The Management of Intellectual property and Related Matters

An Introductory Handbook for
R&D Managers and Advisers

in

NHS Trusts and Independent Providers of
NHS Services

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Preface

In September 1994, the Government published a Report of an NHS R&D Task Force, chaired by Professor Anthony Culyer, entitled *Supporting Research & Development in the NHS*. Implementation of this Report (the Culyer Report) has been a major initiative of the R&D Directorate which has resulted in a completely new system for funding R&D from April 1 1998. Many NHS providers (NHS Trusts and independent providers of NHS services) now have their own explicit budget, R&D Support Funding, to carry out R&D. In addition, these providers, and others contracted to do so, undertake R&D as part of the NHS R&D programme. An essential requirement for those providers receiving R&D Support Funding is high quality management of their R&D in order to achieve best value for money for the NHS.

The emphasis placed by the NHS on the management of R&D to obtain value for money from NHS R&D investment has led naturally to the need to manage intellectual property. The NHS Executive is publishing in July 1998 its new policy on the Management of Intellectual Property Rights Arising from NHS R&D (HSC 1998/106). This new policy sits alongside the main responsibility of the NHS to provide patient care. The intention is to identify and to pursue opportunities to generate additional income for the NHS but to do this with minimum NHS investment. The size of the national pool of relevant expertise in the management of intellectual property is small but growing. The thrust of the NHS policy development is to develop its own management awareness and capability but to make full use of this available expertise when needed.

In support of this policy, the NHS Executive is publishing two further documents:

(i) *Handling Inventions and other Intellectual Property: A Guide for NHS Researchers* (the Researchers Guide)

and

(ii) *The Management of Intellectual Property and Related Matters: An Introductory Handbook for R&D Managers and Advisers* (the Handbook).

The Researchers Guide has been prepared by the NHS Executive to introduce NHS researchers to the rather complex question of identifying, protecting and exploiting intellectual property. The term *NHS researchers* refers here to all people carrying out R&D for the NHS using R&D Levy funds. It includes people in NHS Trusts, in primary care independent contractors and voluntary or private sector healthcare providers. The Researchers Guide is to be given wide distribution. It takes the form of a series of commonly-posed questions, together with short answers. By deliberately leaving much unsaid, the objective is to encourage the reader to make contact with the appropriate person whenever the results of their research appear to be of commercial interest. A further intention is to discourage them from even thinking about going it alone in exploiting their work.

The Researchers Guide points researchers initially to the person responsible within their organisation for managing their R&D Support Funding budget. Some NHS Trusts and independent providers of NHS services with significant R&D activity have a full time R&D Manager, in others with smaller activity this position is filled part time. This person will have ultimate responsibility for managing intellectual property, and may retain the necessary day to day management or delegate it to an Adviser. The Adviser could be internal or external to the organisation. If external, the Adviser could be an employee of, for example, another provider of NHS services, of a university technology transfer organisation or an external consulting organisation.

The purpose of this Handbook is to provide a general introduction to the issues involved in the management and exploitation of intellectual property. It has been tailored for use by R&D Managers and Advisers in NHS Trusts, and for their equivalents in independent providers of NHS services particularly in primary care. The Handbook assumes no prior knowledge of intellectual property rights or their exploitation and thus caters for newcomers.

In bringing together into one document basic information on the main issues likely to be confronted, the Handbook is also aimed at the more experienced practitioner. It is not the intention though to provide all the necessary background to turn every R&D Manager or Adviser into a technology transfer professional.

This Handbook draws heavily on the experience gained by UK universities over the last decade or so. The regime being introduced by the NHS to encourage the commercial exploitation of its research has been modelled to a significant extent on the practice universities have developed. Indeed, those Trusts associated with university medical schools will have observed the process in action. In a few instances a Trust and a neighbouring medical school have already established a joint technology transfer activity, an approach with much to commend itself.

For convenience the questions and answers of the Researchers Guide referred to above are reproduced in Chapter 1 together with an explanatory commentary on each. This should enable an R&D Manager or Adviser to amplify the answers in the Researchers Guide if requested to do so.

Later chapters are devoted to a number of topics of relevance, including patenting, technology auditing, licensing, royalty-sharing with inventors, the structure of technology transfer units and research contract negotiation.

Chapter 1

Commentary on 'Handling Inventions and Other Intellectual Property:A Guide for NHS Researchers'

Introduction

1.1 This Handbook is directed to those who have responsibility for managing and advising on intellectual property within an NHS Trust or an independent provider of NHS services which receives R&D Support Funding from the NHS. Each Trust or independent provider has a designated person who manages the R&D Support Funding agreement or contract (called here the R&D Manager) and may appoint a person with delegated responsibility for advising on intellectual property (called here the Adviser). This Handbook, for brevity, is addressed personally to the Adviser, but it applies equally to the R&D Manager who may be a different person.

1.2 Copies of *'Handling Inventions and other Intellectual Property: A Guide for NHS Researchers'* (the Researchers Guide) will have been distributed to researchers supported by NHS R&D funding. The Researchers Guide is intended to give just enough information to alert them to the advantages of exploiting the intellectual property they generate, but yet insufficient to encourage them to go it alone without seeking professional assistance first from you. The Researchers Guide rightly stresses that the management and exploitation of intellectual property is a highly specialised professional activity. Researchers who believe they may have made an invention, or have generated other intellectual property of potential value, are encouraged to seek your help without delay, certainly before publicising their results in any way. You can then work out with them, or point them towards, possible routes to exploitation.

1.3 A typical researcher will probably have many questions, some prompted by those in the Researchers Guide. The present chapter provides the next level of detail which should enable you to answer most of their questions and pass on as much, or as little, of this extra information as you feel is appropriate. For your convenience the format used below first reproduces the pairs of question and answer from the Researchers Guide, and then adds a further commentary on each.

What must I do if I think I may have made an invention?

Do not publish any details about it before taking advice.

Find out who is responsible within your part of the NHS for giving you first line advice on intellectual property matters. The person who will be able to tell you is the person responsible for the R&D Support Funding agreement or contract with your NHS Trust or your independent provider of services to the NHS.

Throughout the rest of this Guide the word 'Adviser' will be used when referring to your contact person and, where appropriate, the word 'provider' to cover all providers of research services to the NHS, including Trusts and independent providers such as general practices.

Your Adviser may be an employee of the provider (e.g. the R&D Manager) or, perhaps, somebody contracted by the provider to give this advice. Once in contact with your Adviser, you will together be able to plan the best way ahead.

If your research has produced software, in addition to protection by copyright it may embody aspects which can be patented. Please check the position with your Adviser.

If you are a newcomer to intellectual property management, reading what follows will provide some useful background information and initial guidance.

1.4 The pressures to publish on those in academic circles, driven mainly by career prospects, are strong. Once however research results which include a description of protectable intellectual property are published, legal protection can no longer be obtained and an opportunity to improve patient care could well be lost. It may be necessary for you constantly to reinforce this message. (An exception concerning particularly US Patents is mentioned later.)

1.5 There is however less of a conflict here than might appear at first sight. It is not appreciated by many researchers that a patent application can be filed by a patent agent in only a week or so if absolutely necessary, thereby avoiding any significant delay in publication. Also, it is not always necessary to disclose full details of the intellectual property in a publication, the results may be sufficient.

1.6 A consistent policy on exploitation of intellectual property should be applied across your provider. In short, all potential inventions and other commercial prospects should be managed using an exploitation mechanism of your provider's choice. Many small providers will seek partnership arrangements with other providers, others will enter into contractual management arrangements with a technology transfer organisation, perhaps a university technology transfer organisation or a commercial specialist organisation. Experience has shown that researchers often grossly underestimate how much work is involved in technology exploitation, and imagine that they can handle this themselves in addition to their other duties. Where this has been tried it has only rarely turned out to be successful.

1.7 The Researchers Guide advises researchers to contact their Adviser. If you take a pro-active stance and contact them in turn, it will also help to generate a climate in which technology exploitation can flourish. It goes without saying that if you are a Trust with an R&D office, part of your job is to promote the use of the Office across the Trust, and to demonstrate its usefulness. This might be done, for example, by arranging presentations, perhaps jointly with your Regional Office and other providers, to groups of research staff, perhaps involving external speakers who have made a success of technology transfer. The NHS Intellectual Property Adviser, who has been appointed by the NHS Executive to coordinate and support the implementation of the policy, will also help to ensure that you have the support and advice you need to achieve success.

1.8 Probably the best way of getting the message across is by mounting a technology audit of all research projects being undertaken. The agreement or contract for R&D Support Funding expects that you will proceed in this way. Researchers would be visited by you, or someone employed for the purpose, to investigate jointly with them what exploitation prospects, if any, are arising from their research. The process of technology auditing is explained more fully in Chapter 3.

1.9 You will doubtless make every effort to establish easy working relationships with the researchers. Experience in universities has indicated that some researchers will want to play a leading role in exploiting their own work. Others will be quite content to play a very minor role, leaving you and your people to get on with the job. Even here, in almost every case, the scientific expertise of the researchers will be an essential input.

1.10 Flexibility will be needed to deal with these different types of approach. Starting off on the right foot is an essential prerequisite to later success. Unless a really harmonious partnership can be forged between the researcher who created the intellectual property and the person responsible for its exploitation, progress will be hampered. Potential licensees are quick to spot any signs of internal discord, and may try to capitalise upon it.

1.11 A detailed point about patenting software needs to be considered, for it is not generally appreciated that this might be possible in certain circumstances. The matter is highly specialised so, if in doubt, do consult a patent agent with an appropriate background.

What is intellectual property?

The novel or previously undescribed tangible output of any intellectual activity can legitimately be described as intellectual property. It has an owner it can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written work, designs and images.

1.12 Under the terms of the convention establishing the World Intellectual Property Organisation (WIPO), Stockholm 1967, intellectual property was defined as:-

' . . . the rights relating to: literary, artistic and scientific works; performances of performing artists, phonographs and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks; service marks and commercial names and designations; and all other rights resulting from intellectual activity in the industrial, scientific, literary and artistic fields.'

What are intellectual property rights?

They define the legally-protected rights which enable owners of items of intellectual property to exert monopoly control over the exploitation of these rights, usually with commercial gain in mind. They give the right to stop others exploiting this property, sometimes for a fixed period, sometimes indefinitely.

1.13 Intellectual property and intellectual property rights are often mistakenly spoken about as if they were one and the same thing. This is not so. The term intellectual property defines the actual invention or other equivalent item, whilst the term intellectual property rights introduces the concept of ownership which bestows on the legal owner the right to sell or otherwise trade in the intellectual property.

1.14 For example, a patent (or an application for a patent) gives the owner of the patent rights the power to exert monopoly control over its commercial exploitation in whatever way the owner decides.

1.15 For the sake of completeness mention should be made here of 'moral rights' although these are unlikely to be important in the context of NHS R&D. The author of a copyright literary or similar work has the moral right to be so identified whenever his or her work is published commercially or performed in public. Moral rights are not assignable and legally remain the property of the author.

What categories of intellectual property are there?

Categories	**Protected by**
Inventions, each embodying a new idea capable of being made or used by industry and involving a non-obvious inventive step. (There are a number of excluded classes,such as mathematical algorithms, methods of treatment of the human or animal body by surgery or therapy, or methods of diagnosis)	*Patent*
Literary and artistic works, films, videos, records, broadcasts and typographical arrangements, including computer software	*Copyright*
Designs and design drawings, mainly of aesthetic objects	*Registered Design Rights*
Engineering components, architectural drawings, etc	*Unregistered Design Rights*
Product brand names, company logos, etc	*Trade Marks*
Trade secrets, background techniques	*Know-how*

1.16 The relevant Acts of Parliament covering intellectual property rights are the *Copyright, Designs and Patents Act 1988* and the *Patent Act 1977* as amended by the former. Also of interest is a Statutory Instrument, *The Patent Rules 1990*. Copies of these can be obtained from Her Majesty's Stationery Office. Scientific progress, particularly in the field of biotechnology and

genetic engineering, has recently resulted in new EU Directives (which apply to the UK) to control the exploitation of discoveries in these fields in a manner which aims to avoid any danger to the public.

1.17 The UK Patent Office has itself published a very useful document, an unofficial consolidation by WIPO of the *Patent Act 1977* as amended by the *Copyright, Designs and Patents Act 1988*. The Patent Office also distributes a great deal of promotional material on patents, registered designs, trade and service marks, much of it free.

1.18 It is suggested that your provider should obtain copies of a selection of the above documents for reference purposes.

1.19 Patents normally remain valid for 20 years from the 'priority date' of first application. Currently in exceptional circumstances, mainly where pharmaceutical products are involved, an extension of 5 years may be granted.

1.20 A Registered Design Right, which normally applies to commercial objects whose appearance is unique and aesthetic, subsists in the first instance for a period of 5 years, renewable on application for up to four further periods of 5 years each.

1.21 Copyright in literary and similar works expires 50 years beyond the author's death. However copyright in computer software expires 50 years from the end of the calendar year in which the work was created. For typographical arrangements this period is reduced to 25 years.

1.22 Unregistered Design Rights normally expire 15 years from the end of the calendar year in which the design drawing was first recorded or the design object made.

1.23 Trade Marks can be maintained indefinitely. *The Trade Marks Act 1994* (which brought UK law into line with the first European Commission Directive on Trade Marks) defines the initial period of registration as 10 years, with renewals possible for successive periods of 10 years.

1.24 Know-how can obviously persist indefinitely, as can trade secrets and general background techniques. It is worth noting here that in spite of the rather intangible nature of know-how, it can indeed be licensed like other items of intellectual property.

Which of these categories are relevant to NHS R&D?

Patents, copyright and know-how, probably in that order of importance, with perhaps a few cases of unregistered design rights.

1.25 Patents are certainly the most relevant in the context of NHS R&D, and this Handbook concentrates on them. In recent years, for example, important patents have arisen in diverse applications in medical diagnostics, in dental materials, in orthopaedics and in anti-cancer drugs. Know-how associated with patented techniques such as those above is also likely to be important.

1.26 Copyright in manuals or books produced by providers could arise where these are produced commercially, perhaps for sale abroad. Computer software will certainly arise from many research projects supported by the NHS, and some of this may well have commercial value.

1.27 Design drawings, for example, of prototype medical instruments developed with NHS R&D Levy funds could also have financial value as unregistered design rights, themselves comprising part of the exploitation package of the instrument in question. It is however rather unlikely that any of these instruments will embody sufficient aesthetic appeal at their prototype stage to warrant seeking a registered design, but the possibility should nevertheless be borne in mind.

1.28 It is rather unlikely that a provider will need to take out trade mark protection in connection with its research. Where a research project leads to a commercial product, it will normally be up to the manufacturer to decide whether trade mark protection of the product should be obtained.

How can protection be achieved for these categories?

External registration is essential in the case of patents. All patents are published and give full details of the invention.

Copyright, including that on computer software, requires no external registration and comes automatically. It is however as well to establish ownership of each item by attaching a statement such as:

© ABC Trust 1998. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.

Know how protection is achieved by its owner by keeping the information secret. The owner can share its secret with others if it chooses to do so.

For unregistered design rights a wise precaution is to mark all drawings of an object over which rights are claimed with the date and the name of the owner of those rights.

1.29 Protection of an invention is by patenting (including in certain circumstances computer software in which innovative ideas are embodied). The other categories which require external registration are registered design rights and trade marks, although neither is likely to figure largely in the work of providers.

1.30 Written documentation, for example, comprising instruction manuals and textbooks, is covered automatically by copyright, including all computer software. Likewise design drawings and prototype models are automatically covered by unregistered design rights.

1.31 It is always a wise precaution to make the legal position explicit by stating on each such item the name of the owner of the copyright and the date on which the work was created. In the case of design drawings each separate sheet should be dated, and should record the name and address of the copyright owner.

Commentary on 'Handling Inventions and Other Intellectual Property:A Guide for NHS Researchers'

Who decides whether to seek protection or allow immediate publication?

The decision would normally be taken jointly by you, the inventor, and your Adviser on behalf of your employer. The final word is likely to rest with your Adviser if he or she is also controller of the relevant budget for patenting. If your invention has come to light through a technology audit of your research, your Adviser may have already formed a view.

1.32 When a researcher with a potential invention makes contact with you, and then perhaps with an agent nominated by you, you will be responsible, not only for advising on the way ahead, but also for taking the final decisions. In practice, though, you should involve the researcher fully in reaching a jointly-agreed decision. Later you will need his or her full co-operation, so establishing an easy working relationship from the outset is essential.

1.33 Very few scientific advances lead directly to commercial prospects, so the first thing to assess is whether the reported innovation has any significant commercial value. This is rarely an easy task, as explained later in this chapter.

1.34 Reference is made to technology auditing in the answer to the above question. This important subject is dealt with fully in Chapter 3.

What aspects are relevant in deciding between protection and publication?

The NHS supports a broad range of R&D. At one end of the spectrum are general activities, such as the study of statistical data from past patient records to establish the effectiveness of a particular treatment, or the relative cost-benefit of alternative therapeutic regimes. Here the promise is of cost savings which, across the whole NHS, could be considerable if dissemination of the findings were followed by their wide-spread adoption. Immediate publication rather than protection is usually the right course of action in such cases, although cost-effectiveness is an area of increasing commercial value and the possibility of dissemination through a commercial partner (with an associated income stream) should not be discounted.

At the other end of the spectrum is the study of diseases at the most fundamental level, for example the genetic basis of inherited conditions. Here the promise is of the discovery of totally new, and hopefully more cost-effective, methods of patient care based on the exploitation of the associated intellectual property. In such cases, if patenting is possible it should be seriously considered. Remember that to

bring the associated product or process to market will require major investment. This will only be entertained by a commercial concern if it holds a patent or has an appropriate licence to exploit the patent.

The assessment of the commercial worth of the invention is of direct relevance in deciding whether or not to apply for a patent. The Adviser and you jointly should try to reach a clear view about what commercial end-product might result. Will it be a pharmaceutical preparation, or a new medical instrument (perhaps incorporating original computer software), or a novel gene therapy addressing a specific inherited disease? Such assessments are far from easy, but nevertheless ought to be attempted. It should be borne in mind that it can often take from 5 to 10 years to develop a new product or process, and longer if clinical trials are involved. Specialist market research might be necessary.

A word of caution. Most inventions do not even recover their cost of patenting. This illustrates how difficult it can be to judge commercial potential, and then to turn it into commercial reality.

If the invention is indeed patentable, but for whatever justifiable reason the decision is taken not to proceed, the wise thing to do is to publish forthwith. This will ensure that no one else can patent it. Otherwise the NHS may later find itself buying a product based on the invention at a price inflated by royalties.

It is sometimes appropriate to disclose details of an invention in confidence before applying for a patent, for example to a company deemed likely to show commercial interest in it. The position should be safeguarded by requiring the company first to sign a proper Non-Disclosure Agreement. This might indeed lead to the company agreeing to meet the cost of patenting as a precursor to a formal collaboration. The wording of such an Agreement is important, you should ask your Adviser for help.

1.35 The pressure from researchers to publish has already been referred to. Such pressure should normally only be resisted for just long enough to allow a patent application to be made, when this is intended. However, you should be aware that it can be dangerous to publish details of an idea covered by a patent application less than 12 months old. This is discussed in more detail in Chapter 2.

1.36 There are however other sorts of intellectual property for which there could be good reasons for delaying indefinitely publication of full details. For example, the source code of computer programs should never normally be disclosed, it being sufficient to supply only the object code to enable the software to be used. Know-how and trade secrets may also come in this category. Patenting is not appropriate where it is desirable to keep the information out of the public domain indefinitely, for if a patent is taken out and maintained its specification will be published by the patent authorities 18 months after its priority date.

1.37 Conversely, there will be cases where publication should be strongly encouraged. This should happen when dissemination, followed by take-up of the findings, is the only way of obtaining benefit from the intellectual property in question. A whole range of paper studies concerning treatment regimes come into this category, and here the existing dissemination mechanisms of the NHS can be used to good effect.

1.38 Just because an innovative idea is capable of being patented, it does not necessarily mean that it should be. The overriding criterion is whether the idea has commercial potential. Admittedly this is often not easy to judge.

1.39 The history of successful technology transfer is characterised by a modest number of 'big winners', a fair proportion of which have been in the health field. Experience has shown that picking 'big winners' needs good judgement but also good luck. Conversely, a number of potential inventions, originally incorrectly assessed as of insufficient value to warrant patenting, went on to become outstanding commercial successes in other hands, and with the originators receiving no reward.

1.40 Many more technology transfer projects, after first recovering their exploitation costs, have produced modest, but nevertheless worthwhile, returns. In general such opportunities are easier to spot.

1.41 Because of the broad range of research topics likely to be studied by your provider, you are likely to take external advice on commercial potential before deciding whether or not to patent. Where details of an invention are to be disclosed to any external person or body, it is essential that a Non-Disclosure Agreement between the provider and the person or body is signed first by both parties. An example of a Non-Disclosure Agreement is given in Appendix 1.1.

1.42 The Non-Disclosure Agreement will define closely what is intended to be disclosed. By signing the Agreement the external body will have accepted an obligation to use the information supplied only for the purpose of assessing the technology, and for no other. If the other party is also to make disclosures, a two-way Agreement should be signed by both parties, binding both to hold confidential the property of the other.

1.43 Some companies may have difficulty in signing a Non-Disclosure Agreement if they too are working in the same area of research. Such a company will point to the conflict which could arise if the information which was disclosed was already in its own possession, having been derived independently from its own research. In such circumstances, if an appropriate Non-Disclosure Agreement cannot be agreed, it is best to seek an alternative source of advice.

1.44 Sometimes discussions between collaborators lead to the need to exchange material such as cell lines, vectors, clones and antigens. It is important that these materials are exchanged under conditions of strict confidentiality that exclude their use for commercial purposes. A Materials Transfer Agreement signed by collaborating parties needs to be in place before any exchange takes place.

1.45 Although one of the criteria for patentability is whether the invention has industrial utility, statistics show that many granted patents never result in a commercial return big enough even to recover their actual costs of patenting.

1.46 A patent agent will give an expert opinion on whether a potential invention is likely to result in a patent being granted, usually having first consulted databases of existing patents searching for damaging 'prior art'. 'Prior art' covers the content of all published patents which could negate the claims of

the potential invention. It should however be borne in mind that there is always a large number of as yet unpublished patent applications in the pipeline. There is no way of determining whether one or more of these describes prior art which will destroy or diminish the value of the invention under consideration.

1.47 In spite of the above rather unhelpful background, it is nevertheless important for the best possible assessment to be made before the decision is taken on whether or not to incur the expense of patenting. The researcher should certainly be a party to the decision. Only when it is concluded that a real commercial product or process is in prospect should patenting action be taken. Chapter 2 deals in detail with the mechanism of patenting. It is the responsibility of your provider, under your R&D Support Funding agreement or contract, to meet the cost of initial patent applications.

1.48 In exceptional circumstances pressure might be exerted by the research team to publish its results immediately. There may then be no alternative but to apply immediately for a patent, even before a proper assessment of commercial prospects has been made. This might be a price to be paid for working in or near an academic environment.

1.49 Not only does an application establish the 'priority date' of the invention (the date the application is filed), but it also in effect buys a year's grace. Since full claims need not be submitted to the Patent Office until just before the first anniversary of the priority date, further assessments of commercial worth can be made during this period, and therefore before the expensive stages of patenting are reached.

When and how should a patent application be made?

Prior publication means that an invention cannot be patented in most countries.

Describing an invention in the scientific literature, or in a conference paper, or in a poster session, or at an exhibition, or on the Internet, or indeed in any formal or informal public meeting (even over coffee), constitutes public disclosure. It is prudent to check with your Adviser before publicising your invention in any way whatsoever.

Researchers, understandably, wish to publish the results of their work without delay, particularly if they are leaders in their field. If absolutely necessary a patent agent can be instructed to prepare and file a patent application within a week. Thus in general there should be little need to delay publication significantly.

If your Adviser agrees that you have made an invention with commercial promise, the probable next step will be to hold a discussion with a patent agent. The patent agent may suggest that a search be conducted of existing databases to see whether your invention has already been patented, or whether there is any damaging 'prior art' contained in claims of other patents which include your idea and which could negate your invention. Remember that patent agents do not usually possess the skills to assess commercial potential. They are normally less able to do so than technology transfer executives, or industrialists from the appropriate market sector.

The cost incurred when a patent agent prepares and submits an application to the UK Patent Office (or to the European Patent Office) will normally be between £1,000 and £3,000. The date on which the application is filed with the Patent Office will become the patent's 'priority date'. This same date will be carried over into all subsequent foreign filings even though they are filed later.

1.50 When a potential invention is brought to your notice, the first thing to determine is whether there has been any public disclosure about it. If not, the next thing to establish is whether a publication is intended, and if so when. If, sadly, publication has taken place, you should still find out whether the publication was made by the inventor, and in particular whether it had been made within the last year. If so, it may still be possible to apply for a US Patent (and patents in Canada, Japan or the Philippines). The procedures to do so are explained below in paragraphs 1.71 and 1.72.

1.51 Assuming there has been no disclosure, it is possible to apply for a patent which, in principle, could eventually be granted in all countries.

1.52 Any suggestion that publication be withheld for any significant length of time may not be welcomed, but there is every reason to request sufficient delay to enable a patent application to be made and sometimes even for a further twelve months after filing the patent application as discussed in Chapter 2. As mentioned earlier, an application can usually be prepared by a patent agent within a week or so where circumstances require, but a cost penalty for rapid turn-round may well be involved.

1.53 Where submission to a scientific journal is intended, the refereeing process will itself take time, meaning that appearance of the article in the journal is unlikely to occur for some months after submission. The delay of a week or two to allow a patent application to be filed should be seen as reasonable in this context.

1.54 Of more immediate concern will be conference papers and poster sessions at conferences, particularly where abstracts have to be submitted first. Given that a paper or poster at a conference or describing the item on the Internet constitutes public disclosure, unless a patent application has already been filed, any chance of obtaining patent cover in most countries will have been completely lost. It should be remembered that it is disclosing the details of a potential patent application which constitutes public disclosure; with care the results without the detail can be published without endangering the application.

1.55 Where a patent has been applied for, and claims filed within a year, the full patent specification will in every case be published by the patent authorities 18 months after the priority date on which the patent application was made. The underlying principle of a patent is that the owner is given monopoly rights on condition the invention is published, thereby giving the world a useful new technology as a platform upon which to build other inventions.

1.56 In exceptional circumstances the invention might be considered so important that it would be best not to patent, but to try to retain the information secret indefinitely, perhaps an impossibly difficult task in an NHS environment. Whilst this is an approach frequently taken by industry, it can rarely be justified elsewhere.

1.57 If you, as Adviser, acting perhaps on the recommendation of a technology transfer agent, decide that a patent is to be applied for then, depending on the complexity of the invention, the cost of preparation and submission of an application to the UK Patent Office (or to the European Patent Office) by a qualified patent agent is likely to be in the region of £1,000 to £3,000. You will need to select a suitable patent agent. Most of the larger firms of patent agent have a number of specialists dealing with different branches of science and technology. It is important that the actual person who prepares the patent application is scientifically qualified with up-to-date knowledge of the subject area of the invention.

1.58 The expense of taking out a patent should be regarded as a risk investment. Remember that, unless a licensee can be found and signed up before the first anniversary of the priority date, there will be much greater expenditure to be faced at the end of the year to meet the costs of the next stage of maintaining the patent particularly if it is filed overseas.

But don't US patent procedures differ?

Yes. Whereas the rest of the world operates a 'first-to-file' system, the USA still adopts a 'first-to-invent' approach. From 1 January 1996 non-US inventors have however been put on the same basis as US inventors, allowing them to 'swear back' to the date the invention was made.

This raises new issues for non-US inventors. When two or more inventors claim to have made an identical invention, the US Patent Office begins 'interference' procedures to ascertain which was the first to make the invention. Written evidence is required from each party. This is usually supplied in the form of the page of the inventor's laboratory notebook which first described the invention, dated and signed by the inventor and by a corroborating independent witness who also confirms in writing on the page that he or she has understood the invention. Furthermore it is necessary for the inventor to demonstrate that he or she has diligently pursued the 'reduction to practice' of the invention. Reduction to practice means completely defining the process by which the invention can be realised.
To maximise the chance of obtaining a US Patent therefore requires inventors to be able to produce written evidence from laboratory notebooks recording the day-to-day progress of their research.

Following best practice, many researchers already keep such a daily record. If and when a potential invention is made, it is important that the page first describing it is dated, signed and counter-signed in the above manner, and likewise all the following pages whilst the invention is being reduced to practice. If there is any dispute regarding the date of the invention, the necessary evidence will then be available.

It is common practice in some laboratories for research notebooks to be counter-signed by the supervisor once every week. The date of the first counter-signature after the invention was recorded in the notebook is likely to be taken as evidence of when the invention was made.

1.59 *The General Agreement on Tariffs and Trade (GATT)* covers *Trade Related Aspects of Intellectual Property (TRIPS)*. One result of recent negotiations on the latter topic was a change in US Patent law which came into effect on 1 January 1996.

1.60 On the grounds of harmonisation it would be convenient if all countries agreed to adopt the same style of patent law, but unfortunately the United States still retains its 'first-to-invent' system rather that adopting the 'first-to-file' system used by the rest of the world. As a concession, however, US Patent Law was changed from that date to be for the first time even-handed to non-US inventors and US inventors alike.

1.61 The relevance of this change concerning non-US inventors is that henceforth, so long as they can produce the necessary evidence, they will no longer be at a disadvantage if a dispute were to arise about the date of the invention which would be officially recognised by the US Patent Office. Previously, if an identical invention had been made simultaneously both in the United States and elsewhere, the date recognised by the US Patent Office for the US version would be the date on which the actual invention was first recorded, whereas for the non-US version the date of filing the patent application (which obviously must be later than the date the actual invention was made) would apply. In this case the US inventor's patent application would dominate. This change in US Patent Law has removed this anomaly.

1.62 If UK inventors are to reap the benefit of this change, they must be in a position to produce evidence of the requisite quality should a dispute arise about who made the invention first. This is obviously of greatest importance in fast-moving fields of which there are many in medical research.

1.63 Researchers supported by your provider should be strongly encouraged to keep proper laboratory notebooks in which they record the results of their research and record any inventions at the end of each working day. Hopefully they already do this in their normal pursuit of best practice in research.

1.64 If a researcher in your provider believes he or she has made an invention on a particular day, it is especially important that the page describing the invention be signed and dated both by the inventor and by a witness who is capable of understanding the invention, and confirms in writing to having done so. The witness must not be a co-inventor.

1.65 Where two or more inventors claim the same invention in their pursuit of a US Patent, the US Patent Office will declare there to be an 'Interference'. Each inventor will then have to produce their laboratory notebooks as evidence of the dates on which they each made the invention, and furthermore demonstrate that since that date they have diligently pursued the task of 'reducing the invention to practice'. If the inventor who made and recorded the invention first does not pursue the latter consistently, and the second inventor who made and recorded the same invention shortly afterwards proceeded to 'reduce it to practice' before the first inventor, the second inventor is likely to be granted the US Patent.

1.66 Thus evidence that the inventor was diligent in 'reducing the invention to practice' must also be recorded in the laboratory notebook. and signed off in the way described above.

1.67 Since the United States represents 50% of the world market for many products, a US Patent can be of enormous commercial value. There is thus every reason to take the above advice seriously.

What happens next in the patenting process?

If a patent is not to be abandoned, then on or before the first anniversary of the priority date, full patent claims must be filed and decisions taken on foreign filings. This is normally done via a Patent Co-operation Treaty (PCT) application which designates the countries to be covered. If, as would normally be the case, these include the USA, Japan and countries in Europe, the cost will typically rise quite quickly to between £10,000 and £15,000.

During the year following the priority date, two objectives should be actively pursued. The first is concerned with the invention itself. The patent application will have described the novel idea constituting the invention, but it will probably not have been demonstrated at that stage to be feasible in practice i.e. that it can be made. The year gives the opportunity to make progress towards reducing the invention to practice, so that the strongest possible claims can be made in the patent specification. Submission of final claims would normally take place just before the first anniversary of the priority date.

The second objective is to assess industrial interest in the invention, and here your Adviser will be closely involved. It might even be that an option agreement or a licence can be signed with a company during the year giving this company rights to develop the invention in return for up-front fees and a commitment to share in the future success. The company might well agree to pay all further patenting costs, thereby happily off-loading that responsibility from your employer.

Unless the patent is abandoned, the patent specification will be published 18 months after the priority date. Its contents will thus enter the public domain. Many major companies examine all patents relevant to their industrial sector immediately after they are published. This in itself may result in an approach from one or more firms with expressions of interest in acquiring access to the technology covered by a patent.

If no industrial interest is discovered within 2 or 3 years, the patent should probably be abandoned, but this is a matter of fine judgement.

If uncertainty exists on whether it is worth proceeding to the stage of a PCT filing, because the cost does not appear to be justified by the invention's perceived commercial promise, a possible low cost option to keep the patent alive is by resubmitting it as a new application. Resubmission is not however possible if details of the invention have already been published by that time. Resubmission inevitably means that a new priority date, one year later, will apply, bringing with it the risk that the same invention may have been patented elsewhere during that year.

1.68 Chapter 2 describes in detail the process of applying for and maintaining a patent. Other activities which you, as Adviser, should pursue together with the researcher during the year following the filing of a patent application are as follows.

1.69 It is important, if at the patent application stage the idea behind the invention has been formulated without proof that its practical realisation was feasible, that as much work as possible to demonstrate its utility should be undertaken during the year following the priority date. The patent claims which have to be made in a written submission before the first anniversary of the priority date will then be as strong as possible, thereby enhancing the value of any patent which may be granted later.

1.70 Simultaneously the process of assessing the value of the invention must be continued, probably by approaching suitable companies to elicit interest in commercialising the invention under the protection of a Non-Disclosure Agreement. If a company can be persuaded to take an Option or, better still, a Licence, it may well be prepared to agree to pay (or contribute towards) all future costs of maintaining the patent. Normally this would be in addition to an up-front Option or Licence Issue Fee. For a provider or its exploitation partner such an arrangement should be welcomed, for patenting budgets are usually under pressure. It should be remembered, however, that the earlier in its life a technology is licensed or sold, the less in general is the price likely to be obtained for it. This is because there is higher risk for the company the earlier the licence is signed, with funds for further development likely to be necessary.

What can I do if I have already published my invention?

Promise yourself never to make the same mistake again! If by sad chance a public disclosure of an invention has been made, there is still the possibility of a US Patent because the US Patent Office still adopts a 'first-to-invent' approach. A publication made within one year by the inventor is no bar in itself to obtaining a US Patent. The invention date will be taken from the dated, signed, and countersigned page of the researcher's laboratory notebook which first described the invention.

1.71 If the inventor had published the idea within the previous year, a patent can still be applied for in the USA, Canada and the Philippines, and if within the last 6 months in Japan also, but not elsewhere. Evidence will have to be produced of the date of the actual invention, most usually in the form of the page of the inventor's laboratory note book which has been dated, signed by the inventor and counter-signed by a witness as mentioned in an earlier section.

1.72 If publication has taken place within the last year, and the estimated size of the US market warrants it, a US Patent should be applied for even though most other national or regional ones are not possible.

Who owns intellectual property?

The Patents Act 1977 states that:

(1) an invention made by an employee shall be taken to belong to the employer if

(a) it was made in the course of the normal duties of the employee and the circumstances were such that an invention might reasonably be expected to result from the carrying out of his duties, or

(b) the invention was made in the course of the duties of the employee and because of the nature of the duties he had a special obligation to further the interests of the employer's undertaking.

(2) Any other invention made by an employee shall be taken to belong to the employee.

The Copyright, Designs and Patents Act 1988 adopts the same stance on ownership for all classes of intellectual property it covers, namely that intellectual property produced by employees in the course of their normal duties belongs to the employer.

1.73 Experience has shown that considerable confusion about who is the rightful owner of intellectual property exists amongst staff who undertake research as part of their wider range of duties. It is not unknown for such researchers to claim, for example, that they had generated the intellectual property in question 'in their own time', and not during working hours. The law is rather explicit on the point. An innovation belongs to the employer, not the employee, if *'made in the course of the normal duties of the employee'*, and this would cover an innovation arising from these normal duties irrespective of the time of day when the idea actually struck.

1.74 Ownership can be a contentious issue which you as Adviser may have to deal with. Familiarity with the actual wording of the law is important in these circumstances.

1.75 Section 39 of the *Patents Act 1977* (as amended by the *Copyright, Designs and Patents Act 1988*) states on ownership that:

(1) Notwithstanding anything in any rule of law, an invention made by an employee shall, as between him and his employer, be taken to belong to his employer for the purposes of this Act and all other purposes if

(a) it was made in the course of the normal duties of the employee or in the course of duties outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties, or

(b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his

duties and the particular responsibilities arising from the nature of his duties he had a special obligation to further the interests of the employer's undertaking.

(2) A*ny other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee.*

Where by virtue of this section an invention belongs, as between him and his employer, to an employee, nothing done

(a) by or on behalf of the employee or any person claiming under him for the purposes of pursuing an application for a patent, or

(b) by any person for the purpose of performing or working the invention,

shall be taken to infringe any copyright or design right to which, as between him and his employer, his employer is entitled in any model or document relating to the invention.

1.76 In similar vein the *Copyright, Designs and Patents Act 1988* states in Section 11 on ownership:

(1) The author is the first owner of any copyright in it, subject to the following provisions.

(2) Where a literary, dramatic, musical or artistic work is made by the employee in the course of his employment, his employer is the first owner of any copyright in the work subject to any agreement to the contrary.

(3) This section does not apply to Crown copyright or Parliamentary copyright (see section 163 and 165) or to copyright which subsists by virtue of section 168 (copyright of certain international organisation).

1.77 It is the responsibility of the provider to ensure that the terms of employment of its employees include reference to ownership of intellectual property and the rewards it can generate.

1.78 The NHS Executive has published guidelines in HSC 1998/106 defining a policy framework for the management of intellectual property within the NHS to which reference should be made. In brief this states that intellectual property arising from R&D funded by the NHS should normally be owned by the party best able to exploit it. This will generally be the organisation carrying out the R&D and applies in particular to intellectual property generated using funds from the R&D Levy. It is the responsibility of providers to ensure that the question of ownership is properly dealt with in any contracts they themselves issue for R&D.

1.79 Where a Trust is leading R&D funded by the NHS, ownership would normally be vested in the Trust, with the Trust retaining any income earned from its exploitation. Where an independent provider of NHS services is undertaking the R&D, ownership would also normally be vested in the provider, but in this case the NHS requires a share in any income generated by its exploitation.

1.80 The question of ownership of intellectual property produced by those associated with the provider's research programme, but not employees of the provider, is dealt with later in this chapter.

Will an NHS provider always exercise its right of ownership?

For major items, such as patented inventions or substantial computer programs, the provider, particularly a Trust, will doubtless wish to retain ownership for the purposes of exploitation. In practice the provider may waive its rights in favour of an employee for minor items, such as for example the copyright on a medical textbook.

1.81 Whilst a provider has the legal right to ownership of intellectual property generated by its employees in the course of their normal duties, it may decide to waive its rights in certain cases particularly when the income derived is likely to be relatively small.

1.82 It has become traditionally accepted in academic institutions, where the output of staff includes scientific papers and textbooks, that copyright on these classes of items should be waived in favour of the author, particularly if writing these involved the author in putting in extra hours outside the normal working week, as is usually the case.

1.83 A Trust or other provider should establish a policy on this point, if for no other reason than to avoid any chance of disagreement on borderline cases. An example of such a case would be where a staff member of a Trust writes a book about his or her subject area, mainly to assist in the public understanding of science, but which incidentally becomes a bestseller and generates a lot of royalties. The ruling made by the Trust in this case may, or may not, be that writing a best-seller is not part of the normal duties of the staff member, and that therefore the Trust has no claim to any share of the royalties.

1.84 A second example might be where a charity had commissioned and paid for a member of the Trust's staff to carry out a paper study concerning a medical condition, and where the results are eventually published as a book on general sale. In this case, particularly if the trust had met the publication costs, the Trust might reasonably rule that the work of undertaking the study, and writing it up, was indeed part of the normal duties of the staff member. Royalties would then accrue to the Trust which would presumably be shared with the staff member concerned. Also, the charity might have attached to the original grant the condition that any royalty income was to be shared equally between the Trust and the charity.

1.85 Where computer software is written as an integral contribution to a research project, this would normally be regarded as being owned by the provider. Some of it might be of considerable commercial value, either as a stand-alone item or as part of a novel medical instrument which involved the customised software. Some may have potential benefit to the NHS but may only be able to be realised by dedicated effort by the researchers outside normal employment conditions. In a case such as this you may decide to recommend that your provider waives ownership.

1.86 The management of providers, including the administration of patient records, also involves the use of advanced information systems, some of which may have been written in-house. Amongst the latter might be items of commercial worth.

What if non-NHS employees are engaged in the research?

You may be an independent provider of NHS services, for example a partner in a primary care practice, also engaged in NHS-supported R&D. Because of your status as an independent provider the NHS Executive currently requires a share in the benefits derived from exploitation of intellectual property. NHS regional offices will need to agree the exploitation arrangements explicitly with your Adviser.

Alternatively you could be a long term visitor, such as an academic on sabbatical leave or an industrialist on secondment to a Trust, also engaged in NHS-supported R&D. In most cases the situation will be covered by a contract or exchange of letters between the appropriate NHS body and your research group or you as an individual researcher. This will address, amongst other things, the questions of ownership of arising intellectual property and the sharing of any income earned from its commercialisation. The contract or exchange of letters will state the name of a contact to whom any invention must be reported.

Staff in university medical schools commonly have joint appointments with, or honorary positions in, associated teaching hospitals or practices. Similarly, consultants in teaching hospitals or partners in practices may have academic positions in the medical school. If you have such joint responsibilities the question of ownership of intellectual property is usually covered by an agreement between the university and the relevant provider.

You could be a student taking a higher research degree who becomes involved in NHS-supported R&D. If you are supported by a student grant you are not classed as an employee and are therefore not covered by the relevant Acts governing intellectual property. An exchange of letters between the NHS provider and you the student should be used to regularise the position. You would be required to assign to the provider the rights in any intellectual property arising from your research. In return you would be treated exactly like an employee of the provider for the purpose of sharing any income earned from exploitation of the intellectual property you generate.

1.87 If you are Adviser for an independent provider of NHS services you will need to agree with NHS Executive regional offices detailed exploitation arrangements for intellectual property arising from their NHS-funded R&D. Benefits should be shared with NHS Executive in the way set out in the provider agreement or contract for R&D Support Funding.

1.88 It is not the least unusual for research which forms part of the overall R&D programme of a provider to be undertaken away from provider premises, and to involve researchers not employed by the provider. Where an NHS teaching hospital or independent provider of NHS services and an associated university medical school are collaborating on research this will be a common feature, with joint appointments between the university medical

school and teaching hospital or independent provider, such as honorary professorships held by provider staff and honorary consultant or clinical positions held by medical school staff. Where such a situation prevails there should be a comprehensive agreement between your provider and the university or other parent institution which deals with all aspects of intellectual property created jointly, its handling and exploitation.

1.89 Trusts may have an arrangement with local general practitioners or dentists to contribute to certain of their research programmes for which they are located in trust premises, and vice versa. Also secondees may be engaged from overseas medical institutions and industrial companies.

1.90 In all these cases it would be wise for your provider to enter into a formal written agreement with the actual employer of each 'visiting' researcher before his or her 'visit' starts. This agreement would normally cover such aspects as liability and accident insurance, but would also deal with the question of ownership of any intellectual property which the 'visiting' researcher generates or contributes to whilst involved in provider-supported research.

1.91 The formal agreement might call for any intellectual property generated by the 'visitor' to be assigned by the employer of the 'visitor' to the provider, and for the provider to share any exploitation income it eventually receives equally with that employer.

1.92 Students on grants, who legally are not classed as employees, may also be involved in provider research projects. The provider would be wise to adopt the same procedure for students as have most UK universities. As part of the general student regulations, the student is required to agree to assign to the university any intellectual property he or she creates in the course of his or her normal student duties. In exchange the university agrees to treat the student exactly as though he or she were a member of the university's academic staff for the purpose of sharing any income derived from the commercialisation of intellectual property generated by the student.

What happens if the research is externally funded?

That depends on the terms of the contract between the sponsor and the provider undertaking the research. The contract may require the provider to agree to assign the ownership of arising intellectual property to the sponsor, usually with a royalty-sharing provision. Alternatively, ownership may be shared with the sponsor or retained by the provider, particularly if the provider is meeting part of the cost of the research from its own resources as is frequently the case.

1.93 Each piece of externally-funded research undertaken by the provider will be the subject of a formal grant or contract between the provider and the research sponsor. Amongst its various provisions the grant or contract document should define clearly which of the parties will have ownership rights to intellectual property arising from work under the grant or contract. As Adviser you will need to ensure that the interests of your provider are protected as far as you are able.

Commentary on 'Handling Inventions and Other Intellectual Property:A Guide for NHS Researchers'

1.94 Some sponsors that support R&D in providers, for example medical charities, tend to have standard terms covering the projects they support, and so there is limited scope to negotiate a substantially different arrangement. Others, such as commercial organisations, whilst in principle appearing more flexible in approach, do tend to take a harder line on contract terms, particularly on the ownership of arising intellectual property and its relationship with the price to be paid.

What is the position of inventors?

The inventor or inventors must be named on the patent. It is important that only the individual or individuals actually responsible for creating the new invention should be so named. If a genuine inventor is left out, or someone who did not contribute to the actual inventive step included, the patent could be open to challenge.

The situation is different to that for scientific papers where support workers can be and often are named as co-authors.

1.95 Each inventor, if there is more than one, must be mentioned on a patent. Each person so named must have contributed intellectually to the actual innovative ideas behind the patent. It is not enough to have simply done supporting work, for example as a technician working under instruction. It is the originator or originators of the novel idea alone who should be named. If a genuine inventor is left out, or one who is not a genuine inventor included, the patent can be open to challenge.

1.96 The situation is quite different when listing authors on a scientific paper, where it is customary in many fields to include support workers. To avoid any carry over of such thinking into the naming of inventors, it might be necessary for you, as Adviser, to quiz the leading researcher to ensure as far as this is possible that those named are the proper inventors, and only their names are submitted to the patent authorities.

1.97 To obtain a US patent each inventor is required to sign documents. Since this is not usually called for until more than a year after the patent application is made, care must be taken, in a highly mobile scientific community, to keep track of the current addresses of inventors.

1.98 A further, more parochial but important, reason for naming the proper inventors and maintaining contact with them is that, when it comes to sharing exploitation income, the named inventors should stand to benefit.

Can inventors be rewarded?

Yes, but the law does not itself make explicit provision for this. Some research organisations, including universities but not usually companies, have adopted revenue sharing arrangements to reward staff who make an invention, or generate other intellectual property, which later earns exploitation income. Ask your Adviser for details of your provider's revenue sharing arrangement if it has one.

Where there is more than one inventor, that proportion of the income which the provider's sharing formula allocates to inventors would be divided between them. A common arrangement is for each inventor to receive an equal proportion, on the assumption that they each contributed equally to the invention. This need not however be so. It is up to the inventors to agree amongst themselves on their relative inventive contributions, and therefore upon their relative rewards. It is often the case that others not involved in the invention make crucial contributions in achieving a commercial product. It is open to your Adviser and the inventors to include these others in the share of the benefit. Where forms of intellectual property other than patents generate income, the same general arrangement would apply. Those who contribute to the innovation should be rewarded in the ratio of their innovative contributions.

1.99 The NHS Executive has agreed in principle that an employee or equivalent of an NHS Trust or independent provider of NHS services who makes an invention, or who creates other intellectual property, which achieves commercial success may share in the income earned by the provider from its exploitation.

1.100 At the time of writing providers are free to adopt their own individual formula for sharing this income with the inventor or inventors. There are however good reasons for all providers to adopt the same approach to sharing, or indeed the same actual formula, to avoid any criticism that some providers are less generous to their inventors than others.

1.101 The question of reward to inventors and creators of other types of intellectual property of commercial value can be an extremely emotive one. Most will recognise that much effort, and therefore expense, is required in turning a potential prospect into a commercial reality. They will in general co-operate fully with you as Adviser or your technology transfer agent in seeking exploitation opportunities.

1.102 Experience elsewhere has shown however that a small minority of inventors may take the view that their normal duties of employment do not include engaging in research, and therefore that they personally should own any intellectual property arising from their research, and be given all the rewards. They conveniently forget that they are paid a salary for the work they do, and that their research would not have been possible were it not for the expensive research infrastructure provided by their employer.

1.103 The best rebuttal to these views is to be able to point to a contract of employment which, hopefully, specifies research as one of their normal duties. The various Acts of Parliament then make it clear that the employer, not the employee, is the owner of intellectual property arising from the employee's work.

1.104 The usual approach to exploitation revenue sharing is for the employing organisation to have pre-published guidelines for net revenue sharing, and to use these as a basis for the negotiation in individual cases. Generally it is the revenue net of patenting and actual technology transfer costs which is shared, and this typically will add up to around one half the gross revenue.

1.105 Not all providers have existing revenue sharing arrangements, but various types of guideline are in use in UK academic institutions. The principal ones are described in Chapter 5 and their relevance to Trusts and other providers of NHS services considered.

How can income be obtained from intellectual property rights ?

Income can be obtained through licensing, through assignment or by straight forward sale.

A licence allows a licensee exclusive or non-exclusive use of the intellectual property rights for a defined period and in a defined geographical area, but the ownership remains with the provider. The licence will include some form of financial consideration to the provider such as a lump sum on signature and a royalty on sale of products based on the intellectual property rights. An assignment transfers ownership, just like any form of property, with an assignment document signed by both parties. Again there would be a financial consideration, probably a lump sum on signature plus a continuing royalty on sales. A sale would transfer ownership for a once-and-for-all fee at the completion of the sale.

1.106 Licensing is likely to be the most common form of exploitation route, because the provider retains more control of the exploitation of the intellectual property rights, and any new intellectual property generated by further research in the area is then likely to be more valuable. A brief introduction to the very complex subject of licensing is given in Chapter 4.

1.107 Assignment is likely to apply more often when the assignee needs the comfort of owning the intellectual property e.g. when spin-off companies are formed based on your technology. Outright sales of intellectual property are likely to be rare.

1.108 An assignment agreement would normally be drawn up and signed by both parties and would cover the transfer of ownership of the intellectual property from the assignor to the party receiving it, the assignee. Your interests can be protected in an assignment agreement (e.g. the spin-off company may fail) by including a deed of reassignment as part of the agreement. The agreement would specify exactly the composition of the package of intellectual property for which ownership was being transferred, quoting the identification numbers of any patent applications or patents included in the package.

1.109 The consideration, usually financial, for the assignment will also be defined. This would usually comprise a single lump sum payment on signature, plus the right to later royalties for the assignor on sales of a product or process based on the intellectual property.

1.110 Where patent applications or patents are involved, the relevant Patent Offices have to be informed of the change of ownership. After assignment or sale, further patenting costs will be the responsibility of the new owner.

Who is responsible for leading the exploitation effort?

Formally it is your Adviser, but in practice the creators of the intellectual property will need to be deeply involved in almost every case. The professional skills in intellectual property management and licensing which the Adviser possesses, or more generally has access to, will provide an essential complement to the scientific and technical skills of the researchers.

Experience has shown that a surprising amount of work, often spread over 5 or more years, has to be put in to most exploitation projects. The best way to organise the effort is for your Adviser to be the main point of contact with the external world, and for the researchers to be brought in to the discussions as appropriate.

1.111 Some researchers completely underestimate the amount of effort that has to be put into exploiting items of technology and the special skills which are involved. They may indeed think that they don't need assistance from you in commercialising 'their invention'. Others are happy to take a back seat. In the case of almost all projects you will require the active collaboration of the researcher concerned. The above question and answer aims to set the right climate to encourage close co-operation between you and the researcher. Without this it will be difficult to promote properly the exploitation of the technology in question. Since you are likely to be responsible for your Trust's patent budget, or for managing the funding arrangement with your appointed agent, this automatically gives you the leading responsibility.

Will inventors be involved directly in negotiations with potential licensees?

When marketing an invention or other form of intellectual property owned by a provider, the specialist nature of the underlying science or technology will almost invariably be such that the inventors will need to take a full part in discussions with the technical representatives of potential licensees.

However the actual negotiation of the terms and conditions of the licence (or any other agreement) is also a specialist task, requiring the deployment of appropriate professional skills. Your Adviser will be responsible for this aspect and for making the necessary arrangements.

1.112 Again the object here is to point out that you, the Adviser, even though you may employ a technology transfer agent under contract, will be formally responsible for all exploitation activities, drawing on the technical skills of the researchers whenever necessary. It is good policy to keep each researcher fully informed at regular intervals of the progress you are making with their projects.

What about spin-off companies?

In rare cases the best route to exploitation will be a spin-off company. Preparing a business plan to put to venture capitalists or another potential business partner will require access to talents not normally found within providers. One possibility is to engage a 'business angel' with a combination of necessary expertise, time and money to invest, who would be likely to undertake the task for a fee or in exchange for an equity stake in the company. Another possibility is to buy this service on a consultancy basis if funds are available.

Without such input from a suitable person, it is unlikely that the spin-off company will achieve its full potential. Recognising the requirement to make full use of outside support, a number of very successful companies have recently spun off from UK medical schools, hospitals and university life-science departments.

Currently NHS Trusts are not allowed to hold equity in companies. A licensing agreement between a spin-off company and its 'parent' provider, which specifies licence fees and royalty rates, is an appropriate substitute.

1.113 Since NHS Trusts do not take equity stakes in spin-off companies, if you are Adviser to an NHS Trust it is unlikely that you will have to become deeply involved in operations setting up the company. It may be however that a group of researchers from your organisation is considering exploiting the results of their work via a start-up company, and turn to you for preliminary advice.

1.114 If such a company is to go ahead you will have to represent the interests of the Trust as legal owner of the intellectual property which the company wishes to have access to or acquire. This will mean agreeing the terms of the licence or assignment document.

1.115 If the researcher who created the intellectual property in question intends to become involved in the actual running of the spin-off company to any significant extent, for example as a retained consultant or director, then your Trust's regulations for staff will probably insist that the formal permission of the Trust must be given before such a position can be accepted. If the researcher wishes to spend any appreciable time on company affairs, an agreement covering this should be drawn up and signed by both the Trust and the researcher. This might, for example, vary the number of paid hours per week the researcher is required to devote to Trust business, leaving him or her with time to devote to the company's affairs.

1.116 If the researcher is to have a significant financial stake in the spin-off company, perhaps as a major shareholder, it would be as well to consider varying the nature of the intellectual property licence or assignment agreement between the Trust and the company in recognition of this. Normal practice would be to share with the researcher any royalties paid by the company to the Trust under the agreement, and to do so in line with the Trust's usual revenue sharing arrangement. In these special circumstances the researcher may be prepared to forego from the outset the chance of any future share of the royalties on condition that the royalty rate payable to the Trust is reduced accordingly. In effect this would leave more money with the company to accrue to the ultimate benefit of the shareholders, including the researcher.

1.117 No two spin-off companies are the same, so the launch of each requires a great deal of work. It is only too easy to underestimate what is involved. You may have to bring this to the attention of researchers keen on embarking on the launch of a company. Whilst not wanting to discourage spin-off companies, your task is to judge whether the Trust will make a greater financial return by licensing the technology to an existing company, assuming that a suitable one can be found, rather than licensing or assigning to a new spin-off company with no established track record.

1.118 Independent providers of NHS services can set up their own businesses. If you are Adviser of an independent provider who is considering setting up a spin-off company you will need to discuss the situation with the relevant regional office of the NHS Executive which requires a share of any exploitation income.

Appendix I.I

Example Non-Disclosure Agreement

THIS AGREEMENT is made the.....day of.....199.....
BETWEEN .....of ..... (hereinafter called "The Company") of the one part and .....of .....(hereinafter called "The Provider") of the other part.

WHEREAS

(1) In this Agreement where the context so admits the following words shall have the meanings assigned to them:-

(a) "Confidential Information" shall mean all information that is disclosed by or obtained directly or indirectly from the Provider including data information know-how methods procedures processes systems and technical knowledge whether existing at the date of this Agreement or developed or obtained thereafter or any part thereof except that which the Company can establish:-

(i) is in or enters the public domain otherwise than as a consequence of an unauthorised act or disclosure or omission by the Company (or by any person to whom the same is disclosed or suffered to be disclosed by the Company); or

(ii) is properly and lawfully in the Company's possession at the time it is disclosed to or obtained or acquired by the Company and which is not obtained directly or indirectly from the Provider; or

(iii) is received from a third party; provided, however, that such information was not obtained by said third party, directly or indirectly, from the Provider; or

(iv) is independently developed by or for the Company by persons who did not access information disclosed by the Provider under this Agreement.

(b) "Within the public domain" shall mean published or generally available to the public.

(2) The Company recognises that the Provider is developing systems for ..... ("the Systems") and that the Provider has approached the Company with a view to offering information of a confidential and secret nature thereon to the Company for the purpose of evaluating the commercial potential of the Systems.

(3) The Provider recognises that the Company may already have developments which duplicate the Provider's work and which have as yet not been disclosed.

(4) The Company recognises that the Provider has not been able to protect fully its information and developments by patents or other means.

(5) The Provider agrees to disclose its information to the Company on the terms and conditions hereinafter contained.

NOW IT IS HEREBY AGREED AS FOLLOWS:-

1. Representatives of the parties hereto shall meet as soon as reasonably possible after the signing of this Agreement to enable the Provider to disclose to the Company its information on the terms herein contained. All information relayed electronically or orally shall be reduced to writing within thirty (30) days.

2. In consideration of the disclosure of information by the Provider the Company shall preserve the confidentiality and secrecy of and not directly or indirectly divulge or disclose to any third party or publish the Confidential Information or any part thereof without the Provider's prior written consent.

3. The Company shall not use the Confidential Information or any part thereof except for the purpose of evaluating the commercial potential of the Confidential Information.

4. At the Provider's request the Company shall promptly deliver up to the Provider all materials and documentation incorporating the Confidential Information or any part thereof and all copies thereof and all copies or extracts therefrom as shall come or have come into its possession or control.

5. This Undertaking shall continue for a period of ten (10) years from the date hereinabove written.

6. Any forbearance or delay on the part of the Provider in enforcing any provision of this Undertaking or any of its rights thereunder shall not be construed as a waiver thereof or of a right thereafter to enforce the same.

7. This Undertaking shall be subject to the exclusive jurisdiction of English Law in an English Court.

Signed by
on behalf of the Company . . . . . .Date: . . . . . .

Signed by
on behalf of the Provider . . . . . .Date: . . . . . .

Chapter 2

Patenting

Introduction

2.1 Most countries of the world grant patents. A national patent gives its owner the monopoly right to exclude others from commercialising the invention covered by a patent in that country without the owner's permission. This situation persists during the lifetime of the patent which is normally 20 years. By way *of quid pro quo* the owner must agree to the invention being published 18 months after the date on which the patent application was first made, thus placing it in the public domain.

2.2 For an invention to be patentable it must involve an inventive step which is not obvious to someone skilled in the art, and must also be capable of being made or used by industry. An invention will be deemed not to be new, and therefore unpatentable, if details of it have already been published (except principally for US Patents in certain circumstances). There are a limited number of categories excluded from patenting, for example, surgical procedures. Surgical appliances or equipment to undertake those procedures can however be patented.

Preparing and submitting a patent application

2.3 Preparing a patent application is a specialised task best left to a qualified patent agent. Whilst in principle anyone can write and submit a patent application, this is not advisable If an invention is worth patenting, it is worth patenting properly. For more detailed advice on patenting, the Patent Office publication *Patent Protection* can be read.

2.4 If you, as Adviser, agree that an invention by an employee of your provider should be patented, and accept that the cost will fall on a patent budget, the next step is to make contact with a patent agent who has a scientific background which matches the invention. Most firms of patent agents have specialists in the various branches of science, technology and medicine, so it should not be too difficult to locate a suitable individual.

2.5 The timing of a new patent application is inevitably a compromise. On the one hand it should not be filed so late that a competitor will have had the time to publish the same idea or indeed to patent it first. On the other hand it should not be filed so early that experimental support for the invention cannot be generated within a year. If in doubt, though, it is better to file early rather than late.

2.6 Reference was made in Chapter 1 to the danger of publishing details of a patent application within twelve months of filing. In principle, any patent application can be added to within the twelve months to broaden the scope of the invention. For example improvements in the original application may become apparent as research continues. However a recent decision by the European Patent Office (subsequently confirmed in Britain and Australia) gave a European patent after publication had occurred for only what was in the initial application prior to publication, not for what was in the broadened application. This was despite the fact that the publication included no more than the content of the initial application. Where there is the possibility of improvements occurring you should try to persuade the researchers against publication for the twelve month period after filing, otherwise you may end up with a patent of much diminished value. The BTG publication *Publish and be damned* expands on this and other aspects of publication and patentability.

2.7 Your inventor will doubtless have written up his or her invention at your request, and this document can be sent to the selected patent agent. The patent agent will probably wish to talk to the inventor face-to-face or by telephone. The patent agent will prepare the application and probably ask the inventor to check it before submission to the UK (or the European) Patent Office.

2.8 The patent specification will contain several parts:

a) an introduction which identifies the field of the invention and may state the problem addressed by the invention and perhaps list relevant references;

b) a summary of the invention, including definition of terms and an indication of essential and preferred features;

c) a detailed description of the invention, generally comprising worked examples or an outline of one or more specific embodiments;

d) where appropriate, drawings illustrating the invention;

e) one or more claims defining the scope of the monopoly sought. This is the key section. All novel features connected with the invention should be fully described in the specification. In a new patent application the claims should be sufficiently broad to cover the commercial interests and to make it difficult for competitors to take the idea without infringing the patent. The claims should be fairly based on the specification, not enormously broader than the specific description, although some generalisation is permitted. Clearly, the claims should not be so broad as to cover things previously known or obviously impracticable.

2.9 A patent search could in principle be conducted before filing the application, but this could delay matters and you need to judge whether this delay is acceptable.

2.10 The date at which the patent application arrives at the UK or European Patent Office will become the 'priority date' of the application. This is the first event in the patenting procedure. The next event is 12 months after the priority date. All countries that are signatories to the various patent treaties will accept, for a period of up to 12 months from the priority date, that this date should be taken as the priority date for any national patent granted later which covers the invention.

Actions during the next twelve months

2.11 The average patent application is likely to describe an innovative idea, unproven as yet in practice. As much work as possible should therefore be undertaken during the 12 months after initial filing (sometimes referred to as the convention year) to reduce the invention to practice. Thus when the final patent claims are submitted to the UK Patent office, and this must happen before the first anniversary of the priority date, they will be as strong as possible.

2.12 Researchers normally want to publish the results of research without delay. Where inventions are involved this should not of course happen until after the patent application has been filed. If there is no strong reason to publish, as already explained it is better for details of the invention to remain entirely confidential. This does not preclude discussions with a potential licensee so long as these are carried out under the cover of a proper Non-Disclosure Agreement signed by both the potential licensee and by you on behalf of your provider.

2.13 If the patent application is not abandoned its specification will be published 18 months after the priority date, this being the maximum period for which an active patent specification can remain confidential. Once the patenting procedure has been put in train, only by abandoning the patent can publication be avoided.

2.14 During the 12 month period it is also important to obtain the best possible estimate of the commercial value of the invention. Often this is far from easy. If your market research tells you that the value appears uncertain to the extent that you cannot even be sure whether patenting costs will be recovered, clearly there is no point in proceeding to the next stage. In these circumstances a wise precaution would be to publish details of the invention forthwith to stop anybody else patenting the invention, just in case the initial judgement of its value was too low. It would be highly embarrassing later to have to pay royalties on an invention for which one had earlier abandoned patent cover!

2.15 It is perfectly reasonable to seek commercial interest in the invention at this stage under cover of a Non-Disclosure Agreement. If, as part of this process, the commercial concern wishes to make a disclosure to you and your researchers of some of its own propriety information, the Agreement will need to be two way, protecting each party under sanction of civil legal action from wrongful disclosure to a third party of the other's trade secrets. The hope is that the commercial concern will show sufficient interest in the invention at this stage to ask to be granted an option to exploit the

technology. The option fee can then if necessary be used to pay future patenting costs although it may be possible to negotiate inclusion of these costs as part of the option agreement.

2.16 A patent search can be carried out during this year or earlier by accessing on-line databases via the Internet or by commissioning the UK Patent Office or European Patent Office to carry one out. The second of these alternatives is quick and relatively cheap, but the third is more authoritative. An early Search Report will indicate whether the content of your application is indeed novel.

Action just before first anniversary : filing claims

2.17 If after a year's investigation the invention does not appear to have sufficient intrinsic merit, nor to have generated significant commercial interest, then in all probability the best thing to do is to abandon it. If the decision on whether or not to proceed is marginal, a possible way ahead, if no publication or other disclosure of the invention has been made, is to submit the same application again. This can be done at nominal cost, but the consequence is that a new priority date will apply, one year later than the original one.

2.18 If the invention is deemed strong, the patent application should of course be pursued. As Adviser you will have to select, in conjunction with the inventors, the countries where patent protection is to be sought. For inventions arising from NHS-funded R&D it is quite likely that patent coverage will also be required in countries in addition to the UK. It is generally sufficient to seek protection in those countries where licensees may wish to manufacture the product or operate the process based on the invention, without covering countries where they may only wish to market the product or process. Only in rare cases will it be worth considering countries outside Europe, the United States and Japan.

2.19 If patent cover is to be applied for outside the UK, the normal way of proceeding is to file a PCT application. On or before the first anniversary of the priority date, a single international application is made, generally at the UK patient office, designating the countries in which a patent is required. The Patent Co-operation Treaty covers 90 countries, including nearly all industrialised ones.

2.20 There is an optional extension which can be applied to a PCT application under which it can be subjected to an International Preliminary Examination. This involves paying a fee, but delays having to enter the expensive National/Regional Phase for each designated country by an extra 10 months.

2.21 There is also a European Patent Convention, signed more recently, which simplifies patent filing and prosecution in European countries. If protection in more than two European states is required within a PCT application it is worth using this EPC system which operates through the European Patent Office. This system rather than the PCT should also be used if patent protection is to be limited to Europe.

The Process of Granting a Patent

2.22 If the application is to be limited to the UK, or if it is intended to be broadened later, an initial search can be requested from the UK Patent Office. A UK Search Report will be issued and the applicant can amend the description and the claims within the twelve month period. Unless the application is withdrawn it will then be published as it was filed, but including amendments, 18 months after the priority date. Substantive examination of the application by a Patent Office Examiner then takes place and the first full examination report is issued about 18 months after publication. The applicants then have the opportunity to study the findings and to respond by proposing amendments to the claims or by presenting arguments why their claims should stand. This procedure continues until the Examiner is satisfied that the application can be granted.

2.23 A benefit of first filing a UK patent application is that the UK Search Report will allow an early assessment of the strength of the invention before starting the costly process of obtaining protection abroad.

2.24 For a PCT application, a single international search is carried out (by the European Patent Office in the case of applicants from the UK) on behalf of all the designated countries. The Search Report is published by the International Bureau of WIPO and communicated to every country designated in the application. The application will then enter the National/Regional Phase either 20 months or 30 months after its priority date, the longer period applying when an International Preliminary Examination is requested. Each designated country will process the application independently based on the Search Report. The international application can also be treated as an application for a European Patent through the EPC route in designated countries. Appendix 2.1 illustrates the normal train of actions which follow if patents are to be applied for through the PCT route.

2.25 If the application is for European countries only through the EPC route, similar processes to the PCT take place with an EPC filing just before the anniversary of the initial UK filing.

2.26 To the various official fees, of course, you will need to add any costs you incur in retaining your own patent agent. Your patent agent will advise you on the most appropriate action and the various options which exist to contain your costs and to vary the length of the process.

2.27 In practice it is likely that an invention owned by a provider will have been licensed before the 20 month milestone for a PCT application is reached. If not, there is much to be said for requesting an International Preliminary Examination to win a further 10 months for negotiating a licence. If no licence has been agreed by the 30 month milestone, serious consideration should be given to cutting losses and abandoning the patent. In this way the heavy costs including those for translations, printing and sealings associated with the National/Regional Phase, which might bring the total cost of a patent up to well over £50,000, can be avoided.

US patent system

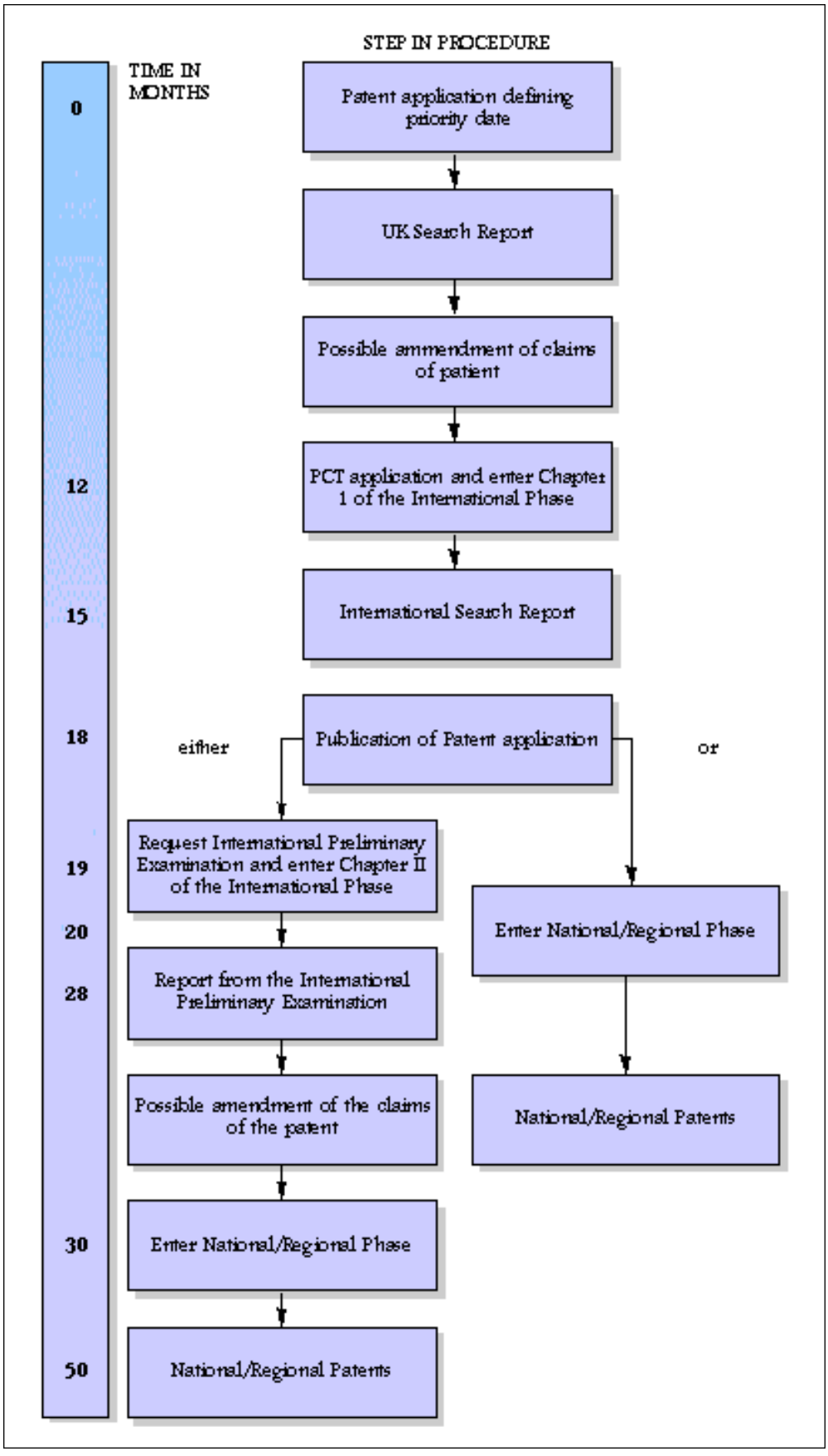
2.28 Although under the World Trade Organisation patent laws and procedures are becoming increasingly uniform across all countries of the world, US Patent Law remains peculiar in several ways of importance to UK inventors. As already described the USA still operates a 'first-to-invent' system whilst other countries operate a 'first-to-file' arrangement. A US inventor alone has in past years been able to 'swear back' his or her invention to a date earlier than that at which the patent application was actually filed with the US Patent Office. Proof was required of the date when the invention was actually made, the most acceptable form of this being the page of the inventor's bound laboratory notebook which records details of the invention. The page has to be dated, signed by the inventor and counter-signed by someone (not a co-inventor) who certifies that he or she had understood the invention.

2.29 As already mentioned in Chapter 1, Paragraph 58 *et seq*, since 1 January 1996, following a change in US Patent Law, non-US inventors are also allowed to 'swear-back' inventions to obtain an earlier priority date for a US Patent. The situation regarding the priority date accepted by other countries remains completely unchanged, this still being the date of filing of the patent application. The change in US Patent Law does mean that advantage can only be taken of it if the appropriate laboratory notebook has been properly kept and dated, signed and counter-signed in the recognised manner. Since it is the date of the counter-signature by the independent witness which will be taken by the US Courts as the date of the invention, it is important that laboratory notebooks are marked read and understood by the counter-signer if not daily then at least weekly.

2.30 Another difference in US Patent Law means that an inventor can publish details of the invention without destroying the chance of obtaining a US Patent so long as the patent application if filed before the first anniversary of the date the invention was actually made. This could be useful if details of an invention by a provider employee have unfortunately been published by him or her before any patent action was taken. Whereas the chances of obtaining a patent in other countries of the world had been destroyed by publication, a US Patent could still be obtained. Currently it also costs less than a European Patent.

Appendix 2.I

PCT Patent Application Procedure through UK Patent Office



Chapter 3

Technology Auditing

Introduction

3.1 Technology auditing, sometimes called exploitation auditing, is an important component of any efficient technology transfer operation. It is the first link in a long chain of events which, if unbroken, will constitute a successful exploitation project. Without a systematic technology audit of research in progress in an organisation, many innovations of commercial importance might never come to light. It is expected that you will organise regular technology audits for your provider so that you are fully aware of the of the content of your R&D programme and can identify potential intellectual property in line with your agreement or contract for R&D Support Funding.

3.2 The cost of technology auditing is usually insignificant when compared to the cost of the research itself, normally less than 1% of the latter. Averaged over all projects, it must constitute a good investment of resources.

3.3 Technology auditing could be carried out by suitably qualified members of your provider staff, by staff of your exploitation partner, or by part-time consultants employed under contract especially for the purpose. For convenience in what follows these staff or consultants will be referred to as technology transfer executives.

Conducting a technology audit

3.4 The technology auditing process might proceed as follows. With the agreement of the appropriate department or directorate head, researchers would be visited in turn by a suitably experienced technology transfer executive. This visit would be informed by the database of individual projects which each provider has available. During the first visit, a short explanation would be given, perhaps to all researchers together, of the arrangements made by your provider for handling and exploiting intellectual property which arises from its R&D programme. Where you are Adviser in a major Trust, particularly where formal collaboration with an associated university medical school had been agreed, you may well have a dedicated in-house or adjacent technology transfer unit, in which case its operation would be explained. In smaller organisations you may be an Adviser nominated as contact point, but it would still be necessary to explain the arrangements entered into. Whatever the circumstances the advantages to the researchers of collaborating on technology transfer would be emphasised, and the dangers of premature publication of the results of research would be stressed.

3.5 The researcher would be asked to explain the objective of his or her research, concentrating on results achieved to date. The explanation must be understood sufficiently well by the technology transfer executive for him or her to make a preliminary assessment of whether there are items of commercial promise. This requires the technology transfer executive to have a scientific background which matches reasonably well with that of the researcher. Hence the need for you as Adviser to have some staff with such skills, or to have access to suitable external experts, or a combination of both.

3.6 The conclusion of a technology audit of a particular research project may be simply that the work does not have commercial value, or that the work is not yet advanced enough for intellectual property of potential commercial value to have appeared but that there is future promise. In this latter case the written record prepared by the executive will flag up the need to visit the project again in perhaps another 6 months. The researcher will however be asked to get in touch with the technology transfer executive if anything of potential interest comes up in the interim.

3.7 Alternatively the discussion between researcher and technology transfer executive might bring to light an innovation which appears to be a possible candidate for patenting. The technology transfer executive, or you as Adviser, would take responsibility for evaluating this prospect, paying particular attention to the likely costs involved.

3.8 A matter of central importance which must be raised by the technology transfer executive concerns the ownership of the intellectual property in question. Was the research done solely with provider funds ? In this case the provider is the rightful owner. Was it done under a research grant or contract with an external body? If so, the covering agreement will need to be consulted, especially the terms and conditions applying to arising intellectual property, in order to establish ownership rights.

3.9 Not infrequently the technology transfer executive might find that the situation is not so straightforward. Larger research groups frequently have a number of inter-related projects, each supported by a different sponsor, but managed collectively as a single programme. In these circumstances it can then often be difficult to be sure which of these sponsors actually supported the research which led to creation of the intellectual property in question. In consequence it might be difficult to deduce which sponsor has ownership rights. Nevertheless it is extremely important in such cases that the question of ownership is settled before patenting action is taken, and settled quickly so that patenting is not held up.

3.10 If the provider is the owner, the technology transfer executive should next ascertain that the owner has funds available for initial patent costs. If so, the researcher should be asked to write a short description of the innovation which would then be sent by the technology transfer executive to a suitable patent agent. If the invention is at all complex, the patent agent and the researcher will probably need to meet so that the patent application, when filed, is as strong as possible..

3.11 If the rightful owner is an external sponsor, the position will be reported to that sponsor who would normally decide whether or not to patent the innovation at its own expense. However if the sponsor declines to proceed, but the technology transfer executive believes that the innovation has commercial worth, the sponsor should be requested to agree to make assignment to the provider of any rights in the innovation which the sponsor may have. Most sponsors will agree to such requests. Some research contracts indeed include a clause which automatically gives the contractor the rights if the sponsor declines to protect a patentable innovation.

3.12 Since the technology audit process involves a meeting with researchers in turn, a fringe benefit of the activity is that the attitude of researchers towards technology transfer can be influenced positively. Establishing the right culture in this way is clearly important.

3.13 The end result of the technology auditing process is a comprehensive record of where intellectual property of commercial potential already exists, and where it is likely to be generated shortly. Repeating the process at approximately yearly intervals should be sufficient to keep the records up to date. These records form the platform from which later stages of the exploitation exercise will be launched.

3.14 A word of caution. There is no point in carrying out technology audits unless a firm intention exists to exploit fairly rapidly the commercial prospects thus uncovered, and the resources are available to do so. Having a database of projects ready for exploitation, and no effort to carry out the follow-on work, achieves little other than frustrating the researchers who will be expecting progress to be made on their projects. In an organisation new to technology transfer, it is therefore best to divide the effort available for exploitation between technology auditing and follow-up activities, achieving a balance between these by experience. Since in reality you as Adviser will rarely have enough resources to do more than pay for the cost of the technology audit and the (initial) cost of patenting, it is important that a suitable partnership for technology transfer has been established with for example a nearby university, by pooling resources with a number of neighbouring providers, or with a suitable commercial organisation. This is discussed more fully in Chapter 6.

3.15 A database of current research grants and contracts can also give useful leads about which projects should have a special eye kept upon them. A good technology transfer executive will have developed a nose for such things.

Chapter 4

Licensing

Introduction

4.1 The aim of this chapter is to give a brief introduction to the subject of licensing, especially directed at newcomers to the field. There are many good specialist books and articles available on the subject to which reference can be made for further details. What is written below should however provide enough background to enable you as Adviser, presented with a draft option or licence agreement by an intended licensee, to evaluate it.

4.2 When presented with a licensing opportunity, the first thing to do is to consider how the best financial return might be obtained. This will involve deciding whether it is best "to put all one's eggs in one basket" by granting a comprehensive world-wide exclusive licence with a single company, or whether it is better "to spread the risk" by licensing a number of companies non-exclusively, or exclusively for defined sectors, and accepting the additional administration that this involves.

Types of licence

4.3 There are two main categories of licence, exclusive and non-exclusive.

4.4 A third type of licence, the sole licence, is less frequently used. It is mentioned here only for the sake of completeness. Since NHS Trusts cannot themselves become involved in commercial operations, sole licences are not relevant to them. A sole licence would be issued, for example, when a commercial company was itself making and selling a product based on an item of its intellectual property, but in addition wished to license a single other company to do exactly the same thing. Perhaps the first company had insufficient manufacturing capacity to meet the anticipated demand for the product, but nevertheless wanted to ensure that the demand is met.

4.5 A prospective exclusive licensee will sometimes suggest that it needs to evaluate the technology, and indeed undertake some experimental work to demonstrate its commercial potential, before deciding whether to take an exclusive licence. The usual way of proceeding is to conclude an option agreement. In addition the researchers in the provider might be called upon to be involved in the proving work, in which case this should be covered by a development contract placed by the prospective licensee.

Option to an exclusive licence

4.6 Under an option agreement the prospective licensee is granted the right to exercise at any time within a specified period the option to be granted an exclusive licence by the licensor. As consideration an option fee will be paid to the licensor on signature of the option agreement. If the option period extends for several years, an annual option fee might be preferable. This would be paid on each anniversary of the signing date of the option agreement until such time as either the option is exercised or the option period expires. The licensor will not of course be free to negotiate with any other potential licensees during this period.

4.7 It is usual to attach to an option agreement a draft licence which defines the terms of the licence to which both parties will be committed if the licensee does exercise its option. This is particularly important if the option covers a potential "big winner" where perhaps the option period will allow the licensee to undertake at its own expense preliminary clinical trials of a promising drug, a new piece of equipment or a new diagnostic product.

Exclusive licences

4.8 When an exclusive licence is granted, the recipient licensee alone has the right to use the intellectual property specified in the licence for commercial purposes.

4.9 Clearly it is a major decision to place exploitation completely in the hands of a single company. Such a route should only be taken after careful consideration as to whether the potential licensee has the capacity to develop the product and service the intended market properly. The type of technology may also determine the outcome. For example, if a new pharmaceutical product is in prospect, this will require major investment in expensive clinical trials before regulatory approval is given. No company can be expected to embark on such a programme unless it will become the monopoly supplier of the product, and thereby hope to recover more than its investment.

4.10 With exclusive licences, not surprisingly, safeguards are normally incorporated into the licence agreement to ensure performance. Usually there will be a major up-front payment by way of a licence issue fee (which would in general be greater than in the case of a non-exclusive licence). The magnitude of the fee which can be negotiated gives some indication of the degree of commitment of the licensee to exploiting the technology properly. The licence issue fee should more than cover patent and other costs previously incurred. Rather than a single one-off issue fee, another approach would be to have annual licence renewal fees. In all cases the licensor should seek to ensure that the exclusive licensee takes over patent maintenance costs.

4.11 There should also be a minimum guaranteed level of annual payment written into the agreement. This is an important safeguard against commercial under-performance by the licensee. It would also protect against the licensee

taking the licence with the object of 'killing' the associated technology, perhaps because it would compete with a (less good) technology the licensee already has on the market.

4.12 With minimum royalty clauses in the agreement, if the licensee fails to perform as expected by not reaching the sales volume corresponding to the stated minimum annual royalty figure, it is nevertheless expected still to pay this figure. It would be normal to have for a series of years minimum royalty figures which start, say, two years after signature of the licence at a modest level, and progressively increase each year over the next few years, until a plateau is reached which corresponds to the anticipated market size at maturity. One variation on this arrangement which is frequently encountered is provision in the agreement for the licence to revert automatically to a non-exclusive basis if sales do not reach the level corresponding to the specified minimum royalties and the licensee elects to pay royalties on actual sales rather than to pay the minimum royalties.

4.13 A further important safeguard is to include in the licence a clause which cancels the licence if the licensee does not take appropriate steps to bring the technology to market within a period of, say, 3 years. The technology would then revert to the licensor who could at that stage seek another exclusive licensee or a number of non-exclusive licensees, but only if the delay had not caused the technology to pass its 'sell-by-date'.

4.14 An exclusive licence may be further hedged around by restricting its coverage to a particular geographical area, for example Europe. In this case an exclusive licence can also be given to another company to make and sell the product in the United States, and a third in Japan, etc.

4.15 An exclusive licence can also be restricted in time to, say, 5 years in the first instance with the possibility of renewal if both parties consent, or downgrading to a non-exclusive licence if they do not. Alternatively or additionally it might be restricted to a particular market sector, such as that for diagnostic products, thereby leaving other sectors, for example, therapeutic products, available for licensing exclusively to another company.

4.16 Whenever an exclusive licence is granted by a provider, a clause in the agreement should safeguard the future in-house use by the provider of the research results covered by the agreement. This is normally done by including a clause in the agreement which grants back to the provider a non-exclusive, royalty free, irrevocable licence to use the results covered by the agreement for its own research and teaching purposes. The approach could in principal be extended so that all NHS supported projects were allowed to use these results for non-commercial purposes, but the licensee might not be prepared to stretch things that far. However where, for example, a provider works closely with a medical school which in turn is associated with a university, every effort should be made to negotiate a clause in the agreement covering these organisations.

4.17 Exclusive licences can fall foul of European Competition Law, so it is as well to ensure that the licensee has taken this into account, because it is the licensee who may suffer if this has not been done.

Non-exclusive licences

4.18 With non-exclusive licences there are none of the hazards mentioned above. In principle many companies can be licensed to compete in the same market place, but individual up-front fees will be lower than those of an exclusive licence, and perhaps royalty rates as well. Sometimes a non-exclusive license is given in return for research support. In practice a commercial judgement has to be made on the total size of the market, and the optimum number of licensees which might be attracted to compete for this market, so as to produce the maximum aggregated royalty income.

Royalty rates

4.19 When a licence is being negotiated the licensor will probably expect, rightly, that it will be through running royalties on sales that most of the licensing income will arise rather than from licence issue fees or annual licence renewal fees. It will therefore be important for the licensor to press for the highest royalty rate which can be negotiated. It is however not easy to give guidance on what these rates should be, for every case will be somewhat different.

4.20 The highest royalty rates will be on products, such as computer software, where the intellectual content of the product is high and the amount of work required for quantity manufacture is low. Here one encounters rates of 20% to 25% on net sales price. A new medical instrument of reasonable complexity might command a royalty rate of between 5% and 10%. A novel pharmaceutical drug is likely to be in this range, probably towards the lower end. For a product, such as a vaccine, which might have several licensed technologies incorporated in it, rates of one or two percent for each licensor are not uncommon.

4.21 Royalty rates can only depend on the development costs a licensee has to meet in bringing the product to the market. The closer the product to the market when the licence is agreed, the higher the prospective royalty rate.

4.22 It will often be worth considering a sliding scale for royalty rates in which sales up to a specified annual threshold are at one royalty rate, and sales above the threshold at another. (There might indeed be a series of thresholds.) Logically, from the licensor's standpoint, the second rate should be higher than the first, for the licensee will be making higher profits on higher sales, having already recovered development costs on earlier sales, and can therefore afford to pay a higher royalty. It is not however unknown for the licensee to argue that the research institution will have recovered its full research costs on the royalties paid on sales below the threshold, and should therefore be content with a lower royalty rate above this threshold. It is in situations like this that skilful negotiation is called for.

4.23 The licence must also specify clearly the basis on which royalties are to be calculated. This will normally be on income arising from the net selling price of the product. Net selling price is the price actually received by the licensee, net of agreed trade discounts, and in some circumstances the cost of packaging such as the cost of the glass vials containing vaccines.

4.24 Where the product is based on technologies from two or more licences, each will have its own individual royalty rate. Where the technology is sold as a 'bolt-on' accessory to an instrument, the royalty should be levied on the difference between the price charged for the instrument with and without the accessory.

4.25 There are occasions where the product builds on existing technology which is the subject of background intellectual property owned by others. In a case such as this exploitation of the product could recognise the background intellectual property by an agreement to share benefits, usually a share in royalties. This is discussed again in Chapter 5.

Licensing of patents

4.26 If a patented invention is to be exploited under an exclusive licence , then either the licensee takes assignment of ownership of the patent (or patent application) or the licensor retains ownership of the patent. The advantage to the licensor of assigning the patent to the licensee is that thereafter all activities associated with prosecuting and maintaining the patent will fall on, and have to be paid by, the licensor. The licensee is however likely to take account of the resource implications of this when assessing what up-front licence issue fee and royalty rate it is prepared to pay.

4.27 If assignment is made to an exclusive licensee, it is up to the licensee to register the assignment with the relevant patent authorities and pay the modest fees entailed. This will ensure that notices when patent renewal fees become due are henceforth routed to the licensee.

4.28 Conversely, if the licensor retains ownership of the patent, it should argue for a higher licence issue fee and higher royalty so that the costs to it of obtaining and maintaining the patent are covered as well as giving a reasonable return. An advantage of retaining ownership is the safeguard it gives if the licensee were to go bankrupt. If assignment had taken place it is doubtful whether the licensor could regain control of its former intellectual property in the event of such a bankruptcy.

4.29 If a number of non-exclusive licences are granted for a patented technology, the licensor will have to retain responsibility for prosecuting and maintaining the patent. In negotiating licence issue fees and royalty rates with its multiple licensees, the licensor should take into account its future costs of patenting.

Liability for patent infringement

4.30 With any patent or patent application questions concerning liability are bound to be raised by prospective licensees. One common question is what would be the position if it turned out subsequently that an earlier patent was being infringed, and this resulted in legal action by the owner of this earlier patent against the licensee. Would liability rest with the licensee or licensor? Whilst in principle the licence could be written to attach primary

responsibility on either, a provider will surely wish to ensure that it is not liable. In these circumstances the licence must contain a carefully drafted clause which makes it a condition of the licence that the licensee accepts such liability. It might perhaps be agreed though that the research staff responsible for the patent would be made available, at the expense of the licensee, to help defend the licensee if an infringement action were brought.

4.31 If a number of non-exclusive licences had been granted for the same technology, these licences should also guard the licensor from liability in any patent infringement action. Again perhaps the relevant research staff could be made available to give evidence at any infringement hearing on the assumption that all the non-exclusive licensees would join together in defending the action and jointly pay for the costs of any involvement of the researchers in the action.

4.32 A further query often voiced is what should happen if a patent application which featured prominently in a licence failed to be turned into a granted patent, perhaps because it was rejected because of prior art considerations. Here again the best approach a licensor can take is to point out that in good faith it knows of no reason why the patent should not be granted (assuming always that this is a true statement) and the licence is therefore offered on the basis that any such risk must be borne by the licensee. The licensee would also carry out its own due diligence investigation before signing the agreement. In short, if the patent failed to be granted, the terms of the licence would nevertheless apply.

4.33 In attempting to place all such liability on the licensee through the wording of the licence agreement, it must be recognised that this will normally result in the licensee only being prepared to pay lower royalties than if it did not have to carry the risk. This is usually a small price to pay for avoiding liability.

Product liability

4.34 Again the licence must make it absolutely clear that the licensor does not accept liability for damages caused by any product sold or otherwise supplied by the licensee which is based on the technology covered by the licence. Liability should reside with the licensee who will doubtless have adequate product liability insurance cover, but this should be confirmed before any licence is signed.

Chapter 5

Sharing Income from Exploitation

Introduction

5.1 It should first be stressed that there is no legal requirement on an organisation to share the exploitation income it earns with its employees who created intellectual property in the normal course of their duties[2].

5.2 Indeed revenue sharing with inventors is rather uncommon in industry. It is however usual in UK universities, but with a proviso, normally recorded in the staff handbook defining the terms and conditions of employment, which emphasises the discretionary nature of such awards. This is done via an entry such as *the university in its absolute discretion may award a share of any net income earned from the exploitation of intellectual property with the staff who created said intellectual property. Here net income means income left after first recovering patenting and other external costs incurred by the university.*

5.3 The terms *net income* and *patenting and other external costs* as used here can be explained by example. If a Trust were to employ an external technology transfer agency, the *patenting costs* plus the costs of the actual exploitation operation (*the other external costs*) could well be met by the agency itself from its income. The agency would retain an agreed percentage of the income from each exploitation project, and the remainder would be handed over to the Trust as *net income*. (*In practice the agency would normally hand over the sum plus VAT and less standard rate tax, which the Trust as a charity would be able to reclaim*)[1].

5.4 Similarly, if a Trust were to set up its own technology transfer unit, perhaps in collaboration with other trusts or a nearby research organisation, it will have to introduce a mechanism for recovering the operating costs of the unit from the income which the unit earns. The two principal types of expenditure on exploitation will be the salaries of staff in the unit and patenting costs, the two probably becoming of roughly comparable magnitude within a few years of start-up.

5.5 If patenting costs are paid by the unit, the unit should perhaps be permitted to retain 50% of the revenue it generates. The other 50% would then become net income available to the Trust for sharing with the inventors.

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[1] There is however some provision in the legislation for inventors to be rewarded, but only when the invention has been judged to be "*of outstanding benefit to the employer*". Application has to be made to the Comptroller of Patents who may refer the matter to the Courts. The procedure is described in an excellent Patent Office publication entitled Patents Act 1977 *(as modified by the Copyright, Designs and Patents Act 1988),* the relevant entries being in Section 40 and 41. Case history however indicates that it is unlikely that any invention made under NHS sponsorship, or indeed elsewhere, would qualify as giving outstanding benefit, so for all practical purposes it is absolutely fair to maintain that such awards are entirely discretionary.

5.6 If the Trust itself with its partners has the means to pay for the cost of patenting and does not levy this as a charge against the technology transfer unit, the unit should perhaps retain 30%, a figure common to a number of technology transfer companies of UK universities. 70% of the exploitation income it earned from a project would then be handed over. The Trust would first recover patenting costs and what was left over would be available for distribution as net income.

Providers collaborating with medical schools

5.7 A number of universities with both science and medical schools have revenue-sharing schemes in operation which cover both. If your provider has a close association with such a university medical school, it would be wise for a similar, and preferably identical, sharing scheme to be adopted by your provider as well.

5.8 It is not uncommon for an invention in the medical field to be made by a pair of researchers, one on the staff of a medical school and one on the staff of the associated hospital. In such a circumstance, if a different sharing formula applied to each of the pair, because one was an employee of the university and one of the Trust, this would clearly be divisive.

5.9 In what follows the types of formula will be described which are used by UK universities to share the net income with the researchers on the project from which the intellectual property being exploited arose. UK universities are used as a model which could be appropriate to the NHS because so much NHS-funded R&D takes place in collaboration with universities.

Types of sharing schemes used in UK universities

5.10 There are two general types of sharing formulae in use in UK universities: constant ratio of sharing; and sliding scale. These are described below.

Constant ratio of sharing

5.11 Here the net income received by the university, irrespective of its magnitude, is shared in a set ratio between three parties, namely the inventor (or inventors), his or her department, and the university centrally. A common arrangement is for *net income* (as defined above) to be divided equally between the three parties, but other arrangements are also in operation.

Sliding scale

5.12 The second type of arrangement embodies a sliding scale which gives a greater proportionate share to the university as income mounts. Such an arrangement was recommended by the so-called Scrutiny Group of the

Research Councils in the mid-1980s, at the time when universities were first being encouraged to become pro-active in technology transfer.

5.13 The underlying rationale for a sliding scale is that modest amounts of exploitation income (which would have little impact on the finances of the institution as a whole) might better be deployed as incentive rewards to the staff whose innovations led to this income. Rewarding individuals in what might appear to be a generous fashion will, as experience has shown, encourage other staff to be more positive about exploiting the results of their research. Quite modest sums distributed in this way can greatly help the creation of the right climate.

5.14 Once the income earned by an exploitation project is on a scale sufficient to make a significant contribution to the finances of the institution, it would seem only reasonable that the institution should keep a major share of this income. Whilst the inventors progressively get a smaller proportional amount, the absolute sums involved do mean that the inventors can still be considered to be well rewarded.

5.15 A typical sliding scale might be as follows:-

Cumulative Net Income	*Inventor(s)*	*Department*	*Institution*
First £50,000	75.0%	12.5%	12.5%
Next £200,000	50.0%	25.0%	25.0%
Over £250,000	25.0%	37.5%	37.5%

Choice between the two types of sharing scheme

5.16 The constant ratio of sharing scheme is obviously easier to administer. It can however be criticised for not giving sufficient incentive to inventors, by restricting the proportion of early income they receive compared to that under the sliding scale scheme.

5.17 The sliding scale scheme answers this criticism, but does entail keeping detailed records of payments made to inventors, perhaps for as many as 10 to 15 years during which time an invention might be earning income. Such records will enable the percentage going to the inventors to be varied as the break-points on the sliding scale are progressively reached.

5.18 A further complication only of the sliding scale scheme concerns the reward to an inventor for further inventions. Some researchers are particularly innovative, and produce more than one item of intellectual property which achieves commercial success. In these circumstances subsequent items often build upon the original intellectual property. The question then arises as to how the inventor responsible for a second, third or further income streams should be rewarded.

5.19 Should the second project be regarded as entirely separate, with the reward to the inventor being determined by starting on the top rung of a new siding scale? Alternately, should the income from the second project and subsequent ones be aggregated with that of the first project, and the inventor's share be determined by reference to the single original sliding scale?

5.20 Experience has shown that the latter method has at least one major advantage, for it avoids the difficulty of defining what a single project actually is, and this can be surprisingly difficult. To illustrate the problem, let us consider the case of an inventor who has generated a patent and associated know-how which have been commercialised as a single successful product. The inventor argues, as has been known to happen in practice, that the patent and the know-how should be considered as separate 'projects', with the exploitation income considered as arising equally from each, and each having its own individual sliding scale.

5.21 If this argument were accepted, the inventor would benefit by continuing to be rewarded for twice as long at the highest percentage defined by the top rung of the sliding scale (assuming always that sufficient total exploitation income were generated).

5.22 Even more bizarre proposals have been encountered, for example, with an integrated suite of computer programmes consisting of ten modules being claimed by the author to be ten 'projects', each with its own independent start on the top rung of the sliding scale.

5.23 Apart from making the administration of the revenue sharing scheme easier, the arrangement under which each inventor benefits only once from the high percentage of the top rung, irrespective of how many genuinely separate inventions he or she makes either alone or with others, can be argued as logically fairer. Some types of research are more likely to lead to a number of small inventions each making a modest return, whereas others are likely to lead to a single major, but highly profitable, invention. Restricting every inventor to just one start on the top rung of the sliding scale tends to even out rewards between these different type of project.

Uniformity of sharing schemes

5.24 Nowadays collaborative research projects involving groups in different institutions are quite common. This would argue for a uniform sharing formula across all such institutions. In the UK university sector, even though collaborative working has been long established, no such common standard has yet emerged. There are however welcome signs of some convergence.

Continuity of payments to inventors

5.25 There is no guarantee that inventors will not move on or retire whilst royalties are still being received by the employer. This should be covered in the agreement between the employer and the employee; the standard condition is that royalties will continue as long as income is received despite any change in employment status.

Foreground and Background Intellectual Property

5.26 It is not infrequent for intellectual property to arise (foreground) which builds on existing technology (background) which has intellectual property rights of its own. There may be different inventors and different institutions.

5.27 Agreement to share benefit needs to be reached by the parties involved well before a licence agreement is in place otherwise there is potential for conflict. Sharing royalties and fees is an obvious way forward, even though the individual amounts will be diluted. As Adviser you will need to judge, in discussion with researchers and the other parties, the cost-effectiveness of the arrangement you enter into.

Chapter 6

The Technology Transfer Unit and its Structure

Introduction

6.1 Your responsibilities as Adviser, if you are an R&D Manager as well, may include the management of both the research grants and contracts portfolio and technology transfer through technology audit, licensing, etc. Experience has shown that if possible it is best to employ different staff on these activities. Not only are the skills required for each slightly different, but so too are the underlying time-scales.

6.2 Staff involved in the administration and negotiation of research grants and contracts will in general be working against fixed deadlines, such as the closing dates for bids for NHS R&D funds and research council grant rounds. The time between the start of framing bids and applications, contract negotiations and the time the agreement or contract is signed is unlikely to be more than a year. In contrast, technology transfer projects can take from 5 to 10 years.

6.3 Where the two types of activities have been undertaken by the same staff, the short-term pressures of the grants and contract activity are likely to drive the technology transfer part of the job to an unacceptably-low level of priority. In some cases this has resulted in technology transfer being neglected. Hence the desirability of allocating the day to day management of the two activities to different people.

6.4 In what follows the phrase technology transfer unit will be used to refer to those staff or consultants who are occupied full or part time in the identification and protection of intellectual property and its outward licensing, sale or exploitation by other means.

6.5 It is generally accepted by those working in the field of technology transfer that the activity is best conducted close to the research to which it relates. Experience has shown that the researcher and the technology transfer executive often need to work closely together as a team for some years before the stage is reached where industry is ready to take over. Clearly the process is greatly aided if the research laboratory and the technology transfer staff are located physically close to one another.

6.6 With so much of the UK national science dependent on academic research carried out in universities, medical schools and hospitals, the technology transfer activity associated with these have a key role to play in the overall national technology transfer scene.

6.7 In deciding your exploitation route, you need to decide what is most appropriate for your provider. If you are big enough in R&D terms you need to consider whether alone or with others a free-standing technology transfer unit, one which could form a self-sustaining business, is a possibility. The threshold size for such a unit is considered below.

Threshold size for a free-standing technology transfer unit

6.8 The wide range of skills which a free-standing technology transfer unit must possess to be effective allows an estimate of a threshold for its size. Experience has shown that a successful technology transfer executive must have an intimate knowledge of the scientific subject area to which his or her exploitation efforts relate. The ideal personal profile is that of a recent ex-researcher who has acquired a working knowledge of the patenting process, and is acquainted with the industrial sector relevant to his or her field of interest.

6.9 It would be unrealistic to expect such an executive to exploit research efficiently in a subject area which is too far removed from his or her own scientific discipline. For example, a software expert could not reasonably be expected to handle an invention in genomics, nor vice versa. The number of executives, each of a different scientific discipline, which a technology transfer unit or organisation ideally should employ depends on the breadth of the research interests of its clients. Collectively such a team should then be equipped to deal with commercial prospects arising across the whole spectrum of topics covered by the provider.

6.10 Let us suppose, by way of example, that a technology transfer unit comprising 2 full-time executives plus a modest amount of clerical support is needed to service a research-active Trust. The cost of running such a unit, including overheads, is likely to approach £150,000 per annum, excluding patenting costs. Typically these might add a further £100,000 per annum, once a portfolio of patents has been built up, some of which by then will have reached their expensive stage.

6.11 There is no point in operating such a unit unless a profitable business develops, at least after its initial start-up years. Suppose that the unit operates on a commission basis, keeping a fixed percentage of the income it brings in. This percentage is likely to be in the range 30% to 50%. If patenting costs are paid by the unit, the percentage is likely to be at the top end of this range. If patenting costs are paid for by the Trust itself, and not charged to the unit, the percentage should be at the bottom end of the range [2],[3]

[2] The commercial technology transfer company BTG plc (formerly British Technology Group) has agreements with some UK universities under which it undertakes to pay any necessary patenting and development costs external to itself. When exploitation income is earned BTG first recovers those costs plus interest, and then passes on to the university concerned 50% of the income.

[3] Several UK universities have technology transfer companies which retain 30% of the exploitation income brought in, with the university itself paying patent costs direct.

6.12 Thus, if a unit which meets patent costs is eventually to break even financially, it will have to generate an annual income of around £500,000 to cover its costs from the commission it earns.

6.13 If, for example, a Trust is contemplating establishing its own technology transfer unit alone or with others, the issue which the Trust has to address (even if it had access to sufficient funds outside patient care to consider it) is whether it believes there is a reasonable chance that exploitation of its intellectual property could produce a revenue stream in excess of £500,000 per annum. This is not an easy question to answer.

6.14 If the Trust's research generates sufficient technology transfer activity to keep the 2 executives fully occupied, each in their own specialist area, a sizeable portfolio of technology transfer projects will come about within a few years. There is then a good chance that annual income of at least this magnitude will be earned from royalties after the appropriate build up period. This though is far from certain.

6.15 Technology transfer by its very nature is a long term and risky business. It can take as much as 10 years or even longer, depending on the subject area, from the time a research result of commercial importance first appears to the time when royalties from product sales based on it start to flow. Furthermore it is a characteristic of the technology transfer business that income arises mainly from a few 'big winners'. Whether or not one of these appears requires good judgement by a technology transfer unit, but also good luck.

6.16 An example illustrating these two aspects is that of a novel chemical compound with unproven, but promising, properties as a therapeutic agent. Because of the need for extensive clinical trials, the proving process will last perhaps 10 years before both regulatory approval has been obtained, and sales of the drug have built up. The cost of the whole process is likely to approach £100 million. No pharmaceutical company will invest such a sum unless it has an exclusive licence to the technology, and there is a good prospect of it recovering its investment through revenue on product sales.

6.17 But there is no guarantee that an undesirable side effect of the drug will not be discovered at some stage during the clinical trials, meaning the project has to be abandoned. Statistics from the pharmaceutical industry indicate that 9 out of 10 potential drugs put into clinical trials fail to reach the market. These of course produce no sales and no royalties. However, if the drug is a 'big winner' and does reach the market, the royalties paid by the licensee to the technology transfer unit could easily amount to several million pounds per year. In short the project will make either millions, or nothing.

6.18 Although the above example is somewhat extreme, it does illustrate what a risky business technology transfer can be. In other cases, perhaps inventions concerned with novel medical instrumentation or devices, there is usually less difficulty in predicting commercial success, but the royalty income is likely to be much less.

6.19 A free-standing technology transfer unit in a Trust attached to a university medical school would probably have to handle a mixture of projects across a spectrum from, at one end, high risk with prospect of high return, to the other end, lower risk with lower potential returns. All other things being

equal, the larger the size of the institution, or collaborating institutions, in research terms, the larger the portfolio of exploitation projects which would be on its books, and therefore, because of economy of scale, the greater the chance of achieving business success.

6.20 It is difficult to estimate how large a portfolio of research grants and contracts might need to be to produce sufficient technology transfer projects to earn an income sufficient to justify establishing a unit of the size described above. Evidence from leading UK universities with medical schools, supported by data from equivalent US institutions, indicates that the figure for income from technology licensing and related activities could on average be a few percent of that for the corresponding expenditure on research. On this basis, a Trust, with or without partners, with an annual R&D expenditure of about £20 million might be capable of producing an income of £500,000 from technology exploitation. (The reader is however warned against placing much reliance on these estimates because of the difficulty in making them. One 'big winner' would dramatically alter the picture!)

Choosing the exploitation route

6.21 Given the considerations above, a Trust with R&D expenditure less than about £20 million (and this applies to the vast majority) is unlikely to be able to establish, by itself, its own commercially-viable free standing technology transfer unit. Also, if its research encompasses a number of specialist areas of medicine and science, each of which needs to be assessed by a person with a different technical background, there will probably be insufficient work to keep that person occupied full time. Employment of a number of specialists part-time is possible, but the operation would need at least one full-time executive.

6.22 There are much more likely routes for a research-active Trust. You could establish a joint technology transfer unit covering more than one research institution receiving NHS R&D funds, you could contract with an independent technology transfer unit of another research organisation (e.g. a university), you could contract with a commercial organisation or you could enter into partnership with a local business centre of some kind. In all of these routes much of the risk can be transferred out of your Trust even though this will reduce the potential return. You should explore which of these options appears most attractive.

6.23 The structure of a joint technology transfer operation set up together with a neighbouring provider or local university or a number of such institutions could be as follows. A small team of full time technology transfer executives, backed as necessary by part time consultants, could be established to undertake technology audit of the research programmes of the participating organisations and to take forward the arising intellectual property management. Costs and rewards would be shared between the participating organisations in a pre-agreed fashion. The approach has much to commend itself. Indeed there are already examples of it in operation where the technology transfer operation of a university services its medical school and associated teaching hospital. Such an arrangement can also be attractive to outside investors both in the public and private sectors.

6.24 It is becoming more common for local business and technology centres, with funds to develop new business opportunities, to form partnerships with universities and Trusts and to invest in the exploitation of intellectual property. You should explore whether such an arrangement is possible.

6.25 A provider, big or small in R&D terms, can employ the services of an existing technology transfer organisation, preferably one which is based geographically close to the provider. The organisation would take responsibility both for the technology audit and the exploitation of any arising intellectual property rights.

6.26 There are a modest number of suitably qualified people in the UK, working at present mainly for universities on a per diem consultancy basis. As an additional alternative these might be employed to handle individual projects as they arise. Discussion with a neighbouring university will determine whether an exploitation partnership arrangement is possible.

6.27 The exploitation route for independent providers of NHS services who generate intellectual property is likely to depend on their relationships with other providers or with university medical schools. As Adviser you will need to assess which route offers the best possibility of return and agree it with the NHS Executive.

6.28 The message really is that are a variety of exploitation routes for each provider, one of which is most suitable for you. It is your responsibility, taking whatever advice you need, to decide the best option.

Chapter 7

Research Contract Negotiation

Introduction

7.1 The subject of research contract negotiation, though peripheral to that of intellectual property management and exploitation, has nevertheless been included in this Handbook for good reason. The objective is to emphasise that it is at the negotiating stage of research contracts that ownership of intellectual property is decided, whether it is to be retained or given away. Obviously, the more that is retained, the more that is available for exploitation, and the greater the potential revenue from royalties**.**

7.2 This chapter concentrates largely on the main arguments for retaining ownership which you can deploy in negotiating contracts for externally sponsored research.. The arguments likely to be presented in response by sponsors, particularly commercial ones, are also given. Related aspects, such as freedom to publish, are covered in addition.

7.3 When a research sponsor approaches a research provider it does so believing the provider has the people, the background, the research expertise, and the environment (perhaps the patient population) to carry out the work it wants done. If it is a commercial sponsor this work may be near market or it could be longer range. The research sponsor also has a research budget, will want to obtain maximum value for money and may have an existing portfolio of intellectual property. The research provider, on the other hand, is usually keen to maximise its external income from research, it wants to enhance its reputation and often has a portfolio of background activity and perhaps background intellectual property which attracted the sponsor in the first place. The research provider does not want to compromise its long term research position without giving due care to the intellectual property which could arise from a research contract with the sponsor, nor does the sponsor want to compromise its own research portfolio or its commercial position by giving away intellectual property unnecessarily.

Contract research and collaborative research

7.4 As a general rule the ownership of arising intellectual property should vest in the research sponsor or the research provider depending upon the price charged for the work. *Contract research* is defined here as work, usually funded by a commercial sponsor, where the sponsor defines what is needed and for which it should be prepared to pay full cost. *Collaborative research* is defined here as work which is jointly funded by the sponsor and the provider, is more open-ended, has research questions to be answered, and the provider has sufficient interest to be prepared to contribute to the cost.

Collaborative research could be funded by a commercial or a non-commercial sponsor. Any work which is not fully funded by the sponsor is collaborative research.

7.5 In its new arrangements for supporting R&D, when the NHS undertakes contract research for a commercial sponsor it gives it the label *commercial externally-funded R&D* for which full cost is expected. Collaborative research is within the category called *non-commercial externally-funded R&D*, and for this the provider acting for the NHS shares the cost with the sponsor. In this context *non-commercial externally-funded R&D* can be funded by a commercial sponsor.

7.6 When a sponsor asks a provider, for example an NHS Trust, to carry out contract research the price should be at a level which recovers its costs, including full overheads, of undertaking the work. The research is usually near-market and the main benefit is to the sponsor. In these circumstances ownership of arising intellectual property will surely be sought by the sponsor. The Trust might have to concede the point, but it should never do so lightly. At the very least the Trust should propose, in lieu of a 'profit', that the sponsor agrees to pay royalties based on the 'added value' of the work if successful commercial exploitation ensues.

7.7 If a Trust aimed to make a straight profit on each contract, this might be viewed as trading, and then there would be a chance of violating its charitable status as well as becoming liable to pay tax on this profit, a situation it will doubtless wish to avoid.

7.8 When the research is of a longer range nature, commercial sponsors might not wish to meet the full cost of the work and may suggest sharing the cost with the provider. If the provider is willing to entertain this prospect, and is financially able to do so (making it non-commercial externally funded R&D in the NHS definition), it should insist that benefits are also shared, since costs are to be shared. The aim should be to apportion the tangible benefits in the same ratio as costs are shared.

7.9 During negotiations, it would not be unusual for the sponsor to argue that there will also be intangible benefits accruing to the provider. These, the sponsor will claim, should be taken into account in assessing how the benefits are to be shared. It might be pointed out, for example, that the intangible benefits to the provider will include enhanced reputation in research as a result of undertaking the work. The response should be that intangible benefits will also accrue to the commercial partner, for example, an enhanced company reputation because of its support of academic research contributing to the national science base. In contract negotiations it is always best to ignore intangible benefits and to concentrate solely on tangible ones.

Who should own intellectual property in collaborative research with commercial sponsors ?

7.10 Intellectual property, its ownership and exploitation, will feature prominently in any assessment of the benefits of collaborative research projects. Such projects are increasingly common between public sector organisations, including providers, and industrial concerns of all sizes. The major companies are invariably well versed in intellectual property handling, but the smaller ones, with some exceptions, are unlikely to be as expert as some providers, particularly where the latter have been engaged on technology transfer in conjunction with university medical schools or with external technology transfer organisations.

7.11 An obvious way ahead, where one partner is experienced in intellectual property management and the other is not, is for the former to assume ownership, and for there to be an arrangement for the equitable sharing between the partners of any revenue which arises.

7.12 Where there is comparable expertise in handling intellectual property on both sides, experience has shown that the issue of ownership can often be contentious, for there are compelling arguments in support of both sides.

7.13 At first sight it might seem that joint ownership is the most appropriate solution in the circumstances. Indeed as an interim solution for inclusion in the initial contract it has much to commend itself. Later, however, if intellectual property of worth arises, such an arrangement will need to be changed because potential licensees will not welcome having to deal with joint owners for fear of being drawn into disputes between them.

7.14 It is also true that joint ownership between a concern which trades commercially and one that does not, such as a Trust, gives the former an important advantage. In principle each partner can manufacture and sell products arising from the research without needing to obtain the formal permission of the other. But the Trust, as a charity, can not trade, and is therefore placed at a disadvantage. However, if either partner wishes to sub-license a third party, it must obtain the written permission of the other.

7.15 Joint ownership is more appropriate where a patent involves named inventors drawn from both partners in a collaboration. Again it is advisable that an arrangement giving single ownership is made before licensees are approached.

7.16 In some sectors of industry, the pharmaceutical and biotechnology sectors being the best examples, the protection offered by patents is of absolutely fundamental importance to the success of the business. No

companies in these sectors will be happy to make the necessary major investment in the development, design, manufacture and marketing of a new product without having control of the underlying intellectual property.

7.17 A general view held in many other industrial sectors is that, since industry must take responsibility for the final stages of exploitation, it might just as well own the intellectual property from the outset. This line went largely unchallenged until the mid-1 980s when the right of first refusal to exploit research council-funded research in universities was removed from British Technology Group. Thereafter universities and other public sector research organisations increasingly began to recognise the penalties of surrendering, and the advantages of retaining, ownership of intellectual property.

Arguments for ownership by a provider

7.18 The main reason why non-commercial research organisations, such as providers and universities, should today seek to retain ownership of intellectual property is to preserve their freedom of action to undertake collaborative research with different commercial partners of their choosing, either simultaneously or sequentially. Loss of such freedom is a serious matter which can threaten the continuity of important research programmed.

7.19 A typical research group in an NHS Trust, particularly one working closely with a medical school, will nowadays need to attract a number of grants and contracts from a variety of sources in order to sustain its research effort at a viable level. 'Foreground' intellectual property arising from an earlier project will then become 'background' to a later project which builds upon the results of the first.

7.20 In many cases the exploitation of this 'foreground' will also require commercial access to the 'background'. If the Trust has already agreed to assign the 'background' to its commercial partner in the earlier project, that partner is likely to deny access to the Trust's intended new research sponsor for very good commercial reasons. It is not unlikely, for example, that the new intended partner is a market-place competitor of the original one. In such circumstances the new sponsor, recognizing that access to essential 'background' is blocked, will be unwilling to proceed, and the Trust will have lost a research contract.

7.21 To avoid such a difficulty the Trust must argue to retain control of intellectual property arising from its work wherever 'core' results, central to the unfettered progress of its research, are involved. The Trust then remains free to work with any commercial collaborator on projects which build upon the past results of its research.

7.22 A second important reason concerns the desirability of maintaining an integrated portfolio of research results. Over a period of years a typical research group will deal with a wide range of different research sponsors, probably including industrial companies, government departments, charities and research councils. The research group will rightly contend that all the intellectual property created from its diverse activities should be kept together as an integrated portfolio. Such an approach will maximise the potential value of the portfolio for all concerned. Items should not be assigned piecemeal to the sponsors of individual research projects, making it impracticable ever to re-assemble the portfolio, or significant parts of it.

7.23 To achieve this state of affairs the Trust, acting on behalf of its research group, will need to persuade each of the sponsors, during the initial stages of contract negotiation, to seek only the right to a non-exclusive licence to arising intellectual property. The Trust can rightly argue that this solution is in the best interests of all.

7.24 Each sponsor will then be able to obtain commercial access to the group's entire portfolio of intellectual property on a non-exclusive basis, should it wish to do so. In most cases this is likely to be of greater potential commercial value to a collaborating company than an exclusive licence to the results of only that small number of projects which the company itself has supported. (Be forewarned however that such an argument is unlikely to be accepted easily by a pharmaceutical or biotechnology company for reasons already given.)

7.25 A company sharing the costs of a research contract with a Trust may argue that to be granted only the right to a non-exclusive licence through the initial contract is not enough. If confronted with this argument it would be as well to point out how strong a position such a non-exclusive arrangement gives to the company. After all, the company, and that company alone, can negotiate later with the Trust to become the holder of an exclusive licence, for the Trust cannot grant an exclusive licence to anybody else.

7.26 Towards the end of the project, when the company has assessed the results of the research, it will be in a position for the first time to determine whether or not the results have commercial potential. At that stage - and not before - it can plan an appropriate exploitation route, and decide whether to exercise its right to a non-exclusive licence, or alternatively whether to seek to negotiate an exclusive option or licence or an assignment. The Trust will by then also be in a better position to judge whether granting the company exclusivity will prejudice the future conduct of its own research activities. Only at this stage can fully informed negotiations take place between the partners concerning exploitation. This approach is in keeping with one of the cardinal principles of negotiators: keep all options open as long as possible.

7.27 An arrangement much in line with that described above was adopted by the European Commission's Framework Programme more than 10 years ago, and has been successfully used ever since. Each partner in a project owns the intellectual property it generates. On request each has to grant a non-exclusive licence to any other partner in the same project. Between pairs of industrial partners the licences are royalty free, but when a not-for-profit partner licenses an industrial partner, the licence is royalty-bearing.

7.28 A further matter relevant to ownership of intellectual property concerns the danger of failure to exploit. When blanket ownership of intellectual property from collaborative research projects is given automatically to a commercial partner, as has happened frequently in the past, much of this intellectual property has remained unexploited. Research, by its very nature, is so chancy that there can be no guarantee that the results of a project which is part-funded by a commercial company will fit in with the business objectives of that company. Where they do not fit, items of intellectual property, which in other hands could lead to commercial success, can become locked away and generally inaccessible.

7.29 Most contracts should however include a clause giving reversion of rights within a specified period in the event of non-exploitation. In principle this provides a safeguard against occurrence of the above situation. In practice however the approach does not always work. In the fast-moving sciences the results of research will have passed their "sell-by-date" well before the clause dealing with reversion of rights becomes effective.

7.30 A provider asked by its commercial sponsor to assign future intellectual property via the original contract, before the research has even started, should argue strongly against this. Generally several years will pass between the time when the contract is signed and when the results of the research can first be assessed. In the interim the sponsor may have changed its business objectives, or perhaps even have been taken over by another company. In consequence it may no longer be interested in the field of research in question. If you have to assign your intellectual property, a deed of reassignment in the event of non-exploitation should be included in the agreement.

'Holding' arrangement for intellectual property ownership

7.31 When a major company and a research institution skilled in the art of intellectual property management have become involved in the past in contract negotiations, it has not been uncommon for an impasse to develop concerning ownership of intellectual property. It is generally acknowledged that attempting to draft a contract or agreement which satisfactorily ties up all the details concerning exploitation before the research has even started is virtually impossible. Much negotiating effort

has been wasted in attempting this, only to find -for such isthe nature of research - that the majority of projects finally produce nothing of real commercial value.

7.32 A far better approach is to put in place a workable 'holding' arrangement. This will safeguard the interim position of each of the parties, and yet leave the way open for them jointly to determine at the end of the project whether there is anything worth exploiting and, if so, how this exploitation should be tackled, and by whom. The main elements of such a 'holding operation' are listed in Appendix 7.1.

7.33 A company which sponsors external basic research in a provider may take the stance that it is doing so primarily to add to its own portfolio of intellectual property. It is therefore likely to seek assignment of new intellectual property arising from any new contract. However if the company can be persuaded at the stage of the initial contract to accept the 'holding' arrangement described above, the way will remain open for later negotiations to take place about assignment of any intellectual property which actually arises - if indeed any does.

7.34 With ownership of intellectual property comes the responsibility of nurturing its exploitation. It is unfortunately the case that many sponsors who argue strongly at the outset for them to be given ownership take no subsequent steps to monitor the progress of the research. Thus they are rarely in a position to detect whether anything of commercial potential has actually arisen. Surprisingly it is not normal practice for the contract to require a final technology audit to be undertaken which would ensure that nothing was missed.

7.35 Experience in UK universities has shown that relying on the researchers themselves to report discoveries is not always enough. In general researchers are not well equipped to assess commercial prospects. Where a provider wishes to argue to retain ownership of intellectual property, it would be wise for it to be able to demonstrate that it had an arrangement in place, not reliant only on the researchers, to conduct regular technology audits of the research in progress in its laboratories. How to conduct a technology audit is described in Chapter 3.

Collaborative projects between providers and universities

7.36 Much of the intellectual property that arises will have been derived from collaborative work between providers and universities. In the past the universities have generally assumed control because, unlike providers, they have had a structure for dealing with its management and the rewards.

7.37 All such collaborative research should be based on an agreement between the university and the providers on how arising intellectual property should be managed. The party best able to exploit should be given lead responsibility, net income which arises should be shared between inventors and partners in proportion to their contributions.

7.38 Where a provider and a university are close and regular collaborators in research, if either wishes to enter into a research contract with an external sponsor under which the sponsor will own arising intellectual property, the contract should in general be written so as to allow the collaborating partner also to use the results of the research for non-commercial purposes. A suitable clause would grant a non-exclusive, royalty free, irrevocable licence for research and teaching purposes to both the contracting institution and its research collaborator.

Publication of research results

7.39 In academic circles there is pressure, often for research assessment or career development purposes, to publish research results without delay. When research is supported by a commercial concern, there will be understandable reluctance on the part of the sponsor to see early release of results which could help a competitor. It is quite normal therefore for contracts covering such work to place some restriction on publication.

7.40 These usually take the form of a requirement that every intended publication by the researchers must be submitted to the sponsor for scrutiny first. A clause in the contract will require the sponsor to study the draft publication, and to request any changes which, in its opinion, might prejudice commercial interests. A period defined in the contract, usually one month (but certainly less that 6 months), will be allowed for the sponsor to respond. It will be understood that complete blocking of publication by the sponsor would only be possible in absolutely extreme circumstances. The safeguard to the researchers will probably take the form of a statement in the contract that for each publication the prior written permission of the sponsor is needed, with such ' permission not to be unreasonably withheld'.

7.41 Prior scrutiny of publications should be viewed by a provider in a positive light. The second opinion on the value of the results to be published can be valuable. There have been cases where the sponsor has spotted a patentable invention which would otherwise have been missed. The Trust is also safeguarded from possible accusations that it had inadvertently released propriety information belonging to the sponsor which the researchers had been given access to. If the research is genuinely collaborative, this later aspect should have been dealt with properly in the contract.

7.42 Commercial concerns which support external research will in general approach the publication of results of such research in a positive light, seeing this as useful marketing material for whatever product or process may emerge. Acknowledgement of the support of the sponsor in each publication which arises, even if this is not strictly required by the terms of the contract, should of course be made.

7.43 Researchers can become concerned, when reading the clauses in contracts on restriction of publication, that their endeavours may be hampered. Experience has shown that difficulties rarely occur in practice.

Appendix 7.1

Guidance on Intellectual Property Terms and Conditions for Collaborative Research Contracts

1. If the cost of the research is shared between a commercial partner and the provider, so too should be the benefits, and in the same ratio;

2. The principle of sharing should extend to initial control over arising intellectual property, and to the planning of its exploitation. As an even-handed holding operation, the provider should have interim ownership of the intellectual property and the commercial partner the right to a non-exclusive licence to commercialise it.

3. At the end of the project (or sooner if important results arise earlier) a technology audit should be conducted and a written report produced. If a potentially patentable invention appears, the partners should jointly agree how to proceed. At this stage - and not before - exploitation plans should be agreed between the partners, in the full knowledge of what, if any, intellectual property of value has arisen;

4. The intellectual property may be of the sort where the optimum benefit to the provider and the national economic good will accrue by multiple non-exclusive licences. The commercial partner should have the right to a non-exclusive licence on (preferential) terms that reflect the latter's financial contribution to the project. Additionally the provider may issue other non-exclusive licences on normal (non-preferential) commercial terms, agreeing to share any net revenue from these with the commercial partner in the same ratio as the cost of the research is shared.

5. The intellectual property may in a minority of cases be of a sort where exploitation will only occur if exclusivity is granted to one organisation, for example, in the case of a potential anti-cancer drug. In these circumstances the provider should offer an option to an exclusive licence, or an exclusive licence to the commercial partner, on fair and reasonable terms which reflect the latter's financial contribution to the project;

6. The permission of the commercial partner, not to be unreasonably withheld, should be required before publication of the results of the project. The maximum delay which the commercial partner should have the right to impose should be 6 months from receiving the manuscript of the intended publication.