A Review Of The LES (USA & Canada) 2007/2008 BioPharmaceutical Royalty Rate And Deal Terms Survey

By Steven Renwick and James A. McCarthy

Intellectual property valuation in the healthcare sector is often achieved through a combination of discounted cash flow (DCF) and net present value (NPV) calculations, supported by benchmarking based on publicly available deal information. Published total deal value figures invariably show upfront and various milestone payments. However, it is an unfortunate situation for dealmakers that royalties, potentially the largest financial component of the deals they would most like to benchmark, are the one piece of information that almost all companies will keep closest to their chest. The details of these figures are almost always kept confidential by the companies involved. In the United States, public companies are required to file the contracts of material licensing transactions with the U.S. Security and Exchange Commission (SEC). However, the relevant sections and numbers related to financials, and royalty rates in particular, are generally redacted in these filed contracts and are protected under restrictive confidentiality clauses for five or more years. These SEC filing requirements are only for public companies and material transactions. Thus, deals not subject to this requirement include public company deals that are not material to the overall size of the company (i.e. "large pharma"), deals by private companies such as numerous biotech companies, small pharmaceutical companies, ex-U.S. companies and university deals. The result is that actual or primary data on licensing royalty rates and deal terms is limited for a large portion of the industry.

Databases, such as PharmaDeals® and ReCap, will provide deal information where it has been made publicly available; or, where possible, request unredacted versions of filed contracts that are over five years old, through the Freedom of Information Act (FOIA). Nevertheless, there remains an unsatisfactory amount of contemporary royalty information available, covering current deals conducted in the last five years, for dealmakers to use as benchmarks in their licensing negotiations.

It was with the aim of filling this knowledge gap that the Licensing Executives Society, (U.S.A. & Canada), Inc. (LES) Board of Trustees commissioned a royalty rate survey project and requested volunteer LES members to execute an extensive survey in 2007.

The basic objective was to provide LES members with relevant, cutting edge licensing information and industry specific data that cannot be found elsewhere. As a result, LES provides to LES members contemporary, value-added information to benchmark themselves against others in the industry and enhance their deal making expertise. The survey report was issued in summer of 2008 and is available exclusively to LES members electronically via the LES Web site. A summary of the results of that survey is presented in this paper.

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Methodology

A previous survey, looking at Licensing Practices and Factors Affecting Royalty Rates, had been conducted in 1991.[1] This survey had covered all industries represented by LES members and had received 118 participants. Other notable, recent analyses of pharmaceutical royalty rates include a paper published in *les Nouvelles* in March 2008,[2] which covered all industries and again relied on publicly disclosed data, and a healthcare-specific report published by PharmaVentures in 2008,[3] which included

1. McGavock DM, Haas DA and Patin MP. Licensing Practices, Business Strategy, and Factors Affecting Royalty Rates. *Licensing Law and Business Report* 13, 205-216 (1991).

2. Porter M, Mills R and Weinstein R. Industry Norms and Reasonable Royalty Rate Determination. *les Nouvelles* 43, 47-64 (2008).

3. A Guide to Royalty Rates in Pharmaceutical Licensing Deals. PharmaVentures (2007).

analysis of a similarly structured deal terms survey.

It was decided that this current survey would look specifically at the biopharmaceutical segment of the LES Health Care Sector and take advantage of Web-based survey tools and technologies. This was done with a view to expand the survey in the future to other industries and on to a global basis, based on the learnings from this survey.

The survey was conducted in the form of an online questionnaire to each LES member company that was a member of the LES Health Care Sector. The survey questions were designed by an LES member survey committee, all experienced dealmakers. The time frame selected was to solicit information only on deals conducted in the prior three years. The online questionnaire instrument was constructed by Veris Consulting, an independent research company, specialized in confidential surveys conducted by professional associations. Use of an independent company to collect the survey data ensured the confidentiality of the deal information submitted by the survey respondents; furthermore, no personal, company or product names were collected. No LES staff member, leader or survey team member had any access to the raw data submitted or knowledge of who participated.

The survey execution was announced and launched at the 2007 LES (USA & Canada) Annual Meeting held in Vancouver. Participation was sought through a series of letters and e-mails to all LES (USA & Canada) Health Care Sector members in each health care company. This was followed up with telephone calls to senior LES members at the top 50 pharmaceutical companies to encourage their participation.

Before looking at the results of the survey, it is important to clarify the nature of the data on which the analysis was based and to suggest a disclaimer. In total, 230 licensing deals were submitted by 86 pharmaceutical organisations of various sizes. Ultimately, 155 deals representing completed surveys were included in the analysis, meaning that a number of organisations submitted more than one deal. This opens up the possibility of data bias due to potential over-representation by a particular organisation type. Furthermore, due to the criteria with which the deal data was sorted and analysed, many of the analyses were conducted on data sets with a relatively small sample size. Therefore, although the results presented in this paper are indicative of industry practices, they should not be construed as definitive representation of the whole pharmaceutical industry. Nevertheless, this data represents the most recent analysis available of contemporary, biopharmaceutical licensing royalty information for deals conducted in the last three years.

It is intended that this survey can act as a pilot for future royalty rate surveys, which may be expanded to the LES International community. With expanded geographic reach and increased participation, this survey can become more robust with each cycle.

Respondents Profile

In total, 230 deal responses were received of which 155 deals were a fully-completed survey and were thus used in the analysis. Respondents were invited to submit data on deals executed in the previous three years. There was a natural bias towards more recent deals, with 78% of them included in the analysis completed in 2006 or 2007 (2005–35 deals; 2006–58; 2007–62). The submission of deals by licensors and licensees was split 70:30. Quality control was conducted and the data was examined for matching deal submissions to ensure that single deals were not submitted by both licensor and licensee; none were found.

Data from PharmaDeals® shows that from 2005 to 2007, there were 2,575 life sciences licensing deals completed, of which approximately 2/3 included a U.S. or Canadian company. As this survey was targeted to U.S. & Canadian companies, the deals submitted to the survey are a narrow but significant snapshot based on approximately 9% of the deals executed over this period.

As mentioned above, 86 organisations submitted deals, meaning that several organisations submitted multiple deals. There was a higher proportion of

Figure 1. Type of Organisation by Respondents

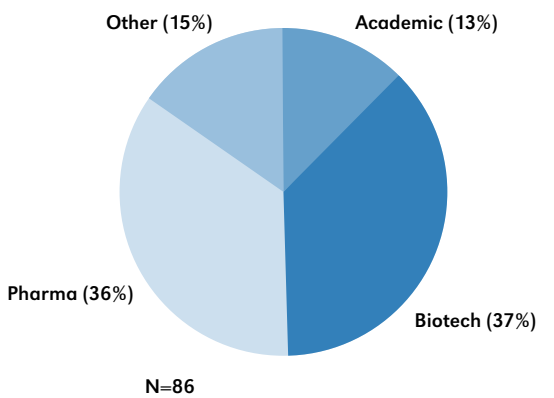
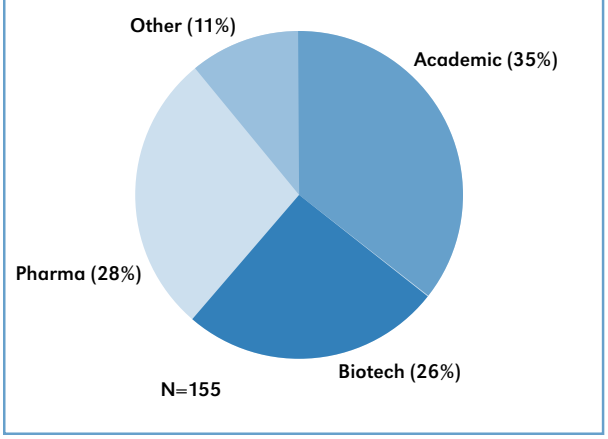


Figure 2. Type of Organisation by Deals Submitted



pharma and biotech respondents (36% and 37% respectively), while academic institutions represented 13% of respondents (Figure 1). The remaining respondents opted to identify themselves as "Other" partnering organizations that included bio/pharma holding companies, law firms, medical devices, and nutraceuticals. Although representing only 13% of respondents, the academic institutes were responsible for submitting 35% of the deals meaning that multiple deal submissions were more frequent amongst this group (Figure 2). Deals submitted by pharma companies represented 28%, biotech companies 26% and "other" 11%. This over weighting of academic deals provides a valuable insight not readily available. It provides a bias toward early stage deals that should be taken in to account when looking at the following analyses.

Nearly half (47.7%) of the deals were for small molecule drugs and about a quarter (24.4%) were for biological therapeutics (data not shown). The remainder were for platform technologies (11.9%), natural products (4%) and "other" (11.9%). For the purposes of this analysis, platform technology deals and natural products were not included in the analysis of therapeutics. The ratio of small molecule drug deals to biological deals in this data-set appeared to be particularly high. This is not reflected in the PharmaDeals data representing the whole industry, where the ratio is closer to 50:50. The reason for a bias towards small molecule deals in this data-set is unclear. The top three therapeutic areas reported in the survey were oncology, CNS and cardiovascular, which corresponds with the therapeutic distribution of deals found in PharmaDeals.

Further details of the analysed profiled deals include a strong majority of the deals (88%) being for exclusive rights; only 10% of deals included co-promotion or co-marketing rights, with a further 7% of deals including commercialisation options. In terms of the territorial profile of the deals 70% of all the deals were for worldwide rights with 90% including at least the U.S. rights.

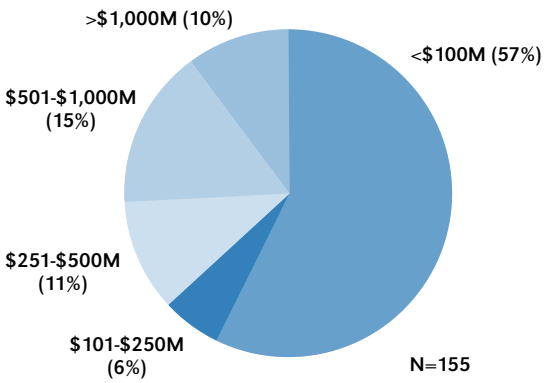
The analysis of the predicted peak U.S. sales for the products shed an interesting light on the profile of the data submitted. Over half the reported deals were for products with predicted peak U.S. sales of less than U.S. $100 M (Figure 3). Although deals for products ranging up to potential "blockbuster"[4] status were submitted to the survey, this analysis does suggest that the data would be biased towards lower value product deals.

An objective of the survey was to capture information on recent deals and provide deal information not available through Freedom of Information (FOI) approaches, especially for small and private pharmaceutical and biotech companies. However, additional analyses were conducted on deals considered relevant to "big pharma" companies.

For example, additional analysis was conducted for deals, considered relevant to "big pharma" that met the following criteria:

- Only deals with biotech or pharmaceutical companies as out-licensors

Figure 3. Estimated U.S. Peak Sales of Deal Product



4. Generally considered to be drugs with annual sales of over U. S. $1 Billion.

- Assets estimated to have greater than $250 million in peak sales potential
- Exclusive deals that included at least the U.S. territory rights
- No platform deals

This "big pharma" criteria produced a subset of 32 deals. It was recognized that this is a small sample, but it did allow for some limited observation on how terms for these deals differed from the overall survey sample.

While only 12% of the fixed royalty deals met the "big pharma" criteria, over 40% of the tiered royalty deals met the criteria (Figure 4).

In the following analysis, deals were separated into those that had fixed royalties (83 deals) and those that had tiered royalties (54 deals). Eighteen (18) deals which did not include a royalty component were not included in the analysis. Also, whereas respondents were asked to be specific about the stage of clinical development for the products at the time of the deal, to avoid analysis of low deal numbers, submitted deals were grouped according to key points in development. The groupings used were: Group 1–Preclinical; Group 2–IND filed through Phase II enrolled (pre-proof of concept (POC)); Group 3–Phase II completed through Phase III enrolled (post-POC); Group 4–Phase III completed through NDA submitted; Group 5–Marketed. An advantage of this approach was to analyze the data based on differences in clinical information available that might contribute to value created. For example, Group 3 deals comprised of Phase II completed and Phase III enrolled have the same set of clinical data to consider for "value" and "risk" assessments.

Fixed Royalty Deals

The clear majority of reported deals with fixed royalties were for preclinical products (49 deals), with comparatively few deals in the other groups (Figure 5). Due to the low sample number, only the preclinical, pre-POC and launched deals were analysed. There was negligible difference between the averages for the two early groups, with the average fixed royalties for preclinical products at 4.3% and for pre-POC products at 4.6% (Figure 6). The medians for these groups better illustrated the expected difference with 3.5% for preclinical and 5% for pre-POC. It was surprising to compare the range between the two groups with royalties ranging between 0.3 and 25% for the preclinical group and 2 to 8% for the pre-POC group. This disparity most likely represents the low 'n' number for group 2 (9) versus group 1 (49). For

Figure 4. Deal Types, Including "Big Pharma" Criteria

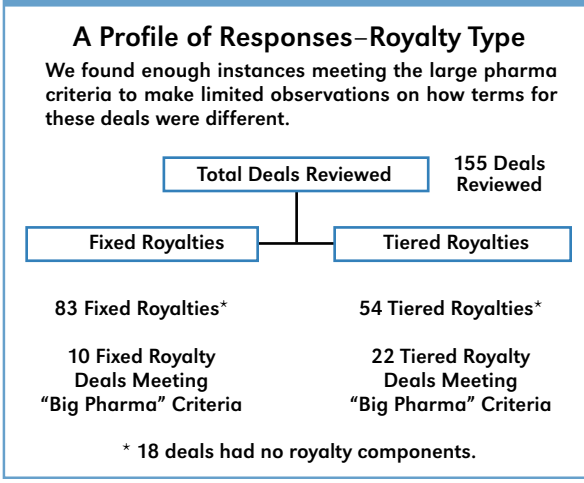


Figure 5. Fixed Royalty Deals by Stage of Development

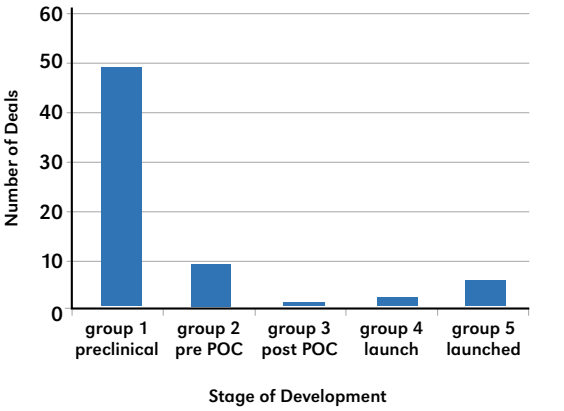
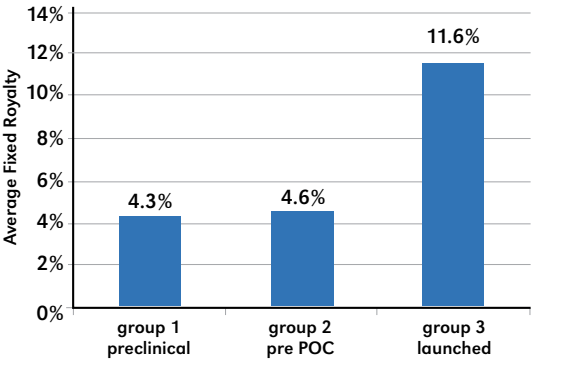


Figure 6. Average Fixed Royalties by Stage of Development



the 6 launched products the average fixed royalty was 11.6% with a median of 7.5%. The maximum royalty found in this range was surprisingly low at 27.5%—data from PharmaDeals suggests that deals for launched products can command royalties of up to 40%.

Figure 7. Preclinical Fixed Royalties by Product Type

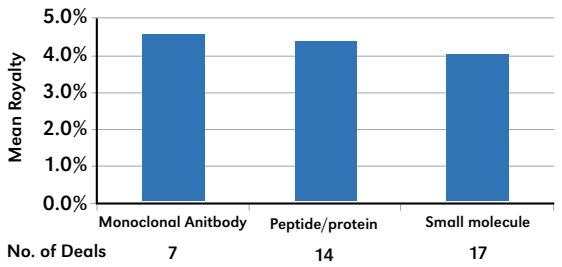


Figure 8. Deals With Stacked Royalties by Product Type

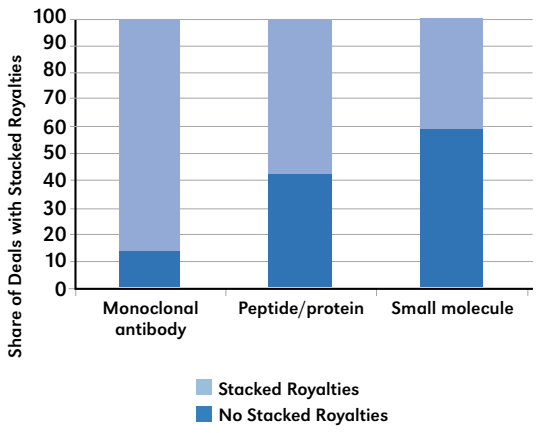
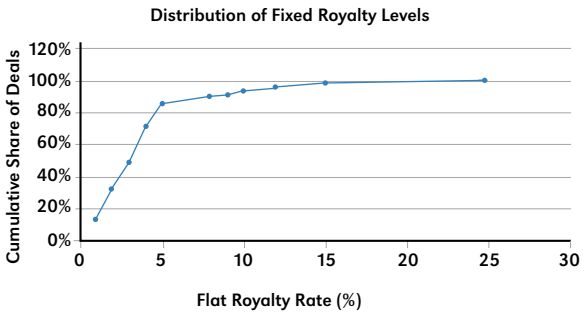


Figure 9. Distribution of Fixed Royalty Rates



Looking at preclinical deals alone, deals for biologicals were found to attract slightly higher royalties than deals for small molecules (Figure 7). Unsurprisingly, given the fundamental IP involved in developing biologicals, nearly all preclinical fixed royalty deals for monoclonal antibodies involved stacked royalties compared to only 40% of small molecule deals (Figure 8). Overall, a plot of the distribution of fixed royalty preclinical deals shows that 86% of deals had a royalty rate of <5% and 49% had a fixed royalty of <3% (Figure 9).

For the fixed royalty deals that met the "big pharma" criteria, the majority (5 of 10) were concentrated in the preclinical phase. Compared to the sample of fixed rate preclinical deals, the "big pharma" criteria deals had modestly higher financial terms with a mean fixed royalty rate of 5.2% vs 4.3% for the total sample and a median royalty rate of 4.0% vs 3.5% (Figure 10).

Upfront payments for the preclinical and pre-POC fixed royalty deals averaged below U.S. $1 M, with pre-POC deals returning slightly higher payments than preclinical deals (Figure 11). While 65% of preclinical fixed royalty deals included development milestones, the average potential payment was U.S. $2.2M. In comparison, only 15% of these deals included sales milestones, although the average for these was slightly higher at U.S. $3.2 M (Figure 12).

Figure 10. Average Fixed Royalties by Stage of Development

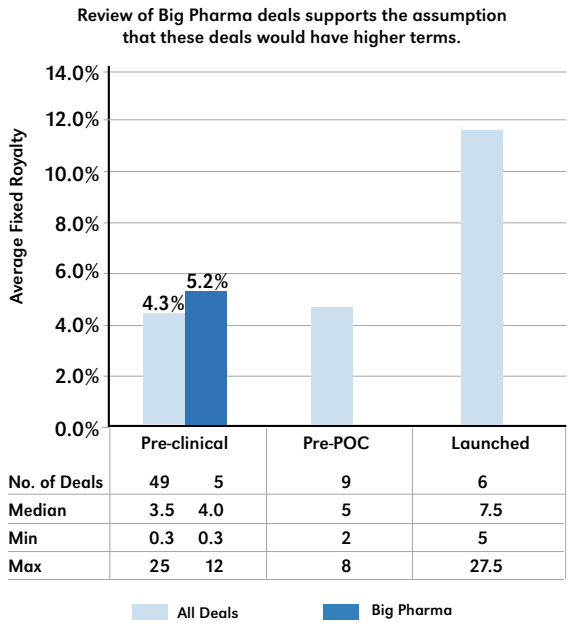


Figure 11. Upfront Payments in Fixed Royalty Rate Deals

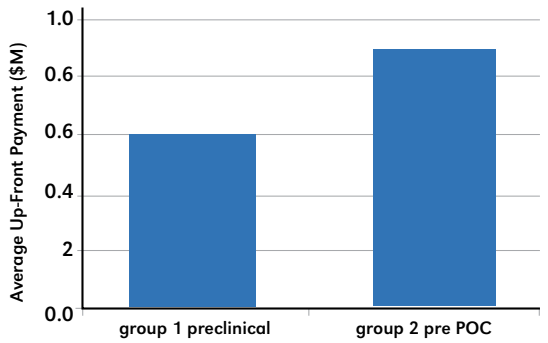


Figure 12. Proportion of Fixed Royalty Deals Including Milestone Payments

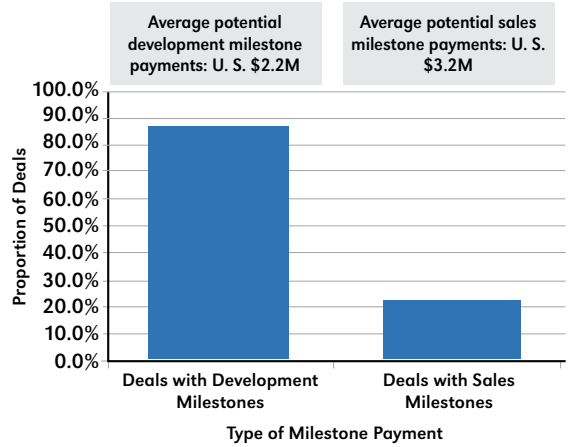
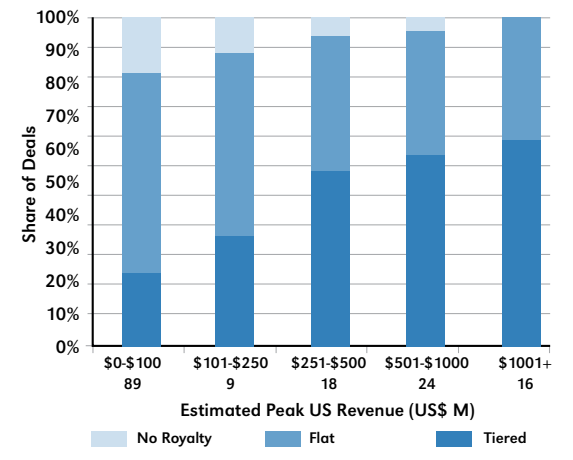


Figure 13. Proportion of Deals with Fixed or Tiered Royalties Against Estimated Peak Sales



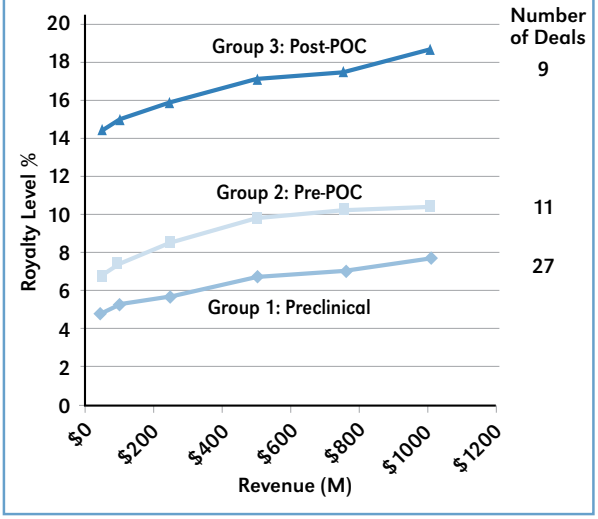
The low average value of the upfront and milestone payments in these deals might reflect the bias of the deal towards low sales-potential products. In comparison, average upfront payments (whether fixed or tiered royalties) for preclinical licensing deals, during that same period, in PharmaDeals were U.S. $11.7 M, while average milestone payments (development and sales) were U.S. $157.7 M.

Tiered Royalties Deals

While the fixed royalty deals showed a bias towards low-potential value products, there was a clear trend that the use of tiered royalties increased as the predicted peaks sales of the products increased (Figure 13). This finding supports the use of tiered royalties as a compromise during negotiations for larger value deals where there is greater potential for disparity between the sales predicted by the licensor and the licensee. In total, 55 tiered royalty deals were included in this analysis.

As different thresholds were used for comparing royalty rates in different deals, the royalty rates at six standardised revenue levels were used to compare royalties. The standardised revenue levels were set at U.S. $50 M, U.S. $100 M, U.S. $250 M, U.S .$500 M, U.S. $750 M and U.S. $1 B. In this analysis there were enough deals to analyse the preclinical, pre-POC and post-POC groups. The findings were consistent with expectations, with the average royalty rate in preclinical deals rising from 5 to 8% through the tiers (Figure 14). For pre-POC deals the royalties grew from 7 to 10%. There was then a significant increase in royalties

Figure 14. Tiered Royalties Against Estimated Peak Sales



for products post-POC, with the royalties increasing from 14 to 18%.

Notably, the range of royalties for preclinical and pre-POC deals involving tiered royalties was higher than averages in the equivalent fixed royalty deals (Figure 15). This suggests that as deals which involve tiered royalties are likely to be for higher value products, they are likely to command a greater share of the revenues for the licensor upon commercialisation.

For tiered royalty deals that met the "big pharma" criteria, the distribution was similar to fixed royalty deals with the majority (13 of 22) concentrated in preclinical deals. As was observed in fixed rate deals, the "big pharma" preclinical deals had higher average royalty rates in tiered royalty deals ranging 1.5% to 2.0% higher than the overall sample (Figure 16).

While tiered royalties can make a deal more acceptable to both sides during deal negotiations, they do also add a layer of administrative complexity for the ongoing execution, analysis, reporting and royalty payment. The most frequent number of tiers in such deal structures was three (Figure 17). It was interesting to note that a number of preclinical deals had four or five tiers. Given the difficulty with which the future success of a product can be predicted at the preclinical stage, many would consider this to be an unnecessary level of complexity. Nevertheless, even with such early-stage products, there can be a large gap in the sales expectations between the licensor and the licensee and multiple tiers may be the only way to resolve such differences.

Average total potential milestone payments in the tiered royalty deals reported in the survey were significantly higher than those of fixed royalty deals. However, for development milestones there was no trend for deals at different stages of development with pre-POC deals having an average of U.S. $48 M and post-POC deals having an average of U.S. $55 M (Figure 18). Sales milestones did show a clear trend through development stages, with potential sales milestones increasing from U.S. $29 M for preclinical deals, to over U.S. $100 M for post-POC deals (Figure 19).

Regarding the milestones for tiered royalty "big pharma" deals, the total development milestones were lower than the universe for early stage/

Figure 15. Comparison of Fixed Royalties vs Tiered Royalties

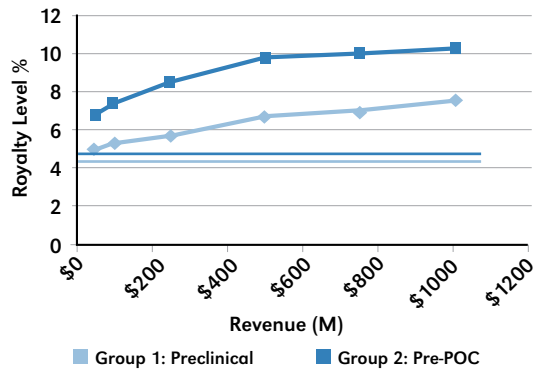


Figure 16. Tiered Royalties by Stage of Development

As we saw in fixed rate deals, the big pharma preclinical deals had higher average royalty rates in tiered royalty deals.

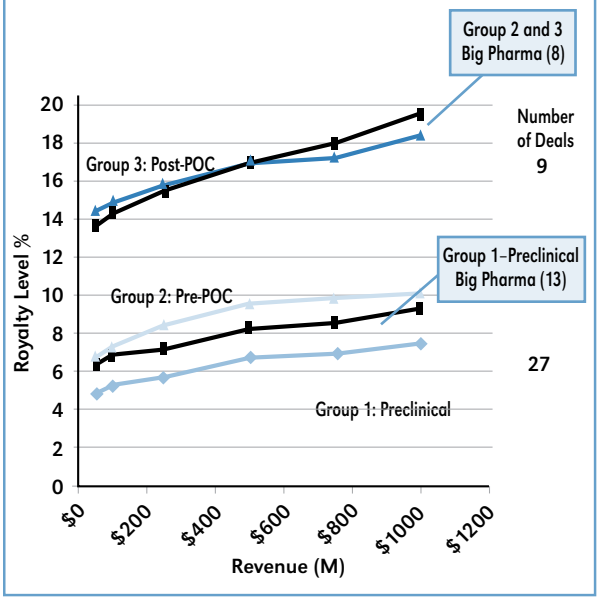


Figure 17. Tier Frequency in Tiered Royalty Deals

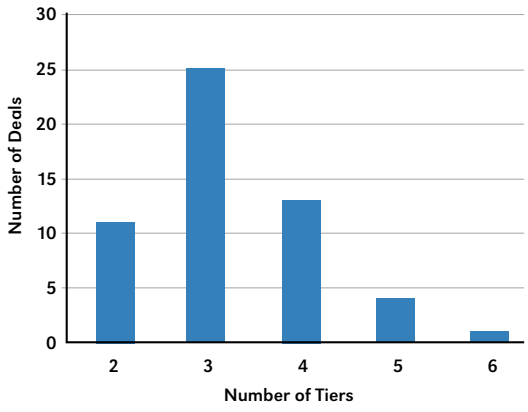


Figure 18. Development Milestones by Stage of Development in Tiered Royalty Deals

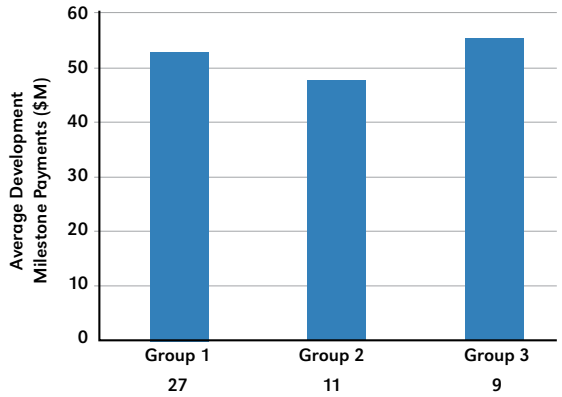
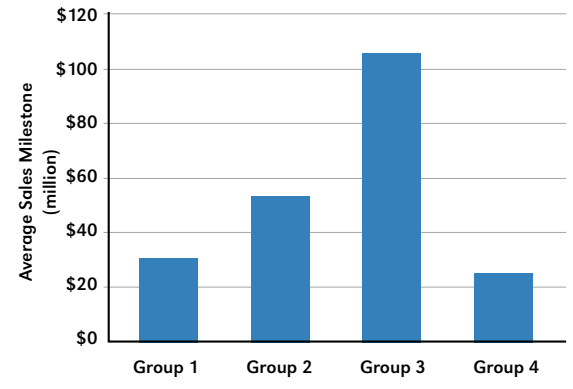


Figure 19. Sales Milestones by Stage of Development in Tiered Royalty Deals



preclinical deals but higher for the post "proof of concept" stage. The sale milestones for the tiered royalty "big pharma" deals were higher at all stages (Figure 20).

In comparison to the fixed royalty deals, the average upfront payments for tiered royalty deals were more in line with expectations and showed a more significant increase as clinical stage progressed. Average upfront payments for preclinical products in tiered royalty deals were just under U.S. $5 M in comparison to U.S. $0.6 M for fixed royalty deals (Figure 21). Pre-POC tiered royalty deals had an average upfront payment of over U.S. $8.5 M in comparison to U.S. $0.9 M for the fixed royalty deals. However, these values were still below the average upfront payments from the PharmaDeals data.

Discussion and Observations

In negotiating the value distribution in a deal, it is common to perceive that the deal may be "front" or "back-weighted." This means that a licensor may sacrifice eventual royalties in return for a higher upfront payment when the need for capital is more immediate, and vice versa when immediate cash requirements are not so urgent. This perception was not supported by the data from the survey, with an analysis of upfront payments vs royalties for preclinical deals showing a general trend for larger upfront payments in the highest royalty deals (Figure 22). One possible reason for this is that in preclinical deals, the high developmental risk associated with the product reaching commercialization means that royalties, which will be very far-off, contribute a relatively small proportion of the value in the deal and might therefore be less sensitive in negotiations. This trend suggests that at the preclinical stage, a strong negotiator can potentially extract both near- and long-term value from a deal and should not necessarily be thinking about whether they want to weight the deal towards either the upfront payment or royalties. Once products move through the clinic and the product is de-risked, it is likely that the balance between upfront and royalties (front/back weighted) would be restored.

In comparison to a typical analysis of deal terms based on

Figure 20. Tiered Royalties Summary

This set of deals indicated increasing financial returns associated with later points in development.

	Group 1– Preclinical	Group 1– Large Pharma	Group 2– Pre-POC	Group 3– Post-POC	Group 3– Large Pharma
Sample Size	27	13	11	9	6
Average Royalty Rate	~5% growing to ~8%	~6.5% growing to ~10%	~7% growing to ~10%	~14% growing to ~18%	~14% growing to ~18%
Up-Front Payment	$4M	$4M	$9M	$19M	$28M
Development Milestones	$53M	$44M	$48M	$55M	$86M
Sales Milestones	$29M	$34M	$53M	$105M	$153M

Figure 21. Upfront Payments by Stage of Development in Tiered Royalty Deals

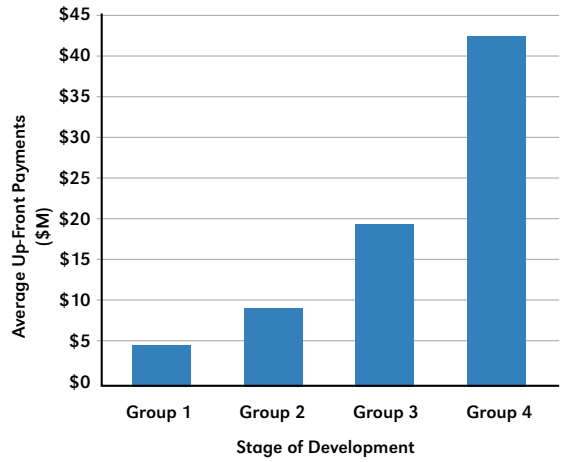
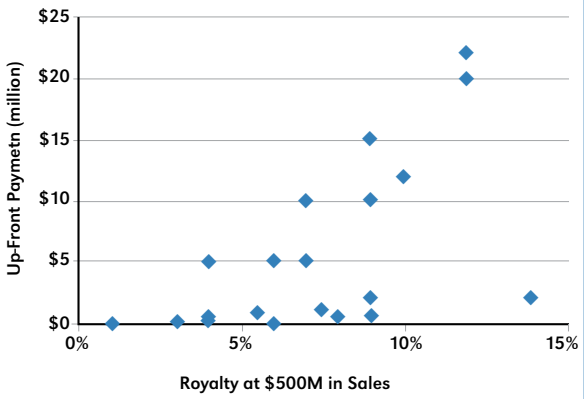


Figure 22. Upfont Payments Versus Royalties in Preclinical Tiered Royalty Deals



data from available commercial databases such as PharmaDeals, the value of the deals analysed in this survey may appear low. However, it is worth remembering that the deal databases that are traditionally used in licensing analyses, are populated with deal information that has been made publicly available or from large "material" deals by public U.S. companies that are required to submit the deals to the Security and Exchange Commission. These deals will tend to have a bias towards the more "eye-catching" deals with large headline values while "less sensational" licensing deals are not publicised to the same degree. For this reason, analysis of deal trends from such commercial database sources may give a disproportionately higher financial valued view of dealmaking than is actually present in the health care industry. As was discussed earlier, the data submitted to this survey had a bias towards deals submitted by universities (35%), biotechs (26%), early stage deals and products with low predicted peak sales potential, which would be expected to attract lower deal values. The deals that met the "big pharma" criteria had higher financial terms and were more aligned with industry expectations based on insights from the available databases

Therefore, while these factors mean that caution needs to be taken when interpreting the analysis of such data, especially with low sample size, the deals represented in this survey provide guidance and possible trends to current and future deal terms that can be achieved in the above context.

In summary, this report illustrated detailed analysis on fixed royalties, tiered royalties, valuation and therapeutic areas in biopharmaceutical deals. It reveals a more current perspective on biopharmaceutical licensing royalty rates and deal terms than the Freedom of Information (FOI) approach allows.

Future Plans

The Licensing Executives Society (U.S.A. & Canada), Inc. plans to conduct the BioPharmaceutical Royalty Rate and Deal Terms Survey on a regular basis. It is planned that the next survey will be conducted in conjunction with other LES International societies and will survey companies worldwide. This will provide LES members a truly global insight into contemporary deal terms information. This 2007/2008 LES (USA & Canada) survey will act as a pilot upon which the global survey can be built. It is hoped that on the back of this survey, and the value-added information gleaned that is not available from other sources, participation in the next survey will be greater, thus increasing the significance of this analysis to all LES members. The roll out of future survey results will continue to provide LES members, on an ongoing basis, valuable insights into contemporary deals that are not readily available, as well as, timely indications of future trends in the ever-changing deal environment. ■

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