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Government alliances with biotechs introduce 'royalty stacking' issues

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By Gary Sutton and Eileen Ewing

Biotechnology companies have been entering into strategic alliances and licensing transactions with one another and with large pharmaceutical partners for years. Lately, another player has been joining the group at the negotiating table with increasing frequency — Uncle Sam.

An aging population, a stagnant economy and public fears regarding bioterrorism have increasingly led the U.S. government, particularly the National Institutes of Health and the Department of Defense, to join forces with the private sector.

While these collaborations may facilitate the discovery and commercialization of beneficial pharmaceutical compounds, technologies and other products, the involvement of these governmental agencies often means that there is "another mouth to feed" when the time comes to commercialize the product and distribute royalties.

Often the development of a pharmaceutical compound or technology already involves a license of intellectual property from one or more universities or teaching hospitals. An additional partner that is looking for a share of the profits can make it more difficult for a biotech company to enlist the aid of a larger pharmaceutical company in bringing the product to market.

This situation is often referred to as "royalty stacking." Patented research tools, such as a composition of matter or a screening process, are much more likely to give rise to royalty stacking issues by their very nature as tools rather than potential end products.

Consider, as an example, a process that enables a biotech company to screen or test certain pharmaceutical compounds. Often, a licensor of such a technology, such as the NIH, would require that it be paid a royalty on sales of the products created using the technology.

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Adding the royalty requirement for the use of the tool to the royalty rate that the biotech company will demand for the license of the compound makes the compound less attractive to a potential large pharmaceutical collaborator.

As a result, there is an increased likelihood that the end product will not be commercialized or will be substantially delayed.

The problem is further compounded if more than one research tool is required in the development process, leading to an even greater royalty burden as yet another collaborator asks for its share.

The issue is made more complex by the presence of a governmental entity. Collaborations with the NIH and related governmental agencies generally take one of several forms. Most commonly, either a biotech company will license a compound or technology directly from the NIH in exchange for a royalty stream or a biotechnology company will enter into a cooperative research and development agreement (CRADA), which sets forth a statement of work, provisions related to ownership of IP, the funding obligations of each party, etc.

In the case of a CRADA, the biotech will have a limited option to license the IP from the NIH on terms to be agreed on by the parties. Whether the technology is licensed to the company through a direct license or as a result of a CRADA, the regulatory and procedural landscape of governmental agency administration further complicates the issue.

While two private sector businesspersons could come to a quick resolution of the matter, a governmental agency has certain rules and guidelines that must be followed.

When such an agency is involved in the collaboration, the parties must determine whether the technology might have royalty stacking issues and if so devise a compromise that will enable the technology to be successfully commercialized.

To that end, several types of royalty schemes may help reduce combined royalties to a more manageable and mutually acceptable level:

Variable royalties. The royalty rate payable to a licensor varies depending on how essential the licensor's technology is to the creation and commercial exploitation of the end product. These provisions are often difficult to negotiate, as it is difficult to quantify the contribution made by any particular piece of technology in a complex process.

Royalty ceilings. The parties agree to a ceiling for combined royalties. If a royalty must be paid to a third entity, the parties will agree to reduce their royalty rates on a pro rata basis so that the combined royalties of all of the parties are equal to or less than the ceiling.

Royalty floors. The parties agree that the licensor's royalty rate may be reduced, but only to a certain agreed on minimum royalty rate.

Shared expense royalties. Royalty payments owed to third parties are deducted from the net sales of the end product. This ensures that each party's royalties are reduced on a pro rata basis.

These are just a few ways to ensure that the combined royalty rates do not overly burden an otherwise promising technology, provided that the parties are committed to negotiating in good faith.

The government can be an excellent source of technology. In attempting to commercialize that technology, planning ahead may make all the difference.

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