

In the first part of this article we considered the mechanisms that pharmaceutical companies use for entering into collaborative agreements with biotechnology/drug discovery companies to remedy the lack of candidates in their pipelines. Underlying any such arrangement must obviously be a means by which the large company ("LargeCo" in our examples) pays a fair price to the drug discovery company ("SmallCo" in our examples) for the rights that are assigned or licensed. Royalties of one sort or another will generally be favoured by the drug discovery company because of the potential for substantial payments if a compound does eventually become a blockbuster drug. Although royalty payments can accordingly be higher than other forms of payment, they have the advantage for LargeCo that they only need be paid if a product is sold.

Calculation of royalties

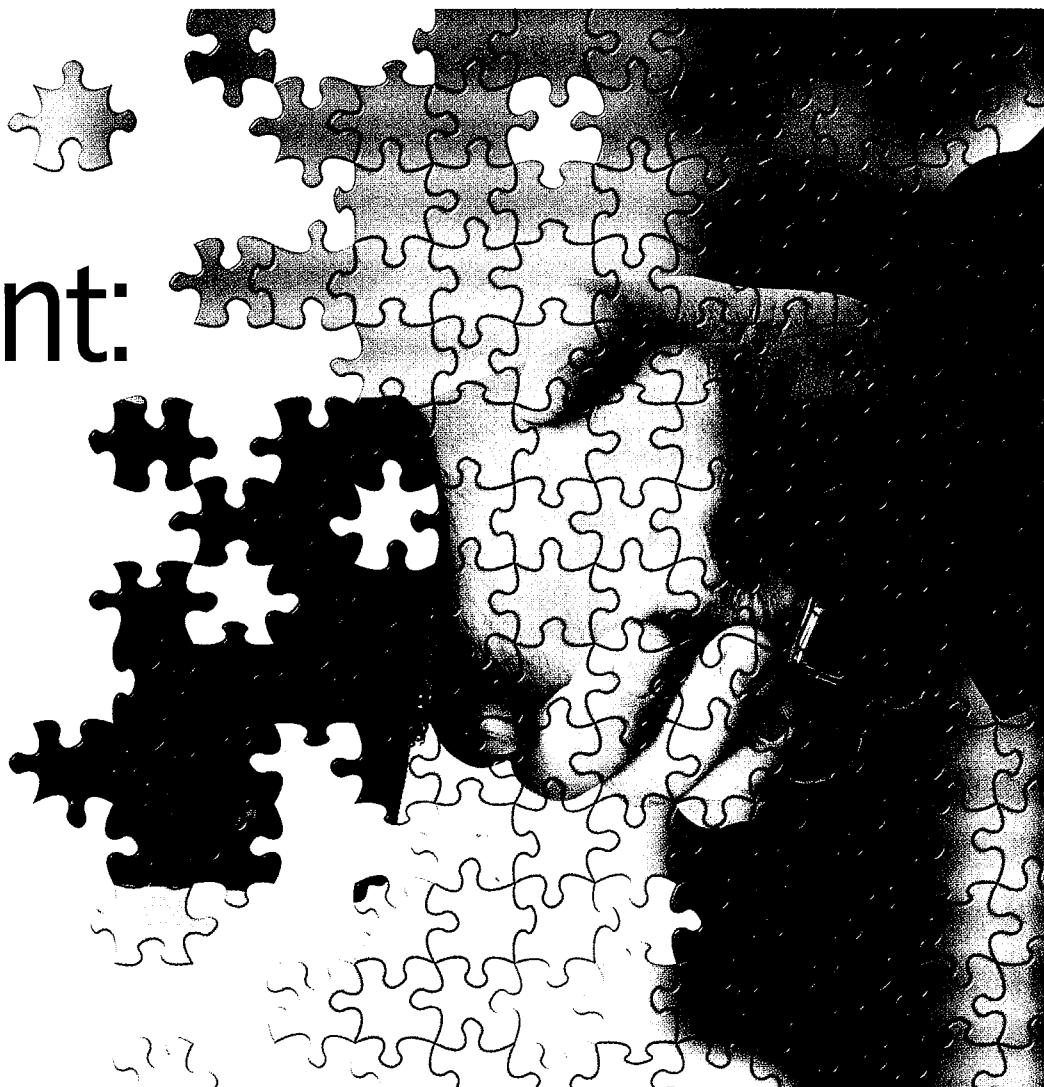
A problem that often arises in the calculation of royalties in the biotechnology industry is that of royalty stacking, because it is

frequently the case that the technology required to manufacture the licensed compound, or to put it into a suitable dosage form, needs to be licensed in from one or more third parties.

It is usual for there to be a provision that the cost of obtaining any necessary additional licences is to be deducted from the royalties payable to the licensor. Unless the agreement is carefully worded, it may be unclear whether royalties paid under licences to use other technologies may or may not be deducted. One extreme is that no other royalty may be deducted from the royalty payable to the licensor (so the royalties that LargeCo has to pay on products that it sells simply add up). The other extreme is that all royalties that LargeCo may have to pay to other licensors in order to exploit the substance can be deducted from the royalty payable to SmallCo (so that SmallCo may finish up by receiving nothing). A suitable compromise may be that technologies required to make the substance that is the subject of the agreement can be deducted from the royalty payable, whilst those required for formulation

Reaching Agreement: Part 2

In the concluding part of an article looking at the advantages and pitfalls of collaborative arrangements, Brian Whitehead, Stuart Jackson and Richard Kempner of Addleshaw Goddard address the complex issue of royalty payments.



may not. Another commonly used compromise is to allow set-off of royalties up to a point, subject to the royalty payable to SmallCo never falling below a specified minimum percentage.

Even with a suitable compromise being agreed in advance, it is important that it is clear which other royalties/licence fees may be set off against the royalty payable, and which may not. It was the failure of the relevant royalty provision to be clear that resulted in the recent, expensive dispute between Cambridge Antibody Technologies ("CAT", UK) and Abbott Laboratories (US). CAT had licensed the use of a biotechnology method to Abbott, and in the licence agreement had agreed that Abbott could set off any royalties that Abbott had to pay to third parties to use the technology, subject to a minimum percentage always being payable. According to Abbott, all of the royalties that it had to pay in order to use the licensed process (including fundamental biotechnological techniques) could be set off. CAT, however, interpreted the provision as meaning that only any royalty payable by Abbott that was necessary for it to use the specific process licensed by CAT to Abbott could be set off. Abbott needed other patented technologies to make the product in question, Humira, and because the product was commercially successful, the difference between the two interpretations amounted to many millions of pounds. Ultimately, the UK High Court and the Court of Appeal agreed with CAT's interpretation, but it clearly would have been possible for the parties to have avoided this litigation with more careful drafting.

Even more fundamental than stacking of royalties is clarity on what value the royalty should be calculated. This is usually relatively straightforward if the licensee sells the final product, although even then care must be exercised in agreeing what costs, if any, of the licensee may be deducted before calculating the percentage. If the licensee assigns or sublicenses its rights to someone else, the position can be more complicated. Such a situation often arises if LargeCo progresses the testing and development of a product only so far, and then transfers the rights to another company for manufacture and marketing of a final product. It may also be that LargeCo manufactures an API based on the licensed rights, and sells this material to a larger pharmaceutical company.

The question arises whether royalties payable to the original licensor (SmallCo) should be based upon a percentage of what its direct licensee (LargeCo) receives, or upon the much higher price obtained by the seller of the ultimate product. If it is the former, SmallCo may feel aggrieved when it looks at the profits made by the ultimate marketer of the product. LargeCo will need to take care that its own royalty income is not wiped out by other royalty payments that its licensee can set off against royalties payable to LargeCo.

Worked examples

The following examples are based on deals on which the authors advised. In each, one of the parties had a particular concern.

1. SmallCo, a drug discovery company, had agreed in principle to collaborate with LargeCo in respect of the development of a promising compound (protected by a patent owned by SmallCo) and a library of similar compounds derived from plants, some of which fell within the same patent. SmallCo wanted payments if any of its compounds reached certain stages of development, such as various phases of clinical trials and marketing authorization (often referred to as 'milestones'). LargeCo wanted to limit its payments, and in particular not to pay if a compound was not protected by any patent. The resolution agreed for milestone payments was that SmallCo would receive payments on attainment of each specified milestone by the first compound selected from the library, provided that it fell within SmallCo's patent.

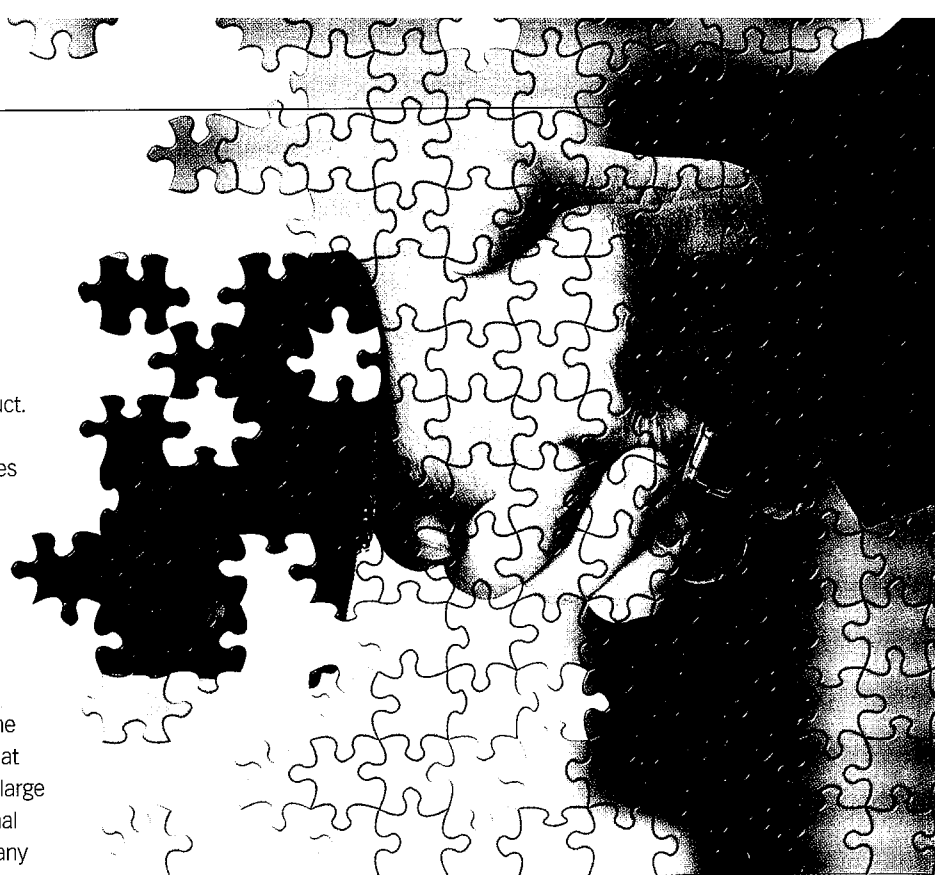
Even more fundamental than stacking of royalties is clarity on what value the royalty should be calculated.

2. SmallCo wanted to ensure that its royalty was not reduced too far by royalty stacking. It was agreed that any payments made by LargeCo under third party licences that were necessary to develop or commercially exploit a product should be deducted from the net sales value on which SmallCo's percentage royalty was calculated, and not simply set off against the amount of the royalty itself.

3. In another deal, a safeguard for SmallCo was achieved by specifying that LargeCo could only set off against the royalties that it paid to SmallCo royalties under third party licences that were necessary because the use of the licensed compound would otherwise infringe a third party patent. It could not set off payments under licences needed to develop or formulate the product.

4. In another collaboration, it was uncertain whether LargeCo would ultimately be marketing a product based on the compound of interest, or whether, having developed the opportunity so far, it would transfer the rights to another company (or chain of companies) for manufacture and marketing. SmallCo wanted to ensure that the percentage it received was not simply a percentage of LargeCo's receipts, resulting in SmallCo receiving only a "cut of a cut." SmallCo's preference was that the percentage should, like LargeCo's, be based on the sales value of the final product on the market.

LargeCo was unhappy about committing to paying a percentage of the sales value of the final product, because LargeCo could not be certain that it would itself receive a royalty higher than, or even equal to, the percentage payable to SmallCo. Furthermore, it was likely, if a chain of subsequent licensees was involved, that LargeCo



would not receive a royalty calculated as a percentage of the sales value of the final product.

The compromise was for LargeCo to pay to SmallCo a percentage of the same value of sales on which royalty payments received by LargeCo were based. SmallCo and LargeCo would accordingly both be in the same boat so far as the basis for calculation of their respective royalties was concerned.

A number of safeguards had to be put in place to ensure that LargeCo did not receive nothing if its own royalty was no higher than the royalty it was obliged to pay to SmallCo, and that LargeCo could not artificially arrange to take a large percentage of a low sales value. As an additional safeguard for SmallCo, receipts by LargeCo of any lump sum payments in place of a royalty were agreed to be shared on an identical basis as for royalties.

5. Royalty stacking was also an issue in the case referred to in example 4 above. Royalty payments required to be made to third parties by licensees of LargeCo could be dealt with in the arrangements as between LargeCo and its licensee, and should not need to concern SmallCo. However, LargeCo was concerned that it may not be able to arrange to have royalties deducted from a sales value before calculating its royalty (as it had agreed to do with SmallCo). It was therefore agreed that if LargeCo was required to suffer a deduction directly from the royalties that it received (as opposed a deduction from the sales value on which the percentage was calculated), then such deduction would be taken from the income of LargeCo and SmallCo in the same proportion as the ratio of the percentage royalties received by each, subject to SmallCo's royalty never falling below 1%.

Summary

Collaborative arrangements between biotechnology/drug discovery companies and large pharmaceutical manufacturers can bring advantages for both. The parties must ensure that the ownership and exploitation of intellectual property right (IPR) is dealt with appropriately and comprehensively, and the use of checklists is recommended. (Our clients find it extremely useful, when negotiating and drafting collaboration agreements, to use checklists to ensure that all areas have been considered. A non-exhaustive list of factors to be considered is set out in *Table 1*).

The parties must be creative in finding a solution for the financial aspects of the deal. Disputes can be avoided by ensuring that events giving rise to milestone payments, and the factors to be considered when calculating royalties, are defined precisely. ■

IN BRIEF

Collaborative agreements can help big companies to expand their pipelines and small companies to get their drugs on the market, but the terms of these agreements must be handled sensitively. The wording of any royalty stacking and provisions must be clear in order to avoid ambiguity; there must be clarity on what value the royalty should be calculated, as transfer of rights and sublicences can complicate contracts. Third party licences and eventual seller royalties can also erode the royalties received by the initial companies; a clear initial definition of royalty percentages can prevent this.

About the Authors

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Table

1. Period of collaboration
 - Fixed period, or indefinite?
 - Termination clause if X is dissatisfied with Y's performance, and vice-versa?
 - Should the agreement prevent the parties from collaborating with others in same field during the term? This will require the field to be determined and expressed in a precise manner.

2. What is being contributed?
 - Registered/unregistered IPRs?
 - Is there any know-how? If so, does it need to be recorded in documents?
 - Samples/materials/compound libraries etc?

3. Who does what in the collaboration?
 - Can the respective parties' obligations be clearly described?
 - Should there be binding milestones and timetables?
 - How is the project to be managed? For example, will the parties set up a steering committee?
 - What sort of technical assistance are the parties required to provide?
 - Do the parties need to make key staff available, and undertake to provide replacements?
 - Is one party to pay the other? If so, does payment depend upon results?
 - What Background IPR will each company provide?
 - Will ownership of Background IPR remain with existing owners?
 - Will improvements in a party's Background IPR be available to the other collaborator?

4. Payments
 - Lump sum or advances?
 - Milestone payments. If so, can the events giving rise to the payment be defined with

sufficient precision?

- Equity payments?
- Minimum royalties?
- Stepped royalties?
- How is the rate to be calculated?
- What can be offset against royalty payments?
- Intervals for payment?
- Are there to be reporting obligations, rights of audit and retention of document clauses?

5. Ownership of Arising IPR?

- Is ownership of Arising IPR to be determined by which party develops it, with jointly developed IPR owned jointly by the parties?
- Or is it better to split the Arising IPR according to its field of application?
- Who is to take care of filing for patents etc? Can one party compel the other to apply?
- If one party does not wish to protect an invention, can the other require assignment of the relevant right?

6. Exploitation of Arising IPR

- What licences are to be granted? For example, will all Arising IPR be cross-licensed, or will exploitation rights be determined by the field of the Arising IPR?
- If there is to be jointly owned IPR, how is it to be managed?
- Will licences of Background IPR be included?
- Can the terms of the licences be agreed upfront, or do the parties need to include a mechanism for deciding the terms. What happens if the parties subsequently cannot agree such terms?

7. Scope of licences?

- Manufacture/sale, sale only, manufacture only?
- Exclusive, sole or non-exclusive?

- Territory e.g. exclusivity in respective parties' countries' markets?
- Duration?
- Single or multiple indications?
- Restriction on fields of use. If so, can they be defined precisely?
- Is sub-licensing/sub-contracting permitted?

8. Infringement

- Who may take action?
- Is anyone required to take action?
- How are decisions to be taken?
- How will costs and damages be divided?