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Characteristics of pharmaceutical patent royalty rates

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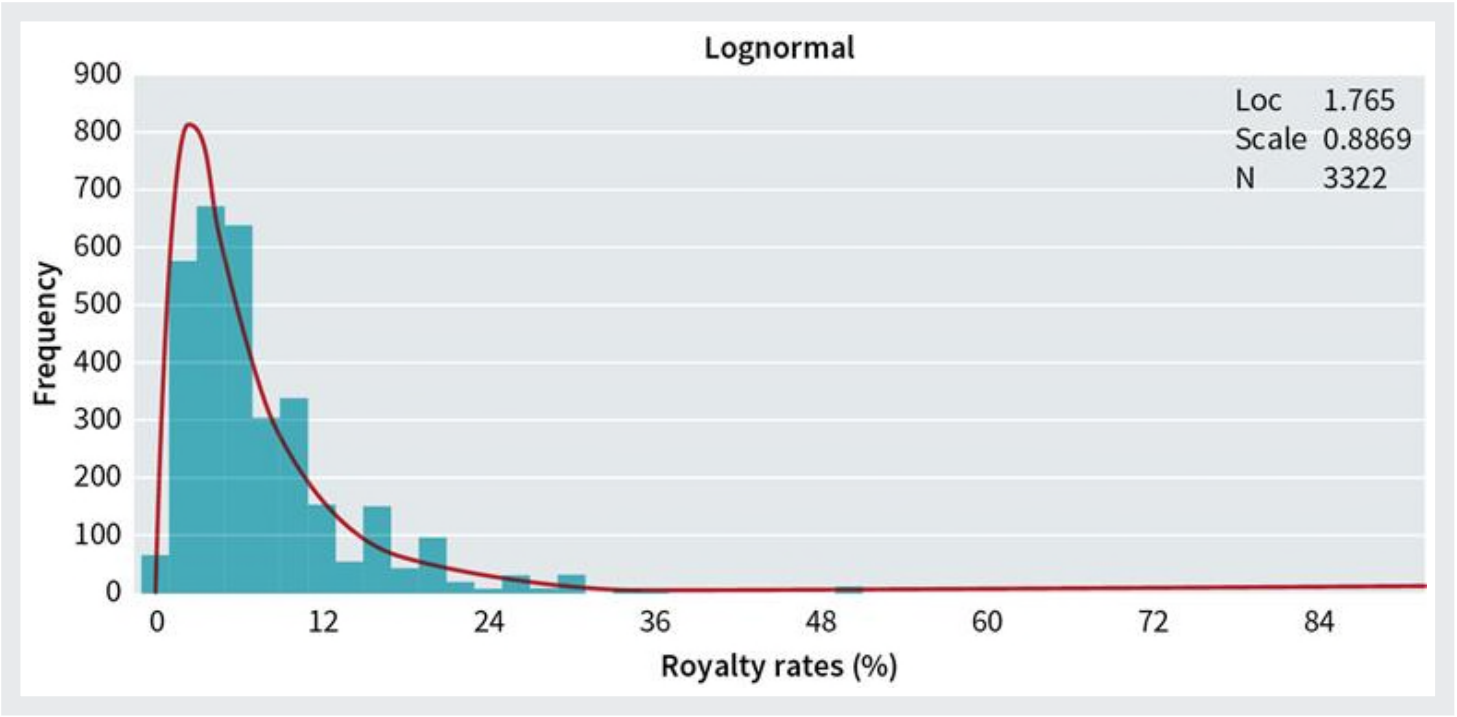
This chapter examines certain statistical characteristics of pharmaceutical patent royalty rates based on the licensee's revenue. It focuses on royalty rates extracted from 3,322 unredacted licence agreements filed primarily with the US Securities and Exchange Commission.

Skew frequency distribution

Like other income variables, royalty rates based on sales revenue approach a lognormal frequency distribution. The lognormal distribution provides a good fit of random variables that are restricted to positive values. A random variable X (eg, royalty rates based on sales revenue) has a lognormal distribution if the natural logarithms of the variable, Y = LN(X), have a normal distribution. Likewise, if the variable Y has a normal distribution, then X = exp(Y) has a lognormal distribution. Here, certain statistical characteristics of the lognormal distribution are highlighted to contravene the pervasive practice of using simple averages or the medium to summarise industry royalty rates. We can write $X \approx \text{Lognormal}(\mu, \sigma)$, where μ is the location parameter and σ is the scale parameter (a detailed discussion is found in J Aitchison & J Brown, *The Lognormal Distribution*, Cambridge University Press, 1969. See also E Limpert, W Stahel and M Abbt, "Lognormal distributions across the sciences", *BioScience*, Vol 51, No 5, May 2001).

Unlike the ubiquitous normal distribution, the mean of the lognormal distribution is given by $\alpha = \exp(\mu + 0.5\ \sigma 2)$ and the variance by $\beta 2 = \alpha 2\ \eta 2$, where $\eta 2 = \exp(\sigma 2 - 1)$. The median is more tractable at $\exp(\mu)$, which coincides with the geometric mean (see Aitchison & Brown, Formulae 2.7, 2.8 and 2.9, p 8). In context, we consider a large sample of 3,322 third-party pharmaceutical patent royalty rates based on the licensee's revenue and show in Figure 1 that the histogram of the lognormal curve provides a good fit.

Figure 1. Pharmaceutical patent royalty rates



Source: RoyaltyStat

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Transfer pricing application

Using industry royalty rates is seldom defensible in specific applications, such as determining reasonable royalty rates to establish patent or trademark infringement damage or determining arm's-length royalty rates in transfer pricing corporate tax compliance. In these applications, judgement (non-random) selection of 'comparables' is made using primarily qualitative criteria that are difficult to survive scrutiny. These judgment samples are often very small, consisting of five to 12 comparables, making it difficult to ascertain the statistical distribution of royalty rates and compute reliable estimates of central tendency and data spread. For example, in a recent transfer pricing litigation the US Tax Court rejected the petitioner taxpayer's (Medtronic) royalty rates analysis based on seven comparables selected from almost 1,300 licence agreements, because an expert proposed "a broad and unconvincing" range of technology (medical devices) royalty rates between 0.5% and 20%. In the same case, based on another expert, the Internal Revenue Service (respondent) proposed extraordinary royalty rates of 49.4% and 58.9% of the licensee's revenue, and such improbable large difference lying between two consecutive years (2005 and 2006) (see *Medtronic v Commissioner of Internal Revenue*, TC Memo 2016-112, Docket 6944-11, filed June 9 2016). The figures in this chapter show that double-digit royalty rates tend to be outliers, meriting a detailed explanation of their incidence in specific applications.

For intangible licences, the comparable circumstances described in US Treasury Regulation Section 1.482 and the Organisation for Economic Cooperation and Development (OECD) *Transfer Pricing Guidelines* require the analysis of the contractual terms covering the licensing of intangibles, including:

- the functions performed by the licensor and licensee;
- rights conferred;

- exclusivity;
- territory;
- duration;
- liability risks; and
- collateral transactions (see US Treas Reg § 1.482-4).

Certain factors are easier to account for than others, because sufficient information is unavailable in the unredacted licence agreement to develop a comprehensive comparability analysis as prescribed in the Treasury regulation and the OECD guidelines. In addition, the licence payments are often more complex than a simple royalty rate based on the licensee's revenue; they may include additional payments (eg, licence fees, milestone payments or minimum royalties), and the royalty rate structure may vary as tiered and non-tiered depending on sales volume, effective year or other factors.

The next section analyses the relation of exclusivity, additional payments and rate structure (ie, tiered or non-tiered) among the royalty rates of the 3,322 pharmaceutical patent licence agreements in the sample.

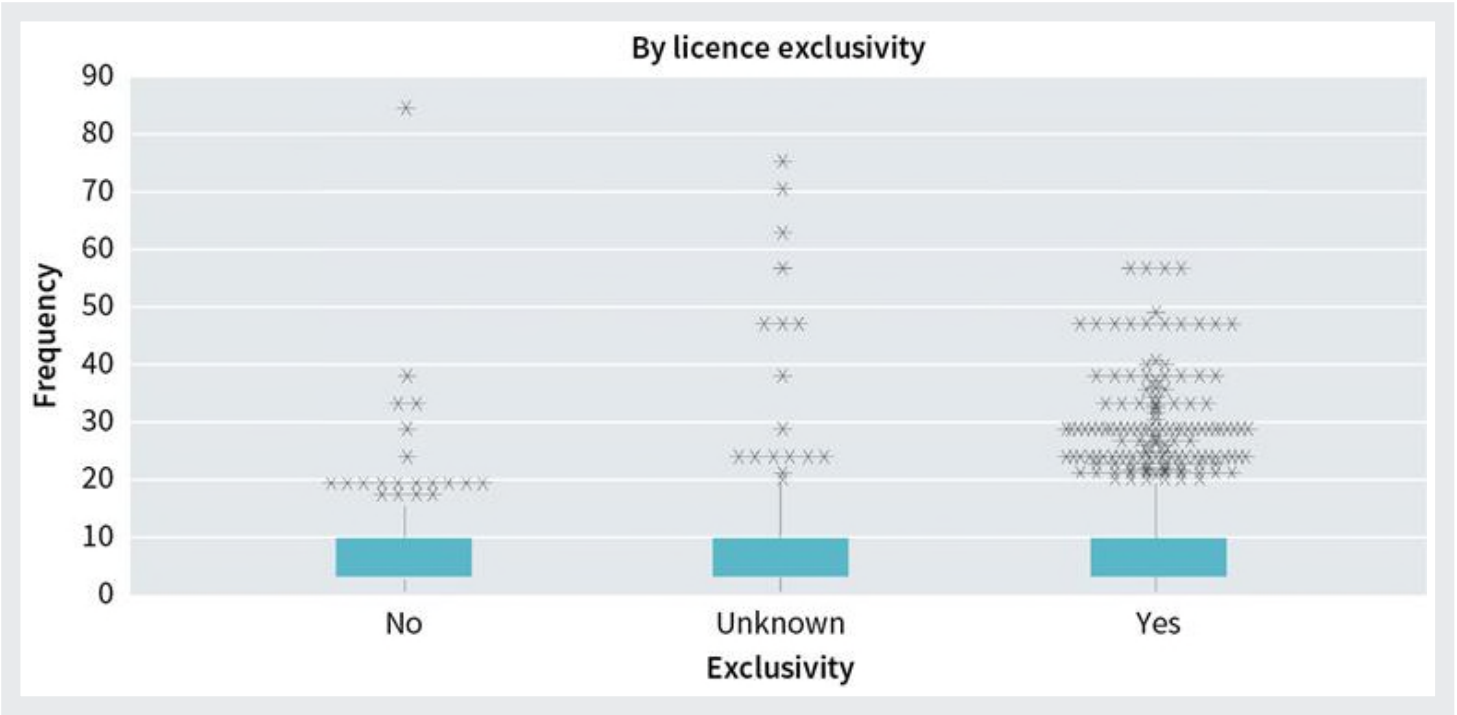
Exclusive agreements

One of the most important characteristics of intangible licences (including patents) is the exclusive or non-exclusive character of the agreement, which may refer to:

- the types of intangible licensed (eg, patents, know-how, trademarks);
- the rights to use and exploit the licensed intangibles; or
- the limitation of the licensed territory.

It may be assumed that an exclusive licence has a higher royalty rate than a non-exclusive license, because the licensee has the sole concession from the licensor of the intangibles; nevertheless, analysis of the 3,322 pharmaceutical patent licence agreements shows that exclusivity has no effect on the royalty rate (as seen in Figure 2). The high occurrence of outliers (represented by asterisks) is typical of large data samples (see D Hoaglin, F Mosteller and J Tukey, *Understanding Robust and Exploratory Data Analysis*, John Wiley & Sons, 1983, pp 59-62).

Figure 2. Pharmaceutical patent royalty rates



The patent licence agreements under review can be divided into three groups: exclusive, non-exclusive and unknown (where information regarding the exclusivity is unavailable in the agreement). The data shows a median of 4.6% for non-exclusive agreements and 5% for both exclusive and unknown agreements. These close results are also found in the first and third quartiles of the three groups, varying from 2.4% for non-exclusive to 3% for exclusive, and from 8.5% for non-exclusive to 10% for exclusive and unknown, respectively. Thus, there is no apparent relationship between the royalty rate and the exclusive or non-exclusive character of the agreement that would merit a more detailed statistical testing of hypotheses about significant differences between their central values.

The majority of the agreements reviewed (2,597 of the 3,322) are exclusive. This indicates that for a pharmaceutical patent, licensors are more willing to license-out their developed intangible rights to a single licensee than to grant multiple licences and diffuse proprietary knowledge regarding the licensed intangibles.

Tiered and non-tiered royalty rates

The royalty rates in a licence agreement may have structures other than a fixed rate. Here, the different royalty rate structures have been divided into tiered and non-tiered royalty rates. Among the 3,322 patent pharmaceutical licence agreements, one-third have tiered royalty rates that vary on an ascending or descending order based on:

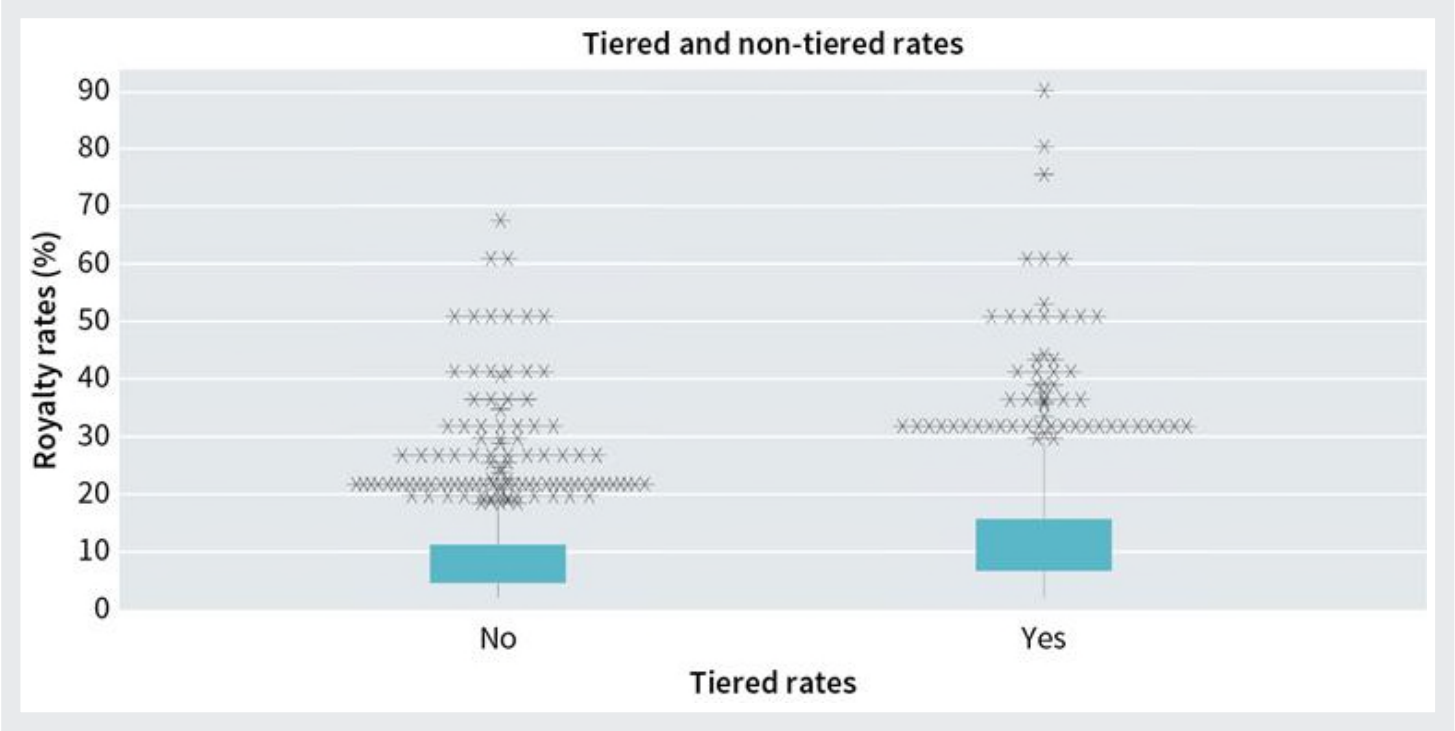
- sales revenue;
- units sold;
- time until expiry; or
- milestone events.

The agreements with a tiered royalty structure present a challenge to comparability analysis, because they provide the royalty rate structure, but it is difficult to identify which of the multiple royalty rates applies during the effectiveness of the licence. For example, if the tiered royalty rates are based on the licensee's revenue, the royalty due is phased per tier and the total royalty payment is the sum of the amount determined in each tier. In such situations, the most defensible selection criterion is to separate tiered from non-tiered licence agreements and not to mix them into an amorphous sample.

The summary statistics of the tiered rate licence agreements examined show a higher median and higher first and third quartiles when the patent licence agreements have a tiered royalty rate structure. The interquartile range of this large sample varies from 2.6% to 8%, with a median of 5% for non-tiered, and from 5% to 14%, with a median of 8.5% for tiered royalty rates. These narrower ranges indicate that the royalty rates presented by the opposing experts at Medtronic are probable outliers and inconsistent with the characteristics of the large sample of royalty rates in a related industry (pharmaceutical versus medical devices) considered in this chapter.

For this study, the high and low royalty rates were extracted from unredacted licence agreements and summary statistics were calculated using the higher royalty rate for agreements with a tiered royalty structure. As a result, the tiered agreements are expected to have a higher rate at their top tier than agreements with a non-tiered structure. However, this top-tier rate may not apply at a certain time during the licence, depending on how the royalty tiers are structured. Thus, licence agreements with a tiered royalty rate structure are more complex than those with non-tiered rates, and using such agreements as comparables to a tested transaction merits a more detailed case-by-case investigation in order to better survive scrutiny.

Figure 3. Pharmaceutical patent royalty rates

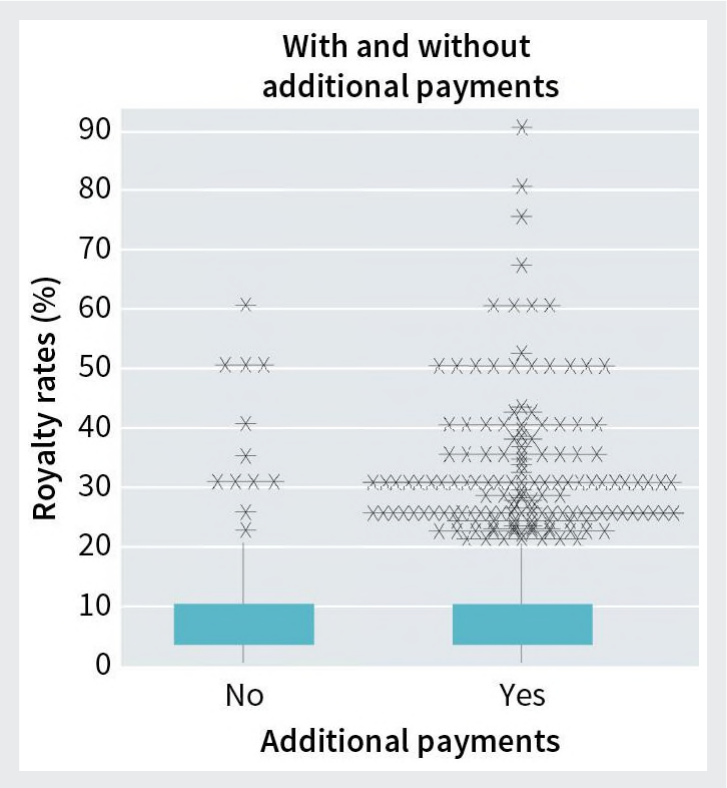


Additional payments

In a licence agreement, contending parties and their experts may consider other payments in addition to an ongoing royalty rate to compensate the licensor for previous R&D activities when the licence is granted (upfront licence fees), as recompense for future R&D or to reflect the attainment of certain sales goals (milestone payments) connected with comparative advantages attributed to the licensed property.

Another assumption is that licence agreements with additional payments have a lower royalty rate, because the licensor is compensated by flat fees established in the agreement in addition to the ongoing royalty rate. However, as seen in Figure 4, the presence or absence of additional payments does not appear to have an effect on the royalty rate. In fact, additional payments are an important factor to consider when determining the value of an intangible, including its profit potential; but this factor appears to be independent of the royalty rate. Using formulae, the additional payments (A) indicate the existence of an intercept in a linear statistical function determining the t-th period royalty payment amount (R(t)), but not necessarily a different royalty rate:

Figure 4. Pharmaceutical patent royalty rates



Where A is additional payment, rho is the estimated royalty rate and S is the sales revenue of the licensee. The naive model posits no intercept, just a fixed royalty rate based on sales revenue (reflecting the motto of 'no sales, no royalties'):

Where the period index is t = 1, 2, …, T years.

The difference between using Model 1 versus Model 2 is that in Model 1 the licensor benefits from the periodic royalty rate plus certain additional payments, irrespective of sales revenue, which may be event driven as describe above. In Model 2, the licensor is compensated only by the running royalty rate and there is no other payment.

It follows that the relevant Model 1, 2 or some other model specification must be considered when projecting future royalties R(t), for t = 1, 2, …, T, because the model used influences the numerator of the present value of the respective intangibles producing the royalty stream. Figure 4 shows that pharmaceutical royalty rates agreed between unrelated parties share similar quartiles. However, the existence of outliers is more frequent among licence agreements with additional payments reflected in Model 1. These summary statistics illustrate the similarities of the quartiles found on the box plot. Among the 3,322 pharmaceutical patent licence agreements, 2,903 include additional payments and exhibit the same quartiles of royalty rates as the agreements without an additional payment.

Conclusion

A large and growing sample of pharmaceutical patent royalty rates based on the licensee's revenue is available in RoyaltyStat. Thus, there is no need to pull pharmaceutical patent royalty rates out of an arbitrary

hat in which some rates are large and some are small, such that unworkable statistical ranges are proposed (eg, from 0.5% to 20%, as in the *Medtronic* tax litigation). Information is available on pharmaceutical patent royalty rates by sub-industries (eg, allergies, cardiovascular, gastrointestinal, vaccines), rights conferred, exclusivity, tier structure, additional payments, territory and other comparability factors. Review of a large sample of 3,322 agreements in a single pharmaceutical industry shows that royalty rates exhibit a lognormal distribution, with more complex formulae to compute the mean and variance than the more well-known normal distribution.

The characteristics (lognormal distribution, central tendency and spread) of pharmaceutical patent royalty rates show that they behave like many other economic variables. From this large sample that was examined with simple univariate and categorical analyses, the selection of comparables under the reasonable royalty rates standard or under the different transfer pricing standard must respect certain factors that may influence the amount of royalties (but not the royalty rate *per se*) earned by the licensor or paid by the licensee – factors such as exclusivity and additional payments. These factors appear (except for tier structure) to be independent of the sampled royalty rates. The statistical characteristics of small judgment (non-random) samples prescribed in certain legal domains, including patent infringement damage assessment and transfer pricing, are more difficult to ascertain. It is also uncertain that assuming *a priori* that such selected royalty rates behave like the normal distribution with well-known and simple-to-compute mean and spread can produce reliable results. These large sample results suggest that comparability analysis would be more reliable if judgment samples were abandoned and more theoretically informed – rather than *ad hoc* case-based – quantitative factors were considered in determining reasonable or arm's-length royalty rates.

Julia Vasconcellos assisted in the preparation of this chapter.

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Ednaldo Silva has a PhD in economics from the University of California at Berkeley and was the first senior economic adviser at the Internal Revenue Service Office of Chief Counsel in Washington DC, a drafting member of the 1994 US transfer pricing regulations and the first economist in the Advance Pricing Agreement programme. Dr Silva introduced the 'comparable profits method' and the 'best method' rule and is a recognised international expert on transfer pricing and intangibles valuation. His practice includes serving as senior tax economist and consultant for large multinational corporations and economic expert on corporate income tax and IP litigations, including in *GlaxoSmithKline Holdings (Americas), Inc v Commissioner of Internal Revenue,* Dockets 5750-04 and 6959-05.