Problems with Royalty Rates, Royalty Stacking, and Royalty Packing Issues

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ABSTRACT

Virtually all products now developed using biotechnology, genetic engineering, and chemistry are technologically complex, incorporating many different inputs. While this alone complicates R&D efforts, there is also the added complexity of potentially relevant intellectual property (IP) rights held by third parties, attached to these inputs. For example, R&D for a new vaccine might have used numerous inputs with corresponding third-party proprietary rights attached: research tools, recombinant techniques, DNA sequences, transformation vectors, cell lines, adjuvants, and delivery devices. Hence, when the vaccine is ultimately ready for use, it will likely be subject to royalty obligations to many licensors. This dilemma of multiple royalty obligations is called royalty stacking. This occurs when various licenses combine to impose aggregate royalty obligations of 6%–20% (or greater). Royalty packing, a similar situation where multiple technologies are bundled together (for example, multiple vaccine packages), is sometimes imposed by the licensor or by best practices within an industry or health ministry. The resulting aggregate-royalty problem is the same as with royalty stacking. There are several techniques to manage royalty stacking and packing: royalty ceilings, royalty floors, variable royalties, and royalty alternatives (lump-sum payments and patent pools). Royalty stacking and packing are serious licensing issues that any organization involved in IP management and technology transfer can, and must, proactively and preemptively plan for and manage.

1. INTRODUCTION

Virtually all products developed using biotechnology and chemistry are protected by one or more tools of intellectual property (IP) rights, for example, patents, material transfer agreements, and trade secrets. Royalty rates that licensees must pay on sales or use of these products can vary widely depending on how the products will be used, where they will be used, and the relative bargaining positions of the licensees and licensors at the time of drafting the license agreement for the product. In addition, most biotechnology products are made using one or more patented-research tools, each of which may have *reach through* royalty obligations; obligations to pay for sales of products made using the research tool, even though the patent holder does not have a patent on the product which is produced. This type of requirement should not be confused with patent misuse which may include a violation of antitrust laws.[1] Those royalties may be related to a product identified using a proprietary research tool and requiring the use of several different patented technologies owned by several different entities.

One example of *royalty stacking* would occur under these circumstances: a potential vaccine is identified and tested using one or more proprietary research tools that have all been licensed by different companies; the vaccine is produced using recombinant techniques and employs proprietary DNA sequences; at the same time, the vectors used for insertion and expression are owned by additional companies, while production of

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the vaccine employs a proprietary cell line; the vaccine itself is packaged with one or more proprietary adjuvants and is delivered to patients using a patented delivery method or device. When the vaccine is ultimately ready for use, it may be subject to royalty obligations to several different companies or licensors. The various licenses involved may ultimately impose combined royalty obligations of 6%–20%, or more, of the selling price of the product. Further complicating matters is the need for separate reporting and accounting to each of the licensors. Table 1 provides another example of royalty stacking involving a multiantigen vaccine with a proprietary adjuvant. This situation might require total royalties on the selling price of 8%, with separate reporting requirements to four different entities.

Often, a burden of 8% versus 4%, for example, can make the difference as to whether the vaccine is commercialized at all. Similar problems arise in agriculture where a genetically engineered crop might be made using proprietary varieties, proprietary vectors, proprietary gene sequences, and proprietary research tools, all owned by different companies. In one case, a published *freedom to operate* report[2] indicated that Golden Rice,[3] a line of rice genetically engineered at a university to have significant expression of pro-vitamin A, was covered by 45 patents or patent families and patent applications by more than 20 different owners in the United States. Fortunately, for the 124 million individuals severely afflicted with vitamin A deficiency (VAD) and the 500,000 cases of irreversible blindness, it was possible to obtain royalty-free licenses for use in developing countries, thanks to the strong support this project received from many companies. However, in the commercial realm, potential royalty obligations for a particular product may be too high collectively to allow for development and commercial implementation of the product. The royalty stacking problem can often be compounded in agricultural technologies. For example, a new vaccine for a pig disease will often need to be *packaged* along with vaccines for other pig diseases, if the vaccines must be administered at the same time.

Individuals that are charged with the management of IP in health and agriculture will need to deal with issues involving royalties and royalty stacking on almost every product or technology they encounter. This paper is intended to highlight some of these issues, explain the competing interests, and provide commentary on practices that can be adopted.

2. WHAT DOES THE ROYALTY APPLY TO?

2.1 *The "royalty basis"*

Clearly, one of the goals of an IP license is to allow the licensor to receive a quantifiable sum of money based on a licensee's use of a proprietary technology, or sale of products made using or incorporating the proprietary technology. The license

Table 1: Royalty Components of a Multiantigen Vaccine

Vaccine component	Royalty on sales of vaccine
Antigen A, Proprietary to Company A	2%
Antigen B, Discovered with proprietary tool of Company B	2%
Antigen C, Nonproprietary	0%
Proprietary assembly technique of Company C	2%
Proprietary adjuvant	2%

should include a provision for basic reports that identify the sales on which royalties are due and that itemize any deductions (for example, documented returns of product, damaged product, and free samples) that have been agreed upon. The licensee should keep accurate records so that sales records can be audited and reports can be verified. The records should allow the licensor to confirm that it is receiving accurate royalty revenue and that the licensee is complying with all milestones and other provisions of the license, such as the reporting of minimum sales figures.

Seemingly simple operations can be difficult in some licensing situations. Tallying up unit sales and multiplying the total by a percentage or price-per-unit royalty can become complicated when the licensee bundles a licensed product with other licensed products. A licensor may believe that its technology makes the product more valuable in combination with others, and that the licensor should be due a royalty on the selling price of the *combination or collection* product. Without a prior agreement on and consideration of such a product-combining approach, the licensee may risk patent infringement litigation. For an example, refer to *Georgia-Pacific Corp. v. United States Plywood Corp.* 318 F. Supp. 1116 (S.D.N.Y., 1970). In this case, the court sought to provide royalties based on the value of the IP, rather than the resulting combination. (Court-imposed royalty rates may be higher or lower than either party has agreed to in advance.)

In cases involving a combination or collection product, the licensee may be of the opinion that the portion of the collection covered by proprietary rights of the licensor constitutes only a small fraction of the value of the combination or collection product. Resolving the value of the proprietary product versus the value of the combination or collection product can be especially difficult if the proprietary product is not being, or has never been, sold separately by the time a dispute arises. One way of handling this type of problem is to add a valuation calculation methodology to the license agreement. However, it should be recognized that parties to a license agreement may be motivated to make the calculation work in their own favor, and disputes can arise on how calculations are made. To avoid this type of problem, the agreement may stipulate that the product be sold only as a single unit unless otherwise agreed to by the licensor. Still another way to address the issue is to specify in the agreement that royalty will be calculated based on the sale price of the proprietary product if it is sold alone, or on the sale price of the combination or collection product if the product is sold as a combination or collection.

Often, license agreements will specify that a licensed product is one that infringes *valid claims* of a licensed patent in a territory where the licensed product is made, sold, or used. This type of provision has the immediate effect of eliminating royalties on products manufactured and sold in areas where licensed patents do not exist. Further, this type of language can permit the licensee to refuse payment of royalties on the grounds that a valid patent does not exist in the territory where royalties are sought. From the licensee's perspective, there will be a concern that the licensee will have competition from unlicensed competitors in territories where patents do not exist. However, from the licensor's perspective, particularly in cases where an exclusive license is given and where data, information, and other know-how is provided in addition to rights under patents and patent applications, a licensee benefits from more than just the patent rights provided under the license and should be obligated to pay royalties on all sales of licensed products.

This issue can be addressed by designing the license agreement to address both patents and know-how.[4] Such agreements should include: (1) provisions that separate royalties from different technologies (such as royalties from patented technologies and royalties from use of trade secrets); (2) provisions that eliminate royalties from patents that expire or are invalidated (see *Brulotte v. Thys.* 379 U.S. 29, 33 (1964) and *Pitney-Bowes, Inc. v. Mestre* 517 F. Supp. 52 (S.D. Fla. 1981), which represent the view that royalties should not be due on patents upon expiration or invalidation; (3) provisions that address when a trade secret becomes known or subject to a patent; and (4) a provision that the license to know-how and/or trade secrets continues after expiration

of a patent. Care must be taken to define what the obligations are for transferring know-how. For example, a university, private nonprofit, or governmental body would likely not want to be obligated to provide the same services implicated in a know-how license that commercial transaction might involve (for example, the delivery of a working prototype or a provision for a certain number of hours of instruction time).

Another way of avoiding the problems involving royalties on products manufactured and sold in areas where licensed patents do not exist is to include a provision that the licensor receives reduced royalties in territories where patents do not exist or to provide for the payment of royalties for a shortened term in territories where patents do not exist. It may be appropriate to set the royalty rate at zero in developing countries where no patent exists.

With respect to tying the royalties to valid claims covering a product produced or sold by a licensee, the technology manager at a university or within a government agency in a developing country should recognize that such a requirement favors the licensee and that the licensee may be able to benefit, for very little money, from a proprietary position on a technology (that is, prevent the licensor from licensing to others for a period of years) by commercializing a product which, according to the licensee, does not infringe the patent claims. Further, the licensee could take this position in any of several different countries or jurisdictions in the world (that is, challenge the validity of a patent in India while separately challenging the validity of a related patent in the United States). Such actions could force the licensor to attempt to prove in court that the product being produced by the licensee indeed infringes the patent claims, or attempt to license the technology to another party (in which case the value of the technology would be likely to be less because the remaining patent term would be less, obviously, than the term of the original agreement with the licensor). Neither option is very helpful to a licensor who has had its technology tied up with a company that will ultimately not commercialize the technology. The licensor could address this potential frustration by requiring the licensee to agree in advance that, regardless of any finding of patent infringement, royalties will be due on the product under development by the licensee.

Further, the license agreement might define valid claim to include any claim in any patent that has not been adjudicated, by a court of competent jurisdiction, to be invalid and from which no appeal has or can be taken. With this provision, the licensor might be able to collect royalties up until a final adjudication of patent invalidity. Of course, such a definition would not benefit the licensee in cases where prior art that is *spot on* is identified to the licensor.

2.2 *Royalty stacking*

Royalty stacking occurs when multiple patents affect a single product and thus involve multiple licenses. As noted above, a biotechnology product may require separate licenses for use of such items as research tools, gene sequences, expression vectors, cell lines, and adjuvants. Thus, from the prospective of the company making the product, the multiple royalty demands must be "stacked" together to determine the total royalty burden on producing the product. Because royalty stacking involves many IP holders, efficient exploitation of a product subject to royalty stacking may be inhibited (that is, development can be delayed or discontinued completely) and the development of future products might be impeded.

2.3 *Royalty packing*

Royalty packing occurs when there is a requirement to bundle one technology with other technologies. Such a requirement could be imposed by the licensor, but also could be imposed by best practices within an industry or by a health ministry. For example, a vaccine could be required to be administered simultaneously with one or more different vaccines that are proprietary to one or more different companies in order to reduce the cost of administration. In this situation, the royalties imposed on each of the proprietary products that are administered will be "packed" together. Royalty packing may result in the aggregate cost of the several packed products being too high.

3. TECHNIQUES TO MANAGE ROYALTY STACKING AND PACKING

A licensee may seek to impose a *ceiling* for royalties in any agreements it makes with licensors. For example, the licensee might establish a ceiling of 6% for combined royalties on product sales. In turn, if the stacked royalties exceeded 6%, each of the licensors would be agreeing to have the royalties they are to be paid reduced on a pro rata basis, so that the total royalties due to the licensors would be 6%. In this situation, the licensee may be motivated to add more technologies to its product or process because its total royalties per unit are capped. To the contrary, the licensor may dispute the need to add the additional technologies to the product and may be frustrated if its own share decreases much below the expected return. In many situations, licensors take the position that their technology is the *most important* and that their share of the royalties should not be depleted pro rata. These types of competing interests require the parties to have a good understanding of how and when reductions would apply when the agreement is made and good communications between the parties when new technologies are incorporated into a product that would affect the licensor's expected royalty stream. Also, there may be a need to differentiate some types of royalties from others. For example, some licensors may be willing to agree to a pro rata reduction in royalties when other proprietary technologies are used in the product to be commercialized. But the licensors may not be willing to agree to a reduction due to reach through licenses resulting from the licensee's use of proprietary research tools.

A licensor may seek to impose a *floor* below which its share of the royalties may not fall. For example, if additional technologies are required to exploit a product, a licensor might agree to have its royalties reduced on a pro rata basis, but not below a specified floor (for example, the license requires royalties of 5% but allows for reduction, if additional licenses are required, with the proviso that in no event will the amount due be less than 2% per unit sold). The licensor may agree to a reduction to the floor only if a license from a third party with a dominant patent position to the licensor is required to effectively use the licensor's technology. That is, a licensor may not agree to a reduction if additional technologies are *desired* by the licensee to make a better product, but not *needed* to use the invention—for example, the license agreement might specify that if an additional license to practice the invention described in the licensed patent(s) is required from a third party, the licensee may reduce its royalty payments by 50% (or by an amount equal to the amount that would have been due to the licensor, but in no event shall such reduction be more than 50%). It is not unusual to have in the same license both a ceiling on stacked royalties and a hard floor below which royalty rates could not fall. The hard floor may need to take into account other deductions from royalty payments that are allowed by the license. For example, a deduction of patent costs may be allowed, but will be limited in any year by the hard floor in royalty payments.

Licensees and licensors might agree to have *variable royalties* that depended on, for example, the importance of the technology in relation to the creation of the product. The more important the role a proprietary technology plays in a product, the higher the royalties, and vice versa (for example, the owner of proprietary antigen in a vaccine raised against the antigen would receive higher royalties than the owner of a proprietary expression system for expressing the antigen). In this situation, however, it is likely that licensors and licensees would disagree over the importance of the proprietary technology in relation to the product being developed.

Packing issues may be handled by requiring that the royalty be calculated based on the sale prices of the product if sold alone, or the sale price of the combination or collection product if the proprietary product is sold as a combination or collection.

4. OTHER MATTERS

Not every arrangement requires revenues in the form of a royalty stream. For example, a lump-sum payment for use of a research tool may be an appropriate way to disseminate and exploit a patented technology. Some technologies may best be

collected in *patent pools* which allow for free use of the technologies or use of the technologies at fixed prices. A patent pool can make the licensed technology more widely available for use in different markets (for example, different products could incorporate the technology), and, further, access to a number of other different but related technologies that would be useful to a university or nonprofit organization might be available within the patent pool. Such arrangements may allow research and development using a variety of proprietary technologies without the need to negotiate licenses.

5. CONCLUSIONS

License agreements should clearly define when and how a licensor will be paid a royalty. An important part of any agreement is a clear definition of the product, such that both parties understand what royalties will be based on. Further, to avoid any disputes on royalty payments, the agreement should also clearly define when royalties are not due. Royalty stacking should be recognized and understood by those involved with managing IP in the health and agriculture fields, particularly when biotechnology products, services, and research tools are involved. Providing agreements that allow commercialization of a product that embodies the proprietary technology of several different companies, and for which royalty payments are due to each of those companies, requires recognition by the parties of the role each technology performs if royalty ceilings, floors, or other mechanisms to address stacking are to be adopted. Finally, alternatives to royalty-bearing arrangements should be considered, including the use of lump-sum payments and patent pools.[5] ■

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