

IP Audits: A Health Check for your Intellectual Property



For most biotechnology and pharmaceutical companies, intellectual property (IP) is the solid foundation on which the business is built. But when was the last time that you reviewed your IP assets? An IP audit is a valuable tool to look at each potential area of IP, including patents, trade marks, copyright, branding and confidential know-how (trade secrets) to ensure that they are being identified and managed correctly. IP audits can address a range of different IP management issues, and offer practical advice on the most effective route forward. The most important aspect of a good audit is the interpretation of the findings in terms of the potential impact on a company's commercial prospects.

Aims of the Audit

An IP audit can achieve many things, and should be repeated at different stages of company development to address different issues. Some of the main areas that can be included are:

- Patents - identifying pending applications, granted patents, potential patentable technology, potential patent infringements;
- Trade marks - identifying registered and unregistered trade marks, use of searching procedures prior to introduction of trade mark, possible infringement of third party rights;
- Designs - identifying registered and unregistered design rights, possible protection through Design Right and Community Design Right, possible infringement of third party rights;
- Copyright - identifying copyright (databases, websites, marketing/promotional material, photography, film), ownership/assignment of copyright from creators, procedure for establishing date of creation,

copyright indicators on protectable works, database rights;

- IP management - including confidentiality (or non-disclosure) agreements, trade secrets, technical know-how, employee agreements and dissemination of IP policy throughout the company, licensing, evaluating existing IP, IP policy including registration, renewal systems, monitoring/watching services and enforcement and international filing strategies.

When commissioning an IP audit, it is vital that the findings are placed in the commercial context of the company, so that the recommendations and advice are relevant to the products which are being developed and the company commercial strategy, rather than being a simple inventory. This interpretation in terms of the potential impact on the company's commercial prospects is where the true value of an audit lies. When a company has identified its intellectual property assets, and ensured that they are appropriately managed, they will be in a good position to develop a suitable IP strategy to take their products to market. An IP audit also puts a company in a strong position when subsequently entering due diligence with a potential partner, funder or acquirer.

Stages of the Audit

The first stage of any audit is information-gathering, which should cover not just the existing and potential IP assets of the company, but also the policies and procedures that are in place for managing IP, and the overall company business strategy. For different types of company, different IP rights will be more important. In the healthcare

arena, patents are the cornerstone of the technology protection, and are usually carefully managed. Other types of intellectual property may not be given such importance, but can still represent very valuable assets. Trade secrets are likely to be important to protect the tips and tricks that make a technology work in practice. Copyright will protect websites, photographs, marketing material and product leaflets. Design rights can protect the look and functionality of a medical device or instrument. Lastly, trade marks and other branding issues affect both the company name and the names of its products or services.

Once the information has been gathered and reviewed, the next stage is to identify gaps in the protection held by the company, and to develop practical advice to fill these gaps. This is where it becomes important to consider not just what *could* be done, but what *should* be done to allow the product to be successfully commercialised. There is little point in spending considerable amounts of money in strengthening the patent protection around a technology which no longer forms part of a company's product development plans.

Whilst every audit will include a broad consideration of all the aspects of IP protection, more emphasis will be placed on different aspects, depending on the needs of a company at that time, on their history, and on the stage of product development. Research may be needed into the overall patent landscape, or existing trade marks, to put the findings into the broader context.

The final stage of the audit is the preparation of a report which summarises the situation, presents the results of the investigations, and gives recommendations on actions that are needed. This should

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be discussed with the company to ensure that the actions are practical and within available budgets, and to clarify how they fit into the overall company strategy.

Functions of an Audit

To illustrate some of the functions of an IP audit, and the many different ways that these can be used to support the growth strategy of a business, we will look at some case studies. These look at how to protect research ideas in an early-stage collaboration, the best strategies for a platform technology, and how to identify whether a service has freedom to operate. Other potential areas for audit include the trade mark protection and branding strategies which should be adopted, or best practice policies for IP identification, review and protection.

Case Study – Early-stage Collaboration

When research is at an early stage, an audit can provide a roadmap for intellectual property protection. This includes advice on when and how to include external collaborators, partners and potential licensees into the development pathway without compromising the IP position.

A research institution was commencing a programme of screening their collection of novel organisms to identify natural compounds with a particular type of activity of value to the food industry. The screen was set up and running, but no lead candidates had yet been identified. They wanted an IP audit which would allow them to map out the steps they needed to take to identify and protect their IP, whilst engaging with potential partners. In this case, the screen itself did not contain any novel or inventive steps, and the tricks to get the best out of the screen were best protected as a trade secret. Depending on the outcomes of the screening, there could be potential to protect the novel organisms, the novel compounds with activity, associated production methods, and claims of methods of use. For each of these types of patent claim a different type of evidence is needed, and advice was given on how



to structure the research plan to gain the broadest patent protection. As no candidates had yet been identified, the audit also examined the broad patent landscape in this technology area to identify companies which are particularly active in the field, areas of high and low patenting activity, and the types of organism which have been investigated.

Recommendations included how and when to approach potential partner organisations and the level of information that could be safely shared at different stages, as well as the appropriate use of confidentiality and material transfer agreements.

Case Study – Protecting a Platform Technology

At a later stage of technology development, an effective national filing strategy will be required, particularly where a patent covers the fundamental technology that underpins an entire product and application range.

A small company had developed a new platform technology, which allowed the use of microwave energy

on a continuous process. The technology has wide applications in a range of industries, and the company has focused on exemplifying the use of their machines in one or two key application areas. They have filed a broad patent application on the technology, which was due to enter the 30-month national phase shortly. This is a very important commercial decision point. It is also typically a very expensive stage of the patenting process, as individual fees are required for each national office selected, together with translation charges in many cases. The selection of suitable territories at this stage therefore needs to balance the desire to protect the technology as widely as possible with the usual requirement in an SME to keep costs low. The patent application covers both composition of matter claims and a method claim. If granted, it can therefore offer protection both in territories where the machine is manufactured and those where the machine is sold and used. Ideally, the company should file national phase applications in as wide a selection of important territories

as possible where either use or production of their machine could be expected. As funding constraints were also important, a prioritised list of countries were recommended, supported by a forecast of the future patent costs which would arise in each territory.

The audit also considered the potential ways in which the company could strengthen their brand by use of trade marks. The company name is descriptive of their technology, and so is not eligible for trade mark protection. There was, however, the potential to develop a non-descriptive word or phrase to use as a name for their technology process, and this could help to distinguish their technology from similar techniques which lack their specific advantages. By using a suitable trade mark and raising its brand profile, it should be possible to build up a reputation for the company as the only supplier of this specific technology.

Case Study – Investigating Freedom to Operate

Once a new product or service is identified, an IP audit can indicate whether there are any existing patents which might affect the freedom to operate the new service or sell the product.

A consortium of academic and commercial partners had combined forces to develop and introduce a new service to the veterinary industry. The service was a new method to support cattle breeding, and involved bringing together, adapting and refining a number of different techniques which were already used elsewhere. The audit focused on whether the consortium was free to operate these methods, or if there might be specific areas where a licence to a use specific technique may be required.

One of the partners in the consortium already had access to third-party patented technology surrounding one of the techniques to be used, and had a license from the patent owners to use the technology to produce sperm cells for commercial use, with royalty payments to be made on the semen dose or the resulting embryos produced from semen. Recommendations were

made to ensure that the way in which the consortium provided their service would comply with the terms of this licence and allow them to continue to use this technique. The patent landscape surrounding advanced animal breeding techniques was examined to identify who the major players are in this field, and the subject matter of the patents that they hold. As the research was still at an early stage, the precise techniques that would be used were not yet known, and so the scope of the audit did not permit a thorough Freedom to Operate search. The group aims to introduce the service into the UK in the first instance, so particular attention was paid to GB patents which are currently in force, as these will be the ones which are relevant to whether the consortium will be able to operate their service in the UK.

The searches that were carried out showed that there are a large number of patents surrounding the advanced breeding techniques to be used in the service. The fundamental techniques used are well over 20 years old, and so any associated broad patent protection will have now expired. There are many patents on specific variations and refinements of the techniques, on apparatus and instrumentation used, and on media and reagents for the processes. Where the consortium is buying such material commercially, freedom to operate should not be an issue. Where they develop their own proprietary variations of these materials, however, it would be sensible to carry out follow-up searches on the specifics of these variations as they are developed. Some particular patents were identified during the review as being of potential concern, and the full patent specifications were provided for further study, and their current examination status and prosecution position were investigated.

It is important to remember that a general patent landscape and search of this kind will be able to identify areas of concern or specific patents which should be investigated. This is different to (but can often be a precursor to) seeking a legally qualified professional opinion on Freedom to Operate once a company

has a definitive product or service it will be selling.

Sources of Support

An IP audit can usefully be completed internally by a company which has suitable in-house expertise, and this process may identify areas where more in-depth help and external advice is needed. Alternatively, the audit may use external professionals with a good understanding of both IP and the commercial space in which a company is operating. The UK Intellectual Property Office (IPO) has run a pilot scheme to provide funding to support IP audits for selected SME businesses with high growth potential. In their discussion paper, "From ideas to growth: Helping SMEs get value from their IP"¹, the IPO proposed to extend this excellent initiative to 200 SMEs in 2012/13. This has now been confirmed in the recently published conclusions to the discussion paper², which will help to ensure that innovative technology in SMEs is built on a foundation of sound IP management. This audit funding can be accessed through the IPO's partners, including GrowthAccelerator, Welsh Government and Scottish Enterprise.

References

1. www.ipo.gov.uk/business-sme.pdf, visited on 8 October 2012.
2. www.ipo.gov.uk/business-sme-conclusions.pdf, visited on 12 November 2012.

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