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Innovation and Market Analysis of INGENASA

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Master of Science Thesis

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ABSTRACT

The purpose of this master thesis project is to identify the intangible resources needed by the biotechnology firm INGENASA to design technological innovations and markets. For this purpose, a theoretical method has been set-up to gather and analyse the information needed to obtain a good overall picture of key aspects of the knowledge based process in this company.

Our analysis indicates that the most critical intangible resource in the innovative process is the company knowledge in the scientific and technical field (e.g. know-how, experience and capabilities in different areas of science). Due the specialised nature of its business, the human capital is one of the most important intangible resource of INGENASA and the key drivers of the innovative process. Therefore, the success of INGENASA is highly depended on its ability to retain and attract qualified scientific and technical personnel. The development of future innovations will be depended on how well the company can manage to create marginal improvement of customer utility (e.g. reliability) by controlling certain parameters of its products such as their technical performance (e.g. specificity, sensitivity, etc), for example, by implementing and applying cutting-edge technologies (e.g. RT-PCR and phage display) and know-how. It will be important to continue creating customer utility of flexibility and efficiency through technical accessibility provided by INGENASA's technical support. The analysis indicates that the most important intangible resources needed in its current market are its brands, patents and contractual agreements with different parties. (e.g. clients, distributors and R&D partners). Also, INGENASA generates structural control based on three intellectual building blocks. The first building block is based on the biotechnical control consisting in patents to claim the key components (e.g. antigens), and their applications in veterinary diagnostic and disease preventions and contractual agreements with employees and R&D partners. The second building blocks is based on trademarks and trademarks rights used to communicate the value experience (e.g. reliability) to the customers and to claim its specific connection to the company. The third intellectual building block is based on commercial agreement with clients (e.g. food and animal firms, and govermental laboratories) and distributors in the diagnostic field to extract financial value from the invention and value proposition.

Our analysis indicates that there is a great window of opportunities for INGENASA in China due the high economical losses in the animal industry, specially in the swine industry, caused by infectious diseases. For example, until now there is not any advanced diagnostic product for porcine rotavirus in this market. When approaching this market, INGENASA can plan to acquire intellectual property rights such as patent rights concerned with antigens, method patents, or design patents to establish a defensive wall for business in China. For the long time development in China, it is necessary for INGENASA to acquire trademark rights and establish brand reputation in this market, which requires this company to get to know trademark system, the culture and customers. Secrecy protection is also of importance in this approaching process. When being infringed, firstly INGENASA can ask for administrative remedy that has become one important feature of Chinese system. In this approaching process INGENASA desires to take use of low labour cost combined with advanced technology to gain competitive edge. There are several entry models that INGENASA can choose such as exporting, licensing, establishing venture or purchasing venture. The analysis indicates that the appropriate entry models for INGENASA at the present stage are license or joint venture. In the way of license or joint venture INGENASA is able to cooperate with Chinese partners by contributing advanced technology to gain low cost labour, marketing network and other valuable local resources. How to balance the relationship with cooperative partner, establish structural control by keeping the leadership in technology, holding intellectual property rights all the time and designing contractual obligations are of significance for business in this market. By getting to know various customers and implementing effective marketing strategies INGENASA is capable to establish brand recognition in this market for long-time development. Being aware of some difficulties, INGENASA needs to pay attention to intellectual capital management and protection as well as other issues, for example, importance of connection and culture differences. In general, intellectual property rights, proper entry model, desirable cooperation partner, designed contractual relationship and customer strategies may enable INGENASA to become a successful actor in this huge market with great potential.

CONTENTS

1. INTRODUCTION

1.1 Background

Epidemics and diseases outbreak are constantly affecting the animal industry having economic and social implications of animal health. Therefore, disease centres and firms are developing new products and solutions for diagnosing, preventing and combating disease in companion animals or animals that provide us with food. One of such firm is the Spanish company INMUNOLOGIA Y GENETICA APLICADA S.A. or INGENASA.

INGENASA has 25 years of experience in the biotechnology field. Efter its creation in 1981, the company has gone through a serie of transitions to reach its current structure.

Table 1. History of INGENASA

Years	Description	Number of products*	Number of patents#
1981	The company was created, 63% own by INISA and 37% by Lab Sobrino, cooperation with Dr. Eladio Vinuela	0	0
1982	Operation at the Centre of Molecular Biology	0	0
1983	Own facilities	1	0
1985	The company was bought by Explosivos Rio Tinto (ERT)	1	4
1992	Fusion of ERT, the new company ERCROS, period of economical crises	1-2	18
1994	New owners, 100% private ownership, new business strategies	10-12	25
1996	Noack, expansion into the European market	10-12	31
2006	Global approach, expansion into the Chinese market.	75	62

* commercialised products

granted and filed patents

Today, INGENASA is dedicated to research, development and commercialization of products for veterinary diagnostic and infectious disease prevention, specially noticeable ones causing important economic losses in the animal health sector. INGENASA has contributed to the "Eradication Programme for African Swine Fever Virus" in Spain and Italy, demonstrating that its diagnostic products and

techniques have been successfully used. By putting together a team of effective and qualified personnel in different areas, INGENASA has been able to convert its scientific effort into innovative products. Spain is INGENASA's main market, however, its goal is to target a global market. Today, 30% of INGENASA's products are sold outside Spain, currenly it is commercializing its products in Portugal, USA, Australia, Argentina and it has commercial representatives in several other countries. The scientific success of INGENASA has been demonstrated in more than 62 granted patents and 72 scientific publications. The company has financed its activities by revenues obtained from its products (2.2 M Euros in 2005) and govermental and European funding (0.4 M Euros in 2005).

Even, when INGENASA has reached an established position on the Spanish market, and it is strengthening its position in European and non-European market, there is an increase competitiveness that INGENASA faces on this marketplaces. Therefore, the company may need to look into new strategies to maintain its competitiveness, for example, focusing on its intangible resources. However, even, when INGENASA has been aware of its intellectual capital for its success and it is willing to implement an Intellectual Capital Management system (e.g. MERITUM), non extended work has been made to identify the intellectual capital of INGENASA.

1.2 Purpose

The absolute purpose of this study is to identify the resources that are of intangible nature, also not included as physical and financial capital, that maybe essential for the value creation process of INGENASA; also elements that are critical for the design of its technological innovations and markets. The idea is to subsequently measure and control these intangibles to help INGENASA to maintain or enhance its competitive advantage or attain its strategic objectives. This study will be an important contribution to INGENASA because it can be the first step in the process of implementing an IC management system (e.g. MERITUM model), serving as a base for future IP activities. The identification process of the intangibles elements/ key drivers will be accomplished by performing an analysis, consisting in three parts: the first part aims to analyse the company's innovations; the second part aims to analyse current market; and

the third part aims to analyse a potential market and business opportunity. The different intangibles will be revealed during the three steps of the analysis. The methods described in the next section of this study will be used as a model for information gathering and analysis.

1.3 Methodology

The basic methodology that has been used to fulfill the purpose of this master thesis is built on three parts or steps set-up by us: systematized method selection/development, information gathering- phase one, and information gathering – phase two.

Step 1: systematized method selection/development

A method that can allow a systematic step-by-step analysis was either chosen among existing methodologies (e.g. TEVA[1], Porter's five forces analysis[2], etc.) or developed by us to fit part of this study (e.g. future market analysis). A Techno-Economic Value Analysis (TEVA) method was chosen among existing methodologies to overview the process of constructing innovations and current market to identify the intangibles resources used during these processes. To identify the intangibles needed to penetrate a potential market (e.g. Chinese market), a step-by-step method was set-up.

The key steps of the TEVA in this study will be:

- Tech – Economic Analysis (TEA)
- Market Analysis
- IP Position Analysis
- Structural Control Analysis
- Business Strategy Analysis

For the analysis of a potential market, we have set-up an approach consisting in lining-up different aspects that can be crucial for the success of the planed business. The potential market will be the Chinese market due its window of opportunities and each aspects connected to this market will be analyzed and evaluated. We will put an extra focus on the intangibles and mechanisms that are

[1] method or model to design technological innovations and markets which has been developed at the Centre for Intellectual Properties studies (CIP) and Innovation Engineering and Management at Chalmers University of Technology, Gothenburg, Sweden.

[2] Porter, Michael E., Competitive Strategy: Techniques for Analyzing Industries and Competitors.

needed to open-up this market.

The key steps of the future market analysis will be:
- Market overview and potential business opportunities
- IP control
- Business models
- Issues connected with proper business model
- Industry/market analysis
- Potential problems

Step 2: Information gathering – phase one
First, a general notion of veterinary diagnostic and INGENASA was obtained by reviewing information available from different sources including technical/ scientific books, homepages, dictionaries, and scientific reviews. A general overview of INGENASA was obtained from INGENASA's homepage, its patents, its product catalogue (online-version) and documentation presented to BSI for the certification of ISO9001:2000. To review the competition in the diagnostic field, we scanned for competing companies and products, competing companies' K-4 documents, annual reports and news. ELISA technical guides published by IDEXX laboratories and KPL provided us with information of the ELISA system. Information of the European and Chinese patent law systems were obtained from EPO and Sip's websites, respectively. The information collected during this phase was implemented and analyzed by the method chosen in step 1, to give us a more general view of INGENASA's innovation and market.

Step 3: Information gathering – phase two
A deeper understanding of the activities of INGENASA, innovations, and IP resources, and of the Chinese market was obtained in this phase. The information needed to perform the analysis was gathering mainly from interviews and questionnaires with top managers at INGENASA (CEO at INGENASA), heads of the R&D department, and head of the quality control department, technology project managers and scientists within the area in question. Collected various materials and information in Chinese, conversations with Chinese lawyers including Miss Cu, Miss Gu, officials of veterinary management station as well as Chinese businessmen helped us to understand the Chinese intellectual property

system, practice, Chinese market and business system. The case study developed by RICARDIS was kindly supplied by Carmen Vela (confidential document). The research project "application of phase display" funding by Torres Quevedo helped us to understand the importance of this new technology for INGENASA (confidential document). The paper published in the Manual of Standards for Diagnostic Tests and Vaccines by R.H. Jacobsson, 1996 gave us an overview of the most important technical performance parameters of a diagnostic product (e.g. ELISA).

2 INNOVATION ANALYSIS

The purpose of this section will be to identify and determine key components, parameters, technologies, and knowledge in the process of design technological innovation by applying the first step of the TEVA analysis, also TEA.

2.1 The innovative products

It is important that we clearly define the areas of innovation that are the based for core business of this company in order to be able to identify their critical intangibles, key drivers and strategic technologies that are involved in the process of value creation. According to the document submitted by INGENASA to the standard organisation BSI[3] and the information found on its homepage[4], INGENASA leverages biotechnological innovations mainly in five areas including diagnostic products, vaccine products, services, linea food products and patents.

Diagnostic products

This is a line of innovative products divided into serological- and molecular biology kits. The serological kits have been developed to detect a certain component in serum[5] usually a specific protein (e.g. antibodies or antigens), and the molecular biology products are used to detect DNA or RNA[6] from an infectious agent (e.g. virus or bacteria). Both lines of products have been commercialised mainly for the detection of infectious diseases in animals.

Serology kits: INGENASA has a long list of serological products in its product catalogue indicating that this company has concentrated major of its R&D effort on the development of serology kits. Also, the serological products are covering more than 25 pathological conditions among 7 different animal species (see table 2), and they are the major source of income for INGENASA. This company has accumulated experience and skills during the course of the years in developing, designing and manufacturing these products, therefore this knowledge is one of the key drivers in the innovative process. This knowledge has allowed this company to be highly specialised in the diagnostic field, indicating that this is one

[3] General information of INGENASA presented to BSI for certification of the normative ISO 9001:2000. (in Spanish). Intern document
[4] www.ingenasa.es
[5] Glossary from ASHA; www.ashastd.org
[6] ASHA; www.ashastd.org

of the most important intangible resource of INGENASA. The serology kits produced by INGENASA can be divided into enzyme-linked immunosorbent assay (ELISA), and immunocromatographic assays. The ELISA system used by INGENASA is described in detail in section 2.2. The immunocromatographic assay is a fast assay which doesn't take more than 15 minutes to be performed, it is simple, and the result is reported either as positive or negative result.

Table 2. Animal species and infectious agents or diseases targeted by INGENASA.

Animal species	**Infectious agents or diseases**
Porcine	Parvovirus, coronavirus, erysipela, Aujeszky disease, reproductive and respiratory syndrome, rotavirus, african swine fever, and classical swine fever.
Bovine	Brucelosis, tuberculosis, paratuberculosis, leucosis, infectious rinotracheitis, respiratory sincitial virus, viral diahorrea, and rotavirus.
Ovine	Brucellosis, and rotavirus
Equine	African horsesickness, rinoneumonitis, and arteritis.
Rabbit	Rabbit hemorrhagic disease
Feline	Panleucopenia, leukemia, immunodeficiency, and infectious peritonitis
Canine	Parvovirus, coronavirus, ehrlichiosis, leishmaniosis, distemper, filariosis, and lyme disease.

Molecular biology kits: This line of products is not as extended as the line of serological kits and only few of these products are fully developed and have reached the market. The implementation of molecular biology in diagnosis of an infection is considered a new area of the veterinary diagnostic, which is still under development, therefore their acceptance in clinical diagnostic has not been as strong as serological kits. Right now, INGENASA is commercializing eleven molecular biology products (e.g. INGENE- LSH, campylobacter, salmonella, mycoplasma, gumboro, laringotraqueitis, marek, PPV, PRRS, and Newcastle) and is putting great effort to design and create new molecular biology products. INGENASA has acquired know-how in recent years to push the development of the molecular biology kits, and today the company has in the pipeline more than ten products (e.g. influenza virus, lawsonia, pneumo-virus, etc).

Vaccine products

The ideal is to have in the product catalogue vaccines complementing each diagnostic product in order to diagnose and prevent the most common infectious diseases affecting the animal industry or companion animals. The line of vaccine products has not been as extended as the line of diagnostic products due the high development and commercialization cost of vaccines. Vaccine's projects at INGENASA belongs to more long-term projects or businesses since they need more resources than diagnostic products to obtain a final products. INGENASA is current commercializing two vaccine products (e.g. PPV and CPV vaccines), to which it has patent protection. INGENASA has developed a new method to reconstruct nucleic acid-free viral particles that allows the production of a new generation of highly immunogenic and very safe vaccines. This method can be considered a strategic technology due the great market potential of vaccines produced by this method.

Innovative services

INGENASA provides services mainly in the form of diagnostic services, and investigation or research by contract. The diagnostic services are divided into services based on serological analysis (e.g. CDV IgG, HER, LSH, and FCV) or molecular biology analysis (e.g. LSH, PRRSV, PPV, campylobacter, salmonella, mycoplasma, etc) of the samples. The main clients of the diagnostic services are the animal-food industry, and veterinary clinics because that do not have own diagnostic laboratories. The investigation by contracts is a service that is provided mainly to biotechnology companies located in Spain and abroad, however, this has not been a common activity at INGENASA. The research by contracts is based on the company know-how and it aims to fit the needs of customers requesting the service. For example, the service can consist in identifying, designing, isolating or purifying antibodies, antigens, or other proteins, mainly using techniques and methods that are used in the daily routine of the company. Among clients utilising INGENASA's investigation by contract services are well-known and prestigious biotechnology firms and research intitutes including Campofrio, Prodecros, Serono, American Cyanamid, Agrolabo, Syva, Pharmamar, CSIC, and CEVA-Philaxia. INGENASA has a valuable resource in the form of knowledge that is being capitalized by providing services.

Patents

INGENASA is considered patents as products because a patent can be sold or licensed, therefore can generate revenues as any physical products developed by the company. Patents are described in details in section 3.2.3 of this thesis.

Linea food products

This is a broad line of products covering animal health products aimed to detect pathogens (e.g. Transia cards E.coli, Transia card Salmonella, VIT-E.coli, VIT-P.aeruginosa, VIT-Legionella, etc), gluten (e.g. INGEZIM Gluten and INGEZIM SEMIQ), micotoxins (e.g. Transia plate Fumonisina, Transia plate Ocratoxina, etc), alergents (e.g. Egg Residue ELISA, Milk Residue ELISA, Soy Residue ELISA, Hazelnut Residue ELISA, etc), and others. Some of these products are developed (e.g. INGEZIM Gluten and SEMIQ) by INGENASA while others are not (only commercialized by INGENASA).

Others products

INGENASA is commercializing in Spain even diagnostic tests for agriculture (e.g. Cry2A Quickstix, Roundup Ready QuickStix, etc) and pesticides (e.g. Cyanazine, Paraquat, DDT, etc).

Product Development

A serologic product at INGENASA go through a serie of steps (shown in figure 1) of development before it is ready to be commercialised. For example, the antigens and antibodies in the serology kits are designed and developed by the "Department of Genetic" and the "Department of Cell Culture", respectively. Thereafter, the antigens and antibodies are packaged into a final product at the "Department of Development" where it is addressed different parameters that can affect the assay performance. Optimal concentrations/dilutions of the antigen adsorbed to the plate, serum, enzyme-antibody conjugate, and substrate solution are determined through 'checkerboard' titrations of each reagent against all other reagents. Additional experiments determine the optimal chemical, and physical variables in the protocol, including incubation temperatures and durations; the type, pH, and molarity of diluent, washing, and blocking buffers; and equipment used in each step of the assay. Selection of the cut-off (positive/negative threshold), and caducity test (the sell-by date on the kits and its compounds). During this process, it is written the description of the assay,

and the book of production. Thereafter, the assay has to be validated and approved by a Reference Center (laboratories set-up by the Ministry of Agriculture) before it can be commercialised.

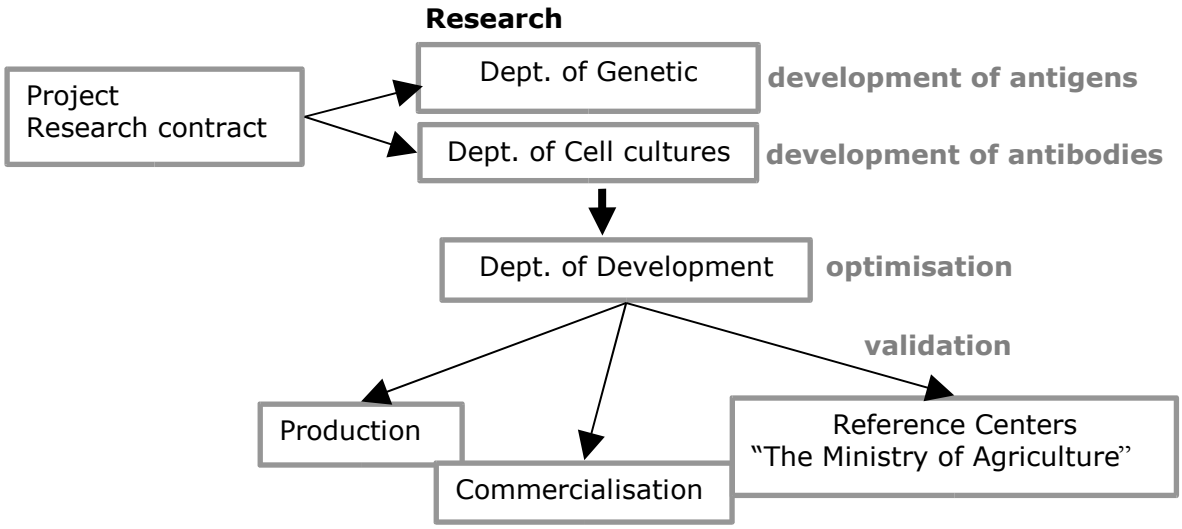

Figure 1. Stages of the development of an ELISA product at INGENASA.

INGENASA is implementing a strategy based on short- and long-term product developments or businesses (shown in figure 2). The short-term product development consists in the developing of products for veterinary diagnostic, including easy-to-use products, which required in some extend less effort in R&D and may not need to be registered to be commercialised. Great part of the revenues generated by these products are invested in long-term product development, specially vaccines, which required a longer R&D effort and higher cost in registrations (e.g. patent registration and others) and development. The results of these products including patent, technologies and partly of the revenues are reinvested in short-term project to generate new products.

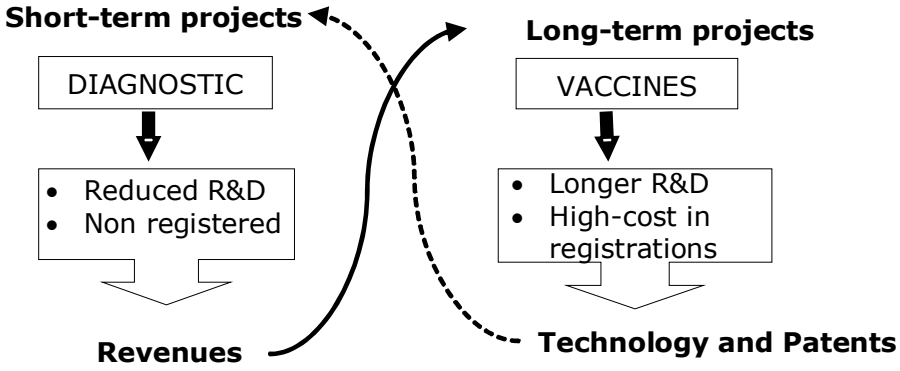

Figure 2. Strategy for the development of diagnostic and vaccines products at INGENASA.

2.2 Identification of technologies and sub-technologies supporting the products

We will focus our analysis on technologies and intangibles that are supporting the serology kits since they are the main line of products commercialised by INGENASA. By checking INGENASA's product catalogue, we found that INGENASA has built its diagnostic products mainly by the ELISA and molecular biology technologies such as PCR and RT-PCR. These technologies/ techniques have not been invented by INGENASA, but by others. However, even, when they are widely available in the field of biotechnology and diagnostic, they have been adopted and applied by INGENASA in an innovative way in its products.

The majority of the serology products found in the catalogue are based on the ELISA technology. We have read different technical and scientific sources[7] to define the function of the technical system supporting the ELISA technology because this is one of the first step of the TEA analysis. We have summarized and simplified the main function of the ELISA system as a technology intended to "detect and measure antigens or antibodies in a sample "[8]. After reviewing INGENASA's products, we found that this function is the only function of the ELISA system used by INGENASA. The knowledge, skills, and experience of the personnel at INGENASA on the ELISA technology have been crucial in the developing of diagnostic products in this company. The know-how in R&D,

[7] Example: BioGlossary at www.everythingbio.com;
[8] An antibody is a protein produced by a host (e.g. human body) to bind to, and thus inactivate, foreign particles. These particles are called antigens.

development, quality control, and production are working together to combine their skills to obtain a final product; being one of the most important intangible resource in the innovative process.

ELISA technology description

The ELISA technology has been widely adopted in the medical and veterinary diagnostic laboratories because it is one of the most powerful diagnostic tool available today according to text books found in the field of microbiology and immunology (e.g. Microbial Pathogenicity). The technology is commonly used to identify the cause of an infectious disease, enabling a physician or veterinary to select appropriate therapy. INGENASA has developed ELISA -based products which can detect and quantify antigens and specific antibodies in a sample; commonly proteins that are good indicators of an infectious disease in the affected animals. INGENASA is dedicated to perform R&D to find these indicators which have been the key elements in its products. According to the information found in the product catalogue and based on our interview with the person responsible for quality control at INGENASA, INGENASA has developed two types of ELISA products, ELISA DAs and ELISA Vet.

ELISA DAs: This product is delivered in a format ("microplate") that is convenient for clinical testing laboratories, allowing the testing of up to 96 samples per microplate (96-wells micropate). The microplate is a solid support and container where the diagnostic reaction occurs. The 96-wells microplate format is one of the most commonly used format today because it is employed conventional testing equipment found in virtually all clinical laboratories. This is considered the traditional ELISA, and commonly when people talk about ELISA, they mean this format. By using this format, INGENASA not only allows their products to be compatible with the instruments used in diagnostic laboratories, but also it is following the ISO normative for diagnostic products.

ELISA Vet: This product is a simplier version of the traditional ELISA, also the technical principle behind these two ELISAs are almost the same. The ELISA Vet is delivered in a format of a plate of four divisible strips of eight wells, the assay is faster to do than the ELISA Das, simple to perform and it is easily automatizable. This type of ELISA do not require an ELISA reader because it

gives a positive or negative result that can be distinguished visually.

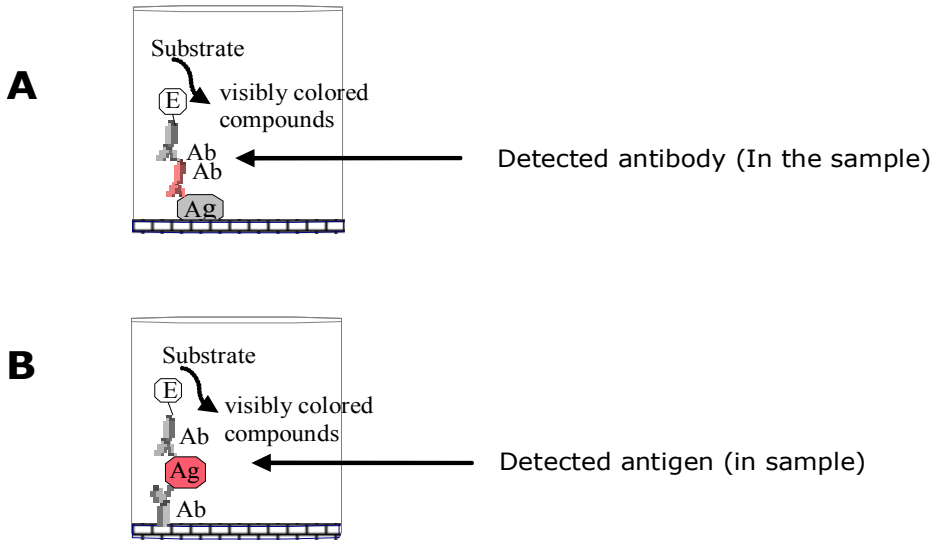

Figure 3. Basic design of the ELISA product produced by INGENASA. ELISA types designed to detect a specific antibody (A) or an antigen (B) . E = enzyme; Ab = antibody; Ag = antigen. The different components in the system are described in table 3.

There are different ELISA types (e.g. direct , indirect, double antibody-sandwich, and competitive ELISA) which are designed differently, but with similar applications and functions. It is out of the scope of this study to analyze the different types of ELISA systems, however, figure 3 illustrates the basics of the two most common types. ELISA is a technique very important in clinical diagnostic and INGENASA has the advantage to use it in its products. According to the book "ELISA: Theory and Practice"[9], what makes the ELISA technology different from other diagnostic techniques, is that it combines the specificity[10] of antibodies with the sensitivity of an enzyme[11]. The test has several steps consisting in the addition of a serie of components which result in the production of a color by the enzyme involved in the last step. The intensity of this color is proportional to the amount of the specific antigens or antibodies in the sample analyzed.

[9] Elisa: Theory and Practice by John R Crowther, 2005

[10] Definition: The statistical probability that an individual who does not have the particular disease being tested for will be correctly identified as negative. www. Medical dictionary.thefreedictionary.com

[11] MedTerms dictionary at www.medicinenet.com

Sub-technologies

To better understand a technical system in an innovation such as the ELISA system, it needs to be breakdown into sub-systems or components and sub-functions. It is important to identify the sub-systems in an innovation because by mastering one or more sub-systems, the company can improve its technical performances in order to increase customer utilities that create subjective experiences to customers. We reviewed the ELISA technical guides published by IDEXX laboratories[12] and KPL[13] as help to identify the sub- systems/ components and sub- functions of an ELISA -based product. Table 3 summarized the sub-systems/ components and sub- functions of an ELISA system built for the detection of antibodies (illustrated by figure 3 A). The sub-components of ELISA products produced by INGENASA are either developed by its R&D department or purchased from third parties. The staff at the product development department has for function to put together these sub-components into a functional final diagnostic product, being a key step in the product development process.

Complementary technical systems

According to TEA, biotechnological innovations or services cannot be viewed in isolation because in order to provide any utility at all, they have to be consumed or used in combination with other products or services in an user system. The ELISA technical guides indicate that the most important complementary technical systems for the ELISA system DAs are the microplate reader, microplate washers, and pipettes. The functions of these complementary systems have been described by the manufacturers of these products; the microplate readers are used to measure the concentrations[14], microplate washers to wash the plates, and the pipettes[15] to measure the volume of the solution added during the test. Some of the factors affecting the selection of the complementary system are the number and types of tests and samples, technical training of staff and financial considerations. Probably the most complex, from a technical point of view, and price are the microplate readers. These complementary technical systems are widely available and have to be added or integrated into process so the ELISA DAs system can interact in an application that works in most of the diagnostic laboratories. The ELISA Vet system does not need these complementary

[12] ELISA technical guide, 2002, IDEXX laboratories Inc.
[13] Technical guide for ELISA, KLP Inc. ; www.klp.com
[14] Tecan, PelkenElmer, Biotek, etc.
[15] www.abbottdiagnostics.com/Glossary

technical systems**.**

Table 3. ELISA sub- systems/components and functions.

Sub – systems/ components	**Sub – functions**
Microplate	Capturing and fixing proteins (e.g. antigens or antibodies). The microplate serves as solid support and its obtained from suppliers
Antigen	Capturing specific antibodies. The antigen is produced in-house.
Specific antibody	Recognizing the immobilized antigens. The specific antibodies are in the patient sample.
Secondary antibody	Recognizing the specific antibodies captured by the antigen. Produced in-house and obtained from suppliers.
Enzyme	Catalyzing the production of visibly colored compounds from colorless precursors substrate. Obtained from suppliers.
Substrate	Producing a visibly colored compound* by being catalysed by the enzyme. Obtained from suppliers.

* The intensity of the visibly colored compounds is measured by a complementary technology.

2.3 Economic value of technologies

The next step in the analysis is to try to access the economical potential and properties of the identified technologies.

Key technologies/ components

Key technologies are technologies that differentiate competitors on the marketplace since they influence the product performance that are linked to specific customer utilities or cost parameters. By reviewing the sub-components used in the ELISA products, we found out that each sub-technology or component in INGENASA's ELISA products are purchased from third parties with the exception of its antigens and specific antibodies which have been designed and produced in-house at INGENASA's laboratories (two examples are shown in table 4). These specific antibodies and antigens are the key drivers in the creation of the innovation since competitors are not able to purchase them from theirs suppliers. To produce them are required skills, know-how and experiences

in a combination of different areas of science that INGENASA possesses in-house or has access to it through joint R&D. INGENASA has used this knowledge to design and develop key components of its products by mimicking relevant antigens or antibodies of an infectious disease by using for example, recombinant DNA and molecular biology techniques. The R&D personnel has unique knowledge and experience in how to find these indicators. In the R&D department, there are nine what its called superior technicians whose are commonly PhDs that have under their responsibilities research projects aimed to find these indicators. Also, any technology that is supporting the development or production of new antigens and antibodies that can be applied to a new diagnostic product, can be considered a key technology for INGENASA (e.g. the expression system vacuoluovirus).

Table 4. Example of key components used in the products produced by INGENASA

Key component	Product name	Diseases
Antigen ORF7	INGEZIM ARTERITIS	Porcine reproductive and respiratory syndrome (caused by PRRSV)
Antigen VP2	INGEZIM PPV	Porcine parvovirus infection (caused by PPV) *

[a] PRRSV infection occurs in most major pig-producing areas throughout the world, the infection is characterized by abortions, stillbirths, and the birth of weak piglets that often die soon after birth of respiratory disease and secondary infections. Older pigs may demonstrate mild signs of respiratory disease, sometimes complicated by secondary infections[16].

[b] Porcine parvovirus (PPV) infection is the most common and important cause of infectious infertility. The virus multiplies normally in the intestine of the pig without causing clinical signs. It is distributed world-wide[17].

Pacing technologies

Pacing technologies are technologies that have the potential to influence the performance or production cost of an innovation, but have not yet been incorporated into the company's products or production processes. Efter been incorporated into the company, they could be considered strategical technologies since they can be used to gain competitive advantage on the marketplace. In this specific field, pacing technology can be, for example, any screening technology that can facilitate or improve the process to identify new target molecules such

[16] http://www.multiplex-eu.org/prrsv.php
[17] ThePigSite Quick Disease Guide; The pigsite.com

as cDNA library construction, peptide synthesis, peptide libraries, phase display, protein arrays, etc. These technologies can be useful because they can allow a rapid screening of a large number of samples to identify a specific peptide or protein. It is important to set-up a strategy consisting in scanning cutting-edge technologies that can be beneficial to the different departments and projects at INGENASA. The next step can be the creation of a technology acquisition strategy at INGENASA consisting, for example, in recruiting high skill personnel or in creating educational program to strengthen the employee's competence regarding these technologies. INGENASA has been aware of the importance of phase display in its future activities, therefore a research proposal was written in this matter[18] and funding was granted from the Spanish Ministry of Education and Science to recruit personnel that can implement the phase display technology in the company.

Phase display is a screening technique that allows the identification of proteins or epitopes that interact with a target molecule[19]. From INGENASA point of view, this technology can influence the development of future innovation by improving some of the most important technical performance of the ELISA system (e.g. specificity and sensitivity, described in more detail in section 2.5). INGENASA will be able to identify molecules with high level of specificity (e.g. antigens and antibodies) that can be used subsequently in the diagnostic products and vaccines. Neutralizing epitopes and neutralizing antibodies can also be identified to be used as components in vaccines. Phase display will facilitate INGENASA adaptation to the new European normative aimed to reduce the use of animals in biotechnology (Directive 86/609/EEC). It will open the possibility to replace or reduce the use of the hybridoma technique for the generation of monoclonal antibodies, which is restricted to mouse as an immunological host. It will provide cost reduction, time reduction; avoid complicated ethical issues, and reduction of applications to regulatory agencies. Knowledge and skills in phase display will be an important intangible resource to INGENASA because it may be adopted in different R&D activities.

[18] Research project "Application of Phage display" presented to the program Torres Quevedo from the ministry of Education and science, 2005.

[19] en.wikipedia.org

2.4 Competitive biotechnological positions

A competing technical system is a system that solves the same technical problem but utilises other technical means. Biotechnology's that have the function to detect specific antibodies or antigens in a sample could be considered competing technologies against the ELISA system. By collected information from the technical literature, company's homepages and by scanning technologies used in laboratory diagnostic, we found out that the most relevant competing technologies against the ELISA system are radioimmunoassay (RIA)[20], agglutination test[21], and the diagnostic chips (proteomics). RIA, agglutination and the ELISA have been compared in the "ELISA: Theory and Practice" as techniques that perform similar functions, therefore they have been classified as competing technologies in this work. We suggest that the diagnostic chips can be considered a competing technology due its wide range of applications and its potential to be used in the veterinary diagnostic field.

RIA

It is an immunological test that employs radioactive markers instead of enzymes and substrates.

Agglutination test

It is a test used for the detection of antigens in serum. A blood sample is mixed with a known antibody. Agglutination occurs when antigens are recognized by the antibodies that are present in the sample. The test has applications in blood grouping and diagnosis of infections.

Diagnostic chips

It is a diagnostic product that is based on proteomic technology. What makes proteomic different from other technologies is that it detects and analyses a wide spectrum of different proteins by one single analysis. The chip plays the function of a solid support similar to the microplate in the ELISA system. There is one type of diagnostic chip that is under development by the Swedish company Åmic (amic.se). The solid supports are more expensive than solid phase supports used in other diagnostic products (e.g. microplate). However, Åmic has for goal to develop a diagnostic chip that will have both price and performance advantage.

[20] thinkquest.org/library
[21] www.wordnet.princeton.edu

RIA and agglutination test are older technologies, while the diagnostic chip technology is an emerging technology. It could be said that ELISA system has replaced in some way the RIA, despite the latter already being established, extensively automated and sometimes more sensitive. This is because an ELISA product is relative cheap to operate, lacks the radiological hazards of RIA and is suitable for use in smaller laboratories that have not the facilities for radioactive counting. The agglutination test has some advantages against the ELISA technology since it has a low production cost, it is simple to perform, and does not require any instrumentation or electrical support. Also, agglutination test could be an alternative technology to the ELISA system to be used in resource-limited regions where stable electricity and infrastructure are lacking, and the cost of ELISA Das tests may not be affordable. INGENASA is using similar techniques in some of its rapid serology kits (e.g. INGEZIM ROTACROM) providing a test than can be performed in less than 15 minutes. One disadvantage of the agglutination test is that it is not a quantitative test, it is only qualitative. The applications of diagnostic chips and proteomics are broader than the ELISA technology since it can detect a larger range of different proteins in a sample by one single analysis. Right now, this technology is used mainly in research laboratories and in some diagnostic areas such as in cancer detection. From our point of view, this is the most serious competing technology to the ELISA system. But, even, when this technology enters the market of veterinary diagnostic in the next years, the adoption will be a slow and costly process for the following reasons:

- The diagnostic chips require complementary technical systems (e.g. scanner in the case of arrays) in order to interact in an application that works in a diagnostic laboratory. These complementary technical systems are at the moment more expensive than the complementary technical system needed by the ELISA Das system (e.g. ELISA readers).

- The production cost of the solid phase components used in the ELISA system

is lower than the production cost of the diagnostic chips. Most plates used in ELISA are either polystyrene or derivatives of polystyrene, which can be obtained from a large number of suppliers.

- It is difficult to overcome the already existing strong and widely adoption of the ELISA system.

However, even, when it is not a direct threat at this point, INGENASA should be aware of the potential threat coming from emerging technologies. Finally, how INGENASA faces the competition of these technologies in the future will be crucial for this company to maintain its position on the marketplace. Probably, it will be necessary to build relationships with companies that possess emerging technologies that could be incorporated into INGENASA's products or complement its current line of products. The joint R&D and technological relationships will be a crucial intangible resource to face competing technologies in the future.

2.5 Impact on performance, and producer cost

Technological performance parameters (e.g. specificity, sensitivity, repeatability, reproducibility, standarbility, safety, size, cost, compatibility, portability, and simplicity) indicate how well the technical functions are performed by a technical system and/ or sub-systems of a diagnostic product. Know-how in technologies that can help to master these parameters could be considered crucial intangible assets for a company such as INGENASA. To identify the most important parameters of the ELISA system, we have reviewed some publications written by experts in the field of laboratory diagnostic (e.g. Dr. R.H. Jacobsson, and Dr. Wright and coworkers[22]) . There are many parameters or variables that need to be addressed in the development process of a diagnostic product such as an ELISA based product, however, the specificity, sensitivity, repeatability, and reproducibility are probably the most critical factors to provide accurate and precise results. These parameters are crucial in the determination of a diagnostic product´s fitness for a particular use. If, for instance, the assay does not detect antibody with the same efficiency as other assays (depending of the degree of sensitivity), or the assay cross-react with other substances in the sample (depending on the degree of specificity) the assay is not suitable as a diagnostic product and it should be abandoned. Therefore, all these variables need to be considered and addressed during the product development.

[22] Wright, P.F., Nilsson, E., Van Rooij, E.M.A., Lelenta, M., Jeggo, M.H., Standardization and validation of enzyme-linked immunosorbent assay techniques for the detection of antibody in infectious disease diagnosis, Rev. sci. tech. Off. int Epiz. 12 (1993) 435-450.

Specificity

According to Jacobsson, there are analytical and diagnostic specificity. The analytical specificity is based on the degree to which the assay does not cross-react with other substances in the sample while diagnostic specificity is the proportion of uninfected reference animals that test negative in the assay. Also, the diagnostic specificity is calculated based on the control samples. The technical guia for ELISA from KPL Inc., describes that the antibodies are the key in the ELISA product and provide the basis for its specificity (and sensitivity). Antibodies can be incredibly specific because they can discriminate atomic differences between single amino acid substitutions in a protein. The specificity of the ELISA system can be influenced by designing new antigens and antibodies or modifying the existing ones. This can be accomplished by using molecular biology techniques, or by implementing pacing technologies.

Sensitivity

According to Jacobsson, there are analytical and diagnostic sensitivity. The analytical sensitivity is based on ability of the test to identify low levels of a specific antibody (or antigen), while diagnostic sensitivity is the proportion of known infected reference animals that test positive in the assay. Also, the diagnostic sensitivity exactly as the diagnostic specificity is calculated based on the control samples. The analytical sensitivity of an ELISA product is depending on several factors including the number of molecules bound to the solid support, the specific activity of the enzyme used in the system, complementary technical systems such as microplate readers, and the antibodies (and/or antigens). According to the technical guia for ELISA, the antibodies is the major factor determining the sensitivity of an assay.

Repeatability

The term repeatability can be defined as the agreement between replicates within and between runs of the assay. It should notice that this parameter is distinguished from reproducibility as defined below. The repeatability is dependent on the optimization of the reagents (e.g. concentrations/dilution's of antigen, serum, enzyme-antibody conjugate, and substrate solution), protocol and controls that allow an assay repeatedly achieves the same results. Optimal all the components used in the diagnostic product are determined by testing each

reagent against all other reagents, following confirmation of the best choice. Several microplates, each with its different binding characteristics, to minimise background activity are tested. Additional experiments determine the optimal temporal, chemical, and physical variables in the protocol, including incubation temperatures and duration's; the type, pH, and morality of dilugents, washing, and blocking buffers; and equipment used in each step of the assay.

Reproducibility

Reproducibility of the assay is determined in several laboratories using the identical assay, including protocol, reagents, and controls. Also, this parameter is the degree of concordance between laboratories.

Standarbility

The standarbility is partly based on the quality of the substances used in the ELISA products, therefore, INGENASA has optimized the methods for manufacturing the substances to avoid variation of the quality of the substances between baches (preparations).

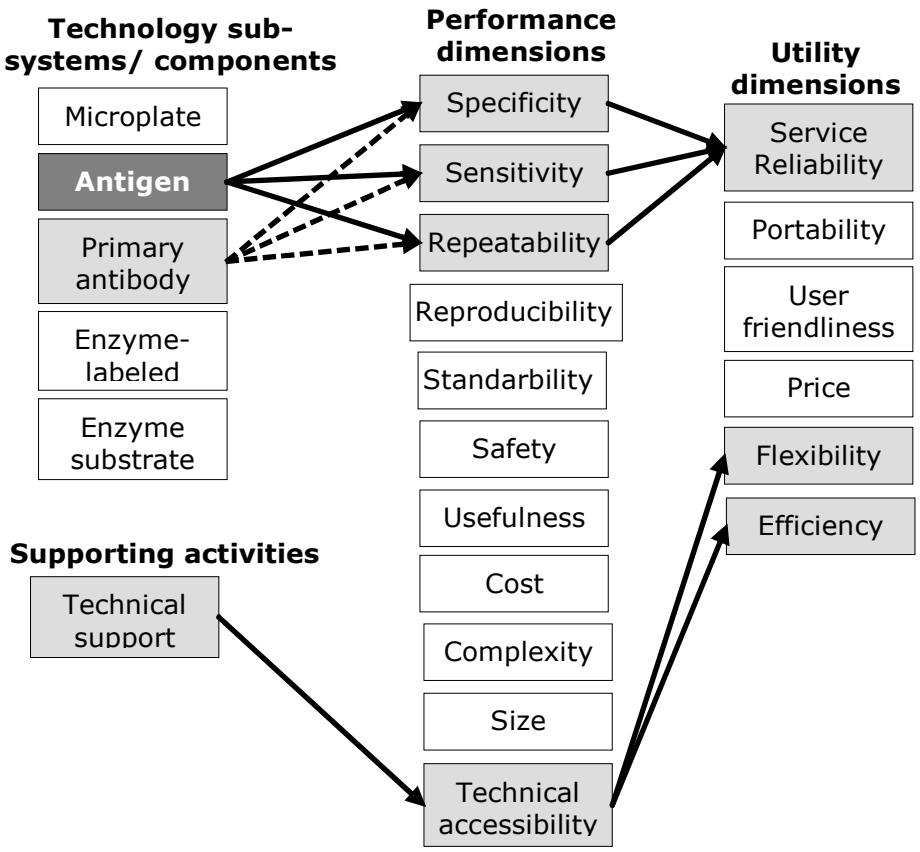

Figure 4. Framework for Biotechno-Economical Analysis of the ELISA system.

2.6 Utility dimensions and relations to technical performance

The customer utility can be defined as the pleasure or satisfaction of an individual from consuming goods or services. In general, the customer utilities related to a diagnostic product can be reliability, portability, user-friendliness, price, flexibility, etc. Some of these parameters can be excluded as utility dimensions for several reasons. For example, even, when the ELISA Das system is considered a technique that is easy to handle, it requires some degree of knowledge and skills, therefore it is operated only by qualified personnel (e.g. technologies, clinical laboratory technicians, etc). This excludes the user-friendliness as an utility dimension because the skilled personnel can handle diagnostic products with different degree of complexity. The price is another parameter that can be excluded as utility dimension because the price of an ELISA Das product is commonly between a certain range. Of course, there are always some customers that are more price-sensitive than others. However, even when the price of an ELISA product is higher than other less specific assays (e.g. agglutination test), the customers may be willing to pay a premium price for an ELISA product that can solve a diagnostic problem, specially if such

product does not exist in the market.

The variables described in previous section are probably the most critical factors to provide accuracy and precision in the ELISA Das product which in turn increases the confidence/ reliability on the diagnostic product. The TEA analysis indicates that the main customer utility of an ELISA Das product is the reliability it provides to its customers (e.g. diagnostic service providers, see section 3.1.3). The reason is that the services provided by the diagnostic service providers are based on and/or built-up by a product that provides accuracy and precision in its results. Without accuracy and precision, this group of customers will not be able to gain market recognition of their services. The diagnostic laboratories in the animal-food industry is another group that appreciate the reliability of the ELISA system used in their laboratories because their products have to pass strict quality controls from government agencies and to meet the expectation of consumers.

Another very important customer utility for INGENASA, that is not directly connected with the product but with the technical services supporting the product, is the flexibility and efficiency. There is a technical support and customers service unit at INGENASA that is committed to make it easier for customers by providing technical advices and help with trouble shooting problems. The services are worked in the form of consultations by phone, and alternative reagents and protocols can be facilitated to customers to make their products work. INGENASA can provide additional technical information of the products to their customers, and in some cases INGENASA can run the customers' samples to pintpoint the problem in their assays.

Based on the information of impact on performance, the reliability of an innovation can be increased by improving the technical performance parameters of specificity, sensitivity, repeatability, reproducibility, and standarbility. Figure 4 illustrates the connection between technology sub-systems/ components (e.g. antigens and antibodies), and these parameters and customer utility dimensions (e.g. reliability) of the ELISA system. By modifying and changing the design of a specific antigen by recombinant DNA technology, it is possible to find specific areas of the antigen that binds better and stronger to its corresponding antibody. This will provide better interaction between the two proteins, which in turn will

improve performance parameters that will increase the marginal utility to customers. Previous experiences in this type of work will be an important intangible resource for INGENASA.

2.7 Summary

We started the innovation analysis reviewing the different areas of expertise of INGENASA (e.g. diagnostic products, vaccine products, services, patent, etc) to identify key technologies and intangible resources needed during the innovative process. Based on the TEA analysis, we can suggest that INGENASA`s intangible resources and key drivers in the innovative process are depended on the company knowledge in the scientific and technical field (e.g. know-how, experience and capabilities of different areas of science). Due the specialized nature of its business, the human capital is one of INGENASA's most important intangible resources. Therefore, the success of INGENASA is highly depended on its ability to retain and to attract qualified scientific and technical personnel specialized in basic -, key-, and pacing-technologies. A key role is playing the development department and quality control units in the innovative process. From a technical point of view, the development of future innovations will be depended on how well the company can manage to control certain parameters of its products such as their technical performance and customer utilities through, for example, the implementation of pacing technologies (e.g. phage display) and know-how. The TEA analysis indicates that the key components in INGENASA's diagnostic products are the specific antigens and antibodies since they cannot be purchased from third parties; therefore they need to be designed and produced in-house. By mastering the design of these molecules, INGENASA can control some of the most important technical performance parameters (e.g. specificity, sensitivity, repeatability, reproducibility, standarbility) that can create marginal improvement of customer utility (e.g. reliability) that can be highly valuated by a specific segment (e.g. professional market). Also, any way of adquisition of the key components in the products are considered intangibles resources in the innovative process, including intern R&D, technology acquisition, know-how acquisition, joint R&D, etc. In this case the antibodies and antigens have been acquired by in-house effort applying different technologies (e.g. molecular biology techniques), know-how, and experiences. Finally, how INGENASA faces the innovative competition in the future will be crucial for this company. Its

intangible resources will be depended on relationship with companies that possess complementary technologies that could be incorporated into diagnostic products. Joint R&D and technology purchasing (e.g. licensing-in) may be crucial to face competing and emerging technologies in the future

3 CURRENT MARKET ANALYSIS

The market where INGENASA is operating, has been analyzed using the steps 2-5 of the TEVA analysis (described in section 1.3) with the purpose to identify intangible resources that need to be controlled in this market through, for example, IP positioning, structural control and business strategies.

3.1 Market analysis

3.1.1 Market segmentation analysis

The purpose of the market segmentation is to lower the risk of failure by defining, evaluating, and locating the segment of the total market since a small to mid-size company such as INGENASA can in no way mobilise all the resources required to target a total market. Market segmentation can serve to answer a number of important questions such as "is INGENASA targeting the right performance parameters in the development process?", or "which sub-technology do this company need to master to target a specific segment?". The key drivers and intangible resources identified by the TEA analysis in previous sections will help us to link the innovation with a specific group of current or potential customers. The current or potential market for a veterinary diagnostic product can be divided in different ways, for example, based on the category of the animal the product is intended for (e.g. companion and industrial animals) or based on the end-users of the products (e.g. professional and non-professional market). Since, there are diagnostic products that need to be operated by a person skilled in laboratory diagnostic or at least to have some minimal training in the product while others diagnostic products not, we divided the market for diagnostic products into professional and non-professional market. By clearly define the market that is targeted or will be targeted by INGENASA, a strategy can be set-up including intangibles activities that can help to approach or maintain the defined market.

Professional market

This market is formed by firms or entities (including institutes, clinics, etc.) that are performing laboratory diagnostic work by using qualified staff such as laboratory technicians or they have trained their personnel for diagnostic work.

We considered that the most important variables for the segmentation in this specific market are the demographic variables, which separates the market depending on type of industry, company size, and location of the operations:

Type of industry. The type of industry for diagnostic products can be divided into, for example, research laboratories (e.g. universities), clinical laboratories (e.g. in hospitals), and diagnostic service providers.

Company size. This variable focus on the company size or resources available in the laboratories that perform the analysis. It divides the industry into small-, medium-, and large-sized laboratories.

Location of operations. This variable defines the geographic location of the operation which in turn is based on the location of the animals affected by the disease and where is provided the veterinary diagnostic service for these animals. For example, the European swine industry is a proper target segment for diagnostic products aimed to detect the classical swine fever (CSF) since this industry has been strongly affected by this disease. CSF caused the loss of more than 11 of the 200 million pigs in Europe during its outbreaks of 1997/1998[23]. The economical losses in the swine industry has been estimated to more than 2 billions Euros. For this reason, the European countries need to monitor constantly for CSF diseases in their pigs, therefore making it a suitable market for CSF detection products. Among the European countries, Spain has been one country with the fastest-growing animal health markets, with sales up of more than 504 million Euros in 2002, being one of the most important market for veterinary products including diagnostic products aimed to detect CSF.

Non-professional market

The non-professional market is formed by end-users of the products that are not skilled in the field of laboratory diagnostic. For example, if the invention is a diagnostic kit that is broadly applicable, rapid, based on an on-site diagnostic test system and it doesn't require a person skilled in the field of laboratory diagnostic to perform or interpret the test, then the invented product is intended to a non-professional market (e.g. farmers, veterinarians, and companion animal owners).

[23] Questions and answers on Classical Swine Fever, Press releases from the European commission, Reference: MEMO/01/422, 05/12/2001. http://europa.eu.int

A diagnostic product can be developed for a segment of the non-professional market such as veterinarians to perform the test on the field, so they don't need to rely upon remote, centralized laboratories for the analysis of urgent samples. Mobile veterinarians do not have access to sophisticated machinery on-site, and remote laboratories require longer cycle times to report the results. The segmentation variables most relevant for this type of market are the geographic and/or demographic variables.

*Geographic***.** This variable is used to segment the market based on the region or country where the end-users of the products are located, which in turn are related to the location of the animals that are affected by the infectious diseases. In order to define this segment, it is crucial to have access to information regarding the geographical distribution of the diseases.

*Demographic***.** Even, when the end-users of the products are not persons ”skilled in the art” of the invention, he may has a professional background that is directly related to animal health care. This variable can be used to define and categorize the non-professional market into animal related professionals (e.g. veterinary, farmers, animal trainers, etc.) and non-animal related professionals (private persons/ companion animal owners), a sub-division can be made based on the occupation of the end-users of the products. The division of the market in this way can help the diagnostic company to create a strategy and to mobilize the appropriate effort to approach the target group. For example, it has been estimated that in Spain there are more than 21000 veterinarians (animal related professionals) [24] and several millions companion animal owners (non-animal related professional)[25] which can be potential customers for easy-to use products. However, even, these two groups can use the same diagnostic product, they may need to be approached differently.

In this section, the market for a diagnostic product such as INGENASA's ELISA product has been defined and divided into two major groups; in the next section, the defined market will be linked to the technical performance parameters and

[24] Atlas de la Sanidad en España, Instituto de Información Sanitaria, www.msc.es/Diseno/sns/sns_sistemas_informacion.htm

[25] Introduccion a la alimentación canina y felina - vision del mercado; XVI Curso de Especialización FEDNA. Ignacio Boixeda de Miquel. Friskies España S.A. Actually, Spain has approximately 3.4 millions dogs and 2.3 millions cats.

utilities identified by the TEA analysis.

3.1.2 Connecting the innovation with a market segment

A diagnostic product can target different market segment depending on the complexity of the product because its complexity may require a person skilled in the field of veterinary diagnostic to practice the invention or have some kind of practical training. In addition, the most important technical performance parameters of a diagnostic product is probably linked directly to a market segment. For example, if the most important performance parameters are the product's size, simplicity and production cost because they provide customers utility of portability, user friendliness, and price, then the product target a non-professional market. On other hand, if the most important performance parameters of the product are linked to customers utility such as reliability, are targeting in first place the professional market. According to the analysis, INGENASA is developing two type of diagnostic innovations; *first*, the dominating innovation in the company is in a form of an ELISA product (ELISA DAs) that is intended to a professional or industrial market for the following reasons:

- The end-users of the diagnostic product developed by INGENASA are commonly persons skilled in the field of laboratory diagnostic or have some basic training to perform the work who are commonly part of a professional market. They work in laboratories belonging to the service providers, food industry, clinics, etc.

- INGENASA has the know-how to master important technical performance parameters in the product such as specificity, sensitivity, and reproducibility which provide more customer utilities (e.g. reliability) in a professional than in a non-professional market. The reason for this is that the reliability of the product is highly appreciated in a professional segment such as the diagnostic service providers since their business is based on providing service reliability to their customers. To this group, the accuracy and precision of the assay are more important than others parameters such as for example portability, simplicity, and price. The professional segment is dominated by stationed laboratories so the portability is not an issue, the staff working in the professional segment are persons skilled in the field of laboratory diagnostic who are used to handle diagnostic tests of any kind, as well as simple as complicate tests, so the simplicity is not crucial. The professional segment is not price sensitive in the

same level as the non-professional market and they may be willing to pay a premium price for a test that is not available at the moment on the market so the price is not the most important parameter in this case. However, if the test already exist on the market, then the price may be crucial to be able to compete with the existing product.
- To perform the test with the ELISA DAs requires complementary technical systems such as the microplate reader which requires a minimum level of resources available; this resources exist mainly in the professional market.

Second, INGENASA is developing innovations in a form of easy-to-use diagnostic product (e.g., immunocromatographic assays sub-branded as INGEZIM ROTACROM, and ELISA Vet) that is intended to a non-professional. The list of easy-to-use products is not as extended as the list of ELISA DAs products.

During the process to design of a product and its market, it is crucial to connect the most important performance parameters with a specific market segment to know that we are developing or improving right parameters. It will important to perform market analysis and surveys among customers or potential customers to identify their main utilities and expectations on the products. INGENASA's commercial director and marketing personnel will be an important intangible resource in this matter due they close contact with customers. Furthermore, the quality control personnel will be an intangible resource due they have direct contact with the customers to assist them with technical problems. The existing database of customers feedback, questions, customers technical problems, etc. will be important to keep track of customer responses and complaints after sale of the product.

3.1.3 The actor system

Based on the information collected from INGENASA and different website in the field, we have classified the actors system of the European diagnostic industry into six main group of actors, including diagnostic service requesters, diagnostic service providers, diagnostic product manufacturers, diagnostic product distributors, regulatory bodies, and standardization bodies.

Diagnostic service requesters

The diagnostic service requesters consist of private animal owners, veterinary,

farmers, veterinary clinics, govermental laboratories, and the animal-food industry. In principal, to this group belongs all those actors in the markets that need to monitor infectious deseases in their animals but are not able to perform the diagnostic analysis by them self, therefore they need to purchase such services from a third party. The govermental laboratories are important actors since it is one of the biggest customer of INGENASA. The animal-food industry is one of the biggest actors in this industry, which consists of a very large number of increasingly diverse enterprises, but dominated by firms of the porcine-, bovine-, and ovine- industry. The largest enterprises in this industry has their own laboratories, while small- to mid size enterprices need to purchase such services from third parties. The animal industry is a big market for a diagnostic product because they produce more than 200 millions swine, 8 million bovine and 100 millions cattle per year[26] in Europe. It is very important to monitor routinely the diseases affecting the animals in this industry to take appropriate measures to prevent outbreaks, such as the once that affect the European swine industry in 1997/1998 by the classical swine fever (CSF). By continuously scanner the needs of this industry, for example, when new diagnostic products are needed to detect emerging infectious diseases, INGENASA can take the lead by developing the needed product and in this way take advantage of the windows of opportunity. Any mechanism that INGENASA can use to obtain appropriate information of this group, that INGENASA can use to develop new market and innovations, can be considered an intangible resource. The current relationship with these actors is an intangible resource.

Diagnostic service providers

These are laboratories whose main business activity is to provide services to the diagnostic service requesters. The diagnostic service providers have built a network of customers and diagnostic suppliers and have professional trained personnel to take care of the analyses, including INGENASA. The enterprises listed as diagnostic services providers in the industry section of the Spanish telephone directory are Alkemi, Hemo-Hidrolac, Biomaro, Labonor Ense, Laboratorio de Análisis y Control, Medidas Ambientales, A&B Laboratorios de Biotecnologia, Alicontrol, Biomaro, Fresenius Kabi España, Laboratorios Alfaro, Laboratorios Olea, and SPM Controler. INGENASA has built-up direct contacts

[26] European Union Livestock and Products Semi-Annual 2003; Foreign Agricultural Service, GAIN Report.

with these actors or indirectly through diagnostic product distributors.

Diagnostic product manufacturers

There are eight major diagnostic product manufacturers that are currenly commercializing their products in Spain and other European countries, comprising INGENASA, Svanova Biotech AB, IDEXX laboratories, Synbiotics, Institut Pourquier, Bommeli Diagnostic, Intervet Inc, and Hipra.

Diagnostic product distributors

In Spain, INGENASA is using only professional distributors to deliver the products intended to the companion animals because the end-users are more geographical spread (e.g. veterinary clinics). The diagnostic products sold to the animal-food industry and govermental laboratories (e.g. national veterinary diagnostic centres belonging to the Agriculture Municipal Departments) are delivered without using third parties such as the professional distributors, also by using only shipping companies. INGENASA has built-up also important business relationships with the Spanish animal-food industry and Spanish govermental laboratories. INGENASA use distributors channels that are loyal to the diagnostic industry to distribute all its line of products outside Spain. The list of European distributors of diagnostic products is long; with some distributors that operate only at a national level such as Proanco, Rodrisal, Ganavicola, Montlab, and TDI that distributes their products in Spain while others distributors target a more extended market. According to the document submitted by INGENASA to the standard organisation BSI, INGENASA has built-up relationships and contracts with a network of European and non-European distributors (shown in table 5), being this one of the most important intangible resource of INGENASA. These distributors are the link between INGENASA and the end-users of INGENASA's products.

Table 5. INGENASA's network of distributors

European distributors	Non-European distributors
Proanco, Rodrisal, Ganavicola, and Montlab (Spain), Noack (Austria, Polen, Hungry, Slovenia, Croacia, and Rumania), Trasco (Portugal), Agrolabo (Italy and Greece), Dolfa (Latonia), Interlux (Lithuania), and Biognosis (U.K).	Institute Rosenbusch (Argentina), BTI (Mexico), Agrovet (Chile)

Regulatory actors

The European diagnostic products market is governed by national and European Union regulations. For example, the national regulation and advisory bodies in Spain includes ”The Ministry of Agriculture” that regulates the manipulation of biological agents (e.g. virus, bacterial cells, and animal cells) and the use of laboratory animals. ”The Ministry of Industry” and ”The Ministry of Agriculture” regulate the production of zoosanitary products (e.g. animal health products). ”The Nuclear Safety council” (e.g. in Spain by CSN) regulates and give approval for the use of product containing radioactive material. These activities are essential for a biotechnology company in the diagnostic and vaccine field in order to be able to perform R&D activities. INGENASA has the approval of these regulatory actors to perform all the activities that have been mentioned above. Some diagnostic product need to be validated and approved by Reference Centers, which has been set-up by the Ministry of Agriculture.

Standardization bodies

They have the function to develop standards and standardization solutions to meet the needs of business and society with the purpose to improve the quality of life through the application of best practices. In the diagnostic industry, the standardization bodies are working mainly on implementing quality standards with the purpose to indicate which diagnostic products are meeting the quality level set-up by the their organisations. They put a lot of effort to promote and regulate quality management systems (QMS) that can be implemented by the diagnostic manufacturers. The most common QMS are the ISO 9000 and EN 46000 systems which aim to ensure consistency and improvement of working practices to provide products and services that meet customer's requirements. The standardization bodies are important actors in the diagnostic industry

because they can certificate the quality of the processes, products and services. The main objective of a diagnostic firm such as INGENASA to adopt a standard is mainly to have compatibility with complementing technical system and to indicate the quality of its products, and ways of manufacturing. INGENASA has implemented in the last couple of years the QMS system ISO9001:2000 which has been certified by the standards organisation BSI[27].

Figure 5. ISO certification of INGENASA

3.1.4 Industry analysis

The diagnostic industry will be analyzed by applying the Michael Porter's five forces analysis model[28]. This model will help us to determine the competition among rival firms in this industry and the context in which INGENASA operates. Based on this information, INGENASA can create strategies to gain competitive advantage over its rivals and improve its position in such industry. For example, one strategy could consist in implementing an Intellectual Capital Management system with the purpose to identify, measure and control INGENASA's intangibles resources that can influence the competition. The existing five forces in the European market are formed by the power of laboratory suppliers, the threats of new entrants, the power of buyers, the threats of substitutes, and the existing competence in the market.

Laboratory suppliers power

INGENASA requires raw materials, including components, and other supplies, to build-up its products and materials are needed to maintain the supporting activities such as R&D, and quality controls. The raw materials required in the ELISA products are microplates, antibodies, antigens, substrates, etc.(see table 3). Some of these materials are produced in-house by INGENASA such as some antigens and specific antibodies, while others need to be obtained from suppliers.

[27] www.bsi-global.com

[28] Porter, Michael E., Competitive Strategy: Techniques for Analyzing Industries and Competitors Competitive Strategy.

These suppliers can have a powerful influence on the industry where INGENASA operates, such as selling raw materials at a high price to capture some of the diagnostic industry's profits. However, in this industry, there is an increasing competition among suppliers today, specially after the Asian – based suppliers have begun to offer demand quality components to lower price (information can be obtained from made-in-china.com). This indicates that the bargain power of suppliers is limited due the increased competition which is favorable for small-to mid size companies such as INGENASA. However, the increasing competition is mainly for the non-biological and not for the biological components of the diagnostic kits because the biological components such as enzymes, and specific antibodies are more difficult to produce and replace. In addition, there are probably some patents that can give the exclusive right of the biological components to some suppliers thus diminishing the competition for the specific component. INGENASA has built-up valuable relationships with key suppliers that can provide the components needed in INGENASA's products. The relationship with current suppliers is an important intangible resource for INGENASA since to build relationships with new suppliers can take time and time is money. To switch suppliers carry a significant switching cost and it can even delay the R&D processes and the launch of new products since brand new sub-components need to be tested and optimized before changing them in the products.

Threat of new entrants

TThere are start-ups as well as incumbent non-European firms in the diagnostic field that want to enter or to expand their operations to the European market presenting a potential threat that can affect the competition in the European diagnostic industry. One threat is comming from large American companies that have the financial power to enter the European market by creating their own channel of distributors or by buying or becomming associated with small European companies, for example IDEXX Laboratories purchased Bommeli Diagnostic during year 2004. The second threat probably is comming from Chinese and Korean companies that can enter the market by offering products to lower prices. These companies will use the economic of scales to have most cost efficient level of production to gain a position in the new market. However, the threats from these companies are depending on their ability to past the barriers to entry created by the incumbent firms by taking, for example, cost leadership

or innovative differentiation. INGENASA in some way inhibit additional rivals from entering the market with some of its intangible resources such as its brand indentity, its access to distribution channels, patents, proprietary know-how, and loyalty among its current customers.

Threat of substitutes

These are companies in process of developing alternative solutions for diagnosis of infectious diseases that might affect INGENASA's products on the market. One of these companies is the Swedish company Åmic AB that is developing diagnostic chips which has a broader range of applications including applications in veterinary diagnostic. However, today, there are barriers to entry that are difficult to overcome by brand new technologies, actually the lower production cost and the cheaper complementary technical systems of the ELISA technology. The threats from companies with new technologies such as the diagnostic chips seems limited at this point due the already existing relationships with distributors of the incumbent firms. The already built relationships with key distributors on the market is a crucial intangible resource for INGENASA. Even, when companies such as Åmic AB manages to overcome the barriers to entry in the European market, for instance, by innovative leadership or price differentiation, the diffusion of a new technology will be a slow process. The reason is that there is the shifting cost that a company has to face to change to a new technology and there are difficulties to overcome the broad acceptance and availability of the ELISA – technology

Buyers power

The buyers in the diagnostic industry consist in the diagnostic service providers, the animal-food industry, clinics, and all those that purchase the diagnostic products. The bargain power of this group is determined by the concentration of the purchasers of the diagnostic products versus the diagnostic product manufacturers (demand versus offer) and the price sensitivity, product difference, brand identity, and impact on quality performance. The diagnostic service providers in Spain are based on 13 major laboratories while the industry of veterinary diagnostic products are based on 8 major companies (INGENASA, Svanova, IDEXX, Synbiotics, Institut Pourquier, Bommeli Diagnostic, Intervet Inc, and Hipra.). In reality, the firm concentration should be viewed for every single diagnostic product because some companies are competing in some

products but not in another. INGENASA, Svanova, IDEXX, Synbiotics are competing mainly on 4 different products which are shown in table 6. The differences between these products are not big; they are based on the same technology and application, however, it is difficult to do a comparative analysis on technical performance without performing simultaneous analysis in the laboratory or by analysing their patents. From our point of view, INGENASA has a brand identity that is stronger than the other three companies in Europe, but specially in Spain, due the fact that INGENASA has built up its brands in the European market during a longer period of time, acquiring recognition for the quality of its products and the technical support offering. This indicates that brand name recognition has been a crucial intangible resource of competitive advantage for INGENASA in the European market.

Rivalry on the market

The rivalty on the European market are created by competing companies that have at least one competing diagnostic product in at least one European country**.** There are competing companies that have the financial, technical, marketing, sales, manufacturing, distribution and other resources similar or greater than INGENASA which they used to gain market shares. There are important competitive factors that INGENASA can use to gain competitive advantage including the product's quality, price, ease of use, customer service, and reputation. The product’s quality is probably the most important of these factors used by INGENASA because its product’s quality is certificated by standard organization and INGENASA put some great effort to follow their normative. The technical support is a factor that INGENASA competitive advantage againts its competitors because it is something that INGENASA has built-up during a long period of time. This has provided trust of the customers on INGENASA’s products. To identify the rivalty on the European diagnostic market it is an important activity that need to perform continously, maybe as a part of INGENASA’s competitive and business intelligence. From our point of view and based on our own analysis, the rivalty in the European and Spanish diagnostic veterinary market are mainly among INGENASA, Svanova, IDEXX, Synbiotics, Institut Pourquier, Bommeli Diagnostic, Intervet Inc, and Hipra.

- Svanova is an important supplier of veterinary diagnostic products in

Scandinavia. The company functioned in the beginning as a research group that was associated with the Swedish National Veterinary Institute, but become an independent spin-off company in January 2001. Svanova is a company dedicated to the developing, manufacturing, marketing and selling products for the diagnosis of animal diseases. Svanova is a small company (25 employees) that has the capacity to become a bigger actor with time. This company is not presenting a direct threat for INGENASA right now, on the contrary, INGENASA has a current cooperation with this company consisting in the use of certain specific antibodies based on license agreements. The only problem that could exist in the future is that Svanova develop new products that target a similar market segment than the segment targeted by INGENASA.

- IDEXX is one of the largest veterinary diagnostic company in the world. It has more than 3,000 employees and conduct operations through 40 locations worldwide. IDEXX has the experience in serving the veterinary market for more than 20 years and has the financial power, capabilities and brand recognition, therefore is the most serious competitor of INGENASA.

- Synbiotics is a leading developer, manufacturer and marketer of diagnostic products dedicated to the companion and food animal industry worldwide. The company has strong scientific and technical skills, and the company exists around 15 years.

- Institut Pourquier is a french company with 45 employees. Institut POURQUIER is today one of the European leaders in the veterinary reagent development, industrialisation and commercialization field. They are specialized in the development and production of ELISA, RIA, molecular biology reagents and also development of new technology for the diagnosis.

- Bommeli Diagnostic is a Netherlands-based animal health company, it is an internationally recognized leader in the production animal diagnostic market, offering state-of-the-art diagnostic reagents and test kits for the control of diseases. Bommeli Diagnostic was purchased by IDEXX Laboratories by the end of 2004.

Table 6. Competing swine diagnostic products among four important diagnostic companies operating in the European market.

Infectious disease	**Antigen**	**Competing companies and products**			
		INGENASA	IDEXX	SVANOVA	SYNBIOTICS
Aujesky's disease	gI (gE)	INGEZIM ADVG1	HerdChek anti-PRV g1	SVANOVIR ™ PRV-gE-Ab	SERELISA PRV gI Ab kit
	gII (gB)	INGEZIM ADVgII	HerdChek PRVgB	SVANOVIR ™ PRV-gB-Ab	non
	gI + gII	INGEZIM ADV Combi	non	non	non
African swine fever	VP73	INGEZIM PPA Compac	non	non	non
		INGEZIM PPA Das	non	non	non
Classical swine fever (CSFV)		CEDITEST CSF	non	non	non
	Epitope of E2 (gp53)	non	HerdChek ® Classical Swine Fever	non	non
	p125	non	non	non	SERELISA HCV Ab detection kit
Porcine parvovirus (PPV)	Proteins VP2	INGEZIM PPV INGEZIM PPV Compac	non	SVANOVIR ™ Porcine Parvovirus	non
Porcine coronavirus (TGEV & PRCV	TGEV epitope	INGEZIM TGEV	non	SVANOVIR ™ TGEV/PRCV -Ab ELISA	non
	PRCV epitope	INGEZIM PRCV	non	non	non
Porcine reproductive and respiratory syndrome (PRRSV)	protein (ORF7)	INGEZIM PRRS	non	non	non
Porcine rotavirus	Type A rotavirus antigen	INGEZIM ROTAVIRUS Porcine	non	non	non

* This table represents a model which can be applied to identify competing products in the diagnostic industry. On the vertical direction the different diseases that the products are intending to detect. On the horizontal direction, competing companies and its corresponding products. The table could be extended by adding more diseases, companies, and products to have a complete view of the competition.

- Intervet Inc. is an animal health company focused on three objectives: discovering, producing and marketing quality products to make animals healthier.

- Laboratorios Hipra is a Spanish diagnostic company that is not a major threat for INGENASA.

Our Porter's five forces analysis indicates that the diagnostic industry is a competitive industry in the European market because the existing rivalty among diagnostic companies, however, INGENASA has a stronger position in the Spanish market due its brand recognition, and extended technical support.. We have reviewed the swine diagnostic products commercialized by the most important competitors of INGENASA to determine the competition among these lines of products (see table 6). We found that INGENASA competes with all three companies on products for the diagnosis of Aujesky's disease, but only with IDEXX and Synbiotics for products for the diagnosis of Classical swine fever (CSFV). With Svanova, INGENASA competes on products for the diagnosis of Porcine parvovirus (PPV) and Porcine coronavirus (TGEV & PRCV). INGENASA has competitive advantage against these competitors regarding certain products where INGENASA is the sole manufacturer in Europe, including the products INGEZIM PPA, INGEZIM PRCV, INGEZIM PRRS and INGEZIM ROTAVIRUS. These type of analysis should be performed for each products and comparing all the diagnostic companies that are considered INGENASA's competitor.

3.2 IP Position analysis

The objects of this part of the analysis are: 1) to identify appropriation mechanisms used by INGENASA to protect its inventions. 2) to determine if whether the company has been able to build-up and exploit its IP position according to the business environment and 3) to determine how its IP position is supporting its business strategy in the current market. The IP position is determined by the structural control of the innovations described in previous section. INGENASA has intellectual capital (shown in Table 7) that is used partly and most important that can be used in the future as a source of competitive advantage since they play a key role in the construction of intellectual product and business.

Table 7. Intangible resources categories of INGENASA

Intellectual Property	Patents, trademarks, domain names, databases, licenses agreements, copyrights, software, designs, etc.
Goodwill and relations	Distributors, suppliers, biotech companies, Institutes and Universities.
Competencies	Immunology, molecular biology, genetic, veterinary, management, etc.
Technological	Biotechnologies

3.2.1 Trademarks and brands

For many companies, the trademark and brand are today their most valuable asset because they stand for much more than just marks that identify a product or a company; they stand for feelings, opinions and values. This part of the analysis will focus on determining INGENASA's ability to differentiate its products from its competitors in the marketplace by using trademarks and brands.

Company name

The official company name for this company is "Inmunologia y Genetica Aplicada" or INGENASA, but during the course of the years the abbreviation INGENASA has been used more often as the company name. The company name is registered in the "Registro Mercantil" which is the Spanish office for company registration similar to the Swedish "Bolagsverket".

Trademarks

Trademarks is a legal concept that represents the ultimate link between a company and its customers. According to INGENASA's product catalogue and to the document presented by INGENASA to the standards organisation BSI, INGENASA has two trademarks (INGEZIM and INGENE). Under these two trademarks, INGENASA has more than 52 product marks. Since the two trademarks have distinctiveness and are represented graphically, INGENASA has obtained the exclusive right of these marks in Spain, by the Spanish office of patents and marks. INGENASA's trademark rights have been a good start point for INGENASA to work on a safer ground for brand building.

Brands

The brand is a commercial concept that can be used in a more widely perspective than a trademark, a brand includes the trademark but also lots of other things like emotions and values. The two trademarks have been used strategically as brands by INGENASA to commercialize two lines of diagnostic products, the serology and molecular biology products. INGEZIM has been used for marketing serology products, while Ingene has been used for molecular biology products. These two brands can be considered an important intangible asset for INGENASA. After reviewing the diagnostic products existing in Spain, we could say that INGENASA has managed to build-up at least one strong brand which is actually INGEZIM. INGEZIM has acquired recognition in and outside Spain after years of brand building effort from INGENASA. The second brand, INGENE, is not as strong as INGENZIM, because the molecular biology products represented by INGENE, is a new line of diagnostic products recently developed by INGENASA. But INGENASA is on the way of acquiring brand recognition of INGENE because INGENASA is a pionner in the application of these type of products in the veterinary diagnostic. We consider that INGEZIM has stronger European position than its competing's brands, specially in Spain and Portugal. The reason is that INGENASA has built relationships with key actors and has commercialized its brand during a longer period of time than its competitors in this market. This effort has probably done that INGEZIM become more than just a product’s recognizer on the market because, in addition, this brand has symbolized innovation, quality, and reliability. INGEZIM stands for innovation due the new applications of the antigens designed by INGENASA and quality because the products it is representing have been carefully optimized to be used in veterinary diagnostic and have been certified by a stardand organization. INGEZIM stands for reliability due the confidence of the assay, therefore this brand has been one important element to provide structural control over its innovations and value proposition (described in section 3.3) because reliability is highly valuated by the professional market. Even, when INGENASA has been successfull with its brand building, INGENASA need to have a clear vision of what it want to communicate to its customers with its brands to be able to create brand identity. For example, INGENASA's brands may accumulate value if the company can manage properly through advertising-, marketing-, internet and domain name strategy and so on. Therefore, a branding strategy need to be implemented with the future implementation of an ICM system. However, even with a brand building strategy,

it can be tricky to know exactly what are the customer's expectations and demands on the products, therefore, surveys amongs customers need to be performed from time to time. This is partly done at this point by the databases of customers feedback build by the technical support from the quality control department.

Co-branding

Co-branding is a type of collaboration between two, often complementing companies with the purpose to launch a new product using the brands of the two companies. There are advantages as well as disadvantages by co-branding. The advantages are the possibility to enter new markets, strengthen the brand name, and obtain a complementary range of products and the disadvantages are the existing risks to lose the control over the brand and conflicts of images. INGENASA has not ongoing co-brand collaborations, but it has a good chance of co-branding some of its products, specially its vaccine products. The vaccine products have been difficult to be commercialized by INGENASA due complicated procedure for governmental approval and high legal cost. For example, by co-brand collaboration, INGENASA can complement its current line of products, acquiring new technologies, and put joint forces in advertising. The ideal co-branding partner for INGENASA can be a company that can provide the resources required to introduce some of INGENASA´s vaccine products into the market.

Domain names

INGENASA has registered 2 domain names with the company name under the Spanish top-level domain *.es* and the generic top-level domain *.com*. The company official homepage is www.ingenasa.es, however, the generic domain *. com* seems not to be used at the moment; it is not linked or URL forwarding to any other homepage. The homepage has an attractive design and contains information written in English and Spanish. It contains an online product catalogue which covers its serology products, but there is not information of its molecular biology - or vaccines products, either information of the company's services, goals, visions, technologies, or distributors's partners are available. Today in the digital era, more and more consumers used internet to find products and services, therefore domain names, and websites have become an important intangible resource for companies. It seems that INGENASA and INGENASA's

products need to be found better on the web, for example, when the keywords INGENASA, INGEZIM, veterinary diagnostic, etc are used in the search engines such as google. After reviewing INGENASA's homepage, we think that INGENASA should be more aware of the importance to implement an internet and website strategy.

Logos

The logotype is equal importance as any other company's mark**.** INGENASA has an attractive logotype in combination with its name. The combination of its company name, logotype, and colors gives a good overall impression of INGENASA and will be a good identifier of INGENASA on the market. Figure 6 shows INGENASA´s current logotypes.

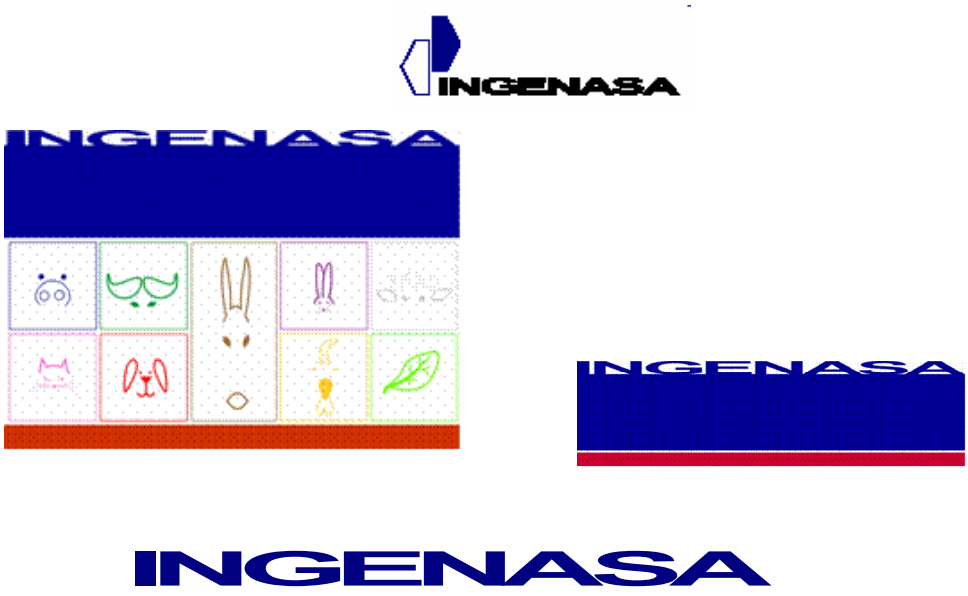

Figure 6. INGENASA's logotypes

3.2.2 Human capital

The human capital is the knowledge possessed by the employees of a company, including their skills, experiences and abilities, also all employees' knowledge that can be practically applicable in the company's operations. Highly skilled employees are particularly important to INGENASA to leverage biotechnological

expertise in the form of veterinary diagnostic products. INGENASA is a highly qualified company because 50% of its employees are holding a PhD. After reviewing its patents and scientific publications, it was found that INGENASA possess know-how in areas considered to be of strategic importance including in the scientific field of molecular biology, immunology, genetic, biochemistry, microbiology, veterinary medicine, etc. Based on this information, we have divided INGENASA's know-how into three categories; general-, industry specific and firm specific know-how.

General know-how

Knowledge possess by INGENASA's employees that is widely found among biotechnology companies such as knowledge in base technologies. These are the minimal level of skills required to perform those tasks that are routine in the biotechnology field such as knowledge in basic cell culture techniques, gene amplification techniques such as PCR, protein analysis techniques such as SDS-PAGE, etc. This knowledge is generic, found in the R&D -, immunology -, quality control- and manufactory units.

Industry specific know-how

Knowledge possessed by INGENASA's employees that is found mainly among companies that operates in the same technical field as INGENASA. These are skills that are required to perform the tasks that are more specific to the field of veterinary diagnostic such as knowledge in core technologies, including, ELISA technology, knowledge in packaging the ELISA product, antibodies production techniques such as hybridoma techniques, etc. Even, when this know-how does not differentiate the competition, it is of crucial importance to INGENASA in order to develop a veterinary diagnostic and vaccine solution.

Firm specific know-how

Knowledge possessed by some of INGENASA's employees that are less common found among similar firms. These are skills that are considered to be of strategic importance to differentiate competition including methods that have been developed or optimized in-house. For example, INGENASA possess know-how in the vacuolovirus and phage display technique since vacuolovirus technique is routinely used at R&D department and phage display technology is being

implemented in different projects at INGENASA. Also, every innovative way that has been developed by INGENASA and can be used specifically for the identification of antigens and antibodies, and their design and production can be considered firm specific know-how. The procedure developed by INGENASA to produce monoclonal antibodies against specific virus (e.g. against virus PVY) can be also considered firm specific know-how. Knowledge in a new method to reconstruct nucleic acid-free viral particle that allows the production of a new generation of highly immunogenic and very safe vaccines can be considered firm specific know-how.

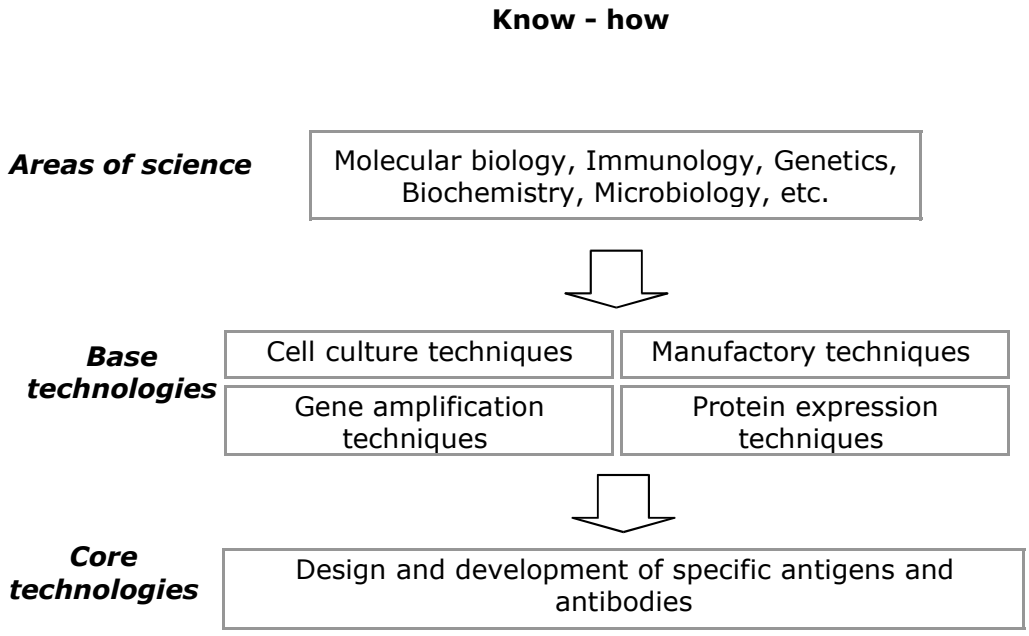

Figure 7. Areas of science, base and core - technologies applied by INGENASA

INGENASA can acquire know-how in technologies that can provide competitive advantage such as screening technologies (e.g. transposon mutagenesis, cDNA gene library construction, etc) and in technologies that are from other scientific field but can be applied to the veterinary diagnostic or its research process (e.g. structural chemistry, animal models, bioinformatics, etc.) through recruitment program or employee competence development plans and education programs in new technologies.

Others employees's attributes that are related to INGENASA's human capital are the employee's loyalty, their dedication to their work, their innovative capacity, their teamwork capacity, etc. The employees at the R&D department has the

ability to obtain research funding for several of their projects due their ability to write research projects, to have innovative ideas, and perform a high standard research. Actually, during 2005, Spanish and EU funding were supporting INGENASA's R&D activities with 0.4 M Euros, being an important economical contribution to its activities.

INGENASA's human capital is a crucial intangible resource for the design of technological innovation and market which is the key of INGENASA's current success. INGENASA is aware of this therefore it has already introduced short and long term benefits such as give some maternity leave days, have flexible working hours, etc. However, additional intangible activities may need to be implemented to improve the value of existing human capital. For examples, training activities may increase the value of the human capital, and staff care program can make INGENASA a more attractive workplace for existing as well as future employees. However, surveys will be needed to perform to assess employee satisfaction to determine which programs need to be implemented. Subsequently, surveys will help to monitor the effectiveness of improvement activities.

3.2.3 Patents

This part of the study aims to analyse patent portfolio of INGENASA to address to what extend its patents are used to establish market advantage. We have reviewed what it is stipulated in the European patent system regarding the patentability of biotechnical and biological inventions with the purpose to define what part of INGENASA's inventions is patentable in Europe.

European patent law

According to the European patent law, the patentability requirements of biotechnical and biological inventions are the same just as to any other area of technology; also the invention must be novel, associated with an inventive step and subject to industrial applicability. However, due the fact that biotechnology as a science emerged after that the patent law was originally formulated, the directive of the European Parliament from 1998[29] did some development in this matter to accommodate biotechnology to the existing European patent law. The adaptation covered the following issues:

[29] The Directive 98/44/EC of the European Parliament

- The isolation and characterization of elements already existing in nature are considered discoveries and not inventions, therefore they are not patentable. However, as long as the material is isolated from its natural environment, or it is produced by means of a technical process, it may be patented, even if it previously occurred in nature.

- The medical use of known substances can be patentable, if such medical use is regarded as new.

- Transgenic plants and animals can be claimed as patentable as long as the claims are not directed to specific plant or animal varieties.

- Essential biological processes cannot be patented.

- Processes for cloning or modifying the identity of human beings; the uses of human embryos for industrial or commercial purposes; the human body and its elements or the stages of its formation and development, and the simple discovery of one of its elements, and sequences or partial sequences of a human gene cannot be patented

- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and the animals resulting from such processes cannot be patented.

- Inventions are not regarding as having industrial applicability if they are considered methods for medical treatment of a human or animal, including methods for therapy and surgery, as well as diagnostic methods.

With this, the European patent convention includes most inventions in the fields of biotechnology, including living organisms, such as microbes and transgenic multi-cellular organisms. In addition, invention in the field of recombinant gene technology are patentable, for example, vectors, cell lines, artificially generated tissues, recombinant proteins (including antibodies), genes, partial gene sequences, and cDNAs. Methods for producing a product can be patentable if the

methods are considered novel. A method for producing a product is novel when either the starting material is novel, or when the combination of processing steps is novel, or when the product resulting from the method is novel.

Patentability of INGENASA's inventions

In accordance with this, INGENASA's proteins (e.g. antigens and antibodies), peptides, genes, fragment of genes, and most of the components of its products are patentable in Europe since they have been isolated from its natural environment, or have been produced by means of a technical process such as an expression system (e.g. vacuolovirus and *E. coli*). Vectors and methods that have been developed to express and purify proteins (antigens and antibodies) are patentable if such vectors and methods are new. The substances (e.g. antigens) used in INGENASA's vaccines are patentable, even when the substances are already known, since the vaccines have been regarded as new medical use of these substances. Some methods of manufacturing specific antibodies have also been patented by INGENASA. The information published in the guidelines of patentability from the European patent office indicates that the provision of diagnostic methods should not exclude diagnostic kits from patentability. The Art. 52 (4) EPC said "Methods for treatment of the human or animal body by surgery or therapy and diagnostic method practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application. This provision shall not apply to products, in particular substances or composition, for use in any of these methods" as it is INGENASA's diagnostic kits because they are components of a diagnostic method.

Purpose of patenting and patent strategy

The main object of INGENASA's patent portfolio is to use its patents as a legal instrument to exclude others from producing, using, selling and importing the components (e.g. specific antigens) developed by INGENASA. With its patents, INGENASA ensured its freedom to operate, also to use the components that INGENASA self is producing in its diagnostic products without to be enforced to obtain licenses from third parties or to diminish the risk to infringe other's patents. This indicates that the primary goal of INGENASA's patents is to make sure that the company's core technology/ key components are protected, by claiming property of its antigens and their applications in vaccines and in

veterinary diagnostic products. INGENASA has patented its innovations mainly in those countries where the company is current marketing its products or it is planning in commercializing its products in the future. INGENASA has patents in European as well in non- European countries (e.g. USA, Canada, Australia, Argentina, and Chile), however, the number of European patents has dominated INGENASA's patent portfolio due the fact that the European market is its principal market. This indicates that its patent activity is supporting the company business strategy. INGENASA has filed 7 patents through the EP and PCT system indicating that INGENASA want to implement a global business strategy for some of its products. INGENASA´s approach is to file its patents first in Spain to obtain a priority date and not later than 12-months after filing this application INGENASA files a PCT application. Filing a PCT application INGENASA secures its right to file national patent applications in PCT contracting states at a later stage. At about 30 months after having filed the first patent application, the PCT application enters into the individual countries in which INGENASA has decided to obtain patent protection.

Key and strategic patents

It is important to know clearly what the company's core technology is before continuing with patent analysis in order to identify key patents. INGENASA's core technology are the key components in the ELISA system that can only be produced in-house, and can not been purchased from suppliers which are the antigens and specific antibodies used in the system. Actually, most of INGENASA's patents have been based on antigens and their applications. This indicates that the patents are one of the most important proprietary mechanisms of INGENASA to protect its products, which are crucial intangible resources for INGENASA. After reviewing INGENASA's patents, we found that INGENASA's patent strategy is focus on a single patent per product looking like as a strategic patent strategy described by Granstrand[30]. Also, INGENASA is patenting one patent per product including its components, its application and the whole package in just one patent. It is difficult to predict how easy is to invent around INGENASA's ELISA products, but in some way is depending on the specificity of the patented molecules (e.g. antigen, or region of an antigen) in the product. If the patented molecule are the best indicators of its corresponding infectious

[30] Ove Granstrand, "The Economics and Management of Intellectual Property: towards intellectual capitalism", Edward Elgar, 1999.

diseases, then it could be considered the patent a key patent for its corresponding product. For example, if the patented antigens are the antigens that provides the highest technical performance (e.g. specificity) to its products, then the patents protecting these antigens could be considered key patents because with this patents will be possible to prevent competitors from inventing around to develop better products, having higher or equal specificity. INGENASA has written in its patents that the patented antigen used in its diagnostic products provide better specificity and sensitivity than similar products existing in the market at the time of filing the patent. To develop a strategy that can block completely the competitors from developing competing product can be difficult in the diagnostic field, however, such strategy could be based on mapping and patenting different regions of an antigen or by patenting a group of antigens that are the best markers for the infection. INGENASA's method to produce DNA free viral particles could also be considered a key patent because its application in vaccine development.

Patent portfolio

INGENASA filed its first patent already in 1984 and continued building –up its patent portfolio during the course of the years. Today, INGENASA has a strong patent portfolio of its inventions, which contain more than 62 patents that have been granted in different countries. Figure 8 shows INGENASA's patent filing development during the course of the years.

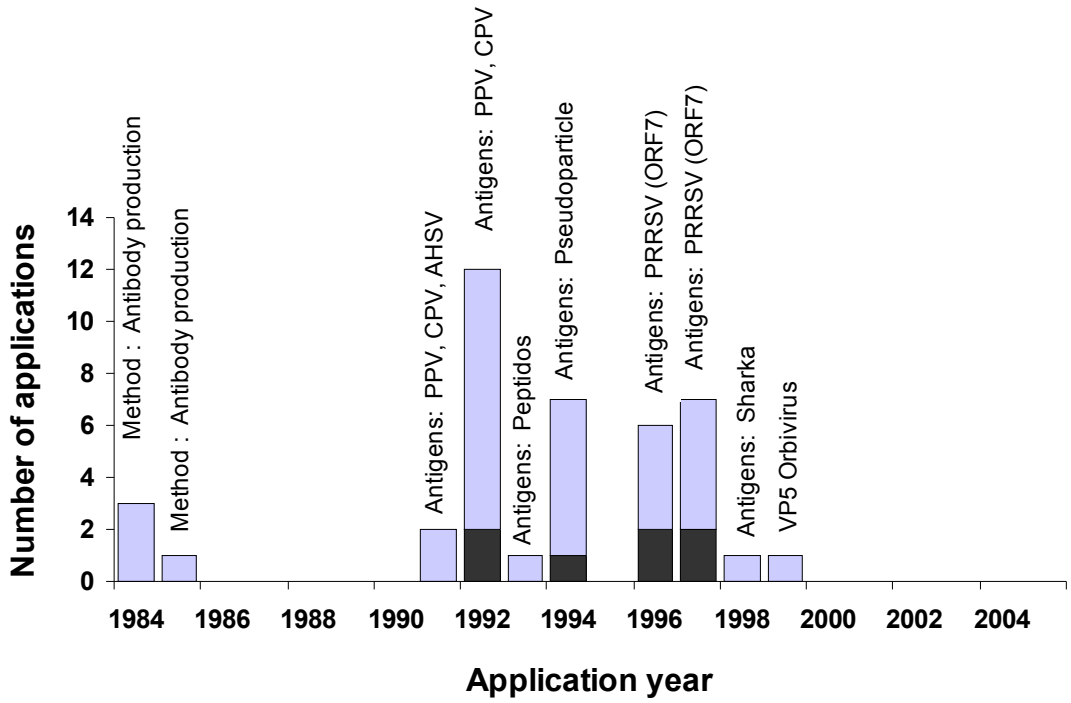

Figure 8. INGENASA's patent behavior. The boxes indicate the number of applications filed, the dark areas indicate the number of international applications (e.g. PCT and EP) filed, the text above each box indicates the object of the patents. The abbreviation PPV stands for Porcine Parvovirus; CPV for Canine Parvovirus; AHSV for African Horse Sickness virus; PRRSV for Reproductive Respiratory Syndrome virus.

We have reviewed INGENASA patent portfolio and found that INGENASA has filed several international patent applications under the PCT patent system, aim to support INGENASA's global business strategy. Also, these patents are supporting products that aim to detect infectious agents that commonly cause problems in the animal industry worldwide, therefore open a great business opportunity for INGENASA.

Porcine reproductive and respiratory syndrome virus (PRRSV) antigen patent: The invention claims in the patent refers to recombinant proteins suitable for the diagnosis of the porcine pathogen PRRSV. The recombinant fusion protein comprise the protein N of the nucleocapsid of the PRRS virus, obtained both from European and American isolates. The protein N (ORF7) is the most immunogenic antigens of PRRSV. This will be a key or strategic patent due the market potential of PRRSV diagnostic products. PRRSV is one of the most economically significant disease facing the swine industry today with costs to the U.S. pork producers

estimated to be $600 million annually. INGENASA is ahead of several competitors by isolating and patenting PRRSV's antigens and their application in diagnostic products.

Infectious bursal disease virus (IBDV) antigen patent: The invention claims in the patent relates to the expression of the variable region of a VP2 protein and its application in diagnostic assays and vaccines. The VP2 protein is one of the two proteins (with VP5) which constitute the virus particle outer capsid. It is the major target of the host immunogenic response. This will be a key or strategic patent due the market potential of IBDV diagnostic products. IBDV infects poultry world-wide and is responsible for many losses in the poultry industry. The control of IBDV infection is a major priority in the poultry industry because losses caused by IBDV are estimated to cost at least $1 billion worldwide[31].

Chemically synthesized peptides patent: The present invention relates to chemically synthesized peptides of antigen VP2 from parvovirus capsid and its application in vaccines and diagnostic products. The peptides can induce neutralizing antibodies that can block Canine Parvovirus (CPV), mink enteritis virus (MEV) and Porcine Parvovirus (PPV).

Canine Parvovirus (CPV) antigen patent: The present invention is related to the production of the antigen VP2 from CPV using expression vectors, and its application in diagnostic products as well in vaccine. CPV is one of the two vaccines commercialized by INGENASA.

PPV antigen patent: The present invention is related to the production of the antigen VP2 from Porcine Parvovirus (PPV) capsid produced in an expression vector. The patent claims its application in vaccines and diagnostic products. PPV is one of the two vaccine commercialized by INGENASA.

Pseudopaticles patent: The present invention is a new method to reconstruct nucleic acid-free viral particle which can be used in the production of highly immunogenic and very safe vaccines. These new technologies can be applied to other viruses and open the possibility of developing vaccines combining antigens from different viruses and other sources. This is a promising patent and

[31] CSIRO Annual Report 1999-2000, CSIRO PERFORMANCE

technology which will probably be licensed-out to bigger actors in the vaccine development market.

3.2.4 Secrecy

A trade secret is the information that has value to a business and which is not generally known to the public. From INGENASA perspective and its business, there are several information that are under confidentiality including biotechnical information (e.g. sequences of antigen and antibodies, applications, method for manufacturing, technical composition of solutions, reagents, etc.), product information (e.g. product packing, optimization conditions, components, etc.), business information (future strategies, databases containing list of customers, distributors, and suppliers, future alliances), and strategical information how the company is planning to shape a new market (e.g. time, segment, product line, etc.). INGENASA actively take measures to preserve secrecy though confidentiality agreements with distributors and collaborators which are stipulated by contract agreement between parties. INGENASA's employment contract does not specifically include a clause protecting the confidentiality of this type of information. However, according to the Spanish employment law, the employees are subject to a duty of professional secrecy with regard to confidential information to which they have access to in the company.

3.2.5 Others IP

INGENASA can claim copyright of databases (e.g. databases containing list of customers, distributors, suppliers, etc.), technical manuals, technical protocols, websites, and published or unpublished scientific papers. The company has current licensing agreements with the Finnish company Diffchamb, the Swedish company Svanova, and the Canadian company Biovet. INGENASA has contract agreements with distributors, business partners, R&D partners (e.g. Instituto Valenciano de Investigaciones Agrarias, Institut Pasteur, Consejo Superior de Investigaciones Científicas, etc.).

3.2.6 Future IP perspective

INGENASA is planning to implement an IC management system (e.g. MERITUM) which consists in measuring, managing or controlling the intellectual capital of an enterprise. MERITUM distinguishes between human, structural and relational

capital. The purpose will be to determine the firm's value based on the identify intangible resources of the firm.

3.3 Structural control analysis

In this part of the analysis, different elements that INGENASA uses to maintain structural control of its value proposition in its current market will be identified. This is an important issue for a company such as INGENASA because the structural control constitutes the basis for the capitalization and commercialization of its biotechnological innovations. The analysis consists in mapping every property claim or intellectual building block that constitutes the basis for the structural control. From our point of view, INGENASA has taken a position in the European market by having control in three different areas: biotechnical innovation, trademarks, and commercial agreements.

3.3.1 Biotechnical innovation

INGENASA has established structural control by claiming the intellectual elements of its inventions via patents, contractual agreements with R&D collaborators and loyalty among employees. One of the intellectual elements is the objectified technical element that is based on the technical function and utilities of the invention. By mastering technical performance (e.g. specificity, sensitivity, and reproducibility), the company controls the utility (e.g. service reliability), that provide the value to the end-user (e.g. diagnostic service providers). INGENASA uses patents as a tool to establish structural control by intellectual claiming of the invention, its function, utility and applications. The second intellectual element is based on the company's biotechnical knowledge that is required to understand a biotechnical problem, and to develop a biotechnical solution. The key in this intellectual process is to possess the know-how that needs to isolate a certain molecule that can be a good identifier of an agent that causes a certain infectious disease. The knowledge is necessary to be able to incorporate the found molecules into a physical product (e.g. in an ELISA product) that can be used in a value proposition. The company generates structural control of this biotechnical knowledge, know-how and skills by contractual agreements with its employees and R&D collaborators. The idea has been to create commitment and loyalty among employees and R&D collaborators to maintain this knowledge inside the company.

3.3.2 Brand name recognition

Even if a company has the world best technical solution, but it does not manage to communicate it, it will not perceive as a value experience by the end-users. INGENASA has managed to communicate the value of its innovation through branding, obtaining recognition for its R&D effort and innovative solutions in the European market. Their trademarks (e.g. INGEZIM and INGENE) have symbolized the intellectual elements that represent the value experience in the innovation. INGEZIM and INGENE have been carriers of the intellectual construction (e.g. biotechnical function) that are associated with the experience of diagnostic reliability. These two brands have given the INGENASA's innovation an experienced identity related to reliability since their product stand for quality in the area of veterinary diagnostics and vaccine. The company has used these trademarks as a communicative tool to show what its products stands for, generating structural control by claiming/ communicating which function and utility will become intellectual experience with its trademarks.

3.3.3 Commercial agreements

Even if a biotech company has one of the greatest innovations, it only helps when the end-user has it in his own hand. INGENASA has created value by controlling the design and production of goods, but leaving the other step in the material value chain (e.g. distribution and retailing of goods) to third parties for distribution of companion animal products and for products that have been distributed outside Spain. The company has managed during the years to build-up a network of distributors from European as well as non-European countries by creating a long-term relationship approach. These distributors have played a key role in the value chain because they have made possible to extract financial value from the value proposition. INGENASA has agreements with distributors from more than 20 countries (shown in table 5) with clear domination of European distributors since Europe has been the most important market for INGENASA. In addition, INGENASA has also established structural control by entering in commercial agreement with important actors in the Spanish food and animal industry. INGENASA has built important relationships with the largest firms in this industry, as well with governmental laboratories. These firms have their own veterinary laboratories to perform routine analysis of their own products as quality control management system. The governmental laboratories have for

function to perform diagnostic analysis of alimentary products (e.g. meat products) sold in the Spanish market. INGENASA is an important provider of diagnostic products to these actors, by direct sales, without to be distributed by professional distributors.

The long-term relationships built with distributors, firms in the food and animal industry, and governmental laboratories have been established by contractual agreements, allowing taking place the transactions that extract the financial value. Furthermore, the contracts have served as a tool to perceive the experience of being in a long-term commercial relationship. The conditions and length of this association have been established in the contractual content.

3.4 Business strategy

The starting point in the implementation of an ICM system such as MERITUM, is to define the vision of the firm and its strategic goals. Based on this information, new intangibles need to be identified that are the main factor to accomplish the define goals of the firm. Based on the analysis in previous section, we have set-up several point that the company could focus on. INGENASA is a firm that is already established in the European market, specially in Spain, where it operates successfully, therefore a new business strategy how to approach this market is not necessary. There are several key aspects that needs to be considered in order to continue doing successfully business. The perspective is that the world-wide market for veterinary diagnostic products will continue growing probably reaching $587 million by 2008[32]. The potential of this market give stimulation to biotechnology companies such as INGENASA to continue developing diagnostic products that can be commercialized in a variety of markets. An overall overview of the company strategy may include:

Expansion into additional markets

INGENASA has focused its resources on targeting the European market, partly the North and South American market and the Australian market. However, INGENASA should take advantages of the window of opportunities that is opening in additional market such as the Chinese market. China is becoming increasingly important in the global biotechnology industry due its rapidly growing economy,

[32] Animal Pharm reports: Market-leading business reports on the world animal health and nutrition industry

cost advantages, skilled workforce, and governmental commitment to the scientific and industrial development. The Chinese animal industry is one of the larger market in the world, having a swine production of 470 millions pigs and a production of bovine of 126 million[33]. Most of the worlds leading companies have invested in this market to take advantages of the growing market and to reduce cost in manufactory. INGENASA has already taken the first steps in this process since its representants, including INGENASA´s CEO, have visited Pekin and Shangai to study the market and to create proper contacts. A strategy how to approach the Chinese market has been presented in the next section of this work. The intangible resources needed to approach this market will be identified.

Leverage sales and marketing resources

INGENASA can continue to distribute some of its products to certain segment in the Spanish market without using third parties. INGENASA should continue to maintain a small marketing and sales organization, leaving part of the value chain to be handled by specialized distributors outside the Spanish market. However, this partnerships should continue being based on contractual agreements by which INGENASA can have granted distribution rights for certain of its products within specific geographic areas. The collaborative partners should have the responsibilities for market development, promotion, and sales of the products.

Development of strategic alliances to leverage and acquire company resources

INGENASA can enter into further strategic alliances to access unique technologies or resources or to develop specific markets. INGENASA may cooperates with:

- Companies that are interested in co-developing diagnostic products
- Companies that have complementary technologies (e.g. molecular biology techniques, diagnostic chips technology, etc.).
- Companies that have complementary products (e.g. vaccines or products to detect other infection diseases not covered by INGENASA); and/or
- Companies that have access to additional distribution channels that can supplement INGENASA’s existing distribution channels.

[33] China, Peoples Republic of Livestock and Products, USDA Foreign Agricultural Service, GAIN report.

Expansion into additional segments with easy-to-use products

By continuing creating new products that are more suitable for a non-professional segment, INGENASA can find new niches, previously not targeting by the company. For example**,** the companion animal market is a highly growing market with increasing need of diagnostic products which has been estimated be one-third of the world market for animal health products, with sales of more than $4.5 billion in 2003[34]. INGENASA could develop additional products that are easy-to-use products that could allow the animal owner or the veterinary to perform simple tests without transporting the animals to clinics or to send the samples to centralized laboratories. With a new line of easy-to-use products, the company can enter a market in those countries or regions where the resource are limited. The farms is another segment for this type of product since they or their veterinarians need to send the samples to remote laboratories which is time consuming. INGENASA has already two lines of easy-to-use products such as the ELISA Vet, and immunocromatographic assays (e.g. INGEZIM ROTACROM).

3.5 Summary

This part of the TEVA analysis indicates that the professional market is the main target for INGENASA's ELISA Das products due its complexity and the reliability it is provided to its customers. The ELISA Vet and immunocromatographic assays are intended to a non-professional market. There are potential threats coming from new entrants and substitutes limited by the difficulty to overcome INGENASA's brand recognition, commercial agreements, broad adoption and acceptance of the ELISA system as diagnostic tool, and an extended technical support. The ability of INGENASA to shape the innovation and market is strongly depending on its IP position and structural control. The IP position analysis indicates that INGENASA has been able to build-up and exploit some of its most important intellectual assets (e.g. brand, know-how, and patents). The brand has been used to communicate the quality and reliability of the products. The know-how has been the based of INGENASA's success due the nature of its business. The patents have been used as a proprietary mechanism to prevent competitors from using INGENASA's technology and to ensure freedom to operate. The company has built a strong patent portfolio to claim property of antigens and its applications in veterinary diagnostic, and vaccines. A technological and patent audit may be useful in this company, for example, by doing side-by-side

[34] Animal pharm reports: Companion Animal Health Products: Prospects for a growth market

comparison of competing products to detect infringements, imitations, threats, etc. The company has a patent portfolio with several patents that could be considered key patents due its possibility to commercialize INGENASA's products in a global market and take advantage of existing window of opportunities (e.g. the method to reconstruct nucleic acid-free viral particle). The structural control analysis indicates that INGENASA has generated structural control of its innovations and market using three different intellectual building block . The first building block is based on the biotechnological control in which is claimed the key components of the inventions, its applications, utilities, and in-house knowledge related to it. This knowledge is regulated by contractual agreements and loyalty. The second building block is based on trademarks and trademarks rights to communicate the value experience of reliability and other customers utilities provided by the ELISA product. The third intellectual building block is based on commercial agreements with distributors in the diagnostic field and key actors of the food and animal industry (e.g. firms and governmental laboratories) to extract financial value from the inventions and value proposition. It will be important for INGENASA to build strategic alliances to access unique technologies, resources and/or to develop specific markets. INGENASA's business may be expanded further, into additional segments (e.g. non-professional segment) with easy-to-use products and into additional market (e.g. Chinese market).

4. FUTURE MARKET ANALYSIS

Until now, INGENASA has been successful in commercializing innovations of diagnostic products, vaccines and other products in Europe. The company desires to gain more markets and benefits by implementing global business strategies. In this part, we will analyse the market that presents a window of opportunity for INGENASA, taking Chinese market as an example. The most important aspects to approach this market have been considered here based on the understanding of Chinese law, practice and the situation of INGENASA.

4.1. Market overview and potential business opportunity

4.1.1. The industry and market

Chinese economy and market

After economic reform in 1978, China has made great achievements in economic construction and social development. In 1998, the gross domestic product (GDP) had an increase of 6.4 times over 1978. The National Bureau of Statistics (NBS) said[35] in 2004 GDP came to 13.65 trillion Yuan (US$1.65 trillion). With a country of 1.3 billion people and a rapidly growing consumer class, the demand for, and consumption of, goods and services will continue increasing. In recent years, the economy of China has grown at a rate of around 9%, and there is no indication this growth will stop anytime soon.

China has become a core part of business strategy for global companies. Many companies are taking advantage of lower production costs in China, recognizing business opportunity that represents one of the world's largest markets for products and services. As the pharmacy industry news reported, European pharmaceutical and biotechnology companies are beginning to explore emerging markets such as China, which offer a low cost structure along with other potential benefits such as a sizable domestic market and opportunities for licensing and outsourcing.

Chinese biotechnology industry

China has established[36] nearly 120 high-and new-technology development zones, which have attracted domestic and foreign investment by offering incentives such

[35] China's economy grows 9.5% in 2004 (China daily newspapaer) (in Chinese)
[36] China's torch plan (in Chinese)

as tax breaks and administrative supports. The China National Centre for Biotechnology Development within the State Science and Technology Commission has been established. The government's role in the biotechnology field is vital. China already has a number of established biotech companies such as Changchun Institute of Biological Products.

One Chinese biotechnology doctor, Liu, introduces that several types of institutions are engaged in biotechnology activity in China: laboratories associated with Academia Sinica (a government-run academic think tank), university institutes, medical schools, biotechnology companies and specialized biotechnology production facilities. In total, scientists, many of whom were well educated, are currently working on biotechnology projects. Chinese biotechnology industry has produced considerable results with a budget considered small by western standards.

Biotechnology market

China's high economic growth has been an incentive to the rapidly rising consumption of biotechnology products. There are two main parts in the biotechnology products including pharmaceuticals products and products in agriculture. The total sales of biotechnological products in China have increased by 50 times during the past 10 years. The materials from global industry data monitor say that in 2003 the Chinese biotechnology market[37] grew by 23.4% to reach a value of $5.1 billion. To further speed the development, Chinese government encourages Chinese companies to establish links with western biotechnology companies. The new interest in this area has created opportunity for biotechnology companies of developed countries. Through early market penetration with carefully planned strategy, biotechnology companies such as INGENASA are able to develop a long-term presence in this rapidly developing and profitable market.

4.1.2. Business opportunity

As INGENASA has the core competence to develop diagnostic products for animals, this section presents general descriptions about the animal industry in China as part of market research.

[37] Biotechnology: global industry guide www.pharmalive.com/special_reports/sample.cfm?reportID=178

Animal industry

China has merged as one of the largest animal product producers in the world. China has the second largest animal health and nutrition market in the world. It was[38] worth $1.5 billion in 2004, which means that it has grown more than one-third since 2000. The main reasons for this dynamic growth are the underlying strength of Chinese economy, and the increases in demand for meat and meat products. This scenario is likely to continue for at least another 10 years, and the growth prospects for the Chinese animal health and nutrition industry are thus excellent. Animal Pharm Reports forecast that the market would be worth $2.4 billion by 2010. In addition, it is said[39] that the amount of pork in China is the biggest in the world. At present, the swine industry is facing the transform from dispersion into collectivisation, from traditional feeding into modernized management. In large cities and provinces, many large-scale piggeries are established for more effective management.

Animal disease

Above analysis shows that livestock industry has held an important position in Chinese economy development. At the same time, according to reports and through telephone conversation with an official in charge of veterinary management, Chinese livestock industry is commonly affected by infectious diseases, which have caused high economical losses, specially in the swine industry. Some swine diseases common in Europe, as well as China are parvovirus, CSF, and PRRS. There are diseases that only affect animals, while others can also be transmitted to human. In 2005 in SHICHUAN province one kind of porcine disease, porcine streptococcus, has affected human, which occurred panic across China at that time. In some provinces of China, swine diseases exploded constantly across large regions, which resulted in great economical losses. All of these have attracted more attentions on defending and curing diseases of livestock. Implementing effective measures based on diagnostic and vaccine products can be helpful, specially it is one of serious problems that sometimes veterinarians cannot diagnose livestock diseases quickly and correctly.

[38] The Chinese animal health and nutrition market, PJB Publication Ltd.

[39] Veterinary biotechnology products analyse of China by Cui zhi zhong, China Poultry Vol.23.No.23.2001. (in Chinese)

Potential business opportunity

Biotechnology research in China has made great progress; however, in many fields technology level is still lower than developed countries. Through conversation with doctor Liu, it is said that most of the current research for diagnosis of infectious disease is focus on human, not livestock. Specially, molecular diagnostic research for animals has not been paid as much attention to by Chinese research institutes as for human. INGENASA has several products for different animals, by which this company can try to exploit the new market. When the competition in this field in China is not so dramatic, it is the time for INGENASA to enter.

In general, Chinese market presents great business opportunity for INGENASA for the following reasons:

- Fast economical development and large markets for products and services
- Increasing biotechnology development and support from the government to establish cooperation with foreign companies
- The importance of livestock industry and existing threats from infectious diseases among livestock
- The difficulty to diagnose diseases of livestock and the limitation of existing diagnostic products

Products planned to market

INGENASA has a long line of products for the diagnosis of infectious animal diseases. At the first stage the company may focus on few products to approach Chinese market in order to find specific niches. Due to great market potential and constant problems of diseases in the swine industry, products for diagnosis of these swine diseases may be the first choice for INGENASA; this is also the core competence of INGENASA.

As the first step, INGENASA can approach Chinese market by commercializing the product intended to detect porcine rotavirus, which is a common disease in China. Porcine rotavirus is one kind of intestines disease that mainly affects swine, but still has the possibility to affect cattle, sheep, even people. In China veterinarians normally diagnose the disease according to symptoms of swine affected; however, sometimes symptoms of this disease are similar with other

swine diseases such as porcine parvovirus (PPV). According to the materials of INGENASA, the product for porcine rotavirus is serology kit that is the main line of product of INGENASA. The innovation analysis is based on the serology. The idea behind INGENASA products and its core competence have been described in section of innovation analysis (chapter 2) in this work. INGENASA has developed ELISA –based products for the diagnosis of porcine rotavirus, which is probably advanced technology at the present stage. Later INGENASA can develop the vaccine for porcine rotavirus by using the antigen designed. After being familiar with the new market, with established brand reputation other products for swine diseases such as PRRSV antigen, PPV antigen and products for bovine diseases can be taken into considerations step by step. INGENASA can market products through its established network, furthermore perform R&D to develop new diagnostic products only to target Chinese market.

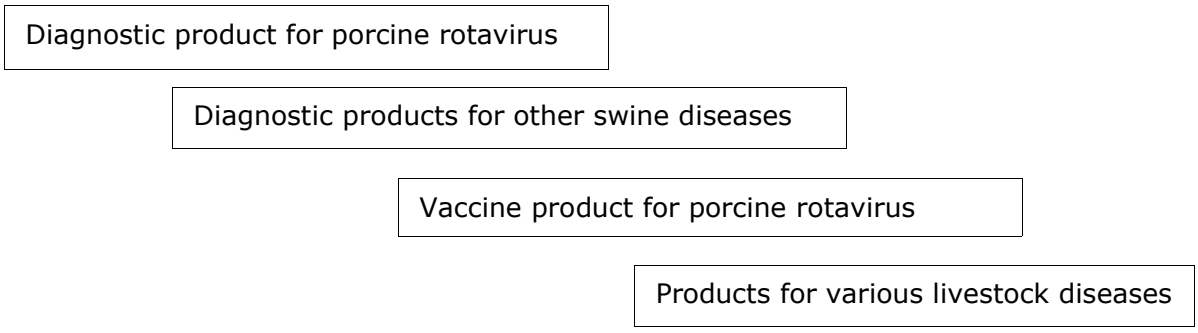

Figure 9. Development of products suitable for the Chinese market.

4.2. Business Steps

There are many aspects that need to be taken in consideration before entering Chinese market. Three aspects that we consider of major importance are mentioned here:

IP issues

Patent and other intellectual property rights can give INGENASA competitive resources to compete in the marketplace and hold a stable position in this field. After INGENASA identifies products that are fit for Chinese market, it is the time to apply for patents for components or technologies that are vital parts of products.

Business models

There are several business models to choose; it is better for INGENASA to make analysis so as to identify one or two entry models that are compatible for this market and situation of this company.

Cooperation issues. Probably INGENASA is required to take several steps in cooperation process, for example,

- Find a good partner that has technology competence and experiences of marketing and manufacturing.
- Negotiate with cooperating partner and make contracts along with other cooperation documents.
- The parties have to implement cooperation plans correctly to reach a win-win situation. There are also possibilities for companies to change their plans for necessary needs.

4.3. IP Issues

As a biotechnology company, doing business in China INGENASA is required to consider acquiring intellectual property, making an inventory of their intellectual property, proprietary and other sensitive information and developing scenarios for the protection of each type. Based on the understanding of the situation of INGENASA, Chinese law and practice, this part tries to give a picture for INGENASA concerned with intellectual property issues in China.

4.3.1 Patent

4.3.1.1. Introduction to Chinese patent system

General introduction

China's patent system can be tracked down to the late Qing Dynasty when China entered into international treaties with the purpose to modernise the country. In 1984, the Patent Law of the People's Republic of China (the "Patent Law") was adopted. China’s patent law has been amended twice (1992 and 2000) to stress patent protection. The duration of invention patent protection has been extended to 20 years from the date of filing a patent application. China follows a first to file system, which is consistent with the practice in other parts of the world, including

the European Union.

Regulations about biotechnology patent

- The Chinese Patent Law provides that no patent right shall be granted for animal and plant varieties. However, the processes used in creating animal and plant varieties can be protected under Chinese patent law.
- DNA fragments, genes, and proteins are also considered to be chemical substances and therefore are patentable. Processes relating to use of microorganisms and microorganisms are patentable.
- A sample of invention concerns new biological material that are not available to the public should be deposited in a depositary institution.

Regulations for foreigner's patents

If any foreign enterprise without residence in China files a patent in China shall commission one of patent agency institutes designated by the China's State Intellectual Property Office (SIPO). Invention that has been already filed in a foreign country, SIPO may ask the applicant to provide within a specified time limit documents concerning any search made, or concerning the results of any examination made, in that country.

Patent administration

SIPO has the responsibility to handle and examine patent applications and grants patent rights in accordance with the law. SIPO is the only authority that has the right to grant patent rights. Patent offices under the governments of provinces, autonomous regions and municipalities directly under the central government are responsible for patent administration work in their respective areas as well as handling matters involving foreign-related patents. They are also responsible for patent enforcement, settling patent disputes, as well as investigating and penalising patent infringement acts.

4.3.1.2. Patent issues

The alternatives

INGENASA has two alternatives for its technology, patent or keep them secret. As we know, though keeping trade secrets is cheaper than patenting, they do not

offer the same level of security or exploitation opportunities. There is always risk that competitors patent the innovation and exclude INGENASA. This method of control is recommended for companies whose technology is too complex for other actors to be able to develop. Now when more and more scientists work in biotechnology field Chinese companies gradually increase their capabilities to study and imitate biotechnology products, which means that it will be risky marketing products without patents. On the other hand, if INGENASA patents the technology, it will not be easy for other companies to patent around it since the specific antigen is unique after all, specially the antigen developed by INGENASA may be the best indicator of the disease. More importantly, INGENASA is required to have patent rights to approach this new market as tools for commercializing technology safely; specially INGENASA may not manufacture by itself, instead license technology. Therefore in the case of INGENASA patenting is recommended to create competitive edge. There are two ways for getting patent right: one is through PCT application since China has joined the Patent Cooperation Treaty; another is to apply for patent directly in China.

Patentability

According to Chinese patent law, INGENASA cannot patent diagnostic methods, however INGENASA can patent the antigen used in the diagnostic product, which is regarded as chemical substance. Based on original investigation, the specific antigen concerned with porcine rotavirus is novel, inventive compared with former technologies and can be applied to the health industry with positive results. Through search at SIPO database there are no similar inventions patented. Therefore, what INGENASA will patent is the antigen designed and produced for porcine rotavirus at the first stage.

Patent agents

As it is mentioned above, foreign enterprises should commission agents that are authorized by SIPO to deal with foreign applications. SIPO has pointed almost 114 patent agent institutions with rights to represent foreign patent applicants. To find a qualified patent agent institution requires INGENASA to do investigations for the reason that there are some "black patent agent institutions" that actually are not qualified to work in this field according to the words of the lawyer, Miss Cu. INGENASA is also required to do investigations

about patent agents. Before choosing one agent besides collecting information about him it is also necessary for technical employees of INGENASA to talk with the agent directly to check if he has excellent English ability, biotechnology knowledge, rich experiences as an agent. The lawyer, Cheng in the VIGN law firm says that even though there are more and more patent agent institutions, it is still hard to find quite qualified agents to do this work, specially for foreign applicants. INGENASA is required to make more preparations for the application by itself, specially sometimes it is hard to identify the responsibility of the agent for failures concerned with patent applications.

In respect of the contents of the creation of the inventions, except for those that have been published or announced, the patent agency shall bear the responsibility of keeping them confidential. If INGENASA is damaged because of mistakes made by the agent, INGENASA can require the agent institute to displace the agent immediately and ask for compensations from the institute. INGENASA can sue in the court and ask for administrative punishment. There is Patent Agent Regulation that gives agents strict requirements and the legal basement to punish agents when breaking laws.

The types of patent

Chinese patent law allows for three types of patents, invention patent, utility model patent and design patent, which are all regulated in the Patent Act. Invention patent has been mentioned above. Utility model patent is mainly about any new technical solution relating to a product’s shape, structure, or a combination, which is fit for practical use. Design patent means any new design of a product's shape, pattern or a combination, as well as its combination with the color, which creates an aesthetic feeling and is fit for industrial application. Utility model patent and design patent only provide 10 years protection, however, they are not subject to substantive examination and can be granted within one year of application. Utility model patent has lowered the level of requirements concerning inventiveness than invention patent; design patent has no requirement about inventiveness. However an invention patent is more likely to be granted injunctive relief than other two kinds of patents on account of substantive examination.

In China some companies take this kind of strategy, lawyer Cu says, file both a utility model patent and an invention patent for the same product that is allowed under the current Chinese law. The purpose of applicants is to easily obtain protection of utility model patent when the invention patent is pending. In this way companies can protect inventions earlier and at last enjoy the longest protection. The requirement is that the application for invention patent shall be submitted before the publication of utility model patent and the applicants shall give up utility model patent before substantive examination for invention patent. Since utility model patent is technical program to shape, construction or both combined of a product, it may be impossible to apply this strategy to the case of INGENASA at the first stage, however later when INGENASA has some products, not antigens to patent, such as diagnosis instruments, this can be taken into great consideration. Now for the antigen INGENASA shall apply for invention patent.

Practical considerations for patent

Time for patent. INGENASA needs to apply for patents before approaching this market, as now many foreign companies[40] did. When they begin to do business, the patents have been granted or gone into substantive examination, which can provide them protection and opportunities for commercialization in China. Once patent applications are published the owner can ask for certain fees for using technology. Furthermore, because veterinary products need to be approved for marketing by the administration according to regulations, it is better for INGENASA to get the approval before submitting substantive examination for patents for the reason that if products are not approved the patents cannot be useful.

Protection scope in the preliminary and substantive examination. There are preliminary examination and substantive examination in the process of invention patent application. The applicant can modify application documents in the process of application, however, cannot exceed the scope of disclosure contained in the initial description and claim. Considering this, at the first stage, INGENASA may claim more rights and broader protection, which can give it better position since the claims proposed can reduce the possibility that competitors may file for other patents concerned with the antigen in this field and INGENASA is given the

[40] Enterprise intellectual property strategy (Hong Xiao Qing) (in Chinese)

right to choose protection scope later. Applicants for invention patents have up to three years from the date of application to request a substantive examination. When submitting application of substantive examination, applicants can modify their patent application within three months. This gives applicants enough time to dwell on if application is a good choice and what kind of claim is better. When INGENASA files for substantive examination, INGENASA may narrow down protection scope after considering benefits of this company and possibility to be approved by SIPO. Normally INGENASA claims that the antigen concerned with porcine rotavirus may be applied in the diagnosis and vaccine field. The applications of patents are determined based on the core competence and market orientation of INGENASA. Except the application in diagnostic test, the company may have capability to develop a vaccine using the antigen, which may become a more important source for business and profits.

Description about inventions. Another issue worth mentioning is that in the Chinese patent examination[41] guidelines applicants are required to give descriptions about technical characters or structural characters instead of functional characters for inventions. Only when technical characters cannot give clear descriptions about the invention, functional characters can be included. This is a little different from the United States and some other countries. Foreign applicants are easy to ignore this difference and always are asked to do modifies of application documents. INGENASA needs to consider it when preparing application documents.

Know-how. INGENASA needs to keep some know-how in secrecy, instead of disclosing all of the information concerned with the invention, in order to prevent imitation and keep advantageous position. However according to Chinese patent law, applicants must have enough description about invention otherwise may face the risk of invalidation. But it does not require applicants to disclose the method to achieve best function concerned with products or process. So how to deal with the balance is of importance. INGENASA may keep some type of know-how such as the purification of the antigen, how to set up diagnostic products and quality control of products.

Patent defensive wall. The technology of designing and producing the antigen is

[41] The functional definition of patent (Liu Li Ping) (in Chinese)

the core competence of INGENASA. Since the patented antigen may be the best indicator of corresponding infectious disease, porcine rotavirus, the patent may be considered as key patent for the product. However there is still possibility that other companies may be capable to produce competing products. Therefore, INGENASA shall consider patenting different regions of this antigen. INGENASA may also try to design other possible antigens around this disease, porcine rotavirus, in order to remove any possibilities that in this field similar products appear. In this case, it can be the secondary antibodies in the assay if those antibodies are not available in the market and can be developed by INGENASA.

INGENASA may develop a special way to purify the antigen, which can be patented too. It is the construction based on the gene (or part of the gene) cloned in a vector that expresses the antigen or part of the antigen, which can be used for purify subsequently. This may enable the function of antigen better. Furthermore, if any equipments or instruments concerned with this business INGENASA may invest in China have not lost the novelty, INGENASA also can consider patenting to get legal protection. In addition, as it has been mentioned above, in China except invention patent, there are utility model patent and design patent that do not require substantive examination. INGENASA can develop special design for diagnostic products that will be marketed in China in order to have the design patent and easier marketing. The reason for these patents is to build safe patent protection net for the business in China where the risk that technologies and products are imitated and counterfeited is not small. In this way the cost of infringement must be improved. In general, the purpose of INGENASA is to establish defensive walls for diagnostic products in this market. Actually in the pharmacy field[42] many companies try to have different patents for one newly developed medicine in China.

If INGENASA determines to patent these together, according to the law INGENASA may be capable to put all of requirements into one application as long as these belong to one general invention idea and have the related technical characters. By the means of one application, applicants may get several rights for related inventions or utility models involved in one general idea. In the process INGENASA is also allowed to change one general application into

[42] Pharmacy intellectual property strategy (Wang Ming Xu, Liu Jia Quan, and Qin Zheng)(in Chinese)

separate applications.

Invalidation issue

Now to defend their market shares, more and more Chinese companies begin to take strong positions to protect their intellectual properties rights. Actually they often successfully come together to initiate invalidation actions against foreign companies' patents. For example, in China there were many reports concerned with that Pfizer, one famous pharmacy company in the world lost its patent for its drug in China in 2004, when almost fifteen Chinese drug manufacturers brought suit to invalidate the patent on various grounds. The Patent Re-examination Board interpreted that there was not "sufficient description". Though it is controversial, this case shows the power of invalidation in China.

According to limited statistics[43] about 30% of patents granted each year in China are invalidated. This is concerned with whether the patent has strong offensive and defensive positions. It is not an issue of local protectionism. Any people can invalidate granted patents as long as they can prove that the granting does not comply with regulations in patent law, for example, the inventions shall fulfill the substantial requirements such as novelty, inventiveness or industry application, the description shall give clear integrate explanation about the invention that enables normal technical persons in this field to understand and implement. In addition, if the description modified goes beyond the scope of original description and claim, the patent also can be invalidated. Therefore, to avoid this kind of risk, INGENASA shall deal with patent application issues carefully not only from the perspective of substantial but also procedure requirements. Though in livestock diagnostic field there are not many competitors in China now, this threat also needs to be paid great attention to.

Infringement

It will not be beneficial for INGENASA to be connected with infringement scandals that would harm the reputation of the company. On the other hand, in the frame of patent law and other relevant laws, INGENASA can not only formulate realistic patent strategies, patent licensing as the main tasks, but also have market monitoring in order to find out infringement, prevent being infringed by other parties, to ensure competition superiority as the main objective.

[43] Managing IP in China (Kalle Chen), working paper of the King Wood law firm

When INGENASA finds infringements, firstly it may go for administrative remedy, which is fast and efficient in China. Chinese patent law allows a patent holder to seek remedy for patent infringement through the People's Court or administrative processes. Actually the majority of all patent actions are actually brought under the rubric of administrative enforcement. Instances of civil and criminal litigation have been growing, however, and may eventually be better able to deter infringement.

The patent protection through the coordinated operation of both judicial administration and administrative law enforcement has been improved. In December 2001 SIPO issued Measures for Administrative Enforcement of Law on Patents, which has made it easier to receive administrative patent protection. In protecting patent rights, administration departments have solved[44] a great number of patent dispute cases due to the fact that their personnel have both technological and legal knowledge, and that their handling procedure is simple and fast. This has become an important feature of China's patent system. The patent administration organ has wide-ranging powers to investigate and collect evidence. For example, the afore-mentioned regulation stipulates that the administrative organ can consult and photocopy companies' account books, which often belong to the companies' confidential documents, and are often difficult for the other party concerned to get. The patent administration organ can mete out certain administrative punishments to the infringe party, which include stopping infringing acts, destroying infringing tools and products and confiscating illegal gains. By comparison with courts, the blow to the infringe party is often more likely to result in the fairly rapid and thorough termination of infringing acts.

How INGENASA reacts against infringement could be crucial for the future. The situation can also be seen as an opportunity where the infringing company was not aware of its patent in the first place. This can create opportunity for INGENASA to offer a license agreement to generate revenues or acquire new technologies. Now in China there are some companies applying this kind of strategy that at the first stage they allow infringements in order to make their products or technologies obtain more market recognition, then they ask for

[44] Broading patent protection (a report from Wu Han University of China) (in Chinese)

license fees or high amount of compensations when other companies have invested much in this field and products have been accepted by more and more customers. For example, there were Chinese reports concerned with that Chinese MP3 manufactures were asked various license fees by foreign companies holding patents after these manufacturers have been working in this field for some time. From personal opinion, this should not be recommended, however from the perceptive of business, this may be taken into consideration, specially if INGENASA tries to approach this market by means of license.

4.3.2 Trademark issues

When INGENASA approaches Chinese market, trademark is also one of important building blocks, specially when it comes to long-time development.

Legal basement

Since 1982, China has successively promulgated and implemented as Trademark Law and amended in 1993 and 2001. The trademark law is "first-to-file" system of registration. Prior use of the trademark is not relevant unless two or more applicants have filed applications simultaneously for identical or similar marks. Products without registered trademarks can be marketed, however are not provided legal protections. Trademark rights cannot be obtained by the means of establishment in the market; only well-know trademarks are protected without registration. In China famous trademarks enjoy great protection, however it is not so easy to be identified as famous trademarks. In fact famous trademarks, specially foreign famous trademarks are mainly identified in the individual case such as infringement case.

Trademark for INGENASA

Although now INGENASA does not have reputation in Chinese market, it is wise for INGENASA to register trademark when it approaches the market because of the first to file system. Specially INGENASA has obtained certain reputation in Europe, and there is still possibility that another company registers this trademark designed or undersigned, which can impede the approaching process of INGENASA. INGENASA can file applications through the Madrid Agreement or file applications directly in this country.

INGENASA may have trademarks including INGENASA and Chinese words the pronunciations of which are similar with INGENASA. Normally it is easier for people in China to remember Chinese words, which is imaginable and reasonable. In fact many foreign companies did that such as Coca Cola Company, Pepsi Company. The Chinese names of these companies are not only similar with their original pronunciations but also funning and meaningful in the Chinese language and culture, which help these companies obtain more recognition in China. Another example is that IDEXX, the competitor of INGENASA, has the Chinese name AI DE HUA that may be understood the love and moral merits in China. The pronunciation of these words in Chinese is also similar with original pronunciation. If INGENASA wants to have long-time development, this job must be helpful even though it is not so easy to be successful. One of possible Chinese names can be YIN JIAN SI, which may be understood as healthy moments for animals and people.

Figure 10. Suggested Chinese name for INGENASA

Trade name is also legally protected in China, however there are only some principles scattering in several regulations. Only the Unfair Competition Law and the Regulation of the Commercial and Industry Department have stressed that companies are forbidden to confuse customers by using the trade names of other companies without permission. The legal protection to trade name is less and weaker than trademark in relation to law and practice. Therefore, some companies use trade names as trademarks so that they can provide these symbols of companies stronger protections. INGENASA may take this into consideration, so INGENASA, the company name can be used as trademark in China, as it is showed above. Also, INGENASA may choose the trademarks got in Europe. Meanwhile, INGENASA may get trademarks for its products in China.

In addition, in China only visible symbols or words can be registered as trademark; sound and smell are not possible to register. Colour combination can

be registered as trademark, however it is hard to show the distinctiveness in China. For example, in November 2005, there was one case in Beijing concerned with if a Sweden company's colour-combination trademark can be registered or not, which is regarded as a landmark case on the register issue of colour-combination trademarks in China.

Brand establishment

As we all know, it is important to establish brand recognition for a company that desires to have long-time development in one market, and it is the same case in China. However this is time-consuming work. Naturally in the marketing and normal business development INGENASA can spread its fame. The function of various Medias is also significant for publicizing brands and products in China; actually multinational companies use this strategy very well in China compared with local companies. In addition, since in China the official function is great, specially in this field some clients are partly funded by government, it is wise for INGENASA to join government-funded activities and publicize itself in some official magazines. Now the health of livestock is of great importance not only for the benefits of this industry but also for the health of people. If INGENASA can shape itself as the technology company bearing social responsibilities, it may achieve more recognition. When patents expire, with brand reputation INGENASA can keep market shares. For example, Johnson& Johnson[45] joined various projects in the education, public medical service and science to shape its perfect symbol in China. Many successful multinational companies have been involved in social activities in the process of brand building.

Infringement

Later after business establishment INGENASA may face counterfeiting or other infringing activities, which requires INGENASA to monitor the market for any potential infringements. As we know, identifying invisible competitors is great challenge and demands effective monitoring programs. Furthermore when asking for administrative remedies, the company is required to provide relative evidences, which is a hard task, specially now some infringing companies manufactured products in one place, then branded products in another place. So lawyer Cheng said that more and more foreign companies begun to hire private investigation companies for collecting evidences in China.

[45] Chinese market strategy of multinational companies (Li Ying Sheng) (in Chinese)

China has two systems of channels to protect trademarks. Same with patent, the double-track mechanism of parallel trademark protection by Administrative Authorities and Judicial Authorities, which is of distinct Chinese characteristics. In 2004 administration authorities[46] carried out the nationwide Special Campaign of Protecting the Exclusive Right to Registered Trademarks, which gave priority to the protection of well-known trademarks, foreign-related trademarks and trademarks used on foods and medicines, and has made remarkable achievements. So when it comes to trademark infringement INGENASA still needs to ask for administrative remedy firstly.

4.3.3 Trade secret and unfair competition

Trade secret

INGENASA also has know-how around the patent for porcine rotavirus and other trade secrets for business. Trade secrets are protected under China's Anti-unfair Competition Law, Labour Law, Contract Law and regulations made by the Industry and Commerce Department. There are requirements for trade secrets in these regulations such as secrecy, economic and application value, and measures taken to protect them.

According to Contract Law of China, a party may not disclose or improperly use any trade secrets that it became aware of in the course of negotiating a contract, regardless of whether a contract is formed. In the contract law it is also said that upon discharge of the rights and obligations under a contract, the parties shall abide by the principle of good faith and perform obligations such as notification, assistance and confidentiality, etc. in accordance with the relevant usages. From these clauses we may claim that even after the termination of contract parties still have the duty, lasting until the trade secret becomes public information. However the relevant usage is not easy to identify or explain, and there are no more interpretations about this kind of regulation. Actually in the practice clear non-disclosure agreements are still necessary to protect trade secrets in China.

Therefore, if INGENASA has business presence in China, INGNEASA should utilize

[46] A speech at the press conference by vice-minister of state administration of industry and commerce.

non-disclosure agreements in negotiations and contracts, identify and restrict disclosure of all technical data only to those who have a "need to know" and compartmentalize knowledge. When a breach occurs in China, INGENASA can seek legal remedies by instituting an administrative action, a civil action or a criminal action against the offending party. However, the most effective protection is to take pre-emptive measures against the breach. INGENASA needs to maintain consistent overall control over its Chinese associates, business partners, distributors, employees, etc. Practical measures should be put in place to control and restrict access to confidential information.

Unfair competition

The main ones containing antimonopoly provisions are 1993 Law against Unfair Competition that is actually mainly about monopoly made by government agency, 1998 Price Law and 2000 Bid and Tender Law. But generally speaking, these laws and regulations are not systematic and specific enough and have not mentioned the newly emerging practices. China's competition law framework has not been established yet. There are many Chinese articles to appeal the government to enact the anti-monopoly law since they think some big multinational companies have misused their great power in the market and damaged the benefits of other companies badly. Actually the draft of China's Anti-Monopoly Law has been revised many times.

4.4. The entry models

How to approach Chinese market is essential for the whole business process. The main business models for foreign biotech companies to enter Chinese market are exporting, licensing, setting up a wholly foreign-owned enterprise or joint venture and purchasing an existing company. Whether one business model is beneficial and suited to a company depends on the goal that the company wants to achieve.

4.4.1 Export

Using a third party to export products to China is an easy way to market products there, but generally is not a good long-term strategy. Perhaps the easiest and quickest way to export products to China is via a Hong Kong distributor. Due to fast development and open policies of China mainland, this

method has not be taken as much as before. In order to fulfill its WTO commitments and duties, China amended the Foreign Trade Law in 2004. The requirement for administrative approval of foreign trade operators engaged in goods or technology import and export has been lifted. Until now in China there are some forms of foreign trading entity for INGENASA to choose such as foreign trading corporations, industrial trading companies, independent trading companies. Foreign companies can also sell to domestic Chinese distributors and end-users directly.

Distribution (export) is the business model that INGENASA uses in European market successfully. In this way INGENASA can sell products to end-users through distributors without any other complicated relationships. Though it is a convenient way for foreign company to do business, however, as it is said, in this way of export, the higher prices, which include manufacture cost, distributors' margin and export fees, limit market penetration, specially China is a country outside Europe Union. INGENASA needs to gain competitive advantages by reducing costs; specially in China the price level cannot be too high. Another disadvantage of this method is the loss of control over market-entry strategy. Foreign companies therefore choose to build sales forces within China, which may provide greater control over sales and lower prices. On the other hand, building a sales force often requires much time to identify and develop relationships with potential Chinese buyers. In addition, there are also difficulties for delivering products in time due to great distance and complexity of international transportation. From the order to delivery enough time is needed, however some customers demand products immediately. The problem for proper storage is also there.

For the reason that INGENASA is a Spanish company located in Europe, it is easy for this company to establish distribution network across Europe. The distance between China and Europe, the language, and culture differences, make it difficult to use the business model in China. In fact establishing distribution networks may require so much time that foreign companies may be unable to grasp market opportunities. Building distribution networks[47] in China can also be the complicated social investment. It is also hard to deal with the relationship

[47] Analysing structural dynamics and selecting a foreign investment (Luo Yadong)

with distributors. For example, Kodak Company[48], one famous Japanese company, had this kind of experience. At first Kodak had almost four first-level distributors for its products in medical service in different regions of China, and later Kodak became more and more dependent on distributors. Distributors controlled the channels of customers and their power to argue with Kodak grew gradually. When at last Kodak cannot satisfy their needs, they switched to other big companies, which gave Kodak a heavy blow.

In general, though this method is possible, at the present stage distribution does not seem a very good choice for INGENASA, which wants to achieve competitive edge compared with other competitors and have long-time developments in this market.

4.4.2 License

A technology license usually enables a firm to enter a foreign market quickly, and poses fewer financial and legal risks than owning and operating a venture. License also permits firms to overcome the tariff and no tariff barriers that hamper the export of manufactured products. Therefore, license can be an attractive method of "exporting" for small companies or companies with little international trade experience due financial consideration. License may be a good option for companies seeking less direct involvement in China.

INGENASA can get patent rights for technologies that this company wants to commercialise in China. With this patent right INGENASA has the license object to obtain profits by establishing license relationship with Chinese companies. This is a convenient way to approach Chinese market, since the company can get royalties from license as well as avoid transportation costs, and have the advantage of low manufacture cost. This is a quick market penetration for INGENASA without making heavy capital investment overseas. Specially INGENASA is not the first new comer in this market, so INGENASA needs to choose some kind of entry model to obtain advantages and avoid risks. The licensed technology of INGENASA is not very difficult to absorb and adapt by Chinese licensees. Furthermore, INGENASA shall have the confidence in retaining a long lead in product development over their Chinese licensees in order to

[48] Case study to marketing and service of Kadak's medical image system products (Mi Chuan Yong) (in Chinese)

minimize the risk of another fierce competitor; actually according to doctor Liu's words, in this field Chinese companies have not had competitive edge until now.

As a form of "exporting," technology license has certain potential drawbacks. One is that control over the technology is undermined because it has been transferred to an unaffiliated firm. Sometimes it may be difficult for INGENASA to monitor actual sales of their products licensed in China, making it hard to make clear whether the Chinese company is paying correct royalties. There are also some difficulties: one is that it is not easy to find a good licensee that has technological and manufacture competence to perform the obligations of licensees. In addition, it is essential for the licensee to have national marketing networks and rich marketing experiences; another is that INGENASA will spend much time on negotiating with this company on many issues included in license contract. Even when some difficulties are there, license is still a good choice for INGENASA since the difficulties can be overcome and advantages can override the disadvantages.

4.4.3 Establishment of Ventures

In 1979, the Joint Venture Law was enacted and for these years foreign ventures have flourished with explosive growth. Many laws concerning foreign investment were passed and China began promoting itself as an excellent place for foreigners to invest. In the pharmacy field[49] almost 20 of the biggest 25 multinational pharmacy enterprises have had joint ventures or wholly owned ventures in China. Almost 40 percent of Chinese pharmacy enterprises have projects connected with foreign parties.

From some Chinese reports about foreign investment, we can see that foreign investors set up ventures in China for a variety of reasons. Most importantly, joint ventures help foreign companies gain access to China's domestic market while maintaining control over their activities. As we know, one disadvantage of license is loss of control. Even INGENASA makes a good selection of its licensees; it remains dependent on the licensee's performance. Second, ventures help many foreign investors take advantage of China's relatively well-educated, low cost labour force to produce their products. There are some other advantages including improving access to local resources, preferential treatment from

[49] The toppest pharmacy companies have had investments in China (daily report in Chinese)

Chinese government such as tax incentive, obtaining direct and indirect support and assist in overcoming difficulties with foreign exchange controls. On the other hand, Chinese government[50] has goals in foreign joint ventures, for example, increasing industrial efficiency, and the creation of new jobs. The goals of Chinese companies include: obtaining advanced technology, regarding the venture as an instrument to get ahead in the local market. As it is said in the BCG report, even though there are some other countries with same or lower labour cost, China has been regarded as most productive country with low cost.

A venture offers long-term market-penetration strategy for biotechnology, even though it is time-consuming and expensive to set up. Many successful foreign biotech ventures already exist in China. If INGENASA verifies that there is a large growing market for products, it has the financial capability and is willing to have business presence there, then a venture is probably the proper long-term strategy to penetrate Chinese marketplace. Through this entry model, INGENASA has the chance to control business directly, and do expanding through its own branding strategy. With physical business presence in China, INGENASA can easily see the real needs of end-users, and prices can be more competitive resulting from local manufacture. Along with more and more technology students graduating from universities, there is a large group of technology human resource that is able to assume various tasks in this field. Of course, there are some risks when establishing joint ventures in view of the fact that INGENASA shall bear obligations of joint venture including financial risks. In addition, INGENASA is required to put original investment in this venture. However this is still a considerable option for long-time development. Due such advantages some disadvantages involved can be ignored.

4.4.4 Purchase

At last, there is another entry model, which is to purchase a Chinese company in the same field. In this way, foreign company can control established Chinese company directly and avoid the difficulty to negotiate with partners. It provides established marketing network and human resources that are essential to approach new markets. However, by means of this, risks to have business in

[50] Why China still need foreign investment. (in Chinese). Collected from http://www.jrinvest.cn/news/26/200542794548.htm

China increase and foreign companies are required to have enough financial capability. What's more, once succeed in purchasing one Chinese company; foreign companies must confront various problems to be in charge of this new company and foreign companies do not know much about conducting business in the Chinese system and business environment. Though this is a simple and direct way to obtain necessary resources to manufacture and approach market in China, this must be costly, and now INGENASA may not have enough financial capability to assume this task. Moreover, it is difficult to find suitable biotechnology company that is willing to be sold with good reputation and other necessary resources.

According to above analysis, every method of approaching Chinese market has its own advantages and disadvantages. So we can try to choose one or two models, which are better for business development based on the capabilities and business goals of INGENASA. At present, it seems that license and joint venture have come to the good options of INGENASA, which are recommended in the thesis and will be introduced more.

4.5. Cooperation partner

For entering Chinese market, as mentioned earlier, INGENASA has to find a partner that is already established in this market. In China there are several types of manufacture and research entities[51] in veterinary product field: manufacturers appointed by the State, laboratory manufacture facilities, affiliated companies of universities or research institutes and other kinds of companies. Finding a proper cooperation partner is a hard work, requiring lots of investigations. Here just present one example taken into consideration.

A potential partner for INGENASA can be the YONGJIAN Biotechnology Company. This is a bio-product enterprise excelling in biotechnology products for animal diseases. The company's home base is in CHONGQING host to national and international companies and one of the most vigorous business environments in China. In its few years of operation, YONGJIAN has attracted more and more persons with biotechnology knowledge in this field and produced some products

[51] The comparison and analysis between Chinese veterinary biotechnology industry and foreign veterinary biotechnology industry (Zhou Qi, Wang Xiao Mei, Bai Xia, and Shun Bai Ming) (in Chinese)

for livestock. YONGJIAN[52] has established animal medicine production plant, animal disease diagnostic centre and one laboratory. The company is in process to build an animal biotechnology product production plant. YONGJINA has current cooperated with Southwest Agriculture University and other institutes related to biotechnology field.

YONGJIAN has several advantages as the partner for INGENASA. Firstly, this company has the competence to produce biotechnology products for livestock diseases and has established market network across most parts of China. Secondly, in the area where YONGJIAN is located, the swine industry develops well that is regarded as quite important industry there. The market for diagnostic products of livestock disease should be desirable. Specially YONGJINA is located in the newly opened special veterinary technology town established by local government. There are a variety of veterinary companies, which makes information collecting and marketing easier in this field. At last, though CHONGQING has become a large international city, those biotechnology companies may have less bargaining power than companies in Beijing, Shanghai and other coastal cities; in the inland regions labour cost is lower. Now Chinese government is trying to encourage foreign investment or trade in the west part of China. There are more incentives provided by local government than other areas. Of course it is also good for INGENASA to find a partner in developed areas, particularly with some companies affiliated to famous national institutes or universities. Cooperating with these companies it may be easier to have great influence, however without enough financial investment and strong technology support it is hard for INGENASA to have better position in the cooperation relationship. Here we still recommend companies in CHONGQING, which is regarded as one of richest cities in the west part. What we shall consider is that China is a big country with large land almost as the whole Europe, so it is of importance to find specific part as the first place to start business based on evaluation to this place including invested industry, labour cost, policies, government and market situation.

4.6. The form for INGENASA

Here we have more introductions and analyses about license and joint venture.

[52] YONGJINA's website(in Chinese), www.yonjan.com

Through the two entry models INGENASA is able to make use of manufacture force in China. License is medium-time strategy; a venture is long-time strategy. INGENASA may adjust entry model with changing situation and practice. Based on the understanding of the situation of INGENASA, Chinese law and practice we try to mention some important issues and ideas concerned with the two models.

4.6.1 License

There are some issues that shall be taked into consideration about license:

Regulations

In China, any form of economic collaboration involving technology and know-how is subject to the "Technology Import and Export Regulation"(The Regulation). There were some clauses foreign licensors dislike in the version of 1985, for example a ten-year maximum term for technology transfer contract, and the centralized approval procedure. These parts are no longer present in the new regulation made in 2001. That helps licensor increase the control.

Categories of licensed technology

The Regulation governs both inbound and outbound transactions involving technology, classified technology and know-how into three categories:

Prohibited Technology: No import or export of such technology is permitted.
Restricted Technology: Prior government approval from the Ministry of Commerce is required to have a valid enforceable contract involving such restricted technology.
Permitted Technology: Government approval is not required and the contract involving such permitted technology is valid upon execution except that the party shall report and register the transaction on the website of Ministry of Commerce.
The State may restrict or ban technology transfer for reasons, for example, public interest and national security, protection of human life or health and protection of domestic industry. In 2001 government issued such a list of technologies that are prohibited or restricted. Technology not falling in the list is permitted for free import. According to investigation, the technology of INGENASA does not fall into the list, and actually welcomed by government due its advance and usefulness.

Technology license

INGENASA licenses patent concerned with the antigen of porcine rotavirus for veterinary diagnosis and some type of know-how such as how to set-up the product.

- License form: INGENASA may be willing to give partner a sole license in Chinese market. It is not convenient for INGENASA to find a lot of trustful licensees, which may distract the company's attentions. Actually the manufacture force of one company may be enough at the first stage since not many end-users for this kind of product are available. By giving sole license INGENASA can have more power to bargain with another party to achieve favourable clauses.
- License field and region: License is limited in swine diagnostic field, which INGENASA has an eye on. It is important to remember that foreign licensees may attempt to use licensed technology to manufacture products in direct competition with licensor. In many instances, licensors may wish to impose territorial restrictions on their foreign licensees, depending on antitrust laws as well as licensing laws of the host country. There is one clause in The Regulation that licensor cannot unreasonably restrict export channels of products manufactured by the licensee with the imported technology. However there is not clear explanation for "unreasonably"; in the practice, as lawyer Cheng says, parties try to come up with this kind of clause with good wording in the contract. INGENASA may allow licensee's marketing only in the regions INGENASA does not have marketing channels, which may not be regarded as unreasonable restriction.
- License period: INGENASA can license technology for a proper period of time. As it is said above, in the new Regulation there is not limit on the license period any more. In this case, the cooperation may last long since INGENASA just wants to market products there and it is not so easy to deal with post-time relationship. In addition, there is possibility that they can continue the relationship in the future, developing a kind of joint R&D where their developments are dependent on this technology. After all with some clauses included, INGENASA can withdraw if the purpose of license cannot be reached.
- Sublicense: If Chinese partner wants to sublicense technology to another party, it must be approved by INGENASA. Chinese partner can only sublicense

technology within the limits of its rights and obligations in the license agreement.

- Guarantee: INGENASA guarantees quality and accuracy of diagnostic technology for swine disease. INGENASA needs to be aware of certain statutory requirements when negotiating transactions with Chinese entities. For example, the licensor has the duty to warrant the technology to be "complete, error-free, valid and capable of accomplishing the agreed technical target". So it is necessary to make clear what the technical target is in order not to fall into any possible raps. In addition, if there has in fact been an infringement of third party rights, the licensor shall be responsible.

Restrictive clause

In this Regulation, it is said that some restrictive clauses to licensees can not be included in the technology transfer contract, for example, unnecessary requirements of purchase of additional technology, raw materials, products, equipments and services; requiring the licensee to pay royalties or undertake obligations for patents that have been declared invalid or has expired; restricting the licensee from acquiring similar or competing technology from other sources. These provisions of the Regulation are mandatory, which means that they cannot be 'drafted around' in the agreement. To the extent that a contract governed by a foreign law contains provisions inconsistent with mandated provisions, a Chinese court will not enforce it. It will be necessary for INGENASA to enforce the license restriction through a Chinese court; this means that mandatory provisions need to be respected.

Patent invalidation

It is risky that INGENASA puts the non-challenge obligation on licensees. In China there is not as detailed competition law as Europe and the Anti-unfair Competition Law is simple with thirty-two clauses, mainly concerned with the protection of trade secret, trademark and deals with other business activities confusing customers. However there is one clause in the Foreign Trade Law of China that if there is non-challenge clause in the contract and damages the order of foreign trade, the department under the State Council has the power to make certain measures. In the Interpretation of Technology Contract of the Supreme Court, it is said that it is illegal to forbid licensees to challenge the validity of

patents. In the practice, as the lawyer Cheng says, some parties still try to include similar clauses with good wording in various individual cases. The Chinese appetite for efficient industrial exploitation of foreign technology is such that the Chinese party will often help its foreign party to circumvent the worst of the problems. On the other hand, parties can agree that if the patent is invalidated, INGENASA as the licensor does not have to return license fees received as long as INGENASA can be proved without wilful intention. This is also regulated in the relative law.

Research development and improvement
INGENASA will develop the technology continually according to business development plan. Specially, consideration should be taken about how to make the technology more compatible for Chinese market.

In China whoever makes an improvement on the licensed technology during the valid term of technology transfer contract shall own the improvement and the licensor cannot restrict the licensee from making improvements to the technology or from using such improvements. The Regulation indeed provides protection for licensees and intends to keep the doors open for Chinese companies to create and innovate without contractual restrictions. On the other hand, in the contract law it is said that parties can arrange how to share the improvements. If there is no arrangement, one party cannot enjoy the improvement made by another party. So INGENASA may not have the ownership of improvements made by licensee, but can reach the agreement for INGENASA to enjoy the improvement of licensee. Furthermore, in the Interpretation of Technology Contract of Supreme Court, any party of license cannot require another party to provide its improvement without any charge or non-reciprocal transfer of improvements. So INGENASA may not ask for transferring ownership of improvements since it must be reciprocal, instead INGENASA can demand the sole license with low charge. In this way the clause is within the legal frame, the rights of licensee are not restricted but also can meet the demands of INGENASA to some extent. In the practice, licensors always try to come up with similar clauses with good wording, and the judgements are based on the analyses to individual cases. In some contracts this kind of restrictive clauses is there, however Chinese partner normally does not want to oppose them for keeping

collaboration based on different considerations.

Another way to bypass this limitation may be to make the improvements as derivative commissioned work, and state in the contract that all rights in commissioned work made by licensee belong to the licensor. That means that INGENASA can commission the licensee to do research on the licensed technology. The commissioned improvements belong to the commissioner, INGENASA. This option is based on the understanding of various Chinese regulations. As we see, this kind of clause does not breach the Regulation and complies with the regulations concerned with commission work in the Patent Law of China. This commission can be loose requirements for research during the period of cooperation, different from other normal commissions. This may avoid the risk that the licensee makes some improvements, which INGENASA cannot have, the ownership. Another method is to draft a carefully worded R&D agreement alongside the main technology license. According to Chinese contract law, two parties can arrange the ownership of developed technology and how to share it in the co-research contract. It may be said that during license process both parties need to do research on improvements together, ownership of improvements belong to INGENASA and another party gets relative compensations according to its contributions.

As to technology development, Liu, one doctor in biotechnology field, said that even though technology development is desirable in China, veterinary biotechnology has not been developed as much as others. Specially the antigen may be proved the best indicator of the disease, so INGENASA can have the confidence to be the leader concerned with technology compared with licensee. In addition, INGENASA may not license some type of know-how in order for INGENASA to have kind of superiority over licensee.

Trade secrets

During the period will be some technology and business secrets. Both parties must keep information secret in order not to lose business competitive edges. In the Regulation licensee is required to keep the technology confidential, except if the technology has already been made public. The confidentiality obligation is limited to the extent and term agreed on in the contract. The regulations also put

confidentiality obligations on the authorities in charge of technology import, under criminal liability. In general, as we said above, in China secrecy agreement is still necessary; detailed provisions in the contract are of importance to control the licensee. Furthermore, lawyer Cheng said, many foreign companies prefer to make documents for trade secrets and other intellectual property protection including detailed requirements as the attachments of license contracts in order to provide overall protections. INGENASA also can require licensee not to disclose any know-how to others even after the period of validity of contract since the Regulation leaves parties the room for post-time use, specially according to relative law the obligation for secrecy can be indefinite in China.

Trademark

During the marketing process Chinese partner uses the trademark of INGENASA on the product. Through this INGENASA can establish brand recognition in this market, which is good for long-time development, specially INGENASA has plans for other products in the future. The licensee is required to only be able to use the trademark of INGENASA in the permitted scope. This is the patent strategy combined with trademark strategy when approaching one new market. However the licensee must guarantee the product quality in order not to damage the reputation of INGENASA. INGENASA may check the quality of products regularly and the costs shall be borne by licensee. Strict quality guidelines can be included in the contractual agreement. In addition, INGENASA may require licensee to buy product quality insurance for problems due to flaws of products.

Post-term

Under the Regulation of 1985 technology transferred in the post-time was free to use by the transferee, unless administrative approval of other terms had been obtained. However the new Regulation leaves the post-term relationship to the parties. Parties can discuss and arrange the continual use of licensed technology by licensees. Therefore, in the contract INGENASA can require that after the valid period licensee cannot use licensed technology unless it is permitted by INGENASA.

Infringement

According to the Regulation, if the use of technology provided by licensor

infringes upon the lawful rights and interests of another person, the responsibilities shall be borne by the licensor. Except infringing other's rights, there are also possibilities to be infringed by others. INGENASA can require that licensee takes all reasonable steps to prevent any part of licensed technology being infringed and shall inform the licensor of any such infringement. If INGENASA takes proceedings against infringes, INGENASA shall receive assistance from licensee and the licensee shall provide licensor with all powers and authorizations necessary. Specially since INGENASA is not familiar with legal system and practice in China, the licensee needs to provide necessary suggestions and assistance. If both of them agree to commence proceedings jointly, they shall decide in advance how the costs and benefits shall be divided.

Communication

It is obvious that communication is of great importance to succeed in this cooperation. For example, an information platform system can be implemented in order for both parties to check important information concerned with cooperation program. A report system will be necessary with the purpose that each party reports its current situation. This is also good for INGENASA to know more about the sales, which is helpful for identifying the royalties. INGENASA provides Chinese partner with technical assistance in the licensed technology, technical consultancy about the use and accuracy of technology. Also, INGENASA has the obligation to send technical persons for on the spot instructing and training the employees of licensee at the first stage. However all of the costs shall be borne by licensee.

Benefits

In China there are not any particular provisions about this. There are several ways for this such as one-time payment, instalment, the first-time payment combined with deducting a percentage of sales per month/season/year. Since now what level the business in this market can reach is vague, it is hard to give a definite number for the license. Furthermore, lawyer Cu, said that in China the licensee is reluctant to accept one big number and would like to give the percentage of sales. The licensee prefers payments to be linked to their output to minimize their risks while keeping the licensor continually interested in helping the licensee in the production and sale. It is better for INGENASA not to make

royalty based on profits because there is possibility that licensee hides profit fingers from the licensor. Only when licensors have good control over management or have good reasons to be confident in the profitability of licensee, they may prefer to base royalties on profits. Cu also said that in China now in most cases those royalties are based on net selling price and place relevant royalty rate in the range of 2 to 5 percent. At the same time INGENASA can get a lump sum for the license agreement at the beginning, usually 10 to 20 percent of total technology price. There also should be minimum for royalty necessary to keep basic benefits. As to the minimum, INGENASA may have European market for reference, however the difference due to economy and consume capability shall be take into consideration since China is still a developing country. In addition, there is opportunity cost for the reason that a licensee may become another competitor, which shall be given due consideration and due to risk of infringement INGENASA also can require higher fees for license.

As we know, technology is becoming more and more important in information and biotechnology era. Even if this company does not invest money into the venture, INGENASA can get what it wants through license. However, monetary compensation should not be the primer objective for INGENASA. From the collaboration INGENASA hopes to open the opportunity for this company to overcome difficulties to enter Chinese market. This will allow INGENASA to use their distribution channels and help INGENASA create brand awareness in this market. In fact many companies[53] are employing licensing agreements to build up their brand name in preparation for future investment. License is flexible and can be easily integrated into other business models.

4.6.2 Joint Venture

When doing business in China foreign companies can set up business presence: a representative office; a branch office under the company law; foreign investment enterprise. The branch office is not regarded as a Chinese legal person. Using a representative office is restricted from directly generating income, or signing contract. According to the Veterinary Biotechnology Product Regulation, the representative office of foreign company is not allowed to market in China. It seems better to establish foreign investment enterprise for long time presence.

[53] International licensing by Luo Ya Dong, included in the international investment strategies in the People's Republic of China, Aldershot : Ashgate, cop. 1998

By the end of 2002, China[54] has ratified an accumulative total of 424,196 foreign-invested companies with contracted investment of US$828.60 billion. Through foreign direct investment, INGENASA can directly control business development in China, and establish manufacture facilities to supply its global markets including China.

4.6.2.1. Types of foreign ventures

There are three major types of foreign investment enterprise in China:

Equity Joint Ventures (EJV)

According to the law about EJV, enterprises of this category have the characteristics that all the parties participating in the joint venture jointly offer investment in it, jointly operate it, share the profits and risks of it in accordance with their different proportions of investment that are accordingly converted into ratios of investment. The corporate form of the Sino-foreign joint venture is liability limited company.

Contractual Joint Ventures (CJV)

The largest difference from equity joint ventures is that the investment from the parties will not generally be converted into ratios of investment. The rights and obligations of all parties including the provision of investment and conditions for co-operation, the distribution of profits or products, the sharing of risks and losses, the form of operation and management, and the ownership of property at the termination of the contracts are all defined in the contracts signed by all parties.

Wholly Foreign Owned Enterprises (WFOE).

Such an enterprise is a limited liability entity solely owned and operated by a foreign investor. In this scenario, the foreign investor receives all profits and bears all risks. This form has its advantages: foreign investor controls proprietary interests tightly and has exclusive management control. However in this way there is no Chinese partner with trained workforce and established sourcing and distribution networks, assisting in the success of the investment. In fact establishing a wholly foreign-owned subsidiary in China is a difficult process.

[54] An overview of China's absorption of FDI in 2002 (Zhong dan trade website)

4.6.2.2. Choosing venture form

Firstly the issue if INGENASA needs a partner shall be considered. The partner should have something tangible to offer, for example as an entry vehicle in an area otherwise restricted to 100% foreign investment, or in other assets such as distribution network or manufacturing premises. If INGENASA can provide all of these without partners, it may go alone since it does not have to negotiate with others. However that must cost this company much money. Furthermore, because it is quite different in China from Europe, it will take a lot of time for INGENASA to be familiar with the market and business system if INGENASA manufactures and markets by itself. China is such a big country with large land, which means that how to have distribution network is one of the important issues for holding a position in this huge market. In fact among these benefits, the local partner's expertise in dealing with local business environment and easier accessing to materials, distribution channels, labours are probably the most valuable. This is one of main reasons for foreign companies to choose joint venture even when they can establish wholly ventures. Local Chinese partner can also help INGENASA to overcome trade barriers. In addition it is not as easy to exit WFOE as with joint venture option. In fact there are many successful stories telling that an appropriate trustful Chinese partner can be very helpful. Johnson & Johnson venture in Shanghai is one example of success. IBM, Siemens and Toshiba each have financial strength, yet they still form alliances with Chinese partners to reduce costs and risks. Merck[55] Sharp & Dohme, one of the world's largest pharmaceutical companies established a joint venture with one Medicine Company in China in 1994. The company's technology skill and good cooperation with local partner has made it become one of the most successful foreign investors in China's pharmaceuticals industry. In the biotechnology field, there have existed many joint ventures, for example, Degussa (China) Co., Ltd., Beijing, an affiliate of Degussa AG, Germany, and Shandong Cathay Lineng Biotechnology Co., Ltd. signed a joint venture contract for the production of L-Lysine, an essential amino acid for animal nutrition in 2004.

How to choose the form of joint venture is another important issue. CJV and EJV are similar in many respects. The differences only are: CJV can take two forms including a limited liability entity with legal person status or a business partnership in which the parties cooperate as separate legal entities. Second, in

[55] Analyzing dynamics and selecting investment (Luo Xiao Dong)

the way of CJV, profits are shared based on a ratio arranged and specified in the contract, not necessarily according to ratios converted from investment.

In China there are many EJV as well as CJV. It is also hard to identify which one is more appropriate for one company. In this case, from our point of view, CJV may be better for INGENASA. Firstly, possible to allow more foreign management control. Foreign partners can often obtain the desired level of control by negotiating management, voting, and staffing rights into articles of association of CJV. Because these rights do not have to be allocated according to equity stakes, the CJV provides more flexibility than EJV. In addition, when there is high risk in the development phase of a project, CJV contracts can be modified without terminating a partnership and forgoing investments.

Secondly, the CJV structure tends to force partners to address rights and responsibilities in advance. The government must approve all CJV investments to allow the establishment of joint venture in the specified business scope. Government approval of detailed CJV contracts has the added benefit and avoiding local partner non-compliance. Thus, CJV contracts may provide better protection than EJV contracts if one partner fails to comply with agreements.

In all, although establishing a CJV can be time-consuming, it may satisfy INGENASA, the foreign investor, because of its flexibility. In real operational terms, EJV tends to be far more rigid, thus giving greater security to the larger amounts of equity that typically such ventures are used for. In fact such security is defined more by State regulations. CJV allows greater contractual flexibility for INGENASA and Chinese party to define the obligations of each of the interested parties. Since INGENASA is not a large multinational company that is able to invest a lot into this venture to hold more advantageous position at the first stage, it is better for INGENASA to negotiate with the partner in details by using the incentive coming from advanced technology to gain more controls of this joint venture. Without much financial capital investment, INGENASA can reduce the risk to the extent that it can bear. In the future if the business goes well and the brand reputation of INGENASA has been established, INGENASA may consider expanding investment to have more control and obtain more profits. There is also possibility to change CJV to EJV in the future.

4.6.2.3. Some issues

Foreign investment guideline

The State Council of China has published a set of foreign investment guidelines. According to these guidelines, foreign investment projects have been divided into four categories, namely encouraged, permitted, restricted and prohibited. For example, the encouraged projects include those concerning new agricultural technologies, energy, transportation and important raw materials, or those high-tech projects that can improve product quality, or enhance the technological and economic performance of enterprises. We can claim that the project of INGENASA belongs to the category encouraged.

The corporation form

Although a business partnership without legal status is more flexible, the parties shall bear more responsibilities by themselves, which is risky. Therefore, the corporation form shall still be an enterprise with Chinese legal status that bears limited responsibilities by its registered capital. To take the legal status, INGENASA and its partners may try to fulfil these requirements such as hold certain financial capitals, have its own name, organization and premises according to relative enterprise law of China.

Contributions

INGENASA mainly contributes with cash or in kind, advanced equipments, technology and technical support service. The Chinese partner mainly contributes cash or in kind, buildings, premises, equipments. As to land use right, INGNEASA needs to check if these rights are granted rights or allocated rights. If these are granted rights, they own the rights. If they are just allocated, it should just be the rental value, which is different. In addition, INGENASA may not invest too much financial capital into this venture at the first stage and add investment step by step. In fact this is the strategy applied by some multi-national companies.

Business scopes

This joint venture will focus on manufacturing diagnostic products that contain patented antigen for the markets of INGENASA. The manufacture process mainly includes producing the antigens or antibodies, putting together the final products

and packaging products to be sale. In case Chinese partner has marketing experience and distribution channels in this market, it shall be responsible for stable marketing of products for joint venture, at least at the first stage. INGENASA is responsible for providing technical assistance and technical training.

The prime interest of INGENASA is to develop the local market in China through joint venture, and the Chinese partner is also interested in exporting products normally except local market. INGENASA may allow joint venture to export products to the markets that INGENASA has not covered. Furthermore, INGNEASA may buy back a percentage of products at an internal price and sell them in the markets it covers, however the internal price cannot be unreasonably low. In this way INGENASA can take full use of low manufacture force at the same time Chinese partner can achieve its goal to some extent. On the other hand, according to one report, in China technology-intensive industries normally tend to be local-market-oriented at present. However, gradually with increased investment by INGENASA in the joint venture INGENASA also can plan to make joint venture become its manufacture base for global markets, as the core part of global strategies.

Technology transfer

INGENASA can invest diagnostic technology into this joint venture as capital. There is an alternative, technology license. INGENASA agrees to give this joint venture sole license of patent in China. In this way INGENASA approaches the market, take use of low manufacture cost but also is able to hold intellectual property rights at the hand of INGENASA. Although the shares of investment may be reduced, INGENASA can still argue for better position through negotiation since INGENASA licenses advanced technology that is the core competence in cooperation process, specially due to characters of CJV there is great possibility that both parties can reach the agreement about how to share benefits and losses based on different considerations. The Chinese hunger for efficient foreign technology makes Chinese party would like to satisfy the needs of foreign party in some fields, as some businessmen and reports[56] said. The technology license fee may be paid in royalties. Relative license issues can be found in the part of license in the thesis. Another alternative is that INGENASA can have technology license as part of capital investment, instead of investing

[56] Problems concerned with intellectual property rights of joint ventures (Lin Xu) (in Chinese)

the ownership of technology into this venture. Therefore INGENASA can control the intellectual property rights, and take them away when cooperation is over. Even though it becomes difficult for partner to accept this kind of arrangement when they begin to realize the importance of intellectual property, there is still possibility to reach the agreement when they desire to cooperate with foreign companies, after all some joint ventures operate like this in the practice. In addition, a foreign manager is normally in charge of technology area in the joint venture, then INGENASA can try to hold some type of know-how in order to make partner depend on it all the time.

Administrative issues.
The Chinese partner is responsible for handling of application for approval, registration, business license and other matters concerning the establishment of joint venture and liaison with the relevant departments in charge in China. The partner also needs to be responsible for applying for preferential tax treatment and other investment incentives available under applicable laws and regulations. National or local preferential treatments for foreign investment are there. Specially if INGENASA cooperates with the company located in the west part of China, there will be more incentives provided according to national policies.

This can save much time for INGENASA since administrative approval procedures are complex in some fields, specially INGENASA does not acquaint itself with relative regulations and how to communicate with Chinese authority. Particularly, in China some policies or regulations are lack of transparency, which may require you to spend more time and find special ways to collect useful important information and materials. However after SARS crisis in 2003, there are special regulations to require that the government or agencies must publicize various regulations, policies and information, otherwise face punishments. This has made people more satisfied with government's behaviour.

Non-compete- Except the obligation for trade secrets, non-compete clause is also allowed in China. Actually now there is no law about this issue; only regulations made by some departments mention it. In the regulation made by the labour department about the shift of employees, non-compete not more than three years with reasonable compensation is allowable. The Scientific

Department made the regulation on technical person's know-how management in which enterprise can reach the non-compete clause with employees. However only technical persons who have access to trade secret can be given non-compete obligation.

Assignment. For the reason that the partner is of great importance in the joint venture, INGENASA needs to assure that who is the partner can be controlled by itself. In case any party to the joint venture intends to assign all or part of his investment subscribed to a third party, consent shall be obtained from INGENASA, and approval from the examination and approval authority is required. When one party to the joint venture assigns all or part of his investment, the other party shall have pre-emptive right.

Highest authority and management. A CJV could allow negotiated levels of management and financial control. The highest authority of the joint venture shall be its board of directors, which shall decide all major issues concerning joint venture. Unanimous approval by cooperating parties shall be required before any decisions are made concerning major issues. The board of directors are composed of some directors, of which some shall be appointed by INGENASA, some by Chinese partner. According to Chinese Contractual Joint Venture Law, if one party appoints the Chairman of the Board, another party shall appoint the Vice-Chairman. The management office shall have a general manager, appointed by one party, deputy general manager, appointed by another party.

Some foreign companies leave the entire operation up to Chinese partner to run. This is not a wise choice. A new business needs all the supports it can get. Usually a foreign company provides technology, management skills and a marketing strategy, and a Chinese partner offers land, facilities, labour, and access to Chinese market and Chinese system. As some businessmen in China say, Chinese party knows Chinese culture and business environment, but may not have good understanding of modern enterprise management and intellectual property management as European companies. So it is nice for INGENASA to have a manager in joint venture keep an eye on operation, specially during the early stages. Correct systems, accounting and quality control issues all need to be taken care of. It is also necessary for INGENASA to monitor its partner

concerned with its obligations.

At the functional management level, there was a consistent pattern[57] in China. Foreign managers take charge in the harder areas of operation such as engineering, manufacturing and marketing. Local managers take positions in the softer areas including human resources, public relations, servicing and administration. Normally there is tendency of foreign domination in management and operation in joint venture on account of modern management experiences and technology expertise. However more and more experienced Chinese managers appear, specially in the coastal cities. But there is still possibility that INGENASA can exercise a high level of control by the use of advanced technology combined with management even though INGENASA does not hold a large percentage of shares, specially INGENASA is in the technology intensive industry. As it is said that, now multinational companies prefer technology intensive industries when approaching China as it can help them overcome disadvantages of newness and foreignness. Therefore, a Chinese chairman of the board may be positioned due to the majority of venture and executives appointed by INGENASA exercise strong operational and managerial control.

Purchase. In some joint ventures foreign parties try to make fortunes through purchasing materials or instruments for joint venture. As it is said, due to contributing advanced technology, management experiences or financial capital, foreign party can have louder voices as to many issues, specially connected with technology. Some[58] of them convince joint venture to purchase equipments or instruments from their company located in foreign countries; some of them insist purchased equipment or instruments must get the authentication from their parent companies to get fees for authentication; some of them establish wholly owned foreign enterprise to produce or provide these kinds of equipments or instruments to make money from joint ventures. As to INGENASA, authentication can be taken into consideration since INGENASA does not have subsidiary to manufacture these equipments and not many special equipments or instruments for this manufacture must be bought from abroad. Specially from the perspective of long-time cooperation, INGENASA needs to consider the benefits of joint

[57] International joint ventures in China by Yanni Yan Basingstoke : Macmillan ; New York : St. Martin's, 2000.

[58] Problems concerned with intellectual property rights of joint ventures (Lin Xu) (in Chinese)

venture, instead of only thinking of its profits in a short term.

Strategy adjustment. Even though the entry model, joint venture, is desirable for INGENASA as it is the first time to approach the market, joint ventures are still difficult to manage due to differences in culture and management style. Foreign companies such as INGENASA have limited control over joint venture, specially when they only have minority equity. So when business goes well and foreign companies are becoming acquainted with the market, business environment, they are gradually beginning to establish wholly owned foreign ventures by themselves and promote integration of the venture into their worldwide system.

In fact the legal system[59] in China and the business climate are changing in favour of WFOE and the restructuring of joint ventures. Joint ventures can be restructured into WFOE. Some of multi-national companies have successfully converted joint venture into wholly foreign owned venture when they became familiar with Chinese market and system. In another picture, the Chinese side may be changed into a "silent partner" without significant decision-making powers by reducing their equity. For this foreign investors may contribute additional capital without Chinese partner increasing their original investment. In the agreement, INGENASA may ask to have one clause to leave room for possible investment expansion. Furthermore it is critical that appropriate exit provisions be established in the joint venture agreement for the buy-out of one side or the other as a means of ultimately resolving the tensions between parties. There is one example. At the formation[60] of Daily Product in 1991 the US partner received 50% equity, then ten years later the same company was able not only to form a second joint venture in China, in which it owns 70% equity, but also to use the new joint venture as a holding company to take shares in the old one.

Termination. INGENASA needs to think about the issue of termination when fails to reach business goal. This means parties are required to define what are to be considered unacceptable levels of business (losses in consecutive years, production below targeted levels, etc.) and have these agreed upon and set in contract and articles. Normally it shall be mentioned that in the event the

[59] The change of multi-national companies investment strategy (in Chinese) (a report about the Chinese economy)

[60] International joint ventures: partner characteristics (Kelley Luo)

venture is unable to continue its operation or achieve established objectives due to failure of a party to fulfil its obligations under contract, the non-defaulting parties shall have the right to terminate this contract and the liabilities shall be borne by the defaulting party. The defaulting Party shall make the consequent payment to the non-defaulting Parties.

4.6.3 Comments about the entry model

Some forms are presented above, however these entry models may be adjusted with business developments. As we said above, some multinational companies change joint ventures into wholly owned ventures when they have had the capability to do business in China by themselves. Foreign companies also can change from license to joint ventures. For example, Lucent Technology Company[61], one famous American company in the communication field, adopted the co-production to approach Chinese market at the first stage. Co-production is mainly about technology transfer. Lucent transferred technology successfully and the local partner was responsible for production and guaranteed payments to Lucent in return. Because of short-time obligations, partners lowered their risks and responsibilities. A number of high-technology transfer projects were running in China at that time. However at that time Chinese government and local authorities did not fully support this type of business since they thought it did not contribute to long-time interests of China. In addition, if a contract only lasts for a couple of years, production will be only kept to a small scale, making future expansion uncertain. China became more open and encouraged foreign direct investment along with technology transfer. Lucent desired to integrate the business in China into the whole global system, took full use of low labour cost in China and make China become its export platform. So Lucent started foreign direct investment. Now Lucent Company[62] has established eight joint ventures, three wholly owned ventures and eight research centres in China. Another example[63] is that Hitachi Company has evolved its entry model strategies over these years. Hitachi first entered Chinese market in the 1960s and 1970s by exporting electric products and building plants for basic industries. Technology transfers were made in the 1980s and now Hitachi has local manufacturing and sales through joint ventures in China. From above, we can see that INGENASA

[61] Lucent technology in China (Luo Ya Dong)
[62] The alliance between Lucnet and Liantong, www.lucent.com.cn/apps/emea/country
[63] Case study of Hitachi in the multinational companies in China (Luo Ya Dong)

also has the possibility to adjust entry model according to development and business environment in China.

4.7 Industry/ Market analysis

The environment

China with its 1.3 billion-population offers immense potential for growth, a large market, and a rich biodiversity, all of which are particularly promising for biotechnology development. The potential business opportunity has been described in the section of 4.1. This indicates that the environment to commercialise biotechnology products is desirable at present, and biotechnology products for livestock are in the growth stage in this market. There are opportunities for biotechnology companies to succeed and it is of importance to grasp opportunities when one industry is growing. For example, Johnson &Johnson entered Chinese pharmaceuticals industry as one of first movers. In order to obtain a head-start effect, Johnson &Johnson set up a joint venture in XI AN in 1985 and became pioneer foreign firm in China's pharmaceuticals sector. As the first foreign mover, Johnson &Johnson has benefits from superior customer loyalty, brand reputation, and strong relationship with business community and government. Now as we know, veterinary biotechnology diagnostic products are in the growth stage there; if INGENAS misses this chance, it will become harder and harder to approach this market when more and more competitors step into it.

As to regulatory environment, there are some regulations about veterinary biotechnology companies and products. Establishment of veterinary biotechnology companies including manufacture or marketing should get the permission of Veterinary Bureau. The veterinary products are also required for examination by the Veterinary Bureau before going into market. As we can see, in this field administration management is a little strict due to connection with animal health.

Degree of rivalry

Chinese market is big with different actors in diagnostic industry. However, the competition for veterinary diagnostic products is not so dramatic as diagnosis for

human diseases, as we have mentioned above. Not great attention has been paid in the past to this type of business, however, the demand for advanced diagnostic technologies increases when Chinese economy and livestock industry develop quickly. This has led some Chinese companies start to develop their own products in this field, or associate with foreign companies. Three of the major competitors of INGENASA in Europe (SVANOVA, IDEXX and SYNBIOTICS) are already selling diagnostic products in China.

In 2003 IDEXX[64] entered into a joint venture with the Beijing Fortunate Century Animal Health Technology Co., Ltd., to form Beijing IDEXX YUANHENG Laboratories Co., Ltd. IDEXX YUANHENG manufactures and distributes veterinary diagnostic products in China. IDEXX YUANHENG has access to trained personnel, good transportation infrastructure. In addition, IDEXX YUANHENG also has plans in the research and development of new animal diagnostic technology specifically for Chinese market associated with Chinese government's new disease management program. At first stage IDEXX has had the 40% of interests in this joint venture and has the right to acquire another 20% of interests subject to governmental approval within several years. IDEXX also has the obligation to license or make available of technology and manage training and so on.

Svanova and Synbiotics do not have this kind of business presence in China now, however they have begun to sell some diagnostic reagent boxes through distributors. There are also some other foreign companies that sell animal diagnostic reagent boxes in China such as Cedi Company of Holland.

Though the three companies have begun to approach Chinese market, they have not got much business in China now. Actually they came to this market a short time ago. Compared with other companies IDEXX has got certain brand recognition in this field on account of longer business presence, more investment and good business strategies in China. However IDEXX primarily focuses on pet health, a growing market around the world, not livestock at least swine in China. So there is still potential opportunity for INGENASA, specially Chinese market is huge welcoming many business actors.

Right now, according to original limited investigation, there are non-company

[64] www.idexx.com.cn/index.jsp

commercializing similar diagnostic products with INGENASA for the diagnosis of infection caused by porcine rotavirus, which is a common swine disease in China. To this disease, one staff in the veterinary station said, in China veterinarians mainly do this through clinical diagnosis or by using agglutination test. The product provided by INGENASA is more advanced than the diagnostic methods used by Chinese veterinarians, which has been introduced in the second part of the thesis. The porcine rotavirus ELISA product of INGENASA will allow the company to open up Chinese market and establish brand recognition. In addition, it is said that[65] Chinese customers think products of foreign companies such as some imported reagents are a little too expensive. So INGENASA can use advanced technology in combination with effective product differentiation, reduced manufacture cost, creative personnel and R&D, to create good reputation in this new market.

Customer definition

According to the analysis in section 3, the ELISA-based product designed by INGENASA targets the industrial or professional market. The customers of the ELISA-based products are not farmers since they do not have the knowledge about how to use these products. Through the conversation with an official of veterinary station in CHONQING, we can see that in China the customers will also be the diagnostic service providers such as biotechnology laboratories and diagnostic centres established by veterinary disease stations, universities, institutions or companies.

In every one of 36 provinces in China there is a provincial veterinary management station that is in charge of livestock disease prevention and management as quasi-official institute. A veterinary disease diagnostic centre that represents high level of diagnostic service in the province is indirectly controlled by a veterinary station. There is also a veterinary management station in every city and county. In cities and counties diagnostic services exist, however, not all of them have diagnostic centres with necessary useful diagnostic equipments of laboratory. These centres are economically independent charging fees for their services.

Various universities or institutes doing research in this field are there such as

[65] Veterinary biotechnology products analyse of China (Cui Zhi Zhong) (in Chinese)

many agriculture universities with veterinary research centres across the country. Some of the centres provide high-level diagnostic services. According to limited investigation[66], there are over 50 important centres of this type.

There are also many companies providing the service in this field. Now more and more companies begin to focus on business concerned with animal health through manufacturing medicine, vaccines, diagnostic products or other products, for example, in CHONGQING city, there[67] are almost 70 companies manufacturing and doing business in this field. Some of them with diagnostic centers also market diagnostic products and provide diagnostic services. Some big piggery plants have their own veterinary centres for the health of livestock.

Table 8. Customers for diagnostic products in China and their respectively influence on the industry.

Customers for products	
National or provincial veterinary diagnostic centers; centres of cities or counties	Certain influence
Diagnostic centers associated with universities	Professional
Diagnostic centers of companies or livestock plants	Big amount

Analysis to buyers

China has the second largest animal health and nutrition market in the world; swine is one of the biggest livestock industries. From the conversation with an official in this field, it is said that in every province of China there are veterinary laboratories and centres that possess complementary technical systems that can be used for the technology and product provided by INGENASA; there is not much switch cost to adopt the product of INGENASA. With the economy and industry development these laboratories are required to have advanced technology to diagnose different diseases quickly and correctly. Though the consume capability is considered lower than some European countries, professional customers such as centres of institutes, universities have higher consume capability than non-professional customers such as farmers. Of course they would compare the prices of products, however, if they identify the high quality of products, most of them would like to adopt these products to provide

[66] The scientific entities (the veterinary medicine website) (in Chinese)
[67] The manufacture company (the veterinary medicine website) (in Chinese)

high-level diagnostic service to get competitive edge.

As we said, even though now veterinary stations are operating economically independently, they still have the quasi-official characters and special relationships with government due to the responsibilities. Actually on the one hand these stations are veterinary institutes associated with government; on the other hand they are economic entity like enterprises. They are ready to adopt advanced technology in the world for stable development of Chinese livestock industry, the traditional important industry. Along with stations becoming more and more economically independent, they begin to pay more attentions to operational costs and have more requirements about prices of products.

Customer strategy

By the way of license or joint venture INGENASA plans to use the sale forces and marketing channels of Chinese partner. When efficiently connecting customers or potential customers good after-sale service is of importance. INGENASA may help improve this kind of service through training programs. As we said, the consumers are professionals in this field, which requires that sales staff need to have certain professional knowledge to explain the functions of products and show various library data and materials to prove the superiority of technology.

For the reason that customers are professionals, INGENASA can contact various associations of professionals in this field such as the Veterinary Medicine Association to spread the reputation of INGENASA and the products. It may be good to organize some activities in this circle such as small introduction meetings for products. For example, when GENZYME Company[68] marketed one kind of diagnostic product, GSP, for diabetes, the company tried to contact the Chinese Diabetes Institute, in which are many experts and doctors in this field. This company also organized activities and published periodicals regularly for doctors or experts to have a platform to discuss.

What shall be stressed here is that there is one important customer, the National Veterinary Diagnostic Centre belonging to the Agriculture Municipal Department of China, due its influence on other customers. This centre is regarded as the

[68] The marketing of knowledge-intensive products in China- one new diagnostic product for diabetes in China. (Wang Xin) (in Chinese)

highest technology level across the country as well as has the function of diagnosing difficult animal diseases. Therefore if this centre begins to use the products of INGENASA that will be a good sign and affect the choices of other customers. Trying to connect and affect the centre and other provincial centres is a useful way for marketing. There is another way. Beijing YUANHENG Technology Company is partly invested by national veterinary disease management station and technically supported by the national veterinary diagnostic centre. If this company can be the agent of diagnostic products of the venture in some regions of China, it may have influence on the national veterinary centre and other provincial centres. In general, the national centre and other provincial centres can be regarded as very important customers due to their influence and demands for advanced products. At the first stage they are the most important targets of marketing.

INGENASA also needs to focus on brand reputation establishment among customers. There are some major quasi-official websites used by many customers in this field. Advertisements or free services for answering questions on website will be helpful. Furthermore INGENASA can take meaningful activities for the society. For example, when IDEXX planed to approach Chinese environment monitor field, another major business of this company, IDEXX donated valuable instruments and reagent worth 300 thousand YUAN (almost 40 thousand dollars) to Beijing environment monitor centre and provided training services. This news appeared in the Chinese newspaper creating good reputation for this company and the measure has closed its relationship with some official centres. Actually this is also one kind of relationship building, which is of great importance in China and has been applied by many multinational companies.

Customer services

By offering high-quality service, it is easier to show the uniqueness of the product and create competitive advantages through value adding activities to the end-customers. The usage of Internet makes the geographical distances not that obvious. To provide services is also a way for the company to create a stable reputation on the market, therefore INGENASA needs to give customers needed support during the usage of its products (e.g. through website or its partners). Along with more requirements for service put forward by customers, this

becomes more and more important in this field, specially these customers are professionals. Consultation for customers and regularly visiting important customers such as official centres must be helpful for joint venture to establish long-time relationship with customers.

Pricing

What INGENASA will make money on, is the royalties of the technology or the benefits according to percentages fixed in joint venture contract. Based on the analysis of Chinese economy and consume ability of customers, the products cannot be at a high price. Right now in China, there are some products from foreign companies that are a little expensive to Chinese customers. Due reduced cost of manufacturing in China, it is possible to commercialise products with a proper price. Since compared with competitors INGENASA is a little late for this market, INGENASA needs to have relative lower price to achieve the attention of Chinese customers at the first stage. In addition, in China there is one kind of popular marketing method, granting discounts. To some followers of products, INGENASA can take granting discounts into consideration; since there are gaps in relation to requirements for life and consumer capability in different parts of China, to customers in the poorer areas INGENASA also may give some discounts to gain sales and markets in a larger area. Another one is that preferential[69] terms of payments, particularly temporal extensions of payment deadlines, are widely used by Asian multinational companies in China as a major marketing tool. This credit-granting practice is, to some extent, a reflection of culture.

Profits

The goal of a company's activities is to create value that exceeds the cost of providing the product or service, thus generating profit margin. In Chinese market the company will be placed in the earlier phases of the value chain through licensing technology. INGENASA can have the guarantee that it at least can get the lump and minimum of license fees as the conditions of license. On the other hand, if INGENASA is planning to manufacture its products in China, it will be placed in different phases including technology license, manufacture process. Not only from technology license can INGENASA get revenues but also share benefits of joint venture as one party. In this process low labour cost can generate the margin for benefits, furthermore the supply of materials and

[69] Performance and Business Determinants in China (Luo Ya Dong)

equipments for production is cheaper than Europe, which also can reduce the cost. In fact now INGENASA has begun to adopt some supplies from China when manufacturing in Spain. In general, cheap material supply, low labour cost and huge market with a great number of customers has made the potential value possible to realize. In addition, with the same production and distribution costs, in China a multinational company[70] usually obtains higher prices compared with a local licensee for some reasons, such as superior product quality, better organization, international brand recognition etc. So the margin earned from the product market is very likely to be higher from foreign direct investment than earned by a licensee.

The control of position

Since INGENASA is not established in Chinese market, it needs partner up with a company that is already established there and have a distribution network. Because partnering up and giving away the contact with the end-customers means losing part of the control, INGENASA will through license create an environment where the partner becomes dependent on INGENASA. If in the way of joint venture, INGENASA will control and push business development through joint venture contract and good cooperation with partner. The advantage of collaborating with a medium-sized company instead of some big companies is that it will be easier to gain the control INGENASA needs; specially INGENASA is not such a big multinational company.

From a licensing scheme or joint venture with a partner INGENASA aims to gain access to their distribution channel and exposition through direct marketing of its technology. INGENASA in this way will be able to brand itself on the market making customers aware of quality of products, which will help to build a loyal customers base. It is therefore really important that the quality of end product is controlled so its reputation is not harmed in any way. What INGENASA offers to the partner is a competitive advantage due to the forefront technology in products for diagnosis of diseases towards other established technologies and actors.

INGENASA has to be strategically in its relationship with this partner, to establish

[70] International licensing (Chen Min)included in the managing international technology transfer, Van Nostrand Reinhold Company, Mar 7 1996.

a long-lasting collaboration where it makes them dependent on the know-how and technology. Otherwise the risk is that they will use the innovations a couple of years and then end the collaboration. The real danger lies within losing the control and making INGENASA existence on the market depend on them. Detailed contract between INGENASA and Chinese partner, advanced technology and intellectual property rights at the hand of INGENASA all the time, operational management of joint venture may give INGENASA structural control of risks.

Barriers to entry and Push force

In theory, any firm should be able to enter and exit a market. However, industries possess characteristics that protect their high profit levels in the market and restrain additional rivals from entering the market. In this case, the barrier to entry is the high requirement for advanced technology, innovative products and the establishment of marketing channels in this big country. Due high requirement to technology, it is hard for companies without unique advanced technology to enter one market if there are existing actors with advanced technology in the same field. The difficulties to establish and keep distribution channels in this big country with a big amount of population scare some companies with the intention of entry.

INGENASA should focus on the area of diagnostic products for swine diseases to penetrate Chinese market. New features in a diagnostic product could create a demand in the market since the customers commonly are looking for new technology with obvious advantages for livestock industry development. Particularly new technology that can make diagnostic service more convenient may be welcomed in China since there are also many diagnostic service providers without professional laboratory equipments as the Chinese official said. In addition, due to usefulness of vaccine products, INGENASA is required to develop vaccine products by using the designed antigens. Vaccine products can be regarded as more profitable business in the long run. With various diseases appearing and biotechnology awareness, INGENASA shall pay attention to customer’s continuing needs and the technology development.

INGENASA as a medium-size company, with limited resources, and non-

reputation in Chinese market, it will be hard to gain market shares, if INGENASA cannot prove clear differentiation in price or product quality. If INGENASA gains loyal customer base, perfect its products and services, always pushes itself to the foreland, the potential profit will always be there. The future and survival of INGENASA on the market will be depending on how well it uses the tools and control mechanisms to diffuse on the market and create a dependency of the technology among its customers and other actors in the market.

4.8 Potential Problems

There are still some problems that INGENASA needs to take into consideration when doing business in China.

4.8.1 IP confrontations

The problem that INGENASA may face in China is IP infringement and contract disputes, which have been mentioned above. As a practical way to reduce IP risk, it is important for INGENASA to select a trustworthy business partner. Each prospective business partner should be carefully checked on the basis of its track record in IP protection and contract performance.

While the best practice is to try to prevent an IP problem, the most practical remedy is to stop infringement or a breach of the agreement through injunctive relief. Injunctive relief is a situation in which administration or courts grant an order, called an injunction, telling a party to refrain from doing something or in the case of a mandatory injunction, to carry out a particular action[71]. Injunctive relief is available in intellectual property actions in China. The IP risk should be evaluated in terms of how can infringement be proven and against whom the remedy can be obtained. The government agencies whose cooperation will be needed in obtaining injunctive relief should be identified. According to the practice in China, significant monetary recovery in China is not so easy to get. There is one case that in 2001 WUXI Ship Equipment Enterprise established by a foreign company succeeded in stopping several patent infringements by injunctive relief in time and avoided the losses of market shares and other damages. In addition, since litigation is costly and time-consuming, GU, the lawyer in China said that, foreign companies more like to ask for remedies

[71] www.nolo.com/definition.cfm

including injunctive relief from administrations than courts in China, as it is mentioned above.

What's more, China is a party to the New York Convention on the Recognition and Enforcement of Arbitral Awards and thus will enforce foreign arbitral awards if such award is first recognized at Court. Arbitration can be efficient and cost effective specially for intellectual property disputes involving multiple jurisdictions. However, arbitration cuts off the remedy for injunctive relief. If the disputes are mainly related to licensing transactions that are less likely to impose injunctive relief, arbitration can be an effective dispute resolution.

Selecting a trusted partner in China with IP practices and security infrastructure is a practical means of protecting IP. Injunctive relief rather than damages is the most realistic legal remedy. Doing business in China has IP risks, however the situation of IP protection becomes better and better. A practical IP strategy and set of best practices can reduce the risk.

4.8.2 IP management

Since INGENASA needs to cope with a Chinese technology company in the approaching process, it is necessary to know the situation of the company involved. Some reports say that many Chinese high-tech companies lack enough awareness and experiences about intellectual capital management. Chinese companies have improved their legal awareness on intellectual property protection but have neglected to make good use of their own intellectual properties. The concept of intellectual capital management has not been used much before for the reason that intellectual assets have not showed great importance in China. This is changing now because of global economy and existence of more technology-based firms in China. However, there are still many companies that do not really know how to manage their intellectual assets. INGENASA needs to pay extra attention to this issue when entering into cooperation with a Chinese company. With its previous IC experience, INGENASA can not only have control of IC management for the joint venture but also protect its own intellectual capital against its partner.

4.8.3 Connections

In China, the business culture's high regard for relationships applies to people outside the company as well as inside. In order to ensure that the business expansion in China becomes successful in the long run, INGENASA must understand one of the most important elements of running business operations in China, the concept of "GUANXI". Technically, "GUANXI" stands for any type of relationship. In the Chinese business world, however, it is also understood as the network of relationships among various parties that cooperate together and support one another. Although it is vital for INGENASA to understand the necessity of external relationships and the role of GUANXI in China, however, the Chinese partner in the joint venture will play a key role in this. If INGENASA wants to have long-time development in China, specially later plans to operate business by itself, INGENASA is required to know how to establish "GUANXIAN" in this place. But one of the mistakes that a foreign company can make in China is to take for granted that the cultivation of "GUANXI" alone will lead to success. Personal relationships in business are everywhere, including in China.

4.8.4 Government function

Government is one powerful force in the Chinese economy. Every firm in China, whether foreign or domestic, public or private, must manage its relationship with government carefully as with regulator, an investor or customer. With economy development Chinese government made reforms to itself gradually. They continue to adjust their roles in modern society for economy development and benefits of people. China's WTO membership holds out the promise of not only more opportunities and more stable business conditions but also a more transparent institutional environment.

China is a big country, where single province has populations that exceed those of the largest countries of Europe. Regional diversity has increased over the past twenty years. Policies from the centre are often intentionally vague and open to interpretation of local government based on local conditions. Local autonomy in China usually means increase-negotiating leverage for foreign firms. Local government has played more and more important roles in economy development. INGENASA can choose the provinces that provide good investment environment and incentives in various fields.

While it is possible to have smooth cooperation with local government, particularly if INGENASA has the support of local leaders, it will make business work more efficiently. For example, Sanofi Pharma[72], a major French pharmaceutical company, has established a joint venture with the Hangzhou Minsheng Pharmaceutical Group Co. After one year in the production business, the venture was awarded the title of 'Advanced Technology Foreign Venture Enterprise'. The success of the joint venture has been credited to its performance and the support of the Hangzhou Municipal People's Government. Therefore, since now Chinese government encourages biotechnology development and foreign investment in the west part, INGENASA can take use of this trend to develop good relationship with local government there.

4.8.5 Culture differences

When cooperating with Chinese partner and doing business in China, it shall be considered that differences of culture, language and other issues are there resulting in different ways of communication according to Chinese materials[73] and conversation with Chinese businessmen. Following is just several examples.

One of the differences is in decision-making. As it is said, rapid decision making, managing gathered information quickly, is a common way of management in West. In China, a quick decision is not considered the best way. In addition, Chinese people dislike to say no in a business setting nor admit that they don't understand something. Misunderstanding of the Chinese cultural norms by a foreign manager can damage business effectiveness. Chinese are reluctant to speak out their opinions due to education received when they were young. In addition, if what you said makes Chinese lose face, especially in public, the relationship can be damaged badly.

The firms in China are still technology driven. A foreign CEO with little technological background may have a little difficulty in China since people are eager to learn advanced technology and expect their managers to be technologically adept. In addition, in a couple of areas, more and more Chinese

[72] Sanofi Pharma establishes joint venture with Chinese pharmaceutical group (company news of China) (in Chinese)

[73] The differences, conflicts and merge of culture in the sino-foreign company, info.motherol.com/Info/job/zhishiku/zzjgywh/2005110178287.shtml. (in Chinese)

like the Westerner's straightforward approach as Chinese often struggle to read the managers signals to interpret their intentions.

4.9 Summary

China is regarded as the biggest market and one of the largest animal product producers in the world. Infectious diseases among animals cause high economical losses, specially in the swine industry; diagnostic products for animal diseases need to be improved in this market. Therefore it presents a great window of opportunities for INGENASA. At the first stage, INGENASA can market the product to detect porcine rotavirus, which is one common swine diseases in China. Until now there is not any same or similar advanced diagnostic product with the product of INGENASA for this disease.

Before approaching this market, INGENASA is required to acquire intellectual property rights and develop scenarios for the protection of each type. According to Chinese law, diagnostic methods cannot be patented, however the specific antigen that fulfils the requirements can be patented. Based on good understanding about Chinese patent system and the technology, INGENASA is capable to make right decisions, such as choose proper type among three types of patents, find right time to apply for patents, define and modify the protection scope, keep some know-how when apply for patents, pay attention to requirements for description about technology and choose proper patent agent. INGENASA is also required to design other possible antigens around this disease or patent other regions of this antigen in order to prevent any competitors. At the same time, INGENASA may consider to have other patents such as method patent, design patent so as to establish defensive wall for business in China. For long time development in China INGENASA shall acquire trademark rights and establish brand reputation in this market, which requires this company to get to know trademark system, the culture and customers. Secrecy protection is also of importance in this approaching process. When being infringed, firstly INGENASA can ask for administrative remedy that has become one important feature of Chinese system.

INGENASA plans to take use of low labour cost combined with advanced technology to gain competitive edge. There are several entry models that

INGENASA can choose such as exporting, licensing, establishing venture or purchasing venture. The analysis indicates that the appropriate entry models for INGENASA at the present stage are license or joint venture. In the way of license or joint venture INGENASA is able to cooperate with Chinese partner by contributing advanced technology to gain low cost labour, marketing network and other valuable local resources. How to balance the relationship with cooperative partner, establish structural control by keeping the leadership in technology, holding intellectual property rights all the time and designing contractual obligations are of importance. By getting to know various customers and implementing effective marketing strategies INGENASA is capable to establish brand recognition in this market for long-time development. Being aware of some difficulties, INGENASA needs to pay attention to intellectual capital management and protection as well as other issues, for example, importance of connection and culture differences. In general, intellectual property rights, proper entry model, desirable co-operation partner, designed contractual relationship and customer strategies may enable INGENASA to become a successful actor in this huge market with great potential.

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