Titanium Implants – A Comparison of a Swedish and an Ohio Firm*

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Abstract. *Two firms in the health care market are studied in a case study of the introduction of two almost identical innovations. The two firms, both in the titanium implant business have been chosen so that they match when it comes to origin, technology and customers. But the diffusion occurred in two different (institutional) environments, the Swedish and the US. The whole process from invention to innovation and diffusion in the market is studied. The analysis takes its starting point in competence bloc theory (a Schumpeterian theory). We find that the institutional environment is crucial for firm growth.*

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This paper focus on the economic performance of two biomedical firms, one in Sweden and one in Ohio, US. The cases have been chosen in order to match each other but "placed" in different environments. Both the Swedish and the American innovation have led to the formation of new companies in the titanium implant business but in two different economic systems. The case studies in this paper cover the process of commercialisation from inventions to innovation and diffusion in the market.

The first example is the Swedish invention of a titanium screw with the unique property of being permanently accepted by the human body. Per-Ingvar Brånemark[1] discovered this possibility in the late 1950's.

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[1] Then a medical doctor now professor.

In 1965, the first patient was treated using Brånemark's method of implantation, osseointegration[2, 3]. During the 1970's, osseointegration began to be accepted. A partnership was entered with the Swedish manufacturing firm, Bofors in 1978. *Nobel Biocare* was officially started in January 1981 for the purpose of developing, producing and marketing the Brånemark System.

The second example is an American invention for treating and repairing the spine, a bone screw and plate, at first in stainless steel but later also in titanium. Arthur Steffee[4] developed the products and the surgical instruments in the early 1980's. He also introduced a new method for implantation in the spine. Steffee and a businessman, Ed Wagner, founded *AcroMed* in 1983.

We study the emergence and commercialisation of two new and very similar technologies (from the firm perspective). By doing so we may gain a deeper understanding of how a technology evolves into a product implemented in the market and eventually leading to firm growth.[5] Most of the company information has been obtained through several interviews at both companies and through unpublished internal material.

The outline of the paper is as follows. Section I presents the analytical framework taking its starting point in Schumpeterian theory[6]. The two firms are placed in the environment of what Gunnar Eliasson and Åsa Eliasson (1996) calls a competence bloc i.e. a minimum set of actors with different but complementary competencies needed for the innovation process in order to create and develop a new industry. We introduce the Swedish biomedical firm, Nobel Biocare and the Ohio biomedical firm, AcroMed in section II and III, respectively. We are interested in the firms as well as their co-operation with other actors thus emphasising the network and institutional set-up surrounding the firms. The paper closes with a summary and a comparison in section IV.

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[2] Osseointegration is a misleadingly simple technique. Specially designed titanium devices are inserted into living tissue using a delicate surgical technique. The titanium components become integrated and accepted by the body as if they were part of its own structure. Hence, an implant is not the same as osseointegration. An implant does not necessarily grow together with the body. "A fixture is osseointegrated if it provides a stable and apparently immobile support of prosthesis under functional loads, without pain, inflammation, or loosening." (Elaine Williams, 1998 p.10).

[3] Brånemark came up with the word in order to give a better meaning of what was happening in the body. "Os" means bone and "Integro" means to renew in Latin

[4] A medical doctor.

[5] In doing this we can link the products to the firm and the firms to cluster and the clusters to the macro level. There is a natural link between the micro and macro level.

[6] See for example Joseph A Schumpeter (1934).

I. The Analytical Framework

We will analyse how two different competence blocs shape (determine) the exploitation of similar inventions in two different companies, one in Ohio and one in Sweden. The two cases are very similar in all-important respects (university origin, technological, market, etc.) but developed in two different institutional environments, Sweden and the US. We can therefore, talk about an experimental design of the analysis.

The innovation process is resource demanding, not least the entrepreneurial task of choosing between different inventions and the integration of inventions into new or different products. This process is economic- not technical- and very costly and resource demanding. Mistakes occur frequently. It takes place within what Eliasson and Eliasson (1996) call a competence bloc.

In the competence bloc the infrastructure needed to *create*, *recognise* (often via venture capitalists) *select*, *diffuse* (often via spill-overs) and successfully *exploit* (via receiver competence) new ideas in firms are identified (Eliasson and Eliasson, 1996). Put another way, the competence bloc defines a minimum set of actors, with different but complementary competencies that must be present to create and develop a new industry in the innovation process. The result and function of the competence bloc depends on the incentive structure that the different actors meet. That in turns depends on the institutional settings.

The actors within the competence bloc are according to Eliasson (1997): (i) *Customers* with receiver competence, for example customers that understand the new technology or its applications. (ii) *Inventors* who come up with technological solutions. (iii) The *entrepreneur (or the innovator)* and his ability to implement innovations/technological solutions in the market. (iv) In addition there is also a role for the *venture capitalist* that recognises and finances the entrepreneur in an early phase of the innovative process. (v) Actors in a *second-hand* well functioning *(exit) market* that facilitates ownership change and provides financing at a later stage of the innovative process. (vi) The last actors are the *industrialists* who have the knowledge to manage large-scale production, marketing etc. If

one of these actors is missing, the whole development can fail to materialise. A system perspective is thus necessary[7].

In the next two sections (II and III) we will follow the two cases NobelBiocare in Sweden and AcroMed in Ohio, US. Focus is on the inventor, the receiver competence by the customer, the entrepreneur, access to venture capital, industrialisation and the market (i.e. diffusion, imitation, spill-over and competition) when describing the evolution of the firms we study.

II. Case I. Nobel Biocare

In this section we will follow the Swedish invention of a titanium chamber and screw used in the human body for replacing, in its first application, the loss of teeth. The unique idea behind this invention is the ability of titanium to integrate with bone tissue, hence the dental implant (or any other implant using the same technique) will be permanently attached to the bone once implanted. Later on the invention has been diffused into various kinds of applications, such as bone-anchored hearing aids, facial construction and other kinds of prostheses and implants in the human body. Bringing the invention to the market has not been easy, as we shall see later on.

NobelBiocare was officially started in 1981, but the innovation that the company is built on had been under development since the early 1960's. Nobel Biocare is a medical device company in Sweden with a leading position in the world market for dental implants (Homepage Nobel Biocare). Nobel Biocare's products support different markets within the health care field developed through research based on the Brånemark technique, which has resulted in more than 40 doctoral dissertations and 750 scientific reports (Williams, 1992). In 1997 the company had more than 800 employees and invoiced sales totalled SEK 1068 million (Nobel Biocare, 1997). Nobel Biocare is today[8] a world leader in dental implants with a world market share of over 40 percent.

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[7] A system can be defined as "an organised or connected group of objects. A set of things connected, associated, or interdependent, so as to form a complex unity; a whole composed of parts in orderly arrangement according to some scheme or plan; rarely applied to a simple or small assemblage of things" (Oxford English Dictionary).

[8] After the acquisition of Steri-Oss in 1998 (Nobel Biocare, 1998; Nobel Biocare, Press Release, 1998).

The main production of Nobel Biocare integrates two different techniques, each responding to a different business area.[9] (i) The Brånemark System, the original business develops and markets components for dental implants. An important supportive activity within the Brånemark business area is to provide information and practical training in the field of osseointegration. (ii) Procera[10] is an industrial technique for the production of dental crowns, made of ceramic and titanium. There was also a third business area within the Nobel Biocare, (iii) Cranio-Facial Rehabilitation and Audiology (CFRA). Based on the Brånemark osseointegration technique it supplies implants for facial prostheses and bone-anchored hearing aids. The CFRA is since May 1999 no longer provided by Nobel Biocare. Today it is only the hearing aid, Bone Anchoring Hearing Aid (BAHA) left in this business area. The hearing aid is based on the principle of hearing by bone conduction. The sound waves are transported to the inner ear in the form of vibrations via the cranium. Nobel Biocare is currently the only company on the market with this kind of bone-anchored hearing aid.

A. From Idea to Innovation

In the late 1950's Brånemark was working with bone studies at Lund University in the Laboratory of Vital Microscopy. Among other things the team was working with a titanium chamber in a rabbit's ear to be able to overview how bone heals[11] by studying the blood circulation in bone and marrow. It was during this time, in 1956, that Brånemark and his team made the discovery that titanium could bond with bone. After months of studies of the rabbit's ear Brånemark wanted to remove the expensive optical titanium chamber. It turned out to be impossible. The bone had grown into the threads and vices of the chamber and it looked like the metal had become completely integrated with the bone.

[9] Originally Nobel Biocare was set up to market and manufacture dental implants but the field of osseointegration has so many applications that in 1985 a separate development company under the leadership of Erik Ahlberg was set up. This was, however, affected by management changes and was later reabsorbed into the dental business. In 1990 a separate unit was set up to deal with oral applications. This led to the bone anchoring hearing aid device and commercialisation. Much of the development of new components has taken place at Brånemarks' own workshop at the Institute for Applied Biotechnology.
[10] This technique was developed by an outside Swedish company that Nobel Biocare acquired in 1988.
[11] The process of bone regeneration. For this Brånemark won considerable acclaim (Williams, 1992).

Later on, in 1960, Brånemark was carrying out another study, this time on humans. He had now moved to Gothenburg University to take up a professorship at the Department of Anatomy. He was studying blood cells in humans when he realised that titanium is accepted by soft tissue. Brånemark had also, in his bone studies, come to the conclusion that bone had to be treated with the same delicacy as tissue and that it had a limited capacity to withstand damage.

Brånemark knew that in order to understand the mechanisms by which bone integrates with titanium, he would need to carry out more in-depth studies and that he had to recruit help outside the medical field. It was during this time that he came in contact with Richard Skalak[12]. Skalak investigated the properties of titanium from an engineering point of view. He also helped out with designing suitable titanium components and devices and testing them. The research team started to carry out dental implants experiments on dogs in the early 1960's. Much of the 1960's was devoted to establishing the conditions under which titanium could be accepted by the body, developing equipment and components, learning about the interaction between titanium and the biological process. The National Institutes of Health in the United States, supported most of the early basic research of the bone and marrow for several years.

During the late 1950's and the beginning of the 1960's it was not uncommon for physicians to cross disciplines. Plastic surgeons were working together with orthopaedists, especially on severe traffic victims. Therefore, the first patient who was treated in 1965 had a severed dental problem and was born with both his chin and jaw deformed.

This was a job for both the orthopaedists and the plastic surgeons. The operation was successful but no further operations were carried out until after one year of follow up. From the beginning it was not at all obvious that Brånemark would work with dental implants; other ideas were discussed such as hip or knee joint replacements.

To succeed a number of supporting speciality competencies had to be developed: (i) The discovery from the 1950's that titanium bonds with bone. (ii) The idea that bone needs to

[12] An American engineer and now a professor at the University of California. At this time he was doing a sabbatical year at Gothenburg University.

be treated with the same delicacy as any other tissue in the human body. (iii) The properties of titanium itself being especially biocompatible. (iv) The design of the titanium components and the importance of manufacturing them in a clean environment. To this comes (v) the surgical technique. Today the technique of osseointegration is widely spread and used in various areas in the human body.

B. Customer Resistance

During this time, the beginning of the 1960's, Brånemark had a small practice in Mölndal outside Gothenburg. Brånemark explains "We started to commercialise the dental implants and we were doing some complementary research on humans but we had some serious trouble getting the dentists to accept the results that we came up with". Initially the dentists were against Brånemark's implants. Among the dentists, osseointegration was looked upon with mistrust. This prevented the penetration of the idea and the impact that this invention could have in this area for a long time. Therefore, there were only a couple of cases and only the most difficult cases from traffic injuries and the like that ended up at the orthopaedic department that could be treated with the method. The surgeons were more receptive. Already in 1967 facial prostheses became possible, and in 1977 the first patient was given a bone-anchored hearing aid.

The experience from earlier mistakes may have prevented the acceptance of Brånemark's new method of implantation among the dentists. The idea to replace teeth is not new. Already in 1809 a device was used, usually leaving the bone and tissue in worse condition than before the treatment (I. Izikowitz, 1961) At the end of the nineteenth century, young girls and boys were paid to have their front teeth removed for immediate implantation into the jaw of wealthy recipients. Long term success was rare (Williams, 1992).

One of the major problems that Brånemark was facing was customer resistance.[13]Brånemark contacted the local mayor and the local dental school where he

[13] One can argue that the real customer is the patient but in order for the patient to be aware of the possibility of osseointegration the dentist has to be able to perform or at least send the patient to someone who masters this method. The first obstacles are the dentists who had to be convinced of the methods superiority over other available options like prostheses. If the dentists do not accept this method they will

was living, but he met nothing but resistance. Finally the dentists even made some attempts to stop the commercialisation of the screw. In 1974 a group of dentists turned to The National Board of Health and Welfare[14,15] and required a full investigation to stop this foolishness, as they called it.

The National Board of Health and Welfare selected 20 patients. Their records were examined closely. The outcome of this investigation was that this was a valuable innovation (Socialstyrelsen, 1975). The National Board of Health and Welfare approved the product in 1976 (Socialstyrelsen, 1976). This means that the osseointegration technique was approved by the Swedish healthcare system and that it was accepted by the National Insurance System. This opened up the possibility to treat a large number of people.

The major breakthrough came in 1982, at a conference in Canada. There another researcher, also a doctor, George Zarb showed in a replication study that he got the same results as Brånemark. This led to the full acceptance of the osseointegration technique, and after this everything went fast. Other companies started to form and competition was now a fact. From 1982 on Brånemark started to visit many centres around the world in response to an increasing demand. Several researchers came to Sweden where they were trained in the Brånemark method.

C. The Entrepreneurial Stage

Already in 1978, Brånemark set up the Institute for Applied Biotechnology to carry out further research and development in the osseointegration field. More than once he was challenged by the authorities and put under threat of complete closure[16] due to, among other things, financial constraints. Therefore, Brånemark also set up a private clinic.

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act as gatekeepers and hence not permit their patients to undergo this kind of treatment. This makes the dentists a key group for the acceptance of the innovation.

[14] Socialstyrelsen

[15] The National Board of Health and Welfare is comparable to The Food and Drug Administration (FDA) in the US.

[16] The first dental implants were carried out on dogs and when the experiments was done and monitored the Swedish Medical Research Council told Brånemark to kill the dogs. If this had been done, valuable data would have been lost. The Council told Brånemark to cease that particular line and start something else (Williams, 1992).

In the beginning, critical components, such as the screw attached to the bone was made by hand by a former watchmaker, Victor Kuikka. He had the skills to work with the precision that was needed to make all the small details of the screw. He also worked out most of the titanium components' design and the medical instruments used in the surgery.

But it soon turned out that Brånemark had to find another way to produce the components in order to be able to meet the increasing demand for the product. When the Institute for Applied Biotechnology was set up, Kuikka had already retired and had passed the manufacturing over to Einar Jörgenson who played a central role in setting up production at Nobel Biocare.

Brånemark was thinking of several solutions for how to go from small to large-scale production and he was thinking of giving a license for the large-scale production to an existing company that he had contacts with, Astra. However, this was not successful and Brånemak soon looked for another company, AGA. This was arranged by Ove Brandes[17] and a lawyer. But not long after the co-operation, AGA decided to go back to its core business and Brånemark had to look for yet another partner.

Ove Brandes knew that the CEO at Bofors wanted to go into the medical technology industry, broadening its business. At this time Brånemark had a lot of trouble raising money for the production and the commercialisation of the dental implants. Brånemark had thought about selling the license for the patented hardware because he did not want any changes in the design or the quality of the components. The funding from The Swedish Medical Research Council[18] that he received initially would only support research. Bofors had the knowledge to produce small and precise components and was therefore a suitable manufacturer of the screw. However, Bofors did not have any previous experience in the medical industry. Bofors decided to set up a subsidiary company to market and manufacture the titanium screws and associated equipment. Thus Nobel Biocare[19] was founded. Even though Nobel Biocare was officially started in 1981, the company had received its first orders already in 1978[20]. Even so, the first

[17] Ove Brandes is a professor in business studies at Linköping University, Sweden.
[18] Medicinska Forskningsrådet
[19] Originally Nobelpharma. The company changed its name to Nobel Biocare in 1996.
[20] During the co-operation with AGA and Astra.

product was not delivered until 1980 due to major production obstacles that had to be overcome.

D. Capital

It was due to "budget money" that had to be spent that led to the first results and research in the osseointegration field. This was shortly after Brånemark's arrival to Gothenburg. It was in the ending of the budget year and in order to get the same amount of research funding the following year Brånemark was asked if he needed money for some project. Ha said he could always use some new instruments for his project in the field of osseointegration.

Lack of money and people willing to take risk was a major obstacle in the commercialisation process for a long time. Brånemark had several projects going on and often he had to use money from other studies to continue with his bone studies. The Brånemark Institute was mainly funded by the Swedish State through the Swedish National Board of Industrialism and Technical Development[21] and from the Swedish Investment Bank (Brånemark Institute for Applied Biotechnology, 1983).

Once contacts had been established Bofors were willing to set up a production of the implant devices and commercialise the license. Nobel Biocare was set up as a subsidiary company within the Bofors concern. Now the capital problem was solved but then the company was facing other problems with the production and commercialisation of the products.

E. Industrialisation

As stated above, the commercialisation process (before contacts with Bofors was established and even a bit after) went slowly. It was not until 1982 that everything started to turn around. The first step was to convince the dentists of the superiority of the

[21] Formerly STU now NUTEK.

Brånemark method. The conference in Canada supported this step. The next step was how to go into large-scale industrial production.

Once Nobel Biocare had agreed to market and produce the devices they built a production plant for this purpose in Karlskoga. But the production was delayed by several circumstances. In the beginning a specific oil, which turned out not to be bio-compatible was used for the machines. The oil could not be removed from the devices once they were made and therefore other solutions for the machines were necessary. Another problem was that the first devices were not sufficiently precise and the production was delayed by six months. The factory was finally operational in 1984, the same year Nobel Biocare set up an American subsidiary.

Nobel Biocare also set up a training centre within the company. In the beginning, Brånemark himself taught and trained the physicians and the dentists in the osseointegration technique. The company did not sell to anyone that had not been trained in the osseointegration technique. A certificate from Brånemark was required in order for the physicians or the dentists to be able to buy the products from the company. Today the osseointegration technique is taught at schools of dentistry and is regarded as part of standard procedure.

Communications between Brånemark and Nobel Biocare have been tense from the beginning and it is no secret that Brånemark has been unhappy with how Nobel Biocare has handled things. Nobel Biocare has chosen to concentrate on dental implants while Brånemark wanted the company to look for new applications. This is also part of the explanation behind the Brånemark Osseointegration Center. The institute was set up with funding from The Swedish Industrial Development Fund[22] in 1989. The Brånemark Osseointegration Center set up its first training centre outside Sweden in 1989 and has a lot of co-operation with researchers in the field of osseointegration world-wide regarding all sorts of implant applications. At Brånemark Osseointegration Center, research is carried out for other applications, such as for arms, legs, joints etc, all based on the same method, osseointegration. Several vendors are used for the production.

[22] Industrifonden

It took a long time for Nobel Biocare to show a profit. It was not until 1988 that the company was self-sufficient. This can be explained by several factors. First of all, Brånemark had no, or little experience in the medical technology industry. There was little experience in how to respond to the attitude from dentists and physicians. Also, knowledge about how the health care sector works was lacking. Over the years a number of CEO's have managed the company. Initially there were also production obstacles to overcome. In 1985 a new president, Leif Ek, with previous knowledge from the health care market was appointed. The new managing director also created better communication with Brånemark and the direction of the business took another course.

F. Broadening the Market – Diffusion, Imitation, Spill-over and Competition

The first patients who benefited from the osseointegration technique were those suffering from severe dental problems. Already in 1965 patients were successfully treated with dental fixtures. The osseointegration technique offered teeth that looked and felt like natural teeth. Nobel Biocare is today doing business in more than forty countries.[23]

Osseointegration is now an established part of dental practice in many countries. Hundreds of thousands of people have been treated. A growing sophistication in design, improved aesthetics and simplicity of the technique has allowed an enormous range of dental problems to be overcome, from the loss of a single tooth to complete edentulism. In 1989 the FDA suggested that dental implants should be subject to full regulation under Class III devices.[24] This gave Nobel Biocare an advantage compared to their competitors. Nobel Biocare is the only company that has clinical documentation with follow-up time with five to twenty years (Nobel Biocare, 1989). In 1990 no dental implant system had received approval from the FDA and yet more than 30 systems were on the market. Nobel Biocare was a first mover and the first one to get FDA approval. However they were quickly met by competitors.

Osseointegration brings many benefits for both the patient and the health care provider. It has led to a shorter time for treatment and the time spent for healing has decreased

[23] The Japanese FDA approved the products in less than four month after the first contact in 1988. The Danish authorities did not approve the devices until 1989 despite the clinical success in Sweden.
[24] See further in the case of AcroMed for an explanation of the classification system by FDA.

drastically (Läkartidningen, 1977). This has also reduced the overall costs, thus opening up the possibility of treating more patients. Today the osseointegration technique has become routine in many areas such as dentistry and facial reconstruction. In some instances, alternative therapies such as plastic surgery are not suitable for rehabilitating patients. Osseointegration can play a significant role in these cases. Already in the early 1970's the first experiments attaching ear prostheses to the bone were carried out. The osseointegration system can provide a secure anchoring point for the prosthesis. In 1977, construction of hearing aids began, and in 1988 the design was approved by the Swedish National Social Welfare Board. Nobel Biocare launched and manufactured this product. In 1986, finger-joint replacement could be done based on the osseointegration principle and some earlier attempts by Brånemark and his team in the early 1980's. Göran Lundborg, a hand surgeon at Lund University, developed this. The first patient to receive a leg prosthesis with titanium screws was treated by Brånemark and his team in 1990.

The major beneficiaries of osseointegration are those who have lost one or more limbs. Even though research has improved the material from which the limbs are made, little has been done to the method of connecting it. Osseointegration provides a new method for connecting the prosthesis with the human body. This means that the prosthesis is directly connected to the skeleton via a titanium component. This eliminates a number of problems such as skin irritation, and it also gives a feeling of stability and security for many patients. Some patients can even feel what kind of surface they are walking on like grass or asphalt. Other procedures such a thumb replacement has been carried out, but this is a complicated issue taking into consideration the joints in the fingers.

A key factor in the diffusion of osseointegration technology has been international co-operation with educational institutions and other groups throughout the world. This work goes on at several levels. There are the Pioneer centres all around the world. They helped confirm many of the clinical findings originally discovered by Brånemark and his colleagues. These centres were vital in showing that consistent, reliable and repeatable results could be obtained by following the techniques laid down through osseointegration.

Another network is made up of the so-called co-operating centres. These centres work closely with Brånemark on a variety of osseointegration matters. Another co-operation is

called associates centres, a less formal link to the Brånemark Osseointegration Centre. Associated centres have been established world-wide providing professional training as well as treatment. These centres have also built up close relationships with hospitals and universities throughout the world. These networks have been vital in spreading the knowledge about the technique.

The Brånemark Osseointegration Centre was set up in 1990 as an international reference centre for osseointegration work. It complements the work done by the Institute for Applied Biotechnology founded in 1978 to carry out basic research in new materials, components and instruments associated with the osseointegration technique. The centre plays an important role in sharing experience and providing further training. This centre enables Brånemark to reach out to the research community. Several universities world-wide now offer osseointegration courses as part of their medical training.

Today there are many companies in the dental implant business, all dependent on the osseointegration technique. In 1986, Nobel Biocare got into a costly legal conflict in the US[25]. Nobel Biocare argued that Core Vent had infringed its patent but had to settle for a mutual agreement in 1989. Core-Vent and Osseointegration Technologies Corporation of America are two big competitors in the US. In Sweden Astra Tech Dental Implants have been on the market since 1989, partly because they were able to recruit an R&D director from Nobel Biocare. And in 1984 a university spin-off, P&B Research was founded to further develop a bone anchoring hearing aid (Bent Dalum et al., 1998). There are over 50 companies on the market today in the dental implant business.

In 1998 Nobel Biocare acquired the American company Steri-Oss. Steri-Oss is the US leader in dental implants. Through the merger, Nobel Biocare doubled its business in the US and now employs 1054 people (Nobel Biocare, 1998). Steri-Oss had sales in 1997 of more than $ 40 million. This can be compared to Nobel Biocare that had an invoiced sale totalled SEK 1068 million ($ 130 million) (Nobel Biocare, 1997).

In May 1999 Nobel Biocare set up a company with Novare and Swedestart to develop the CFRA business area**.** "An agreement has been reached with the venture-capital

[25] In 1996 Nobel Biocare's patent was invalidated due to withholding of evidence in the patent application (US Court of Appeals for the Federal Circuit, 1996).

companies Novare Kapital and Swedestart to transfer operations in Nobel Biocare's CFRA business area to a new company with the aim of financing the development and marketing of bone-anchored hearing aids and facial prostheses, as well as new products for hearing rehabilitation**.** Nobel Biocare will be supplying the staff and industrial expertise, as well as other operating assets via a non-cash issue. Novare Kapital and Swedestart will be supplying expertise and gradually contribute a total of SEK 30 M to the new company via a new share issue. These operations will not be consolidated within Nobel Biocare. The new company will have its headquarters in Gothenburg, Sweden". (Press Release Nobel Biocare, 1999).

Lately Brånemark has developed a new method for dental implants in co-operation with Nobel Biocare. The new patented method, called Brånemark Novum, means that a patient can have new teeth in place in a single day. The treatment time by the dentist is halved with the new method and the cost of treatment is reduced. Nobel Biocare is planning to start a commercial launch in the fall of 2000 (Press Release Nobel Biocare, 1999). Today Nobel Biocare has grown to a world leader in dental implants. Nobel Biocare holds currently 40 percent of the world market. The last three years (1999-2002) the turnover has increased with 25 percent every year. (Affärsvärlden, 2002).

G. Epilogue

In the spring of 2002 it was announced that Nobel Biocare had decided to initiate the establishment of a new Swiss holding structure. The board of directors of Nobel Biocare is convinced that there are significant benefits to the company to adopt a new Swiss holding structure. The holding structure will allow the company to optimise its corporate tax closer to standards of other multinational companies. (Press Release Nobel Biocare, 2002). True this new holding structure, Nobel Biocare will be able to cut the corporate tax to 20 –25 percent from the previous level of 44 percent. (Svenska Dagbladet, 2002). This means that the company will pay 90 Mkr instead of 150 Mkr in tax (Dagens Industri, 2002).

This new holding structure by Nobel Biocare and the reasons for doing so, supports our theory that the institutional settings are important for firm growth. This is an example on just how important they are.

III. Case II. AcroMed

AcroMed[26] is a biomedical device company with a leading position[27] in the world market for spinal implants. AcroMed was founded in 1983 by Arthur Steffee, a spine surgeon, and Edward Wagner, a businessman. The company is a surgeon-driven company. AcroMed's business area is in orthopaedics, where spinal implants in both stainless steel and titanium are used to treat a number of conditions. AcroMed has three different product areas for treating spinal problems and a fourth business area, medical instruments: (i) Cervical pathologies; (ii) thoracolumbar trauma and tumor; (iii) deformatory pathologies and lumbar degenerative pathologies and (iv) spine tools for the surgery.

Compared to the Swedish invention, the time from invention to innovation went fairly quickly, approximately two years, but then one can say that the osseointegration research paved the way as well as earlier methods of treating the spine.

The Variable Screw Placement, (VSP) plates and screws were designed and developed by AcroMed's founder Steffee. AcroMed had a market share of 25 percent and 120 employees at the end of 1997 and nearly $100 million in sales. In Scandinavia the market share was 90 percent in 1999. About one-third of total sales are domestic and two-thirds of the sales are overseas.

As in the Swedish case a number of actors have been involved in the formation of AcroMed. Even though we can identify the same type of actors (the inventor, the customer, the entrepreneur, the venture capitalist, the industrialist) in the two systems they act and behave in different ways. Finally, we will also look at the market i.e.

[26] Acro in Greek means extremity, peak as in acrobat, acropolis.
[27] This was true when the first contacts was established with the firm, in the spring of 1998.

diffusion, imitation, spill-over and competition recognised in the competence bloc theory.

A. From Idea to Innovation

The founder, Steffee, is an orthopaedic surgeon. Before the formation of the company, Steffee was Director of Orthopaedic Services of the Cleveland Spine and Arthritis Centre at Lutheran Medical Centre. He had pioneered a number of surgical techniques and developed new orthopaedic implant devices. Right before the start-up, Steffee was also affiliated with St. Vincent's Charity Hospital. He had also been working as a consultant and principal clinical investigator for a number of orthopaedic manufacturing companies.

Prior to Steffee's invention implants for the spine in form of a hook were available. The hooks could be used to straighten up the spine. But the hooks were not reliable since they could not be firmly attached. Further, they could only be used on a limited number of cases. During a spine operation in the early 1980's, Steffee discovered, while cutting off some bone in the lower part of the spine, that if he could put a screw in this particular bone he would be able to control the spine and hence cure the patient. The bone that he had to cut off was the bone that was used for the hooks, so if he took away this bone the existing implant could not be used. Another problem with the hooks was that it was hard to keep the bone between the vertebrae/discs fixed during the healing process. With the invention of the screw and the plate this was no longer a problem. The plates are screwed into the pedicle, which are two bars of bone on each side of the vertebra that act as side pillars of the spine.

Since Steffee is an orthopaedic surgeon, he was familiar with the screws and bone plates that already were in use for various kinds of fractures. He got the idea to try those, with the necessary modifications, on the spine. He knew that if he put the screw in the right place, there would be enough space for the screw to fix the bone plate, supporting the bars if necessary. But there was not much room for the screws to be attached to the pedicle, making this a rather delicate operation. Putting in the screw a little too close to the spinal cord creates a risk of damaging the nerves and leaving the patient with more problems and pain than before the operation. But if the surgeon instead places the screw

a little too far from the spinal cord, it will crack the bone. Therefore, a delicate technique, also developed by Steffee, is required for a successful surgery and outcome.

The problem with the original implants from the orthopaedists was that they did not suit the spines perfectly, since the spine has a limited amount of bone where the screws can be placed/attached. The bone plate that was used for fractures had holes for the screws so the implant could be locked, hence fixing the fracture. The holes on these bone plates did not match perfectly for the spine, since the distance between the bone (on each side of the spine) where it can be placed is rather precise. Therefore Steffee made some improvement on the bone plate and instead of the holes he made slots that would fit the spine better. The next important improvement that he made was placing the screw first. This makes surgery less risky (as explained above there is only a limited area were the screw can be inserted). Therefore he cut off the head of the screw making the first part of the screw suitable for metal components by making the machine thread narrower and leaving the lower part of the screw, the part going into the bone, untouched. After inserting the screw, the bone plate is placed over the screws and fixed with a nut. This technique is now known as "Pedical Screw Fixation".

In the initial phase Steffee developed the surgical technique using existing well known orthopaedic implants in stainless steel. The new surgical technique and the spinal fixation device consisted of slotted plates and the improved pedicle screw with a nut was marketed as the "variable screw placement" (AcroMed, 1990). In the beginning AcroMed used only stainless steel for the devices but by 1988 titanium was used as well. Stainless steel and titanium are never used together since this would create a battery effect in the body. Both of the materials have benefits. The titanium bar is stronger than the steel bar, but the steel screw is stronger than the titanium screw.[28]

Some patients may even be allergic to steel and then the titanium is used. Depending on conditions the doctor will choose one of them. Therefore, it all depends on what kind of injury or disease it is and also whether the implant should be removed or not.

[28] Titanium is stronger than steel unless there has been some damage to the material. As soon as something has to be bent or cut like when making a screw the steel will be stronger than titanium.

Titanium has two advantages over steel; First some people are allergic to steel and titanium is more bio-compatible. The other advantage is that steel interferes more with the Magnetic Resonance Imaging (MRI[29]) than titanium does. MRI is a special kind of X-ray that shows the nerves and the soft tissue. Today 60-70 percent of the company products are made of titanium. The customers seem to have a preference for titanium, especially the Japanese who use the MRI X-ray a lot. They also have a different view of the body i.e. Eastern medical philosophy where harmony is an important ingredient and therefore choose titanium, which is more biocompatible.

The screw and the plate work as a support for the bone while it is healing. In most of the cases the implants are left in the body; a second surgery for taking the implants out is usually not recommended. In 37 percent of the cases the implants are removed, usually if the patients suffer from the implant, e.g. a very thin person where the implants will protrude out of the body.

B. Customer Resistance – or Non Resistance

Initially the hospital allowed Steffee to use conference rooms and supplies. The hospital also allowed students to attend operations. He could even use the hospital machine shop for modifying the implants. The hospital was paid via royalties and was hence not a capital provider to the company. But the hospital or colleagues made no attempts to stop the invention. On the contrary, Steffee was encouraged to proceed with his ideas and to further develop them. The word was spread from mouth to mouth among the doctors about this new way of treating the spine and he got immediate acceptance among his colleagues.

In the start-up phase, Steffee had several ideas. However, none of them got FDA approval. When Steffee applied to FDA in 1982 for the pedicle screw and its devices the application was turned down with the motivation that it was too dangerous to put a screw so close to the spine. In 1984 FDA classified the pedicle screw as class III device,

[29] MRI is a way of getting pictures of various parts of your body without the use of x-rays, unlike regular x-rays pictures and CAT scans. A MRI scanner consists of a large and very strong magnet in which the patient lies. A radio wave antenna is used to send signals to the body and then receive signals back. These returning signals are converted into pictures by a computer attached to the scanner. Pictures of almost any part of the body can be obtained at almost any particular angle.

which prohibits marketing. However the FDA gave a hint that if the devices were referred to as a bone plate and a bone screw, a 1976 grandfather clause would apply (see below). But then the products had to be marketed as bone plates and bone screws. Of course, the company cannot prevent the doctors from using the product for some other purpose such as for spinal implants. Hence, the company applied for an orthopaedic bone device. This later on led to a great deal of trouble for the company. In 1993 a lawsuit was filed over the company's product.

According to the legislation, a new use for an old device requires FDA approval. This is based on a law from 1976. But already in 1976 there were many rather complicated devices such as the pacemaker on the market, which did not have any pre-market approval. Since the law cannot be retroactive it gave permission for devices that were already in use to be used for unapproved purposes, but not for marketing. This is the stipulation of the so-called grandfather clause. This means that devices are approved if doctors learn about them from other doctors or from journals and articles or in discussions with manufactures. In addition, they are unapproved if a doctor learns about them from marketing (Wall Street Journal, 1997).

In 1984, AcroMed got the implants approved as bone plates and bone screws. Hence they were not allowed to market them as spinal implants but as orthopaedic implants. In 1994 the FDA advisory panel recommended that FDA reclassify the pedicle devices as class II devices, which would allow marketing. In 1995 FDA cleared the first devices as pedicle screw devices. Now AcroMed could start market its products as for the purpose that they were developed.

Not until the summer of 1998 did the FDA finally approve all their products as class II devices, 12 years after the first application. This can be compared with Japan where it took the government institution only 6-9 months to approve the products. Plates and screws have supported arm and leg bones for 100 years, but Steffee came up with the idea of attaching them to the pedicles, an application of an already existing method that the professions welcomed (Plain Dealer, 1993a). The idea of implants was not new. It had been around for some time. In the early 1920's the professionals started with simple implants for arms and legs. In the late 1950's the science had moved on toward more complicated implants such as hip-replacements. In the late 1960's there were some spine

implants for more simple illnesses such as scleroses but nothing as sophisticated as the method introduced by Steffee.

On several occasions AcroMed has been accused of circumventing the law. The FDA administrator David Kessler, who took over in 1990, started a full-scale investigation regarding the marketing of the bone plates and the screw (Plain Dealer, 1993a). In 1992 the company got a warning from the FDA to stop promoting the spinal implants. They have also been accused of profiteering from a device that some patient say has damaged and injured them after a screw had broken inside the body[30] (Plain Dealer, 1993b). And as mentioned above, in 1993 a lawsuit was filed. In 1996 AcroMed agreed to pay 100 million USD to plaintiffs who claim they were injured by the company's products (Plain Dealer, 1996).

C. The Entrepreneurial Stage

In 1984 Steffee went to an orthopaedic conference where he made a presentation of his findings using the new technique on a few patients. This was the breakthrough for the company since AcroMed was prohibited to market the products as spine products. His colleagues were impressed by the good results. After the conference several other doctors expressed their interest in this product. Some doctors asked him if he could make some devices for them, so he did. At this time, Steffee was making the devices in the hospital machine shop. The acceptance of the surgical technique and the use of the plates and screws led to a quick diffusion to other orthopaedic surgeons and neurosurgeons.

Not long after Steffee's first patient was treated, he was treating more and more patients with his method and using the hospital machine shop for modifying the screws and the bone plates and the capacity to produce the devices was becoming insufficient. Steffee met a businessman, Ed Wagner, who had been in the venture capital market for a time. Wagner suggested that they should form a company based on this idea. And so the company was formed in 1983, less than one year after the first patient was treated.

[30] The initial system suffered from a 12 percent breaking range now reduced to 0,1 percent. A broken screw does not mean that the nerve will be damage (Plain Dealer, 1993a).

D. Capital

The new company was based on own money (Steffee's and Wagner's) and loans. Raising capital was the easy part; getting around the regulation was difficult. With the FDA approval of the devices as class III devices they could not market the screw and the plate as pedicle devices but had to market them as bone plates and bone screws.

As stated above, raising capital was the easy part. Venture capital has a long tradition in the US.[31] Already in the 1940's several venture capital firms had arisen in response to the need of new innovative companies which, due to their uncertain future, were unable to get bank loans. Experienced business people began to invest in these new businesses, usually the development of new technologies. In addition to capital they contributed with valuable experience and knowledge as in the case of AcroMed. Investments were typically exchanged for an ownership interest where the venture capital firm shared the returns earned when the company was sold.

In the case of Acromed, Steffee took a bank loan and together with shareholders Wagner supported the rest and also came up with valuable recommendations. The Edison Bio-Technology Centre (EBTC)[32] not only provided competent capital, initiated and presented qualified management, but went in with a partnership in research and development. EBTC also introduced AcroMed to CAMP Inc (another Edison centre) who assisted AcroMed with recommendations on titanium implant surface finishing and introduced them to the CAD/CAM technique as well as computer numerical control (CNC) machining.

[31] By venture capital we do not only mean capital but also the experience and knowledge that the venture capitalists provide.
[32] EBTC is a part of the Ohio Department of Development's Thomas Edison Program, which constitutes the backbone of Ohio's technology policy.

E. Industrialisation

In 1985 the machine shop was no longer effective since demand had increased. Different production solutions had to be decided. Wagner had contacts with people in the steel industry. After looking around a bit they decided to outsource their production. Co-operation with different vendors was established to achieve large-scale production/manufacturing. This probably also reduced the need for capital.[33] All distribution, however, takes place within AcroMed.

According to William Christianson[34] the reason for not producing the screws in-house was that they can charge a high price on the screw when they sell it and therefore they are not so dependent on the manufacturing cost. Vendors have been manufacturing the screw since the beginning and they still are.[35]

At the start Steffee trained all physicians who were going to use the implant and the company had a policy not to sell to anyone if Steffee had not trained them. These surgeons later on became the reference group and advisory board for the company, giving suggestions for improvement and of new products and they also trained other doctors in this technique, diffusing the knowledge all over the world. These doctors were the early adopters of this technique.

Over the years Steffee took an active role in performing surgery himself and giving lectures and seminars all around the world, in the US, Europe and the Far East. This resulted in increased foreign sales. AcroMed has subsidiaries in Holland and Japan, founded in 1989 and 1990, respectively. The company still feels strongly about education and acts as a sponsor for several workshops and for the training of physicians. Today the company is working with its fifth generation of the screw and the bone plate. [36]

Already in 1986, three years after the start, the company was self-sufficient. Based on a good idea a totally new market and a new industry were created. Before AcroMed there

[33] Before this co-operation was established Steffe tried to sell the company in 1984, but the price that he was offered was so low that he decided to make the company work.
[34] Vice president regulatory affairs
[35] AcroMed can break the contract when they like if the vendors do not answer up to AcroMed's quality demands.
[36] Until the summer of 1999 when the company will move to new facilities in Massachusetts.

was no such thing as a spinal market. Orthopaedics was divided into four major groups: hips, knees, fractures and soft goods. Spinal devices were placed under fractures. Today, spinal devices alone are the third largest group and the fastest growing field in orthopaedics. AcroMed made its transition from a fledgling company in 1991 with $25 million in sales to a firm approaching $100 million in sales in 1996. In 1996 AcroMed employed about 150 people and supported another 150 jobs through suppliers and manufactures who provide products to AcroMed (EBTC, 1996).

Wagner once said that he had made two good business decisions; the pricing of the screw and the early market move. However the start-up process was not free from obstacles. A problem that the company encountered was that it took such a long time to get approval for a product in the US compared to Europe. For instance, the company had several products that were approved in Europe but not in the US.

The company also gained from the EBTC who supported the company in the early phase with business and technical help and advice.[37] AcroMed made two major changes due to the EBTC involvement. They established a quality board of directors and they were able to acquire a chief executive who had a solid business background (EBTC, 1996).

As in the case with many start-up businesses, friends and relatives ran AcroMed in the initial phase. As a former CEO William Steffee,[38] said; "I could have stayed in the CEO post and pounded away and not even known what problems I was in. We now have a combination of strong business leadership and an experienced board of directors. It is the unusual physician that can jump in and run a very profitable business. They (EBTC) were of considerable assistance in showing how this company could grow. They presented ideas and visions far beyond anything my medical career and training had prepared me for." (EBTC, 1996 p.14).

Another interesting concept that the company is using is the so-called AcroLink. AcroLink is a global interactive PC-based tele-conferencing network. With this the surgeon can consult with another surgeon so that they both have the same X-ray picture

[37] This is a two-way interaction. The relationship works in booth ways. William Steffe is an active member in the EBTC's board of trusties.
[38] William Steffee (also a medical doctor) is the brother of the founder Arthur Steffe.

in front of them and communicate over the telephone. This also facilitates interactive consulting since one of them can use a marker while giving suggestions or information.

F. Broadening the Market – Diffusion, Imitation, Spill-overs and Competition

AcroMed's business area is in orthopaedics, where spinal implants are used to treat a number of conditions. The company has four different product areas for spinal solutions and AcroMed also provides spine tools for the surgery. An interesting approach is that, since the beginning, the company has established good connections with famous surgeons in the spine area. A good proof of this success is the variety of products that has been developed through this co-operation. Isola®, a leading implant system for surgical treatment of scoliosis, is one example of this. It was developed by Marc Asher of the University of Kansas. The company does business in more than thirty countries.

There is a strong network involving the surgeons in the field, and conferences are important in spreading the new ideas. AcroMed has worked closely with the Edison Polymer Innovation Corporation (EPIC) and the university of Akron in developing an artificial replacement for spinal discs. Another point is how important it is for the company to have connections with the surgeons for feedback on their products. Nowadays AcroMed does not provide education on their system but they have a training room set up for surgeons interested in their products. AcroMed is also donating instruments and implants to various medical schools.

Expansion world-wide began with Europe in 1988 and in 1989 with Japan. The information and knowledge about the company and its products was spread from mouth to mouth (from doctor to doctor) and also via international meetings and conferences.

Both the products for and the surgical technique in the spine originally thought of as inoperable or associated with too high clinical risks grew from a market less than $6 million in 1984 to over $60 million in 1989 (AcroMed, 1990). Steffee originally thought this was a small field within orthopaedics, so small that the big companies would never produce these products. In 1985 the company decided to focus only on spinal products, narrowing its original focus to develop a variety of unique and proprietary orthopaedic

implants. There are a lot of benefits to the patients who can now be treated for various kinds of injuries that did not have any solution prior to Steffee's innovation.

When the big company Sofamore-Danek[39] made copies of AcroMed's products they agreed to give them a license instead of going in to a law fight. AcroMed did not have the resources to put on a fight and they made a misjudgement about the market, which they thought was only a small segment but still big enough for two players. Sofamore-Danek is a world leader in spinal implants. AcroMed was the second largest firm in its field until the acquisiton by DePuy Inc. in March 1998 (Press Release DePuy Inc, 1998a).

In March 1998, DePuy acquired AcroMed for 325 million USD (Plain Dealer, 1998). DePuy was founded in 1895 and is a market leader in the global orthopaedic industry. It is the world's oldest orthopaedic company and one of the leading designers, manufacturers and distributors of orthopaedic devices and supplies. It produces a line of artificial joints for hips, knees, shoulders, elbows, ankles and wrists (Homepage DePuy,). DePuy entered the spinal implant market in 1993 through a joint venture with a German firm, Biederman Motech. DePuy had a profit of 123 million USD in 1997 and sales of 770 million USD (Plain Dealer, 1998).

Thomas J Oberhausen[40] said the acquisition combines two market leaders to form the second-largest spinal implant company in the US and in international markets. Spinal implants are clearly the fastest-growing segment of orthopaedics (Press Release DePuy Inc, 1998b).

Just a few months later Johnson & Johnson[41] acquired DePuy (Press Release Johnson & Johnson, 1998a). As a result of the acquisition, DePuy has become a direct, wholly owned subsidiary of Johnson & Johnson. Ralph S. Larsen[42] termed the acquisition: "a very important strategic addition to our world-wide orthopaedic business". (Press Release Johnson & Johnson, 1998b).

[39] In 1993 The Danek Group Inc. acquired Sofamore a European company.
[40] Chief financial officer of DePuy.
[41] Johnson & Johnson is the world's most comprehensive and broadly-based manufacturer of health care products. Johnson & Johnson has approximately 180 operating companies and 92 000 employees.
[42] Johnson & Johnson board chairman.

The first of December 1998 it was announced that DePuy AcroMed would move from its Cleveland facility to a larger, modern Johnson & Johnson facility in Raynham, Massachusetts, in the summer of 1999. This strategic move was designed to place DePuy AcroMed in the neurological business as well as the orthopaedic business (AcroMed-DePuy, 1998).

AcroMed's competitor Sofamore-Danek was acquired by Medtronics in November 1998. Medtronics was founded 1949 in Minneapolis, Minnesota by Earl E. Bakken and Palmer J. Hermundslie. It is one of the world's leading companies in medical technology, specialised in implants and interventional therapies but also big in neurology (Homepage Medtronic). "The merger with Sofamore-Danek considerably broadens and strengthens Medtronic's market position and technology in the spinal and neurosurgery field, said William W George" [43]. (Press Release Medtronic, 1998). This means that there are now two giants competing against each other in the spinal field.

G. Epilogue

After the acquisition of AcroMed in March 1998 buy DuPuy, Acromed - DuPuy offer a variety of products. Their main products are hip and knee implants. Through the merger, spinal implants will become the single largest product group answering for about 20 percent of AcroMed - DuPuy's business. Today (2002) DePuy AcroMed is an operating company of DePuy, Inc., a Johnson & Johnson company. It is one of the world's leading designers, manufacturers, and suppliers of orthopaedic devices and supplies with its headquarter in Raynham, Massachusetts in US. In 1999 the company had a turnover of 1, 3 billion dollar and has approximately 400 employees and is expecting to continue growing (Homepage DePuy).

IV. Summary and Comparison

In this paper we have focused on the function of the competence bloc, with respect to the commercialisation of products (technologies) from an individual firm perspective.

[43] Medtronic's chairman and chief executive officer.

We have compared two companies in the titanium industry. The cases revealed that the firm growth was faster (in the initial phase) in the US case, AcroMed, than in the Swedish case, Nobel Biocare.

Nobel Biocare was set up to market and produce the dental implants built on the osseointegration technique. The osseointegration technique was discovered in the 1950's by Brånemark. Its first application area was dentistry. Today the osseointegration technique has been recognised in many other fields. Now it is possible to provide life-like facial features based on similar titanium anchors used for teeth for those who have suffered facial damage through accident or disease. The technique is used also in the field of hearing aids.

AcroMed's key products are various kinds of spinal implants, in both titanium and stainless steel. The founder and inventor Steffee invented a particular screw that could be attached to the vertebrae during the healing period. This had never been done before. Before this product and method were introduced in the market neurology surgeons were the major actors in treating and healing back pain and scoliosis. Today orthopaedic surgeons are the major actors; the invention opened up a totally new field of applications.

AcroMed was set up only two years after Steffee's discovery, while Nobel Biocare was officially started more than 15 years after the first patient was treated (more than 20 years after discovery). Even so, the companies were officially started at approximately the same time, Nobel Biocare in 1981 and AcroMed in 1983. Acromed was self-sufficient already in 1986 while Nobel Biocare did not break even until 1988. Part of the explanation is that Nobel Biocare is built on a radically new innovation while Acromed is built on an incremental innovation.[44]

But at the same time Nobel Biocare applied the new technology on an old market while AcroMed created or defined a new market using a known technique but in a radically new way. In this sense, Steffe's innovation was radically new. Both companies are now using titanium for their devices. They are both operating in a new, rapidly growing market but in different product areas within the health care market.

[44] The osseointegration technology had to be tested for long time before commercialisation was allowed while the long clinical testing did not have to be carried out to the same extent for the spine technique.

In the case of Brånemark it was the competence to understand the importance of the unexpected discovery that titanium bonds with bone and is biocompatible that led to a new industry. Furthermore bone has to be treated with the same delicacy as soft tissue (in the body). In the case of AcroMed it was during a surgery session that Steffee came up with the idea/invention of attaching screws to the vertebra. The inventors' competence to see the possibilities and applications, which is a highly individual capability, is one of the keys to success.

Another key ingredient in the innovation process is customers who understand the invention i.e. receiver competence. In the case of medical innovations the customer normally is the physician, acting as a gatekeeper for the patient who does not have access to the new invention if the physician does not accept or "buy" it. Even after clinical verification, Brånemark's method was met by disbelief from the Swedish dentists. One reason might be that the long history of unsuccessful trials with dental implants had coloured the professionals' view.[45] This, among other things, probably prevented an early market penetration of the dental implants. Among the physicians (orthopaedists and surgeons) on the other hand, Brånemark's method met acceptance almost at once. The use of facial prostheses started already in 1967, two years after the first patient had been treated with dental implants. But as late as 1974 a group of dentists reported Brånemark's method to the National Board of Health and Welfare where they demanded a full investigation. In 1976 the National Board of Health and Welfare finally approved the dental implants and included them in the National Insurance System.[46] It was not until 1982 at an international conference, where a Canadian physician presented a replication of the Brånemark method, that the professionals started to fully understand the potential and the benefits for the patient if treated with this method. Competing firms were immediately started in the US.

In the case of AcroMed the customer at once fully accepted the new method, introduced and developed, by Steffee. As in the situation of Brånemark, Steffee got the acceptance

[45] On the other hand, one could argue that the innovation should be accepted fast since it was a new solution on a well-known problem.

[46] One big advantage that Sweden has is that it is possible to follow patient over a long period of time. This is an extremely important variable in the context of competition. In USA you can only follow patient for 5 years and you have to be satisfied if you can reach 15 percent when you follow up. When the FDA proposed that dental implants should be classified as class III and that the company had to provide there own clinical trials, Nobel Biocare welcomed this. They were the only company that would stand for the new regulations since one of their strengths has been their interest in research and clinical follow-ups.

for his method at a conference, implying the importance of a well functioning network with receiver competence for reaching the customer.

Regulation is another important issue. Even though the National Board of Health and Welfare supported the Brånemark method, this did not help much in promoting the innovation. Steffee's method for treating the spine was at first turned down by the FDA in 1982. But when AcroMed sent in a new application form, only with the application area modified from the spine to the bone their product was approved in 1984. Not until 1998 did the FDA finally approve their products as spine products. The company has had several products that have been approved on the European market long before they were approved in US. AcroMed's major problem has been dealing with FDA regulations, which has been both time-consuming and costly. Consequently it is important that regulatory authorities fully understand (radically) new inventions.

Competent entrepreneurs who introduce the inventions into the market and commercialise the innovations are also important. In both cases studied have the invention stage been dedicated to clinical documentation, the design of the products and the medical instruments being used for the surgery. When demand was rising it was time for large-scale industrial production.

Despite the fact that NUTEK funded and supported Brånemark's research in osseointegration for many years the project had a constant struggle for money. More than once Brånemark was faced with the threat of having to close down his research. Lack of competent venture capital was a reality. By contrast AcroMed had no problems either raising capital or going from small to large-scale production (industrialisation). AcroMed uses outside vendors for their production while Nobel Biocare manufactures in-house. This increased the capital needed in the Swedish firm and made production less flexible. AcroMed relied heavily on equity capital. The founders (the inventor and entrepreneur) partly used their own savings to finance the venture. An existing large (and old) and well-known company mainly financed Nobel Biocare. Note that the company had no previous experience in the biomedical industry. This highlights two things. The transaction costs are lower when using own savings, compared to raising external funds, e.g. the inventor and entrepreneur did not have to spend so much time and resources on

convincing financiers. It is important that industrialists understand the use and potential of the innovation but also have the competence to promote and diffuse the products.

We can now sum up the two systems studied in this paper. The nature of the invention by Brånemark led early on to a multidisciplinary approach. Numerous fields were involved in the study of osseointegration and in the probability of titanium being bio-compatible. Nobel Biocare also benefited from the nearby hospital and university and one can say it is built on a university-hospital driven technique. This is true for AcroMed as well. As already mentioned not only did the researchers (Brånemark, Steffe and their co-workers) perform the basic research that was needed, but they also developed the medical devices and the medical instruments together with the surgical procedures. In both cases the network (the hospital, university, researchers and industry) has been of vital importance in the diffusion of the technique.

Both companies sold products only to doctors that had been trained in the surgical technique by Brånemark in the case of Nobel Biocare and by Steffee in the case of AcroMed, thus creating close ties between the company and the customers. One explanation for this is that the basic idea is that the companies are based on surgical techniques originally not taught in the formal education. Therefore they have also been heavily involved in education and development.

Apparently an incomplete competence bloc in Sweden has slowed down the introduction of Brånemarks' product compared to the US product. The incomplete competence bloc, further, has reduced the exposure of the innovation, to the varied competence in the evaluation process and, hence, raised the risk of missing an apparent winner. This is the most valuable insight from the two cases.

In summary we have identified two factors that can explain this difference. (i) We have seen that *lack of receiver competence* a negative attitude had to be overcome in the case of Nobel Biocare. Such lack of competence prevents the invention and innovation process from succeeding.[47] (ii) Another important factor is *access to competent venture capital* e.g. a simple way to commercialise industrially relevant results. It has also been shown that

[47] In the case of AcroMed regulations has been an obstacle to overcome. Receiver competence is important not only among the customer but among the authorities as well.

own equity is important for entry and growth of firms (Douglas Holtz Eakin et al., 1994; Thomas Lindh and Henry Ohlsson, 1996; David G. Blanchflower and Andrew J. Oswald, 1998). Thus, lack of competent venture capital as well as the regulation of the capital market has impinged commercialisation in the case of dental implants. Both receiver competence and venture capital are critical factors in competence bloc analysis.

We have shown that the growth of the Swedish firm was hindered by missing links (incompleteness) in the competence bloc. The study gives some policy implications: (i) *The receiver competence* is important and a broad and competent customer base increases the probability of success. Growth in the Swedish bio-medical industry can thus be enhanced by for instance increased competition in the Swedish market through deregulation and improved conditions for private entrepreneurs. (ii) Access to *competent venture capital* is also important. The deregulation of the capital market in 1987 was a step in the right direction. But, the ability to create fortunes through savings and productive entrepreneurship still has to be improved. (Ann-Marie Pålsson, 1998) shows that the accumulation of personal wealth is higher in the US than in Sweden, creating better incentives and opportunities to innovative entrepreneurship.

We have also seen an example on how important the institutional settings are. Some researchers have been warning for a Swedish emigration of companies if nothing is done about the high tax pressure in Sweden (Pontus Braunerhjelm (ed), 2001; Lars Jonung (ed), 2002) In the spring of 2002 it was announced that Nobel Biocare had decided to initiate the establishment of a new Swiss holding structure. One of the major reasons for doing so is that Nobel Biocare will be able to cut the corporate tax (Press Release Nobel Biocare, 2002).

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