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.

References

1. www.patent.gov.uk/design/glossary/
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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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[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.

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.

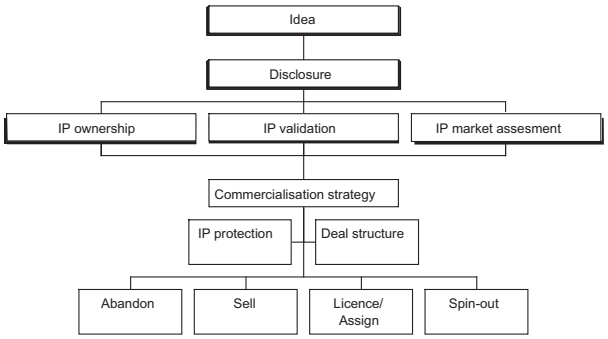

Figure 1. Management of potential exploitable IP.

IP awareness

IP awareness is the first and most important step in IP management. As IP is created though the whole organisation, at any time, employees should know when to discuss their IP. The initial step in raising awareness is usually in the form of a seminar, not only detailing the basics of IP but it also giving relevant examples. The second step is talking with individuals or small groups about the specifics of their work, indicating what may and what may not be exploitable IP. This discussion may end up in a formal IP audit.

IP identification

There are two basic mechanisms how potentially commercially viable IP will be identified in an organisation. The first one, common in organisations new to IP management, is the IP audit. In an audit, someone understanding the work as well as IP will talk with individuals or small groups, focussing on identifying opportunities.

Once an organisation is more mature in its IP management at all levels of the organisation, the IP is often identified by employees themselves. This can then lead to a formal IP disclosure. Standard items in a disclosure are:

- Who has been involved in creating the IP?
- How the work was paid for?
- Why this IP is better then existing products/services?
- Who might be commercially interested in it?

This disclosure forms the basis of a IP evaluation within the organisation.

IP evaluation

The IP evaluation will be performed to determine whether the IP will be taken forward for exploitation. A lot of this information to perform this evaluation is freely available on the internet. However, it is sometimes worth getting advice from individuals familiar with the market, or obtain a detailed market report. The evaluation will detail:

1. The best mechanism to protect the IP
   There are various forms of IP protection (see also Table 1). Patenting, the most expensive form, is the broadest protection, and is very common in (clinical) chemistry and other biosciences areas. Patents grant a legal monopoly for up to 20 years. Patent protection means that the invention cannot be commercially made, used, distributed or sold without the patent owner's consent. Patent owners decide who may – (or may not) - use the patented invention for the period in which invention is protected. Patent owners may license or sell to other parties rights in the invention. On patent expiry, the protection ends, and an invention enters the public domain. To patent IP, it must meet 3 criteria (1): novel, involve an inventive step and capable of industrial application. Additionally, the Subject matter must be accepted as "patentable" under law[2]. Patent agents can advise on the patentability of the IP.
2. The development phase of the IP
   This factor is important for the protection as well as the commercial opportunity. The more it is reduced to practise, the stronger the (patent) protection is. The more developed, the easier it is to find commercialisation partners.
3. Ownership of the IP
   The employer will normally own the IP (2). However, if an employee develops the IP outside his or her normal duties, it may be arguable that (s)he owns the IP. Also, if the IP is developed under a contract with third parties, or using materials obtained from third parties, IP ownership may differ.
4. Market characteristics
   This should include information about who may be potential buyers, the size of the market, the market dynamics and whether it consists of many small or a few big companies.

Table 1. Types of IP, their protected subject matter and their benefits and disadvantages

	Subject matter (3)	**Benefits**	**Disadvantages**
Patent	New Technical Concepts, Inventions	Long life, can be enforced against infringing parties, can be international, strong legal right	Forces public dissemination of invention, expensive to maintain, limited patent life, litigation very expensive
Confidential info	Ideas, Information, Know-how	Not public, unlimited duration, some court protection	No protection if public through independent discovery
Copyright	Text, Graphics, Software, Data	Automatic right, recognised worldwide, free and no need to register	Not registered, easy for infringing parties to avoid, only applies to tangible expressions not ideas or concepts; a weak legal right
Trademark	Brands, Image & Reputation	Inexpensive, registered right, can be perpetual, can be enforced against infringing parties	Usefulness limited to corporate or brand identifiers where product identity is critical
Design Right	Form & Appearance, Decoration	Protects against copying designs, free in case of unregistered design	Easy to circumvent, especially in case of unregistered design

[2] In many countries, scientific theories, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, or methods for medical treatment (as opposed to medical products) are generally not patentable

5. Value of the IP
   Overvaluing of the IP will prevent any deal to take place, whereas undervaluing would be a financial loss.
6. Additional benefits to the organisation
   The IP may have other than direct financial rewards. It may provide good publicity material or create links with a third party that is important to the organisation, e.g. for further research funding.

In summary, the evaluation will lead to a decision whether the IP will be exploited commercially.

IP exploitation

When the evaluation leads to a decision to commercialise the IP, the key to successful exploitation is to find the right buyer and deal structure. There are various ways of commercialising IP. A straight sale is rare. More common is a licence deal, where the ownership remains the same, but the 'buyer' obtains certain rights as described in the contract. In return, the owner will get money upfront and/or a percentage of the sales of the product made using the licence. Assigning IP is similar to licensing, though the ownership changes in this instance. This is therefore less desirable for the original owner.

Conclusion

Although IP management may take up resources initially, it will in time, when set up properly, allow an organisation like a hospital to benefit from this potential high value asset in the organisation. This would potentially lead to an additional income stream, and incentivise individuals developing innovative new ideas.

References

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Een patiënte met een pseudo-verhoogde en EDTA-afhankelijke bezinkingssnelheid

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Inleiding

De bepaling van de bezinkingssnelheid van erytrocyten (BSE) is nog steeds een van de meest aangevraagde bloedonderzoeken in zowel de praktijk van huisartsen als in de klinisch-chemische laboratoria van ziekenhuizen. Hoewel de BSE een niet-specifiek fenomeen is, wordt de bepaling meestal aangevraagd bij afwijkingen die geassocieerd zijn met een verhoogde productie van acutefase-eiwitten. De uitslag wordt dan gebruikt om onderscheid te kunnen maken tussen 'pathologie' en 'geen pathologie' (1).

De gouden standaard voor de bepaling van de BSE is de Westergren-methode, waarbij gebruik gemaakt wordt van 30 cm lange buizen met een inwendige diameter van 2,5 mm. Veneus bloed wordt gemengd met een steriele oplossing van trinatriumcitraat (105 mmol/l) in een verhouding van 0,4 ml citraatoplossing en 1,6 ml bloed. Na goed mengen wordt het verdunde bloed opgezogen in een buis en verticaal in een houder geplaatst. Na exact 1 uur wordt het onderste niveau van de plasmakolom afgelezen (2). Echter, om redenen van logistiek, tijd en kosten zijn hierop verschillende modificaties ontwikkeld, die met name worden gebruikt in combinatie met geautomatiseerde systemen. Voorbeelden hiervan: het gebruik van EDTA-ontstold bloed, 4: 1 vermengd met citraat of zelfs onverdund EDTA-bloed bij de zogenaamde hematologiestraten of bij apparaten die binnen enige minuten een BSE-uitslag kunnen genereren (3, 4).

Wij doen verslag van een fout-verhoogde BSE-waarde in een bloedmonster dat ontstold werd met EDTA. Door de fout-verhoogde uitslag is veel extra laboratoriumonderzoek gegenereerd en is er overbodig arts-patiëntcontact geweest.

Casus

Een negentienjarige vrouw werd door haar huisarts naar de polikliniek Interne Geneeskunde verwezen in verband met aanhoudende klachten van vermoeidheid en algehele malaise. Zij was in de periode daarvoor in verband met onduidelijke klachten regelmatig gezien door deze huisarts, maar een diagnose kon niet gesteld worden. In het ziekenhuis werd routine-bloedonderzoek verricht, waarbij geen afwijkende uitslagen aan het licht kwamen, met uitzondering van een BSE-waarde van 91 mm / uur (referentiewaarde voor vrouwen < 20 mm / uur). De bezinking werd gemeten in een EDTA-ontstold bloedmonster m.b.v. een StaRRsed bezinkingsautomaat (Goffin-Meyvis BV, Etten-Leur). Op grond van de verhoogde bezinking is vervolgens uitgebreid laboratoriumonderzoek inclusief diverse immunochemische eiwitbepalingen, reumafactoren en virologische bepalingen verricht. Ook

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