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# Six Important Strategies To Reduce The Royalty Burden For A Pharmaceutical Product

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A biotech or pharmaceutical company will often need to in-license certain inventions in order to develop and commercialize its products. The company will most likely be required to pay to its licensor a royalty based on sales of its products (licensed products) that exploit the licensed inventions. Although determination of the amount of royalty owed is in large part a business decision and takes into consideration, among other things, the scope and strength of the licensed patent and other intellectual property rights, the breadth of the licensed field of use and territory, whether the licensed product is a therapeutic product (typically a higher royalty rate) or diagnostic product, and whether the license grant is exclusive or non-exclusive, there are many important legal nuances that the licensee could and should consider. Through careful and creative drafting and negotiating with experienced legal counsel, the company can significantly reduce its royalty burden.

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### Less Is More – Reduce "Net Sales" As Much As Possible

The amount of royalty owed is typically calculated by multiplying the royalty rate by the amount of sales of the licensed products. The royalty rate does not need to be a flat rate and could be graduated, for example, with a rate change as sales increase. In determining the "sales" portion of the royalty calculation, the determination of sales should be based on amounts actually received (as opposed to amounts invoiced) by the licensee, thus avoiding the unfortunate situation of being required to pay a royalty on uncollectible amounts. Net sales (as opposed to gross sales) is the typical base, and the licensee should include as many deductions as possible in determining net sales. In addition to typical deductions such as governmental taxes and charges, customer credits and rebates, and transportation, storage and insurance expenses, the licensee should consider less typical deductions such as sales commissions owed by the licensee and, if applicable, the cost of devices used for dispensing or administering the product which are shipped with the product and are included in the invoice price. In the event that the licensed product is a bundled "combination" product that includes both components covered by the licensed rights and other components (*e.g.*, another active ingredient), then the amount of net sales for purposes of determining the royalty amount should be appropriately reduced, and the parties could agree in advance upon one or more of the various methodologies for determining such reduction.

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### Exclude Sales By Sublicensees From The Royalty Calculation

Very important and careful consideration should also be given to whether or not to include sales by sublicensees in the calculation of net sales, as this could have a large impact on the amount owed by the licensee to the licensor. If sales by sublicensees are included in determining net sales (a "pass-thru" royalty), then the royalty paid to the licensee by the sublicensee needs to be (significantly) higher than the royalty owed by the licensee to the licensor in order to provide the

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licensee with a sufficient profit spread. This is sometimes not economically feasible, as the product then becomes too expensive for a sublicensee to develop and commercialize. As an alternative, the license agreement could (and often does) provide that, in lieu of a pass-thru royalty, the licensee must pay the licensor a specified percentage (typically 15-25 percent or so) of royalties and other consideration received by the licensee from the sublicensee, which amount is often less than the pass-thru royalty.

**Limit Royalties Owed With Respect To Patent Applications**

The parties should consider which products would in fact constitute "licensed products" and thus trigger a royalty when sold. Often, licensed patent rights include patent applications (*i.e*., as opposed to issued patents). In the United States, in order for an owner of a patent to successfully bring a patent infringement action against a third party, the patent right must constitute an issued patent. Thus, as a technical matter, a third party could commercialize a product encompassing the subject matter of a patent application without entering into a licensing arrangement and paying a royalty to the owner of the application. However, if and when the patent is ultimately issued, a license agreement with the owner would be necessary. Thus, it is often prudent for the licensee to enter into a license agreement (and agree to pay a royalty) even with respect to patent applications, thus eliminating the risk of having to cease commercialization of the product once the patent is issued. However, the license agreement could provide that if the patent is not issued after some agreed upon time frame (for example, 6 or 7 years), then no royalty would thereafter be owed unless and until the patent is issued. Also, the parties could agree to a reduced royalty until the patent is actually issued or if the licensor does not take reasonable consistent activity to advance such issuance.

**Apply "Stacking" And Other Reductions**

Often, in order to successfully develop and commercialize a pharmaceutical product, the biotech or pharmaceutical company will in-license the use of inventions from multiple licensors. Sometimes the aggregate royalty burden could be so high, however, that profitable commercialization of the product would be impossible. A royalty "stacking" clause allows the licensee to offset royalties paid by the licensee to one licensor (typically pursuant to an ancillary license agreement) against the royalties owed under the "primary" license agreement, thus reducing the aggregate burden. The amount of the offset differs based upon whether the inventions licensed pursuant to the ancillary license agreements are legally required in order to develop and commercialize the product (for example, with respect to dominating patent rights) or would result in improvements to the product but are not absolutely required in order to develop and commercialize the product. The application of the offset is sometimes delayed until the stacked royalty burden achieves a threshold and the amount of the offset is sometimes reduced to equal only a portion of the royalty paid pursuant to the ancillary license agreements, in each case especially if the ancillary licenses are not legally required in order to develop and commercialize the product. The stacking offset, like most other royalty reductions, is usually subject to a royalty "floor" below which the royalty may not fall.

Other royalty reductions should also be considered. For instance, the license agreement could provide for a reduced royalty in the event that there is unlicensed infringing competition of the licensed product in one or more countries. In this case, the competition often must reach a certain minimum level before a reduction is applied and the amount of the reduction might be limited. Also, the license agreement could provide that no royalty would be owed with respect to sales in a particular country if there is no patent protection in such country.

**Credit Other License Payments Against Royalties Owed**

Even after the application of various reductions, the amount of the royalty payments could be decreased even further. The license agreement might provide for certain credits to be applied against the royalties otherwise owed by the licensee. For example, all or a portion of upfront or milestone payments might be creditable against royalties. Also, if the licensee incurs expenses in connection with infringement cases made by or against third parties, all or a portion of such expenses might be creditable.

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**If Applicable, Obtain "Most Favored Licensee" Protection**

In the event of a non-exclusive license, a "most favored licensee" provision could and should be considered. Such a provision provides that, notwithstanding the terms described in the license agreement, in the event that the licensor grants a license for the same inventions to a third party on more favorable terms, the financial terms (and perhaps non-financial material terms) of the license agreement would be reduced and/or otherwise adjusted to conform to the more favorable terms.

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Each of the strategies described above can be used individually or can be combined with these and/or other royalty reduction strategies. Although the interrelation of various provisions could be complex, by understanding the unique issues and concerns that arise when analyzing and negotiating royalty provisions, the licensee is better able to increase its bottom line and, ultimately, increase shareholder value.