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REPORT

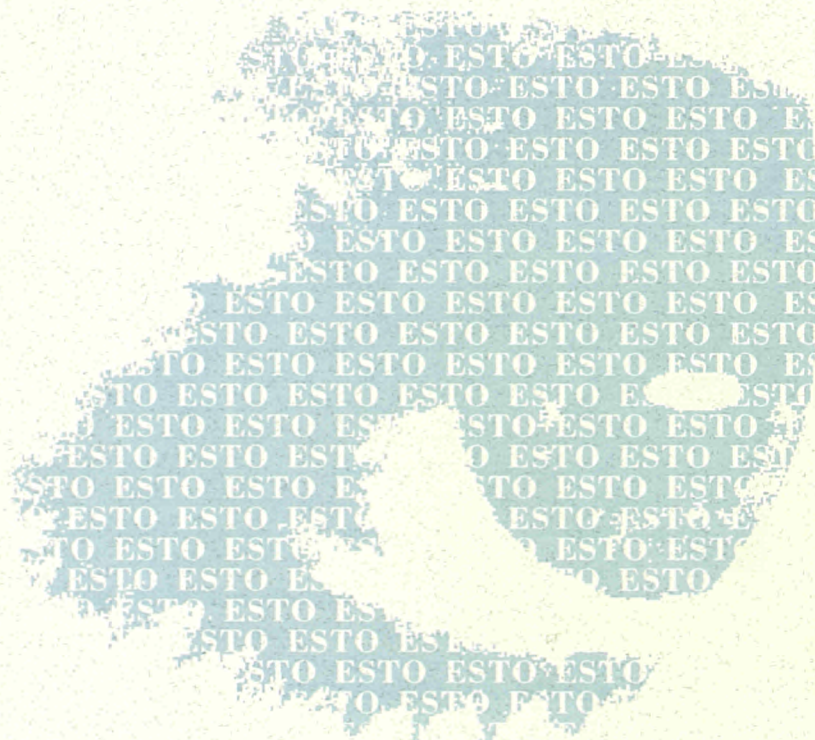
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EUROPEAN COMMISSION
Joint Research Centre



ABOUT THE IPTS REPORT

The IPTS Report was launched in December 1995, on the request and under the auspices of Commissioner Cresson. What seemed like a daunting challenge in late 1995, now appears in retrospect as a crucial galvaniser of the IPTS' energies and skills.

The Report has published articles in numerous areas, maintaining a rough balance between them, and exploiting interdisciplinarity as far as possible. Articles are deemed prospectively relevant if they attempt to explore issues not yet on the policymaker's agenda (but projected to be there sooner or later), or underappreciated aspects of issues already on the policymaker's agenda. The long drafting and redrafting process, based on a series of interactive consultations with outside experts, guarantees quality control.

The clearest indication of the report's success is that it is being read. An initial print run of 2000 for the first issue (00) in December 1995 looked optimistic at the time, but issue 00 has since turned into a collector's item. Total readership rose to around 10,000 in 1997, with readers continuing to be drawn from a variety of backgrounds and regions world-wide, and in 1998 a shift in emphasis towards the electronic version on the Web has begun.

The laurels the publication is reaping are rendering it attractive for authors from outside the Commission. We have already published contributions by authors from such renowned institutions as the Dutch TNO, the German VDI, the Italian ENEA and the US Council of Strategic and International Studies.

Moreover, the IPTS formally collaborates on the production of the IPTS Report with a group of prestigious European institutions, with whom the IPTS has formed the European Science and Technology Observatory (ESTO), an important part of the remit of the IPTS. The IPTS Report is the most visible manifestation of this collaboration.

The Report is produced simultaneously in four languages (English, French, German and Spanish) by the IPTS; to these one could add the Italian translation volunteered by ENEA: yet another sign of the Report's increasing visibility. The fact that it is not only available in several languages, but also largely prepared and produced on the Internet World Wide Web, makes it quite an uncommon undertaking.

We shall continue to endeavour to find the best way of fulfilling the expectations of our quite diverse readership, avoiding oversimplification, as well as encyclopaedic reviews and the inaccessibility of academic journals. The key is to remind ourselves, as well as the readers, that we cannot be all things to all people, that it is important to carve out our niche and continue optimally exploring and exploiting it, hoping to illuminate topics under a new, revealing light for the benefit of the readers, in order to prepare them for managing the challenges ahead.

P r e f a c e



*W*ith the launching of the first call for tender for participation the EU Fifth Framework Programme for R&D is fully under way. The Programme emphasizes science and technology which supports the European Union and its policies. It promotes scientific and technological excellence, addresses socio-economic and competitive needs, and attaches particular importance to the use and exploitation of R&D results. The accumulated experience from previous programmes has given the Fifth Framework Programme the means and preparedness to react promptly to scientific and technological challenges which may arise and directly or indirectly affect the EU.

In terms of structure, as many readers may already know, the Fifth Framework Programme has been simplified and is built on four thematic programmes: the Quality of Life, the Information Society, Competitive and Sustainable Growth, and Energy and Environment. These are complemented by three horizontal programmes on the International role of European Research, on Innovation and SMEs, and on Human Potential.

These programmes will be implemented through a series of actions ranging from shared cost actions between the Commission and participating consortia, to the R&D fellowships, named after the scientist Marie Curie. Concerted actions, thematic networks, together with the necessary accompanying measures, will also be financed.

The first call for tender has ushered the Fifth Framework Programme in. From this point on, and until the end of the programme, annual, joint, dedicated and permanently open calls will co-exist to provide potential participants with a range of opportunities in which to take part.

The Commission has set the course for a sound EU R&D programme and has started the process. Now is the opportunity for researchers to define and submit proposals that will give it substance and momentum, in order to realize the potential benefits which R&D holds for the EU.

Elleson

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A number of EU countries have witnessed considerable growth in the use of wind power. Useful lessons can be learned for application to other environmental technologies.

13 Thinking about EMU and Science

European monetary union is predicted to have wide-reaching effects on the process of European integration. One area that little attention has been paid to is how it might affect European research.

Methods**18 The Consumer Product Safety Database: products, risks and expertise**

The European Commission is putting in place the tools to ensure consumer safety in the single market. In this context a database is being created by the JRC to meet the need for a point of reference for expertise on product safety.

Biotechnology**27 Patent protection for biotechnological inventions: incentive for European biotech innovators**

The debate surrounding the patenting of biological material is far from over. As the directive passes into law at Member State level, it remains to be seen to what extent it will achieve all its goals, including providing the biotech industry the framework it needs in which to grow.

34 Transatlantic investments and human capital formation: the case of biotech firms

An investigation of knowledge flows in the biotechnology sector between Europe and the US shows the European industry to be active in forming alliances with US companies, with a view to acquiring both know-how and finance.

EDITORIAL

Dimitris Kyriakou

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Competitiveness is one of the foggiest concepts to define. It has been used in ways that range from making it effectively synonymous to profitability, to market share, to trade surpluses, to high-value-added exports, to high wages, etc. The above, although potentially useful indicators in individual contexts, do not suffice for a coherent notion.

It has been correctly pointed out that whereas firms clearly compete in the marketplace, nations (excluding military conflict) do not compete in the same way. Nations do not have balance sheets, no identifiable product, or customers. Moreover quite unlike what happens between competing firms selling the same product, the good fortune of your neighbour/rival may be good news for you, to the extent that your neighbour is likely to spend at least a small part of their extra income on imports.

Yet competitiveness reduced to ability of easily recognisable firms to capture profits and market shares does not satisfactorily capture the whole story. Competitiveness has to include a forward-looking dimension. It would be trivial for firms to sell at rock-bottom prices in order to enlarge their market shares. But how long can they go on doing that if profits are negative? Or

if they are positive but not enough for the investment necessary to keep up with the competition? Firms could also boost profits by underpaying their workers. How long however would they remain profitable when the increasingly critical skilled staff will defect to other jobs (and in any case will have little incentive to upgrade skills and considerable incentive to strike)?

Competitiveness, moreover, should extend to all levels, not just the larger firms but also the small ones and even individual economic agents. At the macro-level the forward-looking character of any definition of competitiveness must include characteristics of the social whole that would allow society to function fruitfully and harmoniously.

Competitiveness is then a measure of a society's ability to allow economic entities of all sizes, to accumulate increasingly coveted skills, capacities and products which are differentiated, hard to reverse-engineer, and are handsomely rewarded. The key to success in this sense is the ability to attract the capital (human and otherwise) to generate and nurture economic entities which can compete successfully worldwide on a social fabric which can absorb

the social tensions bound to emerge as demands shift, skills need updating and adjustment is often inevitable.

Note that in this formulation the role of the social fabric is crucial. Unlike older formulations competitiveness is not sacrificed in order to reduce social tensions. Rather competitiveness in the longer run needs social environments which can draw capital – the old-fashioned type, as well as the increasingly more important human type - through the creation of

attractive societies, in terms of social peace, natural environment, open democratic political practices, low crime rates, etc.

To put it in a nutshell: competitiveness marks societies which generate and nurture economic entities (from individual to large firms) which can flourish and perform successfully in world markets, and to which human (and other forms of) capital is attracted. Competitiveness implies attractive societies in which to live, work and invest.

The Impact of Wind energy policy on innovation

Jens Hemmelskamp, *IPTS*, and Olav Hohmeyer, *University of Flensburg*

Issue: Some countries of the EU have witnessed an amazing surge in the development of wind power generation over recent years. National governments, through their environmental policy, are playing a crucial role in influencing the development of wind energy.

Relevance: The significance of the influence of environmental policy on innovation has not yet been properly appreciated in the scientific debate, environmental policy tending to be regarded as just one more decision-making parameter for innovation-related decisions by the companies involved. Consequently, the relationship between these environmental policy instruments and innovation behaviour in the renewable energy technology field must be analysed in the context of numerous economic, social, legal and technological factors. The main question now is what we can learn from these cases for the design of an innovation-friendly regulatory regime of environmental policy approaches.

Over the past 20 years the focus has been on end-of-pipe technologies to meet environmental demands rapidly and without fundamental changes in technology and skills

Introduction

Sustainable development demands the long-term availability of natural resources and preservation of environmental quality. Thus, it requires changes in existing production methods and consumer behaviour. The political and scientific debate has stressed above all the importance of progress in environmental technology with respect to exploiting resources, production, consumption and disposal.

During the past 20 years, innovation has primarily focused on end-of-pipe technologies, and this has already resulted in considerable reductions in environmental pressure. However, the demanding criteria for

sustainable development cannot be met by this approach alone. In the future it will therefore be crucial to work towards additional fundamental technological change and to shift the direction taken by progress up to now, through the development and application of new, sustainable manufacturing techniques and products, and so bring about a shift from end-of-pipe to embedded environmental protection. Thus, policy makers are now faced with the question as to what environmental policy measures are most the appropriate way to bring about this shift in private-sector innovation towards more environmental innovation.

Support for wind energy offers a good example of innovation-oriented environmental policy. Since 1989, with the help of various

environmental policy measures, wind generation capacity of more than 2,800 Megawatts has been installed in Germany and the wind-generated electricity component of net electricity consumption in Schleswig-Holstein has reached over 12% and in Lower Saxony about 6%. Considerable capacity growth can also be seen in Denmark and Great Britain as the outcome of environmental policy measures.

Considerable progress in technological development

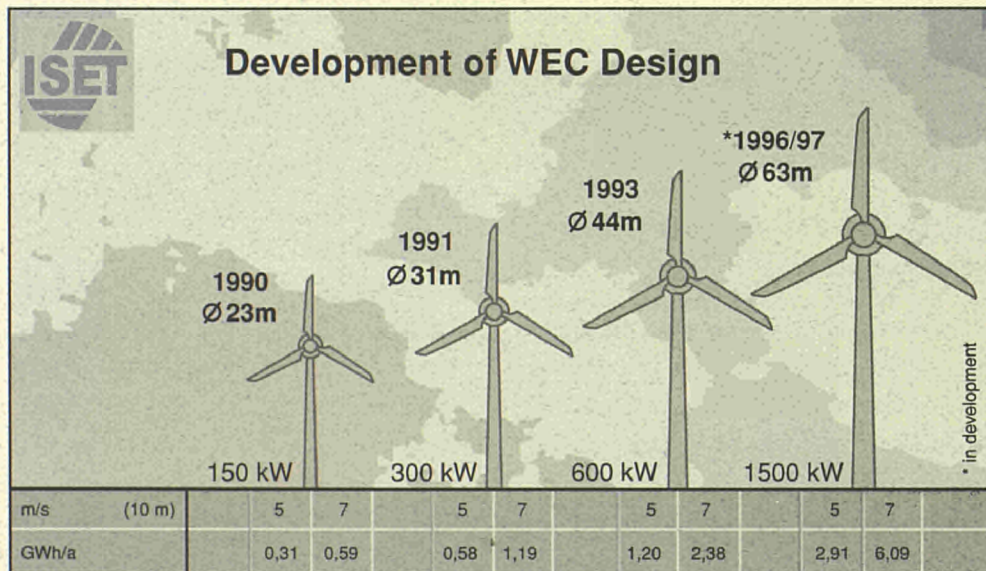
Up until the 1970s, R&D activity in the use of wind energy was directed at meeting the requirements of centralized electricity supply by large power stations with increasingly high performance and falling power generation costs.

These attempts failed, however, as it proved impossible at that time to build large wind power plants or to integrate small wind farms into the central supply structure.

Only after the energy crises of the 1970s there was a change in attitude and changes in energy law and investment subsidies for the use of wind energy were introduced. In the beginning, different technical concepts were pursued, based on systems with one, two or three rotor blades. Most wind generators today have three blades. While in 1989, the available equipment generated less than 150 kW, today's commercially available models can generate over 1.5 MW. The diameter of the rotors has increased from an average 30m to a scale of up to 65m, towers have grown from 30m to 98m (see Figure 1).

Support for wind energy offers a good example of innovation-oriented environmental policy

Figure 1. Development of WEC Design



Source: ISET

Two designs are now emerging as dominant: in smaller models, a three-phase generator powered by a turbine with fixed rotational speed is coupled to a main circuit. The rotor blades are fixed to the hub and their pitch cannot be altered. Power generation is controlled by a cut-out, which is

activated when a particular wind speed is reached. This technology has the advantage of low manufacturing and maintenance costs. Larger wind farms appear to be settling for technologically more complex configurations where the pitch of the rotor blades can be adjusted

The energy crises of the 1970s created the change in attitudes necessary for the framework to be modified so as to allow the decentralized approach needed for wind power

Two designs now dominate: a simpler arrangement for smaller wind farms and a more complex and more flexible design for larger ones

Although wind generators will continue to be improved, fundamental changes in design are unlikely

Developing and introducing integrated technologies is slower to achieve than is the case for end-of-pipe technologies

In Denmark a combination of various policy instruments has proved successful in creating a market for wind power technology and an industry to serve it

and the rotational speed is variable. This system makes it possible to compensate for short-term changes in load or fluctuations in power, and thereby optimizes the plant's suitability for grid-connected operation. Another trend can be seen in large wind turbines towards a gearless cord system with multi-polar generators.

In the future, less fundamental technological change can be expected, and rather more incremental improvements aimed at extending product life, improving efficiency and the quality of the electricity generated, at reducing operating noise, and at improved performance under highly corrosive offshore conditions. Opinion is divided as to further developments of scale. On the one hand it is argued that the best ratio of costs to performance has already been exceeded in 1.5 MW equipment, while others argue that, particularly with respect to exploiting offshore locations, further growth up to and over 2 MW can be expected. Manufacturing processes should become more automated and manufacturers will produce in larger batches.

Different policy approaches in Denmark, the UK and Germany

Environmental policy is often short-term oriented. As a consequence, there is a tendency for minor technical improvements relying mainly on end-of-pipe technologies in order to meet emissions reduction requirements as quickly as possible whilst continuing to use existing technologies and available expertise. In contrast, the development and introduction of clean and integrated technologies needs more time and is rarely turned into a practical reality. However, the definition of a reliable environmental policy framework could give important incentives for the development of preventive environmental protection technologies and the creation of a pool of environmental technology solutions for the

reduction or avoidance of environmental stress. Solutions could then be drawn from this pool at a later date.

In Denmark, such a policy approach supporting the development and launch of environmentally friendly technologies has been a - successful - reality in the wind energy sector since the 1970s. Supported by a combination of various policy instruments, especially subsidies, Danish policy first created a technological niche, and then a market niche, for wind technology, one which has since developed into a functioning market. The important factor was a flexible subsidy policy, which could be adapted to suit the changing socio-economic, and technological framework conditions and which was able to take account of the specific requirements of invention, innovation and diffusion during the entire innovation cycle. The main characteristic of Danish policy was and still is the linkage between wind energy policy and other policy areas, such as environmental and energy policy. In particular, these are:

- the creation of long-term energy plans,
- the support for R&D to create a knowledge base,
- the early transition from investment subsidies to performance-dependent support for diffusion,
- the financial participation by broad sections of the public and
- the induced commitment to the expansion of wind energy on the part of energy suppliers.

In Germany also, environmental policy instruments brought about the emergence of a market niche for wind energy use with a significant volume, where reliable and profitable wind turbines were developed and institutional innovation, such as the formation of industrial associations and business networks made it possible to develop investment models. In principle, the support policy in Germany is similar

to that in Denmark. In Germany also, the sequence of instruments used took account of the various phases of the innovation process (see Figure 2). It should nonetheless be pointed out that this policy did not follow any strategic plan, but rather developed gradually, and was therefore able to learn.

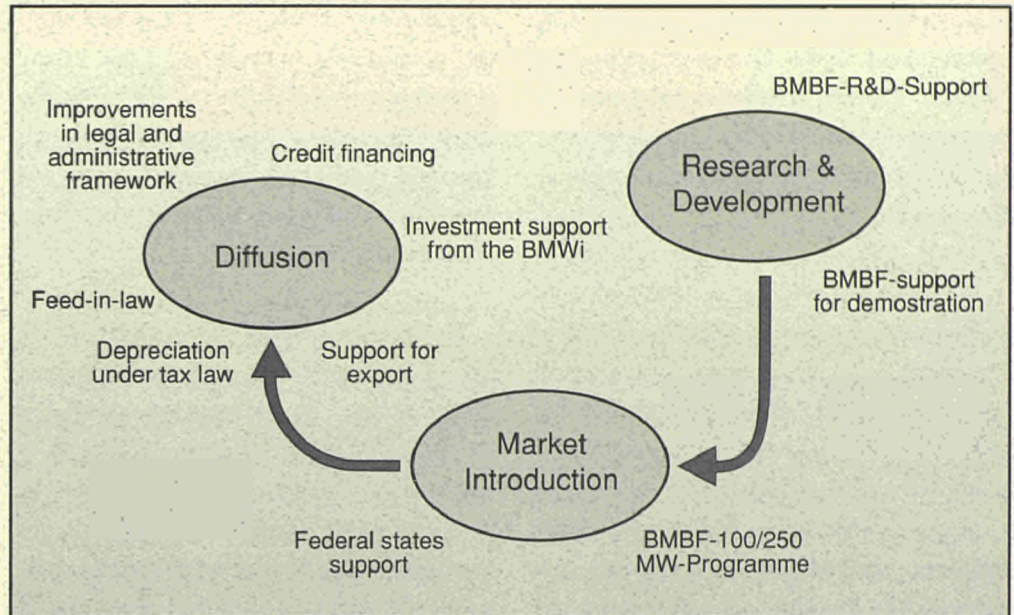
In Great Britain, on the other hand, support for market launches under the NFFO (Non Fossil Fuel Obligation) began before British companies had been able to develop efficient wind technologies with the help of R&D subsidies. In consequence, British manufacturers were not prepared for competition, while self-supporting wind energy industries have developed in Denmark and Germany. This should be no surprise, when one considers that the primary goal of the NFFO is to ensure the survival of existing nuclear

power stations. The differences between the corresponding factors influencing innovation in the development and use of wind energy technology are listed together in Table 1. This also shows the major differences between the framework conditions in Denmark, Germany and Great Britain, which affected the influence of the policy instruments used.

Increasing pressure on costs, both through the type of instruments used (i.e. oriented towards returns or based on tendering procedures) and through reductions in subsidies, is leading to increased competition in all three countries. It is becoming increasingly important for manufacturers to draw upon their experience to reduce the specific costs of their equipment, in order to gain more room for manoeuvre in pricing. This is achieved partly through R&D to

Table 1.

Factors influencing innovation in the wind industry			
	Germany	Denmark	Great Britain
<i>Framework conditions for development</i>			
Technological conditions	Good engineering and craft professions	Good craft professions	manufacturing industry not strongly represented
Market structure	increasing concentration	increasing concentration	
Market volume	Domestic: high Export: low	Domestic: medium Export: high	Domestic: medium
Market growth	Domestic: uncertain Export: high	Domestic: high (offshore) Export: high	Domestic: medium
Learning curve	First mover	First mover	
<i>Framework conditions for use</i>			
Energy system	centralized	centralized, in transition	centralized, in transition
Prices	falling price per kWh	falling price per kWh	falling price per kWh
Risk	high exposure	low exposure	high exposure
Environmental factors	growing problems with public acceptance	slight problems with public acceptance	high problems with public acceptance

Figure 2. Regulatory framework in Germany

As a consequence of market pressure, generating costs per kWh wind power have fallen significantly in recent years. At the same time manufacturers have consolidated

In Germany there has been a lack of agreement on how to exploit the accumulated store of technical solutions in realizing environmental and energy policy goals

produce innovation in products and processes. There are also attempts to secure returns from innovation by being the first on the market and achieving a large market share as quickly as possible. As a consequence of this market pressure, generating costs per kWh wind power have fallen significantly in recent years. At the same time, the market concentration of German and Danish manufacturers has risen markedly. It is possible that a global oligopoly of suppliers may eventually emerge.

Despite its improved competitiveness compared to fossil fuels, the situation of wind energy use in Germany was considerably less certain than in Denmark or Great Britain until the elections in September 1998. However, it is to be expected that the situation in Germany will change considerably since there are new efforts to support renewable energies over the coming years. Up to that point, in contrast to Germany, Great Britain's Electricity Act provided a legal basis for further expansion of wind energy, albeit at a very low level. In Denmark, it was possible to construct a broad consensus on further expansion

of wind energy among the participating actors, i.e. energy suppliers, wind farm operators, the state and the general public.

In Germany there has been a lack of agreement on how to exploit the accumulated store of technical solutions in realizing environmental and energy policy goals. In the first place, there was considerable resistance to the use of wind energy among energy suppliers, who wanted to keep specialization benefits and protect their own very large capacity. This was expressed in capacity planning which takes no account of expansion in wind energy. Thus the already installed wind energy capacity leads to fuel conservation, but capacity effects were scarcely realized. There was consequently a great deal of uncertainty for both the operators and manufacturers of wind technology in Germany as to the future development of the domestic market.


In Great Britain and Denmark, on the other hand, the participation of energy suppliers was forced through legal measures. Moreover, steps have been taken to further decentralize energy

supply. Secondly, in Germany as much as in Great Britain, acceptance among affected local residents was falling as wind energy achieved more market penetration. The response in Germany has included looking at options for involving residents financially in the operating companies, thereby learning from the Danish experience with wind co-operatives, in which the majority of the population has a stake. Due to the structure of the tendering procedure, this would appear hard to implement in Great Britain.

Innovation-oriented policies patterns

It is clear that a pool of technical solutions and a niche market can be built up by means of innovation-oriented environmental policy. It is important firstly that innovation is induced, in order to reduce the costs for a technology to a competitive level, to overcome the essential technical problems and to create the right conditions for exploiting past experience. Secondly, the necessary institutional framework conditions must be created. A decisive factor here is an open, flexible policy framework, which uses a combination of various instruments and is able to adapt both to the specific conditions in each phase of the innovation process and to changes in the technical and socio-economic framework conditions. It is also important for the effects of using an instrument to be monitored through

continuous evaluation. In the wind energy sector, an instrument package which makes an attempt to trigger a technology leap, with the subsequent economic and technological uncertainty and unpredictability, has proved not to be necessarily advantageous. Instead, a gradual approach whereby a new technology is continually improved in small steps has proved to be effective.

After building up a store of technologies and a market niche, further instruments must be used to create a functioning market. Thus, defining the future status of renewable energy in the energy supply system in Germany now has become a crucial task. Also the introduction of the new eco-tax in Germany could be a turning point if the use of wind energy were exempted, which could become more profitable for business than conventional power station technologies. Both measures are characteristic for the success of Danish policy. With the introduction of the energy and CO₂ taxes, Denmark achieved a partial internalization of the external effects of power generation and improved the competitiveness of renewable sources. Moreover, the long-term national energy plans, similarly to Great Britain's Electricity Act, set out concrete goals for the expansion of wind energy and other renewable energy sources as substitutes for coal-fired power stations. 

Promoting a technology to the point where it is able to overcome the essential technical problems and begin to compete is a key part of creating a pool of technical solutions and niche market

About the authors

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studied economics at the University of Heidelberg. His master thesis was awarded by the Chamber of Commerce. Before obtaining his PhD in economics he worked as a researcher at the Prognos AG in Basel, and the Centre for European Economic Research in Mannheim, and as a guest researcher at the University of Wales in Cardiff. He is currently working at IPTS as a member of the Environment Group. His main interests are in the field of economics of innovation with special emphasis on the relation between environmental policy and innovation and on the environmental assessment of policy initiatives.

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Keywords

wind energy, environmental innovation, environmental policy, technology policy, and determinants of innovation

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Thinking about EMU and Science

Stuart Schwartzstein, *LSE*

Issue: The advent of European Monetary Union (EMU) undoubtedly constitutes a major economic and political event. Despite considerable attention to EMU, however, what effects it will have in a wide range of areas is not at all clear and experts are divided. Among those areas like to be affected – at least to some degree – is scientific research and technological development, but as with many other areas at this time one can only speculate on the impact that EMU will have on science in Europe.

Relevance: EMU is not only highly significant, but the success or failure of monetary union can have long term effects on the continued integration of Europe at a number of levels and on the ability of European science to compete effectively on a global scale.

European Monetary Union (EMU), which created a single currency in January of this year, is likely to be seen by historians as one of the most important economic events in post-war Europe. It is certainly the most important event to take place in Europe since the collapse of the Soviet Union. But, even as we consider its importance, it should be kept in mind that the primary impetus for monetary union is not economic, *but political*, and that the tenacity to which most European leaders have held to plans for EMU - despite considerable trepidation and opposition - is more an indicator of the importance attached to political integration than the conviction that a single currency itself will bring significant economic benefits. EMU may stem from the political commitments contained in the Maastricht Treaty, but will overshadow it. Some commentators see EMU as not only of great significance politically within Europe, but an event that will be a watershed in US-European relations. And there are those, like Martin

Feldstein, former chairman of the Council of Economic Advisors to the US President, who believe that while extremely important, the effects will be negative. In a highly-publicized article of November 1997 Feldstein wrote: "if EMU does come into existence, it will change the political character of Europe in ways that could lead to conflicts in Europe and confrontations with the United States" (Feldstein, 1997). Just as much of the impetus for EMU comes from those who want to see an integrated Europe as a counter-balance to the US, there are those in the US who fear that a more integrated Europe will be more a competitor than a partner. But there is a consensus that even if seen by much of the public as an "obscure financial undertaking" it is of great significance and cannot be ignored.

There is much, of course, about the EMU that remains to be seen. In the economic sphere, it is likely to be in the structural effects – first order, second order and other knock-on effects — that

European Monetary Union, which created a single currency in January of this year, is likely to be seen by historians as one of the most important economic events of post-war Europe

But for those concerned with science and technology in Europe, what are the likely impacts?

Within the EU greater ease of comparison is likely to level out costs.

Using one currency will also make administration easier within the euro zone

EMU will have the most impact. By all accounts, it will create a strong currency – one that is likely to rival the dollar as a reserve currency – and no doubt will further integrate those members of the European Union who choose to participate.¹ One might also, reasonably, expect the most careful and prudent fiscal management by both governments of the eleven states which will initially participate in the EMU and concerted efforts to make certain that there are no serious economic downturns, at least in the first year or two of a single currency, when it would be blamed (rightly or wrongly) for any that might occur. The degree to which high unemployment rates can be addressed during this period will also represent a serious challenge to member governments; one we can expect will be given a high priority.

But for those concerned with science and technology in Europe, what are the likely impacts? And for those concerned with cooperation in science and technology between the US (and Japan, as well as other countries) and European Union partners, what can be expected? Interestingly — and somewhat surprisingly, given the importance of science and technology for modern economies — little seems to have been written and published on the impacts that EMU may have on S & T other than those devoted to the administrative and software problems that will inevitably be raised (at least in the initial period). Information that this writer has received from various experts and commentators on science policy indicates that little attention is being paid to what impacts EMU may have on science and technology in Europe – on funding, administration of R & D or on possible changes to EU approaches to support for research and development as a result of monetary union.

There are a few things that are readily apparent. First, cost comparisons between countries will be considerably easier and will not be subject to the

distortions of currency fluctuations. Nor, within the EMU group, will there be disparities in interest rates and thus there will be greater equalization of certain costs. Certainly, with one currency in which all budgets and costs can be denominated, the administration of research (and manufacturing) facilities throughout the Euro zone will be considerably easier and the mobility of researchers also made easier by denomination of costs and salaries in a single currency. Beyond that, the effects are less obvious.

It may, however, be useful to speculate on possible effects of EMU on scientific research at least for the short term. In the view of this writer, we are likely to see the following:

- Commitment to the Euro as a strong currency by the central bank keeping interest rates as high as necessary for strength, but not significantly higher than existing rates: this may have the effect of discouraging some commercial sector investment in research facilities, at least in those areas where payoff is neither in the short term nor of the high-risk, high return sort. The impact of interest rates on investment will, however, be determined not only by interest rates of the Euro but those in other major currencies, opportunity costs and what long-term strategies firms may have.
- Consolidation of both manufacturing and research facilities within the EMU group: This may result in greater rationalisation and more effective use of resources. It may also – perhaps more in the short than long term – result in a decrease in the number of laboratories and other research facilities.
- Greater availability of capital for research: the expected euphoria (Europhoria?) over EMU is likely to push share prices higher, providing firms with capital, at least some of which can be expected to be used for research and development. (If, for some high-tech firms,

they are able to sustain the kinds of high price-earnings ratios that some US high-tech firms currently enjoy, they will enjoy this benefit whatever the interest rates.)

- Greater impact on research collaboration by medium-sized firms than on large ones: for large enterprises, the obstacles to collaboration have been relatively less important and the greater ease of collaborating across national borders will thus have less impact than on smaller firms which may heretofore have been discouraged.
- Increased pressure for standardisation of practices, greater conformity to EU-wide approaches and greater integration within the EU. Greater ease of administration across national borders and an increased need for European-wide perspectives will drive other measures.
- Rethinking of how the principle of "subsidiarity"² applies to research and development, with most likely a strong tilt towards more decision-making and more efforts on a supranational level.
- Greater standardization and integration of national policies and support for scientific research and development. Greater pressure for greater standardization of educational qualifications to promote the mobility of researchers.
- Pressure for greater harmonisation of tax laws and national (and sub-national³) spending policies, including but not limited to those related to research.
- Little impact on the Fifth Framework Programme : long-debated and fought over, EMU is not likely to affect either the decisions already made or the administration of the Commission's Fifth Framework Programme.
- To gain competitive advantage within the EMU, states and regions may well undertake efforts to provide what concessions, tax

advantages, subsidies and other measures possible (to the extent that they can be legally permitted under EU agreements, directives and regulations) to industry and, particularly, those research-intensive high-tech industries which are seen as both having a future and as not damaging to the local environment.

- Greater impetus given to the consolidation and re-structuring of European defence industries across national borders, including defence R & D. Efforts to create pan-European defence industries able to compete effectively with their US counterparts will be given a boost. (This may have a negative impact on cooperation with the US in some areas of defence research.)

But what of relations in science and technology with the US overall? First, this writer believes that both competition and cooperation will continue to mark US-EU relations in this area. The globalization of science, the importance of both the US and of EU member states in science mean that cooperation is inevitable and, indeed, that competition, will also remain a significant part of the relationship. Indeed, with greater consolidation and rationalization, European enterprises may well be tougher competitors.⁴ For US firms, the cost of contracting for research in EU countries may, however, be higher than in the past, if relative to the dollar the exchange rate of the Euro is higher than that of national currencies now used.⁵ For European firms, a strong Euro may well provide an incentive to contract for research or set up facilities in the US – which would argue for greater cooperation.

But a stronger and more integrated Europe will also mean that demands for conformity to American standards will be more easily resisted. The terms on which cooperation is based may shift somewhat towards European preferences,

The removal of obstacles to collaboration across national borders could favour small companies, for whom their relative importance was greater

Greater harmonization is likely also to create greater pressure for standardization of educational qualifications to promote the mobility of researchers

The globalization of science and the importance of both the US and of EU member states in science mean that cooperation is inevitable and, indeed, that competition, will also remain a significant part of the relationship

Better coordinated cross border research and greater mobility for researchers may mean more of them look for opportunities within Europe rather than emigrate to the US

standards, terms and conditions – with the possible exception of what is done in various information technology areas. This will be true of cooperation in science and technology, but also in other areas as well. For “mega-science” or those scientific efforts which are necessarily funded in large part by governments and which inevitably must be dealt with at a political level, one can expect greater influence by Europe.

The greater ease of administration of research facilities across national borders, the lessened difficulty in mobility for researchers and the greater likelihood that European researchers will find and avail themselves of professional opportunities within Europe, rather than emigrate to the US (as have so many scientists in the past), may also create changes in the relationship. US and Western European enterprises may also compete more strongly for researchers from former Warsaw Pact states, particularly as the strong attraction of the dollar is lessened with a rival reserve currency.

It is also likely that the political and defence relationships of the US and the EU, which will have impacts on cooperation in science and technology, will change as well. Some change has already been brought about by the collapse of the Soviet Union and the demise of a military threat from the east. There have been a number of differences in foreign and defence policy and some may say growing resentment of a dominating role by the US. (Certainly legislation like the Helms-Burton bill and the Iran-Libya Sanctions Act have created fears among many Europeans that if they do not unite and do not themselves constitute a formidable bloc, they will be prey to unreasonable extraterritorial demands by the US.) If the EMU succeeds, it will bolster efforts to create the common European foreign and defence policy and, most likely, force changes in the relationship with the US. These changes will

not necessarily be negative, but to maintain the relationship as friendly (and allied) will likely require changes in attitudes and actions by the US.


Even as we contemplate changes likely to be brought about by EMU, we might also give some thought as to what might happen if EMU does not succeed (or if as Professor Martin Feldstein fears, it gives rise to a variety of conflicts). Even with the best of intentions and a good deal of political will, one must consider the possibility of failure and certainly the possibility of increased rather than decreased conflicts within Europe must be at least be considered. Failure of EMU would, in its trail, no doubt bring both disillusionment with the European Union, greater reliance on national approaches and structures and might well, also, unleash a number of centrifugal forces. This would not necessarily mean that relations with the US would warm commensurately; rather there could well be less coherence and less predictability. Although some in the US may be apprehensive about the advent of EMU, once it is in place US interests are more with success than failure – for cooperation in science and technology as well as relations in general.

What might also be considered are what impacts EMU will have on relations with those European states which will not be members of the monetary union (or, like the UK, which have deferred it). One might ask how EMU will affect both relations with states outside the region (like the US) and those within, as well as with respect to those states which are aspiring to join the European Union.

Conclusion

Although a good deal remains to be seen about EMU and its effects, what is clear is that it will be of major significance and will constitute

an important step in further integration of Europe within the framework of the European Union. The impacts on science and technology and the conduct of scientific research will undoubtedly take some time to be felt, but it is likely that there will be noticeable effects. The importance of EMU for science should not, however, be

exaggerated: compared with other developments (like the Fifth Framework Programme starting in 1999) it may well be relatively minor. But for Europe overall and for other countries' relationships with Europe, monetary union and its effects will be important issues to follow closely. 

Keywords

EMU, monetary union, currency, capital, science, technology, research, interest rates, Fifth Framework Programme

Notes

- 1- Eleven members of the EU have met the criteria for membership and are committed to entering EMU as of January 1999.
- 2- As defined by the Treaty on European Union, it means that the EU can act only when it has the necessary legal power and that that which is done at an EU level should only be done when an objective can be better achieved at a supranational rather than national level. How this is interpreted has been a matter of dispute, but greater integration of member states through EMU may well tip the balance further towards those who take an "integrationist" approach.
- 3- e.g. the German *länder*.
- 4- Airbus and Eurofighter may be the models to be followed in other fields.
- 5- Although it may well have minimal effect: One might note that despite the strength of sterling, a number of US and Japanese firms have opened, maintained and expanded research facilities in the UK.

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The Consumer Product Safety Database: products, risks and expertise

José Javier Alba Sánchez, Guy Bordin, Adela Rodríguez, *IRMM*

Issue: The European Commission has made the tools available to the Member States to enable them to ensure safety in internal market for consumer products. However, the situation can never be static, and development of specific tools to extend the existing range is worthwhile. Among these tools, databases have the advantage of being able to store a huge amount of information that can be classified according to real needs. Their availability is immediate when they are deployed on the web, where they have the big advantage of allowing feedback from the users, thus contributing to their improvement.

Relevance: Laboratories, companies, consumer associations and services of the European Commission have shown an interest in the development of a database that collects data about expertise in the field of product safety. The Consumer Product Safety database dovetails with these developments and can fruitfully interact with other systems in the field.

Consumers increasingly demand higher quality and greater safety from consumer goods. This demand is met in a variety of ways and on a number of levels

Introduction: serving citizens through the use of new technologies

Consumers increasingly demand higher quality and greater safety from consumer goods. The response to this demand comes from a number of levels: governments, industry, specialized groups, researchers and other bodies involved in consumer protection.

Each year, a number of events relating to consumer protection are held. These include conferences, congresses, workshops and fairs. The number of different issues tackled in these events is enormous - a sign of the complexity of

the world of consumer protection. In addition, different countries and regions have a multiplicity of policies, legal systems, social and cultural traditions and institutional contexts. There are therefore many approaches to consumer protection issues, depending on regional factors. Supranational organizations such as the European Commission have to face additional problems deriving from the heterogeneous nature of consumer protection subjects.

Moving forward within such a complex framework requires the adoption of a clear strategy. One such strategy is to deal with specific aspects of consumer protection individually. The European Union, conscious of this reality, is

promoting projects serving specific objectives. These projects include those set up by the following acts:

- Decisions of the Council of the European Union 81/623/EEC, 86/138/EEC, 90/534/EEC, 93/683/EEC and the Decision of the European Parliament and of the Council 3092/94/EC; these Decisions introduce a Community System of Information on Home and Leisure Accidents (EHLASS).
- Decisions of the Council of the European Union 84/133/EEC, 89/45/EEC, 90/352/EEC, 90/651/EEC and 93/580/EEC; these Decisions introduce a Community System for the Rapid Exchange of Information on Dangers arising from the use of consumer products (CSREID).
- Council Directive 92/59/EEC on general safety of products.

Having considered the directive on general safety of products, the Joint Research Centre and the former Consumer Policy Service (now Directorate-General XXIV) signed a collaboration agreement for the creation of, among other things, a data bank on the safety of products. This data bank would:

- Contain a classification of consumer products and their potential risks of use excluding food products¹, live animals and chemicals²
- Cover institutes, laboratories, research centres and test and evaluation facilities with expertise in product safety
- Establish for each facility, its capability, means, expertise, specializations, qualified personnel and how its expertise may be accessed

This database was initially designed to complement the CSREID (the Community System for the Rapid Exchange of Information on Dangers arising from the use of consumer products). This system works as follows: the official authorities in Member States of the European Union notify the European Commission when a possibly

dangerous product appears in the single market of the Union by means of the CSREID. When such a product is detected, in many cases it must be carefully tested in order to confirm its danger to potential consumers or users before any measure can be taken (e.g. withdrawal of the product from the market). The intervention in the single market by the relevant authorities can have not only have consequences for consumers relating to the specific product, possibly jeopardizing the freedom of trade within the European Union, but may also affect overall commerce between Member States (see Figure 1). To avoid these unwanted effects, but still provide protection to the consumers, it must be clearly determined whether the product represents a hazard³ to consumers or not.

The way the database on products, risks and experts complements the CSREID is by facilitating the task of finding those experts capable of giving an independent and reliable diagnosis in any field of the analysis (chemical, physical, meteorological, standards and regulations, etc.) relative to consumer products. If the supposedly dangerous product is found to represent a risk to consumers, the European Commission can take the appropriate measures.

This database was originally conceived as a tool to assist in Directorate-General XXIV (DG XXIV) activities, in the event of the introduction of a dangerous product into the market. However, the current situation, as was explained earlier, has suggested an expansion to its use. Namely, the opening of the database for access to a fuller spectrum of possible users: other directorates of the European Commission, the expert organizations present in the database, sectors of industry, consumer associations, etc. This enlargement can be facilitated by the application of new technologies to the database (e.g. its deployment on the Internet).

The Joint Research Centre and Directorate-General XXIV are collaborating to create a data bank on product safety

This database was initially designed to complement the Community System for the Rapid Exchange of Information on Dangers arising from the use of consumer products (CSREID)

The database will be made available to a broad spectrum of possible users: other directorates of the European Commission, the expert organizations present in the database, sectors of industry, consumer associations, etc

Figure 1. The complex framework of consumer protection

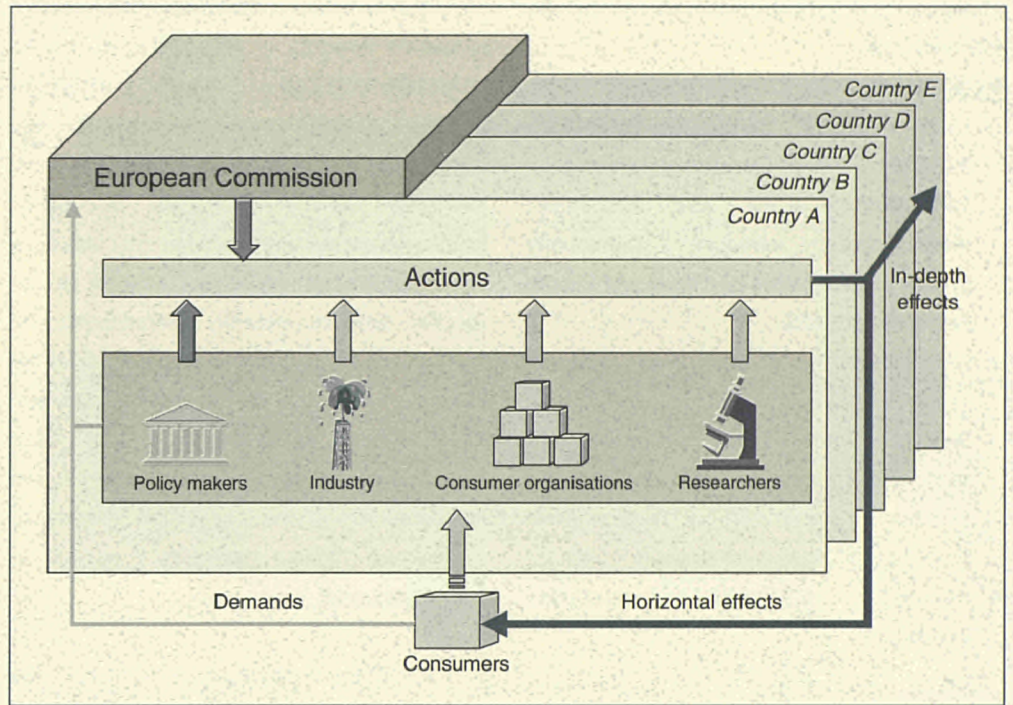
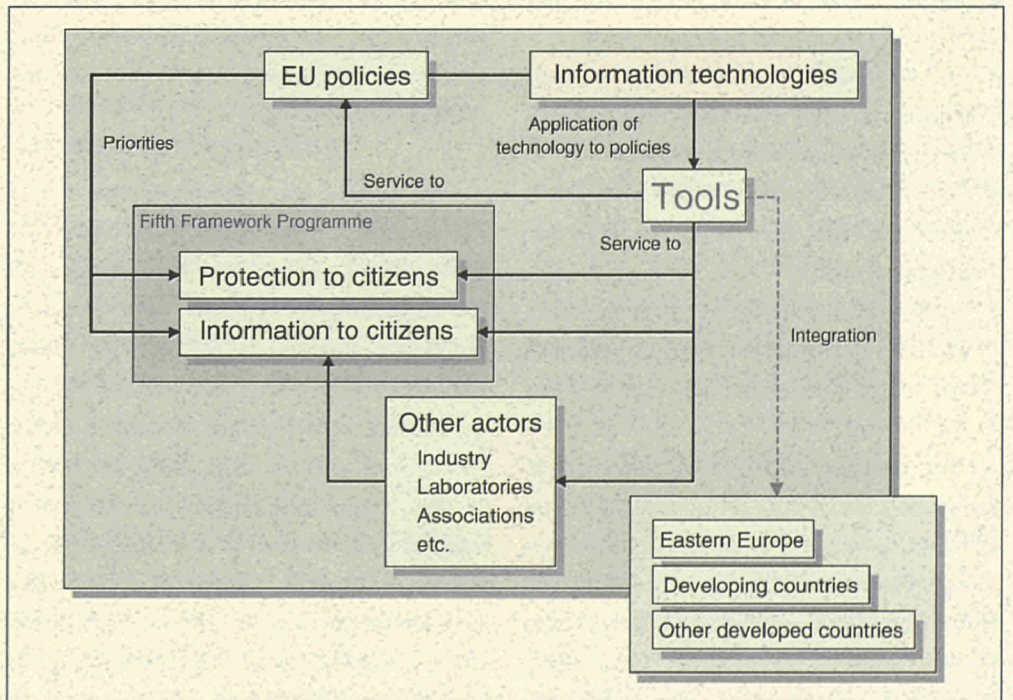


Figure 2. The application of information technologies for the implementation of consumer protection policies



An overview of the application of information technologies for the implementation of consumer protection policies in the European Union is shown in Figure 2.

Characteristics of the database

The first pillar of the database is its relational aspect (Figure 3). A relational database permits the realization of complex query operations involving more than one source of information, thus allowing optimal exploitation of the stored information.

The entities of the database (or elements about which one wants to store information) form another important pillar of the database structure. Each of these entities has a series of attributes, or basic elements of information, such as the description of a product, the type of

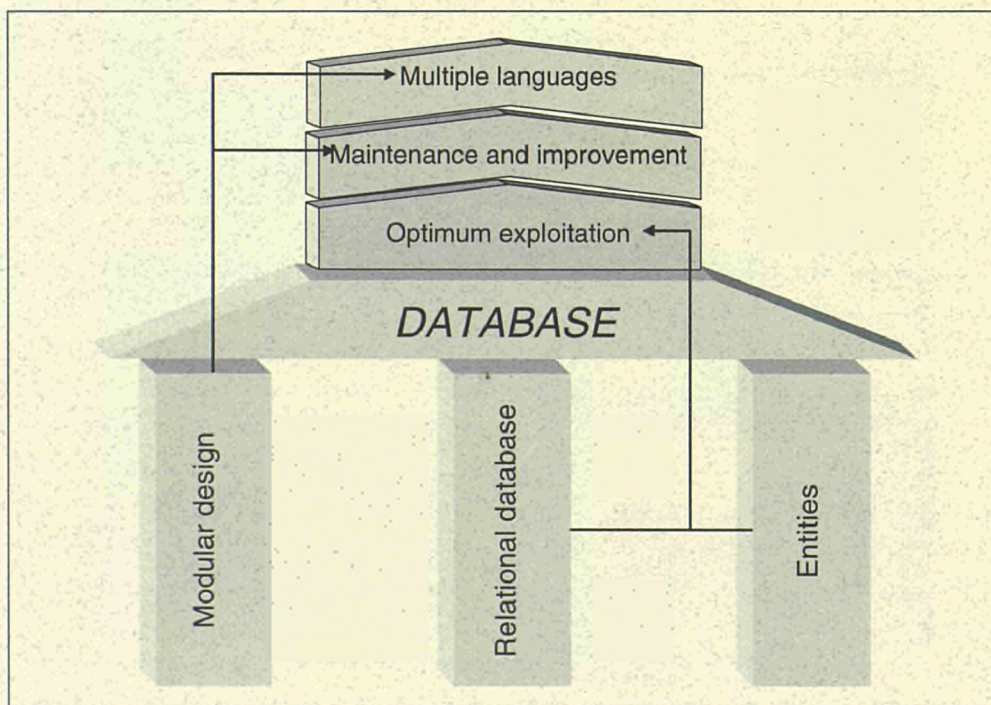
analyses that an expert is capable of making, the description of a risk, etc.

In addition to the classifications of products and risks, there are lists of keywords for each product and risk definition, which allow unlimited scope for expansion of data, without adding extra work to maintenance tasks. There may be hundreds of keywords linked to each heading. Therefore, the possibilities for expansion are unlimited.

Finally, modularity is the third pillar on which the database is supported. The database has been built by assembling units that perform specific tasks, so that either its maintenance or its enlargement and improvement may be made in the most simple and rapid way, and without affecting other structures that perform different tasks.

The database has been designed to be relational, so as to permit complex queries involving more than one source of information

Figure 3. Characteristics of the database on safety of products



The database has been given an expandable multi-language support capability

In order to make the list of experts as complete as possible, the initial action was to contact the corresponding official organizations of all the countries of the European Union, as well as consumer organizations

Modularity was an essential part of providing the database with one very important option: support for multiple languages. As it is conceived, the database can offer its information in any language within a wide spectrum, among which are included all of the official languages of the European Union. For practical reasons, its development is limited to five languages: English, French, Spanish, German and Italian, but the possibility of extending this choice of languages exists and can be easily activated in response to demand.

The general structure of the database is shown in Figure 4, including the sources of data and links to external entities.

Sources of data

This is one of the most complex points, since it involves searching for reliable and stable information which is clearly applicable to the

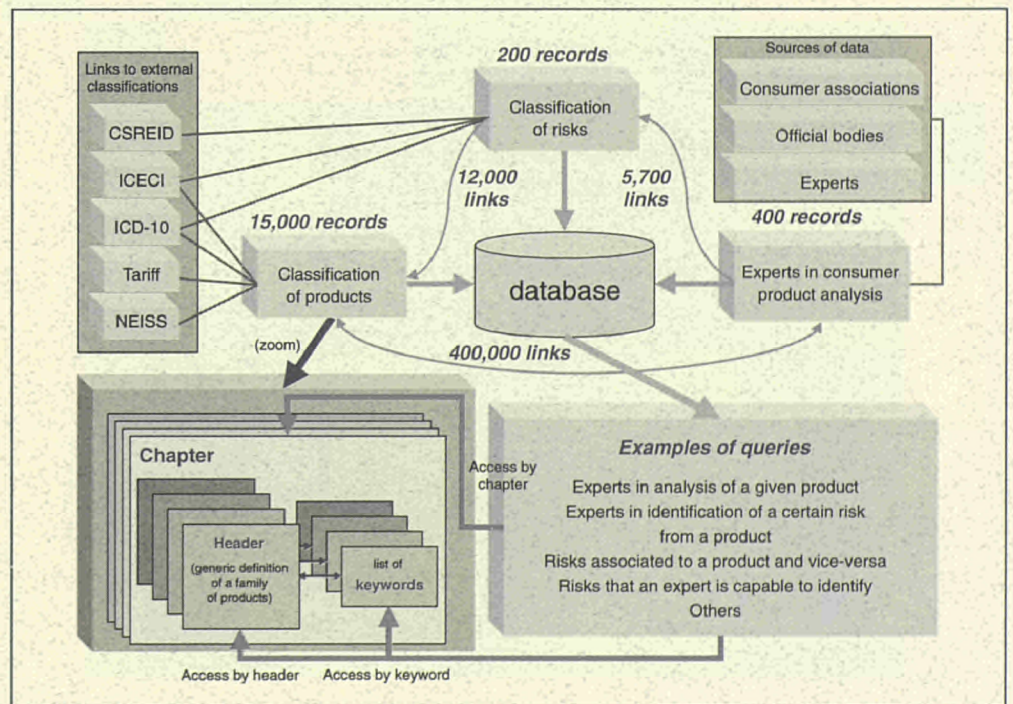
objectives of the project. The information must also obey the heterogeneity of consumer protection subjects as explained in the introduction.

The structure designed for the database allows for three entities, or arrangements of data: experts, products and risks.

The data for the 'experts' entity relate to institutes and laboratories able to perform analyses of consumer goods in any of the possible branches. These data refer to location (name of the organization, complete address, means of location - telephone, fax, e-mail), expert personnel in analysis of products and type of services that the organization is capable of making (for example, chemical analysis of toys).

In order to make the list of experts as complete as possible, the initial action was to contact the corresponding official organizations of all the countries of the European Union, as well as

Figure 4. Structure of the database on safety of products



consumer organizations. This round of consultations produced a list of about 400 expert institutes, with expertise in the analysis of consumer products. This survey is periodically repeated. Furthermore, the expert organizations can communicate by their own initiative any changes in the information.

Regarding the second entity (products) the first version of the database was based on the Tariff and Statistical Nomenclature (European Commission DG XXI). This produced a large classification with more than 15,000 definitions of products. However, the Tariff and Statistical Nomenclature is not specific to the field of consumer protection, and thus added complexity to the database because of its size whilst offering little in terms of precision. This fact motivated the search for new sources of data.

Among the existing classifications of products, the International Classification of External Causes of Injuries (ICECI, World Health Organization), the International Classification of Diseases (ICD-10, World Health Organization), and the National Electronic Injury Surveillance System (NEISS, US Consumer Product Safety Commission) have shown themselves to be more consumer oriented and less complicated. Nevertheless, they are not as complete as the Tariff and Statistical Nomenclature and they still do not entirely fit the objectives of the database.

Therefore, the best solution to finding a source of data for products was to create an original classification of products, fully adapted to our needs. This new classification takes into account the sources mentioned above, associating their advantages and even extending some: reduced complexity and unlimited growth capability.

With respect to the risks, the process of finding a source of data has proceeded in parallel to the

case of products: since none of the studied classifications fitted completely the objectives of the database, the creation of an original classification of risks was decided upon. Certain classifications were taken as a reference, among those mentioned above (ICD-10, ICECI), together with some bibliographical research. The Community System for the Rapid Exchange of Information on Dangers (CSREID), arising from the use of consumer products (European Commission DG XXIV) was also carefully taken into account. That Community system collects real data on consumer goods which could be dangerous, together with a definition of the danger they represent, and therefore is a very valuable reference.

The classification of risks involves about 200 risk descriptions. The possibilities for expansion here are unlimited because of the use of lists of keywords, as explained in the characteristics of the database.

Working methods

Updating the information and the applied technology is essential for the efficiency and reliability of the database. To achieve this goal, we have applied a method that uses the output of one step as the input for the next. This results in a cyclical process of continuous improvement (e.g., the ordinary maintenance tasks reveal the need for a new procedure, then a design process starts, which is implemented and then maintained, thus closing the cycle) (See Fig. 5).

To fulfil the criterion of continuous improvement, in the first place, the deployment of the database on the Internet has been put forward. This application will contain interactive elements, so that communication with the users can be made fast and direct. Feedback from users arising out of applying the cyclical maintenance

The best solution to the problem of classifying data was to create an original classification of products, fully adapted to the project's needs

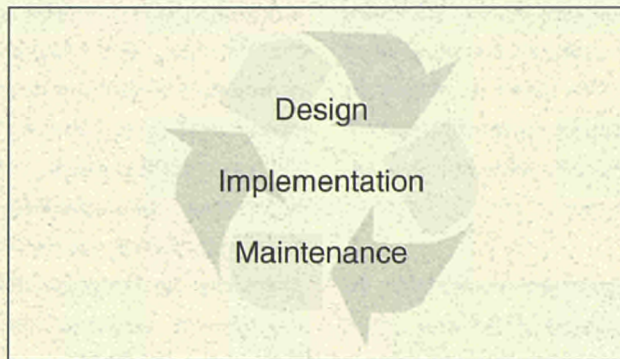
The classification of risks involves about 200 risk descriptions. The possibilities for expansion here are unlimited because of the use of lists of keywords

Making the database available on the Internet would mean that feedback from users would be rapid and direct

A periodic updating process is envisaged, involving contacts with the organizations that serve as a reference for the classifications of products and risks

The European Commission's Fourth Framework Programme for research has supported the development of the Consumer Product Safety (CPS) Database. The database is also in line with the theme of Fifth Framework Programme

Figure 5. The cycle of continuous improvement



philosophy will be a decisive factor in ensuring the validity of the information and tailoring the application to users' needs.

Secondly, the update of the data is not only left to those criteria suggested by users, but periodically (typically once a year), a survey is made between the experts that are present in the database. This survey permits updating the information as well as searching for new experts.

Periodic contact is also maintained with the organizations that serve as a reference for the classifications of products and risks (Directorates-General of the European Commission, the WHO and the CPS Commission in the US) to permit the continual updating of the data.

The principle of continual improvement also affects the technology which is applied. The renewal and improvement in software and hardware, together with the update of the criteria for their correct management, are essential points in the development of the database.

Perspectives within the new framework programme for research

Besides the initial purpose of the database on products, risks and experts for supporting certain Commission activities, the shift towards more

consumer-oriented projects has been fully assimilated by it. As a result, the database has aroused the interest of experts in the analysis of consumer products, and also sectors of industry and several departments of the European Commission involved in consumer protection. This fact supports the idea that tools of this kind (implementation of policies through the use of technology) are valid instruments for the achievement of certain policy objectives, particularly in the field of consumer protection.

Equally relevant is the idea of linking tools to others of the same kind, thereby increasing information retrieval possibilities yet further. For example, since the database on products, risks and experts stores information linked to international classifications of products and risks (Tariff and Statistical Nomenclature, ICECI, ICD-10 and NEISS), it is feasible to create an interface with other databases and electronic systems (such as EHLASS, CSREID or the sub-bases of COST Action 99), which also use these classifications. This associative process would produce much more complete information in the field of consumer protection, and therefore, the potential for exploiting the results is very high.

The European Commission's Fourth Framework Programme for research has supported the development of the Consumer

Product Safety (CPS) Database. That Framework Programme was highly influenced by the RTD provisions introduced in the Treaty on European Union and by the Commission's White Paper on Growth, Competitiveness and Employment. The database is also in line with the theme of Fifth Framework Programme (FP5). Protecting consumers, benefiting from the information society, putting research at the service of the citizen and concentrating efforts in specific areas to help to solve problems are samples of those new themes in which the database fits completely.

In the same vein, the application of the latest information technologies to the database will facilitate immediate reactions to new needs as

they arise. The short time of reaction could contribute to the self-confidence of consumers and entities involved in consumer protection, which is a necessary feature of an open society.

Identifying future needs is a task that must be undertaken by researchers and policy makers. The CPS database will serve the corresponding FP5 objectives, but in addition there are a number of possibilities that should be explored. For example, the CPS database could help to underpin harmonization in the field of consumer safety for the new coming members of the Union. Furthermore, association and co-operation with other systems in the same field can bring to light unexpected possibilities that could be explored.

Keywords

consumer products, consumer protection policy, dangerous products, databases, experts in analysis of consumer products, Information society, risks associated to consumer products, serving the citizen, single market, support to community policies

Notes

- 1- Equivalent systems exist in the field of food safety, such as Languel (<http://food.ethz.ch/languel/>) within the frame of COST Action 99 and the Rapid Alert System for Foodstuffs (European Commission, DG XXIV).
- 2- Equivalent notification procedures exist for pharmaceuticals (Directive 75/319/EEC and 81/851/EEC), animal diseases (Directive 82/894/EEC), products of animal origin (Directive 89/662/EEC) and in the form of the System for the Rapid Exchange of Information in radiological emergencies (Decision 87/600/Euratom).
- 3- A 'safe product' means any product which, under normal or reasonable foreseeable conditions of use, including duration, does not represent any risk or only the minimum risks compatible with the product's use (Directive 92/59/EEC art. 2-b).

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Patent protection for biotechnological Inventions: incentive for European biotech Innovators

Nikolaus Thumm, *IPTS*

Issue: Protection of biotechnological inventions has been and still is a matter of public debate but it is also a recent concern of policy makers. Within Europe an additional task is the harmonization of the different national regulations for the protection of biotechnological inventions.

Relevance: Protection of intellectual property is essential for biotechnology firms and the debate on what, how and when biotechnological inventions can be protected by legal means is continuing. Recent European legislation tried to clarify these issues. How this legislation will be implemented and how firms will react to the new legal framework, however, remains to be seen.

Introduction

Biotechnology is one of the leading future technologies and besides computer and information technology a key-technology for the economic development of the next millennium. This is revealed with particular clarity by the sector's growth rates (table1).

The remunerative aspects of intellectual property rights have particular significance for biotechnology as research and development costs are high but copying marketed products is relatively easy. This is highlighted, for instance, by the fact that it still takes around 12 years to bring a new medicine onto the market and average research and development costs are over \$300 million. Industry will, of course,

Table 1.

Development of Europe's Biotech Industry			
	1996	1997	1998
R&D expenditure	+21%	+20%	+27%
number of companies	584(+20%)	716(+23%)	1036(+45%)
employees	17,200(+7%)	27,000(+60%)	39045(+42%)

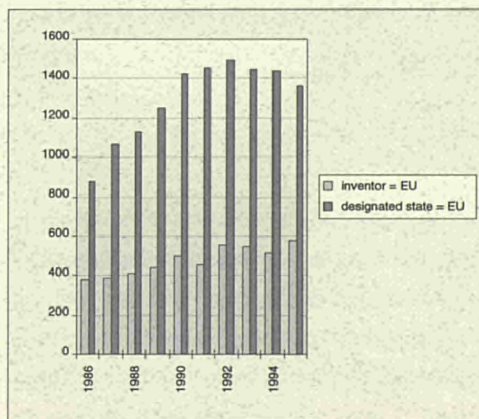
Source: Annual Ernst & Young Reports on the European Biotechnology Industry

The high investment costs involved and the ease of copying the results make the biotechnology industry particularly sensitive to the issue of intellectual property

only make this kind of investment if its return is protected, and intellectual property rights protection, mainly in the form of patents, is the type of protection most frequently sought.

However, the legal framework for patent protection, at least in Europe, is still far from coherent. National, European (European Patent Convention, EPC) and international (Patent Convention Treaty, PCT) patent rights exist in parallel. The use of the European patent has risen tremendously during the last decade and has largely eclipsed the number of national patent applications.

Figure 1. European patent applications in biotechnology (defined by PCT classes C07C,C12M,N,P,Q,R,S)



Source: EPO, ESPACE bulletin

However, the EPC is still not a system which provides a harmonized legal framework for patent rights in Europe, the proposal for a community patent made in 1989 has still not been adopted and one of the main problems for European legal patent protection - apart from the high application and maintenance costs - is the possibility of different interpretations by national laws and national courts, which brings with it a high risk of legal heterogeneity within Europe. Thus the need

for a coherent legal framework is evident and the recent directive on "legal protection of biotechnological inventions" (98/44/EEC) is very much along these lines.

Current issues in protection of biotechnological intellectual property

There is considerable public debate on the scope of what is really patentable so far as biotechnological inventions are concerned. The new European directive on the legal protection of biotechnological inventions tries to lay down the guidelines for the whole debate. Nevertheless, already within normal patent law the requirements for patentability of biotechnological items is clearly defined. Article 52.1 of the European Patent Convention Treaty states that patents may be granted for inventions which are novel, based on an inventive step and are capable of industrial application. Excluded from patentability, according to article 53, are inventions that are contrary to morality or the "public order". However, a decision on this point is a value judgement that is based on principles outside patent law itself. Article 53 b also specifies that animals, plant varieties and breeding methodologies are excluded from patentability. The new interpretation given by the new directive to the patentability criteria (invention, novelty, inventive step and industrial application) may supersede this exclusion.

Invention

Inventions have to be distinguished from mere discoveries. Frequently it is perceived that the natural existence of a substance, especially in the case of genes, means that the item can be discovered but not invented. Thus a protein or a gene sequence are discovered rather than invented. However, legal practice in patenting takes industrial applicability into account in order to distinguish between discoveries and inventions.

In the case of genes, a patenting practice had already been established -and this was reaffirmed by the new directive- whereby a patent can be granted when the gene is isolated and made available for practical industrial purposes. Thus the definition of what an invention is, as contrasted with a mere discovery, depends first of all on whether it is technologically applicable. Genetic engineering, for example, is regarded as a sophisticated form of technical invention.

Novelty

An invention is novel as long as it does not belong to the "state of the art" in the field. This is tested by the previous availability to the public (European Patent Convention (EPC) Art 54(2)). Novelty is distorted by "everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing date of the European patent application" (Article 54(2) EPC). In the view of the European Patent Office (EPO) the mere pre-existence of a substance is insufficient to contradict the novelty criterion (see e.g. the Alpha-interferon case, BIOGEN/Alpha interferons EPO Appeal Board Decision T301/87, EPO Official Journal OJ EPO 1990/8, 335). Consequently also the pre-existence of genes does not destroy novelty.

Inventive step

The test for the necessary inventive step is based on the idea of the invention's not being immediately obvious to an expert familiar with the state of the art in the field. Thus it is more a question of ingenuity in the individual case of an invention. With respect to the isolation of genes the answer to this question is left to a case-by-case decision by the patent authority.

Industrial applicability

Article 57 EPC defines industrial applicability for inventions. This could, of course, be a problem; especially in the case of the

identification of the gene sequence, where many sequences are identified without the knowledge of the exact function and therapeutic value of the coded protein.

The directive on the legal protection of biotechnological inventions

It is now more than ten years since the first draft of the directive for the protection of biotechnological inventions was rejected by the European Parliament. The European Parliament at that time had strong concerns about the patentability of nucleotide sequences derived from human genetic research, but also voiced general ethical concerns. Finally, on 12 May 1998, the European Parliament accepted the Commission's latest proposal with 432 votes in favour and 78 against (mainly the green party) and 24 abstentions.

Basic principles of the new legislation

Article 3 of the directive extends the general prerequisites of patentability to biological material (defined in Article 2) and claims that such material is in general patentable even if it previously occurred in nature, providing, the industrial application is clearly specified in the application. Article 4 tries to ensure consistency with Article 53 b EPC by excluding plant and animal varieties and essential biological procedures for the breeding of plants and animals from patentability. Exceptions however, and this is important, are possible for cases that are not technically confined to a particular plant or animal variety.

Article 5, 1 also establishes the principle of non-patentability for the human body and parts of it. Whereas in part two of the same Article exceptions are defined for isolated elements of the human body that are produced "by means of a technical process", and explicitly including

Part of the difficulty with patenting biological material is that it often resembles a discovery more than an invention. This is overcome by applying the principle of technical applicability

Genes may also be argued to exist already, and therefore lack novelty. However, the novelty criterion applies to the pre-existence of a description of the thing in the public domain, not the thing itself

In the case of patenting material originating from the human body, the traditional ethical grounds for refusing a patent have been extended to explicitly cover issues such as cloning, etc

Despite the length of time the directive has been under discussion the debate surrounding it still continues

sequences of genes. The article also gives a clearer position on what parts of the human body can be regarded as a patentable inventions and not mere discoveries. Just as in existing patent law, ethical and public policy objections are grounds for exclusion. In particular these criteria mean the following are excluded:

- procedures for human reproductive cloning
- processes for modifying the germ line genetic identity of human beings
- methods in which human embryos are used
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes

Article 11 provides farmers with the privilege of utilizing offspring from transgenic stocks without paying any royalties (the so called farmers' privilege).

Reactions to the directive

Already the adoption of the new biotechnology directive is very controversial, though this is not surprising given the fact that it took nearly a decade to get it through the legislative process. The date for transposition into the national law of the Member States is July 2000. Nevertheless, it continues to be debated just as fiercely as before its adoption, as shown by the most recent nullity suit (October 1998) by the Dutch government against the European directive (98/44/EEC), for reasons of non-compliance with the principle of subsidiarity, violation of fundamental human rights and contradiction with international treaties. Press reaction to the directive ranges from vehement rejection to enthusiastic support. Clearly, the doubts concerning the directive are still very much alive and many people have yet to be convinced of its benefits.

Are patents still an adequate protection tool?

Serious concern now exists as to how far the patent system remains an adequate tool for protecting intellectual property. Indeed, the dramatic changes in the structure of the industry during recent decades may also mean that a dramatic change in the intellectual property rights system is needed. The original intention of rewarding invention so as to provide an incentive through guaranteeing economic benefits for research and development has become simplistic and does not match the requirements of new industries like biotechnology or those related to the information society. "The intellectual property rights system was developed for an industrial era, while now complex issues of a post-industrial period are at stake... the time is ripe for a wholesale reassessment of traditional approaches to the definition and protection of intellectual property" (Pirages 1996, page 273). Today's brainpower industries and their complexity pose new challenges to the intellectual property rights system. Furthermore, nowadays it is less and less the case that innovations are driven by breakthroughs than by the routine exploitation of existing technologies. This gives rise to the possibility of innovations consisting of the concentration of all known characteristics plus one new one. This kind of "recombination model" (Foray 1992, page 9) of invention clearly means that the availability and the access to information is gaining in relative importance. An intellectual property right system is also a political tool as it establishes a balance between individual rights and responsibility to society "Society isn't going to let someone have a monopoly on the cure for cancer" (Lester C. Thurow, 1997 page 98). Political value judgements of this type, however, differ a lot between countries according to their degree of economic development. Developing countries tend to emphasize responsibility to the public over individual rights of creators, whereas in industrialized countries it is usually the other way round.

"Patenting life"

An issue which has always been problematic is whether genetic material or information taken from human beings and plant and animal varieties can be patented. According to the new directive for the first time elements isolated from the human body by means of technical process are patentable. Opponents fear that human beings, plants and animals might be reduced to a mere genetic resource.

Since 1977 over 7500 patent applications on human genes, from plants and animals have been submitted to the European Patent Office. The new directive is therefore only formalizing what has been legal practice for a long time anyway. The new directive explicitly excludes procedures for cloning human beings or human germ line interventions and also the use of human embryos for industrial purposes. Scientists fear royalties will be an obstacle to science. There are also fears that farmers might become more dependent on large firms which hold the gene patents on genetically altered plants or animals.

The industry's reaction to the directive, however, has generally been positive given that the patentability of biological material has been confirmed by Article 6. Nevertheless the issue of plant variety and transgenic plants is unresolved and the expansion of ethical issues and the farmer's privilege is disturbing biotechnology firms. From the industry's point of view, any weakening of the draft would put Europe at a further disadvantage and shift the focus of research in biotechnology further towards the USA and Japan. The harmonization of existing national laws on biotechnological patents by the directive is encouraging the invention of new medicines, which could improve life and health of millions of patients by increasing investment in research and development.

Ethical concerns

According to the legal criteria for patentability there are generally speaking no restrictions to the patentability of biotechnological inventions. Nevertheless, there are some major ethical concerns on this subject. The main ethical criticism is based on worries that somehow 'life' itself is being patented in conjunction with a moral view that living animals should never be reduced to the status of an object of invention. A famous case is the decision of the European Patent Office on the so-called Onco Mouse, where a patent was claimed for a genetically altered mouse by Harvard University. In this decision a patent was granted for a transgenic animal. The fact that the mouse in question does not occur in nature made possible the application for patent protection. The underlying argument against patent protection of living beings, however, is that animals should not be used as mere tools for human ends and, in particular, that they should not be caused to suffer. The Examination division of the European Patent Office justified the granting of a patent on the basis of its judgement that the likely benefits for cancer research outweighed the ethical concerns. This decision set the precedent for a utilitarian approach in which possible negative consequences are justified by the invention's usefulness to mankind.

Advocates of the new legislation counter ethical concerns by pointing out that "patenting life" *per se* is a meaningless notion as patent law does not allow the patenting of abstractions. Normal application of patent law already excludes the following:

- human beings
- body organs, limbs, body fluids, and any other known part of the human body
- nucleotide sequences elucidated by human genetic research and other molecules identified by such research in the human body in their natural state

There is some doubt as to whether a patent system designed for an industrial age can really be adapted to meet the needs of sectors such as biotechnology or information technologies

To some extent the directive really only formalizes a trend towards patenting biological material that was already underway

One ethical objection is based on the view that living animals should never be reduced to the status of an object of invention

However, precedent exists for granting a patent on a living organism when sufficient benefit to mankind may be expected to be derived from it

The 'global justice' objection fears that powerful players in the wealthy North will exploit the biodiversity of the South to create a new kind of colonialism

Experience from the USA demonstrates how important the patenting environment is for the development of the biotechnology industry. For biotechnology firms patents may often be a prerequisite to obtaining venture capital

A patent cannot be granted on the ownership of "life". Living organisms can only be patented if they differ significantly from naturally occurring ones. Moreover, patenting material originating from living organisms should not be confused with the emotive idea of patenting life. DNA is not life, as human beings cannot be reconstructed from the sum of human genes. For the evaluation of patenting from an ethical point of view, it makes a big difference whether genetic alterations are allowed for freedom of science or whether they are part of an economic premium system, as in the case of the patent system.

Biodiversity and global justice

Most research is done in the Northern Hemisphere, but broadest species variety is found in the Southern Hemisphere, which has a greater concentration of poorer countries. Western world economies gain huge benefit from owning plants in impoverished southern countries (See for example, Goodman, Walsh, 1997 and the story of taxol or "The European Patent Directive: License to plunder" <http://www.grain.org/publications/reports/plunder.htm>) by establishing a sort of bio-piracy of the genetic resources of the Southern hemisphere. An example of this is Madagascar's rose periwinkle plant which was used to develop anticancer drugs, and other medicines with a great worldwide market success, but which never returned any financial benefit to Madagascar (The World Bank 1998 p. 35).

This and other examples show that at least a minimum level of responsibility towards developing countries is required of the actors involved. Patenting of genes could mean the beginning of an unequal distribution of genetic resources between underdeveloped countries and industrial nations, amounting to a kind of new colonialism by biotech firms. In addition, countries in the South might be forced to uphold patents obtained by foreign companies on their

own biodiversity and on the associated knowledge of their indigenous peoples and local communities, perhaps even endangering biodiversity. On the other hand, biotechnology research can also contribute to providing the world as a whole with a stable food supply. Against this backdrop value judgements seem unavoidable.

The new directive as a "competitive advantage"?


Obviously there is a need for a coherent European legal framework for the protection of biotechnological inventions. Different legal regulations in different European countries may lead to trade problems within the European internal market and industries might hesitate to invest in R&D or shift their research base in biotechnology to the USA and Japan. In the biotechnology field patents can be seen to be effective as an incentive to research and development (see e.g. Mazzoleni, Nelson 1998). For biotechnology firms patents may even be a prerequisite to obtaining venture capital (Ballantine et al. p. 48). Industry has therefore welcomed the new directive since an appropriate intellectual property structure is a crucial factor influencing a company's decision to invest in, and to use, biotechnology. Experience from the USA demonstrates how important the patenting environment is for the development of the biotechnology industry. The real future effectiveness of the new directive and whether it might foster competitive advantage for Europe depends very much depend on its practical implementation by the member states during the next two years.

Conclusion

Further research has to investigate how far the directive will affect the behaviour of firms in order to evaluate the relevance of the new legal

framework as a factor of European competitiveness and how firms will make use of the legislation in practice. One specific line of investigation should look at the management practices of IPR in Europe and also compare them with those of its main competitors, the United States and Japan.

The enormous future responsibility of the whole issue should not be underestimated. This

is even more striking given the relatively low public awareness of biotechnology in Europe. The lesson to be drawn from the debate so far is that the intermingling of economic factors and value judgements will make it hard to reach definitive conclusions. A lot depends on how the directive is implemented at the level of the Member States and the subsequent interpretations given it by the courts. 

Keywords

biotechnology, patent protection, harmonization, innovation, competitiveness

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Transatlantic investments and human capital formation: the case of biotech firms

Oliver Wolf, Jens Hemmelskamp, Ineke Malsch, Per Sørup, *IPTS*

Issue: The launch of young, High Tech start-up companies in Europe is partly a result of the efforts of European policies to create a new generation of competitive companies. A special focus has been placed on information technologies and the life sciences. This European effort has been accompanied by a growing interaction between European and US firms, mainly through the setting up of strategic alliances or other forms of co-operation. Additionally, more and more venture capital, mainly from the US, is flowing into European start-up companies in the life sciences sector as part of a two way flow across the Atlantic.

Relevance: One of the issues raised by these capital flows is that of their impact on know-how and human capital.

We have taken the example of the life science sector given the fact that it is a sector which is undergoing rapid economic and scientific development stimulated by large amounts of EC-funds, in order to analyse the relationship between US-investors and European start-ups. Furthermore, a very lively trans-Atlantic economic activity has emerged. This indicates that if there were indeed a drain of European know-how and human capital, it would be possible to track the impacts on know-how in this sector accurately.

The investigation was carried out in two steps: Firstly we selected a representative sample of firms which had received funding through the European Commission in life sciences related

projects. We then traced the market behaviour of these firms, focusing on their relationship with US firms and investors.

European Commission funding for life-sciences companies

In this first step companies were identified which participate(d) in one or more of the life science related programmes set up by DG XII. Project partners included research institutes, universities and private firms.

In order to reduce the total 1575 projects down to a manageable number for analysis, a limited sample was generated using the search-term tool in the Cordis database. The search terms

Table 1.

Selected funding programs of the EC (DG XII) in the life science sector since 1988			
Programme	Total amount (mECU)	Period	Number of projects
Biomed I	151	1991-1994	274
Biomed II	374	1994-1998	650
Biomed I	186	1992-1994	161
Biotech II	595.5	1994-1998	351
Bridge	100	1990-1994	97
Eclair	80	1988-1993	42
TOTAL	1486.5		1575

Source: Cordis Database

used were "biotechnology industry" and, in a subsequent step, "industrial". The idea behind this procedure was that it is not necessary to take in all the projects with industrial participation but to obtain a sample of projects which would be small enough to work with but large enough to deliver useful information.

The investigation was restricted to companies from the United Kingdom, France and Germany, as these are the countries where the highest rate of new start-ups in the Life Sciences sector can be found at the moment.

The final sample contained 177 projects in which 121 companies participated.

Market performance of the companies identified

Having identified this sample of 121 companies which have received EC-funding in the field of life sciences, we looked at their performance during and after the funding phase. Our aim was to analyse the interaction between these firms and US investors.

Although the sample is not big enough to give a solid statistical basis, as a first approximation it was clear that some start-up companies which have taken or are taking part in EC research projects, were bought by US-companies (~7,5%, see Table 2). Some of the companies in the sample had been founded by US-investors, others were

A small percentage of the companies in the sample had been founded by US-investors, others were taken over during, or after, receiving EC-funding

Table 2.

Ownership of companies participating in EC-life science projects (Sample not statistically representative)				
Location of company owners	Location of EC-supported companies within the sample			Total
	UK	France	Germany	
Owned by US-investors	3	3	3	9
Owned by EU-investors	16	21	32	69
No information available	5	32	6	43
Total no. of analysed companies	24	56	41	121

Source: Cordis Database, Recombinant Capital homepage, literature, interviews

Taking into account other forms of co-operation (joint ventures, licensing, mergers etc.) it turns out that nearly all of the companies are involved in one or more strategic relationships with international partners

US researchers have detected considerable penetration of the US knowledge base by European biotechnology businesses

taken over during, or after, receiving EC-funding. An example of this is provided by the company AgriSense. AgriSense took part in the ÉCLAIR project: "The development of environmentally safe pest control systems for European olives" (1990-1994) and was taken over by the American firm BioSys in 1993 – during the funding period (Biocontrol, 1997).

In another case, the French fine chemicals producer Sipsy was already a subsidiary of an American company when it started in the project "Microbial production of native and recombinant tailor-made enzymes for fine-chemical production" (1996-1999) (Sipsy, 1998). Furthermore it can be seen in Table 2 that 69 of the observed companies are property of European investors. In 43 cases no information was available on ownership.

The whole picture – strategic alliances on a global level

Looking only at acquisitions does not provide the whole picture. Taking into account other forms of co-operations (joint ventures, licensing, mergers etc.) it turns out that nearly all of the companies –are involved in one or more strategic relationships with international partners. These co-operations are summarized under the general

term, "alliances". Recombinant Capital, a research institute analysing the alliances within the biotechnology sector, identified 31 different types of co-operation between firms (Recombinant Capital, 1998) The whole spectrum goes from acquisitions and mergers to joint development agreements and shared marketing activities.

Although most of these co-operations are temporary, the main goal of the alliance is to obtain access to new markets and new technologies, and the reduction of risk and costs for the participating companies.

The most important motivation for cooperation therefore seems to be the further development of technologies and business activities in new areas

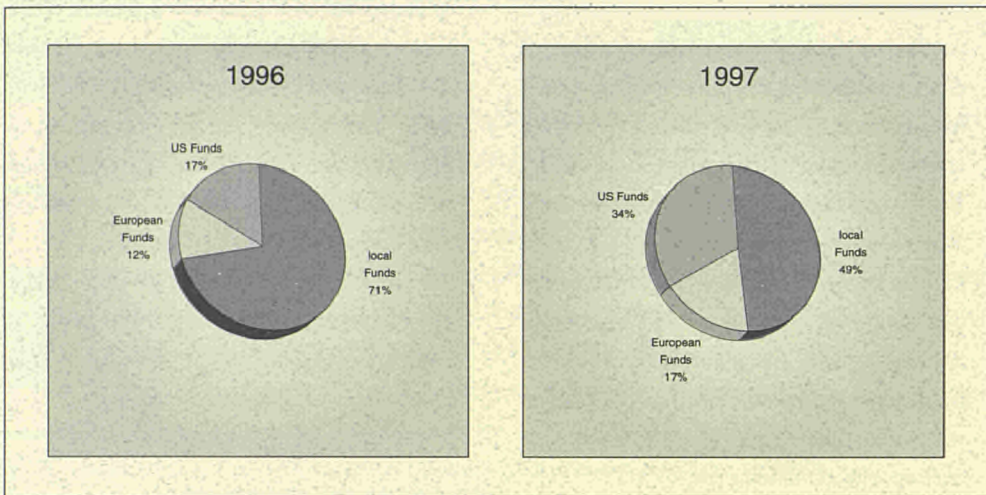
European firms – the reverse trend

One fact stands out, namely that the formation of alliances is not only initiated by US firms, rather, European firms are also active in this area. A look at three large biotech firms from the sample shows the number of inter-firm alliances among them since 1990 (see Table 3). A comparison between European and US Biotech firms shows that intercontinental cooperation is not exclusively sought by large US firms.

Table 3.

Number of inter-firm alliances (since 1990)		
	Company	No. of global inter-firm alliances
Europe	Rhone-Poulenc (F)	93
	Schering (D)	89
	Zeneca (UK)	39
US	Amgen	35
	Pfizer	78
	Pharmacia	89

Source: Recombinant Capital Homepage, <http://www.recap.com>

Figure 1. Shares of venture capital

Source: Interviews with EVCA and BVCA

It is worth noting in this context that US researchers have investigated if there is a drain of know-how from the US to Europe: "The large European-based multinationals in chemicals and pharmaceuticals, in pursuit of the necessary knowledge and skills in biotechnology, have through arrangements of one sort or another widely penetrated the American knowledge base." This implies in the authors opinion "a massive 'technology transfer' from the US to Europe" (Sharp, 1996).

Venture Capital

While the impressive development of biotechnological companies in the US in the early 90s was fed by considerable flows of venture capital, this was not the case in Europe. This 'lack of European venture capital' was often interpreted as a 'lack of confidence' in young European biotechnology companies.

This situation has significantly changed during the last two years, encouraging sufficient venture capital through private European investment funds and by various EU and Member State investment programmes.

In addition, a growing interest by various US investors can be observed. As interviews with the European Venture Capital Association (EVCA), the British Venture Capital Association (BVCA) and with one of the German Bio-Regio administrators show, about 33% of the available venture capital in Europe comes from US sources. This means that the share of US venture capital invested in the EU has doubled during the past year (see Figure 1).

The interviewees stated that European firms often look for funding sources in the US and not the other way round. The success rate shows, among other things, the increasing professionalism of these young companies. Additionally, some European firms are setting up offices in the US, but this is often merely a formality to go public on NASDAQ. The main activities of these firms remain in their home countries.

Bearing in mind that venture capital is invested with the aim of obtaining high returns, these investments indicate international recognition of the growing competitiveness of European biotech-firms.

European biotechnology companies were initially hampered by a lack of venture capital.

Although this situation has improved, a large (and increasing) amount comes from the US

The flows of knowledge and capital in the biotechnology sector seem to be moving in both directions across the Atlantic

The fact that so many European companies look to the US for finance may well point to the existence of a bottleneck in European capital markets

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Conclusions

- Looking at the selected sample of companies it can be stated that in a very limited number of cases, European start-up companies, which had received EC funding for research, were later acquired by US companies.
- The analysis has also shown that the traditional acquisition of companies is only a small part of a broad variety of different forms of alliances (licensing, joint ventures, mergers etc.) Taking this into account, a large number of European technology companies have a US partner, which may have indirect access to knowledge built up with EU funding.
- However, this movement of knowledge and capital is taking place in both directions. Surprisingly, European companies are at least as active in aligning themselves in the US market as the US companies are in Europe.

What lessons can be learnt?

- The high technology life sciences sector finds itself in a state of rapid change, suggesting an initial consolidation phase. These alliances (also between global competitors) form part of a common process.
- The intensive activity of US companies in Europe indicates the rapidly growing

attractiveness of European high tech firms. This is underlined by the increasing amount of US venture capital, currently flowing into Europe. The main goal of these investments seems to be to participate in the growing success of young European companies, in a way similar to the European firms' efforts to earn dividends from the success of their US partners.

- The rapid flow of knowledge and capital demonstrates that this industry segment is knowledge-based and, therefore, largely independent of geographical factors.

Europe on the right track

One implication which emerges is the need to establish an attractive financial environment for high technology start-up companies. The fact that a lot of young companies look for funding in the US may well point to the existence of a bottleneck in Europe regarding capital availability. First steps in the right direction have already been taken, as the First Conference of the Biotechnology and Finance Forum showed. This event, organized by DG XII and the European Association of Securities Dealers (EASD), took place in Brussels on 12 and 13 May 1998 and aimed at linking the biotechnological and the financial sphere in Europe closer together. 

Keywords

human capital, biotechnology sector, EU funding, venture capital

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A B O U T T H E I P T S

The **IPTS** is one of the eight institutes of the Joint Research Centre of the EU Commission. Its remit is the observation and follow-up of technological change in its broadest sense, in order to understand better its links with economic and social change. The Institute carries out and co-ordinates research to improve our understanding of the impact of new technologies, and their relationship to their socio-economic context.

The purpose of this work is to support the decision-maker in the management of change pivotally anchored on S/T developments. In this endeavour IPTS enjoys a dual advantage: being a part of the Commission IPTS shares EU goals and priorities; on the other hand it cherishes its research institute neutrality and distance from the intricacies of actual policy-making. This combination allows the IPTS to build bridges between EU undertakings, contributing to and co-ordinating the creation of common knowledge bases at the disposal of all stake-holders. Though the work of the IPTS is mainly addressed to the Commission, it also works with decision-makers in the European Parliament, and agencies and institutions in the Member States.

The Institute's main activities, defined in close cooperation with the decision-maker are:

1. Technology Watch. This activity aims to alert European decision-makers to the social, economic and political consequences of major technological issues and trends. This is achieved through the European Science and Technology Observatory (ESTO), a European-wide network of nationally based organisations. The IPTS is the central node of ESTO, co-ordinating technology watch 'joint ventures' with the aim of better understanding technological change.

2. Technology, employment & competitiveness. Given the significance of these issues for Europe and the EU institutions, the technology-employment-competitiveness relationship is the driving force behind all IPTS activities, focusing analysis on the potential of promising technologies for job creation, economic growth and social welfare. Such analyses may be linked to specific technologies, technological sectors, or cross-sectoral issues and themes.

3. Support for policy-making. The IPTS also undertakes work to support both Commission services and other EU institutions in response to specific requests, usually as a direct contribution to decision-making and/or policy implementation. These tasks are fully integrated with, and take full advantage of on-going Technology Watch activities.

As well as collaborating directly with policy-makers in order to obtain first-hand understanding of their concerns, the IPTS draws upon sector actors' knowledge and promotes dialogue between them, whilst working in close co-operation with the scientific community so as to ensure technical accuracy. In addition to its flagship IPTS Report, the work of the IPTS is also presented in occasional prospective notes, a series of dossiers, synthesis reports and working papers.

The IPTS Report is published in the first week of every month, except for the months of January and August. It is edited in English and is currently available at a price of 50 EURO per year in four languages: English, French, German and Spanish.



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