
Original Article

Pharmaceutical royalties in licensing deals: No place for the 25 per cent rule of thumb

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ABSTRACT The 25 per cent rule of thumb is often quoted in the context of licensing royalty rates and, in particular, when deriving an appropriate rate of income due to a licensor for an individual asset. We have set out to conduct an in-depth analysis of historic market data from the pharmaceutical industry going back over 10 years to check on the validity of this concept and found little if any evidence of its use, appropriateness or relevance. An abundance of anecdotal references and attempts can be found to make deal making data fit this incongruous notion, and which does not have a sufficiently robust foundation to make its utility appropriate in the pharmaceutical and biotechnology sector. In this paper we review available data and present the case that the use of the 25 per cent rule is at best problematic and at worst inappropriate and misleading to the pharmaceutical and biotechnology industry. We look at the basic principles of value as they apply to the industry's intellectual property. Our conclusion shows that this rule has no suitable place in the arsenal of the thinking licensing executive.

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INTRODUCTION

What is the right royalty rate for a pharmaceutical product? This is one of the most frequently posed questions in the licensing

space where buyers and sellers of assets look to strike the best deals. The reality is that unfortunately there is probably no definitive answer that can be arrived at by a simple calculation or straightforward benchmarking.

Royalty is but one component of the total value intrinsic in a product to be licensed. It is misleading to set a prescriptive

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numerical value in isolation that should be assigned to royalties as value derived by a licensor (and a licensee for that matter) is a function of unique factors such as those relating to licence deal structure, strategic needs and negotiation skills. Yet this is what companies inexperienced in deal making often do.

WHAT IS THE 25 PER CENT RULE OF THUMB?

In order to carry on with our analysis it is essential to have clarity on two key business measures: net sales and profit. Net sales equals total sales (that is gross sales) less discounts, rebates and returns. Corporate reports of pharmaceutical companies commonly report net sales in their financial statements. Profit is defined at different levels in corporate accounts. The most appropriate profit definition to use is that of EBITDA, earnings before interest, tax, depreciation and amortisation.

So as to better understand what the 25 per cent rule of thumb is intended to be, we must first explain a little about what the 25 per cent rule is not: it is not a rule relating to a royalty of 25 per cent as a percentage of sales. In those industries where it is considered, it is taken as a percentage of profit. In his much cited book 'Early Stage Technologies, Valuation and Pricing'¹ Richard Razgaitis proposes that 'The 25 percent rule ... asserts that 75 per cent of the work that has to be done to go from a raw idea to the customer's [licensor's] cash in hand will be done by the buyer [licensee] using extensive business assets it has previously and independently developed, which are also necessary to commercialise the subject technology'. However, the raw idea, the original intellectual property (IP), in the pharmaceutical industry, needs to undergo an extensive and expensive, high risk, development/commercialisation programme before entering the marketing phase. How much will each of these other essential stages justify in terms of added value, or increased share of any eventual profit generated?

Recalculating the 25 per cent of profit royalty target as a percentage of net sales, Razgaitis also outlines the potential benefits to the licensor in avoiding the risks associated with distortion of 'official' measures of profitability. Restating the rule he proposes '[t]he royalty in percent of net sales price should be one quarter of net sales after deduction of (1) cost of goods sold (including depreciation of relevant plant and equipment), (2) appropriately allocated general and administrative cost, (3) appropriately allocated marketing and sales cost, and (4) any other appropriate costs (but not including interest, taxes or dividends)'.

Put another way, the 25 per cent rule states that the licensee should pay a royalty equivalent to 25 per cent of the profit gained by employment of the IP licensed. But in the pharmaceutical industry exactly what constitutes the 'raw idea'? Is it at the approval of patent application? Is it at the achievement of proof of concept through human clinical trials? Is it perhaps at achievement of regulatory approval to allow commercialisation, that is, proof of a marketable asset? We will examine each of these stages of development for pharmaceuticals to see if we can detect a 25 per cent rule playing although a circumstantial role in the royalties therein.

But let us step back a little and look at the origins of this supposedly heuristic measure. A chapter on the use of the 25 per cent rule of thumb in Russell Parr's 'Royalty Rates for Licensing Intellectual Property'² co-authored by Robert Goldscheider, John Jarosz and Carla Mulhern should help us, but on reading the 'history' paragraph perhaps not. The opening line remarks that 'according to some sources, the Rule was formally developed decades ago by one of the authors, Robert Goldscheider', but does not categorically confirm this as fact. As the reader goes on to learn, both Goldscheider and general council of Research Corporation, Albert S. Davis were active in the late 1950s, Davis in print in 1958³ and Goldscheider in research later

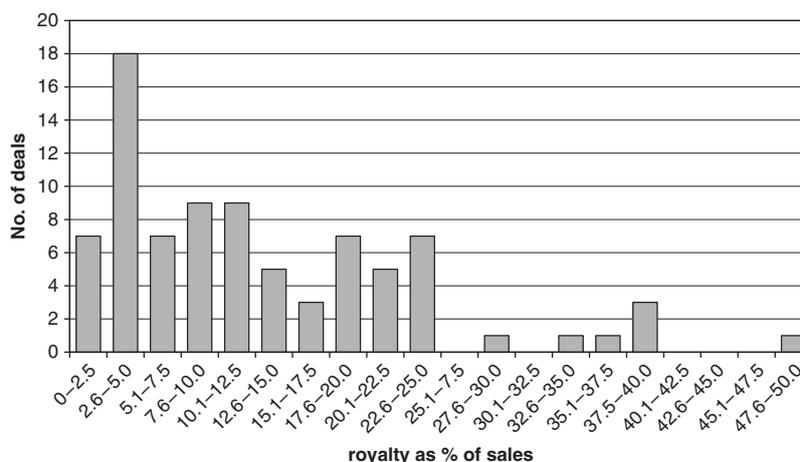


Figure 1: Frequency of royalty rates paid by the top 15 pharmaceutical companies.⁵

reported in 1971⁴ and 1980. Goldscheider’s observation, that 25 per cent of the licensee’s profits was being paid out as a 5 per cent of sales royalty, was based on an analysis of one licensor (a Swiss subsidiary of a US technology company, Philadelphia Storage Battery Company) with 18 exclusive territory licensees. Was the 25 per cent rule of thumb borne from this single observation? Would analysis of a different product type in a different decade covering a different territory have generated a different observation and a different rule of thumb? If this is the only evidence then clearly it lacks the usual rigour one would expect for a sequence of actions to become a ‘rule’. If, however, it is an observation that is reproducible and can be measured, or cannot be disproved then perhaps it holds some scientific integrity and has merit.

WHAT DOES THE MARKET SHOW

Despite the reluctance of the majority of deal makers to disclose royalty data there has been a sufficient number so as to allow some statistical analysis and thereby determine industry norms. Royalties are typically (but not universally) based on sales. If the ‘25 per cent rule’ were applicable might we expect to see products with essentially similar cost

structures clustering around similar royalty rates? A simple analysis of the royalty rates paid by the top 15 pharmaceutical companies, given they have sufficient similarities in product profiles and cost structures, should reveal such clustering if it exists (Figure 1).

At first glance there appears to be no consistency in the royalty rates applied in the pharmaceutical industry with a greater than tenfold difference between top and bottom rates agreed. Add to that the fact that some royalty rates exist well in excess of 20 per cent, some in excess of 25 per cent of sales, the rule of thumb would seem to be of little use in defining a suitable outcome. On first analysis then the rule appears either erratic or inappropriate in this data set encompassing as it does deals involving products at a variety of different development stages, or ‘phases’. Perhaps within the data set lies evidence of the 25 per cent rule hidden within development phase subsets, or dispersed by wide profitability ranges.

ANALYSIS OF PHARMA OPERATING PROFITS

As we stated earlier if it has applicability the 25 per cent rule should be taken as a percentage of profit, best defined we believe

as operating profit or EBITDA. Table 1 shows the 2007 EBITDA for a selection of leading pharmaceutical and biotechnology companies.⁶

Based on these figures if the 25 per cent rule of thumb were being used in the industry we would expect to see royalty rates in deals involving these companies to show the figures in the third column.

The 7.1–11.8 per cent EBITDA derived range is clearly far narrower than the actual rates (for small molecule drugs – the largest subset of licensing deals) shown in Figure 1 where we can see a spread of 1.5–40 per cent of net sales.

But perhaps the clinical development stage is affecting the numbers through a definition of IP completeness or maturity. Is there a stage or ‘phase’ which does show a spread similar to the EBITDA calculated figures?

We analysed royalty rates by phase since 2004. Is there a phase for product deals where we see maximum figures of around 12 per cent with rates below the EBITDA derived range where upfront and milestone payments account for a portion of the royalty’s IP value? As shown in Figure 2 no group shows a peak royalty rate at 12 per cent, all groups have deal terms, which exceed this figure by a significant margin.

The argument over when a product’s IP qualifies as a ‘raw idea’ becomes a moot point in the light of this evidence. At no development stage is the maximum agreed royalty rate equivalent to 25 per cent of EBITDA figures as shown in Table 1.

PROJECT PROFITABILITY

Might the definition of the profit base as being EBITDA be erroneous in our attempt to uncover the 25 per cent rule of thumb in the pharmaceutical industry? Profit, at least in accounting terms can be expressed in a number of recognised formats. Razgaitis recommended the use of total earnings before interest and taxes (EBIT)⁸ and as we have seen the industry data from big pharma at this high level shows no correlation with the

Table 1: Calculated 25 per cent royalty rates for leading pharmaceutical companies based upon EBITDA

<i>Company</i>	<i>EBITDA (%)</i>	<i>25% of EBITDA</i>
Abbott	30.20	7.6
Bristol Myers Squibb	28.30	7.1
Eli Lilly	32.10	8.0
Pfizer	42.00	10.5
Merck & Co	47.20	11.8
Wyeth	33.70	8.4
Johnson & Johnson	29.20	7.3
AstraZeneca	36.90	9.2
GlaxoSmithKline	40.50	10.1
Sanofiaventis	37.50	9.4
Roche	36.90	9.2
Novartis	28.40	7.1
Amgen	46.00	11.5
Genentech	40.40	10.1
Genzyme	32.20	8.1

royalty data set. The earnings data shown comes from the corporate level financial statements published by each company, therefore these earnings are significantly impacted by corporate costs and other non-drug development related investments. When assessing the value of individual projects companies use costs that are directly related to the particular drug candidate. In our experience the average profitability of individual drug products across their lifetime typically fall into the 60–70 per cent bracket. If the 25 per cent rule applies then the spread of royalties should reach a maximum royalty paid of 15–17.5 per cent of sales. No group in Figure 2 shows this maximum figure. Closer to the top line net sales figure in a Profit and Loss account statement for a company the Gross Profit (GP) figure represents sales minus cost of goods. Does GP provide a better point to reveal a tighter correlation and evidence of the 25 per cent rule of thumb’s application? Table 2 shows the calculated 25 per cent of GP for leading pharmaceutical companies.

Superficially at least, the 14–22 per cent range appears closer to the ranges shown in Figure 2 and could explain the data from preclinical, phase I and a significant proportion of phase II. It still does not fit

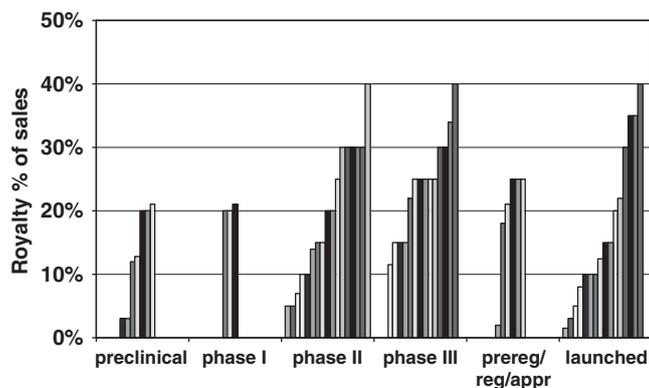


Figure 2: Actual royalty rates paid for small molecules 2004 onwards.⁷
 Note: (each bar represents an individual product royalty).

Table 2: Calculated 25 per cent of gross profit (GP) for leading pharmaceutical companies⁹

Company	GP(%)	25% of GP(%)
Abbott	57.80	14.45
Bristol Myers Squibb	68.80	17.20
Eli Lilly	77.20	19.30
Pfizer	84.00	21.00
Merck & Co	76.60	19.15
Wyeth	72.90	18.23
Johnson & Johnson	70.90	17.73
AstraZeneca	79.70	19.93
GlaxoSmithKline	77.10	19.28
Sanofiaventis	73.00	18.25
Roche	72.30	18.08
Novartis	74.60	18.65
Amgen	84.60	21.15
Genentech	86.60	21.65
Genzyme	76.20	19.05

with a significant proportion of phase III and beyond. The use of GP is fundamentally flawed. If we take an average GP figure from Table 2 of 75 per cent and assign 25 per cent of that to a royalty fee (= 18.9 per cent) the remaining 75 per cent of the GP (= 56.6 per cent of gross sales) should now represent the reward due to the licensee, yet the cost of generating those gross sales has yet to be accounted for. The sales general and administration costs (SG&A) associated with running the business typically run at between 25 and 35 per cent of sales (can be even 100 per cent of sales in the year of launch) in big pharma and without the activities

Table 3: Licensee's share after Royalty at 25 per cent of gross profit (GP)

Sales	100.0%
Cost of goods sold	25.0%
GP	75.0%
Licensor's royalty	18.9%
SG&A	30.0%
Licensee's share	26.1%

associated with these costs there will be no sales to generate royalties for the licensor. Without any other attributable costs a breakdown of the business proposition based on a royalty set at 25 per cent of GP is shown in Table 3.

It is not possible for the licensee to realise his 75 per cent portion from the rule of thumb. The licensor is receiving $18.9 / (18.9 + 26.1) = 42$ per cent of the profit derived in the GP model. Some of the data may therefore show approximation with a '42 per cent rule of thumb' but only a proportion of real-life data would support this in the same way as a 25 per cent rule (which now appears equally unrelated to real data from the pharmaceutical industry). This GP model, if it is to accommodate the early phase deals to which it might show some approximation, will also need to take into account the significant development costs which the licensee will incur further eroding the licensee's share of any returns.

OTHER EXPERT OPINION

Ove Granstrand took a slightly different view in his paper 'Fair and Reasonable Royalty Rate Determination – When Is The 25 per cent Rule applicable?'¹⁰ He proposed a refinement of the rule in that the royalty rate should be a reflection of the relative levels of investment of the parties and therefore the 25 per cent rule did apply but only when the licensor had invested 25 per cent of the total investment required. If the investment split to bring about a successful product is 25/75 then he suggests the royalty reward should be similarly split. Investment is defined here as research and development, production and marketing. If we analyse the cost of a typical successful, although theoretical drug perhaps we can predict at which point in the life cycle the investment split will meet this 25/75 split.

25 per cent investment drug model – The assumptions we have made are as follows:

development cost¹¹: US \$118 million
 (phase I \$15 million, phase II \$24 million,
 phase III \$75 million, reg \$4 million);
 development timeframe: 8 years from start
 of phase I trials until launch;
 sales life: 14 years;
 peak sales: \$500 million;
 marketing spend: 25 per cent of sales;
 discount rate: 12 per cent.

Based on these assumptions the expected net present value of the development programme investment is \$80 million, and the expected net present value of the marketing investment is \$293.5 million. Total investment is \$373.4 million expressed as expected net present value (eNPV).

If the investment-based split applies then the licensor will need to license out the drug in the early launch phase by which time he has invested 25 per cent of the programmes costs, if he is to get a 25 per cent share of the 'profit'. However the data does not support this concept for pharmaceuticals. Even if we

took the favourably higher figure of profitability of individual products (that is not corporate profits) of 70 per cent the share would hit the 25 per cent ceiling at 17.5 per cent of sales, however there is no evidence of this in our available data (see Figure 2).

Not all drugs will hit sales peaks of \$500 million though if we run the model at \$100 million peak sales, then out-licensing in late phase II will coincide with the 25 per cent 'share' of costs. As we showed earlier no 17.5 per cent ceiling occurs at phase II, with half of the rates over 20 per cent of sales for products most likely starting phase II, the start of the phase being the most probable licensing point for all phases. For blockbuster products the licensor would need to out-license well into the sales phase to hit his 25 per cent of investment level; an unlikely event if sales success has demonstrated commercial capabilities.

One might argue that marketing spend was irrelevant (back to the GP argument) as it can be used to justify price and profit levels, though less so the case in the global pharmaceutical market these days, however the point at which eNPV costs in the development programme hit the 25 per cent of total development spend cut off is typically just after the start of phase II trials and the data for phase II does not show that 17.5 per cent of sales maximum royalty was paid.

The situation succinctly put by Ove Granstrand in the final line of his paper 'The so-called 25 per cent rule applies specifically to situations when the license seller's investment share is 25 per cent of the total investment', we would equally succinctly add ... *BUT FOR PHARMACEUTICALS IT DOESN'T WHEN IT IS 25 PER CENT ... AND NEITHER DOES IT WHEN IT IS NOT 25 PER CENT!*

BASIC PRINCIPLES OF VALUATION

We have gone to significant lengths to demonstrate why the 25 per cent rule of

thumb has no place in licensing in the pharmaceutical industry. If not such a rule, what tools should licensing executives use to determine a fair royalty rate in a given licensing situation.

Value in economic terms is measured as an ability to generate cash. In humanitarian terms it may have a diametrically opposite definition relating to cost of lives saved or suffering banished, and although those features will help drive economic value they are not guaranteed to generate profit *per se*. Our focus is on the profit generating value. The key word here is 'generating'. A product with a history of high profitability has no value if it lacks the ability to 'generate' future cash, and profit from that generation. Value then requires a prediction of future cash flow and related costs tempered by risk, probability of relative success or failure of that prediction. An outright purchase of an asset carries all the risk for the purchaser and none for the seller who has his cash in hand; licensing deals on the other hand involve a sharing of risk between the parties going forward, with deal components carrying differing levels of risk. Early paid out components such as upfront sums carry maximum risk for the licensee, longer-term obligations to pay royalties are more risky for the licensor who may not receive the predicted value bearing royalty stream. Risk then is a major driver in value. All projects and all licensing deals will carry risk to varying degrees, but each will be unique. As risk affects value, and value is delivered in licensing deals through royalty streams then it would surely be a strange coincidence to find any statistical norm such as a rule of thumb that adequately expressed this variation in risk. The same can be said of any claim that an average amount of risk can be defined by the rule and will prove useful in the absence of any specific data. IP is by definition unique and deserves a specially considered analysis in every aspect of its valuation rather than a one-size-fits-all or an iterative approach from an average assumption as a starting point.

THE STRUCTURES OF PHARMACEUTICAL LICENSING DEALS

Royalties are often viewed in isolation from other factors related to IP licensing. Too much time, and too much energy, is spent searching for meaning within what little royalty evidence exists in the public domain. The truth is more complex than the superficiality of royalty values alone. Without insight into the value of other deal components, such as upfront payments or milestone payments, two seemingly similar royalty percentages may be seen as indicative of a trend or average, when, in reality, they are components of deals that might have vastly dissimilar values and structures aside from this one coincidental component.

'Effective royalty' is a value concept derived by PharmaVentures that allows all those other deal components to be factored into a valuation, which is then expressed as a single component: a royalty. The effective royalty rate answers the question: if there were no other structural components included in this deal what would the royalty be? In other words, what is the size of the royalty if all the value due to the licensor were incorporated into it? For deal makers, this can be very valuable, as it allows benchmarking and comparison without the confusion caused by the complexity of reported deal structures.

This effective royalty concept shows that the EBITDA derived royalty figures of approximately 7–12 per cent if all of the 25 per cent (following the rule of thumb) of value were rolled into a royalty rate. This then represents a maximum in value for the 'rule', and royalty rates below this may still reflect the rule provided upfront and milestone payments account for the remaining value. Royalty rates above such a maximum would represent a poor deal for the licensee. A large number of successful companies have struck solid deals with royalties significantly above this level therefore, once again, the 25 per cent rule is made invalid.

DRIVERS OF VALUE

Before even accepting the clearly tenuous argument as to whether the licensor should get an arbitrary 25 per cent or any other predetermined portion of the value generated we need to consider exactly what defines the value itself.

The generally accepted industry standard for 'value' calculation is the discounted cash flow methodology incorporating risk through the use of decision tree analysis. In a simple business model value is calculated in cash terms, and usually expressed as an eNPV. It is driven by forecasts for sales, cost of sales and expenses incurred in generating sales. Higher sales should increase value (as long as costs and expenses remain proportional), higher cost of sales percentages will reduce value, and higher expenses may reduce value or increase value depending upon any positive neutral/negative effect on the sales line. Shifting sales further out into the future will reduce value as our value expression brings all money into today's value using a discount rate to account for inflation and lost opportunity to use that money elsewhere. In development phase pharmaceutical products, major gains in value occur as development hurdles are cleared, or conversely major falls in value occur if problems arise, often those falls take the value to zero as for example toxicity or lack of clinical effectiveness force project cancellation. Overall, therefore, a large number of factors may influence outcome and evidently no fixed rule can apply.

DRIVERS OF THE SHARE OF VALUE A LICENSOR HOPES TO GET

Does all IP have the same fixed value when compared to the profit it can help to achieve? Strategic need will determine just how far a licensee is willing to go in a negotiation process. Many of the components of that strategic need are unique to the licensee, intrinsic factors to their business alone which relate to existing expertise and market access,

progress or lack of it in pipeline products, impending or current impact from patent expiry, available cash and alternative investment opportunities, underutilisation of capability, complimentary programmes to the one under consideration, even internal concern for industry analyst's perception, all of which can modify that strategic need and modify the lengths the licensee may be willing to go to do the deal. Extrinsic factors will also affect the potential share of the deal value. Market size and potential, pricing opportunities, unmet clinical need and the competitive environment all play a part and are modified by the product itself. The strength of that product's IP and the performance offered or suggested will also affect the licensee's willingness to agree deal terms. These then are the drivers that translate into such broad ranges of deal values and royalty rates.

CONCLUSIONS

We have clearly shown that the 25 per cent rule of thumb is not reflected in the myriad deals that typify the pharmaceutical licensing arena. We have also highlighted those factors, which determine value and confound attempts to put a set mathematical structure around licensing deal values and royalty components. We cannot justify the rule based on evidence in the pharmaceutical industry, and we cannot justify the rule based on the principles of valuation and deal making in the pharmaceutical industry.

As for the proposition that the rule 'merely' provides a useful starting point in negotiations we believe the data demonstrates little evidence of this (a starting point might be expected to sit at the midpoint in data sets with ensuing negotiation taking the resultant royalty higher or lower in equal proportions and a peak close to this, not surprisingly the evidence did not support this) and the principles of valuation discussed here also reject the proposition of 'usefulness' of what is an arbitrary and unsound value. A more logical approach would be to start at 0 per cent (or

100 per cent) and justify every gain or concession based on deal parties' specifics.

In litigation cases where infringement damages need to be calculated, and potentially on-going royalty payments agreed, use of the 25 per cent rule of thumb could be unfair to either party leading to an unsound outcome and in our opinion to a justifiable contest of the result. The rule was born from overly simplistic and limited analysis and selective retrospective observations in another industry. In a desperate attempt to make the data fit the hypothesis the rule of thumb has been stretched to higher and lower realms totally negating its false hope of usefulness. As far as the pharmaceutical industry is concerned this retrospection does not support its existence. The 25 per cent rule of thumb is not dead; it, in our opinion, never truly existed as a useful tool in the first place.

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