

# PATENTS, ROYALTY STACKING AND MANAGEMENT

**Dr Raju Adhikari, industry manager of Pharmaceutical and Biotechnology, Frost & Sullivan discusses the many issues concerning the protection of intellectual property rights.**

## Company profile

Frost & Sullivan, a global growth consulting company founded in 1961, partners with clients to create value through innovative growth strategies. The foundation of this partnership approach is its Growth Partnership Services platform, whereby it provides industry research, marketing strategies, consulting and training to clients to help grow their business.

Patents have emerged as the most important form of intellectual property (IP) protection for much of the biotechnology industry and, in particular, for the biopharmaceuticals sector. They provide an incentive for innovation for both pharmaceutical and biotechnology companies. IP rights and patent rights are attractive to firms and innovators because they create the prospect of charging monopoly prices from others for access to their intellectual capital and prevent the 'freeloaders' from taking advantages of their investment.

Patents play an important part in enabling biotechnology companies to develop biopharmaceuticals. The ability to stop others from exploiting a patent for a limited period gives biotechnology companies an opportunity to recoup the investment made in developing the patented product. However, patents are sometimes likely to hinder research efforts by restricting access to various research tools and technologies. In turn, this may be a disincentive to commercialisation. Biotechnology companies face unique challenges because:

- The industry is research intensive by nature.
- Biotechnology has seen a massive increase in patent activity.
- The preponderance of upstream patents with broad claims.
- Reliance of downstream companies (pharmaceuticals) on access to patented research tools and techniques.

## Patents and commercialisation

The various patents and their influence on biotechnology commercialisation (see Figure 1) are described as follows.

**Patent thickets.** The term refers to multiple upstream overlapping IP rights that a company must cut its way through in order to commercialise new technology. Patent thickets normally give rise to increased production costs.

**Broad patents.** The term refers to patents granting broad rights to the patent holder. These may be seen as covering later applications invented by others and are normally granted in the early stage of a new technology.

**Reach-through patents.** This provision grants a patent holder future rights in new products that might result from the use of a licenced patent. This may include the right to own the IP of future products.

**Dependent patents.** This is a patent on an invention, the exploitation of which is prevented by an earlier patent. Compulsory licences may offer a solution where the holder of a dependent patent is unable to obtain a licence over the dominant patent.

## Royalty stacking

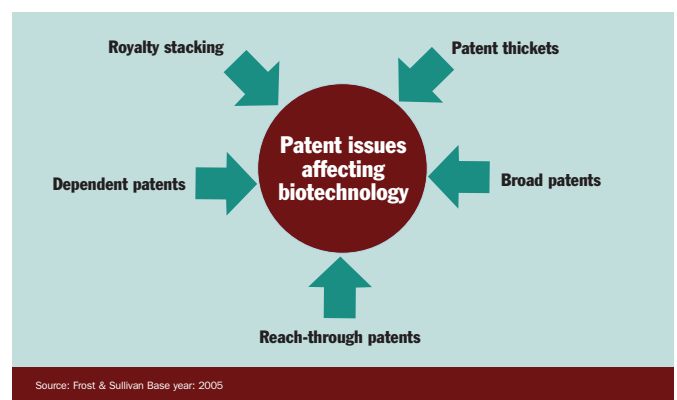
The concept of royalty stacking arises from the risk that multiple patents may affect a single product. Such risks are said to be particularly high in the biotechnology field, which is dominated by patent filing. Royalty stacking arises when, in order to take a product to market, the developer of the product takes licences from all the owners of patents that affect the final product. When the royalty payments are combined, the licensee may find itself with an unprofitable product.

## Patents play an important part in enabling biotech companies to develop biopharmaceuticals

Royalty stacking occurs when several different parties own the IP necessary to get a product to the market and they all demand royalty payments from the ultimate seller of the product in question. This may also occur because there are overlapping patents in relation to the particular product that are owned by different parties or because the product required several different technologies to get it to the stage of being sold commercially (for example, a vaccine plus adjuvant). Additionally, royalty stacking occurs when biotechnology companies enter strategic alliances and licencing transactions with one another and with large pharmaceutical partners.

There are several problems relating to royalty stacking. The patenting of 'information' encroaching on the public domain of science is inappropriate. Innovation is heavily impeded by the practical difficulty of acquiring rights to use all of the required patenting elements of research held by diverse parties – the anti-commons. Access restrictions on upstream, foundational discoveries limit subsequent discovery and improvement. Sometimes access to patents may be possible, but on terms that

**Figure 1. Patents and their influence on biotechnology commercialisation**



make the use of the inventions extremely expensive, especially for non-profit researchers.

### Solutions to royalty stacking

It is in the interest of both pharmaceuticals and biotechnology companies to resolve the royalty-stacking problems. Figure 2 illustrates some solutions to royalty stacking.

*Private contractual deals.* With such deals, partners reach agreements about the level of royalty rates that reflect the business realities.

*Royalty must reflect commercial reality.* Royalty rates must be adjusted to reflect the reality of the commercial situation.

*Options.* Companies signing royalty deals need to look into patent pools, consortia and cross-licensing opportunities available under the free market conditions. However, these may not be effective for increasing access to genetic inventions owing to the difficulty of assessing the contributions that various parties are likely to make to such a grouping.

## Paying attention to the contract details is necessary since doing otherwise may result in prospective financial penalty

*Exclusive and non-exclusive licences.* Rates of these licences vary immensely and attention to these is necessary while signing a deal. The general practice is that royalties for licensing in patents on genes and other 'must-have' technologies are between 1 to 4 per cent of the net sales of the given product for non-exclusive licences. However, royalties can be as high as 10 per cent for such licences. For exclusive licences, royalties are generally at 6 to 10 per cent of net sales.

*Establish clearing houses.* This is to expedite the rapid and low-cost licensing of patents having potential applications in drug discovery and diagnostics. A clearing house can obviate prosecuting infringers.

### Anti-stacking provisions to manage royalties

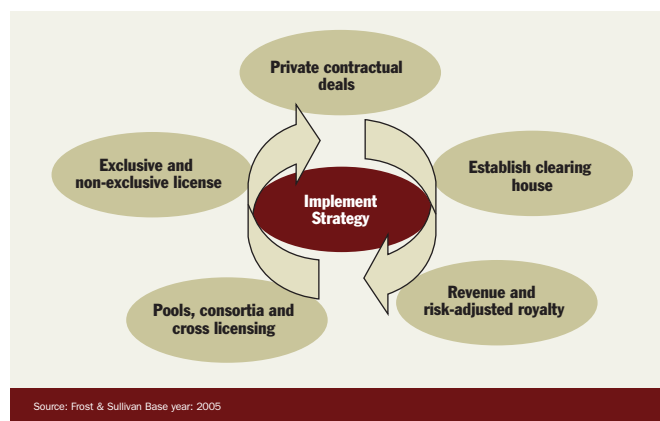
There are different types of royalty schemes for reducing combined royalties.

*Variable royalties.* In this model, different rates apply based on the amount of additional work done by the licensee. The smaller the role the technology plays, the lower the rate the licensor receives. These provisions are often difficult to negotiate, as it is complicated to quantify the contribution made by any particular piece of technology in a complex process.

*Joint venture expense.* Royalty payments owed to third parties are deducted from the net sales of the final product.

*Creditable percentage and royalty ceilings.* In the creditable percentage model, the parties share the third-party royalty. Typically, this

Figure 2. Solutions to royalty stacking



is at a minimum level. Parties involved in the royalty-ceiling model put a top limit on all combined royalties. If a royalty must be paid to a third party, the previous rates are adjusted downwards to stay below the limit. This ceiling is determined by a consensus among all parties.

*Royalty floors and royalty-free.* The parties agree that the licensor's royalty rate may be reduced, but only to a certain acceptable minimum royalty rate. In the royalty-free model, the technology is licensed outright with some combination of up-front and/or interim payment, and no royalties are owed downstream on the product sold.

### Identification, clarity and agreement

Only a few European biotechnology companies have products in the market. Therefore, scant problems with royalty-offset clauses have presently become known. However, as more companies get products to market, there is the likelihood of problems with these clauses becoming more commonplace. The pharmaceuticals and biotechnology industry needs to be aware of this.

Royalty stacking is a complex and sensitive issue. The most important consideration in handling royalty stacking is to carefully identify what each side in the collaboration is trying to achieve through the inclusion of a royalty-offset clause and ensure that the phraseology is drafted as narrowly as possible to reflect the acceptable position. It is also important to try to eliminate any duplicative clause. If this is not possible, the parties need to make sure the overlapping language in the clauses is as nearly identical as it can be made for understanding the goals and objectives of the parties involved. Paying attention to the contract details is necessary since doing otherwise may result in prospective financial penalty. It is vital to focus not just on R&D fees and technology rights, but also on the minute details with arguments and re-arguments until the positions are transparent for both or all sides involved in the negotiation. **END**