Original Article

Valuation of complex license contracts

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ABSTRACT **Licensing is an important business model within the drug development industry. Recently license contracts have become extremely complex, including sublicensing, co-development, or profit sharing. Traditional rules of thumb are not sufficient anymore as guidelines in negotiations of deal terms. The authors explain an easy-to-understand model that enables business developers to negotiate financial terms that are fair for both parties.**
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INTRODUCTION

Licensing has become an important business model within the drug development industry. It is standard that R&D focused companies (usually referred to as biotech companies) license their intellectual property from universities or are spun out of universities or pharmaceutical companies. The same companies plan to partner their projects with large pharmaceutical companies once IND or proof of concept is reached. And although in the 1980s and 1990s these license contracts included a complete change of control over the project, now we observe with increasing frequency co-development deals. Especially for biotech companies these deals are important value drivers. But often it is unclear how these license contracts should be structured so that they represent a fair deal for both sides. To structure and negotiate a complex co-development deal, which might even include multiple indications, we have to understand how license contracts translate into value to not leave value on the negotiation table.

This paper explains the current practice of determining license terms according to the value share principle. We then explain the virtual company model that not only helps understanding the different mechanisms of licensing, but also allows determining fair license terms for the most complicated contracts.

MOTIVATION OF LICENSING

In a project's lifecycle it might be licensed several times. In most cases the in-licensing company wants to broaden its pipeline. In this way it increases the company value and also diversifies its risk profile, because the

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additional project could serve as fallback for other projects in the pipeline in case they fail. It is clear that a company only in-licenses a project to terms that are favourable, that is, the value of the project must be perceived higher as the price, that is, the financial license terms.

Out-licensing has different motivations. Universities usually do not go further than early-stage research as the financial capabilities are too limited. Therefore, licensing is the business model on how universities can monetise their inventions without having to lose focus. Biotech companies on the other hand are business focused; they do not have an official mandate like universities or research institutions. Companies should choose the strategy that maximises shareholder value. This means that they should only out-license a project if this is more attractive than doing it on their own. The transition from a research company to a drug development company requires a lot of financial efforts and time. This must be considered in the decision taking. Out-licensing also has some negative aspects. The company loses control over the project and cannot decide about its fate anymore. And even more importantly, the company gives up a lot of financial upside in case the project makes it to the market. If the project reaches the market the licensor only earns royalties, which usually correspond to a fraction of what the commercialising company earns. In contrast, out-licensing gives access to know-how, presents a proof of quality, and reduces the cash requirements and thus the downside risk.

VALUE SHARE PRINCIPLE

A company should always compare a license deal to alternatives like taking the project further along the development path. Interestingly, the notion of a fair deal in the drug development industry is often completely disconnected from this concept, but linked to the value share principle. The value share principle can be described as follows. Licensor (biotech) and licensee (pharma) split the value of the project between each other. The earlier the license takes place, the more pharma contributes to the project, that is, the more risk it bears and the more money and time it invests. Consequently, pharma should receive a larger share the earlier the project is licensed. Within the industry several rules of thumb are known as displayed in Table 1.

Table 1: Value share rules of thumb, licensor's share

Licensing phase	*ReCap (%)*	*1-2-3-…*	*'Big pharma' (%)*
Discovery	15	1/6 (=18%)	10–20
Preclinical	20	1/5 (=20%)	
Phase I	25	1/4 (=25%)	20–40
Phase II	35	1/3 (=33%)	
Phase III	50	1/2 (=50%)	40–60

At first sight the explanation makes perfect sense and also the rules of thumb seem consistent. As pharma puts much more at stake it should get a bigger piece of the pie. Nevertheless, at the beginning the licensor owns 100 per cent of the project. But after closing the license contract, it then only gets a fraction of the value according to the value share principle instead of the full value. So why should a company out-license its projects? It would only lose a significant part of the value. Investments and risk, which serve as arguments for the value share principle, are already factored in the value – risk-adjusted net present value accounts for costs and success rates. The answer to this intriguing question requires a more detailed look at how the value of the project is determined. First, the project becomes more valuable in the hand of the licensee. A pharmaceutical company is typically experienced in conducting late-stage trials and is less prone to beginner's errors like choosing wrong trial endpoints or filing insufficient data. Also, a pharmaceutical company can better commercialise the product as it has a salesforce in place. So, the project value becomes larger simply because the control moved to the pharmaceutical company. Second, the licensor's and the

licensee's share must be valued at the same discount rate when applying the value share principle, because otherwise the sum of the two parts would not add up to the project value. In the industry a joint discount rate of 12 per cent is fairly standard. The licensor, of course, must value the license contract at its own discount rate (or cost of capital) if it wants to know the value it actually represents. This value then is lower, because the licensor generally has a higher discount rate. But for the sake of finding the terms and negotiating, the valuation is performed at the joint discount rate. Using a joint discount rate that is lower than the actual cost of capital yields better deal terms for the licensor.

So, while the licensor's share in the project might decrease from 100 per cent to a fraction, the value does not necessarily become smaller. A fraction of a project in the hands of a powerful pharmaceutical company might still be larger than 100 per cent of the same project, but conducted by an inexperienced biotech company. The value share principle might yield quite reasonable deal terms, but it fails to explain the economic rationale of licensing – one only sees if out-licensing makes sense by comparing the value of the licensed project to the value of the alternative, for example, when the company takes the project to the market on its own. Furthermore the rules of thumb are quite general and do not consider the specific strengths of the license partners. In case of an advanced licensor – assume a company with a marketed niche product, but now licensing a GP product – a 35 per cent value share for a phase II project might not be attractive enough. As a commercialising company, it might have a relatively low cost of capital and the experience of selling a drug, although not a GP product. The company might well be able to exploit more than 35 per cent of the product's potential, if it commercialises the product on its own.

NEW LICENSE MODELS

Recently more innovative license models have become popular. First, biotech companies form joint ventures on a project level. They conduct projects together up to phase II, where they plan to out-license it to a third party and split the license proceeds between each other. These deals rarely make it to the news because they are usually closed between private companies. For the business developers it is therefore even more difficult to negotiate the terms, as they do not have any comparables. How much should the joining company pay, or contribute more to the costs of the trials, such that it has earned its 50 per cent share in the project? Secondly, some companies only want to license certain rights. Assume company A that wants to partner its lead project that has just passed phase IIa, but would like to keep the North American rights. The partner company, company B, is expected to fund the remaining trials, which obviously also are necessary for the North American approval. In addition, company A also expects milestone and royalty payments. We will see further down how to determine fair deal terms for this kind of contract (Example 2). Thirdly, profit sharing has become fashionable. The Regeneron-Sanofi Aventis deal from November 2007, for instance, contains reimbursement of 50 per cent of development costs to Sanofi Aventis according to a formula (undisclosed) and then a 50–50 per cent profit share in the US and a sliding profit share in non-US countries, including some sales milestones.[1] It is difficult to explain these deals with the value share principle. Furthermore, the Regeneron–Sanofi Aventis deal suggests that great deals are probably not closed using the value share principle, but rather by looking at the mechanics of each license term. Fourthly, we encounter the problem of determining sublicensing terms. If a licensee sublicenses the project to a third party, then the original licensor participates in the sublicense terms, replacing the original license terms. These participation rates depend on the stage of sublicensing. But again, the value share principle is of little help to determine them. This is especially critical as the negotiations of

early-stage license deals most often focus exactly on these participation rates.

THE VIRTUAL COMPANY MODEL

For the sake of the modelling of any kind of deal, be it co-development, an early-stage joint venture, profit sharing, or a plain license deal with possible later sublicensing, the virtual company model is a very useful and explanatory method to determine fair deal terms.[2,3]

In the model a project corresponds to a virtual company. At the beginning the company that owns the project, company A, is the sole shareholder of this virtual company – we call it NewCo. The partner company, company B, can now participate in NewCo in two different ways, either through direct payments to company A or through development cost contributions. Direct payments can be seen as purchases of NewCo shares. If the companies want to develop the project they have to fund NewCo. Each development phase corresponds to a funding round equal to the costs of that phase. If the two companies contribute disproportionately to their share in NewCo, this means that one company dilutes the other company. The ownership in the project is now clearly determined by each company's share in NewCo. In reality NewCo does not have to be incorporated, it only serves for the purpose of the model.

If the companies decide to license the project to a third party, typically a pharmaceutical company, then they divide the license revenues between each other according to their ownership in NewCo.

EXAMPLE 1 (LICENSE CONTRACT WITH SUBLICENSING)

We illustrate an early-stage license deal between a university and a biotech company, including participation rates in case of sublicensing. In early-stage deals it is often too early to tell how well a product would sell; therefore, most deals assume some average sales numbers. The assumptions for the project are shown in Table 2.

The two parties also assume that peak sales are set at US$420 million with an operating margin of 65 per cent and launch costs of US$60 million. Calculated at a discount rate of 22 per cent the project value is US$1 million. The university aims at 3–4 per cent royalties and some increasing milestones. With the upfront payment the biotech company already buys an initial share in the project from the university. An upfront payment of US$200,000 leads therefore to an ownership of 20 per cent in NewCo. The subsequent funding of NewCo to end the discovery phase of US$1.5 million corresponds to a capital increase of NewCo. Its value changes from US$1 million to US$2.5 million, whereof the biotech company owns US$1.7 million (the US$200,000 in purchased shares and the capital increase of US$1.5 million as sole investor), that is, 68 per cent. The same mechanism then again applies at the beginning of the preclinical phase. But after the successful discovery phase the value of NewCo has changed because first the success rate of the discovery phase does not have to be applied anymore, second the project is 1.5 years closer to the market and the cash flows are therefore less discounted, and third the

Table 2: R&D assumptions

In US$ million	*Discovery*	*Preclinical*	*Phase I*	*Phase II*	*Phase III*	*Review*
Duration (years)	1.5	1	1	2	3	1
Success rates	65%	70%	66%	39%	65%	95%
Costs	1.5	2	4	10	42	4

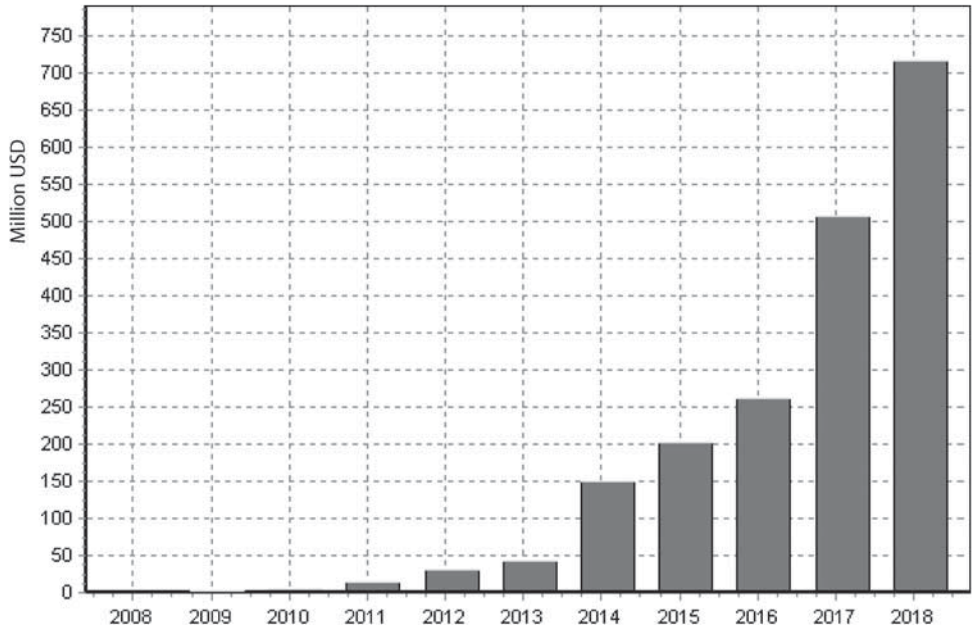

Figure 1: Value development of the project.

discovery costs are sunk. The share purchase through milestone payment and the dilution of the university's stake then happens at a valuation of US$5.2 million. The development of the project's value is displayed in Figure 1.

After the launch milestone the university is still left with a certain ownership in the company. This means that it can claim this percentage of the profit as dividends. This then corresponds to the royalties. And since from that point onwards the profits are more or less defined as the operating margin of sales, the royalty rate should correspond to the margin times the ownership. In Table 3, a license contract is displayed that is designed in a way that the royalty rate at the end is 3.5 per cent as required by the university.

The participation rates are an automatic output of the model, and once the parties have agreed on the license contract these rates are a direct consequence thereof. The model also indicates that the license contract makes sense for the licensor if the value of the project calculated in the model – here US$1 million – is higher than the value of the alternative. The licensee purchases until the end of the lifecycle all shares of NewCo, to the exception of the part it then owes in royalties. Hence the licensor is paid the full price. This model therefore clearly shows if a license makes sense or not. Furthermore, it also returns immediately the IRR for the licensee: it is the discount rate that is used within the model.

Table 3: License terms

In US$ million	*Terms*	*Participation rate (%)*
Discovery upfront	0.2	33
Preclinical milestone	0.2	21
Phase I milestone	0.25	14
Phase II milestone	0.5	9
Phase III milestone	1	7
Filing milestone	2	6
Launch milestone	4	5
Royalties	3.5%	

EXAMPLE 2 (CO-DEVELOPMENT)

The virtual company model is also extremely useful to determine co-development deal terms. Imagine, for instance, that company B

is interested in co-developing a project currently owned by company A. The plan is to license it then together to a pharmaceutical partner after proof of concept in man. In the virtual company model we can then assume that both companies contribute at each capital increase, that is, both companies fund the development. These contributions must be tailored in such a way that at the latest in phase II, company B has acquired a 50 per cent ownership in NewCo. This can be achieved either by diluting company A with funding of the development or with side-payments (milestone payments), corresponding to direct purchases of shares in NewCo from company A.

In this section we will however analyse a different sort of co-development deal. We assume that company A has successfully concluded a phase IIa trial with its project and wants to partner it for the critical phase IIb and phase III studies. At the same time company A wants to keep the financial upside of the North American rights and only puts the rights on the project for the rest of the world (ROW) for sale. The partner, company B, is expected to fund the trials and pay milestones and royalties for the ROW. The trials are obviously necessary for both North America and ROW. In this respect, if company B pays for the remaining trials in full, it actually pays too much, because for the 'North American share' of the trials company A should pay. Consequently the milestones should be lower. So, how can we best determine what deal terms are fair? Let us try to approach this question with the virtual company model again.

In the beginning company A again owns 100 per cent of NewCo. With the upfront payment company B purchases a share package from company A, and with the phase IIb costs it further dilutes company A. The same procedure repeats with the phase III milestone and phase III costs, but then at a valuation that corresponds to the advanced stage of the project. After successful phase III we can imagine that NewCo splits up. At that point we can clearly separate NewCo into NewCo North America and NewCo ROW. After the split, company A is supposed to completely own NewCo North America and a certain share of NewCo ROW. Figure 2 exhibits the development of NewCo and the ownerships therein. We assume the same project as before: North American sales amount to US$200 million, review costs US$1.5 million, launch costs US$30 million, the remainders being for ROW. Furthermore, we assume that the phase IIb trial costs an additional US$10 million and has a success rate of 60 per cent.

With the virtual company model, again calculated at 22 per cent IRR for company B, the license contract could have the following terms: US$5 million upfront, US$20 million launch milestone, and 10 per cent royalties. IRRs of this magnitude are relatively normal in license contracts. But we see here that there is still a lot of leeway in negotiations as for the in-licensing company B the IRR basically just has to be higher than its internal hurdle rate, which is unlikely to lie above 15 per cent for pharmaceutical companies. If we want to negotiate the contract with the value share principle, we need to know how much of each trial is attributable to the North American market. The rest of the paid costs would be interpreted as milestone payments of company B. Assuming a more or less 50–50 per cent split between North America and ROW, the mentioned term sheet corresponds to a 40–60 per cent value split between company A and company B for the ROW rights. But we see that with the value share principle, the calculation already requires quite some shuffling around of payments; we have to split phase costs into North American phase costs and ROW phase costs, we have to interpret additional R&D contribution as milestones, and so on. The virtual company model can accommodate all this in a simple way. Also, it is no problem to consider different markets that are not easily comparable. One regulatory authority might require extensive phase IV

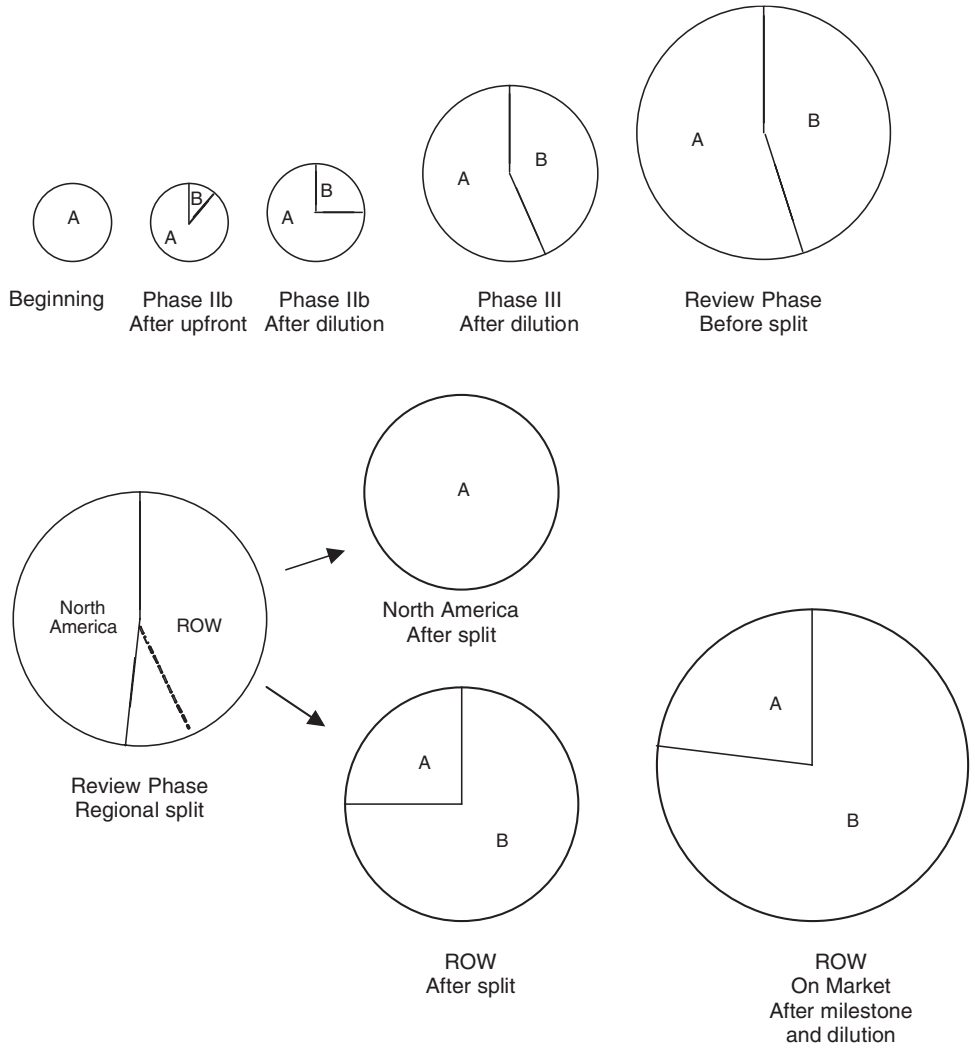

Figure 2: Development of ownership in NewCo for a co-development deal.

studies. How does this impact the split of the earlier phase costs between North America and ROW? In the virtual company model this is naturally factored in.

The two companies can also agree that company B receives cross-royalties on North American sales and company A can increase the other license terms in exchange. This accounts for company B's contribution to the value of NewCo North America as trial sponsor and also reduces its financial downside in case it does not get approval in ROW. Although this license structure becomes rather complicated to justify with the value share principle, the virtual company model explains easily how large the terms should be in order to get a fair deal. In the above-discussed model, company A owns 60 per cent of NewCo before it gets separated into NewCo North America and NewCo ROW. NewCo North America representing 47 per cent of NewCo, company A was left with 13 per cent of 53 per cent (=25 per cent) of NewCo ROW. It is also possible that company B keeps a certain stake in NewCo North America, say 10 per cent of its stake in NewCo should be allocated to NewCo North America (10 per cent out of 47 per cent=21

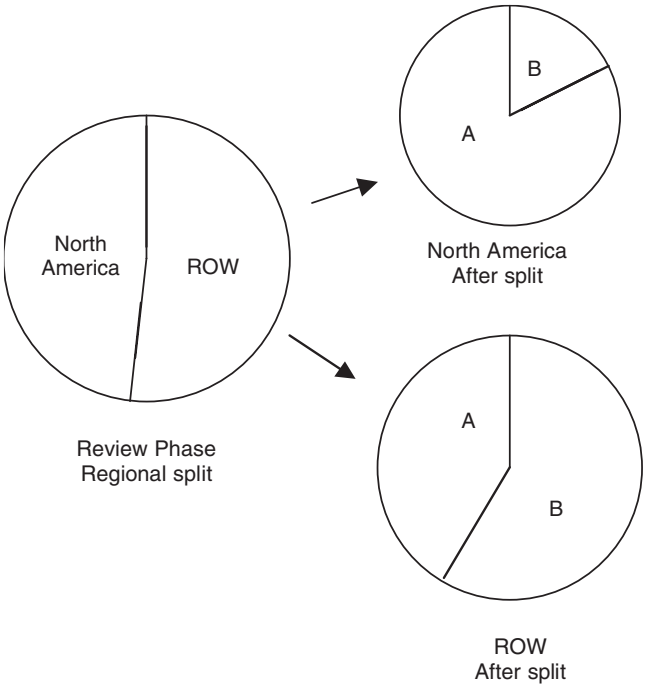

Figure 3: Development of ownership in a co-development deal with cross-royalties.

per cent). In that case, company A's ownership in NewCo ROW would increase to 23 per cent out of 53 per cent (=43 per cent) of NewCo ROW, leading to much higher royalties (cf. Figure 3 and Table 4).

CONCLUSION

With the virtual company model even very complicated license structures can be valued. During the negotiation one can focus on clearly defined and easy-to-understand valuation parameters. It becomes immediately clear if a deal structure is acceptable to a party. The value of NewCo must be higher than the alternatives of the licensor, and the discount rate must be higher than the licensee's hurdle rate. The value share principle, although very popular within the industry, fails to explain why a certain value split should be fair. The discount rate of the joint company is the most important point and will be the most discussed about parameter. But while in standard valuations the discount rate is defined as the cost of capital with respect to outside investors, the discount rate has a slightly different meaning here: The in-licensing company invests in NewCo, but can claim a premium (ie a higher discount rate) because of its knowledgeable contributions to NewCo along the development path, that is, more reliable late-stage trial planning and better commercialisation.

Table 4: Equivalent deal terms according to virtual company model

In US$ million	*Deal 1*	*Deal 2*
Upfront payment	5	5
Launch milestone ROW	20	35
Royalties ROW (to company A)	10%	20%
Cross-royalties North America (to company B)	—	12.5%

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