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Making or breaking a deal

To the editor:

In their recent article "Deals that make sense," Moscho et al.[1] propose a model for valuing the respective contributions of licensor and licensee for biotechnology product deals. They seem to move from their model based on industry average valuations (which are themselves problematic) to the specifics of the Biochem Pharma–Glaxo example as if they are interchangeable. Are the averages, in fact, appropriate for the cited Biochem Pharma–Glaxo example? An important question, as "applying pharmaceutical average numbers" and their "formula for determining the value of financial investments" leads directly to their assertion that Biochem Pharma "would have more than doubled its royalty rate" had Biochem Pharma used the proposed model. The problems with their "industry average" assumptions do not stop there:

For marketing and sales contributions, an "average"of 25% of sales for marketing and sales costs is perhaps reasonable for a product at 3 to 10 or more years post-launch. While they acknowledged that the "marketing and sales costs can vary a lot throughout the different life cycle stages," the use of the 25% average for a major new product probably understates the high cost of a successful product launch (of long-term importance to both licensor and licensee). Depending upon the product, the market segment or segments to be addressed (which largely determine the size of the required sales force and marketing expenses), and the level of competition, the actual required marketing and sales investment may be much greater. Perhaps the use of 25% for the licensee's know-how contribution (cited as the "reported industry maximum") added to the 25% for costs is meant as an offset. However, for a new biotechnology product with significant potential, the licensor would want to "buy" the best know-how they can get, so 25% is probably the right number rather than the maximum.

For the manufacturing contribution, a provision of 10% of sales for manufacturing costs *and* know-how, in most cases, substantially understates the value of manufacturing. Let us suppose, for the sake of argument, that the fully loaded cost of manufacturing a particular product *is* 10% of sales. This would not be an unusual cost-of-goods for a "high-tech" product. However, a provision of 10% for manufacturing completely ignores the value of an established and approved GMP facility, support infrastructure, and the licensee's manufacturing know-how, all of which would cost the licensor dearly in time and money.

For the R&D contribution, as Moscho et al. state, the roles and contributions of the licensor and licensee vary considerably. In the biotechnology arena, however, the "R" is usually contributed by the licensor or continues as a collaborative effort by the licensor and licensee, and, while the "D" is occasionally a collaborative effort by the licensor and licensee, most often it is contributed by the licensee. The "D" includes scaleup of manufacturing, equipment, and process validation, the development of the required quality assurance/quality control parameters and tests for product characterization and lot release, coordination with clinical testing, and, very importantly, the required regulatory interface all along the way. All of these activities are possible due to the licensee's extensive infrastructure, which again would cost the licensor a great deal in time and money. Moscho et al., however, assign no value to this licensor contribution, as "in nearly all cases, this percentage (the 26.7% of sales example) would go to the biotechnology company, which normally has developed the compound at least up to clinical phase I." This ignores the fact that usually a great deal of additional product development is required (as described above) between the start of phase I clinical trials and the submission of a BLA or PLA, most of which is carried out by the licensee.

Net-net, given that these factors have been ignored or undervalued in the cited Biochem Pharma–Glaxo example, it would seem that Biochem Pharma's 13% royalty rate is quite appropriate and perhaps even a bit rich, especially when combined with the millions of dollars in fees and milestones also received. Had Biochem Pharma used the model (as presented) in negotiating a deal with Glaxo and in the process insisted upon a 26.7% royalty, I suspect there may have been no deal at all.

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1. Moscho, A., Hodits, R.A., Janus, F. & Leiter, J.M.E. *Nat. Biotechnol.* **18,** 719–722 (2000).

Alexander Moscho, Regina A. Hodits, Friedemann Janus, and Josef M.E. Leiter reply: We thank Douglas Reynolds for his detailed comments on our article. Our intentions were to provide a rational and easily applicable framework to determine appropriate deal terms reflecting each partner's contribution to the overall value of the product. To test and demonstrate the framework, we applied industry average figures to a specific case and determined the appropriate royalty rate from the results. There can be no doubt that, for a specific deal, all figures have to be adjusted to the characteristics of that unique situation, and that these are subject to negotiations between the licensing partners. We are convinced that it is beneficial for both licensing partners to negotiate deal terms on a rational basis rather than by following rules of thumb. Our view of the individual items to be negotiated is as follows:

For marketing and sales, we agree with Douglas Reynolds that during the launch phase, while sales are low, the marketing budget may even be a multiple of the annual sales. But the figure typically decreases sharply with increasing sales. In our view, the industry average of 25% is therefore appropriate, as it takes the whole patent life of a product into account.

We also agree that the establishment of biopharmaceutical manufacturing facilities and the required certification procedures are usually very time-consuming and costly. However, for blockbusters (e.g., in our article), these expenses clearly play a minor role. Also, the value contribution of manufacturing equals the cost of outsourcing to a third party, and not the cost of building facilities from scratch.

For the R&D contributions, the specific effort, time lines, and expenses need to be weighted on a case-by-case basis. As we noted in our article: "In these cases, the residual value. . .should be appropriately divided between the two partners, depending on how much each contributes to R&D."

In addition, we do want to state that the percentage of sales potential attributed to the biotech company in our example is the total value to be received by the biotech company. Thus, it is the sum of the present values of upfront and milestone payments, as well as royalties on sales. How a company chooses to divide the total value between these components will strongly depend on its individual situation.

Finally, we think it is worth noting that the total amount of payments for Biochem Pharma added up to a little more than US $20 million, which is only a small fraction of the US $824 million in 3TC sales in 1998 alone. Both biotech and pharma companies engaged in either outlicensing or partnering might see this ratio as a reason to think twice about the framework on which their deal terms are based. ///