Conference Paper

Utilization-alternatives barometer for medical devices after basic research in university of research institutes

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Publication Date:
2006

Permanent Link:
https://doi.org/10.3929/ethz-a-010079405

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ABSTRACT

In the age of “open innovation” researchers at universities and other research institutions, who in former times have been focused on “research and teaching” have to become familiar with the new goals “enterprise and innovation”. One new aspect is to ensure the transfer of research results to industrial use.

The purpose of this paper is to develop a tool (the “utilization-alternatives barometer”) which supports project teams in finding the best utilization-alternative of their research results – simply spoken a keep-or-sell decision. This tool is dedicated to R&D projects including product development or target research (development or adaptation of technologies for specific product functionalities). The tool is tested and refined in the context of medical device development, but can also be used in other sectors.

The tool development is based on an in-depth literature review on models and tools supporting keep-or-sell decisions, and utilization-alternatives and their influencing factors in general. The tool is supposed to include the most important influencing factors and to illustrate this factors and their influence on the preferred utilization-alternative.

The resulting tool is a combination of portfolios and a barometer: The most important influencing factors of a project are checked in different portfolios. Each portfolio evaluation results influences the utilization variant barometer. The barometer shows the sum of the portfolio evaluations and hence a recommendation for the best utilization variant.

INTRODUCTION

The collaboration between companies and universities is not a new phenomenon, but the number of collaborations is increasing, also in the area of medical devices. Companies are moving away from a reliance on internal R&D and seeking broader sources for innovation across universities, other firms and federal research labs – a phenomenon referred to as “open innovation” (Chesbrough 2003). The key to success is not just the presence of leading research universities and teaching hospitals, and a sizable base of technology firms – but how they work together.

The industry interested to exchange experiences and know-how with universities and research institutes. But the transfer of technologies and innovation still has to be improved. The university and research institutes can and have to play a major role in promoting technical expertise. In this new age of the innovation economy, the key to success is not just the presence of leading research universities and teaching hospitals, and a sizable base of technology firms – but how they work together.

Hence in addition to “teaching and research” many universities are now adding “enterprise and innovation” as a prominent goal in their mission statements. This commercialization initiative has several key benefits for the university as well as the firms involved (Lerner, 2005). These alliances can generate considerable revenue for the institution, make the university more attractive to current and potential faculty members, and benefit the community and the nation as a whole.
It is also equally important to note that the productivity of technology transfer is ultimately determined by the competencies of university scientists, entrepreneurs, technology transfer officers and other university administrators and their incentives to engage in entrepreneurial activities. Studies in the field of technology transfer indicate that institutional incentives and organizational practices both play an important role in enhancing the effectiveness of technology transfer (Tronchetti Provera, 2005).

OBJECTIVES OF THIS PAPER

The objective of this paper is to propose a tool, which support the decision process in a project on the best utilization-alternative (keep-or-sell decision). This tool should especially meet the needs of research projects in universities and research institutes. These institutions were for a long time focused on the production of research results. In the age of “Open Innovation” they also have to care for the transfer of research results to industry.

Our tool is designated to support this learning process. Therefore the tool is supposed to include the most important influencing factors and to illustrate this factors and their influence on the preferred utilization-alternative. It is developed and tested for medical device product development and medical device projects with target research (development or adaptation of technologies for specific product functionalities). In principle it should be applicable in all sectors.

RESEARCH METHODOLOGY

The tool development is based on an in-depth literature review on utilization-alternatives and their influencing factors in general, and on state-of-the-art models and tools supporting keep-or-sell decisions.

The model was be developed, tested and refined by using it in the decision process of two actual medical tool research projects (projects of Swiss National Science Found, The National Centre of Competence in Research (NCCR) Co-Me: the development of a semiautomatic robotics for coronary anastomosis and monolithically integrated tactile sensor supports for blood pressure measurement).

After the development the tool was be tested with 23 additional projects. 18 of these projects were completed, so the utilization-alternative recommended by the tool could be compared with the applied utilization-alternative. This number of projects is not sufficient to proof the confidence of the tool and the underlying model – but it is sufficient to proof the usability.

TECHNOLOGY TRANSFER MECHANISMS

In the following we describe the basic mechanisms of technology transfer from university to industry: patenting, licensing (with or without royalties), formation of a Spin-off, formation of a Start-up and University-Industry Cooperation. In principle these are the utilization-alternatives of research results.

Patenting

Intellectual Property Rights (IPR) play a very important role in the commercialization of university research and technology. The patent is a legal monopoly for the use, manufacture and sale of an invention. Patents on useful devices, called utility patents, last for 20 years from the date the patent application was filed. Design patents last for 14 years from the date issued. And plant patents last for 17 years from the date issued. A patent is defined as a set of exclusive rights granted by a government to the creator of an invention the sole right to make, use, and sell that invention for a set period of time. In general, either the university or the inventors can
have ownership of the patent. However there are reasons why patenting is not always the preferred option by universities. The primary issue is the ownership and assignment of the patent. The parties also need to sort out the patenting costs and maintenance fees and the rights to use any other invention/technology resulting from the original IP.

**Licensing**

Licensing technology for commercial applications is the direct result of having strong IPR. Licensing of university patents gives industrial companies the right to use and utilize university research results in the codified form of patents or trademarks (Goktepe, 2004). Technology Licensing has been the most common and widely used strategy for universities to commercialize research to existing or start-up companies. Licensing gives the company the opportunity to exploit the IP of the university. Licenses are granted by the owner of IP (university or inventor) to another party (industry) for the use of (i) patented technologies; (ii) for technologies with a patent pending; (iii) for unpatented technologies; (Goktepe, 2004). The license also has to specify the application and the markets in which the technology will be used. The university or inventor gains a revenue in the form of a fee usually paid in advance at the time of signing the agreement and/or annual running payments that are contingent upon the commercial success of the technology in the market. Licenses can generate income in different ways: Up-front fee from the licensee, percentages of royalties on sales, and usage fee. The way in which the university negotiates the various income streams of the license agreement depends to a large extent on the maturity level of the product/technology that is concerned. The main advantage of technology licensing is that the university is able to capitalize on the technology and is able to pursue further research without committing a lot of time towards commercial matters. This in turn means lower development costs and less market risk for the university, and faster product development and entry in the market (Tidd et. al., 2001).

On the other hand, it is quite possible that the nature of the technology may be such that it is not easily patentable and converted to a license agreement. In such a case the university may not be able to capture the full value of their technology through licensing.

**University Spin-off or Start-up**

The term university spin-off has been used a lot lately in relation to the commercialization of university research. There are a number of ways in which a spin-off can be defined. One definition suggests that a spin-off is a firm created to commercialize intellectual property that is owned by the university and/or by a researcher at the university (Cooper, 2005). Other sources define a spin-off as a newly founded company that has received some management resources from a university or universities (Kondo, 2002). Accordingly, spin-offs could then have three types of relations with the university (Kondo, 2002):

- Technology related – based on university’s research results and technology,
- Human-resource related – university personnel involved with the spin-off,
- Capital related – based on the capital provided by the university.

One of the main reasons that Universities may want to spin-off their own company is the lack of industrial receptor capacity, especially in the local economy (Gu et. al., 1999). The absence of local receptors plays an important role in the starting up of a company to license an institution’s technology. University spin-offs may be
established to either i) license the institutions technology; ii) fund research at the institution in order to develop technology that will be licensed by the company or iii) provide a service that was originally offered by the institution’s department or unit.

There are a few factors that need to be understood carefully by any spin-off in order to be successful. The first is the role of the entrepreneur. Whether the academic leaves the university and takes up an entrepreneurial role in the spin-off or runs the company in parallel with his/her academic responsibilities will directly affect the operation of the spin-off. Another factor is the presence of networks in implementing spin-off strategies. These include a technology transfer office with experienced staff, ties with other university spin-offs, and relations with venture capital firms and angel investors. Recognizing a good opportunity when and where it exists is also another important factor in the spin-off. Finally, the distribution of equity within the spin-off company will have important implications for incentives and the ability to make decisions (Lockett et. al., 2003)

University Start-up

The key difference between a spin-off and a start-up is the ties of the firm to the parent institution. Typically a start-up would be formed by an individual or a group of researchers who would leave the university to capitalize on a scientific breakthrough that is potentially relevant to the industry. Hence the start-up would have fewer ties with the university than a spin-off. As a result the start-up might be more successful in creating its own identity. It might be able to deal with newer projects and have more flexibility in choosing its projects. Due to these reasons it is even more important for the start-up to have the right personnel and carefully evaluate the future business potential of the technology and/or product.

University-Industry Co-operation

An University-Industry Co-operation (UIC) is a short or long term alliance between a university and an industry. Typically the goal of long term UIC is joint research in a specific field and area of interest with multiple possible outcomes. (Therefore a long term UIC is not a utilization alternative.) A short term UIC may be limited to the co-development of a technology or product.

MODELS AND TOOLS FOR KEEP-OR-SELL DECISIONS

Table 1 gives an overview of models and tools supporting keep-or-sell-decisions of R&D results. There is no tool available in literature meeting exactly our requirements; nearly all models are dedicated to R&D results of companies, not universities. But these models and tools served as raw material for developing our tool.
Table 1: literature review on models and tools supporting keep- or-sell decisions of R&D results

<table>
<thead>
<tr>
<th>Description research area resp. model or tool</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology portfolios to support make-or-buy and keep-or-sell-decisions in companies</td>
<td>e.g. Pfeiffer (1982), Ewald (1989), Ford (1988)</td>
</tr>
<tr>
<td>Intellectual Property Management (for companies) including external utilization</td>
<td>e.g. Gassmann/Bader (2006)</td>
</tr>
<tr>
<td>Processes to identify external technology sources</td>
<td>e.g. Kobe (2006), Reger (2006), Savioz (2006)</td>
</tr>
<tr>
<td>Description on how to manage technology transfer in the context of corporate acquisitions</td>
<td>Bannert-Thurner (2005)</td>
</tr>
<tr>
<td>Risk management in Incubators (also for start-ups from universities)</td>
<td>e.g. Ruping, von Zedtwitz (2006)</td>
</tr>
<tr>
<td>Principal description of utilization alternatives for universities</td>
<td>See literature cited above</td>
</tr>
</tbody>
</table>

DEVELOPMENT OF THE TOOL

The main components of the utilization-alternatives barometer are:

− the description of the utilization alternatives,
− the evaluation of the influencing factors (Team characteristics, characterization of product or technology, characterization of potential market),
− and the transformation of the evaluation results into a recommendation on the preferred utilization alternative.

Possible utilization-variants

Based on the technology transfer mechanisms described above we have identified six potential utilization-scenarios which are applicable to utilize research results.

Spin-off Level 0: This type of an off-shoot of the university will deal mainly with research and development of the current technology so that the commercially important research is treated separately from the rest. This entity could further carry out marketing of the technology too.

Spin-off Level 1: This entity will do a majority of the work done by a Level 1 spin-off and in addition also be involved with the production. A level 1 unit could be a dedicated supplier to a particular industry.

Spin-off Level 2: This entity will be involved in the production and also do the sales, marketing and distribution of the product.

Licensing: By Licensing we mean that the university or institute will license the particular technology and the supporting IP to a company which will then produce, market and sell the product under its own name.

Patent Sale: This kind of action will entail the selling of the patent and all its associated intellectual property to a third party.

Cooperation: This will ensure cooperation between the university and the industry for possible simultaneous research and production. It will deal with more specific projects and is sort of a middle-of-the-road arrangement when creating a spin-off is
considered too much of a risk and the university would still like to have control over IP.

While constructing the model, we have only considered spin-off as an alternative even though a start-up was also considered during discussion. The method and source of financing (which is a major distinguishing factor between spin-offs and start-ups) was not taken into consideration during this discussion. However the model can be equally applied for start-ups also.

**Characterization of team**

The characterization of the team defines whether the team is ready to go in the market alone (spin-off or start-up), or needs supplementary support (cooperation with other entities: new universities project partners or industries) or if is better that transfer to an extern entities (companies) the complete (sell patent) or part of results application (licensing).

Characteristics included in team evaluation are: “Business skills”, “Conflict” and “Motivation”.

**Business / Entrepreneurship Skills of the Team:** This deals with the business acumen and abilities of the personnel involved in the commercialization process, such as the researchers, faculty members, university officials etc.

**Conflict of Interest in the Team:** This factor deals with the ability of the members involved to work together as a team. It takes into consideration how well each person in the team gets along and how well they can work towards a common goal.

**Motivation of team to proceed:** This factor influences the efficiency of the team for a future project. If actually the more important team members are not motivated to proceed, it is not a wise decision opted for 100% intramural solution as spin-off or start-up.

There is another very important team characteristic: communication and information exchange capability. This characteristic has no influence on the decision if it is better sell patents, licensing or spin-off/start-up. It’s an important factor if the team has to decide between the cooperation and another type of utilization-variant. For cooperation with other universities and/or companies the disability to communicate or to share information can endanger the success of the cooperation.

The three characteristics “Business skills”, “Conflict” and “Motivation” were used to build two different Portfolios (fig. 1). The characteristic “Motivation” was used in both portfolios because is the only one that can influence the other two characteristics. The two portfolios contain for every attributes combination the preferred utilization-variants.

The tool suggests the best utilization-variant to valorize the outcome and the possible ambition of the team. For example in fields with the suggestion “Cooperation” sell patent or licensing are also a possible solution (fig. 2).
Characterization of product or technology

The characteristics “maturity level of the outcome”, “utilization in other markets or businesses” and “time before the next radical innovation” are used to evaluate the resulting product or technology.

Maturity Level of the Outcome: By this we mean the developmental level of the final outcome or result of the work undertaken at the institute, whether it is a technology or a product. This characteristic can have four different levels:

- Mature technology: a technology which is in the final stages of development,
- Product concept & market analysis: a technology which has evolved into a product concept with an analysis of the market, in which it will be applied,
- Complete pre-study: a complete analysis of the technology and the market with competitor situation, feasibility and forecast predictions,
- Functional prototype: a working model of the final product ready for mass production.

Utilization in Other Markets or Businesses: This characteristic deals with the application of the concerned technology or product in other markets or areas of business. This question can be answered with a simple ‘yes’ or ‘no’.

Time before the Next Radical Innovation: This is the period before which a disruptive technology will come along. By Radical Innovation we mean “a product, process, or service with either unprecedented performance features or familiar features
that offer potential for significant improvements in performance and cost. (Leifer et al., 2000)" Such innovations create such a drastic change in processes, products or services that they transform existing markets or industries or create new ones. If the team has a long period before the next radical innovation, it is more probable that the creation of a spin-off/start-up can be successful. The potential levels are:

- Short: less than 4 years,
- Medium: between 4 and 10 years,
- Long: more than 10 years.

**Figure 3:** Outcome characterization through Portfolios “Maturity Level vs. Utilization in Other Markets or Businesses” and “Maturity Level vs. Time before the Next Radical Innovation”

Another very important characteristic of the product or technology is, whether intensive clinic tests phases are required at the end of project. This characteristic has no influence on selling or licensing the patents. But it is important for the decision between cooperation and spin-off. The team with technical competencies needs the support of a team with medical competencies to precede clinical testing. The solution is to create a spin-off/start-up with the medical team or proceed before the creation of a spin-off/start-up with the cooperation.

The three characteristics “Maturity Level of the Outcome”, “Utilization in Other Markets or Businesses” and “Time before the Next Radical Innovation” were used to build two different Portfolios (fig. 3). The characteristic “Maturity Level of the Outcome” was used in the two portfolios because it is the only one that can influence the other two characteristics and describe the type of outcome.

**Characterization of final market**

The situation of the final market can strongly influence the choice of a possible utilization-variant. The characteristics “Time-to-Market”, “Competitive Situation” and “Need of extramural competencies” are used to evaluated the final market.

*Time-to-Market:* Time available for the Product or Technology to go on the Market. This point deals with the speed of the innovation process. It gives us an idea of how long the market is willing to wait for the product or technology.

- Short: less than 2 years,
- Medium: between 2 and 5 years,
- Long: more than 5 years

**Competitive Situation:** This point considers the current level of participants in the market which have viable alternatives or similar technologies and/or products, viz.
- Low: no competing technologies or products in the market.
- Medium: very few (one or two) viable competing technologies or products.
- High: a significant number of competing technologies or products.

**Need of extramural competencies:** Especially in the medical device sector are not enough only technical (development) and medical (clinic tests) competencies. Additional competencies are needed in the area of certification, labeling and packaging process. The certification today is a critical process for industries with long experience in the market too, because the different national certification agencies (EU, FDA, Canada Health Bureau, and other) use different norms. For a team not habituated at these norms jungle, it’s impossible in a short time to go on the market.
- Low: the team has the necessary competencies to go on the market.
- Medium: the team possesses some competencies to go on the market.
- High: the team needs the most important competencies to go on the market.

The possibility to acquire new extramural competencies or to develop and implement a strategy to go in a high competitive market is only in function of the time that the team has. The results of the characterization of the market are depicted in two portfolios with both “time-to-market” as main variable (fig. 4).

![Portfolio Chart](image)

**Figure 4:** Market characterization through Portfolios “Competitive Situation vs. Time-to-Market” and “Need of extramural competencies vs. Time-to-Market”

**The barometer**

To give the model a qualitative as well as a quantitative look we have come up with a ranking scheme to rank each of the probable scenarios which are likely to be encountered when we map out the different characteristics. These rankings will give the relative influence of the combination of the characteristics on the final outcome, whether it is a spin-off or to license the technology etc. In some cases it is possible that there is more than one possible outcome from the type of characteristics that we have. In such cases we have also given rankings for the combined outcome. These rankings are purely relative and have been devised to give the model a quantitative feel and to come up with a spectrum for the various possible scenarios. Since the rankings will have an influence on the final outcome we have named them as “Ranking Influencing Factors” or RIF (fig. 5).
Figure 5: Ranking Influencing Factors

For example, in the model below we look at how the characteristics of the team will influence the final outcome. Assumed the research team at the university has members who have good business experience and entrepreneurship skills and the members get along with each other very well then obviously setting up a spin-off is the best option (top right quadrant). Similarly there are one or two possible outcomes for each of the four alternatives. We can then use the ranking scheme to rank each of these alternatives. We then use a spectrum of the rankings to fit in the possible outcome depending on its RIF. The spectrum reflects the ranking scheme discussed above. The rankings vary from complete outsourcing of the technology (Sell Patent, -2) on the extreme left hand side to in-house production and retention of all rights (Spin-off Level 2, +2) on the right hand side. At the end of each case, we will sum up the RIF for each of the four categories and use the spectrum to determine the possible final outcome. Since it is a sum of four categories the RIF for the final spectrum will vary on a scale from -12 to +12 (fig. 6).

Figure 6: Barometer for one single characteristic and the Barometer for all characteristics.

For the implementation of the tool, the portfolios contain no more the utilization-variant but the different Ranking Influencing Factors (fig. 7). The utilization variants visualization for the user will be displaced in the Barometer at the end of the six portfolios. The addition of all Ranking Influencing Factors of all portfolios give as result the Barometer “field” of one utilization-variant.
In case that the final outcome of the analysis is a “Spin-off” we have to consider some additional points before we decide whether to go with a spin-off or a start-up. The final decision will depend on whether or not there is a need for resources and know-how (Fig. 8). Hence we have the following portfolio to decide the final outcome.

**Figure 8:** Portfolio to support the choice between spin-off and start-up.

**EMPIRICAL VALIDATION OF THE TOOL**

The tool was primarily designed to support the decision process of two actual medical tool research projects (projects of Swiss National Science Found, The National Centre of Competence in Research (NCCR) Co-Me: the development of a
semiautomatic robotics for coronary anastomosis and monolithically integrated tactile sensor supports for blood pressure measurement).

Through intensive interviews with project leaders and project managements of 23 projects the tool was confronted with 23 additional projects. 18 of these projects were completed, so the utilization-alternative recommended by the tool could be compared with the applied utilization-alternative. 5 at one year before the project end.

The following two tables compare the suggested and the implemented utilization variant for 18 completed projects (Table 2), and the suggested with the planned for 5 project one year before their end (Table 3).

**Table 2:** Suggested and implemented utilization-variants of 18 ended projects.

<table>
<thead>
<tr>
<th>Suggested utilization-variant Type</th>
<th>Suggested Number</th>
<th>Implemented Utilization-Variant</th>
<th>Suggested are implemented too?</th>
<th>Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent sale</td>
<td>3</td>
<td>3</td>
<td>yes</td>
<td>Patent sale is the most defensive strategy to transfer outcome in the industries. All cases are successfully.</td>
</tr>
<tr>
<td>Licensing</td>
<td>5</td>
<td>6</td>
<td>4 yes, 1 from cooperation, 1 from Spin-Off L1</td>
<td>A project choice to create a Spin-off. Other two projects choice this solution instead other more difficult solution. All 6 cases are successful.</td>
</tr>
<tr>
<td>Cooperation</td>
<td>6</td>
<td>5</td>
<td>5 yes</td>
<td>Cooperation is the more suggested solution. A project choice an easily solution: Licensing. Of this 5 cooperation only one was not successfully for a wrong cooperation partner.</td>
</tr>
<tr>
<td>Spin-Off L1</td>
<td>3</td>
<td>3</td>
<td>2 yes, 1 from Licensing</td>
<td>Only the not suggested spin-off has today critically problems. The other two cases are actually in a good Business situation in time with the industry plan.</td>
</tr>
<tr>
<td>Spin-Off L2</td>
<td>1</td>
<td>1</td>
<td>yes</td>
<td>The only project that had the characteristics to create a spin-off L2, used successful their changes.</td>
</tr>
</tbody>
</table>

**Table 3:** Suggested and planned utilization-variants of 5 projects one year before the end.

<table>
<thead>
<tr>
<th>Suggested utilization-variant Type</th>
<th>Suggested Number</th>
<th>Implemented Utilization-Variant</th>
<th>Suggested are implemented too?</th>
<th>Commentary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent sale</td>
<td>0</td>
<td>1</td>
<td>1 from Licensing</td>
<td>Only one project choice a defensive solution: patent sale. This decision came from the dictate of a big enterprise that doesn’t want the licensing solution.</td>
</tr>
<tr>
<td>Licensing</td>
<td>2</td>
<td>1</td>
<td>1 yes</td>
<td></td>
</tr>
<tr>
<td>Cooperation</td>
<td>2</td>
<td>2</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Spin-Off L1</td>
<td>1</td>
<td>1</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>Spin-Off L2</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Normally the suggested utilization-variants are implemented or planned. Only four projects choose a different alternative. Three projects chose a more defensive solution: from Licensing to Patent Sale, from Cooperation to Licensing and from Spin-Off L1 to Licensing. The project that has chosen a Spin-off and the barometer suggested a Licensing faces many difficulties today. These results are not sufficient to proof the confidence of our tool – but they give an impression of the usability.

CONCLUSION

What we have developed here is a basic model which should serve as a guide to researchers, investors, entrepreneurs, and university and industry officials who are looking at commercializing university research.

The tool can be used as discussion basis in project where different partners have different point of view about the proceeding of the project. With this tool the discussion dislocate from the solution to the characteristics of project. Define the characteristics of the project can help all project participants to find and discuss the eventually project problems.

In a broader sense the tool is designated to support the learning process of universities to fostering not only “research and education” but also “innovation and entrepreneurship”.

REFERENCES


