ROYALTY RATES : Current Issues and Trends

Sharon Finch

For many small and start up companies, their partnering strategy will be a vital integral strand of their overall commercial strategy. This partnering strategy will often be based on finding a larger company with both development and commercial expertise who can bring their technology through to the market place. Unless the company has access to advisors with relevant deal negotiation experience and expertise [either through its Board or stakeholders], then there is a concern that the assets of the company may be out-licensed at less than their optimal value.

In terms of benchmarks, there is very little published about deal making or indeed about the fine level of details of a given transaction. Headline values[1] are published, but these give little information on the balance of the package, i.e. the split between upfront[2] payments, milestone[3] payments and royalties. Companies are generally very keen to ensure that any perceived competitive advantages gained during their negotiations are kept firmly in house.

There is a wide range of factors that affect the royalty rates that apply to different pharma deals [see table 1]. In view of the dearth of published information and to investigate these factors in greater detail, at Medius we elected to undertake survey of deals in the pharma industry in co-operation with one of our clients. To check the veracity of the primary data we thus obtained, we ran a comparison with data from published deals. The precise findings of this survey remain client confidential but there were some key conclusions that were evident from the published data alone. The survey has been most successful and it is now intended to run the survey on an annual basis to identify any relevant trends.

Table 1
Factors that influence the setting of royalty rates

- strength and scope of the intellectual property rights [IPRs]
- territorial extent of rights
- exclusivity of rights
- level of innovation
- durability of the technology
- degree of competition / availability of other technologies
- inherent risk
- strategic need / portfolio fit
- stage of development
- therapeutic field
- availability of finances
- market drivers [e.g. pricing, competition reimbursement]
- royalty stacking
- deal structure / reward structure

Methodology

The survey objective was to investigate the financial terms for technology deals and to identify any relevant trends and correlation. A questionnaire was designed to address the key factors that were considered relevant to the valuation of a technology deal, [see table 2] [4]. Quid pro quos were not considered as each part of such a deal is valued independently although quids do tend to be of equivalent commercial potential.

An important element in the design was to allow anonymous responses so that it would not be possible to identify either the participating company or the reported deal. Notwithstanding this, one or two companies declined to participate on the grounds that such information could not be released outside the company.

1 A "Headline" value is usually defined as the sum of any upfront payments, milestone and research payments plus estimated royalties to give an estimated value of the total deal package.
2 An "Upfront" payment is the initial payment made on signature of a contract. These are often non-refundable and represent the fee required to access the technology.
3 "Milestone" payments are made when the project has reached certain key development stages and are to reward the Licensor commensurate with the success of the project to date.
4 A copy of the full questionnaire can be downloaded from our website, www.medius-publications.com

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Table 2
• Partner companies • deal type • degree of exclusivity • territorial extent • intellectual property rights [IPR] • the development status of the project • therapeutic field • financial models employed • anticipated peak sales • future development costs • financial elements • performance criteria

The survey was initially run on a small sample [150] of companies representative of the industry where we have close personal contacts to ensure a good response rate. This initial list included the Scrip top 60 companies. Certain companies were not included, for example diagnostic and OTC companies where the product life cycle, profit and promotional costs are very different when compared to ethical [prescription] products. This "personal" approach was successful and from the initial sample we had a response rate of 34 %.

Table 3 Company inclusion criteria
• multinational companies • national companies • biotech companies • drug delivery companies • university technology transfer • independent technology transfer • venture capitalist

However, one fact that became clear during our survey is that it is particularly difficult to compare deals [excluding those deals for marketed products]. Rarely are there enough cases that are sufficiently similar both in terms of the project and the companies involved to allow a strict comparison. Therefore the base sample was extended to over 300 contacts to ensure there would be sufficient data to allow some comparison. The final number of responses received was 68 giving an overall response rate of 23% at the time of closing the survey. This in conjunction with the published data gave sufficient data for further analysis.

Although the other deal parameters were important, the essence of the survey was the financial terms, [see table 4]

Table 4 Key financial elements of a deal
upfront payments milestone payments equity investment royalty levels

Upfront payments

The level of upfront payments is always an issue for intense debate during the negotiations. For the Licensee, it represents the sum most at risk, whereas for the Licensor it represents a commitment to the project by the Licensee and possibly the only fixed return the Licensor will receive in the event that the project is unsuccessful. Depending on the value of the technology, there may be project cash flow demands that dictate that the upfront should be more that just a nominal fee, assuming the upfront would be wholly deployed to the project in question.

Milestone payments

The milestone payments reflect the diminishing risk associated with the project and reward the Licensor receives for the success of the technology. The negotiation therefore tends to centre on the level and frequency of the payments.

Table 5 Typical events used to trigger milestone payments
• filing a patent • granting a patent • identification of a lead within a discovery programme • commencing pre-clinical development • commencing / completing phase I clinical development • commencing / completing phase II clinical development • commencing / completing phase III clinical development • submitting the regulatory dossier to relevant authorities • grant of the marketing authorisation • pricing approval for the product • product launch • reaching a given threshold of sales

Within each of the potential milestone events listed above, there are further possible events, such as : ethics committee approval, completing recruitment for given clinical studies. Also the filing or grant of the product license application or marketing authorisation can be on a territory-by-territory basis. As a general rule, milestone payments increase as the technology nears commercialisation.

Due to constraints on the spacing of the questionnaire, it was difficult to elicit this level of information from the survey. Also, this would potentially allow the identification of the deal in question and remove the cloak of anonymity.

Equity investment

Increasingly companies seek to capitalise their investment in R&D by replacing some of the cash payments with equity investment. This can [depending on the level of investment made] have the added benefit of giving some degree of control within the company. Clearly if the company performs well then there is the added bonus any increase in share price. Exchange of equity is also one means by which biotech companies can consider consolidating and building their critical mass without impacting on their cash position.

During negotiations there is often a concentration on the immediate cash payments (the upfront fees and milestones) but long term, the royalty has more impact on the profitability of the product in the marketplace. Recent reports[5] suggest that product life cycles are changing, thus royalties should be more flexible and adjust to the product life cycle to give maximum profitability.

From the survey, 30% of the respondent companies employed an equity element in their reported deals. However the value of this equity component was generally less than US $ 1 m for 40% of the reported deals, so cash remains an important factor.

Another factor that has a major influence on small start up and biotech companies in their negotiations is the PR impact of the deal when it is formally announced. There are two aspects to this, the headline value of the deal and the perceived calibre of the partner. The latter is influential when selecting which company with whom to progress formal negotiations, but the former can strongly influence the negotiations and final settlement overall.

Assigning royalty rates

Royalty rates are generally the most flexible part of the overall financial package as these are being taken from a revenue stream when there is only the remaining risk is the product's commercial performance. However some allowance should always be made for adverse market conditions e.g. price changes, reimbursement problems or generic competition.

Often the royalties are set and agreed before the cost of goods is finalised, so assumptions have to be made on the eventual profitability of the product. The amount of revenue "available" for royalties will depend on the payback required on the project overall.

Besides the mathematical basis for setting royalty rates, there are emotive issues as well as company precedents to be considered. During negotiations, companies may claim that their company only pays a double-digit royalty in exceptional cases. Other companies will quote a fixed royalty - particularly when the licence is non-exclusive and no more favourable terms can be offered for other additional licensees .

The degree of exclusivity of rights granted by the Licensor to the Licensee in any agreement also has a bearing on the designation of royalty rates. Clearly, an exclusive licence commands a higher royalty level than a sole or non-exclusive licence, broad licensing of platform technologies [which may be field specific] is often at a lower rate. The difference in value however will depend on the particular market sector concerned and the relative strengths of the other licensees.

The extent of the territorial rights granted under the licence will also have a bearing on the royalty rates concluded in an agreement. Although there may be a more limited impact on the specific royalty rate [depending on the pricing policy that is prevalent in the relevant territory] the upfront fees and stage payments will be relative to the market size that the product might command.

[5] John Ansell : More Mileage, Decision Resources

Financial models

Increasingly, companies need to clearly demonstrate that the potential return from a new technology asset is the maximum that one can achieve. Consequently, more sophisticated financial models are being employed to analyse the return on investment.

Thus this survey was considered be an excellent opportunity to review which if any financial models are being employed as a standard across the industry. There is the possibility that larger companies have better resources in terms of financial advice so are able to carry out far more sophisticated financial analyses than the smaller companies. This can confer a significant advantage during negotiation.

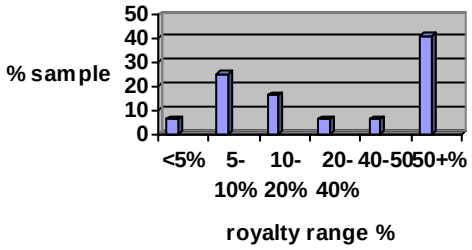
It is evident from the responses received that the one model almost universally applied is Net Present Value (NPV)[6]. Some companies do employ other models such as Option Valuation[7] but this is not commonplace. Only one company reported having developed its own software models for the financial analysis of technology deals. NPV can show a large difference between the value produced now and that two years hence. However, the usual working practice is often simply to run the NPV model only at the time of acquiring the technology and not later on in the development cycle.

In support of calculating royalties, companies often refer to industry averages and precedents. Although this is helpful, we identified many deals which appeared to go against the industry average. There were several agreements with royalty rates > 50% up to the maximum reported level of 70%. The common feature in these cases was the type of alliance rather than the phase of development. Evident in this top sample are marketing, distribution, joint venture and co-promotion agreements. As with all of the ranges we reviewed, there were one or two exceptions, for example the phase II licence between Roche and Trimeris for anti HIV infusion inhibitors. Few agreements featured in either the 40-50% or the 20-40% range. Of these, the agreement type was for either a joint venture, supply or distribution of products.

In the 10-20% range, all the reported deals were licence agreements, from discovery through to phase II development.

Similarly for the 5-10% and < 5% range, the majority were early stage licence agreements. Most interestingly, a significant proportion (- **43**%) had royalty rates below the 12% level.

Figure 1 : frequency of occurrence of royalty rates



Early stage royalties

Royalty rates for early stage projects are more difficult to define for several reasons. Generally there is no well-characterised lead compound so it is difficult to ascertain the product profile and hence the real market potential. Also, the earlier the stage of development, the greater the inherent risk so risk adjusting the financial models tends to bring down the level of calculated royalty. To safeguard a more positive upside position, it may be preferable to specify a defined range for the royalty clearly indicating the factors that will influence any subsequent negotiations such as strength of patent position, level of competition, etc.

Early stage royalties are a strong contrast to the end stage co-commercialisation agreements [such as co-marketing and co-promotion agreements], which often attract very high royalty levels, in the range of 40-60%.

Table 6
Industry average royalty rates

Stage of development	Range of royalty rates %
Pre-clinical	0-5
Phase I	5-10
Phase II	8-15
Phase III	10-20
Launched products	20 +

6 Net Present Value considers the value of technology in today's terms by building in the cost of the capital required to develop the technology; the model can also be risk adjusted by changing the hurdle rate.
7 David Neil : Option Valuation

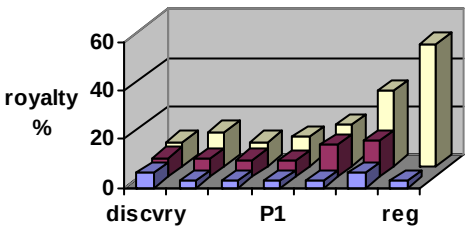
Another key issue to be considered is the licensing strategy. Some technologies will be platform technologies that will be able to be licensed very broadly on a non-exclusive basis. Other technologies may be licensed on field exclusive basis, allowing for a higher level of royalties.

Project development status

There is a strong rationale behind the principle that as a project progresses through its clinical development, the developing company is adding value and diminishing risk. This therefore tends to translate into a higher overall value for the deal and in particular as seen in the royalty rate.

There is also a perceived current trend towards signing deals later than phase II clinical development. Companies are allowing the Licensor to carry the risk and are prepared to pay a higher price for the technology assuming it will still be available at phase III. The graph below illustrates the range [minimum, average and maximum] of royalties seen. Excluded from this analysis are the joint ventures, distribution agreements and co-promotions all of which feature royalties in the range of 40 - 70 %.

Figure 2 : royalties by phase of development [published data]



Intellectual property rights

The extent of the intellectual property rights [i.e. the know-how, patent protection and trademarks] relating to the opportunity has a major bearing on the overall value of the deal and are particularly important for early stage opportunities. Firstly, one needs to consider what constitutes the IPR. Patents and trademarks carry a higher value than know -how simply because one can more easily enforce these rights. The strength of the patent itself is of vital importance. If the essence of the product or technology is not well protected, the technology offer a limited commercial return as the market cannot be protected. Similarly, if the patent is valid but unenforceable against third party competition it may prove to be of little value. One important element is how easy it may be for competitors to circumvent the IPR; this can occur if the technology is easily discoverable or replicable .

Successful licensing tends to endorse the strength of the IPR as it implies that another company finds it necessary or desirable to license rather than re-invent the technology. Ideally there should be a patent portfolio in place providing a "ring fence" of cover to the compound *per se,* composition, analogues and methods of manufacture. The extent of the patent cover is increasingly important, for example covering the most cost-effective method of manufacture can ensure the effective patent cover subsists beyond the life of the patent for the compound per se.

The territorial extent of the intellectual property rights links into the grant of territorial rights in the license. If the patents do not extend to the whole area where the product is to be marketed, then it is reasonable that different royalty rates should apply.

Because of the limited duration of patent rights [twenty years from the date of filing an application in Europe], there may be only a limited amount of time to protect the product from competition in the market place. Thus the duration of the contract needs careful consideration bearing in mind the development time for the technology. Because of the extensive development times required for pharmaceutical products, it was considered that the duration of the monopoly was insufficient to be able to obtain a return on the investment made. Thus there is now the right for the holders of the relevant Market Authorisation for a given product or technology to apply for Patent Term Extensions in certain territories. However the duration of these extensions does vary from country to country across Europe.

Varying the royalty rate is a standard tactic to encourage performance under an agreement. For example, if the patent protection is not sufficient to keep unauthorised competition at bay there may be grounds for a drop in the royalty rate as having a licence to the patent is not conferring any market advantage. Similarly, it is quite usual to see clauses in agreements encouraging the Licensor to enforce any relevant intellectual property rights by the withholding of royalty payments until any infringement actions have been concluded. One needs to carefully review any third party patents that may impinge on the product or technology. Allowances may also be made in the event that it is necessary to pay a third party royalty to allow the technology to be exploited.

Considering all the issues surrounding intellectual property rights, there are sufficient topics to merit an individual study on their impact on royalty rates alone in isolation of all the other factors considered in this article

Royalty rate stacking

When considering the royalty levels, one may need to take account of royalty stacking. Occasionally a product may bear multiple royalties for different components; for example the active ingredient and the delivery technology. It is not unusual in products where many individual components have been in-licensed, for example a monoclonal antibody and an amplification system in a diagnostic product. There will be a threshold level beyond which the profit margin for the product is so eroded that it is no longer economically viable. It is quite usual in such cases to see a maximum overall royalty level set which when reached triggers a reduction pro rata across all the royalty bearing components.

Another situation is in a "licensing -in : licensing-on" model, for example, when technology is in-licensed from universities or spun out into new start up companies who then develop the technology and licence on to an eventual marketing partner. This “license-in : licence-on” model requires careful thought to ensure that there is sufficient return to cover the middle phase development and a royalty to the originator of the technology.

NPV models can be adapted to incorporate such scenarios however different approaches can be taken during the negotiation of the initial license. One approach is to keep the terms of access to the technology at a low level and to share the downstream returns. Thus the milestone fees are kept low but with a greater proportion of the end license fees being due to the originator. Another approach is to safeguard a fixed return to the developing company and then share any additional amounts on an agreed proportional basis.

The survey results reinforced the current trends that are evident from the published data. The most deal activity still takes place between multinational and biotech companies in the classic partnering from small to big pharma. There is also an increasing amount of biotech consolidation evident [biotech to biotech deals]. Even very small companies are actively acquiring new technologies to build their technology portfolios. Also, more biotech companies appear to be seeking alliances rather than trading all of their assets via licensing. This is similar to the change in strategy adopted by Japanese national companies who switched from licensing out to joint ventures and acquisitions to grow their business internationally.

"Classic" licensing strategy used to focus on out licensing at or around phase II clinical development when the product profile is sufficiently well defined to allow reasonable market forecasting and the risk can also be well characterised. This appears to have shifted to phase III indicating that companies are prepared to allow the Licensors to carry the risk in return for the licensee paying a higher entry price. Alternatively opportunities are picked up early stage at a lower cost to build up corporate pipelines.

Interestingly, apparently similar deals did not always show equivalent financial terms. Having said that, clear ranges of royalty rates are evident. For the same level of anticipated peak sales and development costs, the royalty rate appears to be influenced by the agreement type and the phase of development. Reviewing the maximum levels of anticipated peak sales , these do not always translate into higher royalty rates. The converse of this however does hold true and lower anticipated peak sales do correlate to lower levels of royalty rates [generally < 10%].

In conclusion, it is clear that ultimately, market forces, the supply and demand for the technology will determine the “going” royalty rate. For participating companies, the question remains whether the financial terms available represent the best return for the opportunity. External benchmarking of deals, [comparison by independent advisors] is an option that is increasingly being taken up by companies seeking reassurance on this point.

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About the Author—Sharon Finch

Sharon Finch is the founder of Medius Associates and Medius Training with more than 20 years proven experience as an international pharmaceutical business development manager and consultant. She is the main author of a new report on Financial Terms and Royalty Rates in Pharma Deals.

Sharon holds a BSc in Chemistry and Administration and studied for an MA in Business Law.

She is the current Non Executive Chairman of the Pharmaceutical Licensing Group UK, the past President of the European Pharmaceutical Licensing Group Council and a member of the Licensing Executives Society Healthcare Committee in the UK.

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Medius Associates

47 Upfield
Croydon
CR0 5DR
U.K.

Phone: +44 (0) 20 8654 6040
Fax: +44 (0) 20 8654 6046
Email: info@medius-associates.com