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How to Negotiate Reasonable Royalty Rates for Licensing Novel Biomedical Products

By George D. Corey and Edward Kahn

point of view

Despite the current recession, biomedical firms are surviving. Many, in fact, are flourishing. Their lifeblood is technological innovation, and patent licensing is responsible for a fair portion of their technology or revenue or both.

Licensing between firms and from universities and other nonprofits has become standard operating procedure for growing biomedical companies. The licensing process, however, involves many steps and can be complicated. Perhaps the most problematic part of licensing is negotiating royalty rates and other related components of these agreements.

iar to licensing executives appear adequate. These theories include, but are not limited to:

1) *Multivariant economic modeling* of a firm (and its technology), the newest and most sophisticated approach to licensing. However, this technique is too complex to be useful in daily licensing work. It requires the construction of an economic model of the licensing firm using weighted cost of capital, target rates of return on tangible or intangible property, R&D costs and other factors.

Use of such models, while elegant, is time consuming, costly and not necessarily accurate. It also requires consensus among the parties involved in the licensing negotiations to ensure the acceptability of the process by which the proposed royalty rate was established.

2) *The 25% rule* argues that the target royalty rate should result in a licensor's receiving approximately 25% of the profit from marketing a technology. Since substantial risk is involved in final product development, the licensee should be entitled to the bulk of the profit.

The 25% rule is difficult to apply. First, it assumes you can adequately track and accurately estimate costs and revenues from a single product, product line or technology. It then maintains that you can fairly allocate overhead and other expenses to achieve some type of estimated profit, which can then be shared on a 25-75 basis between the licensor and licensee.

Second, it also assumes entitlement to 25%, which itself is arbitrarily set. Third, it requires significant information sharing during the negotiation stage between two firms that do not yet know if they want to do business. In the highly competitive biomedical field, this is not a realistic assumption.

3) The *simple investment theory approach* usually results in a firm selecting a target asset (such as R&D expenses) and then setting an estimated rate of return from that particular investment. Royalty rates subsequently are established to reach that expected rate of return.

Such rationale for setting royalty rates is most useful for selling a particular fee structure to a firm before or during negotiations. Whether anyone will license based on this approach is highly debatable.

4) The *profit maximization technique* shops the technology around

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Table 1. Biomedical Licensing Grid*

Technology Classification	*Running Royalty*	*Up-front Payments*	*Minimum Annual Royalties*	*Comments*
Reagents or Process Method	1-3%	Recapture patent costs	$2-10,000	—
Reagents for use in Research Kits	2-10%	Recapture patent costs	$2-10,000	—
Diagnostics, in vitro	2-6%	$5-10,000, up to $20,000	$2-60,000	sometimes a sliding scale for royalties is used
Diagnostics, in vivo	3-8%	$5-10,000, up to $20,000	$2-60,000	
Therapeutics	4-12%	20-50,000, up to $150,000	(worst case sales scenario) X (base royalty rate) X (10% to 30%)	a sliding scale for royalties is often used
Medical instrumentation	4-10%	$5-150,000	$5-20,000, 1st year $10-25,000, thereafter	—
Software	3-15%	up to $100,000	—	—

*The authors prepared this grid based on their own experience and through the assistance of licensing personnel at various universities and biomedical companies. Since the biomedical markets are fragmented, only approximate ranges of rees are shown.

Underlying Assumptions for Table 1

1. Up-front payments may be combined and such terms are deal dependent.
2. The high end of up-front payments is usually associated with a "hot" technology in a developing field.
3. Exclusive worldwide licenses, anything else diminishes the royalty rates.
4. Licensee holds no equity in licensor. If equity is held or is part of the transaction, then the rates are reduced.
5. There is no claim of infringement by the licensor against the licensee. If a claim exists then the up-front payments can be significantly increased to recapture presumed royalty payments that may have been owed.
6. Terms regarding crediting of any up-front payments toward running royalties are negotiated on a deal-by-deal basis.
7. No significant sponsored research agreements are involved, otherwise the royalties are usually reduced.
8. Overseas licensing rates sometimes command a slightly lower set of rates.
9. Up-front payments are based on 1989-1990 dollars.
10. The technology that is licensed may or may not have been issued a patent, but the patent has been applied for and a reasonable opinion exists that the technology is patentable under the laws of the United States and at least

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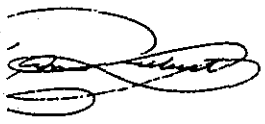

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6. Terms regarding crediting of any up-front payments toward running royalties are negotiated on a deal-by-deal basis.
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9. Up-front payments are based on 1989-1990 dollars.
10. The technology that is licensed may or may not have been issued a patent, but the patent has been applied for and a reasonable opinion exists that the technology is patentable under the laws of the United States and at least one other country.

For licensing biomedical technology (BT), in particular, a unique set of circumstances can pose some problems:

- BT is highly regulated by various federal and state agencies. Regulations cover not only product approvals, which can require years of testing, but approval of the manufacturing process as well.
- BT faces rapid technological obsolescence, which considerably reduces product life cycles, notwithstanding patent protection.
- BT is highly dependent on the approval of third-party organizations (e.g., insurance companies, Medicare, Medicaid) to establish equitable reimbursement rates so that a new technology can become commercially feasible within a reasonable period of time.
- Final product development can be expensive because many technologies are new and untested.

These variables, along with the usual risks associated with commercializing a technology, significantly complicate attempts to establish reasonable royalty rates.

In light of the above discussion, few of the royalty rate theories familiar model of the licensing firm using weighted cost of capital, target rates of return on tangible or intangible property, R&D costs and other factors.

Use of such models, while elegant, is time consuming, costly and not necessarily accurate. It also requires consensus among the parties involved in the licensing negotiations to ensure the acceptability of the process by which the proposed royalty rate was established.

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letter

Writing in *The Washington Post*, Shintaro Ishihara, a member of the Japanese Diet and author of "The Japan That Could Say No," makes a telling point about science and technology. "Technology is of little use," he says, "if it is isolated in the laboratory. To be of value to human kind, scientific knowledge must be developed and applied."

In this country, the partnership between academia and industry has proven astonishingly effective in promoting the transfer of technology from the laboratory to the marketplace and in moving the benefits of science from the bench to the bedside. It is a symbiotic relationship that has served well the interest of scientists, taxpayers, doctors and patients. All Americans have benefited from the prompt practical application of medical research.

Underlying the success of our system has been the tradition since World War II of sustained federal commitment to medical research. To assure that this support continues at appropriate levels, business and academia need to work together in building public support as effectively as they have worked together to develop the fruits of science.

Over the years, industry has greatly increased its investment in biomedical research, to the point that last year, for the first time, the pharmaceutical industry claimed to have invested more in R&D than did the NIH. Appropriately, the vast majority of industry investment has been in applied or clinical research. The basic research effort has been largely governmental, which is as it should be.

It is praiseworthy that business is also prepared to plow back a part of its profit into research. Industry should do this. But it cannot and should not be expected to supplant government as the main force behind medical research.

Pressure will continue to increase, however, for additional industry funding in direct relationship to funding shortfalls by government. Without sufficient support for public funding of medical research, one of two things will happen: funds earmarked by industry for development will have to be shifted to basic research, a redeployment that could delay the delivery to market of new products. Or, the U.S. will sacrifice its global leadership in medical science, an eventuality that would have serious economic consequences for the nation as well as the industry.

Leaders in some other industries have learned too late that their prosperity hinged on public support. I hope that the executive leadership of biomedicine and biotech will not make the same mistake.

Jack Whitehead
Chairman of the Board
Research!America
Alexandria, VA

Point of View

from page four

to find the highest bid or best marketer. Since licensing is a time-consuming task, shopping a technology to the highest bidder adds to the cost of licensing. Also, it tends to forego closing a deal because it argues that "we might get a better offer if we spent just a little more time."

While some biomedical companies have tried this approach, it is less likely to yield true profit maximization in a rapidly changing market where technological obsolescence is a hallmark.

5) An *industry standard approach* looks to previous licensing terms to set a norm for market segmented royalties. Since the basis of these rates is historical, some argue that this approach ignores future problems and opportunities and fails to factor in market changes and the like.

Although these criticisms hold some weight, they miss the point. In a rapidly growing, highly regulated market, industry norms have to factor in (in a less-than-ideal, quantitative way) many variables, including the ones mentioned in the previous models. Also, norms change over time, so they are not written in stone as some have suggested.

The industry standard method is grounded in what the market is willing to pay (within a range outlined in *Table 1*) and helps set a baseline of fairness. This is important because licensing arrangements are long-term relations where more than just the patented technology is transferred. Arrangements often include transfer of specialized know-how and personnel, regular auditing, additional consultation and more.

Industry standards provide a workable basis on which to begin licensing negotiations. If adjustments need to be made in the rate, it is easier to explain a departure from the norm than to make a case for a certain royalty rate *de novo*.

No one theory can address all the fluctuations in economic conditions, different costs associated with additional development of the technology and servicing of the licensing agreement, and comparative rates of return for funds invested in the technology. Even if it were possible, drafting a workable royalty rate would be complicated.

Simplicity and fairness are the most important hallmarks that characterize a workable licensing arrangement. These are embodied by the *industry standard approach*, which most biomedical licensing relies on today.

Types of Payments

Translating theory into practice results in an assortment of payments that are usually found in a typical biomedical license. These fall within the penumbra of royalty payments.

Up-front payments, also called "front-end payments," "disclosure payments" or "initial payments," are made upon signing the licensing agreement. At the very least, these payments attempt to recapture patent expenses and sometimes the cost of licensing and attendant administrative expenses. Some up-front payments go further and reflect a premium based on the importance of the developing market. Research and technology involving AIDS and the basic techniques of molecular biology are areas where "premiums" are more common.

Minimum royalties are regular payments made whether or not a technology has been marketed. The goal is to induce a licensee not to sit on a licensed technology. In the biomedical area, minimum payments may not be imposed for the first few years if the licensee funds sponsored research of the licensor to help complete technology development, or if substantial funds need to be spent by the licensee to develop a final product.

On this last point, certain minimum investment criteria or milestones might be set to avoid the imposition of the minimum payments. By custom, minimum royalties tend to be payable annually, but may be accelerated to quarterly payments or semiannual to ensure that a good-faith effort is being made to commercialize the technology.

Running royalties are usually imposed when a product is given pre-marketing or marketing approval in any form whatsoever, whether or not third parties agree to reimburse for the new technology. Running royalties are ordinarily linked to minimum royalties to provide for a basic level of payment in order to maintain the grant of a license.

Other forms of revenue can include payment of lump sums or periodic lump sums. But these are not used frequently in biomedical licensing unless the licensor is abandoning the technology and does not want to undertake auditing of the records of the licensee.

Some research agreements that are linked to a license of an early-stage technology are deemed to be a form of "prepaid royalty" for at least some of the technology. However, this view does not predominate in the biomedical and biotechnology industries.

Generally, most biomedical licensing agreements include, in some form, upfront payments, minimum royalties and running royalties. Some of the expected ranges of terms for each component are outlined in *Table 1*.

Noncash Trade-offs

Proposed royalty rates may be modified or ameliorated by certain pledges that have value beyond immediate cash. For example, the promise of a licensee to defend the validity of the patent can be very valuable to a small licensor or university. Since this represents only a contingent liability, it requires no immediate cash payments by either side. It also may help defer potential lawsuits by the fact that a licensee has pledged to defend the patent(s).

Some examples of other noncash items that may be used to trade off

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Some examples of other noncash items that may be used to trade off concessions in royalty rates include :

- licensing back technological improvements;
- mandatory sublicensing by the licensee to produce additional cash flow from application of the technology, usually in noncompetitive markets;
- limiting territory, use or product application of the technology;
- stronger march-in rights to resecure the technology if the licensee does not meet certain milestones;
- noncompetition provisions that restrict a licensee from making products that compete with the licensor or other licensees; and
- nonexclusivity, although this can cut both ways since granting a nonexclusive license may make another license for all practical purposes impossible.

Reaching agreement on royalty rates for biomedical licenses is more of an art than a science. Uncertainties about regulatory approval, technological obsolescence, third-party reimbursement and product manufacturing, along with more typical concerns involving economic cycles, development and marketing issues, make biomedical licensing an indisputable challenge.

George D. Corey is program development manager of the Laboratory of Cancer Biology, Dept. of Surgery, Deaconess Hospital/Harvard Medical School in Boston, MA. Edward Kahn is president of EKMS, Inc., a technology transfer firm based in Cambridge, MA.