

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 each of these many 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 is called royalty stacking, that is, various licenses combining to impose aggregate royalty obligations of 6-20% (or greater). Royalty packing, a similar situation where multiple technologies are bundled together, is sometimes imposed by the licensor or by best practices within an industry or health ministry, for example multiple vaccine packages. 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.

Jones K, ME Whitham and P Handler. 2007. Problems with Royalty Rates, Royalty Stacking and Royalty Packing Issues. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen *et al.*). MIHR: Oxford, U.K. and PIPRA: Davis, U.S.A. www.ipHandbook.org

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1. Introduction

Virtually all products developed using biotechnology and chemistry are protected by one or more forms of intellectual property (IP), including patents, material transfer agreements, or trade secrets, for example. 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 the products will be used, and the relative bargaining positions of the licensees and licensors at the time of drafting a license agreement. In addition, most biotechnology

products are made using one or more patented research tools, each of which may have *reach through* royalty obligations (that is, 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 laws¹. Rather, patent owners may charge a reasonable royalty for use of their IP, and that royalty might be related to a product identified using a proprietary research tool), and may include or require the use of several different patented technologies owned by several different companies.

For example, a potential vaccine may be identified and tested using one or more proprietary research tools, where rights in the tools are owned by different companies. In addition, the vaccine may be produced using recombinant techniques and employ proprietary DNA sequences. Further, the vectors used for insertion and expression may be owned by additional companies, and production of the vaccine may employ a proprietary cell line. The vaccine itself may be packaged with one or more proprietary adjuvants, and be delivered to the patient 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*. This results in the problem known as *royalty stacking*, and the various licenses involved may ultimately impose combined royalty obligations of 6-20%, or more of the selling price of the product, in addition to separate reporting and accounting obligations to each of the licensors. For example, Table 1 shows that a multi-antigen vaccine with a proprietary adjuvant might require total royalties on the selling price of 8% with separate reporting requirements to four different entities.

Table 1 Royalty components of a multi-antigen 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-Non-proprietary	0%
Proprietary Assembly Technique of Company C	2%
Proprietary Adjuvant	2%

Often, a burden of 8%, versus 4% for example, may 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 owned by several different companies. A published freedom to operate report² indicated that Golden Rice, a variety 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 over 20 different owners in the U.S. 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 developing country use thanks

to the strong support this project received from many companies. However, in the commercial realm, the royalty obligations due on a particular product may be collectively too high to allow for development and commercial implementation of the product. The royalty stacking can often be compounded in agricultural technologies. For example, a new vaccine for a pig disease will often need to be *packaged* with several vaccines for other pig diseases to be administered at the same time.

Those 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 the issues, explain the competing interests, and provide some commentary on practices which might 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 which are made using or incorporating the proprietary technology. The license should include a provision for basic reports that identify the sales on which royalties are due, and itemize any agreed upon deductions (for example documented returns of product, damaged product, free samples, etc.). The licensee should keep accurate records so that the sales records can be audited and the reports can be verified. This allows the licensor to confirm that it is receiving accurate royalty revenue, and that the licensee is complying with all milestones or other provisions of the license, such as minimum sales figures.

The concept of simply 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. Without a prior agreement and consideration, a licensor may be of the opinion that its technology makes the *combination* or *collection* product more valuable, and that the licensor should be due a royalty on the selling price of the *combination* or *collection* product. Such interpretations and results have arisen in the patent infringement litigation setting (see, for example, the factors in *Georgia-Pacific Corp. v. United States Plywood Corp.* 318 F. Supp. 1116 (S.D.N.Y., 1970) where the court sought to provide royalties based on the value of the IP, rather than the resulting combination—the court imposed royalty rate may be higher or lower than either party might have agreed to in advance). Conversely, 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 or has never been sold separately by the time any dispute arises. One mechanism to handle this type of problem is to adopt a valuation calculation methodology in the license agreement. However, it should be recognized that parties to a license agreement may be motivated to make the calculation

work in their favor, and disputes can arise on how calculations are made. Another mechanism to handle this type of problem is to require that the product be sold as a single unit unless otherwise agreed to by the licensor. The problem can also be handled by requiring that the royalty be calculated based on the sale price 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.

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 might be addressed by constructing the license agreement to address both patents and know-how³. Such agreements should include provisions that separate the royalties from different technologies (such as royalties from patented technologies and royalties from use of trade secrets); include 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 stand for the proposition that royalties should not be due on patents upon expiration or invalidation); include provisions that address when a trade secret becomes known or subject to a patent; and include a provision that the license to know how and/or trade secrets continues after expiration of a patent. Care should also be taken to define what the obligations are for transferring know how. For example, a university, non-profit or governmental body would likely not want to be obligated to provide some of the same services implicated in a know how license that commercial transaction might involve (for example delivery of a working prototype, provision of a certain number of hours of instruction time, etc.).

Another way to address this problem may be to include a provision that the Licensor receives reduced royalties in territories where patents do not exist, or to provide for receiving royalties for a shortened term in territories where patents do not exist. It may be appropriate to set the royalty rate to 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 governmental agency in the developing world should recognize that such a requirement favors the Licensee, and that the Licensee may be able to benefit from a proprietary position on a technology (that is, prevent the licensor from licensing to others for a period of years), for very little

money, only to come out with 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 (such as challenging the validity of a patent in India and separately challenging the validity of a related patent in the U.S.). Such actions could force the Licensor to attempt to prove in a court action that the product being produced by the Licensee indeed infringes the patent claims, despite the position taken by the Licensee, or to attempt to license the technology to another party, the value of which is likely reduced because the remaining patent term is less than when the original agreement was made with the Licensor. Both options are not very helpful to a Licensor who has had its technology tied up with a company that will ultimately not commercialize it. The Licensor might address this type of unexpected frustration requiring the licensee to agree in advance that, regardless of any finding of patent infringement, royalties will be due on a particular product under development by the Licensee.

Further, the license agreement might define *valid claim* to include any claim in any patent which has not been adjudicated by a court of competent jurisdiction to be invalid, and from which no appeal has or can be taken. In this way, 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 may affect a single product, and thus involve multiple licenses. As noted above, a biotechnology product may require separate licenses for use of research tools, use of gene sequences, use of expression vectors, use of cell lines, use of adjuvants, etc. 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 may not proceed at all) 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. This 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 which are proprietary to one or more different companies to reduce the cost of administration. In this situation, the royalties imposed on each of the proprietary products which 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 was 6%. In this situation, the licensee may be motivated to add more technologies because its total royalties are capped per unit. To the contrary, the licensor may dispute the need to add the additional technologies to the product, and may be frustrated if its share decreases well below their expected return. In many situations, licensors may be of 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 have a good understanding of how and when reductions would apply when the agreement is drafted, and good communications between the parties when new technologies are incorporated into a product which 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 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 be reduced. For example, if additional technologies are required to exploit a product, a licensor might agree to have their royalties be 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). In addition, the licensor may only agree to a reduction to the *floor* 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 which would have been due to the Licensor, but in no event shall such reduction be more than 50%). It is not unusual to have both a ceiling on stacked royalties, and a hard floor below which royalty rates will not fall, in the same license. The hard floor may also 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 also might agree to have *variable royalties* which, for example, depend on the importance of the technology in relation to the creation of the product. For example, 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 would

receive higher royalties in a vaccine raised against the antigen 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, it may be that a lump sum payment for use of a research tool is an appropriate way to disseminate and exploit a patented technology. Some technologies may be best 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 might be available within the patent pool that would be useful to a university or non-profit organization. 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 the licensor will be paid a royalty. An important part of any agreement is to clearly define the product, so that both parties can understand the basis on which royalties are due. 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. ■

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