THE ROYAL SOCIETY

Keeping science open: the effects of intellectual property policy on the conduct of science

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Contents

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Summary

Intellectual property rights (IPRs) can stimulate innovation by protecting creative work and investment, and by encouraging the ordered exploitation of scientific discoveries for the good of society. Although IPRs can aid the conversion of good science to tangible benefits, the fact that they are monopolies can cause a tension between private profit and public good. Not least, they can hinder the free exchange of ideas and information on which science thrives. We have considered whether there could be improvements in the ways intellectual property law, its interpretation and its use impact on science.

In the last two decades there has been increased emphasis on wealth creation, and on seeking associated IPRs, as a primary policy objective for UK publicly funded research. Nevertheless, we believe that public funding of the UK Science Base should continue to be based on quality, since high quality research is the gateway both to advances in knowledge and to wealth creation based on science. A narrow focus on research most likely to lead directly to IPRs would damage the health of science in the longer term. Moreover, the net income to the Science Base institutions from IPRs coming directly from publicly funded research is unlikely to be a significant fraction of their total. It is therefore important to ensure that intellectual property (IP) policies on protection and exploitation do not have significant negative effects on the direction or the value of Science Base research.

The evidence received during our study indicates that patenting rarely delays publication significantly, but that it can encourage a climate of secrecy that does limit the free flow of ideas and information that are vital for successful science. A desire by funders or research workers in the Science Base to obtain IPRs may also affect the direction of publicly funded research, encouraging short-term, applied research that has merit but is usually better done in industry if a vibrant industrial base exists. The longer-term work on which industry relies may be displaced partially or reduced. The merits of universities actively obtaining IPRs, as opposed to disseminating knowledge and allowing industry to protect its developments, are not well documented and would be worthy of further study in the UK. We also recommend that the government carries out a study to establish the extent to which the present drive in the Science Base to acquire IPRs affects the directions of publicly funded research.

Patents can provide valuable, although sometimes expensive, protection for inventions. They therefore encourage invention and exploitation, but usually limit competition. They can make it impracticable for others to pursue scientific research within the areas claimed, and because inventions cannot be patented if they are already public knowledge, they can encourage a climate of secrecy. This is anathema to many scientists who feel that a free flow of ideas and information is vital for productive research.

Additionally, research by others may be constrained by patents being granted that are inordinately broad in scope – a particular risk in the early stages of development of a field. This is bad for science and bad for society. We regard it as important that patent offices are sensitive to this risk and make certain that patent examiners are properly trained and equipped to ensure that such patents are rigorously and thoroughly examined.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS - see Box 1 in main report) is intended to harmonise IP laws and facilitate world trade. Whether the flexibilities within it are insufficient, or just insufficiently accessed, is a matter of debate, but it is clear that the benefits that it brings to many developing countries may be outweighed by the disadvantages. We recommend that developing countries should not be required to implement tranches of legislation until their level of development is such that the benefits of implementation outweigh the disadvantages.

Scientific journals have been protected by copyright; traditionally, the publisher owned it in exchange for adding substantial value to the manuscripts as received. The publisher charged for the journals, but scientists relied on 'fair dealing' exceptions to reproduce modest amounts of information. New digital storage and delivery technologies have provided opportunities for cheaper delivery, but the publishing community has introduced various technical measures to prevent access. These threaten to prevent fair dealing usage. Furthermore, the exceptions are now being restricted to non-commercial purposes – though the distinction between commercial and non-commercial purpose is often very difficult to make. The fair dealing exceptions are vital for science and we need to redress the balance. Scientists generally desire wide dissemination of their work and they should, wherever possible, be encouraged to publish in low-cost journals that combine liberal access policies with high quality (eg have careful peer review) and guarantee long-term availability.

New database right legislation, initiated in Europe and introduced in the UK in 1998, has been driven by media and commercial interests and is potentially very damaging to scientific research. It rewards the creator of the database rather than the creator of the data, though in science the latter is the more costly contribution. Unlike copyright, database rights effectively protect the data themselves, which cannot be extracted and re-used except under restricted fair dealing arrangements. There is only limited hope of obtaining liberalisation for

scientific research under the current review of the European Union legislation. However, as things stand it is unlikely that the US and Japan will follow the EU approach and thus that the World Intellectual Property Organisation would seek to harmonise that legislation.

A number of our recommendations encourage scientists to ensure that their data remain accessible to others, and encourage funders to ensure that databases are available that allow free or cheap access to, and manipulation of, data. These databases must be well maintained and of high quality, for example, by indicating the provenance of the data.

The legislation in all three main areas of IPRs relevant to this study - patents, copyright and database right - is very complex, decisions being difficult because they are context-dependent. We believe that it is particularly important that those who use databases to a significant extent ensure that they have a good knowledge of the opportunities and the risks, and their rights and responsibilities.

There are some overarching aspects of IP law that are as relevant today as they have ever been. One is that the law does, by its nature, confer exclusive rights on the rightholder in exchange for well-defined rights for society. A good balance provides just sufficient incentive to encourage research and development by potential rightholders but retains a high level of benefit for society.

Advances of technology and commercial forces have led to new IP legislation and case law that unreasonably and unnecessarily restrict freedom to access and to use information. This restriction of the commons in the main IP areas of patents, copyright and database right has changed the balance of rights and hampers scientific endeavour. In the interests of society, that balance must be rectified.

Key recommendations

		Governments and their Patent Offices	Funding Bodies	HE Institutes	Industry	Learned Societies	Scientists	Courts	WIPO
Issues and principles	2.1 IP policy should be formulated to minimise any negative effects on education and the scientific endeavour whether in industry, PSREs or universities. We recommend that organisations involved in research assess the extent to which attention to IP directly or indirectly inhibits the free flow of information internally and externally.	*	*	*	*				
	2.8 Academe should encourage an environment where IP is exploited appropriately and benefits are shared equitably, rather than focusing on who owns the IP. Appropriate ownership may depend on the form of IPR, the conditions and location under which it was generated, and the optimal method of exploitation.		*	*					
	2.9 All IPR owners, when exploiting their rights, should ensure that long-term development and improvement of the technology is maximised and not impeded.		*	*	*		*		
	2.15 The encouragement and funding of research in universities and PSREs should depend on quality rather than on its potential to generate IPRs.	*	*	*	*	*	*		
	2.16 The UK Government should carry out a study to establish the extent to which the present drive to acquire IPRs affects the directions of publicly funded research	*							
Patents	3.19 Governments should further facilitate compulsory licensing and application of competition law in situations where single or multiple patents do, on balance, unreasonably affect use and development of inventions.	*							
	3.23 Governments should consider clarifying and harmonising the existing exemptions for 'private and non-commercial' and 'experimental' use.	*							
	3.26 Governments should make it clear to their respective national and regional patent offices that their primary goal is to examine patent applications appropriately rather than to strive to grant as many patents as possible.	*							
	3.28 Searches by patent examiners should be broad, including the journal and trade literature as well as patents and patent applications, and examiners should consult experts, particularly in developing areas of science, to ensure that their own understanding is extremely high. They should then be able to apply standards themselves that are as demanding in developing areas as they are in established areas of science.	*							
	3.29 Patent offices should take the lead in defining as clearly as practicable a satisfactory, rigorous test for inventive step that is relevant to research today.	*							

		Governments and their Patent Offices	Funding Bodies	HE Institutes	Industry	Learned Societies	Scientists	Courts	WIPO
Patents	3.31 Patent offices should take the lead in defining as clearly as practicable satisfactory, rigorous requirements for identifying and disclosing utility, and in pressing for a statutory requirement for the disclosure of the best mode of practising the invention in the initial application.	*							
	3.33 Patent offices and Courts should apply the criteria for patentability rigorously, in particular the requirements for inventive step and industrial applicability.	*						*	
	3.35 Patent offices and Courts should also ensure that patents are limited to a scope no greater than that justified by the contribution made by the invention.	*						*	
	3.37 Governments should seek cheaper effective methods of dispute resolution.	*							
	3.38 Governments of countries within the EU should actively pursue a system (such as, potentially, a Community Patent) that simplifies application procedures and minimises the need for resolving the same patent dispute in different jurisdictions. Such a system should be quick, as cheap as possible, and should lead to consistent legal decision-making.	*							
	3.39 Universities should explore ways in which information can be freely exchanged in a non novelty-destroying manner and the law should be clarified to ensure that internal disclosure should not in itself be novelty-destroying. European academies and related bodies should continue to explore further options for the form of a grace period, since despite inherent risks, a grace period may sometimes be of particular benefit to academics, lone inventors and SMEs.	*		*		*		*	
	3.44 Developing countries should be allowed not to implement TRIPS until their state of development is such that the stimulating effect on innovation will be worth the costs and restraints inherent in IP systems. It will not necessarily be appropriate to introduce all forms of IPR at the same time.	*							*
	3.45 WIPO should continue its work with governments to provide guidelines for 'informed consent' and 'profit sharing' that can be translated into the different practical situations involved in the exploitation of traditional knowledge for the benefit of the holders of traditional knowledge and of all humankind.	*							*
	3.46 WIPO should continue its initiatives to address the issue of some countries not recognising unwritten knowledge outside their jurisdictions as 'prior art'.	*							*

		Governments and their Patent Offices	Funding Bodies	HE Institutes	Industry	Learned Societies	Scientists	Courts	WIPO
Copyright	4.13 Learned societies should have liberal copyright policies and should make their publications available at as low a cost as is reasonably feasible.					*			
	4.19 The limitation of fair dealing to non-commercial purposes gives rise to uncertainty, is not useful and is complex to operate, and should be renegotiated when the Copyright Directive 2001 is reviewed in 2005.	*							
	4.21 Neither physical means of preventing copying (which is being employed by the entertainment industry), nor contract law, should be applied to inhibit access to scientific information unless it is first demonstrated that fair dealing access for research and private study will be at least as quick, easy and widely applicable as it has been historically for paper copies.	*						*	
	4.22 The scientific community, with the Royal Society in a leading role, should actively contribute to the European Commission's reviews of the Copyright Directive 2001, particularly regarding its effect on education and access to scientific data and information.			*	*	*	*		
	4.23 Scientists should, wherever practicable, publish in journals with liberal access policies.						*		
	4.26 The duration of copyright protection is unnecessarily long for scientific information and will interfere with appropriate archiving activities, and we recommend that the learned societies explore options for its reduction.					*			

		Governments and their Patent Offices	Funding Bodies	HE Institutes	Industry	Learned Societies	Scientists	Courts	WIPO
Databases	5.9 Copyright and database right laws should be changed to prevent the possibility of contract overriding exceptions.	*							
	5.10 The scientific community, with the active participation of the Royal Society, should promptly raise any unresolvable concerns over data access and monopoly rights in the private sector with the Office of Fair Trading			*	*	*			
	5.11 Scientists should ensure that any publicly funded data that are made available to private databases are done so non-exclusively, and that at least one repository of the information is liberal regarding access to and use and manipulation of the data.		*	*			*		
	5.12 The scientific community, with the Royal Society playing its part, should support initiatives to raise awareness within its community of the issues of accessing and using data and transferring rights to data to others.			*	*	*	*		
	5.17 There should be significant Government support for the organisation, publication and maintenance of data that it has funded, which might otherwise be or become inaccessible. Since the cost of scientific information is high, and the value added by proper access is great, it makes no sense to allow the value of publicly funded data to be constrained by limitations to access in private databases. Databases with public funding should be readily accessible, and be either free or the charge merely be the cost of permitting access or of supplying the information.	*							
	5.21 The *sui generis* database right, that prevents extraction and use of the data themselves, is inappropriate for scientific data and should be repealed or substantially amended following the Commission's review of the Database Directive. Failing repeal, scientists and learned societies should gather information on the impact of the Database Directive on the conduct of science, so that they can give sound guidance to their governments at the European Commission's next review of the Directive, likely to be in 2006.	*				*	*		

1 Introduction

1.1 Productive scientific research requires free and rapid flow and exchange of information. The presence or process of securing formal intellectual property rights (IPRs) may restrict this flow, and thus can impede or conflict with the effective development of science.

1.2 Yet IPRs can simultaneously encourage innovation by leading to reward, and permit publication by scientists in industry of information that would otherwise be withheld. IPRs can therefore increase actual information availability, flow and use, and thus the rate of progress of science. Achieving the right balance between the encouragement of innovation and information flow, and the extent to which restrictions need to be inherent in IPRs, is an important issue of public policy. Many believe that the current balance is not optimal, and additionally is eroding the area of common knowledge that is the very foundation of science. We have therefore considered whether there could be improvements in the ways intellectual property law, its interpretation and its use impact on science.

1.3 The terms of reference given to the Working Group by Council were to consider the effects of intellectual property (IP) policy on the conduct of science, and to formulate policy recommendations, taking account of:

- the need to provide recognition and incentives for discovery, invention and exploitation to achieve wealth creation and general benefit;
- the desirability of encouraging competition that stimulates further discovery, invention and exploitation; and
- the needs of current and future users of the creative work and resulting products, in both developed and developing countries, to benefit from such innovation.

1.4 In the Working Group's view, for an IP system to be completely successful it must balance these three principles in a coherent and rational way across all areas of science, taking account of the legitimate concerns of the public. For the purposes of this report we define IP as any creative work or innovation – a non-tangible possession – that can be protected by an IPR, although we recognise that databases and trademarks may be protected even where they lack creativity or innovation. The main types of IPR include patents (for inventions of new and improved products and processes that can be applied industrially), copyright (for example, literary works and computer programs), database right (for assembled information), design (for product appearance and form) and trade marks (for brand identity).

1.5 As science and technology progress, what seem to be new forms of IP appear. These create dilemmas: should they be protectable by IPRs? If so, is that better done using existing forms of rights, or new ones?

1.6 IP laws define how different forms of intellectual property can be protected, and which IPRs an owner can obtain. Although we generally refer to owners of IPRs and users of the protected IP, further distinctions should be borne in mind where these terms occur. There are several groups involved: those who fund the work (such as research), those who create the IP, those who own the IPRs, those who exploit them (by agreement with the owners), competitors who can or wish to make analogous products, those who use the protected products by agreement with the producers or by making use of the exceptions to IP law, and society as a whole. Often some of these entities will be one and the same person. The forms of available IPR vary widely in how they work, how much they cost, how easy (or hard!) they are to obtain and (especially) defend, and how long they last (see www.intellectual-property.gov.uk). In general, they give the owner exclusivity in that others are not allowed to exploit the property – invention, creative work, database or design – without the owner's permission for some defined period of time. IPRs impact on the conduct of science because they provide incentives for invention and development; but they also reduce the freedom of action for others and can draw activity away from worthwhile work that is less likely to generate IPRs.

1.7 IP laws are therefore relevant not only to owners of IP but also to funders, innovators, competitors, consumers and governments – in fact all areas of society – and the inter-relationship can be viewed as a bargain between the rightholder and the state. In exchange for the rightholder getting exclusivity, society gets access to the benefits of goods and services arising from the commercialisation of the innovation or creative work. On balance, the bargain between the rightholder and the state should benefit society. But if the touchstone of value in IP protection is the benefit of society, in this age of globalisation one must ask 'Which society?' The UK, the EU, the world? It is arguable that uses of IP that benefit the people of one part of the world but conspicuously fail to benefit others, or even act to their detriment, are not what the system is supposed to be about.

1.8 The award of an IPR often requires disclosure of the IP itself; the protection afforded the right makes this

possible. In the case of patents this benefits society by publishing ideas that might otherwise have been kept secret, although there can still be significant problems associated with the relatively long period between conception of the idea and publication. Society can also benefit from use of the IP by others, for example by the owner selling or licensing the right. Finally, since most IPRs are time-limited, society may additionally benefit when the right expires or is allowed to lapse by its owner.

1.9 We considered the forms of IPR that are most relevant to the generation of new knowledge and the development of innovations in science: patents, copyright, and database right. (Know-how is important but it is protectable by the laws of contract and confidentiality rather than a government granted right.) Other forms of IPR, such as trademarks, have less direct influence on the practice of science, though, for example, design rights can be relevant to the extent that they relate to technical rather than aesthetic subject matter. We have focused on those areas where improvement is not only desirable, but may be practicable.

1.10 Before producing this report we sought views widely on all aspects of IP, but in particular we asked for concrete examples of where the system affects the progress of science, or does not work to the mutual benefit of (potential) rightholders or society; and ways in which improvements could be achieved. There were 30 responses and we are grateful for the rich diversity of evidence that was provided, often at the cost of significant time for those concerned. The names of the people or institutions that responded are recorded in Appendix A; a glossary of terms is in Appendix B; some of the references that have helped to shape our thinking are in Appendix C.

1.11 IP regimes should not gratuitously impede scientific endeavour. We have assessed current developments in IPRs and the way that they are used to see if there are any dangers to the overall objective of encouraging both scientific research and the ordered exploitation of scientific discoveries for the good of society. Where there are, we draw attention to them, even when we do not have solutions to propose.

2 IPRs and science: some issues and principles

2.1 Most scientific research is carried out by industry, the PSREs (public sector research establishments - taken here to include other organisations such as the NHS (National Health Service)) and universities. IP laws, including case law, affect all three, and the research of each, whether independent or collaborative, is of value to the others. We feel IP policy should aim to maximise benefits for society and so those in each sector should be sensitive to the aspirations and needs of those in the others. What is best for one sector is unlikely to be best overall, and thus unlikely to be best for society. Wherever practicable, IP policy should not lead to restriction of the free flow of information, eg within and between these three sectors. Innovation is essential for economic and social progress and IP plays an important part in achieving these goals; but **we recommend that IP policy is formulated to minimise any negative effects on education and the scientific endeavour whether in industry, PSREs or universities. We recommend that organisations involved in research assess the extent to which attention to IP directly or indirectly inhibits the free flow of information internally and externally.**

2.2 There have been developments in the IP policies of industry. Patenting and licensing policy has addressed, for example, how to share the benefits of inventions with developing countries. In the areas of copyright and database right there has been change due to the recognition of the opportunities and threats of electronic storage and transmission. Nevertheless, generally within industry, attitudes to the need for protection are relatively well established and although, in our view, a major issue is the impact of IP policy on the flow of information, there are obvious commercial constraints on the dissemination of information from industry.

2.3 Within the PSREs and universities, on the other hand, there has been greater change and continuing debate. Should their staff seek protection for IP, to help achieve benefits from the research by exploitation, or simply to obtain revenue; or should inventions and other creative work be made available for others to develop without hindrance? The policy in the NHS is clear: although protection of IP is encouraged, the primary objective is not to generate revenue but directly to facilitate improved patient care (Cornish et al 2003). We studied the effect of IP policy on the conduct of science as a whole, but with slightly greater emphasis on publicly funded science because that is where recent changes have been felt more generally.

2.4 Our work has built on the major study by a Working Party, chaired by Professor W R Cornish QC FBA, appointed by the National Academies Policy Advisory Group NAPAG. NAPAG is derived from the four Academies: the British Academy, the Conference of Medical Royal Colleges (now the Academy of Medical Sciences), the Royal Academy of Engineering and the Royal Society. The study, hereafter 'the NAPAG report', was entitled 'Intellectual Property and the Academic Community' and was published in March 1995 (NAPAG 1995).

2.5 The NAPAG report discussed the rapid growth in interest in IPRs in universities, outlined the requirements to obtain patents and other forms of intellectual property and drew attention to the effects of lax standards. It recognised the implications of the rapid advances and increasing uptake of electronic technology for IP in computer science, copyright and databases. It noted the potential impact on developing countries of the then recent TRIPS Agreement (see Box 1).

Box 1: TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was formulated in the Uruguay Round of trade negotiations, completed in 1994, to be administered by the World Trade Organisation (WTO). The aim in developing TRIPS was to reduce the disparity in the way in which IPRs are protected around the world by providing an internationally agreed framework of trade rules. A systematic process for settling trade disputes was also set out. All members of the WTO have to comply with TRIPS – as of 1 January 2002, there were 144 Members of the WTO, accounting for over 90% of the world's trade. A body known as the 'Council for TRIPS' monitors the operation of TRIPS and governments' compliance with it.

The full text of TRIPS can be found at http://www.wto.org/english/docs_e/legal_e/legal_e.htm - TRIPs

2.6 In many areas the situation has changed sufficiently little that its conclusions remain valid. In other areas, although change has occurred, the NAPAG report was sufficiently prescient for its comments to be valid today.

2.7 Areas where there have been greatest changes include patents involving genetic sequences – some patents in the US, in particular, having very broad scope (paragraphs 3.12-3.23). Another clear area is in software (paragraphs 3.6-3.9). The ways in which IPRs affect the lives of those in developing countries is another area of heated debate. The recent copyright and database legislation in Europe is in large part a response to the rapid developments in electronic storage and transmission of information. The legislation has been driven by commercial interests unrelated to science and is likely to have significant – and detrimental – effects on science.

2.8 In 1995 patenting and exploitation were key issues – a field of rapid change both for universities and for industry's interaction with academe. There has been much effort in those areas and in our view a key issue for publicly funded research today is not so much how to exploit, but whether it is appropriate in a given instance to protect or disseminate information. When IPRs are sought, **we recommend that academe encourages an environment where IP is exploited appropriately and benefits are shared equitably, rather than focusing on who owns the IPR. Appropriate ownership may depend on the form of IPR, the conditions and location under which it was generated, and the optimal method of exploitation.**

2.9 The ways in which copyright and database right are exercised and exploited will be critical to the progress of science in industry and publicly funded institutions. More generally, the ways in which IP is protected and exploited are critically important, and with care the negative effects of exploitation can often be minimised without harm to the exploiter. For example, licences that require sharing of improvements can bring benefit to all parties. **We recommend that all IPR owners, when exploiting their rights, ensure that long-term development and improvement of the technology is maximised and not impeded.**

2.10 We have also benefited from two more recent studies. These are the Nuffield report 'The ethics of patenting DNA' launched on 23 July 2002 (Nuffield 2002), and the report by the Commission on Intellectual Property Rights, 'Integrating Intellectual Property Rights and Development Policy', launched on 12 September 2002 (CIPR 2002). We broadly endorse the conclusions of these thoroughly researched studies and together with the NAPAG report these two reports should be seen as a foundation for our study.

Universities

2.11 A great deal has been said and written in recent years about universities as generators of valuable IP, and about the means appropriate to its exploitation (eg AURIL 2002). Such activities have the potential to impede scientific endeavour and we have attempted to assess whether there are aspects of current university IP regimes that do so. Three key questions are:

1. Does perceived pressure to patent results inhibit free exchange of ideas among academic colleagues?
2. Does IP emphasis put pressure on academics to produce exploitable results as against advances in pure science?
3. Does the application of IP restrict future use of ideas?

2.12 There is no single answer to these questions. In present circumstances many biologists would answer yes to all three. An engineer would regard the second as inapplicable, and would probably agree with the first at most. Most theoretical physicists would regard them all as irrelevant; other sorts of physicists frequently patent their tools, rather than their science.

2.13 **We believe that society should maintain vigilance on these issues,** particularly today in relation to biology where there seems to be a most unhealthy 'gold rush' mentality. Tomorrow, however, the focus could be on nanotechnology or device physics.

2.14 An increased emphasis on universities exploiting IP, especially by taking out patents, is not only a UK phenomenon. It has occurred in particular in North America too. An interesting recent study by an eminent academic from Columbia University (Nelson 2002) points out that American universities had extensive industrial contacts before they took to patenting, following the Bayh-Dole Act, and that the companies they dealt with were very often uninterested in having exclusive rights to anything coming directly from the university. Increased emphasis on patenting, and strengthened Technology Transfer organisations, has not much increased either technology transfer or resultant net income.

2.15 Research is of great value to science and society, and **we recommend that the encouragement and funding of research in universities and PSREs depend on quality rather than on its potential to generate IPRs.** (Clearly these may be linked more strongly in some fields – such as engineering – than in others.) Even a small percentage change in the direction or efficiency of research, potentially caused by the shift toward acquisition of IPRs, is large in real terms. It is remarkable that a change (with the potential for good or harm) in the emphasis of a multi-million pound budget is being carried out with such little social, scientific and economic analysis. Such studies are complex for many reasons, not least that the current systems and recent changes work for and against different vociferous groups and sectors. Study and evaluation must bear in mind the influence of these forces; but the time is ripe for thorough analysis.

2.16 Although there may be no global answers, it is important that bodies controlling funding or exerting other influence do explore in depth such issues as those mentioned in paragraphs 2.13–2.15. **We recommend that the UK Government carries out a study to establish the extent to which the present drive to acquire IPRs affects the directions of publicly funded research.**

3 Patents

Patentability and exclusions from patentability

3.1 The 1995 NAPAG report identified a growing tendency towards pushing the boundaries of patenting out from inventions into areas of knowledge. The evidence we have reviewed appears to confirm that this trend has continued, mainly because of the increased public recognition of the key role patents can play in building corporate value in the 'knowledge economy'. Such developments need to be continuously monitored to ensure that these moves are not detrimental to the way scientists interact and the pace at which science moves forward.

3.2 As the NAPAG report points out, the principle behind most patent laws is that equal protection will be given to all inventions that meet the essential criteria of being new, inventive and capable of being exploited industrially (see Box 2). However, many patent systems, for example those in Europe, go beyond this and specifically exclude from patentability certain categories of technical subject matter. Some of these exclusions reflect a division between basic and applied research, eg the exclusion of discoveries, scientific theories and mathematical methods, whilst others acknowledge a distinction between inventions generally and those concerned with the manipulation of living entities. Into this latter category fall methods of treating and diagnosing humans and animals, plant varieties (these have their own specific IPR system), animal varieties, and essentially biological processes for the production of plants and animals. Another more subjective category is the exclusion of inventions the exploitation of which are perceived as being contrary to 'public order' or morality.

3.3 United States patent law differs from this approach in that there are almost no statutory exclusions from patentability. The US Supreme Court had ruled that laws of nature, phenomena and abstract ideas are unpatentable (Funk Bros Seed Co v Kalo Inoculant Co 1948). However, in its 1980 decision (Diamond v Chakrabarty 1980) it considered that, if the normal statutory criteria of novelty etc were fulfilled, 'anything under the sun that is made by man' was patentable; a view that was later qualified to exclude human beings. This fundamental difference between the US and elsewhere is one reason why industry has sought to extend the limits of patentable subject matter in Europe. It is obviously very attractive for industries having a transatlantic or global reach to have a uniform standard of patentability around the world. Uniformity arguably also creates a level playing field for US and European industries. On the other hand, many in Europe are content with the existing position, see no need for a change in the law and in some cases are concerned about the consequences of moving in the US direction.

3.4 For the foreseeable future it also appears very unlikely that US patent law will be harmonised to conform with the approach taken in Europe. Certainly there appears no likelihood of harmonising in the other direction. One difficulty, as we see it, is the difference in the way patents are often perceived in the two territories. Much rhetoric in the US has tended to regard patents as an almost absolute or natural right for inventors. By contrast, in Europe patents are regarded less as an absolute right than a privilege granted at the discretion of governments in pursuit of economic, social or

Box 2: Patents

Patents provide inventors or those deriving title from them the right to prevent others from making, selling, distributing, importing or using their invention, without licence or authorisation, for a fixed period, normally 20 years from the application date. Patents are subject to an examination by the Patent Office before grant and to the payment of renewal fees thereafter. In return, the applicant for the patent is required to disclose the invention in the patent 'specification' and to define the scope of the patented invention in 'claims'. Patents normally have to relate to technology. There are three further requirements for an invention to be patentable: novelty (normally over anything disclosed publicly anywhere), inventive step or non-obviousness (the invention would not would not have been obvious to a person skilled in the art at the time the application for a patent was filed) and industrial applicability. Patents are limited to the country for which they have been granted. Granted patents can be contested in the Courts or (sometimes) patent offices in validity proceedings or as a defence to an allegation of patent infringement.

[1] Readers unfamiliar with US legislation should understand that the Bayh-Dole Act was directed to making it easier to patent federally funded research, which had heretofore been very difficult indeed.

technological objectives. We believe that it is important for governments in Europe not to lose sight of this approach as they seek to balance pressure from users of the system against the wider views of society.

3.5 It is of particular importance to the scientific community that modifications to these exclusions from patentability do not lead to a greater risk of scientific knowledge being monopolised. We agree with the view of many scientists that pure knowledge about the physical world should not be patentable under any circumstances. That it should be freely available to all is one of the fundamental principles of the culture of science. Only by having knowledge unencumbered by property rights can the scientific community disseminate information and take science forward. In this context we make the observation that in many areas of new science it is often hard to make a distinction between what is an invention on the one hand and a discovery or scientific knowledge on the other. We therefore agree with those who assert that patents have been granted too readily in new areas of technology, and that the requirements for inventive step and industrial applicability should be applied more rigorously.

Computer-implemented inventions and business processes

3.6 Two overlapping issues under review are the patentability of computer programs and methods of doing business. Whilst it has for some years now been possible to obtain patent protection for computer programs in the US, the situation in Europe has been less clear. The European Commission therefore proposed in 2000 a draft Directive on Computer Implemented Inventions (European Commission 2002), with the aim of requiring EU member states to harmonise and codify practices that have in part evolved through legal precedent at the European Patent Office. The effect of this Directive will be to confirm the patentability of computer-implemented inventions when, as is required under European law, a 'technical contribution' is present and the other patentability requirements such as novelty and inventive step are met.

3.7 Such a proposal has not met with unanimous approval. Many in Europe feel that such protection is unnecessary, that the industry has developed successfully without much use of the patent system and that existing copyright protection for computer programs is probably adequate albeit that it protects only the 'form' rather than the 'substance' of the program.

3.8 This diversity of views extends to the scientific community, with many being strong supporters of 'open source' software (see glossary). The term does of course encompass a great range of types of licence, but open source software, such as the Linux operating system, continues the ethos of the early days of computing when programs were often shared freely without thought to potential IPRs. Open source software promotes the scientific endeavour and has been particularly valuable in areas such as biomedical research. Significantly, it is also making considerable inroads into the commercial arena. Although certain vendors are vigorously opposed to it, many are building lucrative businesses around it: some provide documentation and support, while others are adopting open source software for core products.

3.9 The success of the open source software movement indicates that a high rate of innovation can occur in the computer program industry without recourse to patenting. Nevertheless the practice of the European Patent Office has developed to allow computer-implemented inventions to be patented if they meet the usual requirements for patentability, including the requirement for technical contribution. We do not find the argument that Europe should follow the US practice of favouring patents for computer programs in itself compelling. We do, however, support moves to clarify this area and to harmonise the law and practice on patenting computer-implemented inventions in Europe as much as possible, and to make the scientific community and the software industry better aware of the issues involved. However, we would be deeply concerned if the outcome of such harmonisation was a regime under which patentees could obtain protection out of all proportion to the technical contribution made. Whilst we therefore generally support the European Commission's attempt to bring clarity and simplicity to this area, **we believe that this objective of proportionate reward must guide the thinking of patent offices and governments** as the project moves forward.

3.10 The patenting of 'business methods' is often grouped with that of computer programs, but the issues are somewhat different. Although in Europe methods of doing business are themselves clear statutory exclusions, the 1998 US Court of Appeals for the Federal Circuit Court's decision in the 'State Street Bank' case (State Street Bank & Trust Co v Signature Financial Group 1998) has caused many parts of industry, especially those in the service sector, to embark on a programme of extensive US patenting. In this case law (Primeaux 1999), the State Street Bank had claimed that a patent by

Signature Financial Group Inc was invalid because it was a patent for a business method and because it was a patent for a mathematical algorithm. The Court of Appeal for the Federal Circuit upheld Signature's patent on machines that used a program to pool mutual fund assets, allocating income and expenses. This was because although the machines used algorithms, they produced useful tangible results. This decision has led to pressure for an equivalent possibility in Europe, raising issues such as whether it should be possible to patent traditional business methods when they are computer enabled and what standards of inventiveness should be applied to them.

3.11 Whilst this debate is generally peripheral to the scientific community, we make the following observations. First, we think that there is a real difficulty in applying an objective standard of patentability in this area especially with regard to inventive step. For technologically based inventions the concept of the 'scientific method' and peer review of scientific results means that there is a logical framework within which patent offices can objectively determine whether a threshold level of inventivity has been reached. We believe that this is potentially a much less objective exercise when applied to non-technical innovations. Secondly, there is a real question as to whether the contribution that a new business method brings to society at large justifies the protection conferred by the patent system. We therefore conclude that the current approach in Europe, to maintain the exclusion from patentability of business methods, is the correct one. The reality is, however, that a method of business exhibiting a technical contribution and meeting the other patentability criteria will be patentable.

Patenting in the bioscience field

3.12 The area in which debate about excluded subject matter has been the most vigorous is the biosciences. The patenting of life forms and human tissue not only raises practical and, at least in some people's eyes, moral questions but also has the potential to impact upon the conduct of basic science. Yet nowhere is this debate more critical. Over the next fifty years it is this area of science that probably has the greatest potential to improve living standards in terms of both improved health and access to food. A fair patent system, that meets the needs of industry and academe and is intelligible and rational to the public, will be an important factor in achieving the benefits and encouraging the science.

3.13 When the NAPAG report was published, the European Commission was attempting to harmonise law in this area through a draft Directive on the legal protection of biotechnological inventions. From the very beginning, however, this has been a politically contentious instrument and it remains so. Although the Directive was agreed by the EU member states in 1998 (European Commission 1998), and should have been implemented by 30 July 2000, debate still rages around it. It has been implemented by the UK but by the end of 2002 nine member states had failed to implement the Directive, including those who had unsuccessfully challenged the validity of the Directive before the European Court in 2001.

3.14 Recently, as provided in Article 16(c) of the Directive, the European Commission has completed its first annual report to the European Parliament and the Council on the implications of patent law in the field of biotechnology and genetic engineering (European Commission 2002a). The report concludes that 'the Articles relating to the patentability of plants and animals and the patentability of elements isolated from the human body or otherwise produced, take account of society's concerns and the financing needed for research'. However, the report recognises that the field is developing and therefore recommends that two areas require active on-going consideration: DNA sequences and stem cells.

Patentability issues: DNA sequences

3.15 The first patentability issue is the question of whether or not DNA sequences or partial sequences are eligible for patenting.

3.16 Many have argued for the absolute prohibition of patenting DNA sequences on ethical and moral grounds. We understand and sympathise with these arguments, but as society is becoming more plural and culturally diverse it is becoming more difficult to build consensus on the definition of what is ethical or moral. We do not believe that many scientists would regard the administrative act of patenting a gene to be immoral or unethical in itself, nor that many would regard exploiting such patents or their underlying technology as necessarily unethical, especially where the exploitation led to an improvement in the well-being of others.

3.17 However, patentability considerations do not end with a consideration of whether or not a DNA sequence is or should be excluded subject matter. They also involve an objective determination on whether the isolated sequence itself is novel and inventive over the prior art, as well as industrially

applicable. We concur with the Nuffield report, that technological advances and the existence of large public databases mean that DNA sequences are no longer patentable simply by virtue of being isolated.

3.18 We therefore support the requirement of a significant demonstration of industrial applicability before a patent in this field is allowed (as discussed in more detail in paragraphs 3.29 and 3.30) and also that patents granted should be limited to a scope no greater than that justified by the contribution made by the invention (as discussed in more detail in paragraphs 3.34 and 3.35). The long-term risk of inhibiting an area of science which is still in its infancy is too great to justify speculative protection, even though such a patent might in the short term allow certain innovations to be brought more rapidly to market.

3.19 As we perceive it, the problem is that the monopolistic nature of patents means that there is a risk of their being abused by their owners. This is a risk in all areas of science but when such abuses occur in the biosciences field the outcome may well be an immoral or unethical act. There is widespread concern about Myriad Genetic Inc's monopoly on the diagnosis of mutations in 'breast cancer genes' (Wadman 2002) and the monopoly in diagnostic testing for haemochromatosis (a genetic disorder causing the body to absorb an excessive amount of iron from the diet) (Merz et al 2002), as well as the more general problem of drugs for HIV/AIDS that are not affordable in developing countries. The best way forward is to tackle the abuse rather than to change the patent law. In our opinion, governments, as custodians of the public interest, should closely monitor the activities of patent owners and be prepared to intervene actively with counter-measures where necessary. Compulsory licensing and the provisions of competition law are the obvious tools. Such an approach is completely consistent with the philosophy that a patent is a privilege that must be exercised responsibly. In the long term, such an approach supports and rewards those who are prepared to act responsibly. We also believe that there is scope for governments to work together in this area and for the industry in question to develop and adhere to codes of practice. **We recommend that governments further facilitate compulsory licensing and application of competition law in situations where single or multiple patents do, on balance, unreasonably affect use and development of inventions.**

Patentability issues: stem cells

3.20 The second area highlighted by the European Commission is the patentability of human stem cells and derived cell lines. Research into stem cells is a significant and growing activity that also has great potential for developing technology which can treat many diseases. For this reason we support the possibility of patenting in this area provided that proper account is taken of public concerns. We believe that this can be achieved through applying the same principles as we have discussed above for DNA sequences. Our recommendation in 3.19 is relevant, but it is even more important that rigorous examination procedures are applied to ensure that the exclusions in this area are not further eroded. A good example of the need for more rigorous application of the principles is the recent so-called 'Edinburgh' patent (EP 0695351) which, as granted, had claims arguably embracing the cloning of human beings, but which has since been amended to exclude that possibility.

Research tools

3.21 One particular issue which has been brought to our attention is whether patent protection should be available for DNA sequences which, although having no direct therapeutic application, are valuable research tools for developing, say, a commercially valuable pharmaceutical. Increasingly such tools once patented are being marketed and licenced to industrial and academic researchers. It has been argued that patents on such tools could inhibit future research for various reasons including increased costs, a reluctance to licence generally because of exclusive arrangements and the need to enter into possibly protracted licence negotiations before research starts. The Nuffield report on the patenting of DNA concluded that there was insufficient evidence to decide whether such factors had adversely affected innovation and development in the field but concluded that 'the granting of patents which assert rights over DNA sequences as research tools should be discouraged'. Strengthening that conclusion, it has been asserted that the monopoly patents on research tools – eg the patents on Taq polymerase (USP 4889818), Cre/lox vectors (Sauer 1993) and on Gateway vectors (Walhout et al 2000) - have had severe effects on academic research.

[2] The 'Edinburgh' patent, EP 0695351, entitled 'Isolation, selection and propagation of animal transgenic stem cells', is owned by the University of Edinburgh and Stem Cell Sciences Pty Ltd (Australia). It covers a method of genetically modifying animal stem cells to give them a survival advantage over unwanted differentiated cells (this technology was required to produce 'Dolly the Sheep'). The patent application was filed with the EPO in April 1994 and granted, after examination, in December 1999. At a hearing in July 2002, called due to opposition in the 9-month period after grant, the owner of the patent limited its claims to exclude human and animal embryonic stem cells. The University of Edinburgh stated that it had never intended the scope of the patent to extend to the creation of transgenic human beings. See http://www.european-patent-office.org/news/pressrel/2002_07_24_e.htm

3.22 Research tools are significant enablers of scientific development but DNA-based research tools are at present the result of knowledge and discovery rather than the judicious assembly of components like a spectrometer, or of molecules like many catalysts. Our comments in paragraphs 3.14 to 3.19 apply. In particular, care is needed even when there is a clear inventive step and a significant demonstration of industrial applicability, that patents granted should be limited to a scope no greater than that justified by the contribution made by the invention.

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3.23 Our comments on research tools are of course relevant outside the bioscience field. Also generally relevant is our consideration of the existing exemptions from patent infringement in Europe of 'acts done privately and for non-commercial purposes and 'acts done for experimental purposes' (Community Patent Convention 1975, Art 31 (a), (b)). At present, broadly, people are entitled under the latter exemption to do experiments to establish the scope and application of a patented invention, including experiments to discover an improvement to it. They are not entitled to experiment simply to prepare to duplicate and sell what is already on the market. Between these two extremes there is doubtful ground, and prudent people avoid doubtful ground. It would be conducive to the development of science if the position of scientific work under these exemptions was clearer. A case in point is the difficulties plant breeders face in breeding a non-patent-infringing variety from a patented parent. **We recommend that governments consider clarifying and harmonising the existing exceptions for 'private and non-commercial' and 'experimental' use**.

The application of patentability criteria

3.24 Where an invention does not fall within a category that is excluded from patentability, an applicant will be granted a European patent if the invention claimed is new, industrially applicable and exceeds the threshold level of inventive step. Failure to meet such standards means that the application will be rejected by the Patent Office or, if granted and successfully challenged, revoked by the Courts or the Patent Office. Since patents are monopoly rights that can inhibit the actions of others, especially those actively involved in scientific research, we are clearly very interested in ensuring that these standards are met and not eroded over time. We are also interested in ensuring that there is a consistency of standard across all areas of science so that scientists in no one discipline are disadvantaged. In our opinion these are key issues of interest to scientists everywhere and it is therefore critical that they are addressed fully by all patent offices around the world.

3.25 A number of developments give us cause for concern. First, the numbers of patent applications being filed have increased significantly at all the major patent offices over the last five years. Whilst there are some signs of this falling off as a consequence of the global economic climate and the end of the boom in technology stocks, many patent offices still have a significant backlog of applications to search and examine and conduct searches on.

3.26 The second general concern is that there are trends amongst patent offices to satisfy applicants by granting patent applications, and for governments to see their office's activities as a source of revenue. Such trends carry the risk that the important public interest task of examining patents to a consistent high standard is subordinated to meeting the wishes of applicants for the grant of their patent applications. **We recommend that governments make it clear to their respective national and regional patent offices that their primary goal is to examine patent applications appropriately rather than to strive to grant as many patents as possible.**

3.27 The third general concern is that the problems appear to be greatest in areas where the applications need to be examined the most carefully. There is a view that in many newer areas of science examiners lack skill and experience and do not fully understand the science or have access to all the prior art. This should not be seen simply as a criticism. Often science in these areas is moving fast, and prior art is not to be found in traditional patent office databases. In many instances the applicant will not know all of the prior art either.

3.28 Addressing this problem of expertise, we believe that there should be greater emphasis on training of patent office examiners, and **novelty searches should be broader, including the journal and trade literature as well as patents and patent applications.** There is also potential for patent offices to work more closely with the scientific community to improve standards. Many scientists, especially in academia, have detailed and up-to-date knowledge (often including access to prior art not otherwise easily traceable) and experience in assessing experimental data and the significance of new scientific developments. Efforts should be made to utilise this resource to improve the standards of patenting especially in assessing questions of inventive step. Another spin-off of such initiatives is that patent examiners would become more cognisant of the needs and benefits

of publicly available science, thereby helping to put their work in context. Accordingly, **we recommend that searches by patent examiners be broad, including the journal and trade literature as well as patents and patent applications, and that examiners consult experts, particularly in developing areas of science, to ensure that their own understanding is extremely high. They should then be able to apply standards themselves that are as demanding in developing areas as they are in established areas of science.**

3.29 Inventive step (non-obviousness) and industrial applicability are criteria for patentability that need particular attention. First, we believe that during the patent examining process there needs to be a much more extensive examination of the inventive step criterion, especially where the invention is based less on actual evidence of a significant technical advance than on the allegation that it was 'non-obvious' to some hypothetical skilled person. We foresee that some areas of science will increasingly be done by the brute force of mechanised testing rather than by the traditional creative leap of an individual or team. Without prejudging this issue, **we recommend that patent offices take the lead in defining as clearly as practicable a satisfactory, rigorous test for inventive step that is relevant to research today.**

3.30 Second, in the race to obtain priority of patent protection, there is an increasing tendency to file for patents on new discoveries before a practical application for them has been found and thoroughly proven. Whilst most patent laws have a test for industrial applicability or utility, there is an increasing tendency to try to satisfy this in a general and, at the limit, a speculative way. Such 'prophetic patents' will often contain no practical information about how to apply the knowledge at all, relying on an application being found at a later date. This can lead to much wasted science in trying to prove or disprove an alleged technical effect. More worryingly it means that a scientist proving some new application for the first time can be blocked by a patent that really has brought no technical teaching or practical benefit to the field. We see this as simply an attempt to patent knowledge.

3.31 In many areas these problems arise because patent offices are not rigorous enough in their examination of the usefulness of an invention. We think that patent offices need to do more investigation in this area as part of the examining process, whilst we acknowledge the practical difficulties of doing so. In 1995 the NAPAG report's conclusion was that **a separate utility requirement should be introduced into the European Patent Convention** (EPC 1973) rather than relying on the existing 'susceptible of industrial application' test which appears to be a lesser requirement. This sensible suggestion has not been adopted. The goal can, we suggest, be reached by developing clearer and more stringent guidelines on the existing law and/or sufficiency of disclosure. **One approach would be to build upon the 'specific, substantial and credible' test currently being used by some patent offices,** whilst at the same time acknowledging the difficulties in going too far in some disciplines. We further support the view that applicants in Europe should be required to identify and disclose fully their 'best mode' of practising the invention at the time they file. Such a requirement seems consistent with best traditions of scientific publication. **We recommend that patent offices take the lead in defining as clearly as practicable satisfactory, rigorous requirements for identifying and disclosing utility, and in pressing for a statutory requirement for the disclosure of the best mode of practising the invention in the initial application.**

3.32 Patent offices should collect more data to establish exactly whether there has been a change in standards and whether standards are being applied consistently. To the extent that patent offices are doing this already the results should be more widely available.

3.33 There are, thus, issues about both whether the standards themselves are appropriate, and whether they are being applied rigorously. We are concerned that the general pressures discussed in paragraphs 3.25-3.27, and the specific concerns about inventiveness and utility discussed in 3.28–3.30, may be leading to a lowering of the standards of examination. Granting patents of dubious validity does nobody any good. It lowers public confidence in the work of patent offices and causes problems for industry as it seeks to commercialise technology in the face of 'patent thickets'. For small businesses it can lead to raised expectations about the value of the right they have obtained. For academics and research institutions it makes it very difficult to decide what lines of research they can legitimately pursue. We wish to take the opportunity of this report, on behalf of the scientific community, to remind governments of the critical public interest role patent offices play in examining patent

3 'Best mode' is not currently required under the EPC, although it is in the US, Canada, and in pre-1977 UK law.

applications to a high standard. **We recommend that patent offices and Courts apply the criteria for patentability rigorously, in particular the requirements for inventive step and industrial applicability.**

Scope of patent protection

3.34 Along with the need to grant patents only for significant inventions goes the need to ensure that those that are granted have claims of an appropriate scope. This is clearly an important practical issue as scientists need to be confident that in conducting their work they are not blocked by the patent rights of others. Although this suggests having a simple methodology for interpreting patent claims based solely on their literal wording, there is a recognition in most countries that this may not always be equitable. This has manifested itself in the US as a well-developed 'doctrine of equivalence' and in Europe as the philosophy of balancing 'fair protection' with a 'reasonable degree of certainty' for third parties (Protocol to Article 69, EPC 1973). In the near future, the latter will be amended to allow for the possibility of equivalence whilst in the US the recent 'Festo' decision will now make it in practice difficult for patentees to position the scope of their patent as being narrow before the patent office but later as being broad when trying to enforce it (Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Corp 2002). We are supportive of these developments to the extent that they move towards a position where the scope of claims is determined principally by their literal wording with a small amount of flexibility to encompass close equivalents. However, as has been pointed out to us, consideration does need to be given to the danger of ending up with both a low threshold for patent protection in the first place and a broad approach to interpreting claims in the Court. It is therefore clearly important to look at scope of protection and patentability as two sides of the same public interest equation.

3.35 Of more concern is the practice amongst patent holders to seek a scope of patent protection which is not justified by the contribution their invention made. This trend is worrying to many scientists in that it can lead to healthy competition in research being stifled. We are supportive of the scope of patents being commensurate with the technical contribution they make. For example, there may be an argument for broad protection for an invention that is genuinely pioneering. Beyond this, thought needs to be given to issues such as whether a wide ranging scope should be given to claims on chemical and biological entities or whether such claims should be allowed at all. Consideration could also be given to limiting such claims to the field of application to which the patent is directed. The latter approach in many cases would seem to give the inventor fair reward for his efforts whilst allowing others to take research in the entities forward in other fields. It is our view that most issues of this nature can be addressed by strict application of the patentability and claiming criteria. However we recommend that patent offices and Courts also ensure that patents are limited to a scope no greater than that justified by the contribution made by the invention.

Accessibility of the patent system

3.36 We have received a significant amount of evidence regarding the accessibility of the system, especially with respect to the difficulties of enforcing patents. In fact, a number of submissions highlight this area as being where the greatest problems lie. The evidence shows, and is confirmed by our experience, that particular difficulties are caused by the high cost of pursuing a patent infringement action in the Courts. This is especially the case in the UK and the USA where the costs can be many multiples of, say, those in Germany. At least one submission has characterised the present system, which expends much administrative time and effort on granting patents which many cannot thereafter afford to enforce, as 'absurd', a view with which we have some sympathy.

3.37 Some possible improvements have been suggested to us, especially in the area of compulsory technical arbitration of disputes. This seems one potential way forward but it remains to be seen whether the result is an overall cheaper process. Another possibility is for the Lord Chancellor's department to consider introducing a system similar to that used in continental Europe, which consists mainly of written submissions rather than oral evidence. Whilst some may argue that this could lead to a system of inferior quality, we have seen no evidence that this will inevitably be so. In particular, we are not aware of anything to suggest this is a problem for the rest of Europe. What is clear is that there are many people (actual or potential users of the patent system) who do not want or indeed cannot afford a 'gold standard' system. **We recommend that governments seek cheaper effective methods of dispute resolution.** High costs of dispute resolution are essentially anticompetitive since they discriminate against those with few resources, including academics, lone inventors and SMEs (small and medium-sized enterprises).

3.38 A related point is that the national character of patent rights means that the same patent dispute has to be litigated in different national Courts. Whilst we understand that this is inevitable until

laws are harmonised fully and countries are prepared to accept the judgments of other nations' Courts, it does seem to us incredible in the era of a single EU market that there is neither a unified patent system nor a single forum for resolving EU patent disputes. We believe that member state governments must take more active steps to achieve this through projects such as the Community Patent or harmonising protocols. **We recommend that governments of countries within the EU actively pursue a system (such as, potentially, a Community Patent) that simplifies application procedures and minimises the need for resolving the same patent dispute in different jurisdictions. Such a system should be quick, as cheap as possible, and should lead to consistent legal decision-making.**

Grace period

3.39 The evidence we received on whether useful patenting of academic research had been blocked by lack of a grace period was not clear-cut (see Box 3). Nevertheless lack of a grace period does sometimes trip up individual and SME inventors, and the same may also be true of academic inventors (Royal Society 2002a). **We recommend that universities explore ways in which information can be freely exchanged in a non novelty-destroying manner and that law should be clarified to ensure that internal disclosure should not in itself be novelty-destroying.** Overall we support continuing investigation, eg by DG Research in the European Commission, of the options for an acceptable grace period. Such a system should provide a 'safety net' for inventors rather than be something that is regularly used. Any grace period adds to uncertainty for innovators and carries risks for its users because others may be prompted to patent or, especially, publish analogous inventions. The idea of US-style 'interference' proceedings (see Box 3) in Europe is also something that we believe most scientists would be keen to avoid, if only for reasons of cost. However, **we recommend that European academies and related bodies continue to explore further options for the form of a grace period, since despite inherent risks, a grace period may sometimes be of particular benefit to academics, lone inventors and SMEs.**

Developing countries

3.40 In July 2000 the Royal Society together with six other academies co-authored a report entitled 'Transgenic Plants and World Agriculture' (Royal Society 2000). This report identifies the need to ensure that the potential benefits of genetic modification (GM) technology become available to developing countries to alleviate hunger and enhance food security. Five of its recommendations, pertinent to IPRs, are highlighted here. First, 'where appropriate, farmers must be allowed to save seed for future use (re-use seed) if they wish to do so; publicly funded research should investigate the value and limitations of re-using seed and the results of this research should be made freely available to interested parties'. Second, 'broad intellectual property claims or claims on DNA sequences without a true invention being made, should not be granted because they stifle research and development'. We address this recommendation in the context of recent developments and evidence in paragraphs 3.15-3.35. Third, 'possible inconsistencies amongst international conventions, such as those that pertain to Patent Rights and the Convention on Biological Diversity (CBD) should be identified and clarified'. This is not an issue upon which we have focused but is clearly desirable as a matter of public policy.

3.41 The report on transgenic plants also recommends, fourth, that 'research institutions should enable partnerships amongst industrialised and developing

Box 3: Grace period

To be patentable, inventions must be novel. In most countries novelty is destroyed by any public disclosure by any means (oral or written) anywhere. In some countries, including the US and Japan, such a disclosure can be made without prejudicing a patent application if the patent application is made within 3-12 months of the disclosure. This 3-12 month time is known as a grace period. There are in fact many forms, and potential forms, of grace period. For instance, because the US system is a 'first-to-invent' rather than a 'first-to-file' system, an inventor has the possibility of producing evidence that she/he made the invention before a prior publication of somebody else. This right leads to so-called 'interference' proceedings, challenging an applicant's right to a patent on the grounds that the subject matter had already been invented. If a grace period were introduced in Europe, it would be necessary to agree on its specific characteristics.

countries so that the benefits of GM research, applications and licensing will become much more widely available'. Fifth, that 'an international advisory committee should be created to assess the interests of private companies and developing countries in the generation and use of transgenic plants to benefit the poor – not only to help resolve the intellectual property issues involved, but also to identify areas of common interest and opportunity between private sector and public sector institutions'. Both these recommendations remain valid today.

3.42 The report by the Commission on Intellectual Property Rights (CIPR 2002), set up by the Secretary of State for International Development, references much useful research. We broadly endorse this report's recommendations that relate to our study on IP and science.

3.43 We endorse the importance of ensuring an adequate supply of medicines to developing countries at low prices. Access to such medicines is critical if society is to fight the major pandemics affecting the third world. Poverty is the critical issue but IPRs must not be used to prevent availability of medicines at low prices. A corollary is that developed and developing countries should co-operate in ensuring legal and practical measures to prevent resale in developed countries of low-priced medicines destined for developing countries.

3.44 We endorse the comments in the CIPR report on the costs to developing countries of introducing patent systems, and generally endorse the CIPR's conclusions. Many factors must be taken into account, but with particular reference to the effect of IP on science, many consider TRIPS (see Box 1) to be inflexible. **We recommend that developing countries be allowed not to implement TRIPS until their state of development is such that the stimulating effect on innovation will be worth the costs and restraints inherent in IP systems. It will not necessarily be appropriate to implement all forms of IPR at the same time.**

Traditional knowledge/Existing knowledge

3.45 There is a growing consensus around the need to ensure that traditional knowledge is accorded sufficient respect and worth, as affirmed at the 27th General assembly of ICSU (the International Council for Science) at Rio de Janeiro, 20-28 September 2002. We broadly endorse the comments and conclusions of the CIPR report in this area, including welcoming rules on informed consent and sharing of benefit. **We recommend that the World Intellectual Property Organisation (WIPO) continues its work with governments to provide guidelines for 'informed consent' and 'profit sharing' that can be translated into the different practical situations involved in the exploitation of traditional knowledge for the benefit of the holders of traditional knowledge and of all humankind.**

3.46 Some countries do not recognise an unwritten disclosure to be novelty-destroying if it occurs outside their jurisdiction. This has provided opportunities for firms to obtain US patents, which can disadvantage the original holders and users of such knowledge. We note that a change by the US to recognise as 'prior art' knowledge outside the US, even if not in written form, would help to remove some of the major irritations to developing countries of the patenting of inventions based on traditional knowledge. **We recommend that WIPO continues its initiatives to address the issue of some countries not recognising unwritten knowledge outside their jurisdictions as 'prior art'.**

Implementation of recent revisions of the European Patent Convention

3.47 The UK Patent Office has recently announced a consultation on a proposed Patents Act (Amendments) Bill which will implement changes required by recent revision of the European Patent Convention (EPC 2000), and which takes the opportunity to scrutinise other features of the Patents Act. These features include employee-inventor compensation for patents of outstanding benefit, and post grant re-examination. As many scientists are employees, this issue of compensation is of importance. We have already noted the difficulties of issues involving the validity of patents already granted, and we therefore welcome the opportunity to discuss potential improvements in these areas.

4 Copyright

Introduction

4.1 Copyright grants exclusive rights to creators of original literary, scientific and artistic works, computer programs and (in the EU with overlapping database rights) databases. It protects the form of expression of ideas, but not the ideas, information or concepts expressed, which can be freely available or protected in other ways. Examples of potentially copyright-protected works in the field of science include books, lab notebooks, articles, conference papers, teaching materials and certain databases of information (both electronic and hard copy). The requirement for originality is low – some degree of the author's own work will be sufficient if there is no slavish copying. Copyright in itself does not create a monopoly – there is no infringement if another author independently comes up with an identical work. Infringement is typically by copying the work and/or making an adaptation. Copying need not be exact or whole - it need only be of a substantial part in qualitative terms: if the amount taken is small but nevertheless central to the work, it could still be infringing. The first owner of copyright is the author, but employers generally own the copyright for employees' work done as part of their employment obligations. Authors' 'moral rights' also encourage proper attribution and prevent changes to a work that would prejudice an author's honour or reputation. No formalities are required to claim copyright.

4.2 Copyright is protected internationally, and almost universally, through a series of international treaties, the most important of which are the Berne Convention and TRIPS, to which most countries belong. These conventions define minimum periods and levels of protection that must be available in member countries. They also set out or permit some of the principles of 'fair dealing' that allows use of copyright material in special cases, eg for research, education and library activities. The dealing must comply with the '3-step' test (see Box 4). The fair dealing principles are enacted into national legislation with considerable variations, so that copying which is freely allowed in one country may not be allowed in another. (There are public interest and free speech defences also available, but in practice these add little to the fair dealing principle.) In the UK, the traditional fair dealing provisions in the Copyright Designs and Patents Act (CDPA 1988, the governing UK legislation) which are of most relevance to science, cover dealing with a literary or artistic work for the purposes of research, private study, education or library activities, including review or criticism. It is these fair dealing provisions and their interpretation, and recent erosion, that are of central importance to the scientific community, which has relied widely on them.

4.3 The rationale for copyright is to protect the work of authors and other creative persons, providing an incentive to publish and so disseminate information and ideas for the public good. Copyright potentially rewards those who toil, both for their intellectual effort and their investment, and modern society accepts that reward for effort, innovation and creativity is just, provided that effort or investment is not ephemeral or trivial. This incentive and reward system has generally served the public well; for example, it has recently encouraged massive expansion in the entertainment and software industries. The creation of these copyright-based products is a source of wealth for many countries (particularly in the developed world) and has assisted social and economic development.

4.4 The incentive and reward system has also traditionally worked well in science. It provided appropriate rewards for authors of books and

Box 4: Exceptions to copyright

The Berne Convention and TRIPS - the Agreement on Trade-Related Aspects of Intellectual Property Rights - state the agreed international standards of copyright law. They include exceptions to copyright (sometimes known as 'fair dealing' provisions) as a balance between exclusive use and the social goal of dissemination of information. TRIPS places limits on the availability of exceptions to right to prevent unauthorised use and reproduction. The exception must pass a 3-step test; the use must

- Be confined to special cases;
- Not conflict with normal exploitations of the work;
- Not unreasonably prejudice the legitimate interests of the rightholder.

TRIPS gives member states the power to penalise heavily any member state in contravention of the Berne Convention or TRIPS standards.

textbooks and encouraged the efficient distribution of research results through learned journals. Most traditional scientific publication takes place through articles in journals rather than books. The authors' primary aim is the maximum dissemination of results and research through a prestigious journal, with the rewards coming indirectly through career enhancement, peer recognition, and the satisfaction of prospective public benefit from widespread knowledge of research results. Copyright in journal articles is traditionally assigned to and controlled by the publisher, who takes on the work and costs of refereeing, licensing, printing and distribution. The bargain between author and publisher was therefore equitable.

4.5 The CDPA 1988 brought in licensing schemes in response to the widespread use of the photocopier and consequent loss of revenues to publishers. Under the terms of an agreed general licence, educational and commercial research establishments pay licence fees to collecting agencies such as the Copyright Licensing Agency, which act on behalf of certain publishers for copying outside fair dealing.

4.6 The traditional ownership of copyright by publishers has been increasingly resented by those who employ authors since technically they then need licences to make copies of their employees' published work for most purposes. There is therefore considerable pressure to overcome this requirement; there is an argument that the publisher does not strictly need the copyright but only an appropriate licence to give limited exclusivity to the publication. There are several draft licences, from ALPSP (the Association of Learned and Professional Society Publishers) and AAAS (the American Association for the Advancement of Science), for example, designed to meet this problem. From February 2003 Nature Publishing Group no longer requires authors to sign away their copyright, but only to grant sole licence to publish. Authors are free to reuse their papers in their future printed work and they and their institutions can use their papers in course packs.

4.7 On the other hand, it is clear that the publisher needs some protection against unauthorised copying to safeguard his investment and also to allow future development. For example, the Royal Society (among others) could not have been able to create an electronic database of back issues of its journal if it had not owned the copyright in the individual articles, since the task of obtaining permissions from thousands of authors going back decades would have been virtually impossible. The recent Tasini case in the US highlights the difficulties. Here the US Supreme Court held that the New York Times could not issue electronic versions of articles that had been contracted from freelance authors for the print version, without appropriate permission and (if sought) payment (New York Times Co v Tasini 2001).

4.8 The traditional system is therefore coming under strain. To add to this problem, the last couple of decades have seen changes in technology, an emphasis on exploitation of the academic product and an increase in legal rights provided to rightholders. New technologies and new attitudes to IPRs create both opportunities and threats for science and these developments have combined to upset the balance between user, author and rightholder, as we now discuss.

Changes in technology and communication

4.9 Digital information storage and processing capabilities, digital compression and increased bandwidth coupled with satellite/optical fibre communications have created the capacity for instantaneous and worldwide distribution of text and information. The Grid will accelerate this process and there is a risk that greater access will decrease the ability to check the provenance of IP. Historically, the arrival of printing created pressure for a copyright law, photocopying and telecommunications each revolutionised it and the most recent technologies are having corresponding impacts now.

4.10 These technical changes, together with the increasing cost of traditional publication, have resulted in an explosion in the amount of scientific information on the Internet. An Internet publisher can still add importantly to the value of the publication with peer review, common format, cross-referencing, other quality assurance and maintenance, but the hard work and cost of printing and distribution are no longer necessary. Tempted by the advantages of rapid dissemination and in the face of the apparent disparity in the publishing bargain, the scientific community has turned to other models for the publication of scientific results. One is to use unrefereed e-print servers, as is widely popular in physics. The other is to press traditional journals to offer completely free access after a limited period. Two specific initiatives (the Public Library of Science and the Open Society Institute Initiative), calling on scientists to boycott journals which would not accept this condition, have not been immediately successful but show the way in which grass roots opinion may be moving. The Public Library of Science also recently received some $9M from the Gordon Moore Foundation to establish high profile journals where the copyright

will remain with the authors. Other approaches to facilitate dissemination are used by SPARC (the Scholarly Publishing and Academic Resources Coalition, www.sparceurope.org, supported by SCONUL, the Standing Conference of National and University Libraries (in the UK)), and the Open Archives Initiative.

4.11 In practice, rights on the Internet are often ignored and papers are copied and redistributed, making enforcement difficult for rightholders. They have responded by introducing technical measures such as encryption technology and pay-per-view, by using contract law and good marketing, and by pushing for new legal rights to control their work. Another problem is that documents can become 'living documents' if they are continually being incrementally changed, sometimes making precise attribution and/or ownership issues difficult to resolve. The need for or relevance of copyright law and authors' moral rights in digital publishing has therefore been questioned, although ownership may help maintain provenance, which is vital.

Exploitation of academic copyright

4.12 In copyright the drive to maximise returns on academic output has led some universities to consider changing the basis of ownership of academic copyright. Traditionally the author has always owned copyright but now some universities seek to own copyright of their employees' work. Not only may they now have greater powers of negotiation vis-à-vis publishing houses and reduced photocopy costs, but they are also developing different electronic means of delivering education, eg through sale of distance learning packages and web-based learning. The prime driver is the rise of elaborate e-learning material that may have a large university cash/kind input as well as the authors' own creativity (HEFCE/JISC/SCOP 2003). More importantly than increasing their income, the universities need to cut the costs of licence fee payments and the payments made to the collecting societies such as (in the UK) the Copyright Licensing Agency (see paragraph 4.5). The perceived negotiating gains could again perhaps be achieved by appropriate licensing of rights by universities. A possible downside of the drive to rights ownership is the loss of trust in the relationship between academics and the university. The Association of University Teachers believes that current statutory provisions do not, as they are written, acknowledge the plurality of interests that need to be met when protecting and exploiting IP generated by higher education. To date, contractual arrangements about copyright, exploitation of patents and revenue sharing have usually produced effective and equitable schemes. More could be done to raise the awareness both of individuals and institutions, and of opportunities for dissemination and exploitation of IP, bearing in mind any need to motivate creative people (Keight 2002).

4.13 The learned societies (including the Royal Society) have had to balance the merits of maximising returns and generating revenue from their publications against the desire to provide free access to information and so fulfil their role of serving the scientific and wider community. Ironically, revenues from sale of the journals come partly from the academic libraries, which are ultimately largely funded by the government, as is the research itself. The scientific community has so far largely subcontracted the dissemination of its information out to the commercial sector. An obvious option for the learned societies and the authors of results of government-funded research is to operate and use prestigious publications for which a low surplus is sought; and encourage the same principles nationally and internationally. **We recommend that learned societies have liberal copyright policies and make their publications available at as low a cost as is reasonably feasible.**

4.14 A significant proportion of science is today carried out by collaborative teams. Visits and personal interactions at conferences and seminars break down the barriers between disciplines and countries. The increasing ease of personal and electronic communication, which is facilitated by the Grid, creates tremendous opportunities for science, including e-science. There are also challenges concerning who should own any IPRs, and the management of provenance, as IP is generated by collaborators in real time. If access to the digital libraries is not freely available on comparable terms to all researchers, international collaboration could be reduced. This tension between international collaborations, digital information technology and IP law needs to be solved particularly in the field of global problems such as climate change. Some government organisations have put a price on traditionally free data, eg from meteorology and oceanography, essential for international collaboration, and effectively bar access for those not able to pay for the use. The recent CIPR report (see paragraph 3.42) has noted the problems of access for developing nations and we support their conclusions.

The expansion of IP protection

4.15 The response of copyright owners to the loss of control of their rights with the new technology has been to tighten their grip on the electronic environment. This has been achieved partly by the

increase in strength of IP law and by aggressive enforcement. The entertainment and software industries, with most to lose, have been particularly effective in lobbying nationally and internationally for greater rights to control their content. But scientific libraries have been caught up in their wake. There has been a proliferation of EU Directives to achieve harmonisation across the EU and to provide greater protection for rightholders, all with the goal of preventing unauthorised copying. The UK has implemented all of these diligently. The latest Directive is on the harmonisation of certain aspects of copyright and related rights in the information society, sometimes known as the Copyright Directive 2001 (European Commission 2001). It was required to be formally implemented into UK law by December 2002, but has been delayed. One aim of this Directive is to encourage the development of new services to benefit the market both economically and by increasing the availability of information.

4.16 The Copyright Directive 2001 grants greater rights to rightholders to control the distribution of works electronically. There are general permitted, but not compulsory, fair dealing exemptions allowing reproduction for private (non-commercial) purposes by publicly accessible libraries or archives, and reproduction for the purpose of non-profit scientific research. The Directive also bans the circumvention of technical protection measures (TPMs) and devices that achieve that result. The accompanying Electronic Commerce Directive of 2000 (European Commission 2000), also includes a clause requiring Internet service providers (ISPs) to take down allegedly infringing material following similar legislation in the US and recent moves in that direction in the UK.

4.17 Specifically, exceptions and limitations (commonly known as fair dealing exceptions) proposed for implementation in the UK – which will apply to all copyright works - specify:

- fair dealing for the purposes of research for a non-commercial purpose;
- fair dealing for the purposes of private study;
- fair dealing with a published work for the purpose of criticism and review.

Copyright in a literary, musical, dramatic or artistic work is not infringed by its being copied in the course of instruction, provided that the copying is not by a reprographic process and is by an educational establishment or is for non-commercial purposes.

4.18 Generally, in enacting the legislation into law, the UK government has tried to keep the exemptions similar to those under the CDPA 1988 and to introduce only changes needed to comply with mandatory provisions of the Directive. However, the Royal Society has raised a number of concerns regarding the proposed UK implementing legislation (Royal Society 2002b) and has called for the existing fair dealing exceptions to be maintained as much as possible, for the exceptions to be accessible in practice and for there be clarity in the law so that both users and rightholders fully understand their rights.

4.19 The most apparent change in UK copyright law is the specification that the research must be non-commercial. Protagonists of the change have argued that since all exceptions must comply with the 3-step test (see Box 4) and that much copying in commercial establishments was beyond the limits of the fair dealing exception and subject to licence agreements anyway, the practical effect of the limitation will be minimal. To some extent this may be true. However, the terms of those licence agreements may well be more onerous and the change may lead to more restricted access to copyright material through libraries. Unless licensing schemes or other payments are agreed and made, libraries will be restricted to copying materials for individuals for research for non-commercial purposes. Also, 'non-commercial' research can be intrinsically difficult to define, and many research ventures or collaborations only become commercial subsequently. The Patent Office should use all the flexibility available in the Directive when drafting the UK law to maximise the research deemed 'non-commercial'. **We believe that the limitation of fair dealing to non-commercial purposes gives rise to uncertainty, is not useful and is complex to operate, and we recommend that it be renegotiated when the Copyright Directive 2001 is reviewed in 2005.**

4.20 The exception in the Copyright Directive refers to 'illustration for teaching or scientific research' and concerns have been expressed about the meaning of 'illustration for scientific research' and its potential restriction for science. There is no such limitation in implementing the UK legislation on copyright (although there is on databases – see Databases section) but the terms of the Directive would ultimately take precedence in any dispute.

4.21 In practice most journals are provided online on contractual terms and accessed by an electronic signal from a user. It is important to ensure that contract terms and/or technology cannot be used to frustrate the fair dealing exceptions. Most specialists in this field believe that the only way to protect against unauthorised usage involves employing special hardware. The hardware protection that is

likely to come into use is basically designed for the benefit of the entertainment media industry but could also be used by journal and database publishers. However, the protection is likely to block the fair dealing exceptions on which scientists rely heavily, since these are of no interest to the entertainment industry. In anticipation of this, the UK implementation provides for a complaint procedure to the Secretary of State if an 'effective technological measure' prevents a person from benefiting from the fair dealing exemptions. The Secretary of State will publish details of the complaint procedure. This procedure does not apply to 'on-demand' services, however, which are meant to be time-limited services such as films. There are unresolved issues over the definition of on-demand that will hopefully be clarified on implementation. There are also aspects of the complaint arrangements that are unsatisfactory; for example, if there is no satisfactory redress for the complainant, she/he still has to go Court, which is an unrealistic option. The recitals to the Directive make clear that the fair dealing exemptions should still apply to non-interactive forms of online use such as journals even where such services are governed by contractual arrangements. However, as discussed in the Databases section (paragraphs 5.7-5.9), contract law remains able to override fair dealing exemptions. Neither Irish law (see www.ucc.ie/ucc/depts/law/irlii/statutes/2000_28.htm) nor a proposed Australian law (see http://www.law.gov.au/clrc/, Past Inquiries, Copyright and Contract), permit a licence to remove a user's right to enjoy exceptions to copyright provided under the law. These examples should be considered when framing new copyright and database laws (see paragraph 5.9). **We recommend that neither physical means of preventing copying (which is being employed by the entertainment industry), nor contract law, be applied to inhibit access to scientific information unless it is first demonstrated that fair dealing access for research and private study will be at least as quick, easy and widely applicable as it has been historically for paper copies.**

4.22 The scientific community relies heavily on the fair dealing provisions of the copyright legislation for its normal method of working. It is important that the traditional balance is maintained in the face of the tightening of IP laws designed to meet the challenges of the new technologies. **We recommend that the scientific community, with the Royal Society in a leading role, actively contributes to the European Commission's reviews of the Copyright Directive 2001, particularly regarding its effect on education and access to scientific data and information.**

4.23 Some pressure groups (such as the Campaign for Digital Rights) regard the ban on circumvention of technical protection measures as tipping the balance too far in favour of rightholders. The measure gives the owners in effect a perpetual right beyond the term of copyright without appropriate and/or effective fair dealing provisions. The shift is in effect to perpetual property rights rather than a social contract. To counterbalance this concern, **we recommend that scientists, wherever practicable, publish in journals with liberal access policies.**

4.24 In practice many copyright owners threaten the Internet Service Provider (ISP) who often takes down the allegedly infringing material rather than face the cost of litigation. The same practice has been used against libraries with the same effect. The copyright owner therefore has an effective remedy without the need to prove infringement copyright. The ISP is usually protected from legal action by the terms and conditions of its contract with its customer. The 'takedown' clause in the E-Commerce Directive will strengthen this practice.

4.25 The proliferation of laws has made copyright extraordinarily complicated. For any law-abiding person trying to avoid infringing copyright, the law is inaccessible. Criminal sanctions have also crept in and these can seem draconian especially when the law is misunderstood by daily users. The Royal Society has suggested that the UK legislation implementing the Copyright Directive should contain such guidance in an Explanatory Memorandum. Certainly the opportunity to publish a consolidated version of the CDPA 1988 and its subordinate legislation would help, as would clear advice and information to users on the UK Patent Office website.

4.26 The length of copyright protection in the EU is now the life of the author plus 70 years. This is much longer than the life of a patent (20 years) and is too great a monopoly for some sectors (eg Ernest Rutherford's work is still in copyright until the end of 2007, 70 years after his death in 1937). The balance is perhaps too much in the copyright owner's favour and more than is necessary to protect the investment. The issue of term is less relevant for science as the active life of much scientific copyright is 10 years or so. It is of more relevance to historical archives of electronic publications, access to which should not be frustrated by unnecessarily long copyright protection. **The duration of copyright protection is unnecessarily long for scientific information and will interfere with appropriate archiving activities, and we recommend that the learned societies explore options for its reduction.**

4.27 The international nature of scientific research makes the need for harmonisation of copyright law more acute. This is particularly relevant for fair dealing laws which are not only different between continents, but may also be different within the EU despite recent attempts to harmonise.

4.28 The Patent Office consultation period for implementation of the Copyright Directive 2001 finished on 31 October 2002. The Royal Society advised the Patent Office of these concerns (Royal Society 2002b). There is provision for a European Commission report on the effects of the Directive to be produced by December 2004. The UK Patent Office has noted that it is difficult – as in all IP matters - to obtain quantitative evidence of the economic or other impact of proposed changes. We had the same difficulty for this report. However, the Royal Society strongly believes that these changes will adversely affect scientific research and, as indicated in paragraph 4.22, the Royal Society will monitor the effects of the new law in anticipation of the review of the Directive.

5 Databases

Introduction

5.1 Databases - collections of data organised in a systematic way - play an important role in scientific research. It is an increasing role: for example, developments in the last decade have made databases essential for much biomedical research. Databases are of many kinds. They can be traditional encyclopaedias, books of data or some teaching materials, through to electronic databases available on the Internet. The access to data and the ability to extract and re-utilise those data have always played an important part in the scientific process. As in copyright, digitisation and the potential for instant low-cost global communication have opened up tremendous opportunities for the dissemination and use of scientific and technical databases. There has more recently been a proliferation of both public and private databases, which has started to create tensions between free access and economic models. As always in IP law, it is a question of achieving a balance between a sufficient incentive and adequate protection of investment to encourage the creation of new databases which are necessary and useful to researchers, and the rights of scientific users to access those databases on reasonable terms and to advance scientific knowledge.

Database right and copyright

5.2 A database was traditionally protected under UK copyright law as a compilation, a form of literary work, if the usual requirements (eg originality) were met. Protection for databases was not consistent across Europe; so the EU Directive on the legal protection of databases (European Commission 1996) was passed to harmonise EC law and duly implemented by the UK on 1 January 1998. Under the Directive a higher standard of copyright protection has been introduced; a database will be capable of protection by copyright only if, by reason of the selection or arrangement of its contents, it is the author's 'own intellectual creation'.

5.3 The UK regulations introduced a new 'database right' for databases created as a result of substantial investment in obtaining, verifying or presenting their contents, but not requiring any personal 'intellectual creation'. A database is defined as the collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means. Both copyright and database right are available to a database developer, but the database right is theoretically the lesser right as it has a term of 15 years compared to the life-plus-70 years afforded to copyright. But as database right can be renewed by substantial changes such as updating the database, protection can be effectively perpetual.

5.4 Despite protestations to the contrary in the Directive, the *sui generis* ('special type') database right in effect protects the information contained in the database, particularly when there is only one database source. Previously the information was free, in practice, for the scientific community to use. Whilst database right may be necessary to protect investment in stock exchange or horse racing information where the data are relatively easy to collect, only need to be referred to or may be time-sensitive, its application to scientific data is not appropriate. Database right rewards the investor who assembles the data, not the creator of the data. In most situations in science, the costs of obtaining these data exceed by many orders of magnitude the investment in assembling the database.

Fair dealing

5.5 Database right is infringed by the unauthorised extraction and/or re-utilisation of the whole or a substantial part of the database. There are a number of 'fair dealing' exceptions to the right - for research, education and library use, but fair dealing for scientific research is permitted only for a non-commercial purpose, a limitation which has not traditionally existed in the UK law but which is now being introduced across UK copyright and related rights (see paragraph 4.19). The wording of the exemptions is similar to those of the Copyright Directive 2001 and many of the concerns over their scope are therefore the same. These concerns are:

- The limitation to non-commercial research is vague and unhelpful. Basic scientific research is often carried out in collaborative arrangements which can be difficult to classify as either commercial or non-commercial – they may start as basic, and thus on free publication terms, but may provide the commercial funder with a lead down the line. If the basic research has made use of data from a database relying on the research exemption, it may well be the case that the funder will now have to pay a licence fee or, worse, damages for infringement;
- The fair dealing exception under UK law, in line with the EC Directive, permits only extraction and not re-utilisation. Re-utilisation is an essential part

of scientific endeavour, and so this limitation does not address the scientific community's needs. The effects of these limitations since the implementation of the Directive are difficult to assess quantitatively – as are all impacts of IP law – but in our view they will in the longer term, if vigorously enforced, become a serious impediment to scientific research and hence to the national interest; and

- The confusion over the words 'illustration for teaching or research' is the same as for copyright (see paragraph 4.20).

Technical measures and contracts

5.6 Online databases frequently have technical measures (eg encryption devices) to restrict or control access that may override any legal rights, particularly fair dealing rights. The same concerns over technical measures in copyright (see paragraph 4.21) and the changes to be implemented by the Copyright Directive (which apply to many databases as well) are relevant to databases. The usefulness of fair dealing exceptions is therefore again limited.

5.7 Private databases usually provide access on individual contractual terms either by written agreement or a click-on one on the site, which may limit the use made of the data or override the fair dealing exceptions. Some private databases have individual access arrangements. Generally, access for research is permitted but re-use of the data is not permitted and commercial access is by negotiation. There are no 'reach through' rights, that is, attempts by the companies to share in the success of inventions/products made using the data. It is not clear that the attempt to impose such rights would be unlawful, since there are almost no legal restrictions on the terms that can be lawfully imposed on database users. Freedom of contract prevails, and that freedom is constrained only by market forces, awareness, and public opinion.

5.8 It should be noted that the Database Directive explicitly provides that no restrictions can prevent a lawful user of a publicly available database from 'extracting and/or re-utilising insubstantial parts of [the database's] contents, evaluated qualitatively and/or quantitatively, for any purposes whatsoever.' What amounts, qualitatively or quantitatively, to an 'insubstantial' part is an imprecise matter of judgment. The Directive, in its recitals, is quick to say that these activities cannot prejudice the 'legitimate interests' of the rightholder and bans 'repeated and systematic' extractions and re-utilisations that might have that prejudice. Anything much more than the sporadic retrieval of tit-bits can therefore be banned by contract. The limitation to a 'lawful user' is in itself a restriction if this is defined as someone who is a party to the contract. The Directive's restriction on contracting-out is little more than chimerical in cases of scientific research, let alone other instances. While 'extraction for the purposes of illustration for teaching or scientific research' is allowed in another article of the Directive, if the source is indicated and the purpose is non-commercial, that article does not ban contracting-out. An online database can impose restrictions on extraction and re-use in these respects.

5.9 In summary, contract law may override both copyright and database rights, and the fair dealing exceptions. Access may be effectively limited for commercial, or academic research, and restricted to anybody that is able to pay. This gives the rightholder effective control over the data and information beyond their legal entitlement. The Irish and the proposed Australian copyright legislation, which prevent contract from overriding exceptions to copyright (see paragraph 4.21) is relevant here. **We recommend that copyright and database right laws be changed to prevent the possibility of contract overriding exceptions.**

Monopolies

5.10 Of more concern is where the database is the only source of information, particularly if it is commercially run. This may well happen as science becomes more dependent on databases and public funding is squeezed, and was nearly the situation with Celera and the publicly funded Human Genome Project (Sulston & Ferry 2002). As developed further in paragraph 5.17, one way to ensure that information is kept in the public domain is to fund the public collections adequately so that they can compete with the private sector, and prevent a monopoly arising. However, it would be wrong (and indeed hardly possible) to curtail the private sector, and some information might not be easily available without its involvement. It may also be appropriate to introduce a compulsory licensing scheme to ensure reasonable access to a monopoly and to prevent abuse. Where private databases lead to monopolies in essential information, competition law should be able to prevent abuse of the monopoly. **We recommend that the scientific community, with the active participation of the Royal Society, promptly raises any unresolvable concerns over data access and monopoly rights in the private sector with the Office of Fair Trading.**

Use of publicly funded information

5.11 Database owners may charge for access even if some or all of the information is in the public domain or resulted from publicly funded research. The retention of machine-produced genetic sequence data can be seen as an example of procedures that would result in the control of publicly funded data by a private company (Sulston & Ferry 2002, pp 77-78). The company's terms and conditions required their customers to use their software and accordingly it controlled the mode of access to its customers' data, and indeed their analysis. Thus there is the potential for a privately owned monopoly source of publicly funded information, which could result in the analysis incurring unnecessary delay and expense. **We recommend that scientists ensure that any publicly funded data that are made available to private databases are done so non-exclusively, and that at least one repository of the information is liberal regarding access to and use and manipulation of the data.**

5.12 The example in paragraph 5.11 raises the issue of the scientific community's need to understand the role of database rights and contract law in controlling their data. It is possible to negotiate terms for deposit of data (subject to market forces) and/or to publish data in publications that do not purport to control the data. As database rights and large-scale electronic data sets are relatively new to science, most scientists (and even publishers) have not yet come to grips with the possibilities or ramifications. **We recommend that the scientific community, with the Royal Society playing its part, supports initiatives to raise awareness within its community of the issues of accessing and using data and transferring rights to data to others.**

5.13 For example, increasingly valuable data sets are generated that are published as supplementary data attached to journal articles and are also made available through laboratory, departmental websites and/or curated public domain databases. If copyright and database right are transferred to the journal, then data cannot effectively be redistributed except by agreement. It would be unfortunate for all systemic data to be scattered across individual publication websites, rather than being available for collation and re-use. It may be appropriate that researchers and/or institutions either retain primary data database rights/copyright or transfer them to a public domain archive that will only licence them to publishers on the condition that the publishers point to other sites. Such an initiative was adopted by Dspace (www.dspace.org), which MIT and other US universities have established to archive all data from their institutions.

5.14 Databases offer unprecedented opportunities in the field of bioinformatics. The House of Lords Science and Technology Committee recently conducted an inquiry into human genetic databases, recognising the importance and potential of this field in the UK and the significant contribution it will make to the understanding of disease (House of Lords 2001). The importance and profile of the field will increase with the advent of Biobank UK (see Box 5). The House of Lords inquiry concluded that there were IP issues to be resolved: What role should private databases play in the information chain? Should private databases be allowed to charge for information that is in the public domain or publicly funded? Should publicly funded databases charge for access? (We discuss this last point in paragraph 5.16.) For some databases, such as Biobank UK, there are added issues such as the need for informed consent and to maintain the confidentiality of data.

Box 5: Biobank UK

Biobank UK is a collaborative project between The Wellcome Trust, the Medical Research Council and the Department of Health, to establish a genetic databank of approximately 500,000 volunteers to be studied over 10 years. The databank will monitor medical and lifestyle information and provide data for the study of the interaction between genetic and environmental factors in disease. The project will be run by a private company and overseen by an independent body, but the precise details of the arrangements will be determined over the next 18 months.

The databank is publicly funded but commercial companies will develop drugs using the data. The study raises a number of questions relating to access to the results and commercial exploitation: should public benefit flow from the database? Should charges be made for access? Is charging cost effective anyway? Should the same terms apply for all researchers? Not all these issues involve IP. However, Biobank UK is an opportunity to show that a public database can be set up to maximise public benefit.

For more information visit http://www.ukbiobank.ac.uk/

5.15 An important early example of a publicly funded genetic database is the EMBL Data Library at the European Bioinformatics Institute situated on the Wellcome Trust Genome Campus outside Cambridge. This is a European funded depository of nucleic acid sequence data, which originated in the early 1980s. All data are deposited and freely available, obviating the need for publication in scientific journals. Despite today's climate of ownership of data and focus on economic return, some collaborations are still occurring – eg the ArrayExpress and GEO databases for microarray data (Nature 2002).

5.16 We are very concerned that publicly funded databases can be transferred to private ownership, and subsequently result in unsatisfactory access. For example, the Sequence Variation Database, which is publicly funded, is currently in danger of ending up in private hands and subject to licence. Data on SNPs (single nucleotide polymorphisms) are being collated in both the public and private domain and there is the risk that public funding is therefore seen as unnecessary. A clear example of how detrimental changes can be comes from Proteome Inc Academics collaborated closely with this small company in Massachusetts and in return received free access to the databases. However, Proteome Inc was bought by Incyte Genomics Inc and free academic access to the databases, the quality of which had been greatly improved by the free collaboration of the academic community, was cut off (Abbott, 2002). **It is clearly important that there is long-term commitment to high quality publicly funded databases, lest data become inaccessible.** We are pleased to note that the Government has committed itself to maintaining funding for access to databases in the Science Budget 2003-04 to 2005-06.

5.17 **We recommend significant Government support for the organisation, publication and maintenance of data that it has funded, which might otherwise be or become inaccessible. Since the cost of scientific information is high, and the value added by proper access is great, it makes no sense to allow the value of publicly funded data to be constrained by limitations to access in private databases.** Experience shows that even when access to such databases is satisfactory the situation can deteriorate. **We recommend that databases with public funding be readily accessible, and be either free or the charge merely be the cost of permitting access or of supplying the information.** It may not be appropriate to recover even the cost of supply, since for non-material transfers the administrative cost of collection normally outweighs the value of at-cost revenue. It is particularly important for science in developing countries that access to databases by their scientists is free.

Enforcement

5.18 Given the breadth of protection, the current state of uncertainty of database right (due to its infancy) and the high cost of litigation in the UK, the threat of enforcement may be enough to cause an alleged infringer to back down. The balance of power is therefore currently in the hands of the rightholders and not the users. We believe that this balance damages science and, in the long term, the economy. The situation may improve as more cases go through the Courts, and the breadth of the right is clarified, but cases to date across the EC have demonstrated variation in interpretation of the right. The only UK case to come before the Courts, British Horse Racing Board Ltd v William Hill Organisation Ltd 2001, gave rightholders very broad protection, but the case is currently before the European Court of Justice to elucidate the meaning of 'extraction', 're-utilisation' and 'part of the contents of the database'; judgment is awaited.

International considerations

5.19 The EC is practically alone in the world in extending such strong protection to databases. The USA in particular has, despite industry pressure, so far resisted this form of protection and continues to make available publicly funded scientific information on both electronic and manual databases as a matter of principle. The NIH (US National Institutes of Health) now spends tens of millions of dollars maintaining publicly open databases. For example, they recently bought the European database SwissProt and put it back into the public domain, removing charging to companies. Databases in the US are not protected except to the extent that an original selection or arrangement may be the subject of copyright. An 'uncreative' database such as a 'white pages' telephone directory is thus unprotected there, but a 'yellow pages' business directory may have the creative selection or arrangement of entries protected. WIPO attempted to negotiate an international treaty on databases in 1996 but has currently shelved this idea. However, given the lack of reciprocity which the European legislation enables it is possible that access to important American sources of information might be curtailed for European scientists and, indeed, for those in developing countries. This would be harmful to science in many nations, and is clearly against the long-term national interest.

5.20 Attempts particularly in Europe to limit free access to publicly funded databases in meteorology and oceanography have led to moves internationally to restore the traditional open access. The Inter-Governmental Oceanographic Commission of UNESCO (United Nations Educational, Scientific and Cultural Organisation) states in its recently revised draft data access policy: 'Member states shall provide timely free and unrestricted access to all data, associated metadata and products, generated under the auspices of IOC programmes'. This is more open than the current situation within the World Meteorological Organisation, although there are signs that this body is also rethinking its position in favour of the full and open exchange of data.

Commonalities

5.21 Many of our concerns over copyright are common to database right, but with databases the concerns are more acute given their fundamental role in scientific research. We think that the current law harms science and ultimately the economy of science-based industry, including those of developing countries, and should be changed. There is currently a study under way by the European Commission on the impact of the Database Directive and the Royal Society has submitted observations similar to those above. As expressed before (Royal Society 2002b) **the *sui generis* database right, that prevents extraction and use of the data themselves, is inappropriate for scientific data and we recommend that it be repealed or substantially amended following the Commission's review of the Database Directive. Failing repeal, we recommend that scientists and learned societies gather information on the impact of the Database Directive on the conduct of science, so that they can give sound guidance to their governments at the European Commission's next review of the Directive, likely to be in 2006.**

6 Conclusions

6.1 Developments in the knowledge economy are being driven by science, and in some ways are being facilitated, and in other ways hindered, by intellectual property rights (IPRs). IPRs are essential for many businesses, protecting investment in research and development and helping to provide the revenues on which science depends. Laws that are drafted thoughtfully and applied wisely can encourage innovation, reward creators and entrepreneurs, and promote economic and social gain without leading to unacceptable monopolies or unduly restricting freedoms.

6.2 International harmonisation of IP laws is a reasonable objective, but the optimal balance between the incentives required to achieve social benefit, and the harm caused by the associated restrictions, is different for different countries, especially between developed and developing countries. There are also compromises within a country: the protections that may be required for the entertainment industry, for example, bear little relation to those necessary for publishers of scientific journals. Where the needs of both groups of providers and users cannot be accommodated, society may have to decide whether health and prosperity depend more on the entertainment industry or on science.

6.3 There has been growing emphasis in universities and public sector research establishments on obtaining revenue from creative work. The Department of Health has made it clear, however, that the primary aim of the National Health Service when obtaining and exploiting IPRs is to promote patient care, rather than to generate revenue. IP protection may aid exploitation, but there is a cost in reduction in the free exchange of ideas. We do not know whether, overall, the disadvantages of widespread patenting of publicly funded research outweigh the benefits, but the potential disadvantages are sufficient to be worth minimising by a carefully thought out IP policy.

6.4 The enormous investment in biotechnology and software puts great pressure on patent offices to grant patent applications, but the new technologies are, as ever, testing the boundaries between discoveries (which are not patentable) and inventions (which are). The distinction is not always clear, particularly in developing areas such as biotechnology; yet scientific progress can be stifled if what are actually discoveries are judged to be patentable. Patents with a broad scope can also stifle follow-on research and development by others. Our key recommendations here reflect the need for patent examiners to take all necessary steps to be up-to-date in order to aid their judgement of novelty and inventiveness, and to be rigorous in applying the criteria for the granting of a patent application.

6.5 Access to information is also increasingly constrained and needs to be improved. Investments by publishers are, for example, protected by copyright law; this worked well when most information was stored on paper. Digital storage and transmission of scientific journals and books can permit cheap world-wide dissemination as desired by scientists and needed by science. Equally, publishers can see technology reducing their ability to get payment for their contribution. Recent copyright legislation has more closely met the needs of the entertainment industry than those of science, and difficulties now face the scientific community which has relied heavily on the 'fair dealing' provisions of the copyright legislation to access information. We believe that learned societies should take a more proactive role in promoting more efficient channels for publication on a not-for-profit basis. Several of our recommendations are designed to improve access to scientific information.

6.6 In an increasing number of areas of science rapid progress now requires the generation, storage and manipulation of large data sets. This phenomenon has been achieved by advances in computing, which aids easy and perfect copying – a real concern for those developing private databases, and a reason for recent copyright and particularly database legislation.

6.7 Some privately owned databases have been readily and cheaply constructed but contain scientific data that have been generated at great public expense. These contrast with other private databases that contain cheap data that are commercial rather than scientific in nature. The legislation does not distinguish adequately between databases meeting normal commercial needs, and those databases for science and education where the users have already paid through their taxes for the discovery of the information. Here payment is not appropriate in all situations and our recommendations address potential solutions.

6.8 We feel strongly that those funding, organising and carrying out publicly funded research should ensure that resulting data are made readily available for use by all. It makes no sense to spend millions of pounds on research, the value of which is substantially

diminished because some tens of thousands of pounds are not earmarked to support public databases that ensure full, easy and cheap or no-cost access to allow science to progress rapidly. Private databases can be valuable, but they almost inevitably make access more difficult and they can lead to undesirable monopolies. Several of our key recommendations point the way to more effective rules and procedures to improve the value to society of both privately and publicly funded databases.

6.9 Monopolies can develop where scientific information is protected by copyright, but are even more likely where a dominant position has been achieved using patents or database rights. Competition law is an overriding remedy, but it is best if restraints are such that it need not be applied.

6.10 In short, although IPRs are needed to stimulate innovation and investment, commercial forces are leading in some areas to legislation and case law that unreasonably and unnecessarily restrict freedom to access and use information and to carry out research. This restriction of the commons by patents, copyright and databases is not in the interests of society and unduly hampers scientific endeavour.

Appendix A Evidence received

Submissions from organisations

ActionAid
AllVoice Computing
Association of British Pharmaceutical Industries (ABPI)
Association for University Research and Industry Links (AURIL)
British Copyright Council
British Society of Plant Breeders Limited
Campaign for Digital Rights
Chartered Institute of Patent Agents
Consumer Research Action and Information Centre (CRAIC), India
GlaxoSmithKline plc
Institute of International Licensing Practitioners
Intellectual Property Institute
National Business Angels Network Ltd
Nuffield Council for Bioethics
Oxfam
Rolls-Royce
Trade Marks Patents and Designs Federation (TMPDF)
United Nations Economic Commission for Europe (UNECE) papers (courtesy Peter Rouse, Rouse & Co. International)
Universities UK

Submissions from individuals

Professor John Adams, University of Sheffield
Professor Michael Brady FRS, Oxford University
Peter Cains, Royal Society Industry Fellow
Lachlan Cranswick, Birkbeck College
Professor Paul David, Stanford University
Professor William Kingston, Trinity College Dublin
Daehwan Koo, University of Sheffield
Dr Margaret Llewelyn, University of Sheffield
Professor Fiona Macmillan, Birkbeck College
Dr Christopher May, University of the West of England
Stephen Powell, Williams Powell

Appendix B Glossary

Cell line	A particular type of cell, grown in culture, that can be reproduced indefinitely.
Compulsory licence	A licence granted under order of a Court or a patent office to use certain types of IPRs (eg patents) in accordance with the statutory provisions of IP law. States include compulsory licence provisions in their laws to prevent abuse of IPRs, through broadening access to technologies and information where it is in the public interest.
Computer-implemented invention	Any invention which involves the use of a computer or computer network, and which has features which rely on a computer program to achieve them.
Copyright	A form of IPR protecting the expression rather than the substance of any creative work or innovation. Traditionally associated with protecting creators' rights in literary, artistic, musical and dramatic works, copyright is today recognised as an important IPR for all published works and computer programs.
Database	A collection of data organised in a systematic way, for example an encyclopaedia or an electronic list of information.
DNA sequence	The exact order of the nucleotides (a type of chemical compound) making up a strand of DNA.
EPC	The European Patent Convention, which governs the European patent system. The EPC has Articles which set out the general principles for the grant of European patents and Rules which govern the procedural details. European Patent Office decisions provide interpretation of the EPC and can also influence the interpretation of UK patents legislation.
E-science	Science carried out through global collaborations enabled by the Internet, which relies on access to large data collections, large scale computing resources and frequently high performance visualisation back to individual user scientists. The powerful infrastructure needed to support e-science will be the Grid.
Fair dealing	An exception to copyright or database right infringement that allows use of protected material in special cases, eg for some research, education and library activities.
The Grid	A broadband network that allows many computers to work on the same problem at the same time. This is particularly useful for scientific or technical problems that require a large amount of computing power or access to large amounts of data. The Grid allows for international cooperation and interactive working on a common problem.
Intellectual property (IP)	Any creative work or invention; a non-tangible possession that can be protected by an intellectual property right.
Intellectual property right (IPR)	Legal protection for intellectual property that usually prevents others from exploiting it without the owner's permission for a set length of time. Examples of IPRs include patents, copyright, databases, designs and trademarks.
Inventive step	One of three legal criteria by which patent applications are assessed. An inventive step is one that would not have been obvious to a person skilled in the art at the time the application for a patent was filed. In the US the same or similar requirement is known as 'non-obviousness'.

Licence	A permission allowing defined use of an IPR that does not give the licencee ownership of it.
Non-obviousness	One of the US criteria by which patents are assessed that requires an invention to involve an insight not obvious to a person knowledgeable about the relevant subject matter (see inventive step).
Novelty	One of three legal criteria by which patent applications are assessed, that requires that the claims in a patent must be totally new, ie for an invention that was previously unknown and unavailable to the public when the patent application is filed.
Open source software	Software that has its source code (computer program) available and that may be licensed for use, copying and distribution with or without modifications.
Patent	A form of IPR that protects innovations of a scientific or technical character. The owner of a patented invention may prevent others practising it commercially for a period of 20 years from filing date, unless otherwise constrained (see 'Compulsory licence'). The technical content of a patent is made available to the public 18 months after its application date.
Research tools	The full range of resources and techniques that scientists use in research.
Rightholder	Owner of an intellectual property right.
Science Base	Research and postgraduate training in universities, colleges and research council facilities. The role of the Science Base is to train and develop skilled people and to generate and transmit knowledge in science and engineering.
Stem cell	A type of cell that has the capacity to renew itself as well as to generate more specialised all types as it multiplies.
Sui generis	Literally 'of its own kind', 'unique'; a new, special case or type. In this report, the database right that protects against the extraction of a qualitatively substantial part of the data itself.
Technical contribution	The contribution an invention makes to the technological field in which it subsists.
Technical Protection Measures (TPMs)	Technologies that allow music, publishing and video companies to secure and protect their content from unauthorised use. TPMs can be configured to allow a limited degree of private copying, where such copying can be a considered 'fair' dealing with the work.
Technology transfer	The transfer or licensing of IP, including know-how about an invention, from one party to another. Included in a range of formal and informal co-operations between technology developers and technology seekers. Technology transfer may or may not include IPRs.
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights; see Box 1.
Utility	One of the US criteria by which patents are assessed that requires that an invention must be useful and industrially applicable to be patentable. In Europe the same or similar requirement is phrased as 'industrial applicability'.
WIPO	World Intellectual Property Organisation. The UN agency, headquartered in Geneva, that administers most IP treaties (apart from TRIPS) and that holds periodic conferences to revise them.

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Useful Websites

Chartered Institute of Patent Agents
http://www.cipa.org.uk/home.html

Commission on Intellectual Property Rights
http://www.iprcommission.org/

Dspace – Durable Digital Depository
http://www.dspace.org/

European Patent Office
http://www.european-patent-office.org/online/

Government-backed home of UK Intellectual Property on the Internet
http://www.intellectual-property.gov.uk/

Nuffield Council on Bioethics
http://www.nuffieldbioethics.org/home/

Oxford Intellectual Property Research Centre
http://www.oiprc.ox.ac.uk/

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http://www.wipo.int

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(102 pages, November 2002, 26/02)

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The health effects of depleted uranium munitions *Summary* (8 page summary of Parts I and II 6/02, March 2002 ISBN 085403 5753)

The health hazards of depleted uranium munitions *Part II* (150 page document 5/02, March 2002 £17.50 ISBN 0 85403 574 5)

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