

## PATENT PRIMER

# What to do with your granted patent

*Luke Kempton*

You are a biotech company that has just been granted a patent connected with drug discovery. What do you do with it? The costs of drug discovery and development are so prohibitive that only large companies have sufficient resources to proceed with such an undertaking. Therefore most biotech companies will need to involve a larger third party at some stage in order to develop the product and get it to market. When should your average biotech company try to tie the knot with a big pharma partner?

Ownership of a patent does not give the patentee the right to exploit the invention (for example, in some countries there are restrictions on the exploitation of stem-cell technology, whether patented or not) but it does allow the patentee to prevent others from exploiting it. Whether the patent covers a product (for example, a potential new drug) or a platform technology (for example, a method of drug discovery, such as a screening method), the options are to develop the technology in-house, to sell it, license it out or to collaborate with a third party.

There is, at present, a debate about how patentees should be financially rewarded for the use of platform patents. Many big pharma companies will simply want to pay for the use of the technology as a research tool, paying a modest up-front or annual fee. On the other hand, the patentee will want, in addition to an annual fee, to receive milestone and royalty payments on any drugs discovered by the use of the technology — so called ‘reach through’ payments.

**To licence or not?**

The first decision following the grant of a product patent is whether to develop the product in-house, or to try to license or sell it. This decision will nearly always depend on whether the biotech company has sufficient financial and other resources to take the product to the next stage. At an early stage — before any clinical trials have been done with a drug, and without proof-of-principle in humans — the value of any product patent is likely to be low. If the biotech company decides to sell or license the patent, it will probably not be able to find a buyer or licensee; if it does, it will achieve a low return on its investment. The preferred route for development is through licensing out to big pharma when there is sufficient value in the

product to get a good return, but before the really big costs of clinical trials start to be incurred.

If the biotech company has sufficient resources, then rather than enter into a straight licence, it can enter into a collaboration to develop the product, and share the (substantial) cost of development and risk failure. An important part of any collaboration deal is how, if it is successful, any resulting product is going to be exploited. Will each party exploit it in a different field or in different territories, or both?

Licences can be exclusive in that only the licensee can exploit the patent (excluding even the patentee) or non-exclusive, in which case the patentee can exploit the patent itself and license others to do so as well. Because of the risk and expense associated with developing a potential new drug, a licensee will almost always require exclusivity so that if the drug is successful it has the monopoly position that will allow it to recoup its expenditure. Non-exclusive licences can be more suitable for platform technologies.

Deals are usually structured on the basis of either no or very low up-front payments, with larger sums payable in the future dependent on certain specific events (‘milestone payments’) — for example, initiation of Phase II trials, granting of a marketing authorization and so on. There will also usually be a royalty payable.

**Royalties**

The intellectual property position surrounding a potential medicine can be very complex. There can be rights to the drug target, the drug

itself, the manufacturing process for the drug and methods of delivering the drug to the target. All of these rights can be owned by different people, which can result in the drug manufacturer having to pay a large percentage of its profits as royalties. To reduce this effect, many licences include ‘royalty stacking’ provisions, such that a proportion of the royalties paid in relation to one patent can be offset against the royalties payable on another (see BOX).

**Patent improvements**

When licensing a patent, one of the most important issues is that of the ownership of any ‘improvements’ to the patented invention created by the licensee. The patentee will want at least a licence to such improvements to prevent it being blocked in the future in its own technology area. It can be a breach of current European Community competition law to require the licensee to assign severable improvements (that is, improvements that can be exploited without using the base technology). If the licensee is granting a licence of the improvements, it should carefully define what ‘improvement’ means. Two recent English Court cases have held that the word ‘improvements’ has a very broad meaning; it can include a separate distinct patentable invention that perhaps the licensee would like to exploit itself without licensing it automatically to the patentee.

*Luke Kempton, Ph.D., is at the Intellectual Property Department of Wragge & Co LLP, London UK.  
e-mail: luke\_kempton@wragge.com*

doi:10.1038/nrd1584

**ROYALTY STACKING**

Because royalty stacking clauses can result in the diminution of royalties obtained by the patentee, the circumstances in which any royalty can be offset should be clearly defined. For example, can royalties be offset in relation to any licences needed to get the product to market (for example, those relating to manufacturing and drug delivery systems), or just in relation to overlapping patents covering the same technology? This question has arisen in relation to a clause in a case that came before the English courts in November 2004. It states that the royalties that can be offset are those in respect of patents that “enable [the licensee] to utilize or have utilized the inventions of the [licensed] Patents” and that “This offset shall not include royalties or license fees which are beyond the scope of technology described in the Patents.”

Alternatively, some royalty stacking clauses are deliberately vague. For example, the parties will agree a reduced royalty rate if “the royalties paid to a third party on sales of the licensed product are a significant factor in the return realised by the [licensee] such as to diminish its capability to respond to competitive pressures in the market.” Whatever the mechanism for reducing royalties, these clauses usually set a floor below which they cannot be reduced, which protects the patentee from losing all its income from the exploitation of its patents.