

LAUNCHING A NEW PRODUCT: FREEDOM TO OPERATE

In September 2003, three pharmaceutical companies, *Cambridge Antibody Technology*, *Micromet AG* and *Enzon Pharmaceuticals*, announced that they had signed a non-exclusive cross-license agreement. In the agreement, all three parties obtained substantial "freedom to operate" authorizing each other to use some of their respective patented technology. This enabled them to conduct research and develop a defined number of therapeutic and diagnostic antibody-based products.¹

Agreements of this kind have become common practice in certain sectors, as companies seek to ensure that their products, processes and services do not infringe on patent rights of others. Patent litigation can be an expensive, uncertain and risky affair and, as the say-

ing goes, prevention is better than cure. This article explores different strategies which businesses can consider as a means of reducing such risks and maximizing their freedom to operate.

Whenever a company is planning to develop and launch a new product, a major risk, particularly in technology sectors where there is extensive patenting, is that commercialization may be blocked by a competitor who holds a patent for a technology incorporated within that product. This is why many companies, at an early stage, seek to secure their "freedom to operate," i.e. to ensure that the commercial production, marketing and use of their new product, process or service does not infringe the IP rights of others.

While an absolute guarantee of freedom to operate will never be attainable, there are ways of minimizing the risks that can save a company significant resources.

Searching patent documents

A Freedom to Operate (FTO) analysis invariably begins by searching patent literature for issued or pending patents, and obtaining a legal opinion as to whether a product, process or service may be considered to infringe any patent(s) owned by others. Many private law or IP firms offer such analyses as part of their legal services to clients. Some national IP offices (for example the Swiss Federal Institute for Intellectual Property also offer such services for a fee).

Spotting Opportunities in Patent Limitations

In conducting an FTO search and analysis, it is worth bearing in mind that some of the limitations on patents also offer potential opportunities. For example:

- ▶ Patent protection is **territorial**. While a certain technology may be protected in a company's main markets, it may be in the public domain in other countries. In the latter, no permission (or license) is needed from the patent owner in order to commercialize the product.
- ▶ Patents have a limited **duration**. Patent protection lasts for a maximum period of 20 years. Thereafter, a patent is considered to be in the public domain and may be freely used by anyone. Moreover, the European Patent Office (EPO) estimates that fewer than 25 percent of all patents granted through the EPO are maintained for the maximum 20 year term. Many patents are allowed to lapse through non-payment of maintenance fees by the patent holders before the 20 years are up.
- ▶ Patents have limits of **scope**. The claims section in a patent document determines the scope of the patent. Any aspect of an invention not covered by the claims is not considered to be protected. That said, it is not always easy to determine the scope of a patent. It requires considerable experience in interpreting the claims, the written specification and the history of the application process.

1. www.cambridgeantibody.com/html/news/press_releases/2003/2003_09_03_micromet_enzon.htm

Clearing obstacles

An FTO analysis based on the search of patent literature is just the first step. If the patent search reveals that one or more patents do limit a company's freedom to operate, the company must decide how to proceed. Assuming that the blocking patent is valid, options include:

- ▶ **Purchasing the patent or licensing in.** Licensing involves obtaining written authorization from the patent holder to use the patented technology for specified acts, in specified markets and for a specified period of time. The convenience of such an agreement will depend largely on the terms and conditions of the proposed license. While there is a potential loss of autonomy, and while the patent holder will require payment of a lump sum and/or periodic royalties, it may be the simplest way of clearing the ground for the commercialization of a new technology or product.
- ▶ **Cross-licensing.** This involves two or more companies exchanging licenses so as to be able to use certain patents owned by the other parties. In order to be able to cross-license, a company needs a well-protected patent portfolio that is of value to potential licensing partners.

- ▶ **Inventing around.** A third option is to "invent around" the invention. This implies steering research, or making changes to the product or process in order to avoid infringing on the patent(s) owned by others. For example, if freedom to operate is limited by a process patent, then a company may be able to develop an alternative process for arriving at a similar end result and thus be able to commercialize the invention without the need to pay a licensing fee to someone else.

- ▶ **Patent pools.** This is a mechanism by which two or more companies practicing related technologies put their patents in a pool to establish a clearinghouse for patent rights. A well-known example of a patent pool is that formed by *Sony*, *Philips* and *Pioneer* for inventions that are essential to comply with certain DVD-Video and DVD-ROM standard specifications.

Protecting technology

If the patent search indicates that there are no patents blocking access to market and that a new technology is likely to meet the patentability criteria, a business owner may wish to seek patent protection for the new technology to ensure a greater degree of freedom to operate, instead of keeping it as a trade secret.



Photos: www.photos.com

Starting to evaluate the options early can save time and money.

There is, nonetheless, a clear limit on the extent to which a patent owner has the freedom to operate. A patent in itself does not provide the right to commercialize the protected technology, but only to prevent others from commercializing it. While the distinction may seem subtle, it is a crucial one. A third party may, for example, have an even broader patent that encompasses the subject matter of the first company's patent.

Therefore, in order for a company to commercialize its own technology, it may need to use technology patented by others. In biotechnology, the Cohen-Boyer patent on recombinant DNA is a classic example. For many years, the commercialization of any new technology using the technology developed by Cohen and Boyer required payments to obtain the relevant license. There may also be government regulations not directly concerned with IP which restrict the access to >>>

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market of a patented invention (for example regulations requiring approval for food or pharmaceutical products).

Notwithstanding the above, freedom to operate is one of the reasons why companies apply for patent protection. While the grant of a patent is not in itself sufficient to clear the way for commercialization, it is a useful step and may prevent problems at a later stage.

Defensive publishing or technical disclosures

There are many reasons why a company may wish to *avoid* patenting a given invention, such as cost, or the fact that the invention may not meet the patentability criteria. An alternative that is sometimes used by businesses is "defensive publishing" or technical disclosure. This stands in sharp contrast to keeping it as a trade secret.

Defensive publishing involves disclosing an invention to the public in order to ensure that no one else can patent it. This provides some degree of freedom to operate for all. The disclosure should be done in a well-recognized technical journal or other publication that is likely to be consulted by patent examiners when examining future patent applications, for example, journals that are included as part of the PCT minimum documentation for International Search Authorities.² Some journals devoted exclusively to defensive publishing have become respected sources of technical information. Defensive publication is not generally done for a major breakthrough in technology or for a core technological invention that is likely to be central to the strength of an enterprise.

Some large corporations (such as Xerox) rely on their own technical disclosure bulletins, which are widely disseminated to disclose inventions that are not patented. The United States Patent and Trademark Office enables applicants to request the publication of a Statutory Invention Registration (SIR) of a filed patent. This is effectively a technical disclosure of an invention for which a patent was applied. With an SIR, the applicant abandons the prosecution of the patent in exchange for the disclosure of the invention by the patent office.

Choosing the right path

Whichever means is chosen, technology companies are well-advised to consider their options at an early stage. In some cases, minor product adaptations, or payment of a small licensing fee to the patent owner, may be sufficient to avoid future disputes. Systematically evaluating a company's freedom to operate prior to launching a new product is, therefore, a way of minimizing the risk of a patent infringing the patents owned by others. It will also improve a company's chances of finding business partners and attracting investors to support its business development plans.

For more information on various practical aspects of the IP system of interest to business and industry, please visit the website of the SMEs Division at <http://www.wipo.int/sme/en/>



2. For more information on the International Search Authorities and the PCT minimum documentation, see website of the PCT at <http://www.wipo.int/pct/en/index.html>