

Viewing Licensing Opportunities

Pharmaceutical industry and personal experiences are used to describe opportunities in large international company

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I. INTRODUCTION

When discussing the licensing function one can distinguish between general rules applying to the whole field and additional conditions relating to a specific branch and even to an individual company. The following thoughts about "Taking advantage of licensing opportunities in a large international company" have been based on the situation of the pharmaceutical industry and on personal experience I had within this branch and as an employee of C. H. Boehringer Sohn.

It might therefore be useful if I explain first some of the more important characteristics of the pharmaceutical industry, adding also why licensing seems to be an important alternative to solving problems in the industry. At the end I shall demonstrate an example of a licensing contract for which I shall use and condense some of the experience we gained in the licensing field during recent years.

II. PERTINENT CHARACTERISTICS OF THE PHARMACEUTICAL INDUSTRY AND THE HEALTH MARKET

1. "The pharmaceutical industry is par excellence a science-based industry. It has spent, in proportion to its turnover, more on research and development than any other industry, except the aircraft and electronics industries, and no other industry employs a higher proportion of qualified staff".¹ There is a permanent discussion within and outside of the industry as to how much is really spent on research and development in proportion to turnover.

The problem is that the R&D activities are not only taken care of by the relevant departments of the research division, but that a number of other divisions also make partial contributions to the research function. Dr. Jann, President of Hoffmann la Roche in Basel, indicated recently for his company a percentage of 11 percent if only the research division is taken into account of 16 percent if one would add research and development cost hidden in other divisions and areas.

The results of the enormous research effort of the pharmaceutical industry with regard to various ill-

nesses, life expectancy etc. cannot be dealt with here. But one does get an impression of the scope of this topic and also of its implications for the licensing function if one looks at the number of innovations and of patents granted. Reliable figures of this nature are difficult to procure, but the "Bundesverband der Pharmazeutischen Industrie e.V.", being the official representation of the German pharmaceutical indus-

From Know-How '74

try, published in this connection the following data:²

- during the 10 years from 1961 to 1970 a total of 755 new compounds have been developed in the world and introduced to therapeutical practice.
- the German patent office granted approximately 600 patents in 1971 and 700 patents in 1972 which related to uses by the pharmaceutical industry.

Research and development in our industry is mainly dealing with remedies for the very broad spectrum of all human and animal diseases with improvement of pharmaceutical applications and with new devices for hospital care. One pharmaceutical company cannot possibly deal with all or a great number of those fields. The size of the total R&D activities of the branch and the growing specialization of the segments requires from everybody a concentration in selected areas of research and development.

To quote a few examples:

- Hoffmann la Roche are best known for their work with tranquilizers and vitamins.
- Pfizer and Beecham have been very successful in the antibiotic area.
- Schering and Syntex have a major stake in steroids.

Last, but not least, one should draw attention to the fact that the R&D of the pharmaceutical industry is loaded with growing uncertainty and risk. Of course, I realize it is not the nature of any R&D to guarantee success. Statistics of pharmaceutical R&D show, however, a trend in recent years where now only one salable compound can be expected out of 6 to 10 thousand syntheses. According to the rules of probability, an individual company faces the remarkable risk that, for instance, the competitor will have two salable compounds in his 6 to 10 thousand syntheses whilst your own efforts remain fruitless.

Let us conclude this part by saying that innovations through research and development have been and

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will continue to be a most important element for the success and reputation of the pharmaceutical industry. The individual company, however, has to take into account in this field, mounting cost and increasing risk.

2. "Effective marketing is an indispensable adjunct to scientific progress for the simple reason that proven advances are not adopted in practice unless they are sold".³ Marketing in turn also has influenced the industry and the single enterprise to gear its policy so that the needs of the health market are considered and met by research, development and the other important industrial functions. What is the situation of the world's health markets? Let us cast a quick glance at the summarized opinion of the Stanford Research Institute formulated after extensive studies of the situation:

"In the less-developed countries, overpopulation, malnutrition, environmental hazards (poor sanitation) and infectious and parasitic diseases constitute the main health problems. Many of these problems await an economic rather than a medical solution. In developed countries, heart disease, cancer, other degenerate diseases of later life, and accidents are the most important causes of mortality. Causes of death are not necessarily an indicator of the nature of the demand for health care, however; in most countries, including the less-developed countries, common and usually nonfatal diseases of the digestive and respiratory system, accidents and injuries, child birth and mental health problems account for most of the medical care provided."⁴

What is the situation of the pharmaceutical industry which meets these demands? According to Stanford, some 100 companies account for about half of the world sales. Concentration is still relatively slight compared with most other research intensive industries. Although Stanford predicts an increasing consolidation in the 1970's on account of the expanding R&D requirements, thus far, this prediction does not seem to materialize. In Germany, for instance, the market share of the leading 20 companies has gone down during the last nine years, whilst the more medium-sized firms have gained in importance as can be seen from the following tabulation.⁵

	Market Share	Market Share
	1965	1973
leading 5 firms	20,17	17,51
leading 10 firms	33,09	30,09
leading 20 firms	48,62	45,02
leading 50 firms	68,66	69,11
leading 100 firms	82,22	85,00

This picture reflects the brisk competitive climate one finds in most of the geographical and product markets all over the world. In the U.S.A. the leaders in the pharmaceutical market do not reach 10 per cent of that market, in Germany we have a similar situation with a total of about one thousand firms competing.

Bearing the foregoing characteristics in mind, we

shall now direct our attention to the question of appropriate marketing strategies.

One of the most important developments of recent years influencing marketing strategies of the pharmaceutical industry is the reduced time for economical evaluation of patents. It is estimated⁶ that the industry has on average for the marketing of a R and D product only about eight years of effective patent protection, although the life time of patents runs in most countries to 17 or 18 years. The reason for this is on the one hand the necessary early application for a patent and on the other hand the enormously increased demand for human and experimental data as well as delays encountered during the registration of products. If a company is to formulate adequate marketing strategies under these circumstances, with the objective to ensure a satisfactory return on the research and marketing investment, it should consider in the main the following points:

- immediate introduction after clearance of product with health authorities
- simultaneous penetration of the important countries of the world
- provision of sufficient financing for strong and enduring marketing
- development of a convincing promotional platform
- protection against imitations, "by-passers" of patents and losses after expiration of patents.

In summary one can state that an integrated policy of a company requires a harmonization of the activities in the marketing and in the R and D section. To gain or maintain a satisfactory position in the light of the world-wide competitive situation one has to develop strategies reflecting speed of action, international integration, strong financial support, convincing promotional platform and protection against expiration and misuse.

III. THE ALTERNATIVE OF LICENSING AS A MEANS TO SOLVE PROBLEMS

When we looked at some of the pertinent characteristics of the pharmaceutical industry we came across quite a few problems which this industry has to solve. Basically, the management of a company is facing for most of these points these questions. Whether one should solve the problems by its own and existing means and possibilities, or whether cooperation with a third party might be the better solution. One alternative of such cooperation, which is widely and internationally accepted, is licensing.

When we regard the licensing function we should distinguish between the view of the licensor ("out-licensing") and the licensee ("in-licensing"). To demonstrate how much the licensing opportunity can contribute to an international company within the pharmaceutical industry to solve its problems I will enumerate some examples of major problems in the industry and state the relevant incentives for licensor and licensee to solve the problems through licensing.

Let me, however, also caution that I do not want to create the impression licensing is in every case the
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which to my mind is getting more into its own in the modern world. It is, however, being very much criticized by the developing countries. The argument used is that in the national interest the licensee should be able to acquire the technology and use it freely. Another argument is that the know-how in fact does not develop as promised. Therefore, long-term contracts are seen as a way of tying the poor licensee to the strings of the strong licensor. There may be something in this reasoning. On the other hand, short-term contracts would tend to restrict licensing very seriously. Finally the people arguing for short-term agreements are also adamant of exchange of information within the technology transfer situation. Here I fail to see the logic.

Another admittedly difficult question deals with the problem that the licensor would like to be the owner of all *developments*.

There are good arguments on both sides here. If you look upon licensing as a marketing alternative, it is in the interest of the licensor and the licensing group that all information should be exchanged by him to all his licensees, and that he as "the papa" should be holding the ownership.

Two Views

Payment is another field of argument between the technology transfer view and the view of licensing. Two views are here bitterly opposed. One can be stated by saying that the Western sell of technology to Japan was one of the biggest realizations in the world, implying that the price paid for the transfer was very low indeed. Another view is held by authorities, putting a definite ceiling on payment (e.g. royalties about five per cent). Again this could prove a hindrance to licensing. After a while most countries will have to admit that. Payments for technology transfer including training, technical assistance and the like will remain high.

Of other clauses one might like to talk about, I should point out the *tying clause*, the *limited territory clause*, *joint venture clauses* and others. Specially difficult are the *guarantee clauses*, especially in licensing to developing countries. This is because licensees in developing countries often do not have the qualifications required. This means that there is a sort of credibility or aid gap.

Therefore licensing to developing partners might be more difficult in itself. If, on top of that, strict guarantee clauses are being insisted upon, this will certainly mean that a lot of small licensors will drop out of the game.

Last, I would mention *arbitration and choice of law clauses*. I have seen examples where it is stated that the law of the licensing contract should be the licensee's country and that any kind of arbitration or legal dispute should be held in that country. There are at least three arguments against this.

First there is usually more than one licensee. Should all disputes be held in different countries, this would create an uncertainty. Therefore most specialists would agree to choose *one* legal system, and one place where possible disputes could be heard. Last, but not least, this should be a place and a legal system suitable to the technique of economic cooperation.

These brief remarks are meant to create a framework. No pretence is made that all or any points have been fully covered.

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preferable and only way to solve a problem. There are obviously also disadvantages connected with licensing. For instance the sharing of technological secrets with the impending risks of such a step and the remote control over the commercial activities of a licensing partner. Of course one is trying to cope with such risks by careful selection of the licensing partner and by elaborate contracts and systems for cooperation. However the effects of such means are somehow limited and it is more the necessary personal and subjective climate which constitutes the major reason for success or failure of a licensing project.

Following are five examples of major problems of an international pharmaceutical company, adding the incentives for licensor and licensee to seek a solution by the alternative "licensing".

Problem: Mounting cost of research.

The incentive for the licensor is to share research and development cost. For the licensee access to a new field is the most important incentive.

Problem: Increasing uncertainty of research and development activities.

For the licensor a carefully selected partner with a high standard of technology will improve the chances of success. The licensee would, in turn, face much greater uncertainties, if he would start a research project by own means and resources.

Problem: Simultaneous and adequate penetration of international markets.

Assuming licensor and licensee both market the innovation, licensor can select a partner with a strong representation in areas where the licensor is weak. In turn to the licensee it is an incentive to cover such areas.

Problem: Provision of sufficient funds for a strong international marketing effect.

Licensor and licensee can share the financial burden of international introduction and marketing. If both parties market in the same geographical area, this incentive is however somewhat reduced.

Problem: Protection against competition during and after lifetime of patents.

Licensor must take into account in his projection for a successful innovation the interference by competition. Such interference will less likely be successful during and after the lifetime of the covering patent, if the market potential is sufficiently exploited by additional sales of a licensee, who in turn enjoys the incentive to build up a strong marketing position still during the protection of patents.

Footnotes:

1. Reference: Dunning, J.H.: *Introduction in Science, Industry and the State*, editor: G. Teeling-Smith, 1965 pp 15-34.
2. Reference: *Pharma Daten 74* published August, 1974.
3. Reference: Dunning, J.H. see above.
4. Reference: *The World Pharmaceutical Industry*, Stanford Research Institute, Report No. 384, October, 1969.
5. Reference: *Pharma Daten* see above.
6. *Pharma Daten 74* see above.