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Clinical Chemistry and Intellectual Property: Should we care?

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Introduction

Intellectual property (IP) is a general term for intangible property rights which are a result of intellectual effort. Patents, trademarks, designs and copyright are the main intellectual property rights (1). IP is generated and used on a daily basis. Experience learns that clinical chemistry is one of the main contributors of the use and development if IP in hospitals. IP management is not only important to allow the institute to benefit from their IP, but also to manage the use of third party IP. In IP management there is often a perceived conflict of interest between commercial and non-commercial (eg scientific) activities. However, proper IP management "manages" this conflict. It ensures that the IP is harnessed without delaying dissemination and allows scientific and commercial activities to co-exist under mutually agreeable terms. This article will explain the various situations where IP management is relevant within hospitals.

Requirements for funding

If (laboratory) hospitals want to engage in research they may require income from grants or other third parties. Most grant awarding bodies, such as the European Union, have specific IP clauses insisting that recipient institutions take steps to identify, protect and exploit IP arising from grant-funded work (2). Where the third parties are commercial organisations, these IP considerations are even more prominent. They may have implications not only on freedom to publish, but can also prevent the use of the results for further research. In extreme cases, it can hold the organisation liable for IP disclosures infringing the agreement.

IP management as source of information

European Commission has estimated that 30% of R&D carried out in Europe, is wasted on work that is already described in Patents. 80% of the technical disclosures appearing in patents appear nowhere else (i.e not in literature databases). Furthermore, all of this information (>30 million documents) is freely available (3). In conclusion, knowledge of IP and Patents can ensure and improve the "cutting-edge" character of laboratory research.

IP management and dissemination

IP management enables the control of dissemination. Scientific publications, (public) annual reports, even a poster in a public hallway, or answers to questions from the floor given at a conference are considered disclosures. It is therefore important to raise awareness of disclosures of this kind for the following reasons: dissemination may lead to contract infringement; dissemination may lead to invalidation of patents and dissemination may give away cutting edge know-how to (potential) competitors.
To prevent unintentional (early) disclosures, internal procedures of evaluating potentially valuable IP need to be in place. When discussions with third parties may disclose confidential IP, confidentiality agreements (CDA's, NDA's) will protect the IP.

IP management to prevent infringement

An important aspect of IP management is the prevention of infringement of IP rights of third parties. For example, methods are developed to detect characteristics (such as the Rhesus factor) or diseases (such as Down's syndrome) of foetuses in maternal blood. Should a hospital decide to set up facilities to use these technologies, they will need a licence to a patent, presently held by BTG (4) to prevent infringement of their patent rights. Proper IP management will identify this issue before such investment is made and enable a licence to be negotiated prior to using the technology, which is a more favourable position than negotiating a licence after infringement has occurred.

IP Management to enable better exploitation

Many good inventions have not entered the market because the IP has not been managed well. Early disclosures, thus preventing strong patent protection, dis-incentivices organisations to invest in the 'prototype'. For example, if a company were interested in taking up a diagnostic tool developed in a laboratory, investment can be expected in the following areas:

- Improving reliability
- Enabling mass production
- Approved by regulatory bodies
- Inclusion by the reimbursement bodies
- Market buy-in (physicians, and for larger investment hospital management)

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[1] Note to the reader: The author works for a company in the UK, primarily focussed on the commercialisation of IP of a local university (the University of Sussex). With the change in the political views on innovation, the company widens its service to regional SME's and other organisations. The view of the author does not necessarily reflect the company's perspective.

The company wants, therefore, to have some guarantee that competitors can not sell a similar product – patent protection enables this.

Commercialisation
Commercialisation of IP is done on a case by case basis. For example:
- A new antibody with a high affinity for a certain infectious bacteria may be best exploited by issuing it under a Material Transfer Agreement[2] to a catalogue company. This company will sell it, take the administrative burden and give an income stream to the original owner of the antibody.
- A new compound that enhances the contrast in a microscopic analysis of a certain type of infection is possibly best commercialised by patenting and licensing.
- A new inventive way of 'point of care'-diagnosis that is robust and economically attractive, may be a considered to be patented and then exploited through a dedicated company (a spin-out).

Conclusions
IP management is important for many reasons, including but not limited to economic benefits. Commercialisation activities of organisations such as hospitals are generally characterised by a small number of big successes, a larger number of modest successes and some failures. Identification and assessment of IP is important and to be followed by correct responses to strengthen the organisation rather then to create unnecessary costs and procedures. In order to achieve this, there needs to be an ongoing dialogue between staff dedicated to IP management and all other staff in the organisation.

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[2] A Material Transfer Agreement (MTA) is a contract that governs the transfer and use of one or more materials from the owner (or authorised licensee) to the researcher and organisation wishing to use the material for research purposes. Materials may include cultures, cell lines, plasmids, nucleotides, proteins, bacteria, transgenic animals, pharmaceuticals and other chemicals.

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Clinical Chemistry and Intellectual Property: How do we manage?

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Introduction
Although IP management is important for various reasons, this article will concentrate on IP management for commercial exploitation. Intellectual property (IP) is developed within hospitals on a daily basis. Part of this will have little commercial value, and will be best utilised through the normal routes of dissemination: publishing and/or sharing information among colleagues. However, some IP will need further investment to reach its full potential, and this will only be obtained through proper protection of the IP. This presentation will explain how to manage IP in a structured approach, which will create an interesting new activity within the organisation without hampering the core activities.

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Methods

IP management procedures
A clear IP management structure is needed for any successful exploitation. It consists of various steps (see Fig 1). It will normally be articulated in an IP policy document. The IP policy covers: roles and responsibilities of individuals and organisations; procedure for disclosure of IP and reward (if any) for the individuals and units involved.

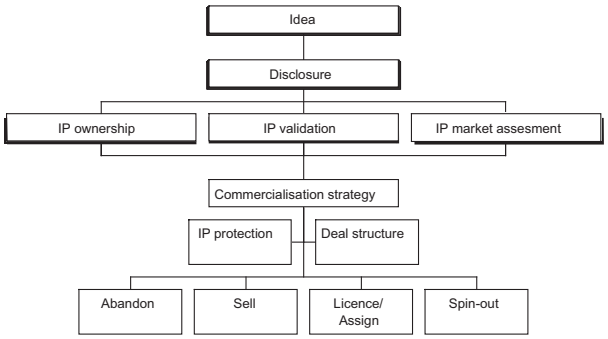

Figure 1. Management of potential exploitable IP.