

IP in the life sciences industries 2011

An *IAM* management report

A keen understanding of how best to build, manage and protect intellectual property is essential for companies operating in the life sciences industries today. As intellectual property is often a company's most valuable asset, an appreciation of the integral role that it will play in the business must begin at the company's inception, well before investment into research and development begins. Whether that company is a multinational pharmaceutical manufacturer, a biotech business preparing to go public or an early-stage university spin-out, its IP portfolio will be crucial to its success.

It is with all this in mind, and more, that

we have put together *IP in the Life Sciences Industries 2011*. This management report is designed to highlight, in a practical and business-focused way, some of the major IP issues facing life sciences executives and the people – such as venture capitalists and other investors – with whom they deal.

We trust that the articles featured will provide insights that will be of significant benefit to readers and *IAM* thanks all those taking part for helping to produce this unique guide.

Sara-Jayne Clover
Reporter, *IAM* magazine

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Patent licensing in the life sciences industry

It is not always easy to gain ownership of valuable IP assets through one's own inventiveness. As such, a key way of remaining profitable and competitive is by acquiring licences from the legitimate owners of IP assets. In recent years, many pharmaceutical and biotechnology giants have begun licensing Indian technology

By **Vidisha Garg**, Anand and Anand, New Delhi

Ownership of intangible intellectual property does not in itself constitute wealth; rather, such property is a tool for the generation of wealth. It confers on its owner the right to exclude other parties from making, using and selling it, thereby giving the owner a monopoly in the market. However, it is not always easy to gain ownership of such valuable assets through one's own inventiveness. Another way to acquire a monopoly over the market is by acquiring a licence from the legitimate owner of an IP asset. Increasing numbers of businesses are seeking to enter into licensing agreements with rights owners in order to acquire intangible assets and enjoy exclusivity in the market.

Therefore, a licence agreement is a contractual relationship between the IP owner (or licensor) and the licensee, wherein the licensor transfers its proprietary rights, under certain conditions, to the licensee, so that the licensee can exploit the relevant asset to its fullest extent, thereby creating value. Under such agreements, the licensee generally receives monetary compensation. Thus, a licence

agreement is a legal and commercial relationship, which must be beneficial to both parties.

Need for patent licensing in life sciences industry

Despite the remarkable growth of the life sciences industry over the past two decades, it is not easy to survive in the market, as the process of drug development is slow and expensive. The amount of uncertainty is high and the likelihood of bringing a new drug to market is very low.

Further, most research is done by universities and small commercial units which lack the resources to manufacture and commercialise new products and thus recover the costs involved and profit from their innovations. Therefore, their best strategy is to license out the technology to large pharmaceutical and biotechnology companies which have sufficient capital, expertise and capacity to bring the new products to market.

Records show that there are almost 40 products worth US\$64 billion whose patents will expire between now and the beginning of 2012, resulting in the loss of several billion dollars in annual revenue. This state of affairs has put tremendous pressure on top companies to develop new blockbuster drugs. Licensing-in is considered to be the easiest way to acquire the latest drug candidates and bring them to market as new, life-saving drugs.

Licensing constitutes:

- A way to reach new markets which were not accessible to the licensor without taking on the risks associated with product development.
- A method through which the licensor can control the product and its market development.
- A means to gain rights in improvements,

modifications and new innovations during the course of exploitation of the patents.

- A means of turning an infringer or competitor into a business partner by paving the way to end litigation.
- A means through which the patent holder can obtain new rights in return for some of its own (ie, through cross-licensing).

When to license

Normally, a patent can be licensed upon grant, when the scope of the patent is determined. In several cases licensing can be commenced while the patent application is pending. In such cases the licence is enforceable only after grant of the patent, although royalties and other payments may start while the patent application is pending. Before entering into any sort of contract, due consideration should be given to the fact that the patent may not be granted.

Who can license

Only the person or persons registered as grantee or proprietor of a patent, or person authorised thereby, has the right to grant a licence in respect of any given patent. Where two or more persons jointly own a patent, a co-owner cannot license his or her share in the patent without the consent of the other co-owners.

Patent licensing procedure

A licensing contract must be executed in writing and must be reduced to the form of a document embodying all terms and conditions governing the rights and obligations of the contracting parties, and should be duly executed. Licence agreements must be duly registered by filing an application with the controller of patents. Failure to follow the correct procedure renders the agreement invalid.

Key factors in developing licence strategy

Licensing agreements must be negotiated in order to reach a “win-win situation” for both parties. However, there is often the danger that licences may run into antitrust-related problems. The imposition of certain restrictive conditions may lead to unfair competition and market practices, and harm the public at large. In order to avoid such conflicting situations, it is advisable to negotiate the licence with utmost care. Certain factors should be strictly taken care of while entering into a licence agreement.

Exclusivity of rights

It is important to evaluate the technology to

be licensed with respect to the industry in which it will be applied. In the case of fundamental technology, it is possible that an innovative product may have several new applications in several industries. Therefore, non-exclusive licences are preferred for fundamental innovations. On the other hand, while dealing with improvements or non-pioneer technologies, exclusive licences may be granted in order to attract potential licensees. However, in the pharmaceutical sector most licences grant exclusive rights to the licensee.

Cross-licensing and patent pools are common mechanisms through which parties can share and retain control over technology. Cross-licensing is a two-way blocking relationship in relation to a patent through which it becomes impossible to exploit a patent without infringing the other party's rights. Patent pools are created when multiple patents from several patentees are packaged and licensed to a third party. Sometimes, companies may have to cross-license many patents on account of the existence of patent thickets.

Territorial restrictions

The licensor can grant a licence for the use of technology in a particular geographical region or global exploitation rights. This decision is taken depending upon the nature of the technology and the ability of the licensee to exploit the technology for the maximum mutual benefit. The licensee may acquire the exclusive right to exploit the technology in a particular territory while the licensor retains the right to license the same technology to third parties in other territories. In the case of pioneer technologies, territorial restrictions are preferred so that several key players may exploit the technology in different jurisdictions, resulting in the technology reaching distant, untouched markets.

Field of use restrictions

A licensing agreement may sometimes restrict the use of technology in a particular field. Through such restrictions, the licensor can retain the right to exploit the technology in some areas of application and license particular fields to other licensees, thereby keeping control over the development and exploitation of the technology. In the case of pioneer technologies, field of use restrictions are ideal, as they allow for the optimum exploitation of technology in different industries.

Restrictive conditions

The licensor may impose certain restrictive



Vidisha Garg
 Managing associate
 Anand and Anand
 New Delhi
 Tel +91 120 405 9300
vidisha@anandandanand.com

Vidisha Garg is a managing associate in Anand and Anand's patent department. She has a degree in law and is a patent agent. Her area of specialisation is chemical and pharmaceutical sciences and she has about three years of research experience in synthetic organic chemistry. Ms Garg's main areas of practice include patent searches, drafting of patent specifications, patent prosecution, pre and post-grant oppositions and contentious patent matters.

conditions or tying arrangements which may be anti-competitive in nature, imposing various restraints on trade which may conflict with the interests of the licensee and the industry as such. Commonly imposed conditions which have been considered to be restrictive are:

- Conditions requiring or prohibiting the licensee to acquire compulsorily any article other than the patented product or article prepared by the patented process from the licensor.
- Conditions prohibiting or restricting the licensee from acquiring any article other than the patented product or article prepared by the patented process from any other person.
- Conditions prohibiting or restricting the licensee from using any article other than the patented product or article prepared by the patented process from any other person.
- Conditions restricting, in any manner, the right of the licensee to use any process other than the patented process.

However, the licensor can impose conditions on the licensee to sell only its products and abstain from selling a competitor's products. Further, the conditions by which the licensor reserves the right to supply certain parts of the technology under patent, as this may be done to keep a check on the quality of the products.

Improvements, enhancements and modifications

The exploitation of technology may result in improvements, enhancements and modifications, either by the licensor or by the licensee. Such improvements are important as they enhance the commercial return from exploiting the technology. It is therefore important to address clearly the rights of the licensor and licensee with respect to improvements. Sometimes, improvements can be developed by the third party, and in such cases the licensor or licensee may obtain a right of use.

A primary issue involved in considering improvement of a licensed invention relates to ownership. The licensee wants access to improvements to the patent in order to be better equipped to commercialise the technology. In certain cases the licensee is entitled to all improvements and modifications. On the other hand, where the improvements are the result of the licensor's efforts and the subject of an independent patent, the licensor may grant them to the licensee for an additional fee. If

the licensed technology is rendered obsolete by the improvements, the licensor may be interested in some rights in the improvements made by the licensee.

Another concern arises over whether an improvement lies outside the scope of a licence. In such cases it will be difficult to decide on the ownership of the improvements.

Therefore, it is in the interests of the licensor and the licensee to define "improvements" broadly. Judicial comment on what constitutes an improvement is important. Further, consideration needs to be given to whether the improvement is capable of standing on its own. Ownership issues also need to be clearly taken care of.

Grant-back

The requirement on the part of the licensee to assign the ownership rights to the licensor in the improvements in the licensed technology made by the licensee is called "grant back". Such conditions are considered as anti-competitive, as the licensee is forced to accept such conditions in order to gain the licence. Such restrictions may reduce the licensee's incentive to engage in research and thereby reduce competition.

Instead of grant back, the accepted methodology is one whereby the licensee requires the licensee to grant non-exclusive, royalty-free rights in the improvements. This may be coupled with the right to grant sub-licences in the improvements to third parties.

Ownership

In the life sciences field, ownership of the technology is a critical and complex issue. It is important for the licensor to conduct due diligence with regard to the ownership of technology because of the complexity and time involved in technological developments in the field (particularly biotechnology). The licensor must investigate the proper source of the biological material, and scrutinise the material transfer agreement and the contracts involved in funding the relevant research projects. Further, the licensor must warranty the licensee regarding ownership of the patent to guarantee that the commercialisation of the patent will not infringe the rights of third parties, and that the patent is not already licensed and not encumbered by the owner.

Liability considerations

Product liability is a new area of law and relates to the imposition of a legal liability

in case of personal injury or property damage arising out of a defect in the product. Such liabilities can be imposed by the court by way of either breach of contract or negligence. The liabilities of breach of contract are strict, as the vendor cannot make the defence of exercising utmost care. However, such liability can be imposed only where the parties involved in litigation are the parties to the contract. Product liability based on negligence arises by way of design defects, manufacturing defects and failure to warn.

The licensing agreement should make clear provision for product liability and responsibility should be specifically allocated between the parties. This can be dealt with by including indemnity and insurance clauses in the licence.

Patent enforcement

Any sort of infringement of the patent will leave the two parties in distress: the licensor loses its property and the licensee loses its business. Therefore, it is important to determine who will sue infringing parties. In case of a non-exclusive licence, the licensor assumes this responsibility. However, in case of an exclusive licence, it is the licensee that is accorded with the right to take necessary actions against the infringing parties. However, the rights of the licensee are independent of the rights of the patentee, which may take necessary actions either simultaneously or in conjunction with the licensee. When determining the damages or accounts of profits or granting any other relief, the courts will take into consideration the loss suffered by or likely to be suffered by the exclusive licensee.

Conclusion

Indian patent statutes provide clear-cut guidelines for the licensing of patent rights. The patentee can transfer its rights by way of licence, assignment, mortgage or the creation of another interest. However, any licence agreement for patents will be valid only during the term of the patent. When the patent expires, the licence also expires. Therefore, any claim by the licensee after expiry of the patent is invalid.

The statutes have recognised the “exclusive licence” as a licence from a patentee which confers on the licensee (or on the licensee and persons authorised by the licensee), to the exclusion of all other persons (including the patentee), any right in respect of the patented invention. The exclusive licensee has been conferred with the same rights as the patentee to file suit in case of infringement.

The avoidance of the restrictive conditions has been strongly mandated in the statute. Any condition in the contract or licence which is anti-competitive is considered as unlawful. However, the licensor reserves the right to impose conditions which are beneficial for the business.

In order to remain profitable and competitive, and maintain an edge in the global market, the licensing-in and licensing-out of technology have become obligatory practices. According to data provided by the Department of Biotechnology, in 2004-2005 around 14 technologies were transferred to private companies for commercialisation. Many pharmaceutical and biotechnology giants have ventured into the Indian markets by licensing their technologies. Pharmaceutical companies such as Wockhardt Ltd, Torrent Pharmaceutical Ltd, Dr Reddy's Laboratories Ltd and Nicholas Piramal India Ltd have signed licence agreements with several innovator multinationals. The domestic industry is not far behind, with corporations in the United States and Europe (eg, General Electric and Du Pont), becoming partners in several of India's national research and development laboratories (eg, the Council for Scientific and Industrial Research). As such, India provides a safe haven for patent licensing. ■

Anand and Anand

B-41, Nizamuddin East
New Delhi 110 013
India

Tel +91 11 2435 0360

Fax +91 11 2435 4243

www.anandandanand.com