Creative Royalty Structures for Life Science Companies

Depending on the segment of the life science industry (e.g., pharma, medical device, diagnostic) and the stage of development (discovery, preclinical, Phase 1, Phase 2, etc.), there are generally accepted ranges for royalty rates in license or partnering agreements. Typically, the royalty is a percentage of net sales (gross sales less certain expenses such as shipping, taxes, packaging, rebate costs, etc.). However, rarely is the royalty as simple as a single percentage on all net sales. The royalty provisions of any major license or partnering transaction will include some or all of the structures described below[1]. By using many of these creative royalty structures, licensors and licensees can bridge negotiation divides and improve their respective deals terms.

Tiered Royalties

A flat royalty rate on all net sales may not make sense where there is uncertainty as to the commercial value of the licensed product or technology or where there is disagreement between the licensor and licensee as to its value. Given that licensed products or technologies are usually several years from commercialization there will be substantial uncertainty regarding the ultimate commercial value. Since a billion dollar a year drug has more value and deserves a higher royalty than a two hundred million a year drug, a tiered royalty that increases with net sales can enable the parties to reduce risk and bridge a valuation spread, aligning the royalty with success of the licensed product. Typically, the tiered royalty rate will operate so that the increased royalty rates will apply to net sales above a specified threshold (e.g., net sales up to $250 million at 8%, net sales between $250 million and $500 million at 10% and net sales above $500 million at 12%). As discussed below, a tiered royalty will have an impact on other royalty structure variations.

Combination Products

When the licensed technology may be sold as one component of a product, the license or partnering agreement usually will provide that royalties are payable only on the percentage of net sales of the product that are attributable to the licensed technology. If the components of the product are also sold on a stand-alone basis, this calculation is simple (i.e., the stand-alone price of the product based on the licensed technology divided by the aggregate stand-alone prices of all the components). If the components are not or cannot be sold individually, the method of calculation is open for negotiation (e.g., the relative cost of manufacture of the components, the increase in net sales of the new combined product, etc.). If the product with which the licensed technology is combined is not patented, the licensor may seek to have the royalty percentage paid on the combined product (i.e., no reduction in the net sales subject to the royalty). In some cases where the licensed technology is likely only to be commercialized as a component of a product, it may make sense to fix the value through the royalty rate on net sales of the combined product and not to attempt to calculate the relative values of the components.

Sublicensing

Frequently a licensee will sublicense the licensed technology to a larger pharmaceutical or biotech company as part of a partnership or collaboration. In such cases where the original licensee will not be commercializing the licensed technology, a royalty on the licensee's net sales will result in no payments to licensor. Therefore, provisions dealing with payments due to the licensor in such context are

[1] There are a number of royalty issues that are not discussed in this article such as how to calculate net sales, whether to apply any offsets to royalties due, how to determine royalties where payments include non-cash consideration and the effect of foreign currency fluctuations on royalty payments, among others.

necessary. Typically, such provisions will either grant the licensor a royalty on the net sales of the sublicensee or grant the licensor a fixed rate of the payments received by the licensee from the sublicensee. In either case, the rate received by the licensor may vary based on the size of the royalty or other payments received by the licensee from the sublicensee (e.g., the rate increases if the sublicensee royalty obligation is over 12%). This enables the parties to taken into account that a partnering deal done at a later stage will result in larger payments to the licensee from the sublicensee than an early stage deal.

Multiple Sublicenses

Often a company developing a product will license it to different parties in different territories (e.g., U.S. rights, European rights, Asia rights, etc.). Therefore, a license with tiered royalties should take into account that the licensee may sublicense products to multiple parties under different terms. The license agreement should provide a mechanism to adjust the net sales amounts at which the royalty rate adjusts based on the percentages of net sales that are and are not subject to a sublicensing arrangement compared to the total net sales.

<u>Know-How Royalty/Patent Misuse</u>

Royalty payments are often tied explicitly to patent protection, in which case the term during which royalty payments are due is limited to the term where patent protection still exists in a particular jurisdiction. However, from the licensor's perspective there may be reasons it feels justify the payment of royalties beyond the patent term, such as the fact that the licensee may benefit from the market share built up during the patent term even after patent expiration. However, under the doctrine of patent misuse it may be deemed an anti-trust violation for a royalty to be payable beyond the term of the applicable patent and limit the licensor's ability to collect royalties from the licensee. Where significant know-how has been transferred from the licensor to the licensee, the licensor can argue that the royalty term should extend beyond the patent's expiration because the know-how can still provide the licensee an edge against generic competitors. When a license does provide for royalty payments beyond the term of the licensed patents, typically the royalties are structured to be payable for the longer of a period of time following first commercial sale of the licensed product (e.g., 15 years) or the expiration of the patent coverage. Following the patent expiration or in some cases generic competition entering the market, there will be a step-down (reduction) in the royalty rate and the post-expiration royalties will be in consideration for the know-how license.

In the event it contains both a know-how or step-down royalty and tiered royalties, the license or partnering agreement should provide a mechanism similar to that described in the Multiple Sublicenses section above to adjust the net sales amounts at which the royalty rate adjusts based on the percentage of net sales that are in jurisdictions with patent protection and the percentage of net sales that are in jurisdictions that are only subject to the know-how royalty compared to total net sales.

<u>Anti-Stacking</u>

It is not unusual for a licensee in the course of developing a licensed product to license additional intellectual property from a third party, either because it is required to commercialize the product or it will improve the product. Therefore, licensees will typically request anti-stacking provisions, which reduce the royalty percentage payable to the licensor by percentage of the royalty being paid to the third-party licensor. Typically, the licensor will seek a maximum percentage (e.g., 50%) that the royalty rate may be reduced regardless of the total third-party royalty obligations of the licensee. A licensor may also want to distinguish between a license from a third party with a dominant patent position (i.e., a license necessary to effectively use the licensor's technology) and a license from a third party that the licensee desires to make the product better, granting a reduction in the former but not the latter situation.

In the event it contains an anti-stacking provision and tiered royalties, the license or partnering agreement should provide a mechanism similar to that described in the Multiple Sublicenses section above to adjust the net sales amounts at which the royalty rate adjusts based on the percentage of net sales that are in jurisdictions were a third-party royalty is also due and the percentage of net sales that are in jurisdictions that are not subject to any third-party royalty compared to total net sales.

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