Is Innovation Important in Europe?

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Innovation is not simply an economic mechanism or a technical process, it is a social phenomenon through which individuals express their needs and creativity. Christopher Hodges assesses the implications for legal policy resulting from the process of innovation.

Innovation as a goal of Community economic and social policies

EU policy developed during the 1990s recognizes the fundamental importance of innovation in the development of growth and competitiveness and decreasing unemployment [1] and has in 2000 resolved to establish a European area of research and innovation.[2] Indeed, there is recognized to be an innovation deficit in Europe.[3] In adopting guidelines on strengthening the competitiveness of European industry, the Council has stated that this is: 'A prerequisite for lasting economic growth and the creation of new jobs and will contribute to economic and social cohesion.'[4]

The pursuit of innovation is also a fundamental element of EU social policy: 'To act for innovation is in [the] first instance the responsibility of citizens, of industry and of national, regional and local authorities.'[5]

'Innovation and Society

Innovation is not just an economic mechanism or a technical process. It is above all a social phenomenon. Through it, individuals and societies express their creativity, needs and desires. By its purposes, its effects or its methods, innovation is thus intimately involved in the social conditions in which it is produced. In the final analysis, the history, culture, education, political and institutional organization and economic structure of each society determine that society's capacity to generate and accept novelty …

Finally, by its nature, innovation is a collective process which needs the gradual commitment of an increasing number of partners.'[6]

Making this link between, on the one hand, the role and interests of consumers and, on the other, those of industry, by seeing both as being inextricably linked in a single economic and social system is significant and is also, I suggest, correct. But it is not often seen in practice, as current socio-political arrangements tend to emphasize the distinct and sometimes opposing interests of consumers and of industry.

Community legal policy

A principal goal for the achievement of innovation is recognized as being the substantial stimulation of investment in research and development, whether into products, processes or management systems. Some innovation is revolutionary (new technology) whereas other developments are incremental (eg gradually evolving design changes in machinery).

There are the following implications for legal policy:

'It is essential to create a legal environment which will stimulate the development of such investments and guarantee that they are used in the public interest.[17]

'Effective legal protection is a vital incentive for innovation. It offers innovators the guarantee of a right to profit form their innovation. There is also a need for existing rules to be constantly adapted to the new circumstances introduced by technological innovation. This is particularly crucial in the field of new technologies. The various systems for giving legal protection to innovation are, over and above their protection function, of growing economic importance in conquering export markets, combating piracy and in valuing a business (in the event of take-over or acquisition of holdings, for example).'[8]

The Commission's 1996 first action plan for innovation identified three priority areas for action:

(1) to foster an innovation culture;
(2) to establish a framework conducive to innovation;
(3) to better articulate research and innovation.

The second of these three priorities was stated to be to set up a legal, regulatory and financial framework conducive to innovation, pursuant to which the legal and regulatory environment needs to be adapted and simplified. Specific initiatives related to the Community patent[9] and facilitating business startup and innovation support through simplification of barriers. These initiatives included:

- the Simplified Legislation for the Internal Market (SLIM) programme;
- promoting forms of enterprise at European level (such as the European company (SE), the EEIG, a proposal for a statute for joint enterprises in research and development);
- the establishment of the Business Environment Simplification Task Force (BEST) to bring forward proposals aimed at simplifying administrative procedures; and
- mobilizing all Community instruments to support innovation.

Successive increases in regulation

The SLIM programme is of significance when seen against the fact that during the 1980s and 1990s in particular there has been a continuous increase in Community legislation dealing with product regulation. This has extended to encompass a considerable number of product sectors, including pharmaceuticals, motor vehicles, cosmetics, machinery, medical devices, toys, electrical and electronic equipment, personal protective equipment and general consumer products.

At least partly as a result of this increase in regulation, there has been a considerable increase in the costs of bringing a product to market. For example, the total capitalized costs of bringing a new pharmaceutical to the market were around US$100 million in 1960 but by 1995 were at least US$600 million. The proportion of sales of pharmaceutical being spent on research and development increased from around five per cent in 1970 to around 15 per cent in 1999. Less than one per cent of 5,000-10,000 synthesized molecules reach the clinical evaluation stage and only one in ten compounds which enter the clinical evaluation stage eventually enter the market. Furthermore, industry has come under increasing pressure from EU governments in relation to the level of reimbursement of the costs of medicines sold. In Europe, governments and their social security institutions continue to be the major purchasers of medicines-unlike the United States, where the systems are essentially led by private insures.

Accordingly, drug prices in the United States are on average double those found in Europe. European governments with limited public resources face an increase in demand for medicines and medical devices as the population ages and innovative treatments become available, and they are increasingly establishing systems to limit pharmaceutical availability and reimbursement costs. The price of an innovative market leader drug invariably falls significantly when its patent expires.

As a result of regulation, the costs of pharmaceutical in Europe cannot be increased so as to fund large damages awards which might be made by the courts-contrary to classical product liability theory. Thus, pharmaceutical companies are concerned that the financial risks are enormous and the ability of companies to spread their risk is severely limited. The commercial risks of the enterprise have led to significant market consolidation of companies, each of which is concerned about protecting its innovative position with as wide a base as possible. These companies feel extremely vulnerable to any increase in either regulation or the threat of product liability.[10]

Further issues on the extent of safety regulation can be illustrated by medicines, for instance:

(1) the need to fast track products for which the need is urgent and serious, eg for AIDS, since a delay of 12 years to collect pre-marketing data would be too great;

(2) eased requirements for ‘orphan drugs’ for which the low number of patients would not justify commercial expenditure on the full pre-marketing requirements;

(3) the inclusion of traditional remedies such as herbals and homeopathics can cause problems – full testing may disclose problems, eg the ban on ginseng, yet the size of the market might not withstand the cost of full pre-marketing testing.

There is strong anecdotal evidence that the introduction of regulation of the medical devices sector during the later 1990s has led to a number of enterprises discontinuing their marketing of products. The sector contains a small number of multinationals but a large number of small and medium-sized enterprises, many of which did not have the financial resources to satisfy the costs of regulation.

The product liability example

The fair apportionment of the risks which are inherent in the use of products is a principle which is accepted to underlie, for example, the balance of interests as between consumers and industry which is provided for in the Product Liability Directive 85/374/EEC.

In particular, the justification for the 'development risks' defense in the Product Liability Directive is the protection of innovative industry, such as the pharmaceutical sector, from potential destruction as a result of an overwhelming volume of claims in relation to a safety defect in a product which could not have been foreseen despite the adoption of best practice by the manufacturer.

Article 7 of the Directive provides a defense for a producer of a defective product where the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered. It is recognized that this sets a very high standard for the defendant producer to establish.[11]

The Confederation of British Industry has written:

'We are concerned that proposals to remove or alter the development risks defense will stifle innovation… The high level of safety of products means that the level of injury caused by defective products in low. The level of product liability claims is correspondingly low. There is no body of evidence to show that consumers are being widely injured by dangerous products and that such genuine claims as are made are not being settled. Indeed, genuine claims are settled. If the balance of the Directive were to be changed, however, it would simply bring about an increase in unmeritorious claims, resulting in pointless additional cost. (Take the example of the US, where unnecessary product liability costs are enormous.)'[12]

There may be fear that any change, such as the introduction of new product, introduces a new risk of hazard, product safety and injury. It should be remembered that EU policy is to require a high level of protection of safety and health (EC Treaty, Article 95). The extensive application by industry of quality systems, together with ever-increasing regulatory requirements, should significantly assist in reducing this risk. It is well-known that the primary safety problems with consumer products within the Community arise

from cheap electrical products or toys which are imported into the EU by small or medium-sized companies, typically from the Far East, and that the general level of unsafe products in circulation in the EU, particularly products which remain unrecalled after a safety problem has been identified, is very low.[13]

Extension of post-marketing controls

The SLIM programme seems to be slow in producing significant practical effect. Indeed, the Commission is proceeding with measures to increase the regulatory burden. A comprehensive review of EU pharmaceutical legislation was carried out during 2000 and it will be interesting to evaluate whether any proposals which emerge from this will have the effect of reducing the regulatory burden. Meanwhile, however, the Commission's Directorate-General on Safety and Consumer Protection has proposed that producers and distributors of all consumer products should be subject to an obligation to notify national authorities if any product which is in use is identified as being unsafe.[14] Industry has objected that the trigger level for this notification obligation is far too low. If the triggers is set at the safe/unsafe test, which is the same test as applies for the right to initially place a product on the market, it is argued that this will result in a large, and possibly overwhelming, number of reports. Most of those reports would relate to low-level risks in relation to which any further action might be entirely unnecessary. The number of reports might be increased as manufactures seek to avoid regulatory prosecution or liability claims by over-reporting where there is uncertainty. It is, therefore, argued that the imposition of a notification requirement may simply impose enormous costs on manufacturers, distributors and regulatory authorities in managing vast quantities of information of limited value, and that this would be disproportionate to the potential benefits. In short, this over-regulation would be irrelevant to safety and would not assist in identifying the small quantity of data which could be genuinely relevant to safety. It might be appropriate to record, investigate and notify every adverse post-marketing safety event for medicines but is the same approach really justified for every other type of consumer product?

Implications: cost impact assessments and conflicting principles

An important question which is raised by the above considerations is the extent to which reliable cost-benefit analyses are carried out by legislators before action is taken. In particular, the European Commission is not required to undertake or publish a cost impact analysis before putting forward legislative measures-it does this purely on a voluntary basis for those legislative proposals which it considers are likely to have a significant impact on business. This limited practice and the scope of assessments have been criticised[15] and the Commission is currently reviewing the position with the aim of developing a 'flexible, yet structured' methodology for improved assessments. It may strongly be argued that a robust requirement should be introduced by those responsible for advanced economic systems, particularly those which profess economic policy aims which stress the encouragement of innovation, competitiveness and employment.

Further, is there a lack of communication on this issues between different areas of government? Different Directorates-General of the European Commission are responsible for European policy on the regulation of safety, and on competition.

Evidence on how the two streams might coordinate, particularly when conflicts arise, seems to be lacking. It may be asked on what basis principles of safety or of competitiveness/innovation/employment are valued and applied when they themselves compete.

Notes

[1] For an analysis of the Community literature to the end of 1996, see C J S Hodges, *Unknown Risks and the Community Interests: The Development Risks Defense in the Product Liability Directive* (McKenna&Co,1996).

[2] Council Resolution of 15 June 2000 on establishing a European area of research and innovation, OJ 2000 C 205/1.

[3] European Commission, *The First Action Plan for Innovation in Europe: Innovation for Growth and Employment* COM (96) 589 Final, 20 November 1996.

[4] Council Decision of 25 June 1996 on the implementation of a Community action programme to strengthen the competitiveness of European industry, 96/413/EEC, OJ 1999 L 167/55.

[5] *First Action Plan, supra*.

[6] European Commission, *White Paper on Growth, Competitiveness, Employment: The Challenges and Ways Forward into the 21st Century* (1994).

[7] European Commission, *White Paper on Growth, Competitiveness, Employment: The Challenges and Ways Forward into the 21st Century* (1994).

[8] European Commission, *Green Paper on Innovation* COM (95) 688 final, 20 December 1995.

[9] See European Commission, *Promoting Innovation Through Patents – Green Paper on the Community Patent and the Patent System in Europe* COM (97) 314, adopted by the Commission on 24 June 1997.

[10] European Federation of Pharmaceutical Industries and Associations, *Response to Product Liability Green Paper* (1999).

[11] J Stapleton, *Product Liability* (Butterworths, 1997); AM Clark, *Product Liability* (Sweet & Maxwell, 1988); C J S Hodges, *Product Liability: European Laws and Practice* (Sweet & Maxwell, 1993); C J S Hodges, *Unknown Risks and the Community*

Interest: The Development Risks Defense in the Product Liability Directive (McKenna & Co, 1996).

[12] Confederation of British Industry, *Response to Product Liability Green Paper* (1999).

[13] See research papers published by the UK Department of Trade and Industry on unsafe products.

[14] European Commission, *Proposal for a Directive of the European Parliament and of the Council on general product safety* COM (2000) 139 final, 29 March 2000.

[15] European Parliament Resolution on the strengthening of the impact assessment system, A4-0413/96, OJ 1997 C150/69.