

PATENTS, RESEARCH AND TECHNOLOGY

- *Compatibilities and Conflicts*

- *The patent system and new technologies*
- *The ethical/moral dimensions*
- *Universities and patenting.*

Intellectual property rights (IPR) go back hundreds of years, but are now subject to many new pressures, as patents are being sought for life forms, computer software etc. IPR are also increasingly seen as a weapon of both corporate and national competitiveness, while they also protect the positions of both inventor and university in publicly-funded research. Some innovations have taken the patent system into areas some regard as unethical, leading to calls to expand its 'moral' dimension.

In view of the Parliamentary interest in many of these aspects, POST carried out a review. This note summarises the findings of the full report¹.

THE CURRENT PATENT SYSTEM

The full report reviews the current patent system whereby the state grants a monopoly (for up to 20 years) for exclusive use of an invention in return for the inventor disclosing its details. Others are then able to use the knowledge for research or, subject to obtaining a licence from the proprietor of the patent, for commercial purposes. Thus, the rationale of all patents is to stimulate investment in invention and innovation through a temporary monopoly while ensuring disclosure of technical information.

Within the European Union (EU), inventors have a choice of using national systems such as the UK Patent Office (UKPO), or may apply through the European Patent Office (EPO) which implements the European Patent Convention (EPC). The pros and cons of the different routes are discussed in the full report. Before the establishment of the EPO, the UK Patent Office granted approximately 40,000 patents each year, but this has now declined to 9,530 in 1994 (Figure 1). The full report also describes the main features of the systems in the USA and Japan.

Internationally, the Patent Cooperation Treaty (PCT) has established an international system for simplifying the filing of a patent in any of the 84 contracting states (including UK and the rest of Europe), involving the United Nations World Intellectual Property Organisation (WIPO). The GATT system has also established the

1. "Patents, Research and Technology - Compatibilities and Conflicts" (60pp) is available from Parliamentary Office of Science and Technology (POST), 7 Millbank, London SW1P 3JA (tel 0171-219-2840). Free to Parliamentarians; external price £14.

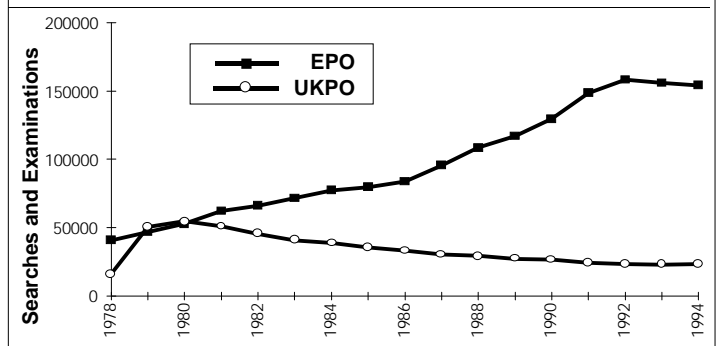


POST
REPORT
SUMMARY

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This is a summary of a 60-page report available from the PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY (extension 2840).

Figure 1 APPLICATIONS TO THE UK AND EUROPEAN PATENT OFFICES



Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement. This establishes minimum universal standards on patents, copyrights etc., and establishes that failure to comply with its provisions could lead to settlement by the World Trade Organisation (WTO) under the GATT rules and may result in trade restrictions against non-compliant countries.

A mechanism for harmonising patent law across the EU is the **Community Patent Convention (CPC)**, which would form a complementary process to the EPC, allowing **unitary** patent protection within all Member States, rather than the current EPC system which generates a 'bundle' of national patents. A patent issued under the CPC would be in effect a 'Euro-patent' automatically protected in all Member States. Although the UK has ratified the Convention, not all Member States (e.g. Spain and Italy) have, so it has not come into force.

PATENT SYSTEM AND NEW TECHNOLOGY

Most of the strains on the patent system arise in the fields of the newer technologies such as biotechnology and computer software, and its interactions in these areas is examined in some detail in the full report.

For **biotechnology**, the report covers:

- patenting of micro-organisms;
- patenting of plants;
- IPR ownership issues between developed and developing nations;
- patenting of animals;
- patenting human material.

Several issues are elucidated in the full report:

- What are the differences between protection of varieties under plant breeder rights and patents?
- What are the religious and ethical aspects to

- patenting animals such as the Harvard Oncomouse?
- Are such considerations relevant to the provisions of the EPC itself with the Article 53(a) prohibition on grounds of public order or morality.
- Should human genes be patentable *per se*?
- Should partial gene sequences whose function is unknown be patentable?
- Should patients share IPR for useful inventions developed from their tissues?
- How broad should biotechnology patents be drawn?
- Is there a need for a EU Directive on patenting biotechnological inventions?

On **Information Technology**, the full report looks at protection issues for a range of software inventions, including the role of copyright, patenting and open publication in software, icons, procedures and function, databases, and protecting intellectual property on the Information 'Superhighway' Infrastructure.

Particular issues are raised over the patent protection of **software**, and how far this should be allowed. Here there are legal differences between the EU and the USA, and practical differences between the UK and EPO, and there is debate within the software industry over the extent to which software patents should be allowed or encouraged. Some argue that the current exclusion for software creates the (erroneous) impression that patents are not available for any invention that includes software, which may discourage new ideas and innovation. The contrary view is that granting too widespread patent monopolies would damage the smaller software companies (typified by many UK software 'houses'), because increasing numbers of sub-routines, icons, etc., would have to be licensed when developing new 'second-generation' software. This debate remains unresolved.

PATENTING AND PUBLIC RESEARCH

One area where patents are having an increasing influence is within the Public Sector Research Base (PSRB), encompassing research by universities, government research establishments and Research Council Institutes. The full report reviews trends in public sector research funding and finds that the effect of Government policy has several potential implications for the role of patenting in public sector research. On the one hand, the substantial decline in the amount of applied research carried out by Government may have reduced the amount of work amenable to patenting in the PSRB. On the other, there has been more emphasis on improving links between the UK's basic scientific research and industry. Other influences at work include:-

- The former British Technology Group (BTG) monopoly right of first refusal was removed in 1985.
- The 1993 White Paper (Realising our Potential) aims support for basic research towards enhancing wealth creation and competitiveness.

- The Technology Foresight Programme, and more recently the Foresight Challenge programmes.
- Collaborative research with the private sector, particularly the LINK initiative.

Recent trends are examined in the full report - for instance there have been painful lessons in some universities in finding out that it was easy to patent too much and too early, so that many applications proved to be unwarranted because their commercial value had not been explored fully or the institutions involved had not realised the potentially high costs involved.

Recent surveys show that the total number of patents held by 34 universities was 510, and the highest number held by any one establishment was 60. Compared with the UKPO's 10,000 patents granted per year, universities are only a very small contributor to demand. These figures are only part of the picture however. Many university-based patents are pursued by exploitation organisations, including BTG, who estimate that it now holds an additional 314 patents on university inventions, bringing the total to 824. Moreover, there are no data on patents held by industrial partners. Overall UK universities, on average, earn income from patents equivalent to 1-2% of their total research expenditure, which can be significant to the university.

The full report examines the question whether the current level of patenting is optimal, too high so that resources are being wasted, or too low so that opportunities to benefit from research are being missed. In this respect, many caution against a 'more patents the better' philosophy, and point to potential tensions between the interests of the partners from industry and academia - particularly over the **priority of disclosure**. Here, industry's priority would be to constrain disclosure of results in order to safeguard any patent rights, whereas academics would wish to publish their results as quickly as possible. If such conflicts are resolved by publishing too early, this could jeopardise any chances of gaining a patent. On the other hand, patent disclosure too early as a concession to an academic's wish to publish, can lead to poorly written patent claims that fail examination, or open the patent to challenges.

In view of such tensions, some argue that protection of university IPR may do more harm than good. They point out that much collaboration is about exploiting intellectual **ability** and this does not necessarily equate to exploiting intellectual property, and thus some regard publicly funded research as being publicly available. This 'open' model remains however a minority view, but with the unpredictable and complex network model of innovation where many different sources of information and insight come together, formal procedures governing who can say what to whom may actually present barriers to innovation. A consensus is emerging however that it is the **exploitation** of research

results that should be the prime objective, and management of IPR is an issue within this. Such exploitation could come about by protecting and licensing intellectual property where appropriate by the PSRB institution itself, or equally by entering into an agreement with BTG or a similar organisation to protect, defend and exploit the IPR on their behalf, or else engage in collaborative research, where the intellectual property rights structure is that which suits best the individual partners' relative capabilities to protect, exploit and defend the IPR.

GENERIC ISSUES

In addition to the technology-specific issues covered in the earlier part of the full report, there are a number of more generic issues on **how well is the patent system coping with new technology?**

The European system employs a number of **exclusions from patentability**. The specific exclusion of computer programs from gaining patent protection has already been mentioned and remains unresolved. There may be **a need to determine whether it is in the interest of UK competitiveness to seek to reduce software and related exclusions**. If a consensus is reached that it is, UK practice could be brought more into line with that of the EPO by amending UK law to avoid the difficulties that currently arise from the interpretation of the exclusion of 'mental acts'. Alternatively, the UK could broaden the debate it has initiated to other Member States of the EPC to assess the case for amending the EPC to reduce or eliminate software exclusions.

The EPC has an exclusion under Article 53a to allow examiners to reject innovations aimed at some antisocial or **immoral purpose**, typified by patents on letter bombs or instruments of torture. Subsequently, developments in the fields of biology have raised ethical questions not envisaged when the Convention was drafted - over the patentability of genetically engineered plants and animals, and of human material (e.g. genes).

The central issue is **whether the patent system should seek to judge the moral and ethical aspects of an invention**. There are basically two sides to this issue - industry points to the existence of laws and moral/ethical frameworks in Society governing behaviour (e.g. regulating the use of animals in science and agriculture) and argues that the patent examination should be confined to technical matters related to proving novelty, inventive step and technical application. Others see the ethical issues raised by biotechnology in general and patenting of animals and human material in particular as central to the public credibility of the patent system, and that ethical considerations should remain an important part of it. **Policy makers are thus faced with a need to satisfy legitimate public concern about the ethics of certain inventions, while ensuring**

that this is done in such a way that it does not inhibit innovation and discourage economic investment. Possible options are explored in the full report.

As mentioned earlier, the European Commission proposes a **Directive on patenting biotechnological inventions** - to clarify perceived ambiguities and to harmonise practice between Member States. In particular, the original directive sought to make explicit patentability of animals/plants. Since the original draft was rejected by the European Parliament in 1995, there have been mixed views on whether it should be re-introduced, but in December 1995, the Commission decided to put forward a revised directive.

There are real questions over to what extent the original circumstances which triggered the Directive still apply. Opponents of the proposed directive argue that:

- the need is much reduced relative to earlier years;
- some of the proposals are in any case ill-founded or unnecessary;
- the new proposals will merely serve to generate public opposition to biotechnology in general because of the raised level of debate and disagreement over unrepresentative cases such as the Harvard Oncomouse.

There are however supporters in industry who still see biotechnology patents as requiring clarification and believe the directive offers an opportunity to remove uncertainty over the patentability of plants, animals and genes, particularly in the light of recent appeals. Groups opposed for example to animal patents, also welcome the directive as offering more specific protection against unjustified animal suffering and also providing an opportunity to raise again their concerns over the ethical aspects of biotechnology and to develop a social consensus on what should and should not be patentable in a humane society.

Given the ground-breaking nature of a decision to adopt a directive over and above the EPC, many see a **serious responsibility on the Commission to demonstrate a substantial need for the measure** and not just a wish to reverse its earlier defeat by the European Parliament. Many argue that little remains for a Directive to achieve, and that **the complicating effects on the patent regime may not be worth the limited additional clarifications that could emerge**, particularly since the possible 1998 review of the EPC could present a more constructive means of reconciling the debate over biotechnological inventions. **The UK Government view on this issue is still under development.**

Breadth of Claims. A recurrent theme has been the difficulty patent examiners may have in correctly assessing the breadth of claims in new technologies, particularly in biotechnology, where patents have been awarded for any genetic modification of whole species

such as cotton to one company. In this respect, there are differences between the EPC and US and Japanese law and practice which make it more difficult to challenge the breadth of European patents after grant. **This could be remedied if one relevant article of the EPC (Article 84 that “the claims shall... be clear, concise and supported by the description”) were to be allowed to be invoked in opposition.**

International Harmonisation. The primary issues over which much international negotiation has taken place in recent years concern:

First to file versus first to invent. Almost all countries except the USA operate on a first to file basis - i.e. the inventor's priority is established by the application filing date. In contrast, the United States operates the first to invent system, which means that irrespective of the date at which the patent application is lodged, if an applicant can prove that they were the first to invent the discovery, then they assume precedence. This can and does lead to extremely costly and complicated interference proceedings between companies seeking to establish a date of priority, where legally acceptable evidence of laboratory work is crucial. By and large the consensus outside the United States is that first-to-file is the preferred mechanism. However, first-to-invent continues to have support in the USA, particularly among lawyers and smaller 'hi-tech' companies who see the special US system as offering competitive advantage.

The second major issue is whether there should be a **period of grace** - i.e. a period during which disclosure in an academic or other publication would not prejudice a patent application. This rule (which is related to the first-to-invent system) has been responsible for some fairly major differences in patenting policy between the US and the UK, and there is widespread support for allowing a period of grace of six months to one year between the date of publication and the expiry of the opportunity to lodge a patent application.

While there are other differences, any proposal for modifications to international agreements **must deal with the key two issues to be worthwhile**, and this is the basis of UK policy in discussions which continue under the auspices of the World Intellectual Property Organisation (WIPO). Although three years ago there was a widespread optimism about a willingness to compromise on this, currently the prospects of any action involving the USA appear to be low.

Issues Specific to the UK Patent Office. Patent experts point to a number of advantages in maintaining a viable UK patent office, including a much cheaper and swifter route to patenting if UK patents are all that is of interest; an efficient patent search capability; maintaining the UK's historically high level of influence in the interna-

tional patents arena; and providing an alternative to the EPO or, eventually, a route through the CPC. Viability is, of course, dependent on being able to cover the whole field of technology, which the UKPO estimates would require a minimum critical mass of 100 examiners - about 70% of the current size of the office.

Given the strategic advantages of maintaining a national patent office, **there have been attempts to identify ways in which the expertise available at the UKPO can be applied in other areas of UK activity.** The DTI has employed the UKPO to conduct patent searches to identify prior art related to applications under its SMART scheme, where grants are awarded for product development in unique and innovative technologies for small companies. One option would be to examine whether patent office expertise might also inform selection of grant applications in other areas - e.g. LINK programmes or even other fields of research supported by the Research Councils.

IN CONCLUSION

Intellectual property rights have become an increasingly important feature of international competitiveness, and thus attract considerable attention at national, regional (i.e. EU) and global (e.g. GATT) level. The whole field of intellectual property is very broad and complex and this review has only been able to tackle some more focused interactions between patents and copyright, and the advance of new technologies, as well as considering the impact on basic research of the Government's increased emphasis on exploitation of basic research towards the creation of wealth.

Overall, the systems for protecting IPR seem to have coped very well with many of the challenges arising from the new technologies, and the problems identified in this report do not indicate any fundamental weaknesses of the system, but do flag areas where lawmakers and policy makers may well need to intervene in the next few years to 'fine tune' the system. Such interventions may be at national level, or through the European Union or via international agreements ranging from GATT to the Biodiversity Treaty.

In view of the importance of the IPR system to economic competitiveness and its wide-ranging implications for the location of investment between, say, Europe and the United States, many Parliamentarians will have an interest in this issue. In addition IPR relates increasingly to international relations between the developed and developing nations, which may be another source of interest. It is thus hoped that this report will be of assistance to MPs and Peers wishing to participate in the debate over these matters.