Successful licensing strategies: making the most of voluntary out-licensing

Out-licensing can bring major benefits to both licensees and rights holders, offering higher profits and enhanced competition. However, reluctance to out-license still remains

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Since the implementation of the Agreement on Trade-Related Aspects of IP Rights (TRIPs), much has been said and written about successful licensing strategies for technology and research-based businesses. Be it IP audits, due diligence, identification of licensing opportunities or other key steps that enable a company to generate a sustained revenue stream based purely on patent licensing, scholars and practitioners have unanimously and exhaustively favoured this option. Stories of IBM's patent licensing business model and how it has profited from it are well known. However, in the Indian context, certain issues related to out-licensing are crucial for consideration before a full licensing strategy is put into action. In addition, even today, many corporate strategists remain closed to the idea of placing their technology in the hands of competitors or even smaller entities. This reluctance can be either general or specifically related to a market such as India wherein a company – for reasons best known to itself – refuses to license a technology.

This article examines out-licensing in light of Indian patent law under two broad headings:

- why companies should consider out-licensing in India; and
- strategic issues for consideration.

Why out-license in India?

In addition to the much-discussed benefits of out-licensing – such as sustained revenue streams and a competitive edge – certain legal issues are extremely relevant and must be considered when deciding whether to license a patent in India.

Compulsory licensing has garnered much attention recently, both within India and abroad. Broadly speaking, a compulsory licence is granted by the Patent Office to an interested party (most likely a competitor) under special circumstances and conditions: the rights holder is remunerated, but has no control over who becomes its licensee.

In India, an interested party can seek a compulsory licence three years after grant of a patent on one of the following grounds:

- Reasonable requirements of the public with respect to the patented invention are not met;
- The patented invention is not available to the public at a reasonably affordable price; or
- The patented invention is not worked in the territory of India.

The interested party must also satisfy the Patent Office that reasonable efforts were made to obtain a licence from the patent owner, but were unsuccessful, and that it has the capacity and capital to work the patented invention. The Patent Office also considers several other factors which may not be directly relevant here.

Thus, contrary to the prevailing global perception, the grant of compulsory licences is not a common phenomenon, but rather an exception. An effective licensing business model can be a tool to hedge the odds against a rights holder in a compulsory licensing scenario.

In analysing this issue, the *Bayer* case is of importance. Natco Pharma, a generic pharmaceutical company, applied for a

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compulsory licence to kidney cancer drug Nexavar, patented by Bayer. The controller of patents granted the licence to Natco in March 2012. Bayer filed an appeal before the Intellectual Property Appellate Board (IPAB). However, the IPAB dismissed the appeal and upheld the grant of the compulsory licence, holding that:

- the reasonable requirements of patients of the drug were not satisfied;
- the drug was not affordable; and
- the invention was not worked in India.

While several aspects of the decision have been discussed and analysed by academics and professionals around the world, several observations in the decision are pertinent to this discussion. The IPAB analysed the guiding principles to determine whether a patented invention is worked locally.

The board opined that the meaning of 'working' a patent locally must be determined on a case-by-case basis (in accordance with Article 31 of TRIPs, which states that use of a patent without authorisation of the patent holder must be dealt with on a case-by-case basis). The meaning of 'locally working the invention' may sometimes exclude import from the working requirement, and yet in other cases working can be synonymous with importing.

Further, the IPAB laid down some guidance for determining the 'working' of the invention. It observed that working of the invention must be ascertained from sales of the patented invention by the rights holder and the licensee, and nothing else.

The IPAB also maintained that the rights holder or licensee must take measures to make full use of the invention, and this will be relevant in determining the reasonable requirements of the public, and consequently in deciding whether to grant or refuse a compulsory licence. In *Bayer* the IPAB found that Bayer "had not 'worked' the invention on a commercial scale". It held that Bayer could not give reasons as to why working (ie, manufacture) of the patented drug was not possible in India.

A number of points must be considered in order to determine whether to license valuable patents in India. The IPAB's observations are not limited to the pharmaceutical sector; rather, they constitute the most comprehensive judicial opinion on compulsory licensing in India, which many believe will not be altered by higher judicial authorities. The IPAB's opinion repeatedly referred to licensing when discussing the guidelines for determining whether a rights holder has worked the patented invention. It is clear that if Bayer had had some form of licensing arrangement for manufacturing the drug in India, it could have made a much stronger argument against compulsory licensing.

Where a rights holder faces a request for a compulsory licence, the odds will clearly fall heavily in its favour. Of course, patent out-licensing may not be the simple answer, as other variables and risks may need to be considered before making a decision to license. Voluntary licensing certainly goes a long way towards reducing the likelihood of grant.

Assuming that the patent at issue is valuable, it may be riskier to fail to work a patented product sufficiently locally than to look for opportunities and take the risk of licensing the patented product to an entity of the patent owner's choosing on its own terms.

In some cases having more than one non-exclusive licensee may encourage competition, which is better for pricing – a key issue in compulsory licensing cases. Moreover, by opting for the voluntary licensing path, the rights holder also has the option of choosing licensees of varying capabilities, and may have access to different geographical markets. A reasonable argument can also be made that the revenue stream from the patented product in a voluntary licensing scenario is likely to be stronger than that from compulsory licensing. This is because in case of voluntary licensing, the rights holder is in a more competitive bargaining position, whereas the terms of compulsory licensing are less flexible.

Issues for consideration in licensing strategy

It is clear that voluntary out-licensing in India is important from many angles. Having decided to out-license a patent in India, certain key issues must be considered.

Assessment of patent portfolio

The team carrying out the patent audit or the strategist must flag up high-value patents – particularly those which could hold special value for the Indian market. The question of whether competitors operating in that market would be keen to share in this valued asset is vital. The high-value patents must be assessed by the patent analyst team in order to determine whether the patented inventions are merely being imported into India and sold, or whether they are being manufactured there. Input will be required from the team responsible for designing or making the product. The reason for this is that under the law, a 'patented invention' is defined by the claims. The actual product may differ or include the patented invention only as a part, starting material or component, in addition to other valuable or non-valuable patented inventions. This assessment is critical because when it comes to the local working requirement, the law will consider what has been claimed in the patent and whether that alone was worked, and not other features of the product which are not part of the claims. This leads to different conclusions for different types of technology, product and process.

This assessment should enable any company to ascertain clearly which products or parts of products are covered by key patents that are vulnerable to attack under the compulsory licensing provisions, and calls for an aggressive strategy to identify out-licensing opportunities and increase the reach of these patented inventions in order to fulfil the local working requirement as far as possible.

Covenant not to challenge validity

One of the most important considerations when discussing out-licensing arrangements is the choice of licensee, whether exclusive or otherwise. This is because in India, as in the United States and Europe, a contract or licensing agreement cannot include a term barring the licensee from challenging the validity of a patent. This means that even after an express written agreement to license one or more patents has been concluded, a licensee can challenge the validity of a patent or patents that are subject to such agreement. Any such term in an agreement that prohibits a licensee from challenging the validity of the patent(s) in question is void. This issue arose before the IPAB which, relying on Section 140(iii)(d) of the Patents Act, upheld this position. In *Wobben v Enercon (India) Ltd* the validity of certain patents was challenged by a former licensee. While the question of whether the patents were actually part of an earlier licence was also disputed, the IPAB, in discussing the doctrine of licensee estoppel, held that no licensor can bar a licensee from challenging the validity of a patent that is the subject of the licence.

Co-ownership rights

Section 50(1) of the Patents Act gives equal and undivided shares to the co-owners of a patent, unless a contract provides otherwise. This means that if there is more than one owner of a patent, they are free to decide on their respective shares in the patent by agreement. In the absence of such agreement, they will have equal and undivided shares in the patent.

However, under Section 50(3), subject to such an agreement, no rights holder can give a licence to a third party without the consent of the co-rights holder or co-owner. This requirement may sometimes be overlooked in international transactions because patent laws on co-ownership can vary dramatically between countries. Some countries may not require consent from the other owner. Thus, this becomes critical in avoiding future disputes involving the subject patent and licences. This must be factored in when preparing a licensing strategy.

Avoid certain restrictive conditions in licence

Often, a rights holder tries to incorporate certain restrictions into the licence agreement that may benefit or advance the sales of its patented product and keep the licensee under its control. Certain instances of such restrictive conditions have been barred under the Patent Act.

A rights holder cannot include a condition in a licence that prohibits or restricts a licensee from purchasing, procuring or using non-patented articles or products from anyone except the rights holder. This is to ensure that licensees are not unfairly forced to acquire non-patented articles from, or to use non-patented articles provided by, the rights holder exclusively.

Further, in any patent infringement proceedings, the law provides for the defence that at the time of such infringement, a restrictive contract including such condition was in force.

A rights holder also cannot include in a licence a condition providing for exclusive grant back to the rights holder. This is relevant for collaborative research work, where a licence is granted to a party to undertake research or develop derivative products. In such case, the initial licence cannot provide that the licence must exclusively grant a back-licence on the derivative invention to the initial licensor.

However, a rights holder can reserve for itself the right to supply such new parts of the patented article as may be required for the repair of such article.

Right of exclusive licensees

If a rights holder decides to grant an exclusive licence to a party with regard to a patent, the licensee shall have the right to sue and initiate proceedings against infringers as if it were the owner of such patent. The law also provides that losses incurred or likely to be suffered by the exclusive licensee due to infringement shall also be considered when awarding damages and other relief.

Finally, it is always advisable to register a licence agreement with the Patent Office. Under the Patent Act, a licence agreement shall not be admissible evidence in any court or before the controller unless it is registered in the official Patent Register. Thus, if an exclusive licensee seeks to enforce the patent against an infringer, the agreement by which it holds the right to sue may not be admissible in court if it has not been registered with the Patent Office. Of course, the courts have the power to allow an agreement as evidence, but only in special cases and for specific reasons.

Comment

Even in a large and diverse market such as India, patent wars are rare – but they are slowly picking up pace. While patent regimes have become increasingly advanced in the developed West, calls for 'patent peace' can already be heard, because compromise can create far more value than conflict. There is no reason why lessons from expensive and extensive patent battles cannot be applied to a nascent patent regime such as India's. In any case, some rights holders may be constrained to adopt a voluntary licensing approach in India in fear of compulsory licensing.

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