despite cuts in fundamental research, applied research is receiving support from biotechnology programs of several British ministries.

In 1980, A.C.A.R.D., The Advisory Council for Applied Research and Development commissioned a report on biotechnology, more commonly known as the Spinks Report. The results of this report led to the allocation of extra funding toward research facilities and the encouragement of collaborative research.

A surprising outcome of this report was the establishment of a public sector biotechnology company, Celltech (since privatised). This company built up a program based on contract research, licensing and product development and is profitable as the world's largest monoclonal antibody producer.

In the early 1980s, the Science and Engineering Research Council established a Biotechnology Directorate for the purpose of establishing links between academia and industry. It has encouraged the cross fertilisation of ideas through a series of workshops where groups of companies co-operate in developing research of mutual interest by using the skills and expertise of

researchers in universities or the public sector. Because more than one company is involved in each workshop, the research is necessarily pre-competitive.

Many of the larger multinational firms have major research facilities involved in biotechnology and as a result of British strengths span pharmaceuticals (Glaxo, BP, ICI), single cell protein (Shell, BP, ICI) and the agrifood field (Shell, Unilever, Rank Hovis, Mac Dougall).

There is also an increasingly strong small firm sector in the UK. Celltech is the only British company equivalent in scale and style to the more publicised American NBFs. Celltech's research capability is of undoubted weight. The quality of its research team ranks with the top one or two scientific institutions in the UK and in the area of hybridoma technology at least, with its leading US competitors.[160]

Monotech IRI, although a subsidiary company, has its origins in the initiatives of a group of academic scientists based at British universities, to raise industrial money for collaborative research in a specific area of hybridoma technology.[161]

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[160] Fishlock, 1989
[161] Faulkner, 1986

The development of UK biotechnology has seen the emergence of a number of specialist supply companies to care for the needs of the biotechnology firm, just as in the US case.

4.6.5 WEST GERMANY

The federal Republic of Germany has had major public expenditures on biotechnology since 1970 by both central and regional governments. The intellectual base for biotechnology is very strong, with the main centre for research, the Gessellschaft fur Biotechnologische Forshung (GBF), renowned for its fermentation development and general process technology including bioreactors.

Government funded agencies such as GBF have helped to stimulate early industrial involvement in biotechnology not least by their policies of financially supporting products and encouraging collaborative research with universities and specialist institutes.

Large corporations such as Hoechst and Bayer have invested heavily in biotechnology in the areas of yeast expression systems and single cell protein, and waste treatment. Such investment has

put them in the same league as American corporations Du Pont and Monsanto.

However, European opposition to biotechnology is strongest in West Germany, where the Green Party seems to view the technology with the same reservations as it has towards nuclear power. Opponents persuaded the European parliament to impose a ban on growth stimulants for beef cattle without even considering the evidence of a scientific committee that Euro MPs had commissioned.

Furthermore, in Brussels, the European Commissioner for research and development blocked a planned £10 million European Community participation in the international human genome program, in response to the lobbying of West German Green Party lobbyists.[162]

New developments in biotechnology have seen venture capital opening up in West Germany, and a number of new small firms enter the field. However, restrictive legislation, enacted as a result

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[162] Fishlock, 1989

of the Green Movement, means that some companies may look elsewhere for new R & D activity.[163]

4.6.6 FRANCE

In 1982, the French socialist government spurred industry into the biotechnology field with its ten year "mobilisation plan". The program sought to mobilise both research and commercialisation around centres of development and to build on France's traditional strengths i.e. food production and agriculture.

Core teams of institutes and universities were focussed on different areas of biotechnology research. For example, the core team to research on genetic engineering involved the Pasteur Institute, I.N.R.A. Strasbourg based agronomics institute and Inserm, the institute for health and medical research.

The programme sought commercialisation to be led by a group of core firms and at its inception, the government proposed to invest considerable financial support hoping that industry would match the investment. Political changes at government level, and cut

[163] Script, 1988

backs in public expenditure have caused a reduction in the financial input of the program but the strategy remains.

France now has a number of nationalised large firms, such as the government-owned oil company Elf-Aquitane and its subsidiary, Sarofi, which are now spearheading government efforts in the company sector with their interest in biomass energy and pharmaceuticals.

4.6.7 THE NETHERLANDS

Although it is a relatively small country, Holland is host to several multinationals (Unilever, Phillips, Akzo, Gist - Brocades) and as a result, biotechnology revenue comprises 7% of the world's total.[164]

National skills include the development of enzymes, yeast and dairy product and protein engineering.

In 1983, the M.I.P. Equity fund, a $500 m state funded but privately operated venture capital pool was established. This fund has the

[164]Simpson, 1988

dual purpose of fostering innovation in areas such as biotechnology and making a profit.

Another source of venture capital is provided by Robobank, a banking co-operative which has pursued a national biotechnology policy which has the dual purpose of making a profit and strengthening Dutch agriculture to meet the high technology challenges of the next century.

A further asset to Holland's biotechnology strategy has been its Innovation Orientation Program for Biotechnology (IOP-B) which brings together industry initiative, university know-how and government subsidies.

However, recent developments have seen Holland's progress in the area of genetic engineering retarded by regulations relating to experiments using recombinant DNA (rDNA) techniques.

4.6.8 IRELAND

An Irish National Biotechnology Programme as initiated in 1983 by the then National Board for Science and Technology (now EOLAS) and the Industrial Development Authority. The programme's objective is to promote and assist the application of biotechnology in Irish Industry, agriculture and other areas of social and economic development.

The major areas of application in Ireland are in food & drink and in the healthcare / pharmaceutical industries.[165]

The healthcare and pharmaceutical sector is also important for Ireland and has undergone considerable growth in recent years.

As in many other countries, much of Ireland's expertise in biotechnology is located in universities and other higher education colleges and research institutes. Areas of biotechnology expertise in Ireland include, genetic engineering, diagnostic technology, speciality chemicals and pharmaceuticals, biopharmacology, mammalian reproductive technology and plant biotechnology.[166]

[165] BioResearch Ireland, 1990; personal communication

[166] BioResearch Ireland, 1990 Personal Communication

These areas of biotechnology expertise are discussed in this section, however, discussion of the biotechnology infrastructure in Ireland can be found in Section 6.10.

(1) GENETIC ENGINEERING

Research on genetic engineering is conducted in 6 Irish colleges but particularly in Trinity College, Dublin and the University Colleges of Cork and Galway.

Microbial genetics is the main area of interest at the Department of Genetics, Trinity College Dublin, where the research teams has performed work for many companies. This group of researchers has recently signed a research agreement with the Agricultural University of Beijing to jointly clone the gene for Porcine Growth Hormone.

Another interesting area in Trinity College Dublin is in vaccines at the department of microbiology. Among other projects is one with the objective of developing a vaccine for mastitis.

In animal genetics, research is in progress at University College Galway, in collaboration with the Agricultural Institute to develop

transgenic animals including fish. This work is funded by the EEC in association with French researchers.

The Dairy Microbiology Department at University College Cork, and the Agricultural Institute in Cork, have developed considerable expertise in the genetics of dairy starter culture organisms. Strains of bacteriophage resistant bacteria developed by this group are now used to produce almost all of the 50,000 tonnes of cheddar cheese produced in Ireland. Further work on the genetic manipulation of important dairy microorganisms is currently underway.

(2) DIAGNOSTIC TECHNOLOGY

Ireland has much expertise in the area of diagnostic technology. The close contacts between the biological and clinical scientists in Ireland has been an important factor in the development of this area of biotechnology.

The major centre for research on diagnostics is in University College Galway, where work is ongoing on solid phase immuno-diagnostic technology, and on the development of kits for various human and animal hormone indicators.

Veterinary diagnostics is an area of particular interest in Ireland because of the country's large livestock population. Work at University College Galway has resulted in the first animal progesterone assay to be put on the market.

Ireland has also a very important thoroughbred horse industry. Research on behalf of this sector is conducted by the Irish Equine Centre, a privately funded organisation, in association with university researchers.

This centre is currently researching indicators of stress, for example, travel stress, in performance horses with a view to developing diagnostic kits for equine health. Diagnostic kits are also in preparation in other centres for Epstein Barr Virus, Chlamydia and others.

(3) BIOPHARMACOLOGY

Ireland has a large pharmaceutical and healthcare industry. To service the needs of the industry, both for technical services and for trained staff, Irish colleges ave developed centres of expertise in several relevant areas. Of particular interest are development of in-vitro tests for pharmaceutical screening and for toxic effects. Among the projects in process at the moment are in-vitro assays

for detection of drug-related specific neural tube defects, for example, spina bifida (which has a high incidence in the Irish population) and also an assay for assessing efficiency and toxic effects of cancer chemotherapeutic drugs.

The developments of novel drug delivery methods employing biotechnology techniques are also ongoing in Irish research institutes and universities.

(4) MAMMALIAN REPRODUCTIVE PHYSIOLOGY

Ireland is one of the major milk and meat exporting countries in the world, and the breeding of sheep and cattle is therefore of great importance. Both the universities and the Agricultural Institute perform research on many topics of relevance to the breeding and production of cattle and other livestock. A topic which is of relevance to biotechnology is the area of mammalian reproductive physiology.

The research group at University College Dublin was among the pioneers of embryo transplantation.

Work by the UCD group and the associated roup at the Agricultural Institute continues on areas such as immunological control of reproduction, embryo sex determination, oestrous control and in-vitro fertilisation.

(5) PLANT BIOTECHNOLOGY

The major crops of interest to Irish biotechnologists are potato, cereals and ornamentals. Ireland has a large seed potato industry based on exports to Mediterranean and North African countries. The majority of these exports are two varieties which were bred, employing biotechnological techniques, at the Agricultural Institute. Forestry research focuses on the use of mycorrhizae to assist the reafforestation of Ireland's marginal lands at UCD.

4.7 SPECIFIC ISSUES RELATED TO BIOTECHNOLOGY

This section examines a number of issues that arise when one considers biotechnology as a means towards innovation.

Issues such as public attitudes and acceptance of biotechnology, the financing of biotechnology research and development and the protection of intellectual property arising from biotechnology developments (especially patenting and trade secret law), have proven to be significant in the overall development of the global biotechnology industry.

Each of the above issues is discussed separately in the following subsections.

4.7.1 PUBLIC ATTITUDES AND ACCEPTANCE OF BIOTECHNOLOGY

Section 5.2 indicates that the successful diffusion of new technologies is conditioned by a number of factors, amongst which are societal and environmental acceptability. The microelectronics based information revolution satisfied the criteria of societal and environmental acceptability, whereas nuclear power encountered increasing difficulties, which largely explains why its diffusion has come to a halt in many countries. Public acceptance of new biotechnology, or public confidence in it, has emerged as a central factor in the diffusion of this technology.

The human and social impacts of biotechnology are pervasive and in this sense biotechnology is clearly not comparable with microelectronics, for example, which has few direct environmental or health impacts. Furthermore, just as the pressure of public opinion has reduced nuclear power developments, one might question whether certain applications of biotechnology will not encounter similar obstacles.

If biotechnology, as a broad generic technology, is not comparable to microelectronics, it is even less comparable to nuclear power, and it is important to understand why. Three main characteristics separate biotechnology from the controversial new energy technology, nuclear power.

* Nuclear power consists of a small number of core technologies (reactor, fuel, waste disposal). these core technologies are closely linked so that the failure of non-acceptibility of any of them could lead to the abandonment of the entire industry. Compared to nuclear power, biotechnology has a great versatility, covering a wide range of technologies derived from and relevant to every form of life, from microorganisms to wo/man. Thus, holding up one development of this multidisciplinary technology does not necessarily put a stop to "biotechnology" on the whole. On

the contrary it has been suggested that such a delay of progress in certain areas may accelerate other developments. For example, temporary difficulties with the introduction of genetically modified microorganisms into the environment are said to have accelerated plant research, and may help explain a recent increase in the number of plants submitted to regulatory authorities for approval.[167]

* In the context of nuclear power generation technologies, the terms "health impacts" or "environment impacts" have clearly negative connotations. Societal acceptance of such technologies became more difficult when it appeared that they would have undesirable health and environmental impacts. In contrast, biotechnologies have the potential to address hitherto unsolvable health and environmental problems and to replace other, potentially harmful technologies. Thus, even if the concerns about possibly detrimental side-effects of some biotechnologies are justified, and whether they are is not discussed in the scope of this study, it has never been denied that numerous biotechnology developments will effectively reduce risks and have beneficial health and environmental impacts.

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[167] OECD, 1989

* A third feature of biotechnology, which could be decisive for its ultimate acceptance by society, is that the discussion on the risks and benefits associated with the technology, began earlier than in the case of any other 20th century technology and before new products or processes existed. Contrary to what occurred in nuclear, information and other industries, this debate, focussing mainly on the new genetic engineering methods, has helped to shape the direction and rate of scientific and technical change from the very beginning, and before the first large industrial investments were made.[168] Table 9 selects a number of key events in the US where the main safety and regulatory discussions as well as many of the scientific and technical successes have occurred. It should be noted that the events listed in the two columns of Table 9 bear little or no relations to one another, but the lists show that, in the early stages, safety and regulation considerations have preceded scientific and technical developments by several years.

The discussions on safety risks and benefits, and public acceptance have lasted fifteen years. For the sake of greater clarity, it has been proposed to distinguish between issues related

[168]OECD, 1989

Table 9: A Selection of Key Events in Biotechnology

Research and Innovation	Safety and Regulations
1977: First successful genetic manipulation (Cohen-Boyer)	1973: Letter of Prof. Paul Berg to National Academy of Sciences warning of rDNA risks (US)
1978: First successful Expression of Insulin in rDNA Microorganisms (US)	1974: Asilomar Science Conference I decides Moratorium for rDNA experiments (US)
1982: First production of Human Insulin by Microorganisms (US)	1975: Asilomar Science Conference II lifts Moratorium (US)
1982: First Gene Transfer in Mammals ("Supermouse") (US)	1976: First rDNA Safetey Regulations / Guidelines (NIH, US)
1982: First, unsuccessful Gene Transfer in Man (Italy, Israel)	1985: Columbia District Court prohibits release of microorganisms into the Environment (US)
1986: First Release of rDNA plants (US)	1986: US Court of Appeal overturns Columbia District Court decision (US)
1987: First Release of rDNA micro-organisms into the environment (US)	1986: First inetrnational Guidelines on rDNA Safety considerations, Paris, OECD, adopted by the OECD council.

Source: OECD, 1989 "Biotechnology - Ecqnomic and Wider Inpacts"; OECD Report, Paris, 1989

to the "acceptability", and those related to the "acceptance" of biotechnology.[169]

Acceptability derives from rational, scientific evaluation of biotechnology, mainly rDNA safety issues which, however, does not exclude rational dispute when different weight is given to external social or economic criteria.

Acceptance is the reaction of the public rooted in a large number of motifs, including emotional ones. In cases where the public has shown concern about a technology, scientific acceptability is a necessary, but not sufficient condition of acceptance. Furthermore it has been suggested that when a gap between acceptability and acceptance appears, it will be a goal of public policies to attempt to close it.[170]

Both acceptability and acceptance affect the diffusion of biotechnology. For example, a biotechnology company developed a new diagnostic test to detect the virus for cervical cancer but feared that the relevant drug authorities would not approve it.[171] This meant that the company anticipated a problem with the acceptability of the innovation.

[169] Heusler, 1986
[170] OECD, 1989
[171] OECD, 1989

A major food company developed a new rDNA based yogurt that was not only economical, but satisfied all its country's safety and health criteria, yet decided not to market it out of concern that journalists might quote this innovation in a misleading headline[172].

This company foresaw problems with the public acceptance of its products.

Experts believe that more research is necessary to develop risk assessment in biotechnology, particularly to analyse both the probability and scale of conjectural accidents in comparison to other technologies. Thus, expert discussions on risks, safety and acceptability will probably continue as long as techniques relevant to biotechnology advance and multiply. However, the fact that these discussions began comparatively early has already had three major effects:

1) Biotechnology laboratories and industry have been encouraged to choose low-risk microorganisms.

2) A public institutional framework to review and if necessary supervise new biotechnology processes and/or products

[172]OECD, 1989

has been put in place in most, if not all, OECD countries with biotechnology laboratories and industries.

3) A strong movement towards international harmonisation of rDNA-safety criteria has begun within and beyond the OECD area, guided by OECD work. This harmonisation will facilitate the international diffusion of a technology which depends so heavily on global markets.

Fears about the potential impact on the environment should novel "man-made" organisms be released or accidentally escape has led to calls for higher controls on the technology within the European community.

In 1988, three organisations decided to make their own start on involving the general European public in a debate on biotechnology. The organisations involved included ERICA (European Research into Consumer Affairs) an independent research organisation set up to study consumer questions in the European Community; The European Foundation for the Improvement of Living and Working Conditions, a research foundation of the EC located in Dublin; and CUBE (Concentration

Unit for biotechnology in Europe), a team in the Directorate General XII, Science, Research and Development of the EC Commission.

The above organisations held a workshop in Brussels (1989), the first of its kind in relation to the subject of biotechnology. The workshop entitled "Consumers and Biotechnology" involved participants of all the EC member states, except Luxembourg and Greece, and included scientists, industrialist, trade unionists, press , radio, tv journalists and leading members of consumer and environmental organisations.

The EC Commission, after studying the laws of all its member states, has made proposals for several directives related to the regulation of biotechnology. Three of these directives related to the use of genetically engineered organisms and silage additives, have been approved by the Council of Ministers of the 12 member states (1990). The status of all proposed EC directives relating to the regulation of biotechnology are shown in Table 10.

The community under the Irish presidency in 1990, introduced two new directives setting strict controls on biotechnology in European industry. At present there are moves to add a "fourth criterion" to

Table 10: Status of EC Directives on Biotechnology Regulation (July 1990)

EC Directive / Regulation	D.G.	Status
* Intellectual Property Protection	III	Draft
* Food Labelling	III	Draft
* Harmonisation	III	Draft
*New Foods	IV	Draft
* Protection of Workers	V	Draft
* Plant Breeder's Rights	VI	Draft
* Plant Protection	VI	Draft
* Marketing Ornamental Plants	VI	Draft
* Marketing Transgenic Plants	VI	Draft
* Marketing Transgenic Animals	VI	Draft
* Silage Additives	VI	Approved
* BST (Bovinesomatotrophin)	VI	Draft
* Productivity Enhancers	VI	Draft
* Transport of Biological Materials	VII	Draft
* Contained Use of GMO's	IX	Approved
* Deliberate Release of GMO's	IX	Approved
(GMO=Genetically Modified Organisms)		

Source: EC Commission (1990), Brussels.
Personal Communication

the existing regulatory criteria of safety, efficacy and quality, that of socio-economic need.[173]

Many researchers believe the "fourth criterion" to the existing regulatory criteria would bring an end to much biotechnology research and industrial projects it generates. It is also suggested that this fourth regulatory criterion would add a new and complex subjectivity to the development of science.

The pro-biotechnology argument raised by many researchers in the field is that biotechnology has, in fact, the potential to improve the environment through, for example reducing pesticide use by developing pest-resistant plants.

Furthermore, powerful industrial groups investing in biotechnology research in the US, Europe and Japan object to any restraints on the introduction of biotechnology products including the Senior Advisory Group on Biotechnology in Europe (SAGB).

These groups employ the simple logic that there will be no market for dubious products, and so, manufacturers will not bother supplying them.[174] However, this logic does not consider whether

[173] Ahlstrom, 1990b
[174] Ahlstrom, 1990b

or not the ultimate consumer is capable of deciding what is and what is not a "dubious product". Thus effective safeguards to protect humankind and its environment, including restraints on the introduction of biotechnology products, where required, are essential for the protection of both humankind, and its environment.

The current situation with regard to biotechnology regulation in Ireland is discussed in greater detail in Section 6.10.4.

4.7.1.1 PUBLIC CONCERN

Public concern and confidence in biotechnology products and processes can have a significant impact on commercialisation. There are real fears, particularly in West Germany (see Section 4.6.5), Scandinavia and The Netherlands, that biotechnology is likely to open up a "Pandora's Box" of mutant strains onto the environment. At the other extreme, there seems to be a cultural acceptance of biotechnology and its products in Japan with colours, enzymes and various additives produced from biotechnology finding use in for example, foodstuffs, for example, a biotechnology wine called "Fusion Bio A".[175]

[175]Smith, 1988

Compared to the scientific "acceptability" of biotechnology, it is much more difficult to assess and summarise "acceptance", because the public has understood the term biotechnology in various ways, and also because there are large international differences in public acceptance as discussed above.

These differences in public acceptance are deeply rooted in national traditions related to food, medicine, and health, which explains why they are changing only very slowly and why different countries do not seem to strongly influence each other.

In contrast to the scientific assessment of rDNA Safety, there has been little or no international convergence of public attitudes towards biotechnology, neither in a favourable or unfavourable direction. An opinion survey conducted in 1979 indicated wide variations between popular attitudes in European countries towards genetic research and R & D on synthetic food.[176] For example, 61% of the interviewed people in Denmark thought genetic research to be "unacceptably risky" while the corresponding figure for Italy was 22%.

Not enough is known about the wide and diverse social and cultural roots of attitudes towards biotechnologies, and why they

[176]Office of Technology Assessment (OTA), 1984

vary so widely. Understanding public attitudes is important for policy formulation and perhaps even for predicting future trends. In fact, Denmark has subsequently (1988) been in the forefront of legislative initiatives constraining genetic engineering, while of all EC countries, Italy has given least effect to the 1982 EEC Council Recommendation on the registration of rDNA research.

Unfortunately, surveys of public attitudes are infrequent and often not comparable between countries. Regular and internationally comparable surveys of professional quality would be very helpful to policy makers and to industry.

4.7.1.2 PUBLIC ATTITUDES TO BIOTECHNOLOGY IN IRELAND

In recognition of the importance in understanding public attitudes to biotechnology for policy formulation and predicting future trends, research is currently being carried out in Ireland. Bioresearch Ireland, a contract research organisation set up under the National Biotechnology Programme for Ireland (see also Section 6.10) has

commissioned opinion surveys on public attitudes to biotechnology in Ireland.[177]

From preliminary opinion surveys, as part of this research, it is revealed, that in general Irish adults have a very limited spontaneous understanding of biotechnology. Interestingly, men tend to have a slightly greater knowledge of the topic than do women. The extent of knowledge is also slightly higher among 25-34 year olds. Furthermore, levels of awareness concerning biotechnology vary depending on social-class, with those from upper-middle-class backgrounds being most informed about the technology. With regard to attitudes to biotechnology, overall public opinion tends to be more positive than negative, with younger people expressing the most positive attitude.

Although this research must be treated with caution in generalising public opinion to Biotechnology in Ireland, it is a progressive step in assessing the level of awareness and public opinions of the technology in Ireland and hopefully further research in this area will illuminate the issue further and probably serve as useful information for companies developing biotechnology products and the Irish government in formulating policies with regard to the technology.

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[177] Bioresearch Ireland, 1989 (Personnel Communication)

TABLE 11

PUBLIC ATTITUDES TO BIOTECHNOLOGY IN IRELAND
N = 1401 (AGED 15+)

(1) Understanding the term "biotechnology" is very limited amongst Irish adults: only one in four have any spontaneous knowledge of the topic.

(2) Over half of all adults have never heard of biotechnology. A further third have heard of it but know nothing about it. Only one in ten Irish adults feel they know anything about biotechnology, when asked about the extent of their knowledge regarding the area.

(3) The chemical industry is most commonly associate with biotechnology, mentioned by one in six adults. Agriculture and biology achieved the next highest levels of association.

(4) Overall public opinion regarding biotechnology in Ireland at present tends to be more positive than negative. It would appear that the more knowledgeable the people are about the area, the more positive their outlook. To a limited extent, the public recognise that biotechnology will play a more important role in the future in Ireland than it does at present.

(5) Agriculture and health are seen to be the areas on which biotechnology will impact most in the future, with agriculture being the most prominently mentioned.

SOURCE: "Attitudes to Biotechnology", December 1989.
Study prepared for Bioresearch Ireland Ltd
by Landsdowne Market Research Ltd.,
Dublin

The principle findings of a preliminary opinion survey on public attitudes to biotechnology in Ireland are listed in Table 11.

4.7.1.3 GOVERNMENT AND INDUSTRY RESPONSES TO PUBLIC ATTITUDES TO BIOTECHNOLOGY

While national differences may be difficult to interpret, it has in general not been too difficult to understand what the public's main concerns are with regard to biotechnology. The following are most often mentioned;[178]

* Ethical concerns about genetic modifications in general or more particularly in humans;

* Safety concerns about health, and about the introduction of modified organisms into the environment;

* Concerns about the alleged, radical novelty of biotechnology, or about its alleged unpredictability or irreversibility;

[178]OECD, 1989

* Concerns about negative employment impacts.

However, these concerns are often found mixed up with issues of health and life which have no direct link with biotechnology, such as in-vitro fertilisation.[179]

Governments, parliaments and in some countries, industry have paid exceptional attention to public acceptance, and public fears. Some reviews of public opinion have been conducted, as indicated in Section 4.7.1.1, and numerous, often extensive debates have taken place in national parliaments.

The single most persistent response of governments to cope with the confusion between biotechnology and medical ethics in the public's mind, has been to keep debates and committees on human genetics or medical ethics strictly separate from those which review gene technologies for scientific and commercial applications.

Apart from this it can be said that public authorities and industry have shown a remarkable degree of innovation developing a wide range of responses to address public concerns.

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[179]OECD, 1989

Amongst the main responses, some of which have also been used in combination, are the use of communication techniques (information campaigns[180], books, industry visits, poster campaigns) to demystify biotechnology by improving information for the public. Public participation in safety assessment such as the UK's Advisory Committee for Genetic Manipulation (ACGM) where trade union representatives and members of the public sit side by side with industry and government representatives.

However, what people need is more trust in biotechnology risk-management, in the credibility of those who inform them, and in the willingness of governments and industry to abandon projects when risks become more important than benefits.

4.7.2 FINANCE

The use of biotechnology as a tool towards new product development can present extra problems in terms of financing. As with all innovation, the financial questions of profitability, level of uncertainty and cash flow are raised.

[180] Including the current Biotechnology Information Campaign in Schools in Ireland, conducted by BioResearch Ireland in conjunction with the Department of Education.

Biotechnology research and development presents additional risks in that it is research-intensive high technology, and many projects may be long term. Cash flow problems can present themselves if the firm is small, the extreme case being an innovative start-up, and the level of investment required is proportionally large in relation to the total resources of the firm or entrepreneur.

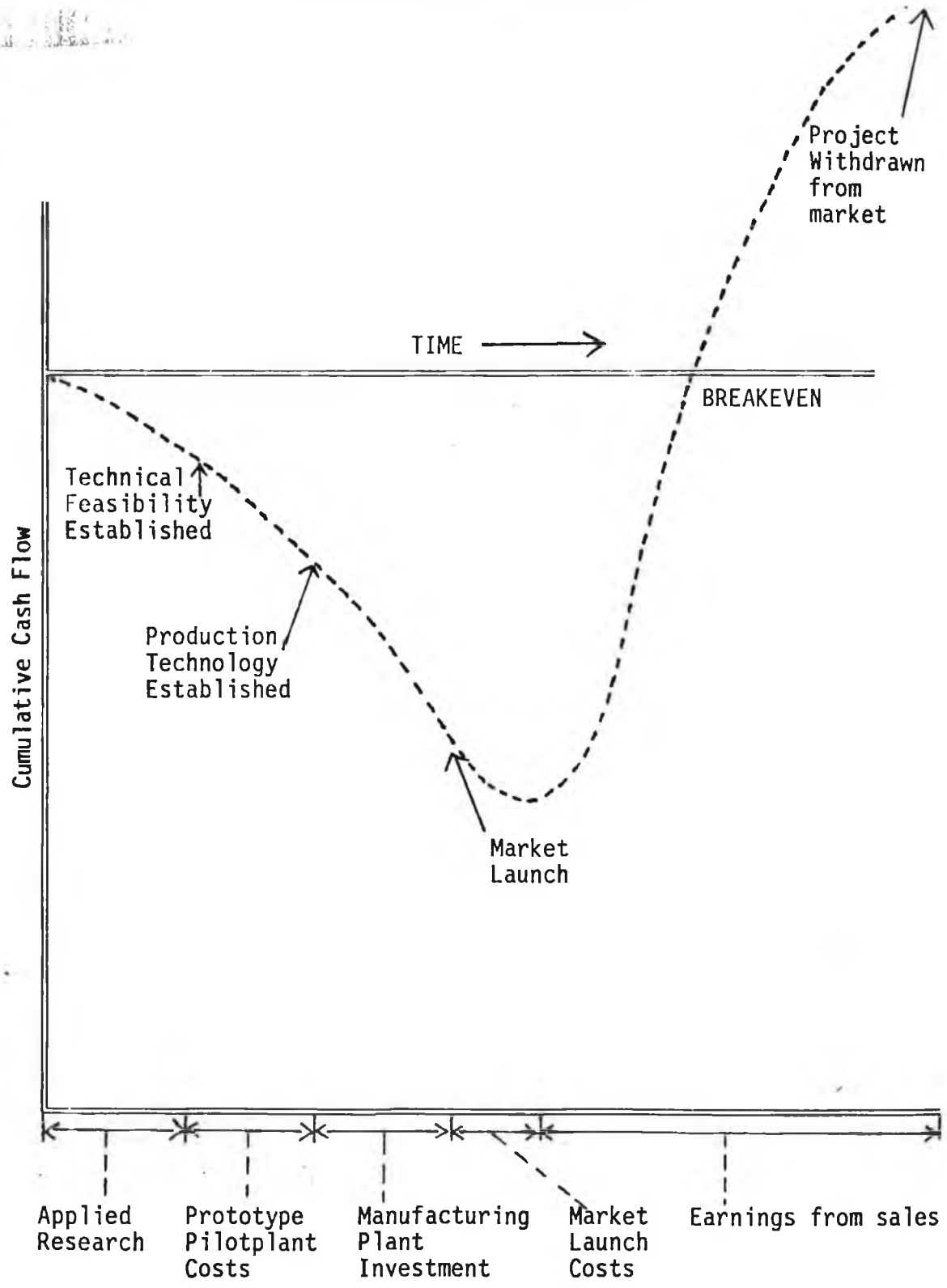
Figure 17 presents a model of cumulative cash-flow of the typical firm in the course of innovation.[181] The costs of the various development stages vary. The product development stage represents a critical point because of the escalation in level of investment required. The investment of both time and money increases proportionally with the technical complexity of the new product or process. Quinn (1985) however, has shown that in spite of spiralling investment costs, many of the large innovative companies have parallel prototype programmes, so that if one prototype proves to be inappropriate another can be invoked.

The duration from the R & D through to commercialisation can vary significantly depending on the area of research. Monoclonal antibodies have opened up a whole new field of diagnostic testing and because of less regulation provide good opportunities for cash

[181] Twiss, 1980

FIGURE 17:

CUMULATIVE CASH-FLOW MODEL OF INNOVATION



Source: Twiss, B 1980: "Managing Technological Innovation" - 2nd ed London: Longman, p 108.

flow while therapeutic products with inherent regulation delays require long term investments.

Financing is central to the growth and commercial reality of biotechnology. According to Burrill (1986), the maxim that a company's business strategy dictates its financing strategy does not hold for biotechnology in the US. Instead, the financial strategy adopted by a firm drives the business strategy and in turn the kind of products it produces, determining the length of time a product could remain in development and thus the ultimate profitability of the product.

Various methods of financing are discussed addressing this issue.

In the case of Public Financing the public company must project steady earnings, growth and consistently improved results to support shareholder confidence and thus safeguard the public market as a source of future finance. Therefore, the biotechnology company seeking public financing through the equity markets will require a number of short term relatively uncomplicated products that can be quickly commercialised, generate profits and initiate a history of stable growth. However, the corollary to a short development time is usually a short product life, and smaller profits.

Generally, an early stage financing source is Private Financing. Private equity investors are prepared for the high risk investment, anticipating and understanding the fluctuations of developing companies. In the case of biotechnology, private financing is ideal for the development of major therapeutic products. The rewards of long term projects are exemplified by the American company Genentech's tissue plasminogen product. Activase^{tm} which, when it finally made it through F.D.A. regulations to the marketplace, generated $58 million in revenues in its first 45 day of sales.[182]

Debt Financing is not usually feasible for startups since credit-worthiness is based upon tangible assets and not on the long term potential of the firm. Furthermore, it is not recommended for companies still in the R & D phases because the loan must be serviced immediately, detracting from funds that would otherwise be available for research and development.

Like a public company, the firm must develop products it can bring to the market quickly or it must have established products that can provide servicing the debt.

The source of the Venture Capital firm's funds will dictate whether it is suitable for a biotechnology company's needs.

[182]Burill, 1988

Limited partnerships have fixed lives and as such are only interested in companies exhibiting potential for growth in the short term. Because management surrenders large portions of equity in return for a venture capital infusion, owners of biotechnology companies should be sure that the venture investor shares the same goals.

More long term investments are also made by venture capitalists and this form may be suitable for biotechnology startups, or those working on products which are long term to market. The development of the Irish venture capital industry in Ireland is discussed further in Section 6.1.1.

In a symbiotic Corporate Partnership the smaller company usually benefits through access to corporate capital resources and sales and marketing channels which the larger company benefits by tapping into the new and evolving technologies. Prior to such alliances, the smaller high technology company should seek an agreement on product development goals, otherwise corporate purse strings will dictate which direction it goes.

Furthermore, if a biotechnology company can wait and prove the value of its product under development before entering a strategic agreement, then it can dictate more favourable terms for itself, from

the commercialisation of a product. Such a tactic would be beneficial if delays in the R & D costs could blunt a company's competitive edge. Either way, Burill (1988) has stated that,

> *... strategic linkages are emerging as one of the most important financing tools biotechnology companies can use.*

4.7.3 INTELLECTUAL PROPERTY PROTECTION

COMMERCIAL ASPECTS OF THE PATENT SYSTEM

Intellectual property generally encompasses patent, trade marks, designs, copyright, and know-how. The term "industrial" property is also used but it is not as appropriate. One cannot over-emphasise the importance of intellectual property.

Patents are monopolies for the protection of inventions, that is original processes and products. The monopoly is granted by the state, in return for the disclosure of the invention. Designs relate to the aesthetic appearance of the articles while copyright, so far as it affects scientists and engineers in their industrial applications relates to the protection from copying drawings.

Know-how is industrially useful knowledge which is available to allow a process to be performed or products to be produced. It is often referred to as "Trade Secrets". Trade marks are words or logos used to identify one trader's product from another trader's and thus to protect business good will.

This discussion focuses on intellectual property as it relates to biotechnology and therefore focuses on patenting and trade secret protection.

Standard patenting gives its owner the right to take legal action against others exploiting his/her invention without consent. In return for such protection, a patentee is legally bound to provide full technical details of the novel product or process. The full technical details are then published , or otherwise made publicly available by each of the patenting authorities to which applications have been made for protection.

The stage at which publication occurs varies with the country. It should be noted that in granting a patent, society allows the inventor to control the commercial exploitation of the invention for a limited time only. In most industrialised countries, the patent term provided by law ranges from sixteen to twenty years. The patent term allows time for product development and a subsequent sales

period during which the costs of research and development can be recovered.

Payne (1988) defines trade secrets as

> *commercially valuable information that is not widely known to competitors, thereby giving it owners a competitive advantage.*

In the event of misuse by a former employee or competitor the owner of the proprietary information may be entitled to an immediate injunction, compensation damages and reimbursement for legal fees.

Trade secret law offers protection to innovators during the R & D stage prior to patent application, pending patent approval or in the event of a patent application being rejected.

4.7.3.1 PATENT PROTECTION IN BIOTECHNOLOGY

Modern biotechnology has depended, from its beginning, upon an appropriate legal framework. This is the first case in history where the law has come to play a dominant role in the very emergence of a new technology. Among various legal issues, those relating to patenting have remained a reason of concern for governments and industry alike.

The "Chakrabarty Decision" of 1980, when the United States' Supreme Court ruled that a man-made, oil-eating micro-organism developed for industry was patentable under US law, has freed the discussion on patent protection in biotechnology from doubts, as far as microorganisms are concerned. The principle of patenting industrially useful microorganisms is now widely accepted throughout the OECD area.

The crucial importance of this and other court decisions to grant patents to new biotechnology inventions was, in its time, hailed as a breakthrough in the history of modern biotechnology. In many countries, law-makers and judges have recognised that the new biotechnology, often derived from genetic modification,

represented a great novelty due to human ingenuity, and a departure from past practice, and hence deserved a change or reinterpretation of law or legal practice, which is not easily granted.

Thus while the need to reassure a worried public has led policy makers to emphasise the old roots and safe traditions of biotechnology (see Section 4.7.1.1), the need to improve patent protection has also led to greater emphasis on the scientific and technical novelty of the new inventions.

Biotechnology is a particularly good example of the patent questions raised by rapid scientific and technological change. Change leads to problems of legal adaptation, particularly when the law is embedded in international treaties which can be changed only with the approval of a large majority of its signatories. The latest important international legal conventions relevant to biotechnology, (International Convention for the Protection of New Varieties of Plants, 1961; Strasbourg Convention, 1963; European Patent Convention, 1973) were discussed and ratified before the spread of the new biotechnology innovations, especially those of genetic engineering and therefore do not take them into account.

Three is no technology where patent laws vary so widely, and on so many points as they do in biotechnology. New technical and ethical questions are raised by the fact that biotechnology uses living organisms as production tools. Contrary to all other inventions, public disclosure of a new organism may defy description by scientific formulae and words. It is also important to remember that both government and industry serve as major sources of funding or biotechnology research carried out at public institutions. The patent system makes it possible to establish a proprietary position for the results of this research without unnecessarily delaying the researcher's transmission of these results to the research community as a whole. Once the position is established, a company can invest time and money in turning the innovation into a product, and the license fees paid by industry on the resulting products provide the public institutions with support for further research. Failure to provide adequate unambiguous patent protection will have a significant impact on both the future of biotechnology research as well as the resultant diversity of products coming from the private sector.

As stated in Section 4.6 national patent laws differ, however, the US law and Japanese law, are on the whole, more open and flexible to new developments in biotechnology, than are the laws of other OECD countries. It is worth mentioning three critical differences in

terms of patent protection relating to biotechnology because of the detrimental effects of European law:

(1) Grace periods exist in the national laws of the US, Japan and Canada. These grace periods allow scientists to submit, within a certain time limit, a patent claim on invention, even if they have already disclosed it in scientific publications or n any other way that would contravene the "novelty" requirement of patent law. These make patent law more compatible with the habits of the academic scientists, whose impulse is to publish their findings without forfeiting patent rights.

There is a widespread conviction in industry and universities that the importance of the academic contribution to the development of biotechnology will make the introduction of an internationally recognised grace period of six months , if not a year, more and more necessary. However, this proposal has met with strong opposition because, amongst other reasons, it would require a modification of the European Patent Convention (EPC).

(2) The European Patent Convention places an absolute ban on patenting new plant and animal varieties, and also new breeding methods. In contrast, the US patent law provides for the patenting of new plant varieties, however the law for the protection of higher organisms has yet to be decided in the courts, although it does allow for the protection of animal breeding processes.

(3) The practice of depositing microorganisms in culture collections for the purpose of patent application is now widely established to fulfil the needs of public disclosure. However the European system involves the re-release of deposited microorganisms to the public with the first publication of the patent application, that is, before the depositor knows whether the patent claim will be accepted. This may lead to the "unfair" situation where the "public" could commercially exploit a deposited microorganism until a patent is granted, which could take several years depending on the country. In contrast, however, the US and Japanese systems release the microorganisms only when the patent is granted.

According to Coleman (1988), should the less favourable European system encourage European firms to file for patents under US

patent laws, then they might be in for a shock. The US Patent and Trademark Office will award a patent to the first inventor, but in doing so it will consider only "invention activity" that takes place in the US.

This problem potentially affects every US patent sought by biotechnology companies performing research abroad and is most acute in those areas where many competitors are simultaneously conducting novel, "state of the art" research. This problem could possibly help explain the lack of investment of American biotechnology companies in Europe (see Table 2).

There are other components of patent protection particular to biotechnology which have been found unsatisfactory. The lifetime or term of patents is one such component. This patent term/period may not be long enough for innovative companies to recover their investment in R & D, as most companies are compelled to apply for parent protection as soon as research results confirm that the invention is successful. After this a significant time period is required for further testing and approval before the innovative company is in a position to recover R & D investments. Also, protracted patenting procedures for biotechnology innovations further erode the normal 16-20 years life-span of patents.

It would seem appropriate therefore for legislators to establish a more market effective patent life in fields such as biotechnology, where product development and registration approval take up such a large part of the patent life.

The rising wave of oppositions, as in the case of Wellcomes's successful challenging of a patent granted to the US biotechnology company Genentech, relating to techniques of tissue plasminogen activator (tPA) production, a therapeutic substance for heart attack victims, will no doubt eventually lead to clearer guidance on the nature and extent of biotechnology products.[183] [184]

4.7.3.2 TRADE SECRET LAW IN BIOTECHNOLOGY

Trade secret law is beginning to emerge as a vital aspect of biotechnology development. As stated already in Section 4.7.3, trade secrets are commercially valuable information that is not widely known by competitors, thereby giving its owner a competitive advantage.

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[183] Fishlock, 1988
[184] Marsh, 1987

Trade secret law offers protection to innovators in biotechnology during R & D stage prior to patent application, pending patent approval or in the event of a patent application being rejected.

CHAPTER 5: ECONOMIC IMPACTS OF BIOTECHNOLOGY

5.1 INTRODUCTION

This section of the present thesis discusses the future diffusion of biotechnology through the economy, in particular, the probable time-scales and consequences. Parallels are drawn with the diffusion of the electronic computer and of electric power. This section also discusses biotechnology as a "techno-economic paradigm" (referred to in Section 2) accompanied by many potential changes, including structural adjustments in the sectors affected by the technology. Finally, the section reviews prospective employment impacts of biotechnology.

5.2 DIFFUSION OF BIOTECHNOLOGY THROUGH THE ECONOMY: THE TIME SCALE

It has been shown that modern biotechnology is opening up innumerable exciting new possibilities which may dramatically affect society over the next century, (see section 4.5).

Some of these developments are already finding commercial exploitation, especially in the fields of healthcare and agriculture.

But the results of previous research[185] coupled with the results of interviews with Irish companies operating in biotechnology (as part of present study), suggest that we are still only in the early stages of the full scale application of this revolutionary new technology. This section discusses the problems of diffusion of the technology through the economy as a whole and considers the probable time-scale of this diffusion process and the resulting consequences.

Comparisons are made with other pervasive technologies which have had very widespread economic consequences in the past, such as the introduction of electric power and more recently computer technology and micro-electronics. In making such comparisons it is extremely important to take into account of the differences as well as the similarities between the various generic technologies which have impacted on industrial society.

However, although the unique features of modern biotechnology and its distinct areas of application must always be kept in mind, there are useful lessons which can be learnt from earlier technological change which had very widespread economic and social consequences.

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[185]OECD, 1989

It is evident, for example, that a transformation of the technologies in use in many sectors of the economy must lead on the one hand to large-scale investment in new types of plant and equipment and on the other hand to a change in the skill profile of the labour force.

From the past experience of the introduction and diffusion of such revolutionary new technologies it is still clear that the changes they exert are realised over decades rather than years or months. The recognition of the relatively long time scale involved in diffusion is extremely important as it can avert two dangers which might otherwise have adverse policy consequences both at Government and industrial levels.

First is the danger of "technological super optimism", which tends to ignore the hard economic realities of relative costs, profitability and size and consumer acceptance of entirely new products. Second is the danger of "technological conservatism" which fails to recognise the enormous long-term potential of generic technologies for the ultimate development of an entirely new range of products or services. The first can lead to serious under-estimation of the time-scale involved in diffusion processes, the second to equally serious errors of under-estimation of the potential of long term transformation[186].

[186]OECD, 1989

5.3 THE ANALOGY OF THE ELECTRONIC COMPUTER

The example of electronic computer technology illustrates the general problem scale and timing of a new technology. This example is cited because (at least until the advent of biotechnology) it is probably the best known example of a pervasive technology in the second half of the 20th Century. Moreover, it is one which is well documented and which is generally agreed to be of extraordinary importance for all OECD Member countries[187].

With the first application of the electronic computer during and just after the Second World War it was realised that this new technology had an enormous potential for transforming industrial processes, office systems and records and communication systems. However, opinions differed sharply on the probable time scale and the extent of these developments.

Some scientists and engineers anticipated very rapid and large-scale applications with immense social consequences, (including large scale unemployment), already in the 1950s and 1960s. On

[187] OECD, 1989

the other hand, it was well established that such a well-informed leader as Thomas J. Watson (Senior) did not believe, even in the early 1950s that there would be any big commercial market for electronic computers:

> *He felt that the one SSEC machine which was on display at IBM's New York offices could solve all the scientific problems in the world involving scientific calculations. He saw no commercial possibilities. This view, moreover, persisted even though some of private firms that were potential users of computers - the major life insurance companies, telecommunications providers, aircraft manufacturers and others were reasonably informed about the emerging technology. A broad business need was not apparent.*[188]

It was not until the Korean war that IBM was persuaded to undertake production of a small batch of electronic computers and even then it was only with a change of management that they entered the commercial market. As against this conservative view of a very limited market for computers, imaginative scientists like Norbert Weiner (1949) envisaged a huge scale of applications and forecast large scale unemployment as a result.

A much more balanced view of the probable time-scale and social consequences of the diffusion of the electronic computer was taken up by one of the most imaginative and authoritative consultants in this field, John Diebold. In his book "Automation: The Advent of the

[188]Katz and Phillips, 1982

Automatic Factory"[189], the author showed remarkable foresight and depth of understanding of the problems involved.

While recognising the enormous potential of the electronic computer for the transformation of all industrial and office processes, he saw quite clearly that this would be a matter of several decades and not a few years. Indeed, most of the "factory automation" which is today described as "FMS" (Flexible Manufacturing Systems) or "CIM" (Computer Integrated Manufacturing) did not show a really rapid take-off until the 1980s event though most of the technical innovations which come under this heading were clearly seen by Diebold in 1952. The "automation" of the 1950s was really a kind of advanced mechanisation, mainly in the automobile industry, rather than computerisation.[190]

Diebold stressed several reasons for believing the diffusion process would be much slower than many computer enthusiasts imagined at the time. The most important of these were as follows:

(1) True computerised "automation" would involve the redesign of all industrial processes and products. It would be quite

[189]Diebold, 1952
[190]OECD, 1989

impossible to achieve this in a short period. The simple availability of computers was only the first step. An enormous amount of R + D, design and new investment in machinery and instruments would be needed in every branch of industry.

(2) Such a process of redesign would affect both products and processes. Diebold gave examples to show that this could only occur if there was a change in the structure and organisation of firms, as well as in the attitude of management. This change would involve much closer integration of R & D, design, production engineering and marketing - a horizontal rather than a vertical flow of information and communication within firms.

(3) Not only would computer-based automation change the configuration and organisation of every factory, it would also involve a big change in the skill composition of the workforce. Diebold rejected the idea of mass unemployment arising from automation and also the idea of "deskilling" the workforce. On the contrary, he stressed the new skills that would be required, especially in design and maintenance, and saw automation as a means of overcoming the fragmentation and dehumanisation of work. But he also

realised that it would take a long time before the skills were available and people were retrained.

(4) Diebold recognised the importance of the economic aspects of diffusion. Computers would diffuse not only because they were technically advantageous, they had also to be cheap. It was only in the 1960s with the advent of micro-electronics and in the early 1970s with the advent of the micro-processor, that computerisation took off in small and medium-sized firms, as well as in large firms, and in batch production as well in flow process industries such as chemicals. Moreover, and this is the most important point when we are looking at economy-wide effects, computer technology could only realise its potential outside a few "leading-edge" industries when computerised systems became relatively cheap and accessible.

Events since 1952 have fully confirmed Diebold's analysis. Even though the computer industry itself was growing at an extremely rapid rate for the next thirty years, it took a whole series of complementary radical and incremental innovations such as Computer Aided Design (CAD), Computer Numerical Control (CNC), Large Scale Integration (LSI) and big developments in software engineering and process instrumentation before

computer-based automation could diffuse to most industrial and service sectors. In fact, even now, the economic advantages are by no means always clear cut and there are often considerable teething problems when firms attempt to introduce FMS or other forms of automation[191].

5.4 THE ANALOGY WITH ELECTRIC POWER

A similarly long time scale was necessary for the diffusion of electric power and its innumerable applications, from the time of its first appearance in the 1880s. Not only did it take two or three decades before generating and transmission systems made the new energy source universally available in the industrialised countries; it took even longer to redesign machinery and equipment in other industries to take advantage of electricity, and to make the necessary skills available.

An illuminating account of the debates which took place at the end of the 19th Century and the early part of this century on the implications of electric power for the future of factory processes is given by Warren Devine:

[191] OECD, 1989

> *Replacing a steam engine with one or more electric motors, leaving the power distribution system unchanged, appears to have been the usual juxtaposition of a new technology upon the framework of an old one. Shaft and belt power distribution systems were in place, and manufacturers were familiar with their problems. Turning line shafts with motors was an improvement that required modifying only the front end of the system. As long as the electric motors were simply used in place of steam engines to turn long line shafts, the shortcomings of mechanical power distribution systems remained.*[192]

It was not until after 1900 that manufacturers generally began to realise that the indirect benefits of using unit electric drivers were far greater than the direct energy saving benefits. Unit drive gave far greater flexibility in factory layout, as machines were no longer placed in line with shafts, making possible big capital savings in floor space. For example, the US Government Printing Office was able to add 40 presses in the same floor space[193].

Unit drive meant that trolleys and overhead cranes could be used on a large scale, unobstructed by shafts, countershafts and belts. Portable power tools increased even further the flexibility and adaptability of production systems. Factories could be made much cleaner and brighter, which was very important in industries and printing, both for working conditions and for product quality and process efficiency. Production capacity could be expanded much more easily.

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[192] Devine, 1983
[193] Devine, 1983

The full expansionary benefits of electric power to the economy depended, therefore, not only on a few key innovations in the 1880s, but on the development of a new "paradigm" or production and design philosophy[194]. This involved the redesign of machine tools and much other production equipment. It also involved the relocation of plants and industries, based on the new freedom conferred by electric power transmission and local generating capacity.

Finally, the revolution affected not only capital goods but a whole range of consumer goods, as a series of radical innovations led to the universal availability of a wide range of electric domestic appliances going far beyond the original domestic lighting systems of the 1880s. Ultimately, therefore, the impetus to economic development from electric power affected almost the entire range of goods and services.

But this complex diffusion process took about half a century and it was not until the 1920s that electricity overtook steam as the main source of industrial power in the United States. It was not until the 1950s and 1960s that widespread ownership of electric durables became the norm in Europe and Japan.

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[194]OECD, 1989

From these historical analogies it is evident that there is a major difference in the diffusion process for a single product and the diffusion process for a generic technology with numerous potential applications in a variety of different industrial sectors. Once it is on the market in an acceptable form, a single product may be adopted by more than half the potential adopters within a decade. This accounted, for example, in many OECD countries for a variety of consumer durables such as television in the 1950s and 1960s[195].

Mansfield's studies also showed that this rate of adoption, occurred for some types of industrial and transport equipment, such as the diesel locomotive and the continuous stripmill. However, there are cases of both agricultural and industrial innovations such as Metcalfe's 1970 study of the diffusion of the sizebox in the cotton industry[196]. Such studies show many "laggards" and non-adopters even when the economic and technical advantages are clear. When one considers whole clusters of related innovations with new generations of products, such as biotechnologies, a much longer timescale is involved.

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[195]Mansfield, 1961
[196]Metcalfe, 1970

5.5 NEW BIOTECHNOLOGY AS A CHANGE OF TECHNOLOGY SYSTEM

Most diffusion research in the post-war period has concentrated on the diffusion of individual products and processes, and on incremental types of innovation. Schumpeter was almost alone among leading 20th Century economists in looking at "creative waves of destruction" - the effect of major new technologies as they pervade the economic system[197].

More recently a number of economists have made further contributions to this Schumpeterian approach. Nelson and Winter (1987) used the expression "generalised naturalised trajectories" to describe cumulative clusters of innovations, as for example, those associated with electric power.

Dosi (1982) used the expression "technological paradigm" by analogy with Kuhn's (1982) scientific paradigms. In these terms "incremental innovations" within an established paradigm may be compared with Kuhn's "normal science". Carlota Perez (1983) has developed the concept of the "techno-economic paradigms" to describe those changes in technology which pervade the entire

[197]Schumpeter, 1939

economy and provide the new "common sense" for a whole generation of engineers and managers.

Clearly, biotechnology is already a new paradigm in Dosi's sense and a new "natural trajectory" in Nelson and Winter's sense for the development of products and processes. Whether it is such an important trajectory that it will ultimately come to affect management decision-making in most branches of the economy remains an open question. The new biotechnology has undoubtedly led to enormous excitement in the US research community and many new companies were established with venture capital to pursue R & D, (see Sections 4.6.1).

This "research explosion" was indeed unique. However, the pervasiveness of a new technology system depends on the range of profitable opportunities for exploitation. Until recently, despite its undoubted importance for the future, biotechnology has led to profitable innovations in only a relatively small number of applications in a few sectors and in a few countries[198].

In Schumpeter's model, the profits realised by innovators are the decisive impulse to surges of growth, acting as a signal to imitators. But this "swarming" behaviour, generating a great deal of new

[198]OECD, 1989

investment and employment depends on falling costs of adoption and very clear-cut advantages and/or competitive pressures. Later on, of course, after a period of profitable fast growth, profitability may decline.

Schumpeter stressed that changing profit expectations during the growth of an industry are a major determinant for the sigmoidal pattern of growth[199]. As new capacity is expanded, at some point, varying with the industries in question, growth will slow down. Exceptionally, this process of maturation may take only a few years but more typically it will take several decades and sometimes still longer.

Biotechnology is a very long way from this mature stage and the main interest is in when it will enter the "swarming" phase and on what scale[200].

For a new technological system to have major effects on the economy as a whole it should satisfy the following conditions[201]:

(1) A new range of products accompanied by an improvement in the technical characteristics of many products and

[199]Schumpeter, 1939
[200]OECD, 1989
[201]OECD, 1989

processes, in terms of improved reliability, new properties, better quality, accuracy, speed or other performance characteristics. This leads to the opening up of many new markets, with high and rapid growth potential and the rise of new industries based on these products.

(2) A reduction in costs of many products and services. In some areas this may be an order of magnitude reduction; in others, much less. But it provides another essential condition for Schumpeterian "swarming", that is, widespread perceived opportunities for new profitable investment. The major revolutions such as electric power and computing, were both labour-saving and capital-saving, but also offered a reduction in the cost of other major inputs, such as energy.

(3) Social and Political Acceptability. Whereas the first two advantages are fairly quickly perceived there may be long delays in social acceptance of revolutionary new technologies, especially in areas far removed from the initial introduction. Legislative, educational and regulatory changes may be involved, as well as changes in management and labour attitudes and procedures.

Changes in taste, especially in sensitive areas such as food and drink, are often unpredictable.

(4) Environmental Acceptability. This may be regarded as a subset of (3) above but especially in recent times, it has become important in its own right. It finds expression in the development of a regulatory framework of safety legislation, and procedural patterns which accompany the diffusion of any major technology.

(5) Pervasive Effects throughout the Economic System. Some new technologies, as for example, the float-glass process, have revolutionary effects and are socially acceptable, but are confined in their range of applications to one or a very few branches of the economy. However, for a new technology to be capable of affecting the behaviour of the economy as a whole, in the Perez sense[202], it must clearly have effects on technical change and investment decisions in many or all important sectors.

Using these five criteria it is relatively easy to see why nuclear technology, for example, does not qualify as a change of "techno-economic paradigm" since it fails on almost every one of them. By

[202]Perez, 1983

contrast, however, electric power or the microelectronic computer-based information technology satisfy all five criteria.

5.6 NEW BIOTECHNOLOGY AS A TECHNO-ECONOMIC PARADIGM

From the evidence in Sections 4.4 of this report, the new biotechnology is likely to satisfy the first of the five criteria, outlined by the OECD (1989), necessary for a new technological system to have major effects on the economy. It is beginning to give rise to a range of new products and processes in healthcare, in medical diagnostics, in veterinary applications, in the food and drink industry and in agriculture and forestry. The future potential is even greater, extending to a broad range of chemical and food products and processes and perhaps ultimately to an even wider spectrum. If the hopes of "bio-chips" are realised they could extend to the whole range of micro-electronics.

With regard to the second criterion; a reduction in the cost of many products and services; the application of new biotechnology is less clear-cut. Perhaps the best analogy is with the first two generations of electronic computers before the advent of the integrated circuit

and the microprocessor. At this stage, in the early 1950s, computers certainly found cost-reducing applications in such areas as pay-roll and invoicing, but the cost of computers was still relatively high so that the range of adoption was limited.

In the case of new biotechnology there are indications that rDNA derived and other processes will be less costly than traditional manufacturing processes in certain Healthcare and Agricultural sectors (see Section 4.5.2), but it is also evident that in other important areas, such as animal feeding stuffs (see Section 4.5.3), the lack of cost competitiveness has slowed down or prevented more widespread applications. This is an important limitation on the speed of diffusion in key industrial sectors. However, these limitations may be overcome as a result of further research and development, or as a result of rising costs and diminishing supplies of non-renewable materials, or both.

In his analysis of the "Economic Potential of Biotechnologies", Rehm (1982), pointed out that future research and development was needed not only in the area of chemical feedstocks but also in relation to biomass and oil-recovery. Relative prices and estimates of probable profitability have not yet led to a major expansion of these fields of R & D.

In the NAS Report on "New Frontiers in Biotechnology" Cooney (1984) pointed out that:

> *Products from the biochemical process industry take advantage of the same economies of scale experienced in commodity chemicals production. Most biochemicals are made using inexpensive raw materials, such as sugar, and they offer good potential value added. The profit margins depend on the efficiency in transforming these raw materials into products. It is this biochemical problem that needs to be translated into a biochemical process. At this point one begins to see the need for integrating improved conversion yields, better metabolic pathways and new reactor mechanisms. This requires integrating biochemistry, microbiology and chemical process technology.*

However, this integration of disciplines and skills is by no means easy to achieve as it requires new forms of organisation and structure in both firms and universities. It is a problem comparable to that identified by Diebold in the case of factory automation[203]. Diebold realised that there was an enormous amount of design and development work necessary for each specific application of computers to industrial processes and that the skills were not often available for this work. Nor were firms organised to achieve results. In the case of biotechnology similar points are valid but the extent of "re-design" may be far less reaching[204]. Postgate may be right when he says that one major disadvantage of biotechnological processes need not prevent them from becoming cost effective,

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[203]Diebold, 1952
[204]OECD, 1989

that is, that the product usually has to be concentrated from relatively dilute solutions[205]. However, the experience so far with the scaling up of biotechnological processes to meet the requirements for large scale production of bulk commodities has not been encouraging in relation to comparative costs. Costs remain high and it is an open question whether biotechnological processes will replace the present processes for bulk chemicals in the next twenty years.

Applications in the copper industry appear more promising[206].

Links upstream to more fundamental research have been a central feature of the new biotechnology and exceptionally important for chemical and drug firms[207]. This will continue to be extremely important in relation to most new products. At present, the dependence of biotechnology on information technology is considerable. Advanced information systems are essential for advanced research, development and design work in molecular biology.

The discussion so far has concentrated mainly on the problems of process technology in relation to the potential large scale future

[205]Postgate, 1984
[206]Warhurst, 1986
[207]Faulkner, 1986

applications of biotechnology outside the present rather limited area. This is because the economy wide effects of the new biotechnology depend on the resolution of these problems. It is already clear that biotechnology is having an effect in the pharmaceutical industry, medical care and agriculture (see Section 4). Whether these effects extend to the whole of the chemical industry, oil recovery, energy industries, the food industry and ultimately an even wider range of manufacturing and service industries depend upon the progress of research, development and design over the next 10-20 years.

This in turn relates to social and organisational problems in the "national system of innovation", the management and scale of R & D, the interfaces between different parts of the system, the availability of skills, the encouragement of experimental application to new processes and so on. Finally, the incentives to conduct research and development and to introduce new processes depend on the development of relative costs in alternative processes.

Whether or not the new biotechnology becomes a "techno-economic paradigm" dominating future economic development in the next century depends also whether it satisfies other criteria. So

far, the first two criteria relating to technical and economic performance have been discussed. The third and fourth criteria of social, political and environmental acceptability are dealt with more comprehensively in Section 4.7.1.

This speculative discussion serves to illustrate the type and magnitude of the structural changes and the social and institutional adjustments which may occur as biotechnology begins to have really widespread effects.

Big changes in the internal structure of agricultural production within each country are also probable. One small example of this may illustrate the point. The UK is now exporting date palms on a significant scale to the Middle East. This business has been pioneered by what was once a small horticultural enterprise on traditional lines but is now a medium-sized firm with R & D facilities and hundreds of employees[208].

Classical and neo-classical trade theory would probably have considered the idea of the UK being an exporter of date palms as absurd on grounds of comparative advantage. But new

[208]OECD, 1989

technologies change many parameters and this certainly applies to biotechnology.

The following discussion focuses on the fifth and final criterion outlined by the OECD in assessing the macro-economic consequences of a new technological system: the pervasiveness of the new technology.

The new biotechnology is clearly more pervasive than more narrowly focussed technologies, such as nuclear power. It has already found applications in primary industries (agriculture, forestry and mining), secondary industries (chemicals, drugs and food) and tertiary industries (healthcare, education, research and advisory services).

However the actual range of applications is still far narrower than the potential applications if one compares the information presented in Sections 4.4.

In fact, biotechnology has often been compared to information technology, whose influence can be felt in all economic sectors[209]. However, it is necessary to emphasise some fundamental

[209]OECD, 1989

differences. Firstly, the fact that biotechnology operates through living organisms, or parts thereof, limits the field of activity to materials that can be biologically manipulated. Numerous industrial sectors would then be excluded from the direct influence of biotechnology such as the steel industry, telecommunications and so on, although an indirect or mediated influence cannot be excluded. On the other hand, information technology, operated through substitution or change of a given production factor, labour, has been able to penetrate almost all products and processes of human activity.

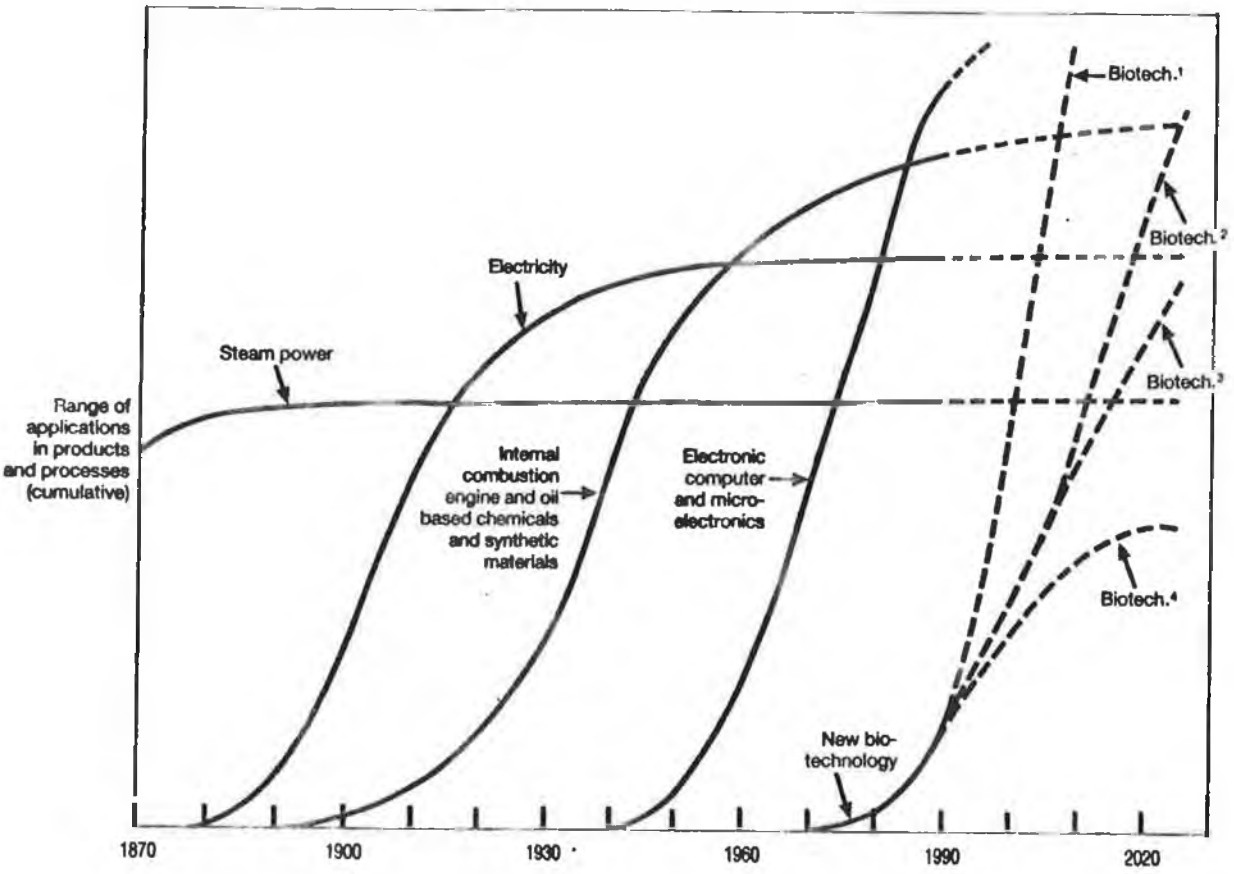
From this feature derives the functional pervasiveness of information technology: informatics and telecommunications are employed not only by technical personnel (production, R & D, engineering), but also by non-technical personnel (administration, financing, marketing, sales). This does not presently hold true for biotechnology. However, in the longer term, a linking of biological and information technologies might materialise in specific devices such as biorobotics and neurocomputers, endowed with much higher capacities for storage and processing. The merging of information technology with the power of the new biotechnology would give the latter all the pervasiveness-aspects of information technologies and would influence human activity in ways which are difficult to imagine at present.

Three possible scenarios have been illustrated for the future path of diffusion of new biotechnology (Figure 18). For the purposes of comparative discussion the two extreme cases Scenario 1 and 4 will be discussed first.

Scenario 1 would represent an accelerated diffusion of the new biotechnology into many industrial sectors and applications, including the rapid development of many new industrial processes as well as products. It would represent a more rapid advance than that which occurred historically with earlier waves of new technology. For reasons which have been discussed, time and scale of R & D, education/training, capital investment, social and structural change, this scenario seems highly improbable. Only rapid changes in relative costs, prices and profitability might induce such a development.

Scenario 4 would represent a much slower rate of diffusion than now seems likely from the identifiable potential of the technology. It suggests that many of the potential applications of biotechnology in the chemical, food, agricultural, medical, energy and other industries remain still in the far future even after another 20 years of R & D.

FIGURE 18 A SIMPLIFIED ILLUSTRATIVE REPRESENTATION OF THE DIFFUSION OF "MEGA-TECHNOLOGIES"



Source: Freeman,C. Technology Policy and Economic Performance : Lessons from Japan, Frances Pinter, London, 1987.

This scenario also seems a rather unlikely scenario in the light of information based upon the current pace of R & D activity and the technological potential.

Something between Scenario 2 and Scenario 3 is therefore the most probable, with biotechnology beginning to be a major basis for new investment and the growth of the economy in the second or third decade of the next century[210]. It should be noted however that the level of aggregation of this scenario is very high. A more precise analysis would require that biotechnology be broken down into various fields of application in order to asses both promoting and retarding diffusion factors in each of them.

It has been recognised that diffusion rates vary greatly between sectors[211]. Health applications of biotechnology are likely to diffuse much faster than agricultural applications, and within the health sector, diagnostic products are diffusing faster than therapeutic products, mainly as a result of regulatory influences (see Section 4.5.1).

Past experience in agriculture indicates that new technologies often take 10 - 20 years before they are adopted, but these rules may not

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[210]OECD, 1989
[211]OECD, 1989

always apply to the innovations coming from biotechnology (see Section 4.5.2).

The fact that the new biotechnology is not likely to become the predominant technology for most industries and services, to which it can be applied, in this century should be no cause for surprise. Nor does it mean that it is unimportant for economic growth and international competitiveness. On the contrary, it is clear that already it will be at the heart of a rapidly growing cluster of new industries and an essential element of survival in an increasing number of established industries.

Moreover, one reason for the intense research interest is that the unexpected can always happen in such a fast-moving area.

5.7 THE NEED FOR STRUCTURAL CHANGE

Section 5.2 discussed the complex problems related to the diffusion of new biotechnology, and mentioned that structural changes and system transformation are prerequisites of a pervasive diffusion throughout the economy. This section focuses

on some of these changes, particularly emphasising those in the healthcare and agricultural sectors, as they are the first sectors affected by the new technology. It should be noted that assessing structural changes inevitably implies an element of speculation as biotechnology is still in its infancy in terms of new commercial products and processes.

5.8 IMPACTS ON PRODUCTS AND PROCESSES

A number of biotechnology developments will have a profound impact(s) on products and processes. Structural changes in the economy and society are likely to follow from these technical changes. Some of them are already detectable in the progress of biotechnology and are briefly discussed in the following sections: a new emphasis on diagnosis and prevention; an increase in the specificity and effectiveness of new products; a reduction in the intensity of use of energy and materials which has been called "dematerialisation"; and increasing compatibility of technology with the environment and with natural resources.

5.9 A NEW EMPHASIS ON DIAGNOSIS AND PREVENTION

A recent OECD report indicates that new biotechnological methods of diagnosis and prevention are expected to multiply in the fields of health, agriculture and the environment[212]. Already some of the greatest successes of new biotechnology are tied to the commercial introduction of the growing number of immunodiagnostic tests based on monoclonal antibodies, biosensors and gene probes[213 214]. Empirical data resulting from the present study also indicates that this is the case in the biotechnological activities of Irish companies (see Section 8). These new devices will allow for an extension of hitherto limited physical and chemical measurements, to a wide number or organic molecules, as well as for potential control and regulation of complex systems in the human body, in animals, plants, the environment and in industrial processes.

The new tests are rapid and highly specific. The range of applications could be extremely wide: clinical controls and online monitoring of patients; in vitro and in vivo diagnostics of humans

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[212] OECD, 1989
[213] Dodet, 1987
[214] Schmid, 1988

and animals; monitoring of the effectiveness of drugs; quality control of food, air, water and soil through detection of pollution agents; criminal investigation and industrial purifications systems.

In another field of healthcare, new vaccines for humans and animals presently under study will significantly increase the number of diseases which can be dealt with through effective preventive measures rather than with more costly therapeutic treatment[215].

The situation outlined as above for healthcare is valid also in other sectors. For example, the mass productions of clones with desired characteristics and the transfer of new traits to plants using the techniques of recombinant DNA has resulted in the production of superior plants with qualities fitting the need of the eventual user, or the production of plants highly resistant to disease, climatic and environmental conditions, (see Section 4).

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[215]Bona, 1987

5.10 DEMATERIALISATION

Several authors have shown that in industrialised societies, new materials and energy inputs into the economy tend to diminish at least in relative terms; this can be measured at the macroeconomic level for most OECD countries with the reduction of intensity of use of raw materials and energy (expressed as the relationship between energy or raw materials demand and the GDP, in kcal / $ or kg raw materials / $)[216] [217]. It has been suggested by these authors that such reductions are linked with the displacement of the production mix towards "light" industry and services, which in general are low hardware-intensive sectors and with the impact of modern technology, which acts towards the efficiency in use of resources, optimisation processes, increasing effectiveness, specificity of materials, waste reduction and utilisation.

It has been suggested that new biotechnology operates in the same direction, and will contribute to reduce energy and raw materials needs per unit of GDP, thus accelerating the movement of industrialised societies "beyond the era of materials"[218] [219]. Examples of this include, production of chemicals through

[216] Malenbaum, 1978
[217] Larson et al., 1986
[218] Larson et al., 1986
[219] OECD, 1989

enhanced fermentation, enzymatic processes, tissue culture, the insertion of a pest resistance function into the genome of plants to reduce the use of pesticides and the substitution of sugar by new compounds with dramatically superior sweetening properties. For example, studies of sweeteners and flavour enhancers have involved the cloning of genes for thaumatin, a protein isolated from the fruits of a West African shrub: 1 gram of thaumatin is equivalent to 2 kilograms of sugar.

Dematerialisation may also have structural aspects. One is a shift in the utilisation of natural resources from rare to more abundant raw materials. Modern technology allows humankind to generate new materials and energies from easily available and cheap sources. It is possible, for example, to produce electricity without high-energy content fossil fuels, but by solar energy, the least expensive and most abundant energy source.

Biotechnology contributes in very similar ways to dematerialisation. For example, the first practical results of genetic engineering have been obtained by using modified microorganisms to mass produce already known pharmaceuticals which, up to now, have been obtainable only in small quantities (such as growth hormones).

Quantitative and structural dematerialisation of economic activities induced by biotechnology may lead to better environmental capability of new products and processes, as the amount of materials to be mobilised decreases and rare resources are preserved.

5.11 "RATIONALISATION" OF THE INNOVATION PROCESS

It should be noted that the potential of biotechnology relies on sound and rigourous scientific knowledge in numerous areas. The methodologies employed in the development of new products and processes increase rationality, while the contribution of pure empiricism is diminishing. This phenomenon is fully apparent in the radical change which has occurred in the last decade in the approach to the development of new drugs. The method of screening of large number of molecules (that is serendipity) has been to a great extent abandoned in favour of a large number of research projects aimed at understanding the mechanism of various diseases.

With this knowledge it becomes possible to target a suitable molecule to act upon those mechanisms. The change in the "paradigm" of pharmacological research has simplified the process of innovation and has made it more rational. This change, made possible by biotechnological research instruments and products, has profoundly affected the pharmaceutical industry.

A similar evolution towards rationalisation of the innovation process in industry is expected to emerge on other sectors where biotechnology may apply, from agrochemical to food industries[220].

5.12 THE HEALTHCARE SYSTEM

Advances in biotechnology offer the possibility to collect more precisely, and on a wider scale information about biological and biochemical aspects of a particular organism, and about the mechanism of action of drugs, in order to arrive at a more specific drug design, with fewer secondary effects (side effects). An example of this can be seen in the possibilities offered by the identification, isolation and production of new factors; for example, proteins with different functions in the human organism, which can

[220]OECD, 1989

be used as drugs themselves (tissue plasminogen activator as a thrombolitic agent). Also, monoclonal antibodies can be used as ultraspecific drug reactors against specific tissue antigens (targeting). These advances involve complex research and the time and cost factors associated with new drug developments (up to 12 years and $125 million) are high; hence new problems of risk assessment and experimentation continually arise.

The slowness with which new therapeutic drugs become available suggests that structural change in medical practice is not imminent and not immediately required as a result of "therapeutic innovation". However, this may change in the future with the introduction of medicines specific to individual patients, such as personalised cancer therapy (LAK therapy), anti-idiotype monoclonals for auto-immune diseases, and others.

However, economic, social and institutional changes deriving from the wave of immunodiagnostic tests based on the monoclonal antibodies and gene probes may be faster and deeper. These tests arrive on the market at regular intervals, as their development requires relatively minor costs, time and risks, at least compared to therapeutic drugs.

The diagnostics revolution will cover a broad spectrum, including prenatal diagnosis, early diagnosis of the onset of diseases, and the monitoring of degenerative diseases. The new tests have many interesting characteristics: rapidity, specificity, facility of use, a wide spectrum of applications and great sensitivity to small quantities of material needed (urine, blood, cells etc..). A recent example of such developments is a pre-natal diagnostic test, developed by a team of Australian doctors, which examines foetal genetic material for the presence of genetic defects, replacing earlier techniques such as amniocentesis[221].

The availability of a large number of simple diagnostic kits will also favour the diffusion of tests performed at home or by the doctor. The best known example is the home pregnancy test. Here also, the change is important because the possibility of self-control of infective diseases or of biological parameters becomes available at the patient level.

It should also be mentioned that technological progress which substitutes laboratory by home tests, corresponds to an apparently growing social demand for self-diagnosis and self-therapy which

[221] Sunday Business Post, 1990

opinion surveys have recently detected in industrialised countries[222].

The transfer of technology from the laboratory to the doctor (doctor's test) or to the private individual (home test) represents a great organisational and functional innovation. Since this breaks with traditional practice, obstacles from the health care sector, from conservative bureaucracies and from professional categories which have a vested interest in the existing system are predictable.

The pharmaceutical industry has been for some time in a state of change: from product supplier (principally drugs) it is becoming an "industry of function" or a healthcare industry, that is a supplier of a wide range of therapeutic products, diagnostics, auxiliary materials, equipment, machines and biomedical systems. The scientific basis is more and more interdisciplinary, relying not only on chemistry, biology and medicine, but also on physics, electronics, computers, lasers etc.. These transformations have already brought with them problems of internal reorganisation.[223]

In the future, the massive diffusion of diagnostic will probably move the current process of transformation further towards an extended

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[222]OECD, 1989
[223]OECD, 1989

multidisciplinary base. The diffusion of mass health screening through the population carries with it not only biological tests, but also the parallel development of automated equipment and software for data processing. This trend is, therefore, towards more integration of biotechnology, microelectronics and telecommunications. In fact, in the area of medical technology, it has been suggested that the traditional pharmaceutical industries may find themselves competing with the electronic industries.

This is a new challenge to the innovativeness of the pharmaceutical industry; it may be noted in this context that the first development of new diagnostic tools arose from small biotechnological start-up companies and not the pharmaceutical industry. The critical success factor in this new challenge may be the ability to further integrate different functional departments during the innovation process rather than biotechnological knowledge itself.

The organisation and institutional implications of this evolution are far-reaching. Such developments offer private enterprises the possibility of extending their activity to services, directly running diagnostic centres, for example and in this way substituting part of the public health system. It has been suggested that this emerging trend could spread, above all in countries where the public health

sector has great difficulty in adapting to technological change, suggesting that Governments would be obliged to turn to the organisational support of private industry[224].

5.13 THE AGRO-INDUSTRIAL SYSTEM

In the agricultural sector, the new biotechnological techniques may have a very dynamic power extending beyond agriculture itself, to ancillary activities, such as fertilisers, agrochemical, machinery, as well as to other downstream activities concerned with food, biomass and the transformation of agricultural products. A discussion of changes in agribusiness related to new biotechnology necessarily involves the complex question of biomass utilisation (that is the constituent material of vegetable and animal organisms) as agricultural surplus-production in many OECD countries is causing great concern.

The diffusion-time of agricultural innovations may become shorter as a result of the strong industrial involvement in agricultural biotechnologies[225] (see also Section 4.5.2).

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[224]OECD, 1989
[225]OECD, 1989

There certainly are agricultural commodities where quantitative production increases would be much appreciated. For example, countries which have a trade deficit in soya or in lumber may welcome the potential of new biotechnology to increase the production of both.

However, the introduction of new biotechnology know-how will bring about a further increase in agricultural production on a broad front because productivity will grow and by-products may find new applications. The example of whey utilisation, a by-product of cheese making, to produce alcohol for use in many commercial applications supports this claim.

The OECD has suggested that while increased efficiency of agricultural production and reduction of resource inputs must be encouraged, the net effect of the new know-how could be to exacerbate the problems of excess agricultural production in the OECD countries as long as there is no fundamental change in the latter's agricultural policies and systems.

Furthermore, it has been suggested that the surplus problem will be overcome by finding new solutions which do not rely on subsidies that place too great a burden on governments; for instance, the fermentation of large amounts of biomass to produce

ethanol for use as gasoline additive, would arouse opposition because it requires at present oil prices, conspicuous government subsidies.

Resistance to the introduction of new biotechnology into agriculture has been fuelled by concern about the quantity impacts of the new technology. It is therefore increasingly evident that agricultural biotechnology should be directed more towards qualitative goals than quantitative production increases, and more towards the development of novel industrial uses of biomass. Quality has several facets. First, there are market demands, at least in wealthy countries, for food with better taste and aroma etc. Such quality areas are those which the traditional food industry has often neglected, although it has applied high quality standards to manufacturing processes and safety. In the future, new biotechnology could open up larger markets for the food industry by focussing on their quality aspects. Marketing studies in wealthy OECD countries have indicated that consumers are ready to pay up to 30 per cent more for quality increases of this type, which could increase food sales in OECD countries by the year 2000 by up to $30 billion[226]. However such predictions based on future intentions must be treated with caution as several factors, including

[226]OECD, 1989

economic conditions and consumer attitudes, will obviously change during the next decade.

A second quality aspect relates to safer food and food with fewer chemical residues from pesticides and other agrochemicals and also synthetic colours and flavours.

In a third and more general sense, quality means greater specialisation and diversification of products in order to respond to specific demands. Products derived from agriculture may, in many cases, better respond to differentiated needs than synthetic or inorganic needs (see Section 4.5.2).

In food companies, the biggest opportunities are presently expected to arise from improved processes through the use of enzymes, for example[227].

The applications of new biotechnology are more controversial in the agricultural sector than in any other. As mentioned previously in this section, the potential of new biotechnology to increase productivity growth in agriculture, entails the danger of increasing food surpluses. In a survey of 94 industrial companies in 17 OECD, including Ireland, the opinions of industrial firms with regard to

[227] OECD, 1989

biotechnology was investigated[228]. With regard to agro-industrial applications of biotechnology, bovine growth hormone (BGH), also known as bovine somatotrophin (BST), was cited as the most important example of a new biotechnology mistake. The administration of BST in lactating dairy cows supplements the natural level of BST in the blood stream. It has been claimed that with the quota system in operation in Europe, BST will enable farmers to produce the same amount of milk more efficiently and cheaply in terms of land and resources[229]

Although at least five companies continue to work on BST, including the parent of an Irish subsidiary, others have stopped development. The possible consequences of a product that could increase milk and meat production on the one hand, and reduce agricultural employment on the other, has made a number of potential manufacturers uncertain[230] and might lead to more comprehensive technology assessment methods in industry, whereby R & D and marketing costs will be confronted with market perception and acceptance.

Interestingly, independent economists predict that BGH / BST will have little overall impact on the dairy industry. They expect that

[228]OECD, 1989
[229]Elanco, 1987
[230]Fishlock, 1989

BST will gradually be taken up by farmers, and used only on a percentage of cows for a selective period of time. BST requires no capital outlay and can be used to increase productivity on any farm, large or small. Farmers may reduce cow numbers to remain within quota, but the number of farms should be largely unaffected by the introduction of BST[231]. At present, the development of bovine growth hormone by industrial companies operating in Ireland is banned by the Government unless milk used in the development work is dumped. Such a restriction is not acceptable to industrialists and hence development by the Irish subsidary of a multinational involved in BST development is not carried out here[232].

The development of new, economically viable uses of agricultural products, particularly for industry, is a critical challenge of our time, and biotechnology greatly adds to the currently available chemical and physical processes to transform otherwise useless biomass. However this is a very complex task. It includes the development of new products to absorb not only excess cereals, typical of temperate climates, but also other types of products from different climatic and geographic conditions. This strategy could also help countries to find new uses for marginal lands, hills and mountains,

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[231]NOAH, 1988
[232]Personal Communication; confidential source

which are being abandoned whenever governments consider this to be an ecological or other risk.

Such measures will take time, and they cannot under any circumstances solve the present surplus problems of many OECD countries. Also, they should not be expected to greatly affect the historic downward trend in agricultural employment of OECD countries. However, while the development of industrial uses for agricultural products is unlikely to reverse this downward trend, it might, in some instances, slow it down.

The proposed shift of emphasis in agriculture from quantity to quality, and from food surpluses to new industrial products, calls for structural transformations in agribusiness, and for changes in the interaction between agriculture and industry. Trends are already emerging towards a closer integration between agricultural, input industries and user sectors. For example, the transfer of the crop protection function from pesticides to biotechnological modified seeds has structural implications for the concerned players, as can be seen in the large-scale acquisition of seed companies by the agrichemical industry[233]. The trend is towards an integration of input and output industries, which would operate

[233]Financial Times, 1989

as a global service to agriculture. The farmer would, in turn, change his/her activity almost into that of an industrial entrepreneur; delegating several functions to specialists whenever growing technological complexity requires specialised competence.

Although the most dynamic actor in the transformation of agriculture is likely to be the industrial enterprise, governments farmer lobbies and the ultimate consumer are likely to play equally critical roles.

5.14 PROSPECTIVE IMPACTS ON EMPLOYMENT

A large and growing literature discusses the impacts of technology on employment, particularly the question of whether and how new technologies have affected jobs in industrialised countries since the Second World War. In the late 1970s the beginning of the "microelectronics revolution" coupled with the economic downturn fuelled concern that widespread use of microelectronics would have labour-saving bias and thus lead to a period of "jobless growth".

Studies indicate that global employment levels in the OECD area in recent years have not been significantly increased or influenced by technological progress. and that macroeconomic factors, particularly growth rates, shifts in demand patterns and international competition have been much more important[234].

Employment impacts have varied considerably between economic sectors. Technological progress has contributed to job losses in manufacturing sectors, although employment in high-technology industries has increased in a few countries without, however, changing the negative net balance. In the service sector, for example, technological progress has been accompanied by the creation of new jobs, particularly in business, financial and communication services. The sum of these new jobs more than compensates for the technology-induced losses incurred by the manufacturing sector[235].

Hence, the major effect of technological progress has been felt less in total employment levels, than in changes in the structure of employment and in higher skill requirements.

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[234] Brainard and Fullgrable, 1986
[235] Brainard and Fullgrable, 1986

TABLE 12

EMPLOYMENT IN SECTORS WHICH WILL BE AFFECTED BY NEW BIOTECHNOLOGY
(AS A PERCENTAGE OF CIVILIAN EMPLOYMENT; 1983 UNLESS DATED OTHERWISE)

COUNTRY	Agriculture	Health	Chemical Industries	Food Industries	Total
AUSTRALIA	6.6	7.0	-	-	-
AUSTRIA	8.6	5.4 (1982)	2.0	2.1	-
BELGIUM	3.0	4.6 (1981)	2.7	3.1	-
CANADA	5.5	4.9 (1981)	-	-	-
DENMARK	7.4	4.8 (1980)	1.5	3.1	-
FINLAND	12.7	5.8	-	-	-
FRANCE	7.9	6.2	2.6	2.9	19.6
GERMANY	5.6	2.5	3.5	1.8	13.4
GREECE	29.9	2.0 (1981)	-	-	-
ICELAND	10.7	6.9 (1979)	1.0	12.3	-
IRELAND	17.1	5.2	-	-	-
ITALY	12.4	3.0	1.8	1.1	18.3
JAPAN	9.3	3.1 (1981)	3.7 (1979)	2.2 (1980)	-
LUXEMBOURG	4.7	3.8 (1981)	-	-	-
NETHERLANDS	5.0	6.5	2.4	2.7	16.6
NEW ZEALAND	11.2	6.0	1.9	5.9	25.0
NORWAY	7.5	6.7	1.4	2.8	18.4
PORTUGAL	23.6	2.4	1.5 (1980)	2.2 (1980)	-
SPAIN	18.6	3.3	2.1	3.2	27.2
SWEDEN	5.4	7.9	1.6	1.6	16.5
SWITZERLAND	6.7	5.5	2.9 (1980)	3.8 (1980)	-
TURKEY	58.9	-	-	-	-
UNITED KINGDOM	2.7	5.3	2.9	3.2 (1978)	-
UNITED STATES	3.5	5.8	1.7	1.5	12.5
TOTAL code	9.5	1.3*	1.3*	1.2*	-

* Refers only to countries for which 1983 data are available

SOURCES: Labour force statistics 1964-1983, OECD, Paris, 1986
Historical Statistics 1960-85, OECD, Paris, 1987 (Agriculture)
Measuring Healthcare, OECD, Paris, 1985, (Health)
OECD Database Sector ISIS, in segment ISIC (Industry)

With regard to biotechnology, industry and governments have not linked their support for biotechnology to hopes that its development could create many new jobs. In fact, the few surveys conducted in the 1970s shed doubts on the labour-creating potential of the new biotechnologies at least during the first years of development[236]. Persistent manpower shortages have, since 1987, led to a somewhat more optimistic assessment of the labour-creating potential of biotechnology, both in the short and long-term, at least for well trained/qualified people.

In view of the economic size of the sectors which will be affected by biotechnology, particularly their importance for jobs, the employment question is a legitimate one. Even excluding the possible impacts on sectors which biotechnology might penetrate at a later stage, such as energy, the number of jobs the sectors which could be affected are large.

Table 12 gives employment in the OECD area, as a percentage of total employment, in the sectors which will be first and most affected by the new biotechnologies; agriculture, public health, and the food and chemicals industries (including pharmaceuticals).

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[236]Bull et al., 1982

Large international variations can be found reflecting mainly the variations in agricultural employment between OECD countries. However, even in the most industrialised countries, employment in all sectors together exceeds 10 per cent of total employment, in at least nine countries (Finland, France, Spain, Italy, New Zealand, Norway, Switzerland, Iceland, Japan) it is approximately a quarter or fifth of all employment, and in three countries (Greece, Portugal, Turkey) it is much higher due to the large size of their population still active in agriculture.

It is more difficult to find data on employment in biotechnological activities or industry directly. Estimates in the 1970s indicate that in the United Kingdom and the Netherlands, between 20 and 25 per cent of the production of food and beverage industries comprises fermented products. If it is assumed that manpower percentages in this sector do not deviate from production percentages, then relatively large numbers of people are employed in classical biotechnological manufacturing.

In the pharmaceutical industries, an estimated 25 per cent of all products go through a fermentation process, including antibiotics and some vitamins (mostly modern biotechnology), but it would be hazardous to take this as a basis for a manpower breakdown in the drug sector.

The numbers employed in genetic engineering companies in the United States are better known; trade associations published figures of more than 30,000 employees working in these companies in 1982-3, and of approximately 40,000 in 1987[237]. This figure is probably an underestimate as it does not include the manpower of some large corporations working on new biotechnology projects.

According to many experts however, it is the qualitative employment impacts which in time will be most important and their direction is already more clearly visible than that of quantitative impacts.

Qualitative impacts will result from the responses to current training and manpower needs in biotechnology, which continue to be a source of concern for governments and industry alike and which have, therefore, been scrutinised in various countries.[238] [239]

There is agreement that a high qualification profile is a predominant feature of the manpower needs in biotechnology. The Irish government's approach to the manpower needs of biotechnology is discussed in Section 6.10.3).

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[237] Biotechnology News 1983; 1987
[238] OECD, 1986
[239] OECD, 1988

The diffusion of biotechnology through the economy, and the productivity increases this will bring about, will have larger employment effects than those which can be expected in the bio-industries themselves. New biotechnology products and market will lead to demand widening which could be felt across the economy.

Of the numerous possible employment effects of biotechnology, those which are expected to be most critical, both politically and economically, are in the area of agriculture. They are the only prospective employment effects of biotechnology which have already provoked counterveiling forces.

Agriculture has, in the last years, adopted biotechnology more slowly than would have been technically possible because a perceived threat to employment has acted as a barrier to diffusion. Still notorious is the 1979 decision of the EEC to impose a quota system on isoglucose, a biotechnology derived sugar substitute, to protect the European Community's 300,000 or more sugar beet farmers.

TABLE 13

GROWTH OF OUTPUT, PRODUCTIVITY AND EMPLOYMENT IN AGRICULTURE, 1950 - 1978

(ANNUAL AVERAGE COMPOUND GROWTH RATES)

Growth of Output		
	1950-73	1973-78
France	2.0	0.1
Germany	2.3	1.0
Japan	3.2	-1.0
Netherlands	3.1	3.2
United Kingdom	2.6	0.9
United States	1.9	0.9
Average	2.5	0.9

Growth og Output per Person Employed		
	1950-73	1973-78
France	5.6	5.4
Germany	6.3	5.0
Japan	7.3	-1.2
Netherlands	5.5	4.9
United Kingdom	4.7	2.8
United States	5.5	1.2
Average	5.8	3.4

Growth of Employment		
	1950-73	1973-78
France	-3.5	-4.2
Germany	-3.7	-3.8
Japan	-3.8	-2.1
Netherlands	-2.3	-1.7
United Kingdom	-2.0	-1.9
United States	-3.5	-0.3
Average	-3.1	-2.3

Source: Angus Maddison, Phases of Capital Development, Oxford., N.Y. 1982, p117.

TABLE 14

EMPLOYMENT IN AGRICULTURE
(AS A PERCENTAGE OF CIVILIAN EMPLOYMENT 1978 AND 1985)

COUNTRY	1978	1985
AUSTRALIA	6.41	6.17
AUSTRIA	9.63	8.15
BELGIUM	3.19	2.91
CANADA	5.75	5.22
DENMARK	7.85	6.70
FINLAND	14.43	11.54
FRANCE	9.19	7.56
GERMANY	6.10	5.44
GREECE	32.02	23.90
ICELAND	12.87	10.34
IRELAND	20.64	15.86
ITALY	15.45	11.20
JAPAN	11.70	8.77
LUXEMBOURG	6.41	4.38
NETHERLANDS	5.38	4.93
NEW ZEALAND	11.24	11.14
NORWAY	8.68	7.30
PORTUGAL	31.26	23.15
SPAIN	20.64	18.24
SWEDEN	6.10	4.45
SWITZERLAND	7.30	6.62
TURKEY	60.69	57.06
UNITED KINGDOM	2.75	2.55
UNITED STATES	3.70	3.12
TOTAL OCDE	10.62	8.88

SOURCES: Labour Force Statistics 1964-1983, OECD, Paris, 1986
Historical Statistics 1960-1985, OECD, Paris, 1987 (Agriculture)

The European consumer still pays approximately twice the 1987 world market price for sugar and this price has in part been maintained by lack of availability of the cheaper sugar substitute.[240]

Present difficulties with bovine growth hormone in Europe have various explanations, one of them being the agricultural labour-saving potential of a product which could increase milk production considerably (see also Section 5.1.3).

However, with regard to fears of job-reducing effects of biotechnology in the agriculture of OECD countries, one can argue that taking a historical perspectives, many OECD countries have their biggest agricultural adjustments behind them. Table 13 shows in the case of six countries that these adjustments, characterised by a dramatic growth of output per person, and by large annual job losses have mainly taken place in the 1950s and 1960s and that already in the 1970s, annual job losses tended to become smaller in some countries.[241]

Table 14, which compares agricultural employment as a percentage of civilian employment between 1978 and 1985, tends to confirm this general trend. In some countries with still large

[240]OECD, 1989
[241]OECD, 1989

agricultural employment, including Ireland, Greece, Finland, Italy, Portugal in the 1970s substantial reductions of agricultural employment (up to a third in relative terms) have taken place in the seven years between 1978 and 1985, before new biotechnology could have had a significant impact.[242] Agricultural productivity will keep rising, employment will decline further and agricultural adjustment will thus remain a continuous long-term process, with or without biotechnology.

Obviously, biotechnology could facilitate agricultural adjustment if it were to concentrate its efforts more on quality improvements and the development of new, industrially useful crops (see Section 4.5.2) rather than on further agricultural production increases. However, even if biotechnology does increase quantities as well, it will do so in the context of other, parallel technological advances which act together.

Junne's examination of the possible impacts of bovine growth hormones in Europe is an interesting case study because the figures are perhaps more widely significant for the relative weight of biotechnology impacts, particularly in the employment context.[243]

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[242]OECD, 1989
[243]Junne, 1987

The dairy sector is the most important subsector of European agriculture, accounting in 1986 for almost 19% of the total value of agricultural output in the EEC area. It has been calculated that the combined effect of continuous upgrading of breeding, improved feed conversions, progress in veterinary sciences and the use of growth and other hormones, will add up to tremendous productivity increases. If total production volume is not allowed to increase, approximately 33% of the current livestock would have to be taken out of production by the year 2000. Even if growth hormones were completely banned in Europe, the necessary reduction in cattle numbers will still be 22%, and many cattle farmers will have to leave the sector.[244]

Thus the prohibition even of one of the most important new agricultural products, could delay but not stop an apparently inevitable evolution, because of the ongoing synergistic effect of other innovations on productivity.

Agricultural employment effects of biotechnology will also depend upon a country's international trade in agricultural products. A leadership position in agricultural biotechnology innovation translated into increased exports, may create jobs. Imports of biotechnology products may lead to loss of jobs.

[244]OECD, 1989

Technological progress leads to productivity increases, reduced production costs and hence to higher profits or wages, or to lower prices. This will increase real income and demand which is likely to be translated into higher employment in the economy in general. Thus employment reductions in one sector, if they are due to general factor saving effects and not compensated for by increased capital costs, will after a time-lag, theoretically result in higher employment in other sectors.

In conditions of competition, productivity increases and factor-saving effects will find their way into price reductions. In monopolistic and oligopolistic conditions, productivity increases will find expression in higher profits and/or wages.

This discussion has mentioned the production costs of biotechnology as they have important implications for a number of economic issues, including economic pervasiveness and structural changes in industry. Looking at costs from a third economic perspective, that of employment consequences, one must consider long-term factor-saving effects. Discussing the economics of biotechnology, Hacking refers both to current uncertainties in assessing costs, particularly of fermentation, and to the potential for further cost-reducing improvements.[245]

[245]Hacking, 1986

However, there are already more than a few examples of factor-saving effects of biotechnology which go beyond labour. Many result from the "dematerialisation" trend (see Section 5.10) whereby traditional raw materials are replaced by rDNA derived products and processes.

The perhaps extreme example of thymus hormone can be given. Thymus hormone is produced from calf thymus glands. The global supply of calf thymus glands is limited to approximately 50 tons per year, which is much less than would be necessary for world-wide therapeutic treatment.

The production costs of the necessary therapeutic dosage per person, amounts to $1000 (1985). However, with the help of rDNA technology, the same product could be manufactured without any raw material supply limitations and calculations indicate that production costs could come down from $1000 to less than $1 for one therapeutic dosage, during the 1990s.[246]

Other examples include the production of insulin, human growth hormone or interferons.[247]

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[246]Hacking, 1986
[247]Fishlock, 1989

To summarise the net result of so many possibble trends cannot be precisely evaluated. In the short and medium terms, biotechnology might add somewhat to the unemployment problem, particularly in countries with large agricultural sectors, such as Ireland, although it is impossible to separate biotechnology from other job-reducing effects of technology. In the long term, after fundamental advances in many, including health-related sectors and with an increasing number of new products, biotechnology could well become a net creator of jobs.

CHAPTER 6: INDUSTRIAL INNOVATION IN IRELAND

6.1 INTRODUCTION

This section of the present thesis focuses on government innovation policies, the promotion of innovation and the creation of an environment for innovation. The importance of exploiting local resources for innovation is highlighting the impact of technology transfer and the role of the university / research centres for innovation are considered.

The evolution of Irish Science and technology policy is discussed to illuminate the environment in which technology-based Irish industry operates.

The discussion then turns to the specific government policy and state-support framework for innovation through biotechnology in Ireland. Finally, the role of the Irish Venture Capital Industry in assisting the development of indigenous Irish industry is briefly discussed.

6.2 IRELAND AND INNOVATION

> *Ireland has experienced unprecedented levels of growth since the early 1960s and has undergone major change in all areas of economic, social and cultural activity. Ireland now displays the features of both a developed and an underdeveloped economy and is characterised as a society in transition in which both traditional and modern values and attitudes co-exist. Against this background of a society in transition, the transformation of work occurring in the industrialised countries of the world presents both opportunities and challenges.*[248]

Over the past forty years many studies have been carried out to identify the sources and determinants of economic growth. These studies have indicated that technological change is one of the most important factors related to economic growth.

A recent OECD report highlights the need for Ireland to get involved in three key future technologies which it identifies as microelectronics, new materials and biotechnology.[249]

The application of these new technologies is seen as a means towards revitalising existing products and services, improving manufacturing processes and the exploitation of natural resources.

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[248] O'Connor, 1989
[249] OECD, 1987

6.3 GOVERNMENT INNOVATION POLICIES

Government policy towards science and technology is not new. Governments have long since followed policies designed to encourage innovation on the assumption that technical change will ultimately lead to the improvement of living standards. For instance, one of the earlier measures to encourage inventive activity and spirit were the patent Acts, which in essence rewarded inventors for their discoveries.

Throughout the industrialised world these numerous measures were later followed by a large number of institutional steps to enable industry to make use of developing technology.

For example, in the UK, the Department of Scientific and Industrial Research (DSIR) was established in 1917, aimed at making science and technology contribute to the benefit of society. In the Netherlands, a similar body - the Organisation for Applied Scientific Research - was set up in 1932. Similar organisations were established in many more countries including Ireland. The evolution of science and technology policy in Ireland is discussed in detail in Section 6.9.

Today, therefore, almost all industrialised countries take at least some steps to help the innovative capacity of industry. There are a number of different approaches with respect to innovation policy that a government can adopt, both in the economy and in industrial development generally.

Here, two kinds of state intervention with regard to planning and industrial policy can be discerned.[250] In some countries state intervention is seen as a major process of indicative planning. This is the case in such countries as France and Italy where industrial policy is used as an important instrument for economic policy and where the objectives of that policy are formulated within a framework of economic and social development plans, which are indicative for the private sector. Industrial innovation policy is then formulated through consultative an co-ordinate procedures by institutions within government and between government and industry.[251]

In other countries, industrial policy is seen as part of general economic policy aiming to create a favourable climate for industrial development. Although these countries, such as the Netherlands, Denmark and the German Federal Republic use industrial policy

[250] Rothwell and Zegveld, 1982
[251] Condon, 1986

instruments or even sectoral policies, these policies are not formulated within the framework of a national plan, nor are they used as selective policies in an intensive or systematic way.

Regarding state assistance aimed at small industry, Kennedy (1985) also distinguishes between two different contrasting patterns of state intervention, what he describes as "active neutrality" and "positive discrimination".

Active neutrality consists of state intervention designed to remove disadvantages facing small and medium sized firms, found wherever free market forces are allowed to operate. Such "disadvantages" usually arrive from legal, institutional or administrative factors or as is more usual, from imperfections in the marketplace itself.[252]

On the other hand, positive discrimination involves the provision of facilities and incentives to small firms which are not offered to large firms. The generally accepted basis for this approach is that the market is sufficiently imperfect in relation to small firms that only positive discrimination can place such small firms in a competitive position with their larger counterparts.

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[252]Condon, 1985

Kennedy (1985) believes that the balance between either approach being adopted by different countries is primarily determined by political philosophy and by economic environment. For instance, the US and Japan are examples of countries that employ positive discrimination in favour of small firms operating within their economies.

However, it has been suggested that the policies followed by these two governments are far from protecting the small firm sector from the strenuous forces operating within the free market economy.[253]

In the US, for example, small firms are expected to create more competition in an environment that already is among one of the most competitive in the world. The Japanese government, for instance, places stronger emphasis on flexibility and adaptation and small firms are expected to co-operate with each other, as well as with larger firms, in achieving these goals.

Traditionally, most western governments have tended towards a more general policy of active neutrality, although in recent years there has been a substantial increase in the scope of policies and institutions aimed at helping small industry in many countries. The impetus for this change has come from a number of different

[253]Condon, 1985

sources. Firstly, the increase in unemployment in many countries, especially over the last decade, has forced policy makers to look at small firms as sources for new jobs. Also, the technological "backwardness" of so many small firms plus the innovative potential of some, have also helped to improve the technological services offered to small firms.

A valid case can therefore be put forward for the provision of special assistance for small firms, not alone here in Ireland, but throughout the industrialised world. However, specifically regarding Ireland, a number of clear-cut factors are generally put forward in justifying the assistance provided for small and medium sized firms by a large number of state sponsored agencies.[254]

(i) Ireland has a sizeable proportion of its workforce employed in the small and medium firm sector. Almost 60% of this country's manufacturing workforce is employed in establishments employing less than 200 people.[255] It is also estimated that small firms employing less than 50 people, represent 80% of all Irish owned manufacturing firms.[256] The small firm sector is therefore of crucial importance to the

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[254]Condon, 1985
[255]Kennedy, 1985
[256]Kennedy, 1985

national economy. While many of these firms may never become large, the most important consideration of employment creation and indeed employment preservation, requires the state to provide the assistance needed to help improve the general efficiency of such firms.

(ii) Small firms are now thought to be an integral part of regional policy, and the trend of Irish industrial policy has been to disperse manufacturing industry throughout the country. Regional development has long been an important factor in this country's industrial development and small firms have an important role in this area.

There has been a remarkable tradition of public intervention by successive governments, in the Irish economy. The Irish approach to public intervention as dealt with matters according to their practical significance or immediate importance, promoting economic development by certain kinds of activity which were unlikely to be generated by the private sector, and which therefore required public support.

By far the most popular mechanism for state intervention in the Irish economy has been the "state-sponsored body". The Irish semi-state sector is usually divided into two parts. On the one hand

there are those bodies which receive most of their income from the sale of their products; they trade openly on the market, offering products and services to the consumer, and counterparts of such bodies in other countries. Examples of such bodies are An Bord Bainne and Aer Lingus.

On the other hand, there are those bodies whose income comes totally or mainly in the form of government grants and whose function is the implementation of certain aspects of public policy. The state support framework for innovation in Irish industry is almost totally comprised of agencies of the latter type and among the most notable of such semi-state bodies are the Industrial Development Authority (IDA), An Coras Trachtala Teoranta (CTT), the Irish Goods Council and EOLAS.

During the last decade issues related to the impact of new technology-based sectors has moved to the forefront. Research on the effects on the rate of innovation of various kinds of policies outlined above has also highlighted the fact that governments tend to adopt a narrow view of various kinds of policies which influence a nation's technological capabilities and pattern of development. They also tend to compartmentalize problems associated with

stimulating and effecting development and with its concomitant social and economic impact.[257]

In this connection, it has been suggested that governments tend to assume that a nation's technological capabilities are influenced by various forms of technology policy rather than by policies in other related areas, such as entrepreneurship, economic and trade policy instruments - government expenditure and investment competition and protection.[258]

However, such policies may have a greater effect on the rate of innovation than policies purely concerned with research and development in the narrow sense. However, in accordance with underlying assumptions many countries have geared their policy instruments increasingly towards promoting industrial research and development.

Furthermore, while explicit attention has been given to national issues and the national context, regional and local areas are increasingly seen as important. The regional and local area's role in the promotion of activities to stimulate science and technology

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[257] OECD, 1987
[258] O'Connor, 1989

development is seen as one of the key stimulants to economic growth.[259]

6.4 PROMOTION OF INNOVATION

Before discussing the promotion of innovation and the creation of an environment for innovation it is necessary to consider the changing social and economic environment in which initiatives aimed at improving the indigenous capacity of a country are being undertaken.

The developed world's economy is undergoing radical change and the process of adjustment has had major impacts particularly on the nature of work. These developed countries are moving from an industrial era to an information era, or from a society based on energy and raw materials to a society based on brain power and the flow of data. Figure 19 outlines the kind of transition that has taken place. In this kind of society, it is suggested that people or "human capital" are the primary resource. The focus is on individuals, and on their skills as entrepreneurs or innovators. In this connection, economic redeployment is seen to be restricted by

[259] O'Connor, 1989

FIGURE 19: COMPARISON OF THE AGRICULTURAL SOCIETY, INDUSTRIAL SOCIETY, AND THE INFORMATION SOCIETY*

Key Characteristics	Agricultural Society	Industrial Society	Information Society
Time period	10,000 years and continues today in most of the world	200 years (began circa 1750)	? years (began circa 1955)
Key element / Basic Resource	Food	Energy	Information
Main Type of Employment	Farmers	Factory workers	Information workers
Key social institution	Farm	Factory	Research University
Basic Technology	Manual Labour	Steam Engine	Computers Electronics
Nature of Mass Communications	One-way Print Media	One-way Electronic Media (Radio, Film, TV)	Interactive Media that are demassified in nature

*O'Connor, Joyce (1989) "Creating an Environment for Enterprise", paper presented at conference, Entrepeneuring the Midlands, (Bord na Mona), Feb 27th, 28th, 1989

the scarcity of people with the necessary skills and requisite qualities or people capable of responding to the challenge of creating new business, either with or without new technology, and directing growth within established firms.[260] [261]

Accompanying this shift from an industrial society there has been a move towards the important role of technology and the way in which it can help further economic growth and development. New technology has changed the development potential of small and medium sized enterprises. The exploitation of their development is dependent on overcoming the disadvantages inherent in the lack of technical and managerial expertise, of technological facilities and support structures as well as socio-cultural factors such as the absence of an entrepreneurial tradition.

In the creation of new enterprises or the further development of existing ones, the limitation in many places is the absence of a strong climate for nurturing ideas and entrepreneurship. An example to support this view is the success of the American experience of California's Silicon Valley, a scientific industrial area. This demonstrated that the supporting environment, the climate that activates entrepreneurial activity is all important.

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[260] Cooper, 1970
[261] Roberts, 1968

Encouraged by such success, regions in Europe, including Ireland, are launching initiatives to promote science and technology development in their own local economies.

The success of these initiatives shows that there is are some basic principles involved, that is, that they are usually based on a careful consideration of a country's needs and of its existing industrial base.

It has been suggested that in creating the climate and environment for building on indigenous strengths, countries need to become aware of their strengths, to nurture those that are emerging and to strengthen those that clearly exist. So while being receptive to new ideas, the strengths which already exist must not be neglected.[262]

It is appropriate at this stage to indicate what is meant by "high technology" and science and technology development. High technology is difficult to define and isolate statistically. Basically however it describes the application of

> *new and old technology to whatever we do.*[263]

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[262] O'Connor, 1989
[263] O'Connor, 1989

Clearly both new and traditional industries and services can be and are improved by better technology.

What is important to emphasise, especially in relation to the industrial applications of biotechnology developments, is that not enough attention is placed on "high technology" industries per se. Rather the emphasis needs to be on the process of technological innovation and diffusion and on its impact for promoting industrial development and sustainable economic growth.

It is important therefore to become aware of and build on the local indigenous strengths rather than concentrate purely on the attraction of high technology businesses from outside the country.

Clearly, the key role which small and medium enterprises play and will increasingly play in the Irish context, in economic growth, in terms of output, new employment and sustained economic growth must be emphasised. The key issues which Ireland must address in this context relate to the questions as to whether they can first successfully exploit the results of research and development in new technologies and second whether the climate for entrepreneurship becomes more encouraging.

It has been argued that systems of support are necessary for small and medium sized enterprises in the changing contemporary industrial world, but what is required will vary according to the **different types** of small and medium enterprises.[264] [265]

It has further been suggested that differentiation of type of enterprise, often overlooked is extremely important when considering systems of support and the mediation and transfer of technology.[266]

It has been discussed that in order to directly stimulate technological development in the firm, governments have a remarkable tradition of public intervention in the form of grants and infrastructures. It is important however, to briefly look at the role of entrepreneurship as a complementary tool in economic development strategies.

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[264] FAST Programme, 1988
[265] O'Connor, 1989
[266] O'Connor, 1989

6.5 THE ROLE OF THE ENTREPRENEUR

The important role of entrepreneurship as a vehicle of economic growth is now generally accepted. Schumpeter, (1950), pointed to the essential role of the entrepreneur in business formation and business development. He saw business as an evolutionary process, in which old industries were continually being placed by new ones in a series of upheavals which he called "creative destruction". In his view the entrepreneur played the pivotal role in the process and was responsible for recurring booms and recessions which, he argued, were due to the upsetting impacts of innovations. The main function of the entrepreneur "consists" of getting this done. While economists generally dislike theories that emphasise the role of the individual rather than of conditions that enable individuals to act, the central role of the entrepreneur is now generally recognised.

The entrepreneurial society has brought about a change in values and has resulted in new cultural role models. It also offers new ways of operating within both established and new organisations. The structure of the corporation is changing and is attempting to facilitate an entrepreneurial approach.

The phenomenon of entrepreneurship is relevant to this context. This essentially means that one does not have to leave an organisation to become an entrepreneur. Rather one may and is encouraged to innovate and adopt an entrepreneurial style within the established, existing organisation.

In discussing entrepreneurship and/or intrepreneurship, it is important to see that both the entrepreneurial and intrapreneurial individual and the type of organisational structure that will support such individuals are mutually dependent on each other. It is also important to underline that entrepreneurship or intrepreneurship is just one way in which firms can revitalise themselves.

In this connection the question as to whether governments should provide incentives to those organisations willing to adopt serious entrepreneurial programmes must be addressed. This emphasis on intrapreneuring would then get beyond the barriers that have hampered traditional discussions of industrial policy as to what types of industry should be supported. The emphasis would be on where it should properly be focussed, namely on those industries and specific companies willing to undertake systematic programmes of long-term demonstrated, institutionalised creativity and innovation.

6.6 IMPORTANCE OF EXPLOITING LOCAL RESOURCES FOR INNOVATION

It is entrepreneurs / intrapreneurs who will enable regions to keep their competitive edge, using all the resources available to them to make solutions and create new products and processes. The results of studies however do highlight that the important conditions for science and technology development within a regional context are the technological infrastructure and the entrepreneurial network that encourages the creation of indigenous technology based firms and supports their survival.[267] [268] However, the science and technology development activities of a region are dependent on a number of interrelated factors.[269]

* the pool of potential entrepreneurs / intrapreneurs

* the relative costs of doing business

* the level of activity in the industrial sector

* regional economic conditions

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[267] Roberts, 1968
[268] Roberts & Berry, 1985
[269] O'Connor, 1989

* quality of the labour force

Research indicates that it is not possible to give one single factor as a causal explanation as to why some regions and communities have been more successful than others in nurturing science and technology development and benefiting from its development.[270]

Evidence from various states in North America and Europe suggests that the following factors interacting together in a supportive climate increase the likelihood of success.[271]

* Research development and technology transfer

* Human capital including education and training

* Entrepreneurial training and assistance

* Financial capital

* Information gathering and dissemination

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[270] O'Connor, 1989
[271] O'Connor, 1989

Hence, strategies for developing the technological level of a region are multi-faceted. Furthermore it is clearly important to play close attention to developments elsewhere. While the importance of basic research is recognised, the regions should also ensure that mechanisms are in place for scanning and evaluating what is going on elsewhere in the world and for applying that information to the development of technologies in the region. As the Japanese experience highlights, most of the important basic research in any given field is going on outside the region.

O' Connor, (1989) suggests that there are factors over which a community has very little control, such as population, industrial base, presence of research institutes and proximity to high technology centres. In this regard she suggests that science and technology development objectives and strategies should be adjusted accordingly. For example, areas without an existing "high-technology" base choose the strategy to bring in branch manufacturing or assembly plants rather than research institutes. Over time, these plants can help create a skilled workforce and technical infrastructure. This, in turn, will help attract more sophisticated operations and encourage spin-offs. The mid-west region in Ireland is a successful example of this approach.

Science and technology development initiatives need to take a realistic view. In any region a number of complementary strategies need to be considered. Most local strategies involve infrastructural developments, the establishment of centres of technical and financial information as well as incubator units. In the mid-west region of Ireland, for example, there is a Technological Park which has both a university and an innovation centre and is complemented by government support agencies which provide other technical and financial assistance to existing companies as well as training interventions for members of their workforces.

6.7 IMPACT OF TECHNOLOGY TRANSFER ON INNOVATION

In this era of rapid technology change, the economic health of a region will depend on its abilities to "capture" knowledge in science and technology and to foster innovation and entrepreneurship. As suggested in Section 6.4 knowledge and its utilisation are replacing the possession of a natural resource base as the key to economic prosperity.

Any reason which chooses to remain competitive in this next phase of industrial development must adapt to this new order and devise mechanisms to exploit the economic potential of developed knowledge and technology. Therefore, managing the technology transfer process is an important key to development.

O'Connor (1989) points out that the most technology transfer takes place at the enterprise to enterprise level and it is in the enterprise that the competence to manage technology transfer must reside.

Because of this, training in the process of technology transfer within the firm is essential. Technology transfer however, is not a one-time event, it should be a continual process of learning, evaluation and action. It is with this in mind that training intervention for all employees needs to be structured.

6.8 ROLE OF UNIVERSITY/RESEARCH CENTRES FOR INNOVATION

A desire to strengthen their local economies by claiming a share of the jobs in the high-growth, high-technology science and engineering fields has acted as a catalyst for regions and

universities to attract and expand high-technology organisations in their areas. In some cases the universities also act as incubator units promoting entrepreneurial internships to facilitate the early stages of development of a high-technology industry.

Many of the efforts have involved the creation of "research parks" or science and technology centres in which a number of high-technology organisations share a common campus. Frequently, this places them in a position to call on the expertise of researchers at a nearby college, university, government faculty or an industrial complex with a substantial R & D facility. A case in point in Ireland is the Plassey Technological Park.

However, in order to ensure that the positive impact of universities for innovation is realised, the universities must be structured to preserve traditional academic values with teaching and research while meeting the commercial needs of business.

It is important to note that another vehicle for technology development that builds on the resources already in place in the university system is the growing number of university-industry research and consultancy arrangements. Thus through interventions in technological innovation, third level educational

institutions can become agents for innovation and major contributors to industrial strategy and development.

A Technological Park can be seen to attempt consciously to create an environment supportive of new ventures in high technology as well as providing a service to mediate technology to prospective entrepreneurs. An issue here is that on a practical level, universities frequently do not have the ethos, management-style or structure that is appropriate for the development of new small companies. A central issue for third level administrators to address relates to the way in which administrative policies may be adjusted so as to create an environment in which the academic, within limits, will be able to act on his/her own initiative and in an entrepreneurial manner.

In the creation of new enterprises the limitation in many places is the absence of a strong climate for nurturing new ideas and entrepreneurship. The growth of high technology firms can be maximised within the context of a supporting environment - an environment with a strong excitement about converting good ideas into successful businesses.

Many new technology based firms which played a crucial role in the evolution of the US semi-conductor industry were established in such areas. In the Boston areas of the US, in particular, biotechnology development was linked to private venture capital companies and to university departments. It is argued however that a centre of "knowledge" in the form of an R & D unit for a multinational "branch" plant also acts as a catalyst and encourages entrepreneurial activity.

6.9 THE EVOLUTION OF IRISH SCIENCE AND TECHNOLOGY POLICY

It was not until the late 1960s that science and technology policy became a real issue in Ireland. In the mid 1960s there was a beginning of consciousness planning in science and technology leading to the publication of the Irish Science & Economic Development Report in 1966. One year later, the National Science Council was set up to support individuals, teams or university departments that were involved in research. Little emphasis was placed on transferring the results of this research to Irish industry and in the next decade this gap was recognised as a fundamental weakness.

In 1973, the National Science Council's report, Science, Technology and Industry in Ireland (1973), emphasised the importance of both supporting research itself and stimulating technology transfer and promoting indigenous R & D. The 1970s witnessed the emergence of the National Board for Science and Technology, and the already existing institutions, An Foras Taluntais (AFT; Agricultural Institute), the Institute for Industrial Research and Standards and An Foras Forbatha continued to grow in parallel with an increased research effort at the Irish universities.

However, the 1980s saw increasing concern with the state of public finance, and as an era of fiscal rectitude dawned, science and technology drifted into a crisis situation.

Fortunately, the availability of the first EC Framework programme funds at this time helped ease the situation. This programme (1984-1987) was not only a welcome source of funding for research but it also brought Irish researchers in contact with European partners for collaborative projects. Such extended contacts broadened the awareness of knowledge in areas such as information technology and biotechnology among other fields, and the need to take strategic initiatives in such fast developing fields became obvious.

The European Council's launch of the S.P.R.I.N.T. programme (Strategic Planning for Innovation and Technology Transfer) in 1987, for example, was designed to give further impetus to innovation throughout Europe.

To date, thirteen joint-venture/collaborative agreements have involved commercial or technological exchanges between firms and research institutes in Ireland, and other member states of the European community. (See Appendix C).

These agreements provide valuable linkages between firms and large institutions. Even though the main phase of the ESPRIT programme is due to run from 1989 - 1993 many activities are up and running such as the European Venture Capital Association (EVCA), a non-profit making organisation, with 160 members including the Industrial Credit Corporation, Allied Irish Investment Bank and the Development Capital Corporation (Ireland).

The second EC Framework programme (1987-1991) and third EC Framework programme (1990-1994) further contribute to the development of science and technology in Ireland. To discuss the various individual programmes that are involved in both the second and third framework programmes would be exhaustive. Thus for the purpose of this study, the main programmes under the second

TABLE 15

BIOTECHNOLOGY RESEARCH PROGRAMMES AS PART OF THE EUROPEAN SECOND FRAMEWORK PROGRAMME (1987-1991)

(1)	BAP (Biotechnology)
(2)	BRIDGE (Biotechnology)
(3)	ECLAIR (Agro-industrial technologies)
(4)	FLAIR (Food Technologies)
(5)	AGRICULTURAL RESEARCH
(6)	HUMAN GENOME ANALYSIS
(7)	STEP (Environmental Protection)
(8)	MEDICAL AND HEALTH RESEARCH
(9)	ESPRIT (Information Technologies)
(10)	STD (Science and Technology for Developing Countries)

SOURCE:

COMPILED FROM PERSONAL CONSULTATION WITH EOLAS; THE IRISH SCIENCE AND TECHNOLOGY AGENCY (1990)

framework programme relevant to biotechnology development are listed in Table 15.

The current government gives a high priority to science and technology and has increased the expenditure in certain areas of science and technology which are related to economic growth (see Section 6.10.3).

The appointment in 1986 of the first Minister for Science and Technology was a firm indication that the state as becoming more confident about a practical role for science and technology.

In 1986 a series of Programmes for Advanced Technology (P.A.T.S.) were established, to enhance industrial development and competitiveness in a particular sector or niche, through advanced technology, and also to raise the international profile of Irish research and development. The PATS attempt to develop new technologies and transfer them to industry, through the provision of contract research and services. It is the aim of each PAT to become self-sustaining in time. At present, three PATS are underway and these include BioResearch Ireland (Biotechnology), Advanced Manufacturing Technology and Optronics Ireland. The minister for Science and Technology has since announced three

new PATS, in April 1990. These will be in the areas of Power Electronics, Software Technology and Advanced Materials.

Since taking office in 1987, there have been significant changes in the administration of Irish Science and Technology. The major science policy and research funding agency, the National Board for Science and Technology (NBST) has been merged with the Institute for Industrial Research and Standards (IIRS) to form Eolas - the Irish Science and Technology agency.

Further rationalisation was witnessed when An Foras Taluntais and its sister agency, ACOT, (the Agricultural and Food Development Agency) were merged to form the Agricultural and Food Development Agency, TEAGASC, while An Foras Forbatha, with responsibility for physical planning, as absorbed into the Department of Science and Technology to become the Environmental Research Unit.

The restructuring of Irish agencies has been directed towards providing a cost effective support for Irish Science and Technology and the shift in emphasis has been towards applying the results of research to the benefit of the Irish economy. The allocation of IR£ 111 million through EC structural funds to science and technology

(1990) and the inclusion of support from the International Fund for Ireland and the new EC Framework Programmes, means that a high level of activity is expected in Irish Science and Technology.[272]

6.10 GOVERNMENT POLICY AND THE STATE SUPPORT FRAMEWORK FOR INNOVATION IN BIOTECHNOLOGY IN IRELAND

While the innovation process as outlined in Appendix D could be used as a model to describe the support framework for innovation in Ireland under the headings of idea phase, research and development and market phases, as well as their subheadings, such an analysis would be both protracted and tedious.

Thus for the purpose of this study, the issue is treated by examining the critical policy areas for biotechnology and the main agencies which support biotechnology innovation in Ireland.

Government policy is a critical factor as it establishes the environment in which bio-industry must developed. Ryan (1988) suggests that the critical policy issues for biotechnology are:

[272]EOLAS, 1990; Personal Communication

* Industrial Policy

* Biotechnology Research Policy

* Education and Training

* Regulation of Biotechnology

However, one of the limitations of national policy on biotechnology in any country is that the sector is becoming dominated by multinational companies. Investment in manufacturing by these companies can be made in almost any country. As a result, an important aspect of government policy has been to create an environment which is attractive to multinational biotechnology companies. The critical elements in this environment are the technical skills and infrastructure, the regulatory environment, and the grants and tax packages available. These factors are however also very important and relevant to the development of indigenous industry.

Additional relevant factors for the latter include new enterprise development assistance, availability of risk capital and technical assistance to start-up companies.[273]

[273] Ryan, 1988

Each of the critical policy areas for biotechnology in Ireland outlined above are elaborated in the following subsections.

6.10.1 INDUSTRIAL POLICY IN IRELAND

In 1979, the Irish government commissioned the National Economic and Social Council (NESC) to undertake a fundamental review of Irish industrial policy. The major part of this review was undertaken by the Telesis Consulting Group. Since its publication 1982, the Telesis Report and the NESC's comments on it, has brought about an unprecedented debate on various aspects of industrial policy.

The government has contributed to this debate and the publication of the White Paper on Industrial Policy[274], was largely designed to give a new impetus to industrial development in Ireland. The White Paper (1984) incorporated innovation into one of the major strands of industrial development strategy. However, the new effect of this has been a slight shift in the restructuring of grant-aid, away from capital intensive grant aid and an improvement in grant-aid toward product and market development.[275]

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[274] N.E.S.C., 1984
[275] IDA, 1989

Ultimately, the 10% corporal tax introduced in 1981 continues an inbuilt bias against conducting R & D in Ireland, thus hitting at the very heart of the innovation process.

Recommendations with regard to technological industrial policy in Ireland were given by the Sectoral Development Committees Report on the Technological Capacity if Irish indigenous industry.[276]

The Irish government has adopted some of the suggestions of this report by providing incentives for firms to access new and emerging technologies, in their areas of operation, including larger grants for higher risk projects, support for prototype development and certification.

The development and application of new technologies, including biotechnology are now seen as providing a range of opportunities to develop a strong and internationally competitive industrial sector in Ireland, both from Irish and foreign owned industry.

Since 1970 the implementation of a policy of attracting foreign manufacturing industry to Ireland has resulted in a significant change in the Irish industrial economy. The implementation of this

[276]Sectoral Development Committee, 1985

policy is carried out by the Industrial Development Authority (IDA). Among the industry sectors targeted by the IDA for development are chemicals and healthcare (including pharmaceuticals).

International companies have been attracted to Ireland by a combination of tax incentives and grants, and a technical educational infrastructure which can supply graduates with the required skills (see also Section 6.10.3). The grant package includes up to 60% capital grants, 100% training and 50% R & D grants.

Biotechnology industrial policy has been approached by the creation of the National Biotechnology Programme (1987) as part of the government's efforts to develop science and technology in economically important sectors.

The National Biotechnology Programmes' objectives include the following:

(1) To encourage research activity in Ireland both by home-based and overseas companies.

TABLE 16

BIORESEARCH BIOTECHNOLOGY RESEARCH CENTRES IN IRELAND

* NATIONAL DIAGNOSTICS CENTRE (UNIVERSITY COLLEGE GALWAY)
* NATIONAL CELL AND TISSUE CULTURE CENTRE (DUBLIN CITY UNIVERSITY)
* NATIONAL FOOD BIOTECHNOLOGY CENTRE (UNIVERSITY COLLEGE CORK)
* NATIONAL AGRICULTURAL AND VETERINARY CENTRE (UNIVERSITY COLLEGE DUBLIN)
* NATIONAL PHARMACEUTICAL BIOTECHNOLOGY CENTRE (TRINITY COLLEGE DUBLIN)

SOURCE: BioResearch Ireland (1990); Personal Communication

TABLE 17

BIOTECHNOLOGY - RELATED RESEARCH SPECIALISATIONS OF IRISH COLLEGES AND RESEARCH INSTITUTIONS

INSTITUTION	RESEARCH AREAS
(TEAGASC) Agricultural Institute	
* Kinsealy Agricultural Centre	Micropropogation of trees and ornamental plants; protoplast culture and mutagenesis, plant breeding;
* Moorepark Research Centre	Plant pathology and mycology, Protein engineering; Cheese starter culture technology; Physiology and Biochemistry of lactic acid bacteria.
* Oakpark Research Centre	Crop breeding
* Western Research Centre	Embryo Transfer Technology
UNIVERSITY COLLEGE CORK	Applications in dairy and food industries; plant biotech; nitrogen fixation; virology; protein chemistry.
UNIVERSITY COLLEGE DUBLIN	Fermentation/chemical engineering; enzymology; plant pathology; mammalian reproduction; enzymology; Im munodiagnostics; waste utilisation/fermentation; Immunology.
UNIVERSITY COLLEGE GALWAY	Enzymology; Immunodiagnostics; Waste utilisation/ fermentation; Immunology.
ST. PATRICK'S COLLEGE, MAYNOOTH	Microbial Crop Protection; Plant Tissue Culture, Cellular Biotechnology
DUBLIN CITY UNIVERSITY	Monoclonal antibodies; Cell culture to pilot scale; Fermentation Technology
TRINITY COLLEGE DUBLIN	Genetic engineering; Diagnostics; Virology; Microbial Pathogenicity.

SOURCE: Ryan, Jim. (1988): "Development of Irish Industrial Biotechnology" Intl. Industrial Biotech, 8:1, Jan/ Feb,1988, p.8

TABLE 18

AGENCIES INVOLVED IN DEVELOPMENT OF BIOTECHNOLOGY IN IRELAND

AGENCY	FUNCTIONS	MECHANISMS
BIORESEARCH IRELAND	Development and Marketing of Irish Biotechnology Research	Staffing and equipping research centres. Marketing and management of biotechnology research services
IDA IRELAND	Development of Irish Manufacturing and Service industry and promotion of Ireland as a location for overseas industry	Up to 60% capital grants; 100% training grants; 50% R & D grants, low cost finance; assistance with company development and planning licensing and joint venture agreements
EOLAS - THE IRISH SCIENCE & TECHNOLOGY AGENCY	Promotion of Irish Science and Technology and Provision of Technical Services to Industry	Basic and strategic research grants to university researchers. Encouragement of university-industry co-operation Analytical and technical advisory services to chemical, pharmaceutical and other industries.

SOURCE: Ryan, J.: "Development of Industrial Biotechnology in Ireland" in International Indusrial Biotechnology, 8:1 (1988)

(2) To establish a significant reputation for Irish biotechnology research and thus help attract overseas companies to locate in Ireland.

(3) To engage in the transfer of biotechnology from Irish 3rd level colleges to industry.

The programme objectives are to be achieved by establishing, equipping and staffing centres of biotechnology expertise dealing with research topics in which there is existing Irish expertise and which are of relevance to Irish industry.

To date, five research centres have been established in the area of biotechnology (see Table 16). These centred are maintained, managed and marketed by BioResearch Ireland, a contract research organisation set up under the National Biotechnology Programme. These research centres as to the existing research institutes and agencies involved in the development of biotechnology in Ireland (see Tables 17 and 18).

6.10.2 BIOTECHNOLOGY RESEARCH POLICY IN IRELAND

With the appointment in 1987 of a Minister of State for Science and Technology, a special science and technology budget was established to promote industrial development through the use of science and technology. This budget is funded by the office of science and technology within the Department of Industry and Commerce and is largely administered by EOLAS. Among the initiatives funded from this budget are a series of programmes in Advanced Technology; what is significant for the purpose of this study is the Biotechnology PAT. This programme draws together teams from industry, the state sector and higher education industries to develop expertise in identified niche areas.

The total allocation to publicly funded science and technology in 1989 was IR£ 420.9 million.[277]

Table 19 shows that education and training/manpower has increased its share of the total budget from 37% in 1980 to 50% in 1989. Expenditures on supporting university-based researchers

[277] EOLAS, 1990; Personal Communications

are in biotechnology related fields. Thus biotechnology related research in universities will benefit from this increase in expenditure.

The healthcare sector has increased its share of the total science and technology budget by 2% to a total of 16.4%, while environment and forestry and timber showed marginal increases over the same nine year period.

Agriculture has decreased its share of the total science and technology budget by ten percentage points between 1980 and 1989. (See Table 19).

What is significant about these figures is that those sectors where the impact of biotechnology is most promising receive the highest percentages of the total science and technology budget, thus indicating the government's commitment to biotechnology research policy.

TABLE 19

CHANGES IN SECTORAL SHARE OF TOTAL SCIENCE AND TECHNOLOGY BUDGET (1980 - 1989)

	SHARE OF TOTAL S & T BUDGET		
	1980	1989	Percntage Point Change
INCREASES			
Education and Manpower	36.6	50.0	+13.4
Health	14.2	16.4	+2.2
Environment	1.3	1.5	+0.2
Forestry & Timber	0.5	0.6	+0.1
DECREASES			
Building & Construction	0.7	0.6	-0.1
Transportation	0.4	0.2	-0.2
Economic & Social	1.4	1.1	-0.3
Marine	1.1	0.7	-0.4
Energy	1.0	0.2	-0.8
Manufacturing	16.6	14.7	-1.9
General Public Services	9.7	7.5	-2.2
Agriculture	16.5	6.5	-10.0

SOURCE: EOLAS (1990), Personal Communication

6.10.3 EDUCATION AND TRAINING POLICY IN IRELAND

Uniquely in Europe, almost half the Irish population is under twenty five years of age, and almost one million young people are now in full-time education. Approximately half the graduates from second level education go on to third level studies. Consequently, education and training forms a high proportion (50%) of the overall government spending on science and technology (see Section 6.10.3, Table 19).

Irish higher education colleges have long established strengths in the biomedical and agricultural sciences. Government policy has been to further develop those aspects of the educational infrastructure which are relevant to industrial growth. This has resulted in a large growth in technical education, including the establishment of Regional Technical Colleges and refurbishment and expansion of technology-related facilities in existing colleges.

Over half the 38 degree and certificate awarding institutions in Ireland were established in the last twenty years. The emphasis on technical education has resulted in 30% and 63% increases in the

number of science and engineering undergraduates respectively in the last ten years.[278]

Apart from courses in the biotechnology-related disciplines, there are currently eight courses specifically on biotechnology in Irish colleges.

Four of these are undergraduate courses in chemical or biochemical engineering (B.E.), biotechnology and chemical technology. The remaining four are M.Sc. courses, three of which deal with biotechnology in general and one with genetics.

The 1988 output from these courses and other relevant disciplines from six of the major colleges is shown in Table 20.

Further graduates will have obviously qualified from the Colleges of Technology, and the Regional Technical Colleges.

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[278]Ryan, 1988

TABLE 20

BIOTECHNOLOGY-RELATED GRADUATE OUTPUT FROM SIX OF THE MAJOR COLLEGES[1] DURING 1988

	BSc (Hons.)	MSc	PhD
Biochemistry	56	13	10
Chemistry	79	26	27
Microbiology	56	12	3
Biology [2]	94	14	20
Pharmacy/Pharmacology	65	5	9
Food Science	24	11	3
Genetics	13	3	2
Biotechnology	31	17	-
Analytical Science	29	-	-
Biochemical Engineering[3]	39	-	-
M. Applied Science	23	24	-
Industrial Microbiology	23	13	-
TOTAL:	532	138	74

1 = UCD, UCC, UCG, TCD, DCU, ST. PATRICK'S COLLEGE MAYNOOTH
2 = ZOOLOGY, BOTANY OR BIOLOGICAL SCIENCES
3 = UCD AND CORK RTC

SOURCE:

Adapted from "Irish Biotech News"
Sept. 1989, pp. 5

6.10.4 REGULATION OF BIOTECHNOLOGY IN IRELAND

The major regulatory considerations are those relating to the use of recombinant organisms, and to authorisation of biological products for medical or veterinary use.

Government policy on recombinant DNA (rDNA) has been to ensure reasonable safeguards without unnecessarily hindering research progress, or industrial use of genetically engineered organisms.[279]

The minister for industry and commerce in his opening address to a biotechnology seminar in 1987 addressed the issue of regulation in biotechnology in Ireland.

> *In fostering the development of biotechnology, we have been careful to regulate developments involving genetically engineered organisms. We recognise that in many countries industry has suffered because of over-restrictive regulations on the use of these genetically-engineered organisms, and more particularly because of over-bureaucratic procedures for licensing of such work. In Ireland, we have been careful to streamline these activities and procedures without in any way reducing our safety standards. We will, at the international level, continue to be on the alert for, and will oppose the adoption of, any*

[279] EOLAS, 1990; Personal Communication

proposals that might to lead to over-elaborate licensing procedures.[280]

Regulation of the research in recombinant DNA (rDNA) was the responsibility of the Medical Research Council from 1974 until 1981 when a National Recombinant DNA Committee was established.

The committee is representative of government departments, research and regulatory interests (including EOLAS, the Agricultural Institute and the National Drugs Advisory Board), and also members from the higher education sector, trade unions, an the Confederation of Irish Industry.

The committee uses as its guide-lines for the work the "Guide-lines for Research involving Recombinant DNA molecules" issued by the US National Institutes for Health (NIH). These procedures are also applied to industrial situations with relevant modifications.

As in most OECD countries, "large scale" is defined as over 10 litre volumes of cultured organisms. The NIH guide-lines on containment levels appropriate to the volume in use are applied where relevant.

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[280] Reynolds, 1987

Good Industrial Large Scale Practice procedures (GILSP) are also recommended by the committee. A guide to the committee's procedures has been published (NBST, 1987).

When a company applies for permission to use recombinant organisms in their processes, the committee acts by advising the local planning authorities on the specific conditions to be met regarding the plant's design and construction, process operation and worker safety. In cases where industrial applications have been granted, the recommendations have been incorporated into the planning approval for the company.[281]

The existing legal framework provides a basis for action by government if it is felt necessary. The relevant laws are the Water Pollution Act (1977), the Dangerous Substances Act (1972), Destructive Insects and Pests (Consolidation) Act (1958), and also relevant EEC directives and regulations.

Research institutions conducting or sponsoring rDNA research are responsible for ensuring that the research is carried out in conformity with the provisions of the guide-lines. They are required to establish an Institutional Biosafety committee. At least two of the

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[281] Ryan, 1988

members of these committees must not be affiliated with the institution.

Approval for the medical preparations is administered by the National Drugs Advisory Board (NDAB), while veterinary preparations are the responsibility of the Department of Agriculture. The guide-lines for applications to NDAB have been published.[282]

6.11 VENTURE CAPITAL AND INNOVATION IN IRELAND

In 1983, a report by the then National Board for Science and Technology (now EOLAS) on finance for small innovative manufacturers in Ireland addressed five key issues with regard to financial support for such companies (see Tables 21).

To discuss in detail each of the financial issues arising from this report is beyond the scope of the present study. Nonetheless, the development of a venture capital supply system targeted to the needs of high risk and/or high technology projects, such as biotechnology is extremely important when considering financial

[282] NDAB, 1987

TABLE 21

FIVE KEY ISSUES OF FINANCIAL SUPPORT FOR INNOVATIVE SMALL MANUFACTURERS IN IRELAND

ISSUE	DESCRIPTION
1	Financial institutions may need to develop new lending mechanisms more suitable for first-time entrepreneurs and innovative small firms.
2	The government may need to stimulate the development of a venture capital supply system targeted to meet the needs of high-risk and/or high technology projects.
3	Private financial institutions and public sector development agencies must become more responsive to the needs of innovative small firms.
4	A range of climatic or environmental factors, notably in the area of taxation, must play a more central role in stimulating innovation.
5	The financial supply system must be better co-ordinated and more effective in catering for innovative small firms.

SOURCE: NBST (1983) "Finance for Innovative Small Manufacturers", NBST report, pp.32

support for innovative small firms, which comprise part of the total population of the present study.

For this reason, an outline of the role of the Irish venture capital industry in assisting the development of indigenous Irish industry is given in the following sub-section, along with some recent venture capital investment patterns in Ireland.

6.11.1 THE ROLE OF THE IRISH VENTURE CAPITAL INDUSTRY IN ASSISTING THE DEVELOPMENT OF INDIGENOUS IRISH INDUSTRY

In Ireland, as indeed in other countries, venture capital activity has been practiced for a very long time on an ad hoc basis by such investors as private individuals, industrial companies, banks and other financial institutions. The emergence of a dedicated venture capital industry as such has taken place during the last ten years. It has evolved from what could most aptly be described as "equity stake" type of investment activity where the focus by the investor

was usually on an established business and where investor participation in the investment was minimal.

During the last ten years, the industry has developed to the point where it has become reasonably well established, and there are a number of well funded organisations engaged in venture capital investment in accordance with the now internationally accepted meaning of that term, that is risk investment with a capital gain as the primary objective, in a start-up or established business, run by one or more entrepreneurs where the investor assists the company in maximising the development potential of the company.

Significant events in the evolution of the Irish venture capital industry have included the formation of equity stake investment vehicles by Ireland's two main banking groups, the Bank of Ireland (BOI) and Allied Irish Banks (AIB) in the late sixties and early seventies.

Both of these vehicles were formed with the support of other financial institutions as minority shareholders. This was followed by the formation of the Development Capital Corporation (DCC), as an independent venture capital and development capital company in 1976. In more recent years, as venture capital activity has expanded, some UK venture capital organisations have become

involved, with 31 having a permanent presence and some others participating in syndicated financings with Irish based venture capital investors.

In November 1980, the industry was given a boost by the introduction of the Unlisted Securities Market (USM). This made it more easy for young companies to achieve a public flotation and therefore brought improved prospects of marketability of their investment to both the venture capital investor and the entrepreneur. The marketability of one's investment and the associated high public profile given to the entrepreneur when his/her company achieves a successful flotation are important contributors to the whole process of breeding entrepreneurs and encouraging the development of successful new businesses.

Another development which has become significant during these formative years of the industry has been the beginning of co-operation between venture capitalists and some universities and 3rd level educational institutions. This has already led to the establishment of some new high-technology businesses with venture capital backing.[283]

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[283]DCC, 1990; Personal Communication

6.11.2 LEGAL AND FISCAL ENVIRONMENT

The government has also played a major part in providing the necessary legal and fiscal environment in Ireland for venture capital investment and in actively participating through state sponsored funds. The three main incentive schemes that exist to encourage private investment in the area are the Business Expansion Scheme, the Research and Development Scheme, and the Share Acquisition Scheme.

6.11.3 BUSINESS EXPANSION SCHEME (BES)

This scheme was introduced in 1984 to encourage high risk investment in developing companies and enables the individual to subscribe for ordinary shares in a company or a designated fund and to deduct up to IR£ 25,000 per annum in computing taxable income, within the regulations imposed by the scheme. However, with the rising uptake of the scheme there has been criticism regarding the reduced risk nature of some of the more recent investments. The recent Finance Bill (1989) introduced a number of

provisions designed to reorientate BES investments back to its original objectives.

6.11.4 RESEARCH AND DEVELOPMENT SCHEME

Like the BES, the Research and Development Scheme provides annual deduction of up to IR£ 25,000 to individuals investing in a research and development company. This is separate from, and additional to the BES deduction.

6.11.5 SHARE ACQUISITION SCHEMES

These schemes enable employees to acquire shares in their own company in tax favourable ways. Under the Share Option Scheme, an individual may be granted an option to buy shares in the future at a price which must not be less than the market value on the date the option is granted.

In addition, regulation to implement the EEC directive on Undertakings for Collective Investment in Transferable Securities (UCITS) took effect in June 1989.

Furthermore, venture backed companies in Ireland may achieve a quotation on the International Stock Exchange of the UK and Republic of Ireland, most commonly on the Unlisted Securities Market (USM). In addition, the Smaller Companies Market (SCM) has been operating since 1986 in Ireland and is similar to the Third Market in the UK. Venture Capital Investments are also commonly exited through corporate acquisition.

6.11.6 VENTURE CAPITAL INVESTMENT PATTERNS IN IRELAND

The latest survey of venture capital activities in Europe, conducted by the European Venture Capital Association[284] reveals that progress in Ireland is failing to keep pace with that in the rest of Europe.

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[284] EVCA, 1990

European countries venture capital companies raised just over ECU 5.8 billion in 1989, a 67% rise on the 1988 figure. In Ireland however, new funds raised by the industry in 1989, at ECU 13.8 million (IR£ 18 million), was virtually half the level raised in the previous year.

In part this can be explained by timing differences. Investment patterns in Ireland may also be running at a slower pace than the European average, possibly due to earlier recessionary climates, but are still showing a reasonable level of momentum.[285]

On the down side as far as smaller start-up companies are concerned, 1989 was an apparently disastrous year for seeking funds. Ireland's venture capitalists put more into supporting takeovers and buyouts than in previous years. While there was a slight increase in funds to finance expansions, the volume of "seed" and "start-up" investments was insignificant.

These figures however should be treated with caution, as the survey[286] on which the data is based, takes a very narrow definition

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[285] EVCA, 1990
[286] EVCA, 1990

of venture capital, not in terms of investment strategy but in the agencies which are included in the survey.[287]

Furthermore, total investment in Ireland in 1989 was £ 30 million, slightly above the £27 million invested in 1988. Buyouts represented 55% of the total amount invested, although their average value is disproportionately high.

From these findings it appears that the Irish venture capital industry still finds it hard to identify sufficient projects which provide good prospects to justify the risks of investment.

Critics of the industry argue that true venture capital is about taking interest in a number of risk projects in the full knowledge that while some of the investments will fail, they will be more than offset by those that succeed. However, this argument can be rejected on the basis that to a large extent this approach is inhibited by the small size of the Irish market. It is also certainly true that venture capital companies are increasingly in competition for investment opportunities with a number of others, including the Business Expansion Schemes (see Section 6.11.3), accountants and solicitors, who also have access to private savings.

[287] Four Irish venture capital companies, supplemented by estimates for the activities of others made by Venture Economics Ltd. which compiled the survey for EVCA.

For a discussion of the potential use of venture capital organisations by companies involved in biotechnology R & D see Section 4.7.2.

CHAPTER 7: RESEARCH METHODOLOGY

7.1 INTRODUCTION

This section of the present thesis, describes the research design of the study. focusing on the general research method, the research population and specific procedure employed.

7.2 CHARACTERISTICS OF RESEARCH DESIGN

> *The most relevant of the presuppositions that determine one's research perspective is that methodological issues must always be answered within the context of a particular research setting.*[288]

Hence, methodologies are neither appropriate or inappropriate until they are applied to a specific research problem.

A qualitative methodological research approach was taken for this study, based on a framework of "direct research".[289]

(1) The research has been as descriptive as possible.

(2) The research has relied on simple, direct methodologies.

[288]Downey and Duane, 1979
[289]Mintzberg, 1979

(3) The research has been as purely inductive as possible (that is, inferring of general case from particular information received during field work).

(4) The research has been systematic in nature with a well defined focus, related to the research study objectives (see Section 1).

(5) The research has measured in real organisational terms. The systematic nature of the research does not mean a detached approach was taken, on the contrary, measuring in real organisational terms means "getting out into the field", into real organisations, which questionnaires often will not do. Thus by measuring in real organisational terms the research has focussed on the organisations inherent complex and dynamic nature.

7.3 METHODOLOGY

7.3.1 DESK RESEARCH

"Desk research" is an established method of covering secondary data. It is essential for the researcher to thoroughly appraise existing literature relative to the subject under investigation as a first step. The fundamental reason of this,

> *... will either be to orientate and educate the research executive or to avoid unnecessary repetition where research might already have been done.*[290]

Moreover, desk research has the attractive advantages of being,

> *... non-reactive or unobtrusive ... it is economical, comparatively speedy, and can be undertaken with complete confidentiality.*[291]

All relevant secondary sources of data were appraised prior to the commencement of the actual field study. Such preliminary investigative work provided a useful indication of relevant

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[290] Newson & Smith, 1980
[291] Chisnall, 1981

parameters of the study - an essential requisite for the development of the overall research strategy.

Secondary sources of data included journals books and reports relevant to the subject area of the study. In addition to these sources, preliminary interviews and telephone calls were made to individuals working or studying in the subject area.

The sources which were principally drawn on are listed as follows:

- Journal of Product Innovation Management
- Research and Development Management
- Journal of Marketing
- Managing Technological Innovation (Twiss 1980)
- "New Products Management for the 1980s" (Booz, Allen and Hamilton, 1982)
- "Marketing Management" (Kotler, 1986)
- "Competitive Strategy" (Porter, 1980)

- OECD Reports
- Bio/technology Journal
- The Economist
- Financial Times
- Irish Times
- Irish Biotech News
- Research Management Journal
- Research Policy Journal
- Eolas (formerly, NBST) Reports

The relevant articles contained in the above sources provided useful further references. The "Anbar Management Services Abstracts" were also used to cite further relevant material.

Any references unavailable in the Dublin City University library were invariably obtainable using the "inter library loan" facility. This

service proved to be invaluable, as it provided the means of appraising various British and American literature.

7.3.2 EXPLORATORY TELEPHONE ENQUIRIES

Due to the paucity of secondary data on the biotechnology industry in Ireland, it was considered necessary to also obtain primary data at this early stage.

Thus preliminary, informal, exploratory telephone calls and face-to-face interviews were made with individuals in relevant institutions including academic research institutions, the Industrial Development Authority, FAS, BioResearch Ireland, Eolas, and the Business Innovation Centre (Dublin).

With enquiries such as these it was indeed not possible to do other than acquire what may be termed a "general impression" rather than a complete picture of the specific research field.

7.3.3 SAMPLE DESIGN

The first stage in sample design was to define as closely as possible the population to be covered by the research enquiry. The population to be studied comprised of those Healthcare and Food & Drink companies operating in Ireland, involved in biotechnology research and development either through in-house or contracted research and development, as a means towards innovation.

This criterion was used to screen potential respondents, because areas of enquiry of the study necessitated direct experience of this early stage of the innovation process.

From preliminary primary research involving exploratory telephone enquiries and personal interviews with relevant members of Irish organisations (including the Industrial Development Authority, BioResearch Ireland and Eolas), it was established that biotechnology research and development in Irish industry is mainly in the health care (including pharmaceuticals) and food and drink (alcoholic beverages) industries. As indicated in Section 1 these two sectors of Irish industry are extremely important to the Irish economy. Furthermore, these two sectors are among those

industries in which the impacts of biotechnology developments can be seen, and in which biotechnology will have important effects in the future. (See Section 4.4)

Thus, these two industry sectors, namely the health care (including pharmaceuticals) and food and drink (alcoholic beverages) industries in Ireland were chosen as the focus of the study.

> *One of the decisive factors in sample design is the nature of the sampling frames available - the lists, indexes, maps or other population records from which the sample can be selected at each sampling stage.*[292]

Yate's (1953) five criteria provided the researcher with useful standards by which to judge the suitability of the available sampling frames. These may be summarised as follows.

(1) ADEQUACY

The sample frame should adequately cover the population to be surveyed, that is of course, relative to the purposes of the study.

(2) COMPLETENESS

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[292]Moser and Kalton, 1977

If the sample frame does not include some of the population members who should be included, "missing elements" will have no chance of being selected, so the sample will be unrepresentative to that extent.

(3) DUPLICATION

With some frames it is possible for an element to be entered more than once. If the risk of duplication occurs, some sort of weighting system should be applied to avoid bias.

(4) ACCURACY

A sample frame should contain accurate, up-to-date information.

(5) CONVENIENCE

It is convenient to have the frame in an accessible place; moreover, it is also preferable if it is arranged in a very suitable way of sampling.

Although no sampling frames can not be expected to satisfy all these exacting requirements, they alert the researcher to the basic problems which may arise.

The International Biotechnology Directory 1988[293] was used as a first stage in the sample design. In total, eighty companies plus research institutes, operating in Ireland in various industry sectors were listed. However, this directory did not satisfy the five criteria of suitable sampling frames outlined previously, notably in its accuracy and completeness.

Furthermore, this directory referred to companies with different levels of involvement in biotechnology. The levels of company involvement in biotechnology in Ireland ranges from

(i) Supply houses that solely distribute biotechnology products, to;

(ii) Manufacturers of biotechnology products (usually the parent company is involved in the innovation process and subsequently allocates the production of biotechnology products), to;

(iii) Those companies in control of their biotechnology research and development programmes.

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[293]Coombs & Alston, 1988

TABLE 22

PRINCIPAL SAMPLING FRAMES RELEVANT TO THE SAMPLE DESIGN OF THE PRESENT STUDY

DIRECTORY / LIST TITLE	YEAR
KOMPASS DIRECTORY	1989
INTERNATIONAL BIOTECHNOLOGY DIRECTORY (COOMBS & ALSTON)	1988
NBST DIRECTORY OF IRISH RESEARCHERS MANUFACTURERS, DISTRIBUTORS OF DIAGNOSTIC PRODUCTS	1988
IDA LIST OF HEALTHCARE SECTOR COMPANIES IN IRELAND	1989

To add to this the International Biotechnology Directory (1988) does not specify the level of involvement in biotechnology of each company listed. This fact alerted the researcher to the problems of using the directory as a sampling frame, as some of the companies listed are not relevant to the purposes of study, notably those companies that solely distribute biotechnology products and those companies only involved in manufacture (i.e. with no research and development activities in biotechnology in Ireland).

Hence, to obtain a suitable sampling frame, which would include those companies operating in Ireland in both the health care and food and drink industry sectors, which are involved in biotechnology research and development in Ireland as a means towards innovation, it was considered essential to compile one.

To this end a number of individual directories and lists were used as a starting base. The principal directory used was the Kompass (1989) Directory, from which those companies in Ireland operating in the health care, and food and drink industries were selected. Other relevant directories were employed to add to this list, and also to serve as confirmation that the final list adequately completely and accurately covered the population (see Table 22).

A useful list of information relative to the purposes of this study was obtained from the School of Biological Sciences, Dublin City University[294]. This list included those companies that were invited to an open day at Dublin City University in October 1989. The purpose of this open day was to introduce companies operating in Ireland to recent biotechnology graduates of Dublin City University. Thus, this list included companies in Ireland that are involved in biotechnology in different industrial sectors. This list is extremely accurate as it was compiled by academics who are familiar with the biotechnology industry in Ireland. Hence, companies included in this list in the health care and food and drink industry sectors were taken, and supplemented the "starting base" list obtained through reference to the main lists and directories (see Table 8).

Thus a combination of the sampling frames referred to in Table 22 and the Dublin City University Biotechnology open-day (1989) list were used to obtain a complete list of those companies in Ireland in the health care and food and drink industry sectors, as these "collectively" were considered to be representative of the initial population under survey. A combination of lists naturally gave rise to problems of duplication of companies. Thus a rigourous, double-checking procedure was adopted to ensure that this was avoided.

[294]Personal communication, 1989

Finally it should be noted that when a complete list of the companies operating in the Irish health care and food and drink industries was compiled, certain companies were automatically omitted as a result of information received from the Industrial Development Authority and BioResearch Ireland.

Such information from these two agencies indicated that certain companies included in the list were not involved in biotechnology research and development in Ireland.

After omitting these companies from the compiled list, it was considered necessary to carry out a preliminary survey, employing a short postal questionnaire to confirm which of these companies in the "reduced" list were actually involved in biotechnology research and development in Ireland.

This preliminary survey was considered necessary as even though information regarding certain companies' involvement in biotechnology was obtained from relevant agencies, such agencies could not confirm the biotechnology involvement of the remaining companies in the "reduced" list. (In fact, BioResearch Ireland are at present compiling an up-to-date Irish Biotechnology Directory due to the fact that such information is not readily available at present; which the present study may contribute to).

Thus the preliminary postal survey aimed to establish those companies in Ireland, in the health care and food and drink industries, actively involved in biotechnology research and development (in Ireland) as a means towards innovation and thus establish a suitable sampling frame, relative to the purposes of the study. To this end a postal questionnaire was sent to all companies in the final "reduced" list.

7.3.4 POSTAL QUESTIONNAIRE

> *A questionnaire is a method of obtaining specific information about a defined problem so that the data, after analysis and interpretation result in a better appreciation of the problem.*[295]

Questionnaires can be employed in three basic ways; by personal contact, by telephone or by post. The choice of a postal questionnaire for this preliminary primary research stage was considered most appropriate for the information required.

The design of the questionnaire for this preliminary research stage was guided by certain principles. The first stage in this design process was to define the information required and therefore

[295]Chisnall, 1981

establish the type and scope of questioning required. As stated earlier in Section 1.2, the survey aimed to establish those companies in the Irish Healthcare and Food & Drink industry sectors, that are involved in biotechnology research and development as a means towards innovation.

Faber and Hauck (1964) have stated three basic conditions which are necessary for ensuring a true response to questions.

(i) Respondents must be able to understand the question.

(ii) They must be able to provide the information requested.

(iii) They must be willing to provide the information.

A preliminary version of the postal questionnaire was developed as a first stage and pre-tested on ten companies from each of the two industry sectors. By such preparatory testing, the researcher was able to ensure that the basic guide-lines outlined above, were observed. In fact, due to the brevity and nature of questions asked, the initial draft of the questionnaire was employed in the final "preliminary research" questionnaire. (See Appendix F. For the purpose of each question, see Appendix G).

The ability of selected respondents to provide accurate information was indisputable; all were either company chief executives or research and development managers who were all au fait with the nature of the problem which the postal survey posed. Their willingness to provide this information was clearly reflected by the high response rate (100%) achieved by the pilot test. In the light of this, it was considered unnecessary to alter the final questionnaire.

In the case of a postal questionnaire, particular care must be taken to ensure that the respondent is able to understand the question, as of course there is no opportunity to seek clarification of confusing terms with an interviewer.

The general form of questionnaires lies between two extremes. They may be either (i) highly structured (close-ended), with a series of formal questions designed to attract answers of limited response or (ii) unstructured (open-ended) where formal questions are designed to be replaced by a freer style of investigation.

The majority of the preliminary postal questionnaire employed in this study was highly structured due to the nature of the enquiry only requiring such depth of questioning.

7.3.5 POSTAL SURVEY

RESPONSE RATE ACHIEVED

In postal surveys, "response rates" may be defined as the proportion of contacted respondents who complete and return the questionnaire. Among the problems in the use of postal surveys, one of the most serious drawbacks over the years has been the low response rate, estimated to be as low as 25%[296]

For this postal survey, as Table 23 shows, a highly acceptable response rate of 82% was finally achieved. In order to achieve such a successful result, various techniques, as discussed in Section 7.3.6 were carefully employed.

It is interesting to note that the first mailing achieved a 59% response rate (N = 61) which was effectively then increased by 23% (N = 24) by the telephone follow-up procedure discussed in Section 7.3.6 to achieve a total response of 82%.

CONTRIBUTORY FACTORS

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[296]Boyd et al., 1977

TABLE 23

POSTAL SURVEY RESPONSE RATE
SAMPLE SIZE N = 104

	Number Received	% Response Rate
INITIAL MAILING (Further to pre-notification by telephone)	61	59%
FOLLOW-UP (By telephone)	24	23%
TOTAL	85	82%

Aside from methods specifically employed to improve the response rate of postal questionnaires, discussed below in Section 7.3.6, certain other contributory factors arguably also influenced the favourable survey response rate result. Ognibene's (1970) study suggests that surveys are more likely to be effective with special interest sample populations. The postal survey rate of 82% was undoubtedly also aided by the fact that the subject of innovation through biotechnology was of particular interest to the population under survey, most of whom were professional research and development managers or company chief executives.

Evidence also suggests that people with higher levels of education and higher IQs are more likely to respond[297]; research and development managers naturally fall into this category.

7.3.6 METHODS OF IMPROVING RESPONSE

Kanuk and Berenson's (1975) review of the empirical studies to increase postal survey response rates reveals the limited evidence on which most widely accepted techniques are based. The efficacy of the different techniques is a point of dissension among

[297] Ognibene, 1970 and Macek & Miles, 1975

researchers. Research concerned with increasing postal response has variously been directed at three phases of the postal survey process:

(1) PRELIMINARY - NOTIFICATION

The effect of contact with the respondent before receipt of the questionnaire.

(2) CONCURRENT TECHNIQUES

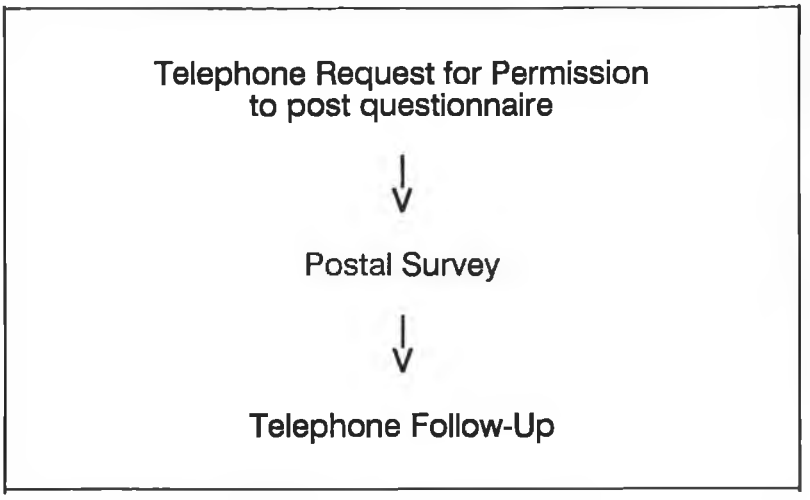
The effect of all of the techniques embodied in or peripheral to the time the respondent receives the questionnaire; all of these are considered concurrent.

(3) FOLLOW-UP EFFORTS

The effect of reminders at the time at which the respondent is deemed to be a non-respondent by failure to answer the questionnaire.

The following sections further elaborate on each stage of this process of "three-phase" approach (see Figure 20)

FIGURE 20: "THREE-PHASE" APPROACH TO POSTAL QUESTIONNAIRE SURVEYS



PRELIMINARY NOTIFICATION

One of the most valuable tools for increasing response to postal surveys is to pre-notify respondents of forthcoming mailing. Pre-contact by letter, postcard, telephone or earlier personal contact all appear to increase response rates: but the maximum improvements are evident from pre-contacting by telephone.[298] In the light of this evidence a telephone pre-notification procedure was adopted for this postal survey. Moreover, this chosen method also had the added advantage of ensuring that questionnaires would only be addressed to those persons qualified to deal with them effectively.

Contact made with each respondent carefully followed a set procedure, which was designed to accomplish the following:

(1) To convey the fact of individual attention to the respondent.[299] This is very important as the degree of personalisation is thereby increased.

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[298] Linsky, 1975)
[299] Dilman, 1978

(2) To explain the nature of the study, create interest, assure confidentiality and express the intention of forwarding a postal questionnaire.

(3) To provide an opportunity for the respondent to pose questions and allay any doubts.

(4) To emphasise that the respondent is individually important to the success of the study.

(5) To elicit the respondent's promise to co-operate, and thus create a sense of obligation and prior commitment.

(6) To alert the respondent to the impending arrival date of the questionnaire.

CONCURRENT TECHNIQUES

All efforts were made to ensure that the questionnaire was of a high quality reproduction, as it is of course, imperative that the respondent form an initially favourable attitude to the survey. Confidentiality was another extremely important matter that had to be given due consideration. For this reason, the fact that the information received would be treated with the strictest of

confidentiality was printed on the cover page of the questionnaire in bold black print. The cover letter attached to this survey, as submitted in Appendix E, was deliberately kept short and easy to read, whereas at the same time it was used to involve and win further the cooperating of the respondent. The objectives of this letter may be listed as follows:

(1) To remind the respondent of his/her pre-notification and commitment to responding.

(2) To give a reasonable explanation of the subject of the study and of the respondent's place in it.

(3) To further follow the standard practice of assuring respondents that responses would be treated as strictly confidential, a matter of concern to the respondents considering the nature of the enquiry.

(4) To draw the attention of the respondent to the eventual use of the information as part of the researcher's worthwhile pursuit towards the attainment of masters degree in Business Studies (MBs) and the fact that the researcher had

a particular interest in the subject area having studied biotechnology as an undergraduate.

The covering letter was then reproduced on high-quality letter headed Dublin Business School stationary. As is customary, pre-addressed reply-paid envelopes were included with the postal questionnaire.

FOLLOW-UP EFFORTS

A follow-up may be considered as one of a variety of reminders between the researcher and the respondent. Research favours the telephone follow-up procedure for producing the best response rate, and for being quick, efficient and easy to control.[300] [301]

For these reasons a telephone follow-up procedure was chosen, this was carried out three weeks after the postal date. The pre-notification procedure, discussed earlier in Section 7.3.6, had already established a personalised frame of reference from which these follow-up calls were made. This final procedure successfully increased the response rate by 23% (see Table 23).

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[300] Sheth and Roscoe, 1975
[301] Lang et al., 1975

7.4 PRELIMINARY RESEARCH POSTAL SURVEY RESULTS

As stated in Section 7.3.5 a postal response rate of 82% was achieved which comprised 85 individual questionnaire responses. Each of the 85 questionnaires were screened to determine if the respondents satisfied certain criteria in order to be included in the major part of the research study. The criteria to be satisfied included that,

(1) The individual company operates in the health care or food and drink sector in Ireland (obviously this criterion was established when constructing the sampling frame).

(2) The individual company is actively involved in biotechnology research and development in Ireland, as a means towards innovation, either through in-house or contracted research and development activities.

Of the 85 responses received, a total of 19 companies were found to be involved in biotechnology research and development (as defined in the questionnaire, see Appendix D) as a means towards

innovating products or processes. Thus the stipulated sample requirement effectively ruled out all other companies.

Tables 24 and 26 (Section 8.2) list the results of the postal survey (it should be noted that only those companies which satisfied the criteria to be included in the major part of the research study are considered in the results of the postal survey).

Due to the fact that the number of companies satisfying the criteria to be included in the major part of the research study totalled 19, and considering the time period for the research, all of the 19 companies comprise the sample population.

Each company was contacted two weeks after receiving the completed preliminary research questionnaire, to establish if the company was prepared to contribute further information to the research study.

This stage of the research required that most of the nineteen companies (17 out of 19) were sent an interview outline prior to committing themselves to an interview.

In certain cases where company policy was not to discuss information relevant to the study, it was necessary for the

researcher to assure the respondent of complete confidentiality and to indicate that specific references to individual companies would not be made.

The major part of the research study involved in-depth interviews with 18 of the 19 companies; the remaining one company in the alcoholic beverages sector, permitted two interviews (one R & D manager, one marketing manager) but was only prepared to discuss very general aspects of the research enquiry.

7.5 DEPTH INTERVIEWING

The postal questionnaire discussed in Section 7.3.5, usefully served the purpose of identifying those companies operating in Ireland in the Healthcare and Food & Drink industry sectors, which are involved in biotechnology research and development (either in-house or contract) as a means towards innovation.

However, this postal survey was not intended to provide a detailed insight into the actual innovation strategies employing biotechnology of such companies. Such a relatively new and complex system and subject area may not be adequately covered

by a postal survey alone as the parameters for enquiry are obviously very difficult to precisely define and thus a direct research approach employing "depth interviews" was necessarily required.

"Depth" interviewing describes a wide range of different types of interviews. Interview types can be classified to cover a range of possibilities. Such classifications cover such varied descriptions as: clinical, free, focussed, non-directive, extended, unstructured, semi-structured and intensive.

Collectively, these interviews represent a "less structured - more intensive" interview type, than a standardised questionnaire administered interview.[302]

This classification delineates three broad types of informal interviewing which can be visualised along a scale of increasing formality. At one end there is the "true depth" or clinical interview, which is more akin to the psychoanalyst's approach, requiring several sessions, it is generally speaking not commonly used for conventional market research purposes.

With regard to the non-directive approach to interviewing where, although the interviewer retains the initiative regarding the course of

[302]Sampson, 1978

the interview, the respondent is given maximum freedom to respond as he/she wishes, without reasonable bounds of relevance.

The "semi-structured" or "focussed" interview aims to cover a given set of topics in a more or less systematic way. Although the respondent is still allowed to respond freely, as the name suggests, much tighter control is exercised by the interviewer.

Informal interviewing is open to criticism on the grounds that it is more vulnerable to the personal influence or bias of the interviewer, than the formal methods. Interviewer bias,

> *... occurs when the influence of the interviewer on the respondent is such that it results in responses that do not accurately reflect the attitudes and opinions of the respondent.*[303]

Informal interviewing is additionally relatively slower and more expensive than the formal methods. However, informal methods can delve into a subject area and get a richer understanding than the formal interview.

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[303]Chisnall, 1981

This need to explore and acquire a fuller understanding of a relatively new complex subject area prompted the researcher to turn to depth interviewing.

The interviews were semi-structured, guided by a list of questions determined a priori and which served as an aide memoir for the researcher (a copy of the aide memoir used throughout the interview sessions is listed in Appendix H). In most cases (16 out of 19) both research and development and marketing managers in the sample companies were interviewed. Tape recordings were not made but the researcher took notes in shorthand. The researcher usually began with an open-ended invitation to tell about work related activities, and then directed discussion towards major aspects of technology policy and innovation strategy. On average, each interview with one company executive took two hours to complete.

It should be noted that each respondent was sent an interview outline prior to the interview date to allow the respondent to prepare for the interview. An interview outline was also required in most cases before the individual company executive would agree to participate in depth interviews.

In some cases, the research also involved the study of documents. Obviously company literature and financial annual reports were appraised prior to the interview. However, one key set of documents was the "innovation charter" or innovation activities schedule of the organisation studied, for a particular innovation. In some cases after repeated requests for permission, permission was given to read these documents on site and make notes. These official descriptions of the evaluation of certain projects were compared with the empirical interview data. Finally, occasional behavioural observations were made, for example when both the R & D and marketing managers were interviewed together, or in informal discussions during lunch at the research site. These observations, though not systematic, led to the formulation of new questions for further interviews and a wider scope appreciation of the subject area.

It should also be noted that after completing an interview the researcher made a type-written copy of the conversation/interview. A copy of this information was sent to the respondent (marked strictly private and confidential) to ensure that the information was not misinterpreted by the interviewer, and to provide the respondent with a further opportunity to contribute any further information which might be of use to the researcher. All in all

approximately one hundred type-written pages of field notes resulted from these interviews.

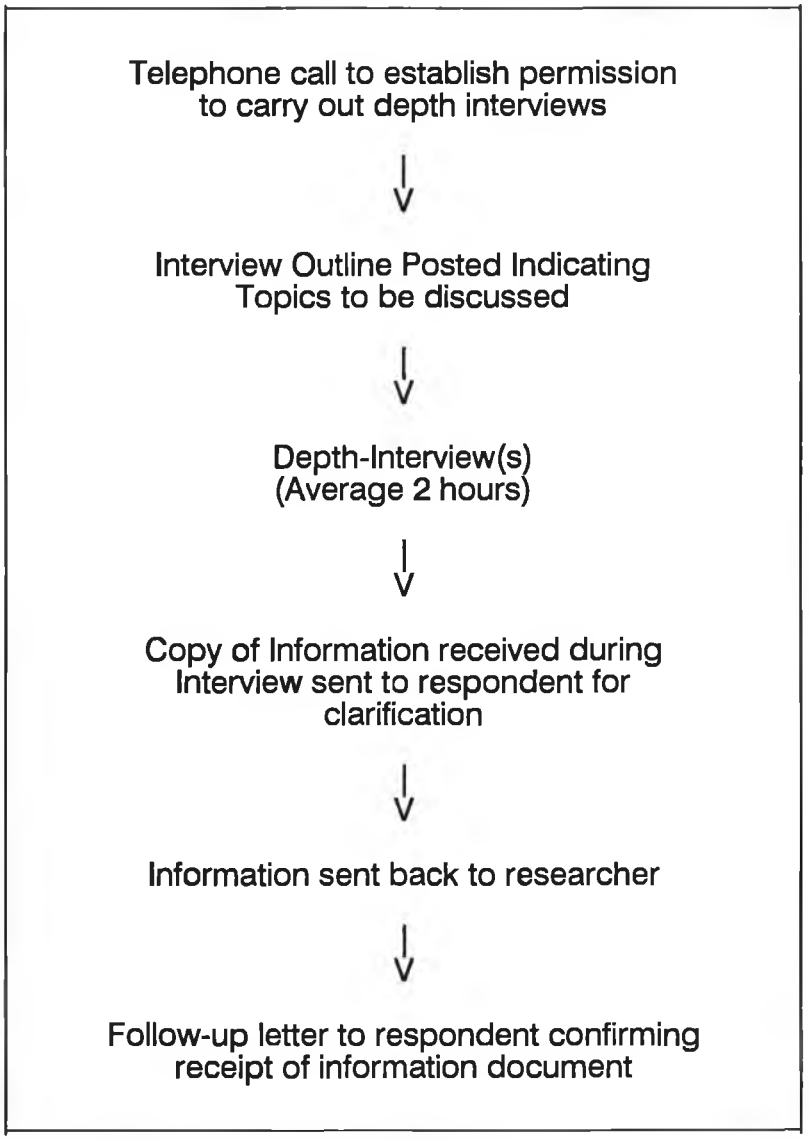
The respondent then returned the information to the researcher indicating any discrepancies that may have arisen from misinterpretation of the information given. However, there were only four cases in which minor discrepancies occurred.

Figure 21 indicates the research process conducted during the "depth interviewing" process of the research study.

7.6 VALUE OF MULTIDIMENSIONAL RESEARCH

No research method is without bias of some kind. This study therefore employed a carefully designed multitechnique approach, in order to minimise some of these research problems. In this way, additional information was obtained, which otherwise would not have been derived from using one research approach in isolation. To summarise, all three basic market research data collection techniques were employed, in a series of linked operations as follows;

FIGURE 21: "SIX-PHASE" APPROACH TO DEPTH-INETRVIEWING USED FOR STUDY



(1) Telephone:

The telephone was used in several ways; for exploratory preliminary enquiries (see Section 7.3.2), and for minimising the limitations of a postal survey by telephone pre-notification and follow-up procedures.

(2) Postal Survey:

A postal survey was employed to accurately define the research population (see Section 7.3.5).

(3) Personal Communication:

"Depth interviewing" was employed in order to acquire a fuller, deeper understanding of innovation strategies employing biotechnology in the two industry sectors chosen (see Section 7.5).

As Chisnall (1973) states,

> *It is not so much a question of which method is best, as which set of methods is likely to result in an objective research programme.*

The researcher therefore considered it necessary to integrate postal, telephone and personal research techniques, in order to meet the needs of this particular study.

Further results of this multidimensional research are given in Section 8.

CHAPTER 8: RESEARCH FINDINGS, OVERVIEW AND IMPLICATIONS

8.1 INTRODUCTION

This section of the thesis discusses the qualitative research data collected during the course of the present study. Each of the two industry sectors studied are discussed separately. For each industry the discussion focuses on:

(1) The level of biotechnological activity.

(2) Reasons for developing biotechnology as a means towards innovation.

(3) The type of innovation strategies employing biotechnology currently pursued.

Finally, the conclusions of the present study are presented.

8.2 PRELIMINARY RESEARCH POSTAL QUESTIONNAIRE RESULTS

The purpose of the preliminary postal questionnaire was to establish those companies involved in biotechnology research and development in Ireland, either through in-house or contracted research and development activities, in the Irish Healthcare and Food and Drink Industries. Tables 24 and 26 represent the results of the preliminary research postal questionnaire.

Table 24 indicates that a total of eleven companies in the Irish Food and Drink industry are currently involved in biotechnology research and development in Ireland, either through in-house or contracted research and development activities. These companies are in the dairy, alcoholic beverages and food ingredients sectors (see Table 25). Both foreign owned and indigenous companies comprise this population.

Considering that there are more than 900 companies in the Irish Food and Drink industry this result may at first appear quite surprising. However, a number reasons for this low involvement in biotechnology research and development are suggested.

TABLE 24 FOOD & DRINK COMPANIES INVOLVED IN BIOTECHNOLOGY R & D IN IRELAND

COMPANY TYPE/ R&D TYPE	INDIGENOUS	FOREIGN	TOTAL
IN-HOUSE R&D ONLY	-	-	-
CONTRACTED R&D ONLY	-	-	-
BOTH IN-HOUSE & CONTRACTED R & D	6	5	11
TOTAL	6	5	11

TABLE 25 FOOD & DRINK COMPANIES IN IRELAND INVOLVED IN BIOTECHNOLOGY R & D BY SECTOR

COMPANY TYPE/ SECTOR	INDIGENOUS	FOREIGN	TOTAL
DAIRY PRODUCTS	6	1	7
ALCOHOLIC BEVERAGES	-	2	2
FOOD INGREDIENTS	-	2	2
TOTAL	6	5	11

TABLE 26 HEALTHCARE COMPANIES INVOLVED IN BIOTECHNOLOGY R & D IN IRELAND

COMPANY TYPE/ R&D TYPE	INDIGENOUS	FOREIGN	TOTAL
IN-HOUSE R&D ONLY	-	1	1
CONTRACTED R&D ONLY	1	-	1
BOTH IN-HOUSE & CONTRACTED R & D	4	2	6
TOTAL	5	3	8

FIGURE 27 HEALTHCARE COMPANIES INVOLVED IN BIOTECHNOLOGY R & D IN IRELAND BY SECTOR

COMPANY TYPE/ SECTOR	INDIGENOUS	FOREIGN	TOTAL
PHARMACEUTICALS	2	2	4
DIAGNOSTICS	3	1	4
TOTAL	5	3	8

Firstly, the majority of food companies in Ireland are mainly small indigenous companies; of the 900 or so companies in this sector only 100 can be termed large (ie 100 or more employees). Similarly, on the basis of turnover, only 13% sell over 20 million per annum. With the exception of dairy and alcoholic beverages, almost 70% of Irish food and drink firms have turnovers less that 4 million.

Furthermore, the major sectors in the Irish Food industry are dairy and meat while fish and cereal products have become more important in recent years. The dairy and meat sectors are highly concentrated sectors dominated by large producer co-operatives.

Similarly, the manufacture of alcoholic beverages in Ireland is highly concentrated, undertaken by a small number of companies of various size, the larger companies being foreign owned.

Thus the number of companies in the Irish Food and Drink industry with the internal capacity to conduct biotechnology research and development is low, considering the high cost and risk of such research and development. This is reflected in the results of the postal questionnaire (Table 24).

Another factor which may affect the capacity of a company to take technology on board is the proportion of employees with third- level training. A survey by Eolas found only 1 -2 % of the total workforce (42,000 employees) in the Irish Food and Drink industry have this level of training. However, the dairy and alcoholic beverages sectors were exceptions to this, with 6% of employees with third level training. (Eolas, 1988)

Furthermore, the Food and Drinks industry is a sector which does not spend heavily on research and development in any country. (Ryan, 1988)

Thus considering the above facts, it was expected that the number of companies in the Irish Food and Drink industry involved in biotechnology research and development would be low. It was also expected that the dairy and alcoholic beverages sectors would have more involvement in biotechnology research and development relative to other sectors such as confectionery, fish products etc. on the basis that:

(i) such sectors are dominated by large companies with the potential internal capacity to carry out research and development,

(ii) the relatively high level of employees with third level training and

(iii) that the applications of biotechnology are at present most relevant to these sectors and are expected to have significant impact on the future.

This was reflected in the results of the postal questionnaire, with those companies involved in biotechnology research and development being mainly in the dairy sector. Two companies were found to be involved in biotechnology research and development from the alcoholic beverages sector; this result was not surprising considering the highly concentrated structure of this sector. A further two companies were found to be involved in biotechnology research and development in the food ingredients sector, both of which are foreign owned (see Table 25).

Table 26 indicates that a total of eight companies in the Healthcare industry are currently involved in biotechnology research and development in Ireland. This low number was not surprising due to the fact that healthcare companies in Ireland are mainly subsidiaries of international companies and consequently research and development activities are carried out abroad in the parent company or parent company country. However, several foreign

owned Healthcare companies have added research and development functions to their manufacturing operations in Ireland or invest in research and development in Irish academic and research institutes. Of these, a total of 6 are currently involved in biotechnology research and development in Ireland, either by in-house or contracted research and development.

The number of indigenous healthcare companies in Ireland is low and may be related to several factors, including the small size of the home market, the dominance and control exercised by the multinationals over the Irish ethical pharmaceutical market, limited import substitution opportunities given the raw material base of most products, high technology and regulatory entry thresholds in many product areas and low levels of linkage in the industry.

However, of those Irish indigenous healthcare companies, five are currently involved in biotechnology research and development in Ireland. Interestingly, three of these are in the diagnostics sector, one of the healthcare sectors in which biotechnology developments have major commercial applications (Table 27)

From the results of the preliminary postal questionnaire, it was established that of those companies involved in biotechnology research and development, all of the companies in the Food and

Drink industry and 6 out of 8 in the Healthcare industry are involved in both in-house and contracted research and development which suggests that linkage between industrial and research institutions in this technological field is very important. (Tables 24 & 24)

8.3 INNOVATION THROUGH BIOTECHNOLOGY IN THE HEALTHCARE INDUSTRY IN IRELAND.

This section discusses the findings resulting from qualitative research (depth interviews) with those healthcare companies operating in Ireland that are involved in biotechnology research and development in Ireland as a means towards innovation.

8.3.1 COMPANIES INVOLVED

There are currently eight healthcare companies operating in Ireland that are involved in biotechnology research and development as a means towards innovation. A distribution by relative size shows:

- 3 large international companies (including one Irish international company). Turnovers (1989) range from 100-200 million pounds. All have considerable research and development budgets.

- 2 medium-sized companies (including one Irish indigenous company). Turnovers (1989) of approximately 50 million pounds. Both have limited research and development budgets.

- 2 small indigenous companies. Turnovers below 10 million pounds. Both have relatively small research and development budgets. (For the purpose of further discussion these companies are referred to as biotechnology "start-ups").

- 1 small indigenous company, turnover (1989) less than 5 million pounds, with a very small research and development budget.

Each company interviewed indicated that it has a survival strategy which is primarily based on the attainment of a certain market share and a certain profit. Each company indicated that biotechnology is but one tool used in this strategy.

8.3.2 REASONS FOR INVOLVEMENT IN BIOTECHNOLOGY

The precise reasons for involvement in biotechnology depend on the following factors which vary from company to company and include:

(1) New Product Development;

(2) Relevance of biotechnology concepts to current product lines and fields of activity;

(3) To strengthen market position;

(4) Part of a general approach for improved efficiency in production processes;

(5) Familiarity with Biotechnology Concepts;

(6) Innovation Oriented Top Management.

All companies interviewed indicate that they want to develop new products through biotechnology research and development.

Screening of possible new products is the next and crucial step upon which further activities will depend.

Biotechnology is of relevance to all the interviewed companies' product lines and fields of activity. The overriding motive for each company to develop biotechnology is a perceived need to increase know-how in order to improve its market position. Five companies, all involved in the large-scale manufacture of pharmaceutical products, point to the opportunities for process rationalisation. Process rationalisation includes improvements in raw material supplies, in waste disposal, purification and numerous manufacturing techniques, and is thus extremely important with regard to a company's competitiveness.

Six of the companies interviewed are already familiar with biotechnology concepts and view biotechnology research and development as an addition to current research and development capabilities. Of these five companies, three are in the diagnostics sector and two in the ethical and over-the-counter pharmaceutical sectors.

For those three companies which in contrast to the preceding group are not already familiar with biotechnology concepts, the presence of an innovation-oriented top management is crucial in

the decision to develop biotechnology in the company. The three such companies interviewed indicate that management creativity does not so much depend on training in biotechnological disciplines but on the capability of decision makers to see biological and economic factors in combination and on the availability of sufficient information to those decision makers. Two of these companies are in the human and veterinary pharmaceuticals sector; and are not familiar with biotechnology concepts as they have employed organic synthesis for the manufacturer of their products. The remaining company in this group has only started to become involved in the manufacture of clinical laboratory diagnostics for the diagnostics sector and thus has no former familiarity with biotechnology concepts.

8.3.3 INNOVATION STRATEGIES THROUGH BIOTECHNOLOGY IN HEALTHCARE COMPANIES

Two major items of interest emerged from the investigation of general company information. First is the relative success of most of the companies in the specific healthcare sub-markets, in which

they are active. This reveals differences in strategic thinking and in innovative capability employing technology.

Second is the structure, organisation and management of corporate research and development. Among the healthcare companies involved in biotechnology research and development, there is wide difference on this front, particularly between those companies that are part of a multinational, and smaller independent companies. For this reason, effectiveness related to the direction of biotechnology research and development and secondly, internal communications in the companies were expected to differ and impact on the innovative capabilities and innovation strategies pursued.

The implications of company decisions to innovate through new biotechnology activities vary widely, according to general company outlook, the capabilities and resources available to the company and the competitive opportunities and threats faced by the individual company.

Three types of innovation strategies through biotechnology can be distinguished:

(1) Some companies plan to use new biotechnology for changes or extensions of their current product lines or for diversifying into product groups where other companies are already competing.

Of the eight companies interviewed two healthcare companies pursue this strategy.

(2) Other companies have, thanks to their structure or management competence built up a capability to link together biological phenomena, technical possibilities and socio-economic issues and needs. This capability has in most cases, led to novel product lines.

Of the eight companies interviewed, four healthcare companies pursue this strategy.

(3) A third strategy aims at large future markets through long-term accumulation of biotechnology know-how. Those companies pursuing this strategy see biotechnology developments as increasing the already existing biotechnological base of the company.

Of the eight companies interviewed, two healthcare companies pursue this strategy.

Each of these innovation strategies employing biotechnology and the companies involved are discussed individually in the following sections.

(1) "LOW INVOLVEMENT LONG-TERM PLANNERS"

Those companies who plan to use biotechnology for changes or extensions of their current product lines or for diversifying into product groups where other companies are already competing, have a relatively low involvement in new biotechnology at present. One of these companies is a subsidiary of a multinational company which develops, manufactures and markets a range of pharmaceutical bulk drug products, pharmaceutical intermediates and fine chemicals. The company's main technological skills are in organic synthesis of these products. The company falls into the category of those companies not already familiar with biotechnology concepts and sees the presence of an innovation-oriented top management as crucial in the decision to develop biotechnology in the company. The company plans to diversify into product groups where other companies are already competing through biotechnology research and development. The area of

biotechnology currently pursued is relatively new but already a number of pharmaceutical firms are active in this area. According to a company source, the decision to enter this area of biotechnology-related research is technology-driven rather than a response to market demand.

The Irish operation of this company has an innovation-oriented top management which has allocated a specific research and development budget for this area of biotechnology related research and development. However, at present the scale of the research and development operation is small and is carried out through in-house activities only. The main reason for in-house activity only is the secretive nature of the research. Being a subsidiary of a multinational company, the resources are available for this exploratory research. The results of such exploratory research will be the next and crucial step upon which future activities depend.

The second company in this group employs biotechnology research and development for changes or extensions in its current product lines. This company is a medium-sized Irish indigenous company which is involved in the development, manufacturing and marketing of both human and veterinary pharmaceutical products. This company falls into the category of those companies not already familiar with biotechnological concepts and sees the

presence of an innovation-oriented top management as crucial in the decision to develop biotechnology. The company involvement in biotechnology research and development is low in terms of the proportion of total research and development funds spent on biotechnology, but the company intends to increase expenditure in this area over the next few years. The company's involvement in biotechnology is relatively recent, that is in the last two years. The company initially contracted out biotechnology research and development to academic research institutions both in Ireland and in the UK. The main reason for contracting out research and development in the particular area of biotechnology relevant to the company's operations was lack of in-house capability and the relatively costly nature of the research involved.

The company considers the decision to enter biotechnology research and development as a offensive move considering the competitive opportunities facing the company. Already, basic research carried out at an academic research institution in Ireland has resulted in process improvements in the company's manufacturing processes.

The company does not feel that involvement in state of the art biotechnology is essential to achieve its objectives in its products and markets and also indicated that an innovation strategy relying

heavily on state of the art biotechnology would make the company vulnerable to rapid change in the technology. The company instead focuses on applied research in-house and contracts basic research to academic institutions if the basic research has not already been carried out at such institutions.

Thus, the late-to-market innovation strategy employed by this company is characterized by nimbleness in adopting the new developments in biotechnology as a result of a very flexible and integrated research and development in-house function.

(2) "MEDIUM INVOLVEMENT LONG TERM PLANNERS"

Four healthcare companies who plan to innovate or innovate through biotechnology pursue strategies which rely on the capabilities to link together biological phenomena, technical possibilities and socio-economic needs. In three of the companies pursuing this strategy, this has already led to the development of novel product lines. The remaining one company has only recently pursued biotechnology as a means towards innovation and falls into the category of those companies not already familiar with biotechnology concepts. This company again sees the presence of innovation-oriented top management as crucial in the decision to develop biotechnology in the company. In fact, three members of

management have strong science backgrounds. This company has not developed products employing biotechnology as yet.

The remaining three companies employing such a strategy all operate in the diagnostics sector of the healthcare industry. One is a medium-sized foreign-owned independent company with a strong technology base. The other two companies are small indigenous biotechnology "start-ups".

Due to smaller costs and greater flexibility, all four companies represent a potential of considerable creativity in the innovation of products through biotechnology. This applies particularly to two of the small indigenous biotechnology "start-ups" which possess very specialised know-how and focus on few product lines.

The key strategic strength of all four companies is the ability to match technology with specific customer requirements or perceived customer needs. Furthermore, these companies believe their key strategic tasks are finding and maintaining a stable product niche and benefiting systematically from user experience.

Both biotechnology "start-ups" indicate the importance of innovation oriented top management in the decision to pursue biotechnology R & D programmes. It is interesting to note that the

particular individuals primarily responsible for the formulation of innovation strategies in these two companies have both relevant scientific backgrounds and many years of international industrial experience in new product development in the healthcare industry. This "manpower strength" is cited by the companies as adding further impetus and direction to the companies innovation strategies.

The two biotechnology "start-ups" are particularly interesting in terms of products developed through biotechnology and the strategies employed.

These companies pursue a first-to-market strategy (see Section 3.6) through their own innovative research and development programmes. Such a strategy has already resulted in the development of novel niche market product lines in the human and veterinary diagnostic market sectors. It was suggested in Section 3.6 that companies employing a first-to-market strategy require state of the art research and development in the product area and both are involved in such state of the art diagnostic technology through in-house biotechnology research and development.

However, both of these companies rely on strong academic/industry linkages as well. It is interesting to note that one

of these companies established a new campus biotechnology company to further develop successful collaboration between the parent company and academic researchers. The other company collaborates with academic research institutes both in Ireland and abroad, but is more involved with those abroad as it feels the relevant advanced technology required in diagnostic technology is not available in Ireland.

These companies also follow a second-to-market strategy with regard to new product development through the development of "me-too" products which are very much market driven products. Such products generate cash-flow which can be injected into their own programmes of research and development for innovative first-to-market products. One of these companies performs contract research in biotechnology to the diagnostic/healthcare industry at large. The second biotechnology "start-up" is involved in both contract research and development and manufacturing for multinational labels in the diagnostics sector. Again, these activities generate resources for the companies' own research programmes. In this respect, these two companies are the closest equivalent to the American phenomenon, the New Biotechnology Firm (NBF) discussed in Section 4.6.1.

Interestingly, one of these companies recently, (1989) raised new funds through a combination of rights issue and private placing to accelerate product and market development. It was suggested in Section 4.7.2 that due to the fact that management surrenders large portions of equity in return for a venture capital infusion, owners should be sure that investors share the same goals. The sources of this company's venture capital are ideal for the first-to-market innovation strategy of this company, including among other investors, an Irish venture capital company and a UK publicly-quoted investment company which specialises in Biotechnology venture investments. This company has also sold an 18% equity stake to a UK biotechnology company and, as part of this arrangement, now acts as the European manufacturing centre for the UK company's operations. This agreement provides cash for research and development for the biotechnology "start-up" and provides the UK company with the necessary manufacturing centre in Europe to generate revenues from international business. Thus, this co-operation has led to a successful mutually-beneficial symbiosis between the two companies.

Thus, the innovative small biotechnology "start-ups" are specialised in their technological strategies concentrating on product innovation in specific producer goods, that is diagnostic products.

The medium-sized foreign-owned diagnostic company in this group also indicates that the presence of an innovation-oriented top management is essential in the decision to develop new products through biotechnology. The main technological strength of this company is cited as a strong in-house R & D capability as a result of a continuing policy of recruiting highly specialised R & D managers with several years international industrial experience in the diagnostics sector of the healthcare industry.

To add to this strong in-house R & D capability the company has acquired technology related to its current output from both US and UK companies. The US deal involved the purchase of a controlling interest in one of the US company's operations and has thus significantly increased market access in the US. Of interest in considering the future innovation strategies of this company is the recent (1990) acquisition of this company by a large multinational in the diagnostic machinery sector. The change in majority stake in the company has already resulted in a considerable shift in the research and development activities of the company to fit in with the innovation strategies of the acquiring company. Thus, the development of new products, and the strategies employed to realise such products in the company may take a different direction in the future as a result of the recent acquisition. Interestingly,

however, the acquisition has actually fuelled new product ideas not considered previously by the company.

(3) "HIGH INVOLVEMENT/BROAD-FRONT LONG-TERM PLANNERS"

Two healthcare companies focus their innovation strategies employing biotechnology on large future international markets through long-term accumulation of biotechnology know-how. Such strategies are seen as increasing the already existing biotechnological base of the company.

These larger innovating companies are all large multinational companies. One company is a subsidiary of a multinational which develops, manufactures and markets therapeutic pharmaceutical products. The other company is an Irish indigenous international company developing, manufacturing and marketing ethical and over-the-counter pharmaceutical products, medical nutrition products and diagnostic reagents.

These companies are broad front in their technological activities related to biotechnology. Their key technological strengths are based on access to a network of research and development carried out in different research and development laboratories as part of the total company.

In order to have optimal access to new biotechnology know-how and to reduce overheads, research and development co-operation between companies as well as skilled co-operation management is considered essential by these companies. These companies are unanimous in stating that the number of research and development co-operations has grown continuously and keeps growing. These co-operative ventures have led to a successful, mutually successful symbiosis between big and small companies, including small US biotechnology firms and one collaboration involving a Swiss microelectronics company.

The companies in this group are developing a number of products. Often the relevant know-how for one product development is not concentrated in one place, which forces companies to combine several co-operations and partners. Two of these large companies tend to co-operate internationally, the reasons given being lack of know-how in Ireland in particular areas and also the perception that university know-how often has strong national ties.

Co-operation also occurs at the distribution level. Two of the companies focusing their innovation strategies employing biotechnology on large future international markets have interesting products with a small market niche but are unable to add up the

niches of various countries in order to have a global market of sufficient size and to reach break-even point.

The concept of globalisation in marketing referred to in Section 2.8 is of paramount importance to these companies, and the world-wide distribution networks of these companies are considered a critical condition for success in biotechnology innovations. However, these companies have to realise the realities of entry costs into the large markets and have therefore developed a strategy of licensing products to the major pharmaceutical marketing companies for the large markets and reserving niche markets for either joint ventures or direct marketing activities.

8.4 INNOVATION THROUGH BIOTECHNOLOGY IN THE FOOD AND DRINK INDUSTRY IN IRELAND

This section discusses the findings resulting from qualitative research (depth interviews) with these healthcare companies operating in Ireland that are involved in biotechnology research and development in Ireland as a means towards innovation

8.4.1 COMPANIES INVOLVED

There are currently eleven companies in the food and drink industry operating in Ireland that are involved in biotechnology research and development as a means towards innovation. Two of these companies are in the alcoholic beverages sector, two are in the food ingredients sector and seven are in the dairy sector.

A distribution by relative size shows:

- six large companies (all of which are indigenous) with turnovers (1989) between 100 and 300 million. These companies have considerable R & D budgets.

- 1 large autonomous unit of an international company with a turnover (1989) of 300 million pounds. This company has a considerable research and development budget;

- 4 large international companies with turnovers (1989) over 300 million pounds. All of these companies have considerable research and development budgets.

Each company interviewed indicated that it has a survival strategy which is primarily based on the attainment of a certain market share and a certain profit. Biotechnology was cited by each company interviewed as but one tool used in this strategy.

8.4.2 REASONS FOR INVOLVEMENT IN BIOTECHNOLOGY RESEARCH AND DEVELOPEMENT

The precise reasons for involvement in biotechnology depend on the following factors which vary from company to company and include:

(1) To strengthen market position;

(2) Relevance of biotechnology concepts to current product lines and processes;

(3) Familiarity with Biotechnology concepts;

(4) New process development for in-house use as part of a general approach for improved efficiency in production processes;

(5) New Product Development.

The overriding motive for each company to develop biotechnology is a perceived need to increase know-how in order to improve its market position. Biotechnology is of relevance to all the interviewed companies' product lines and processes. All of the companies are already familiar with biotechnology concepts and view biotechnology research and development as an addition to current research and development capabilities. All companies point to the opportunities for process rationalisation.

Of the total 11 companies, most (total 10) indicate that they want to develop new products through biotechnology research and development.

Three types of innovation strategies through biotechnology can be distinguished:

(1) Some companies plan to use new biotechnology for process rationalisation and "modest" changes or extensions of their current product lines.

Of the eleven companies interviewed, four companies pursue this strategy.

(2) Other companies plan to use new biotechnology for new process development, existing process rationalisation, for "modest" changes or extensions of their current product lines and for new product lines

Of the eleven companies interviewed, six companies pursue this strategy.

(3) A third strategy aims at large future markets through long-term accumulation of know-how. This strategy is seen as increasing the already existing strong biotechnological base of the company.

Of the eleven companies interviewed, one company pursues this strategy.

Each of these innovation strategies employing biotechnology, and the companies involved are discussed individually in the following sections.

8.5 INNOVATION STRATEGIES THROUGH BIOTECHNOLOGY IN FOOD AND DRINK COMPANIES

Again, two major items of interest emerged from the investigation of general company information. First is the relative success of most of the companies in the specific markets, in which they are active. As suggested already in Section 8.4 this reveals differences in strategic thinking and in innovative capability.

Second is the structure, organisation and management of corporate research and development. Among the food and drink companies involved in biotechnology research and development, there is wide difference on this front, particularly between those companies that are part of a multinational and smaller independent companies.

For this reason, effectiveness related to the direction of biotechnology research and development and secondly, internal communications in the companies were expected to differ and impact on the innovative capabilities and innovation strategies pursued.

The implications of company decisions to innovate through new biotechnology activities vary widely, according to general company outlook, the capabilities and resources available to the company and the competitive opportunities and threats faced by the individual company.

(1) "LOW INVOLVEMENT LONG-TERM PLANNERS"

Those companies who plan to use biotechnology for process rationalisation and "modest" changes or extensions of their current product lines have a relatively low involvement in new biotechnology at present as reflected in the proportion of total research and development funds spent on biotechnology research and development. All of these four companies are large indigenous companies involved in the dairy sector of the Irish food industry.

These companies' main technological strengths are in dairy processing and they view biotechnology developments as primarily

having major applications in dairy process rationalisation and for modest changes or extensions of their current product lines. It should be noted that "modest" changes or extensions refer to product developments aimed at increasing the quality, flavour, texture, stability or functionality of products. Such developments are extremely important in terms of competitive advantage for companies in the dairy sector.

Each company in this group has indicated that both strategies of process rationalisation and "modest" changes or extensions of current product lines through biotechnology are primarily market-driven. In particular innovation strategies employing biotechnology for process rationalisation result from pressure to reduce costs. Strategies employing biotechnology for "modest" changes or extensions of current product lines result from specific customer requirements or perceived customer needs.

All four of these companies are involved in both in-house and contracted research and development at research institutions.

These companies believe that close proximity to state of the art technology in dairy processing is essential to achieve their objectives in process rationalisation. To achieve this, such companies pursue a strategy of close collaboration with research

institutions in Ireland and abroad. Collaboration with research institutions involves access to basic research in the particular area of interest, normally of a pre-competitive nature, and access to applied research in the particular area of interest through contracted research and development of a competitive nature.

The main reasons for collaboration with research institutions in order to access state of the art technology are, limited financial resources, lack of in-house expertise and the fact that dairy processing related biotechnology is changing and developing rapidly, which leads to reduced predictability as to the direction in which the technology will develop. Thus collaboration with research institutions minimises the risk associated with the adoption of the new biotechnologies by the companies.

In achieving their objectives of "modest" changes or extensions of current product lines through biotechnology such companies employ a strategy of applied or developmental research and development through both in-house and contracted research and development programmes. Contracted research and development programmes to achieve such objectives are placed at research institutions where the research programmes have a specific commercial application and in this sense are of a very applied nature.

An alternative strategy to achieve objectives in process rationalisation and "modest" changes or extensions of current product lines is the licensing of technology (referred to in Section 3.7). This strategy is employed by two of these companies, which have indicated that high development costs and long payback periods associated with the areas of biotechnology pursued are the main reasons for pursuing such strategic alliances.

(2) "HIGH INVOLVEMENT LONG-TERM PLANNERS"

Those companies who plan to use new biotechnology for new process rationalisation, "modest" changes or extensions of their current product lines and for new product lines have a relatively high involvement in biotechnology at present, as reflected by the proportion of total research and development funds spent on biotechnology research and development.

Of the eleven companies interviewed, six companies fall into this group. Three of these companies are in the dairy sector; two being large indigenous companies, the other being part of a large multinational company.

A further two companies develop, manufacture and market alcoholic beverages, both are large international companies, one

being a large multinational and the other a large autonomous unit of an international group.

The remaining company in this group operates in the food ingredients sector and is a subsidiary of an international company.

Process rationalisation efforts of these companies focuses on increasing efficiency of existing production processes as a result of pressure to reduce costs and price, and is very much market-driven, according to each company interviewed.

"Modest" changes or extensions of these companies' current product lines focuses on increasing quality, functionality or flavour of certain products, as a result of consumer demand and is also indicated as being very much market-driven.

New process development of these companies focuses on alternative processes for some current product lines, and is part of a general approach to improve efficiency and possibly license such technology.

New product development of these companies focuses on developing new products to respond to changing consumer

demand, identification of speciality markets and utilisation of by-products resulting from existing processes.

All companies pursuing these innovative strategies indicate that close proximity to state of the art biotechnology in the areas pursued is essential to achieve their objectives in process and product development. A number of strategies are employed by these companies to develop know-how in state of the art biotechnology including in-house research and development through plant and capital investment, licensing-in of technology, and collaboration with research institutions, involving both pre-competitive and contracted competitive research and development.

Five of the companies focus on building up in-house know-how in biotechnology research and development through major investment in plant, capital and manpower. Due to their large size and access to resources, these companies feel they can pursue such a strategy. Those companies operating in the dairy sector have availed of state-supported plant and equipment grants to develop biotechnology. One company in this sector, being a subsidiary of a multinational, has access to several other research and development facilities, through which in-house know-how is built up. Such in-house activity is of a basic nature but with a specific focus for potential commercial developments. Basic

innovative research in the past has led to the pioneering development of a process to utilise waste by-products from existing processes, resulting in the development of a high-value-added product with several applications. This process technology, being the first of its kind world-wide, has since been licensed out in several countries and provides major resources for further in-house process and product developments.

Those companies in the alcoholic beverages sector pursue a strategy of building up in-house capability in biotechnology through major plant, capital and manpower investment to obtain close proximity to the state of the art biotechnology in the areas pursued. Both companies have set up major central laboratories in Ireland, where all corporate research is carried out. Each of these companies indicate that this approach is taken to "internalise technological discontinuities" and has led to an increased effectiveness in internal communications and in the direction of biotechnology research and development pursued.

In all companies interviewed in this group, in-house biotechnology research and development programmes over the last five years have resulted in significant savings in all of the companies' fermentation processes through increased yields employing genetically engineered microorganisms.

Licensing of technology to access state of the art biotechnology and achieve company objectives in its products and markets is pursued by those companies in the dairy and alcoholic beverages sectors of the food and drink industry. Licensing of product and process technology is employed where the costs of development and the long pay-back periods of such developments are otherwise prohibitive.

A major strategy employed by those companies in the dairy, alcoholic beverages and food ingredients sectors interviewed is to access state of the art biotechnology through collaboration with academic research institutions in both Ireland and abroad. Apart from pre-competitive research, such collaborations involve proactive basic and applied research with specific commercial emphasis. Four particular pro-active biotechnology research and development programmes involving such collaboration with academic research institutions have resulted in major process rationalisation through cheaper alternative raw materials. It is noted that such collaborations are employed most frequently in cases where in-house capabilities are not available or the costs of in-house development is prohibitive.

(3) "HIGH INVOLVEMENT/BROAD FRONT LONG-TERM PLANNERS"

Of those companies involved in biotechnology research and development in the food and drink industry, only one company interviewed indicated that innovation through biotechnology is aimed at large future markets, through long-term accumulation of know-how in order to increase the already existing strong biotechnology base of the company. This company operates in the food and drinks ingredients sector of the Irish food and drink industry and is now part of a giant multinational corporation.

The overall objective of a division of this giant multinational is to become a major biotechnology company supplying the world food and drinks industry with biochemical ingredients. The Irish operation of this division pursues a strategy of innovation through biotechnology which contributes to the total research and development network of this division.

The Irish operation is broad front in its technological activities related to biotechnology. The company's key technological strengths are based on access to a network of research and development carried out in different research and development laboratories as part of the total company. In order to have optimal access to new biotechnology know-how, research and development co-operation between individual companies in this division of the giant multinational, as well as skilled co-operation

management is considered essential by the Irish operation of the division. This is reflected not only in the frequency of use of other research and development laboratories within the group, for particular new product and new process developments but also in the development of computerised in-house internal index systems to facilitate on-line information on research and development and new product/process developments.

The Irish operation of this division is involved in research and development collaborations with Irish academic institutions as a means of accessing particular technology not available in-house or through the research and development network of its parent company.

8.6 CONCLUSIONS

It was suggested in Section 1 of the present thesis that industry plays the pivotal role in transforming new biotechnology into an economic force. It is assumed that present industrial involvement levels and strategies are an indication of future economic developments. The present study set out to determine, in a pragmatic manner, the level of activity and types of innovation

strategies pursued by Healthcare Companies (New High-Technology-based Companies) and Food and Drink Companies (Established Low-Technology-based Companies) operating in Ireland in the same generic field - biotechnology. Within this overall research objective, the study had a number of specific aims:

(1) To establish those Healthcare and Food and Drink companies in Ireland involved in biotechnology research and development as a means towards innovation;

(2) To establish the reasons for developing biotechnology;

(3) To determine the innovation strategies of these companies, through the use of biotechnology.

LEVEL OF BIOTECHNOLOGY ACTIVITY

The results of the present study indicate that on the whole there is a relatively low level of biotechnology activity in these two industry sectors. Several suggestions have been made in Section 8.2 as to why the level of activity is so low considering the total number of companies operating in these sectors. These suggestions include:

- the small number of Food companies with the internal capacity to conduct biotechnology research and development, which is very costly;

- the concentrated nature of certain sectors in the Food and Drink Industry (including the dairy and alcoholics sections)

- the structure of the Healthcare Industry, which is mainly made up of foreign-owned subsidiaries of international companies, who tend not to locate their research and development facilities in Ireland.

8.6.1 REASONS AND STRATEGIES FOR DEVELOPING NEW BIOTECHNOLOGY

The overriding motive for a company to develop biotechnology is to increase know-how in order to improve its market position by using a technology which is relevant to its products and processes. Most companies indicate that they want to develop new products through biotechnology. Screening of possible products is the next and crucial step upon which further activities will depend. Long established companies involved high-volume production,

particularly in the dairy and alcoholic beverages sector, point to the need for innovation in their production processes. They indicate that biotechnological techniques are a means towards such process innovation. Furthermore, companies in these sectors indicate the use of biotechnology in process development is a means of satisfying market demands for greater sophistication, uniformity and lower cost.

Three types of innovation strategies through biotechnology have been distinguished in each industry as a result of the present research study.

8.6.2 INNOVATION STRATEGIES THROUGH BIOTECHNOLOGY OF HEALTHCARE COMPANIES IN IRELAND INVOLVED IN BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

(1) "LOW INVOLVEMENT LONG-TERM PLANNERS"

These companies plan to use new biotechnology for changes or extensions of their current product lines or for diversifying into product groups where other companies are already competing.

(2) "MEDIUM INVOLVEMENT LONG-TERM PLANNERS"

These companies have, thanks to their structure or management competence, built up a capability to link together biological phenomena, technical possibilities and socio-economic issues and needs. This capability has, in most cases, already led to novel product lines.

(3) "HIGH INVOLVEMENT LONG-TERM PLANNERS"

These companies pursue an innovation strategy aimed at large future markets through long-term accumulation of biotechnology know-how. These companies see biotechnology developments as increasing the already strong existing biotechnological base of the company.

8.6.3 INNOVATION STRATEGIES THROUGH BIOTECHNOLOGY IN FOOD AND DRINK COMPANIES IN IRELAND INVOLVED IN BIOTECHNOLOGY RESEARCH AND DEVELOPMENT

(1) "LOW INVOLVEMENT LONG-TERM PLANNERS"

These companies plan to use new biotechnology for process rationalisation and "modest" changes or extensions of their current product lines.

(2) "HIGH INVOLVEMENT LONG-TERM PLANNERS"

These companies plan to use new biotechnology for new process development, existing process rationalisation, for "modest" changes or extensions of their current product lines and for new product lines.

(3) "HIGH INVOLVEMENT/BROAD-FRONT LONG-TERM PLANNERS"

These companies aim at large future markets through long-term accumulation of know-how. This strategy is seen as increasing the already strong biotechnological base of the company.

The results of the present research study indicate that high biotechnology involvement has begun to grow, not exclusively, but to a considerable extent within the framework of already strongly concentrated sectors such as dairy, alcoholic beverages and food ingredients, and also in globalised pharmaceutical companies.

These companies seek to use biotechnology as a way of consolidating and enhancing their comparative advantage in pharmaceuticals, dairy processing and fermentation technology, which they have gained through earlier phases of research and development. Thus, it was noted that biotechnology involvement in the Food and Drink industry is mainly in concentrated sectors (dairy, alcoholic beverages, food ingredients). Similarly, in the Healthcare industry, biotechnology has been adopted by those sectors shaped by globalisation (pharmaceuticals). These facts raise a number of important issues with regard to the place of small or medium companies in the future biotechnology industrial base.

The entrepreneurial potential of the medium-involvement long-term planners in the healthcare industry should, however, be noted.

Such entrepreneurs are important if the markets, which could be created by the ubiquity of biological phenomena, are to be fully exploited. These companies have the flexibility to react quickly within market niches, which high-involvement/broad front long-term planners in the healthcare sector may ignore due to the high adaptation costs.

These medium-involvement long-term planners in the healthcare sector have indicated that the key strategic task facing them is competence in large-scale marketing. Policy makers must investigate the implications of this finding for future biotechnology policy-making in Ireland.

This type of interdisciplinary research was carried out to integrate the disciplines of science and business. The study has found the results to be of interest to:

* Companies involved in the commercialisation of biotechnology; and

* Policy makers attempting to develop strategies for the diffusion of biotechnology in Ireland; and

* Academics trying to make the discipline of business more relevant to the development of new technologies.

For these reasons further research of this interdisciplinary type are recommended.

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APPENDIX A

COLLABORATION INVOLVING IRISH ORGANISATIONS UNDER THE AUSPICES OF S.P.R.I.N.T.

1. EOLAS (Dublin) and Industrial Science Division (N.I.)

2. The Innovation Centre (Limerick) and The Danish Innovation Centre, Newtech (Wales)

3. University College Galway

   University of Groningen, Netherlands

   University of Galleca, Feuga, Spain

4. Industrial Development Authority, Ireland and WVIB Warlschaftsverband ind., Unternehmer, Baden, Germany

5. EOLAS (Dublin) and Technova (Lyon, France)

6. Technology Guidance Ltd., Dublin

   Shekell Moring International Licensing, UK

Regional Development Authority, Limberg

Belgium and Gotz Schaude Innovations, Beratung, Germany

7. EOLAS (Dublin); Technomedia (Udine, Italy) and Impiva (Valencia, Spain)

8. Shannon Development Co. Ltd. and Scottish Enterprise Board

9. Byrne, Lowe and Associates (Dublin); PAX Technology Transfer (London); Helicon Technology Marketing (Appledorn, Netherlands); Bree and Co. Marketing Consultants (Germany) and Durexport (Spain)

10. IDA,Ireland; Chambre Regionale de Commerce et D'Industre de Lorraine (Nantes, France) and Danish Technical Information Service (Copenhagen)

11. EOLAS (Dublin); Danish TEchnical Information Service (Copenhagen); G.O.M. (Antwerp, Belgium) and Technical University of Eindhoven (Nethrlands).

12. IDA, Ireland and Ostbayerisches Technologies, Regensburg, Germany

13. EOLAS (Dublin); Offshore Service Metek Engineering and Contracting S.A. (Athens) and Laboratories National de Engeharia Civil, Portugal

SOURCE:

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APPENDIX B

SUMMARY OF STATE SUPPORT FRAMEWORK AVAILABLE FOR INNOVATION IN IRISH INDUSTRY

(1) Idea phase: Locating ideas and feasability studies

(A) INDUSTRIAL DEVELOPMENT AUTHORITY (IDA)
Joint ventures
Licensing services
National Linkage Programme
Feasability Study Grants Scheme

(B) CORAS TRACHTALA (CTT)
Market Research Grants

(C) IRISH GOODS COUNCIL (IGC)
Industrial Sub-Contract Service

(D) FAS
Training in Joint Ventures and Technology Transfer
Youth Enterprise Programme
New Product Development Training Programmes

(E) EOLAS
Inventions Service
New Products Programme
New Ventures Programme

(2) Research and Development Phase: Research, Development, Pilot Production

(A) INDUSTRIAL DEVELOPMENT AUTHORITY (IDA)

Product and Process Development Scheme

(B) CORAS TRACHTALA

Product Design and Consultancy Service

(C) FAS

Young Scientists and Technologists Employment Programme
Product Development Programmes

(D) EOLAS

Inventions Service
Development Support Scheme
Research Programmes in Third Level Institutions and Contract Research.

(3) Market Phase: Planning, Testing, Launches

(A) CORAS TRACHTALA (CTT)

Market Research and Consultancy Grants
Sales Personnel Recruitment
Group Promotional Programme
Marketing Support Services

(B) IRISH GOODS COUNCIL (IGC)

Marketplace Programme
Market Development Programme

(C) FAS

Overseas Marketing Training

DUBLIN CITY UNIVERSITY
Ollscoil Chathair Bhaile Átha Cliath
DUBLIN BUSINESS SCHOOL
DUBLIN 9, IRELAND.
Telephone: 370077. Facsimile: 360830. Telex: 30690.

APPENDIX C

Dear

I am a recent graduate of Biotechnology at the Dublin City University (1988). At present I am involoved in research at the Dublin Business School, DCU, for the award Master of Business Studies. The subject of my research is "Innovation Through Biotechnology".
I enclose a copy of the questionnaire which you kindly agreed to complete.

The findings of my research and any recommendations I might make would be made available to all contributors.

You may rest assured that any information given will be treated as strictly confidential.

I would be very grateful if you could spare the time to complete the questionnaire, and return it to me in the stamp-addressed envelope within 14 days as I have a deadline to meet.
Thank you for your time and co-operation in this matter.

Yours sincerely,

(DEIRDRE MULLEN).

APPENDIX D

This questionaire represents part of preliminary research carried out by Deirdre Mullen (postgraduate research student at the Dublin Business School, DCU) for the awardof Master of Business Studies.

The purpose of the questionaire is to establish those companies in the healthcare and food and drink sectors actively involved in biotechnology research and development in Ireland, as a means towards innovation.

All replies are treated as strictly confidential and are for academic use only.

Thank you for your co-operation.

DEFINITION OF TERMS USED IN THE FOLLOWING QUESTIONAIRE

INNOVATION: Refers to new product and/or new process developments, either new to the market or new to the company.

BIOTECHNOLOGY Refers to the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services. This term is understood to exclude biomedicine and agriculture - excepting those areas which now involve the application of cellular or molecular biology.

NOTE: PLEASE TICK THE RELEVANT BOX

Q.1 (a) NAME OF COMPANY: _____

Q.1 (b) NAME OF RESPONDENT: _____

Q.2 IS YOUR COMPANY INVOLVED IN BIOTECHNOLOGY RESEARCH AND DEVELOPMENT?

YES ☐ NO ☐

Q.3 IS THE FIRM:

☐ AN INDEPENDENT COMPANY

☐ A SUBSIDIARY OF A MULTINATIONAL

☐ A PARENT COMPANY WITH SUBSIDIARIES

Q.4 NUMBER OF EMPLOYEES: _____

Q.5 TURNOVER (1989): _____

Q.6 IS YOUR COMPANY INVOLVED IN ALL STAGES OF NEW PRODUCT/PROCESS DEVELOPMENT?

YES ☐ NO ☐

IF ANSWER IS NO, PLEASE INDICATE WHETHER YOUR COMPANY IS INVOLVED IN R&D, MANUFACTURE OR MARKETING, OTHERWISE PROCEED TO NEXT QUESTION.

INVOLVED IN R&D ☐

INVOLVED IN MANUFACTURING ☐

INVOLVED IN MARKETING ☐

Q.7 WHAT GENERAL AREA(S) OF BIOTECHNOLOGY R & D IS YOUR COMPANY PURSUING?

Q.8 WITH REGARD TO BIOTECHNOLOGY R & D, IS YOUR COMPANY?

INVOLVED IN IN-HOUSE R & D ☐

INVOLVED IN CONTRACT R & D ☐

Q.9 IS YOUR COMPANY'S BIOTECHNOLOGY R & D INVOLVED IN:

NEW PRODUCT DEVELOPMENT ☐

NEW PROCESS DEVELOPMENT ☐

BOTH ☐

Q.9 ARE YOUR NEW PROCESS DEVELOPMENTS FOR IN-HOUSE USE OR ARE THEY FOR COMMERCIAL USE?

THANK YOU FOR YOUR TIME AND CO-OPERATION

APPENDIX E

PURPOSE OF INDIVIDUAL QUESTIONS ON PRELIMINARY RESEARCH POSTAL QUESTIONAIRE

Q.1 (A) AND (B) AND Q.2

Used for screening purposes and classification purposes.

Q.3 - Q.5

Sought background information on the company type, number of employees and turnover, with a view towards finding (a) potential variable(s) affecting responses/information from further research (i.e. depth-interviews) or differentiating the respondents.

Q.6

Concerned vertical integration. Full integration implies sufficient capital to fund the integration processes and that the company is a growing concern in which product sales fuel the next cycle of growth, in the case of indigenous companies. Although the subsidiaries of multinationals, as expected, are not fully integrated in their Irish operations, that is either R & D and/or marketing operations are carried out by the parent company.

Q.7

Sought to find out the scope of biotechnology R & D and also served to screen the respondent companies.

Q.9

Examined whether biotechnology R & D was aimed at product or process development or both, as a means towards innovation.

APPENDIX F

OUTLINE OF "AIDE MEMOIR" EMPLOYED DURING DEPTH INTERVIEWS

SECTION I

This section seeked to gain further background information on the company, to add to the information already obtained through the preliminary research postal questionaire and information obtained from "desk research" (including company literature and company annual financial reports).

This section of the interview invited the respondent to talk about the business activities of the company and to provide further historical information on the company. This section also established the corporate strategy of the company.

SECTION II

This section of the interview seeked to obtain information on the research and development (R & D) activities and organisations of the company including biotechnology R & D. Specific questions are listed below which cover a given set of topics relating to R & D in a more or less systematic way. However, due to the "semi-

structured" nature of the interview, the respondent was allowed to respond freely but nevertheless guided by the interviewer/researcher. The interviewee/respondent was "guided" by suggesting areas in which responses were required

SECTION II R & D ACTIVITIES AND ORGANISATION

Q.1 Is the R & D function of the business considered an important function of the business operation?

Q.2 What are the key technological strengths of the company?

Q.3 What, in your opinion, is the principal contribution that R & D makes to the company?

Q.4 Is the company's research emphasis on basic, applied or developmental work?

Q.5 What is the size of the R & D department?

* Number of qualified technicians?

* Number of graduate scientists and engineers?

* Number of doctoral scientists and engineers?

Q.6 How are R & D staff organised, isit according to academic discipline, techniques/equipment used, specific tasks etc.?

Q.7 How flexible is this schedule?

Q.8 How are R & D budgets calculated?

Q.9 Has the R & D expenditure been increasing, decreasing, constant over the last five years of operations (where appropriate)?

Q.10 How are strategic objectives and plans in R & D efforts formalised?

Q.11 Is there a formal procedure for determining the allocations of funds to specific projects?

Q.12 What methods and criteria are employed for selecting, monitoring and evaluating specific projects?

Q.13 How many additional R & D departments of the company are involved in biotechnology R & D (in the case of subsidiaries and/or parent company with subsidiaries abroad)?

Q.14 What proportion of R & D effort does this represent?

Q.15 With regard to contract research carried out by external organisations/universities for the company:-

- Where is such research carried out?

- What are the expected impacts of such collaboration on te company's R & D efforts? (suggest the following;)

  * generating new lines of research?

  * suggesting new ways of solving problems arising during the innovation process?

  * providing information for use in more routine work (please specify)?

  * other?

- What research areas are explored through contract research?

- Is Bioresearch Ireland involved in carrying out contract R & D for the company?

Q.16 Apart from contracted R & D what are the company's formal links with academic or research institutions? (suggestions made by interviewer/researcher included the following)

* Consultancy services

* Use of equipment or facilities

* Exchange of personnel

* Support of studentships

* Other

Q.17 How frequently are such formal links employed?

Q.18 Do informal links with academic/research institutions exist, how did they originate? (suggestions made by researcher included the following)

* Education

* Attendance of conferences

* Membership of professional bodies

* Other

Q.19 How frequently are such contacts used?

Q.20 In general, what is the impact of such contacts on the company's R & D efforts?

Q.21 How does biotechnology (as defined) figure in the structure of the R & D department?

Q.22 Has the company always been involved in the areas of technology currently pursued? (researcher suggested some reasons which are listed below;)[1]

EXTERNAL FACTORS RELATED TO MARKET SITUATION

- response to customers' direct request(s)
- to meet customers' perceived needs
- response to competitors' actions
- to block market to competition
- to enter new markets
- to strengthen position in existing markets
- the erosion of markets for existing products

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[1]This part of Section II of the interview was adapted from a checklist devised by Roy Rothwell for his study of innovation in the textile industry (Rothwell, 1977)

- other

INTERNAL FACTORS RELATED TO THE ECONOMICS OF THE COMPANY

- falling profit margins on existing business

- part of a general approach for improved efficiency

- other

EXTERNAL FACTORS RELATED TO SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS

- new scientific understanding

- new technological capability

INTERNAL FACTORS RELATED TO THE SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS IN THE COMPANY

- accrued experience, expertise, investment in equipment/plant

- falling returns on current research activity

- problems with other research areas for commercialisation of existing/new products/processes

- other

GOVERNMENT INITIATIVES

(Please elaborate)

AVAILABILITY OF FINANCIAL ASSISTANCE

- through government grants

- access to R & D finance, through venture capital, for example

- finance support resulting from merger (where applicable)

Q.24 Was the decision to pursue biotechnology R & D considered more risky in terms of technical success compared to previous R & D activities?

Q.25 Is biotechnology R & D considered an OFFENSIVE or DEFENSIVE more commercially.

Q.26 Is biotechnology R & D expected to have a radical or more incremental impact on the company's existing activity?

Q.27 Was the decision to pursue biotechnology research intended for use in product or process applications or both?

Q.28 Were there others already at work in the field of biotechnology R & D that you are involved in?

Q.29 Products/processes developed or being developed involving biotechnology R & D?[2]

Q.30 How close to the state of the art should the company be to achieve its objectives in its products and markets? What is the company's present situation with regard to this?

Q.31 How much emphasis is given to advancing knowledge of biotechnology through basic as opposed to applied research?

Q.32 Is the company developing biotechnology capabilities beyond those strictly related to its current output?

Q.33 What area(s) of biotechnology is promising commercially from the perspective of the existing output or future output?

Q.34 Typical innovation process? (This question invited the respondent to discuss the innovation process of the company; the discussion was guided by referring to specific aspects of the process including:-

[2]This question initiated a discussion of innovation strategies pursued in the past and those pursued at present and for the future; the respondent was invited to discuss examples of past, present and potential future innovations employing biotechnology R & D. The discussions also focused on specifics such as products marketed, patents sought/filed etc. ..., licensing of technology etc.

- time scale?

- R & D/marketing/production integration?

- how effective is the communication between the different functions?

- how could communication be improved etc.?

SECTION III

This section of the interview seeked to obtain information on the innovation process pursued by the company, focusing on specific issues related to biotechnology.

Q.1 How important is innovation (as defined) to your company?

Q.2 Are both new product development and new process development equally important or does one have a greater weighting over the other in the company?

Q.3 What percentage of products have been developed totally within the country in the last five years?

- All products

- Over 50% of all products

- Under 50% of all products

Q.4 Has the financial contribution to new product/process development been increasing, decreasing constant (allowing for inflation etc.) over the past five years?

Q.5 Who is primarily responsible for innovation strategy formulation?

Q.6 How do you generate new product/process ideas? (The researcher indicated possible ways of generating new product/process ideas:)

- direct search?

- exploratory consumer surveys?

- technological forecasting?

- creative group methods (if so, specify)?

- "consumer engineering" (process of matching consumer needs to technological capabilities)?

- other?

Q.7 What is the main initiating factor(s) for new product/process development in the company to date?

- financial goals?

- externally generated pressures such as competitive position, product life cycle, technology, regulation, material costs and availability?

- specific market stimuli/opportunities such as lifestyle changes, customer requests, supplier initiatives?

Q.8 Where have your most successful new product ideas come from? (Researcher guided respondent by suggesting some sources of new product/process ideas:)

- patents?

- competition?

  * acquisition (where relevant)?

- market needs?

- users' solutions (where relevant)?

- technology?

- business development manager(s)?

- other?

Q.9 What in your opinion have been the main causes of new product failure in the company to date? (Again, respondent was guided by several alternatives but free to add specific causes of new product failure where applicable)

- inadequate market analysis?

- product defects?

- lack of effective marketing effort?

- higher costs than expected?

- poor timing of introduction?

- technical or production problems?

- other?

Q.10 What are the main factors to be considered in idea screening and selection? (Researcher guided respondent with alternatives:)

- product's potential in terms of market size, sales growth etc.?

- probability of technical success?

- development or production costs?

- complementary to existing capabilities?

- other?

Q.11 Does the company have a specific innovation "charter" or does it depend on the particular project?

Q.12 What formal provisions exist for interactions between R & D and marketing departments during the innovation process? And how frequently are these formal provisions employed?

Q.13 Is there more emphasis on changing existing products/processes or developing radically new products/processes in the company?

Q.14 What impact has technological learning (through biotechnology) had on the company's new product/process strategies, if at all?

Q.15 With regard to protection of new products/processes, is the patent route preferable to trade secrets? If not, why?

Q.16 Has your company ever licensed technology related to biotechnology R & D (either in or out of the company)?

Q.17 Have legal regulations in Ireland or abroad affected your innovation strategies?[3]

Q.18 With regard to biotechnology R & D, has the company received grant-aid from the government? (The researcher enquired as to the nature of the grant-aid)

* Scientist Employment Grant?

* Plant Capital?

* Equipment Capital?

* Specific Project Finance?

* Other?

Q.19 With regard to biotechnology R & D has the company received venture capital either from the European Venture

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[3]This question initiated a discussion on regulation in biotechnology R & D and marketing of products or use of processes.

Capital Association or other venture capital organisations in Ireland or abroad?

SECTION IV

This section of the field research included a "tour" of the R & D facilities and manufacturing plant (in most cases 16 out of 20). Further aspects of R & D and individual research projects for commercial applications, were discussed during the tour. This proved to be very useful in backing up the information received during the depth interview.