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CHRONOLOGY OF DEVELOPMENT STEPS DURING A PARALLEL INTEGRATION OF A NEW TECHNOLOGY, A CASE STUDY

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1. Introduction

The industrial product innovation process in the field of biomedicine underlies a continuous optimisation due to influence of the market like the increase of published patents, faster initiation of new technologies or individual product configuration for customers [Schlich 2002]. Therefore, a strictly applied process with regard to changing boundary conditions is of fundamental importance during a product development [Sandmeier 2004]. In the orthopaedic market (artificial joint replacement with prosthesis systems), a implementation of innovative technologies in the product portfolio to the right time assures the interests of customers (surgeons) and could finally lead to a better postoperative outcome considering the patients' health and life quality.
The product development represents an inherent part in the technology supply chain and can support a faster acquisition of mentioned technology [Tatikonda 2003]. In this case study, a procedure is presented to adapt a parallely guided technology acquisition process with respect to an ongoing innovation designing process. Specified topic was considered, how far an implementation of a new technology during an ongoing product development is possible and reasonable. This has been considered for the case that the idea of a possible technology acquisition and implementation appeared after start of the Product Development Process. Presented procedure represents a compromise between a strictly separated technology acquisition process and a product oriented technology acquisition. A balance between availability of the technology on the one hand and feasibility study within the product development on the other hand has to be determined iteratively. Some steps had to be done - before proceeding with the innovation designing process - to assure needs or benefits of the new technology. Some steps to evaluate the technology were integrated sequentially to the innovation designing process, particularly if mentioned technology was discovered during the development. That specific case study contains a development of a knee prosthesis based on new biomechanical findings while applying a new technology in form of an innovative plastics material. Advantage of a parallel implementation of a technology in a product development is a precise and defined practical example in form of a real development. The product development itself represented an accelerator for a faster acquisition of the technology. This was leading to a shorter cycle time. Appeared problems while applying such a process combining technology acquisition and product development have been listened and discussed in the presented study.

2. Problem

The topic of a separation of the product innovation process and the technology acquisition was often discussed [Tschirky 2003]. In the development during diary work, such a strict handling of these

declarations is only approximatively convertible: For instance, the advantage of a new technology is often recognized during the ongoing product development process by project leaders. The recognition of an available technology is the first important step, but sometimes already too late to implement that technology in a product as well [Kobe 2001]. To reduce the necessary time from recognition until the application of a technology, an early formulation of needs by responsible people in development should be made. A close collaboration between people to acquire the technology and from product development side is of high importance.

3. Aim

This case study should give an answer to what extent a technology acquisition process could be adjusted and implemented in consideration of an ongoing product development.

4. Case description

4.1 Product portfolio in the market

The product portfolio in the field of orthopaedics often shows comparable products considerung time consumation for the development, financial expenses or future customer support. Beside these given boundary conditions for every new product development, the product itself consists of up to four assemblies (Figure 1) and an instrumentation set to implant the artificial replacements.

Figure 1. Typical product assemblies for a hip joint comprising an acetabular cup, head, and stem (left), knee prosthesis with a polyethylene-Inlay, femoral condyle and tibia plateau (middle) and shoulder with head, middle part and stem (left)

Used materials for the implants are Titanium, Cobalt Chrome, Stainless Steel, Polyethylene or Ceramics. All have a huge variety of surface modifications to meet the requirements concerning optimised bone ingrowth or reduced friction in an articulating system.

4.2 Market and customers

The interests in product innovations in medical technique are immense. Advantages and progresses should result into a better postoperative outcome, which leads to a better quality of life of the patients. Therefore, primary interest of surgeons and patients is the application of new technologies which should lead to improvements in implantable products and applied operation technique.
The orthopaedic market (including artificial joint replacement for knee, shoulder and hip) is highly conservative due to strict regulations for newly developed medical devices. Normally, product innovations are customer oriented and hence market driven – surgeons try to realise their product ideas together with companies in biomedicine. An early involvement of the customers is of high importance due to further acceptance of the product, because it is the decision of the surgeons if a product will be used and implanted in the human body.
The knowledge and education of surgeons is based primary on anatomic and biomechanical topics. Therefore, some space is given for the companies as technical knowledge carriers to adapt technologically driven innovations. Thus, a lot of processes and tasks during development follow according a specific procedure. These steps represent repetitions for every new product development

like for example the involvement of the customers in the early phase of the designing process, biomechanical tests of the implants or animal studies.

4.3 Product to be developed

Idea of the product development was the realisation of a new total knee prosthesis considering anatomic and physiologic conditions in the natural knee. Actual state of the art in that field of orthopaedics does not represent the biomechanical in vivo situation. The function of the menisci in the natural knee allowing suspension in axial and horizontal direction has not been implemented yet in a prosthesis system. These requirements could be realised by an assembly made of a material allowing higher deformations. This material based on an elastomer is already proved and applied in implants treating spine degeneration. Therefore, specified material is available by different suppliers in "medical grade" constitution but not applied yet in the market of orthopaedics.

4.4 Implemented technology

The new material can be classified as an established basic technology. It does represent a new technology in orthopaedics for that specific company: Knowledge concerning "handling" and manufacturing can not be found in the company itself, it has to be internally built up first. Market acceptance from the customer's side is always really restricted based on a conservative attitude towards new materials in biomedecine. The material is established in other areas in biomedicine like spine deformities - but not in orthopaedics. Two US-companies sell the raw material. Basic data about the product according standards (mechanical properties, biocompatibility tests) are marginally available. Knowledge has to be built up concerning manufacturing and production methods.

4.5 General boundary conditions

Development was done in a swiss company of 300 employees producing artificial joints like hip, shoulder and knee prosthesis (Mathys Medical Ltd, Bettlach, Switzerland). The company has an annual turnover of 300 millions of swiss francs. Research investments are about 5% of turnover.
A part-time job of 50% (20 hours a week) was used to realize the first two milestones of the project. Responsible person was an mechanical engineer with an industrial experience of 3 ½ years. Head of development was the responsible person for decisions and definitions of further steps.

4.6 Applied product development process

The product development was done according to the reference model of the innovation design process of the federal institute of technology ETH, Zurich [Meier 2002], Figure 2.

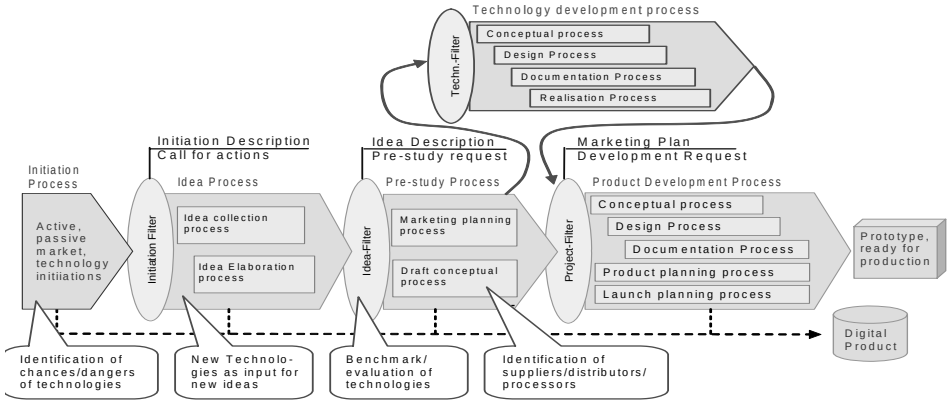

Figure 2. Product innovation process integrating technology considerations [Meier 2002]

It is not a process specially assembled for biomedical products. The process contains sequential procedures like the introduction phase, idea phase, concept phase, evaluation phase, construction,

realisation, and implementation of the product. The idea of an application of a universally valid process used for different product developments was of high interest to get new findings and conclusions.

5. Procedure to determine important steps

All necessary steps and subsequent deliverables to realise the entire technology transfer were virtually listened first by the product developer's view. A global consideration of presumable deliverables and time expenses for each step was subsequently estimated. In order to determine a defined sequence of the required processes to acquire the technology, necessary input parameters to proceed in the development were listed. To continue with the single steps of the product development process, imput data are needed which often represent output parameters resulting from the technology supply chain. Taking that into account, an adjusted technology acquisition process considerating the needs for each single step of the product development process was constituted. So, the sequence of the technology acquisition is aligned and adjusted with respect to the ongoing development. As a result, not only a sequential transfer occurs, interactions during parallell steps between technology acquisition and product development support the ongoing development in form of an iterative exchange: The development should act as an accelerator for an efficient technology supply.

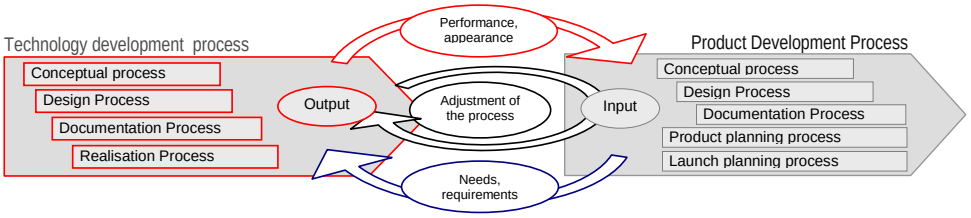

Figure 3. Adjustment of the technology development with respect to the product development

6. Results and experiences

Presented study shows a special case of an adaption of a technology acquisition process with regard to an ongoing product development. The performed procedure shows findings concerning process designing aspects of a technology acquisition. Based on an employment of a product leader in development as interacting person between responsible departments, exchange and communication had to be intensive to assure the realisation of the important steps. Considering the specific case that the technology acquisition was initiated and managed by the developer, required steps to do first were constituted according to their importance to get required data used for the ongoing development.
A complete listing of single steps before starting the process supports an overwiew and a determination of the sequence of single steps [Pleschak 1996]. Based on such a listing where results and deliverables of each technology acquisition step are written in the right column (Figure 4), specific important steps to assure the further development were determined. Therefore, a feasibility study within the product development was done due to an early delivery of the required data. Some specific examples can be mentioned with regard to functionality, producibility or rentability:

- Material properties like elastic modulus or maximum tensile strength had to be used as soon as possible to determine the strength of the planned design by finite element studies. After realising pre-contracts with the knowledge carrier, these data were soon available to start with calculations.
- Further evaluation concerning producibility showed that the product assemblies made of that specific plastics had to be manufactured by an "injection moulding" method. This fact resulted in further evaluation for an external partner to produce these elements.
- A business plan could be realised focussing on that specific product, where the new technology should be applied. Expenses for raw material, machines and other deliverances were estimated due to an application to a specific product.

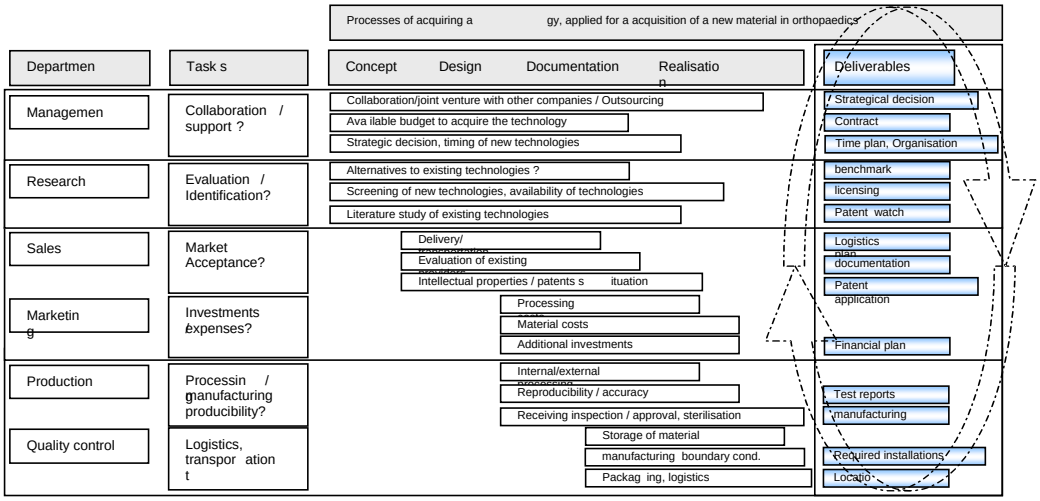

Figure 4. A listing of important steps and deliverables while implementing the new technology

Some general findings and conclusions concerning this study can be postulated after collection of a broad experience while adapting mentioned sequences:

- Technology adaptation was always referred to the specific product development: With respect to a practical example, the technology acquisition process was simplified concerning importance and succession of each single step.
- More realistic statements can be made concerning financial expenses for the technology to be acquired with respect to a real product development. Risk can be reduced not to find a specific application of the technology with an ongoing product development.
- In consideration of the immensely important documentation process of the product in the field of biomedicine, elaborated protocols, test data, and generally used documents during the technology acquisition were directly adjusted for a future registration process.

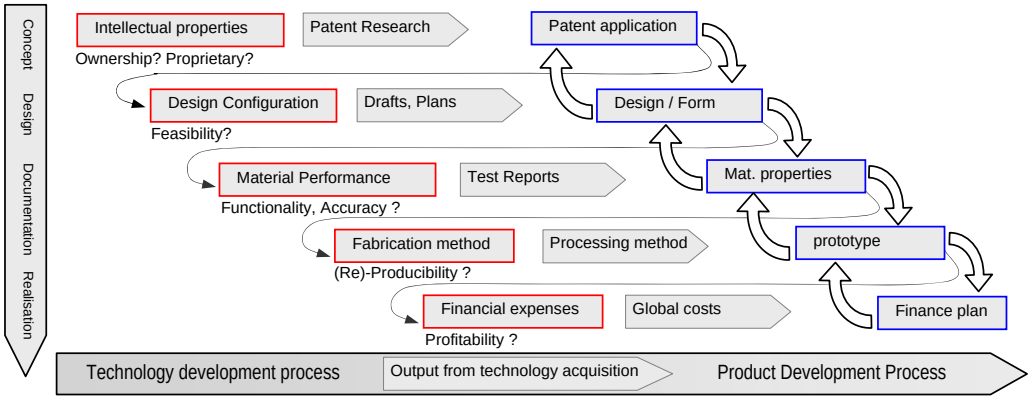

Figure 5. A possible example of a sequence is shown: Deliverables from the technology acquisition process were used to initiate the development process in form of a feasibility study

- Requirements regarding the new technology have been formulated by a responsible person in development. Customisation for a fast application in the product is therefore assured (e.g. patent applications, question about external manufacturing as described in [Swan 2003])

- A direct application of the technology can be instantaneously prooved at the product itself. No additional manpower is necessary to accomplish this directly applied feasibility study, if the mentioned steps are managed by the product developer himself.
- Barriers to innovation [Bond 2003] have been easier classified because they appear more realistic during the applied product development (Producibility, Functionality, or Rentability).

7. Discussion

It is obvious, that present study considers one specific case about one applied technology in the field of biomedicine. A balance between possible acquisition of the technology and feasibility study of the product to be developed has to be found. Some organisational questions considering a further implementation of that new technology had to be answered to the same time like the proceeding of the product development. A compromise has to be found because the development is not primarily the responsible department to acquire that new technology, but they have the best knowledge for other applications to future products. In that specific case, responsible person in development was managing the important steps. This person could be as well a person from another area of the company. It has to be determined which tasks are useful to do next and assurance has to be given that they are realized and initiated to the right time.
As a result, the important aspect of such a proceeding will not be primarily a shorter time consumption, but maybe a prevention of non applicapable technologies and a credible assumption concerning further use of the technology. Described succeeding should sensitize to detect the important and time consuming steps for an optimised knowledge transfer into a development.

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