INFORMATION

Handling Inventions and other Intellectual Property

A Guide for NHS Researchers

NHS Executive

Purpose of this document

The purpose of this document is to raise awareness amongst researchers involved in R&D funded by the NHS as to the potential value of intellectual property arising from their work and of the issues involved in its exploitation.

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This document is for information

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Foreword

Probably no field of research is more intellectually challenging today, nor more important in both humanitarian and economic terms, than research into all aspects of health.

The aim of this Researchers Guide is to raise awareness amongst researchers involved in R&D funded by the NHS, both employees of Trusts and independent providers of NHS services, as to the potential value of intellectual property arising from their work, and of the issues involved in its exploitation. Independent providers of NHS services include primary care independent contractors and voluntary or private sector healthcare providers. The Researchers Guide indicates how to decide in specific cases whether the right course of action is widespread dissemination or protection first by patenting.

A natural instinct of researchers is to publish their results without delay, so contributing new knowledge, for example, to the improvement of human health and the alleviation of suffering. However, early public disclosure of intellectual property can sometimes be counterproductive. If results of R&D lead to ideas for a new product or process, be it a potential new treatment, a new diagnostic technique, a new piece of equipment or a new drug, if details are published before the intellectual property is protected (usually by a patent application) then the product is unlikely to be made or the process is unlikely to be developed.

By way of illustration, if a new potential drug has been discovered, no pharmaceutical company will be prepared to invest the £100 million or more needed to conduct clinical trials and bring the product to market unless it has exclusive rights to the intellectual property.

It is therefore imperative, if intellectual property rights are to be established for any invention, that protection by patenting precedes publication. Not only might a new treatment then become available, but also substantial royalties could be paid for the invention, so providing twin benefits to the NHS from its investment in the research.

The management of intellectual property is a highly complex subject requiring professional advice at all stages. This Guide provides a very simplified introduction to the subject, and must certainly not be taken as a substitute for such advice.

This Researchers Guide takes the form of a series of commonly posed questions with answers.

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.

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.

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.

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	*Registered Design Rights*
of aesthetic objects	
Engineering components, architectural drawings, etc	*Unregistered Design Rights*
Product brand names, company logos, etc	*Trade Marks*
Trade secrets, background techniques	*Know-how*

Which of these categories are relevant to NHS research?

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

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.

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.

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.

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.

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.

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.

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.

Who owns intellectual property rights?

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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