LUND UNIVERSITY
CENTER FOR EAST AND SOUTH-EAST ASIAN STUDIES
MASTER'S PROGRAM IN ASIAN STUDIES
SPRING SEMESTER 2010

Obstacles to Trade in Light of Contemporary Economic Development in China

Are Foreign Medical Device Companies Affected?

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Abstract

This thesis concentrates on foreign medical device companies´ difficulties in getting access to the Chinese market in a fair way. China has, just like Japan and Taiwan, implemented industrial policies in order to develop the domestic economy. Certain industries have been handpicked as champions for future growth and are therefore subject to preferential treatment. The preferential treatment, among other things, consists of non-tariff barriers, which in turn negatively affect the operations of foreign medical device companies. In-depth interviews have been conducted with Swedish medical device companies to understand the gist of the problem and secondary sources have in addition been used to back up the evidence and facts from the interviews.

Key words: Trade obstacles, industrial policy, medical device companies, Chinese registration process, developmental state

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List of Abbreviations

AQSIQ	General Administration of Quality Supervision, Inspection, and Quarantine
CE	Conformité Européenne
FDA	Food and Drug Administration (in the United States)
GDP	Gross Domestic Product
IMDRC	Import Medical Device Registration Certificate
MITI	Ministry of International Trade and Industry
MOH	Ministry of Health
NTB	Non-Tariff Barrier
RMB	Renminbi
SFDA	State Food and Drug Administration (in China)
SOE	State Owned Enterprise
SMS	Short Message Service
TRIMS	The Agreement on Trade-Related Investment Measures
US	United States of America
USD	United States Dollar
WTO	World Trade Organization

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1 Background

Based on a survey of nine foreign medical device companies of varying size that are applying or have applied for access to the Chinese market, the majority of them are of the opinion that the registration process takes unreasonably long time. It is not the process in itself, i.e. filling out forms or getting information of what is needed for the paperwork that troubles the companies. Instead it is the length of the process, which in some cases has taken 24 months. This is troublesome according to the companies since the equivalent process takes not more than 10 months for the same products when applying for access to the U.S. or European market. The question these companies ask is if this is a case of protectionism that the Chinese government has established.

The purpose of this paper is to investigate if these companies are subject to discriminatory action and in that case what the nature of it is and where it originates from. The study emanates from interviews with nine foreign medical device companies. The companies vary in size and they also have different experiences with the registration process in China. Three of them are multinationals with considerable experience from exporting medical devices to China, while the rest are small start-up companies based in Sweden with none or very limited experience with exporting products at all. What is striking is that seven of the companies responded in more or less the same way when asked about the registration process and it was in particular the long time it took before access to the market was granted that stood out. Other administrative work were not particularly problematic when it comes to exporting medical devices and did not stand out as an obstacle to trade with China.

To get a picture of why the registration process for medical devices look the way it does today it is necessary to understand where contemporary China has sprung from. The economic reform initiated in the late 1970's has functioned as a platform for substantial growth in gross domestic product (GDP) year after year since then (Khandke, 2007). The Chinese population has benefited from this in terms of an increase in disposable income and a higher living standard. The demands, in terms of social welfare and life quality, from the

citizens have in turn increased (Naughton, 2007). Improved health care is one area in which the citizens demand better service and quality. The Chinese government has realized this and has as a consequence taken steps to reform the health care sector. The financial package released after the 2008 global financial crisis clearly depicts this as a large sum was set off for investments in the health care sector (Xiaohuo & Tian, 2009).

What in addition has been apparent, before, during and after the crisis, is the protective measures the government in China has taken to favor the development of domestic manufacturers in the medical device industry. These protective measures stems from top-level management in the Chinese government and are part of the industrial policies China inaugurated in the 1970's (Naughton, 2007). Import substitution and export promotion are two tools that the Chinese government has utilized to accelerate the domestic economy and getting access to technological know-how. These policies have operated as a fundament for the successful economic growth in China, and they will be closely discussed later in the paper with parallels drawn to the industrial policies in Japan and Taiwan.

Another important event that influences today's trade with China is the nation's accession to the World Trade Organization (WTO) in 2001. The basic thought of the agreement is to ease the trade between China and the nations they are conducting business with but the effect has been reverse according to many experts (Erixon, Messerlin, & Sally, 2008). Nevertheless, when looking at developing nations in a historical context China is following a pattern that has been undertaken by other Asian nations during their time of development. Other trade obstacles, such as non-tariff barriers, have been utilized more frequently in order to cover for the decreasing importance of tariffs and quotas since the accession to the WTO. Non-tariff barriers are not regulated by the WTO agreement and can thus be used without repercussions (Rumbaugh & Blancher, 2004). Is this something that the Chinese government has taken advantage of? Based on the answers of the companies this will be examined in the paper.

By concentrating on the industrial policies carried out in China since the 1970's and China's accession to the WTO in 2001, the objective is to find out if the lengthy registration process for the medical device companies is a fact or not. The industrial policies

consist of protectionist measures with the purpose of protecting and developing the domestic economy. As discussed later in the paper, this has been the bitter truth for foreign companies operating in the PC gaming industry and in the bottled water industry, and the intention is to find out if that also can be applied to the medical device industry. China's agreement with the WTO and the effect it has had on foreign trade will in addition be scrutinized to explore the consequences it has had on trade between China and foreign medical device companies.

2 Purpose

The purpose of the thesis is to analyze the answers given by nine foreign medical device companies regarding their process of gaining access to the market in China. Swedish companies have been interviewed in this case study. This will be carried out by exploring China's industrial policy of today in conjunction with the changing nature of protectionism that the accession to the WTO has brought about.

The hypothesis that will be explored in the thesis is:

If there is a discrimination towards foreign medical device companies that are trying to gain access to the Chinese medical device market?

- *And if there is a discrimination the next issues to explore are:*
    - *If China's industrial policies have anything to do with the possible discriminatory acts?*
    - *If China's accession to the WTO have affected China's use of the possible discriminatory acts?*

3 Delimitation

Only Swedish companies operating in China were included in the study. The results may for that reason have been different if interviews with companies from other countries had been carried out as well. Moreover, the companies interviewed are all operating in the medical device industry and either have a large number of employees (more than five hundred) or one to five employees. The result may as a consequence have been different if the study had

included companies from other industries, as well as middle size companies seeking to start up in the region.

4 Methodology

4.1 Research Approach

In this thesis nine companies were interviewed and qualitative data was collected during the interviews. When it comes to the theories and the topic none or very limited knowledge was previously at hand. As a consequence data was collected, analyzed, and utilized to understand the correlation between China's use of industrial policies and the lengthy registration process for foreign medical device companies. Since the theories were developed after the data collection an inductive approach was used (Bryman, 2004).

The advantage of this approach is that a deeper understanding of the underlying issues when applying for market approval for medical devices in China can be attained through the use of in-depth interviews. General assumptions can in turn be drawn explaining why China has its lengthy registration process for imported medical devices despite its accession to the WTO (Saunders, Lewis, & Thornhill, 2006).

4.2 Research Model

The purpose of this thesis is to study the lengthy registration process that foreign medical device companies are faced with when applying for market approval to the Chinese market and to find out if it has a connection to China's industrial policies. Prior to this, research has not been conducted on the topic or is very limited in the specific area although adjacent studies have been performed. Exploratory research is therefore the most favorable way to describe the research model as the purpose is to gain basic knowledge and understanding about the issue (Björklund & Paulsson, 2003). One can argue that similar research has been conducted when Japan and Taiwan went from developing nations to developed nations by using industrial policies consequently making necessary room for domestic companies to catch up and improve their technological knowledge and production. This was a period when industrial policies played an important role for these nations just as they do for China today. However, each nation's phase of development is unique and medical devices have furthermore not been researched in this setting.

4.3 Data Collection

During the first interview an obstacle to trade was encountered that the foreign medical device companies active in the Chinese market faced. Since previous academic knowledge regarding the specific topic was limited data collection was needed and primary data was first gathered followed by secondary data.

4.3.1 Primary Data

Interviews are defined by Björklund and Paulsson as getting access to primary data. Furthermore, an interview can be in the form of direct contact, by the means of using the telephone, or via e-mail and sms. (Björklund & Paulsson, 2003). The first interview conducted was relatively unstructured. The main purpose was to find a topic to write about by asking broad questions. As the interview prolonged an issue arose that, according to the interviewee, was well-known within the industry. The issue was the frustration with the long registration process for foreign produced medical devices when applying for approval onto the Chinese market. Focusing on that issue, the subsequent interviews were more structured with better defined questions that evolved around the specific topic. In order to get answers that were not biased or prejudiced it was important to ask open-ended questions that weren't leading**.** By gaining more and more knowledge during the interviews the questions became more specific and more in-depth information was as a result gathered. At this point in time it became more and more difficult not being affected by the information given and the questions may have been more biased as the interviews prolonged.

What in addition should be mentioned is that the in-depth interviews were not recorded. Notes were on the other hand taken during the interviews which in turn were written out fair afterwards. Another advantage was the access, through telephone or e-mail, to the respondents afterwards if clarifications were needed.

4.3.2 Secondary Data

The literature utilized was primarily written for other purposes, mostly for a more general purpose, than for this specific study. One problem with that is that the literature as a result may have been influenced to suit a specific purpose or to demonstrate a certain point not specific for this topic. Another problem may be that the literature doesn't cover all aspects of the study conducted and therefore may be imperfect. The consequential problem of that

can be that conclusions may have been drawn that are not based on enough evidence. Moreover, the routines used to find the literature, for instance the databases used and the terminology used when searching for articles, may have limited the success in finding relevant books, articles, reports and so forth. (Björklund & Paulsson, 2003).

Even so, it is the belief of the author that an enough number of different secondary sources were studied to find sufficient material to test the hypothesis and find an answer that to a certain degree reflects the reality for the foreign medical device companies. Through the use of secondary sources sufficient knowledge was gained about the topic and a theoretical framework was in addition attained. The secondary sources used were books and articles written by scholars, articles published by well-known journals, and reports from different organizations. The choice of primarily using scholastic literature was to make the study as reliable as possible but also to find out if something had been written about this specific case previously. The intention was to search through all the available databases and other sources of information to find similar reports that could have been used to build the case. None was however found on medical devices in combination with obstacles to trade in China. This rather surprising result forced the author to look at other, less reliable literature such as journal articles, reports by companies, and articles from newspapers. The cases with companies operating in other industries and from other countries than Sweden that have had problems with the registration process in China used to support the case of this thesis are for instance taken from journals and newspapers.

4.4 Quantitative and Qualitative Study

The two most common approaches when collecting primary data are the quantitative and the qualitative method. (Bryman, 2004). The quantitative approach focuses mainly on numbers and frequencies in order to analyze the data while the qualitative approach uses words (Denscombe, 2007). Furthermore, the qualitative method utilizes the collection of data to describe rather than to draw statistical analysis. This approach will provide a more in-depth understanding through the transformation of the information collected into written words (Collis & Hussey, 2003). Information is moreover gathered through a rather small number of interviews thus making it possible to keep the interviews open for adjustments if additional questions should arise.

Because of the complexity and the purpose of the study this thesis uses the qualitative approach in collecting the primary data. In order to get a deeper understanding of the topic the information generated in the thesis is of a descriptive nature. Besides, the employment of a qualitative approach enables the use of a small sample size as the focus point is to understand the individual subject rather than drawing generalizations. (Björklund & Paulsson, 2003). Since the prior information on the topic, as described above, is very limited it was necessary to conduct in-depth interviews to gain knowledge about the registration process for foreign medical device companies wishing to market their products in China. Only they and officials employed by the Chinese government handling this could give insight in how it works in reality. Having made attempts at contacting the Chinese officials with no result, the only source of information was the Swedish companies. Since the purpose was to dig deep to grasp if there really was a problem and in that case find the nature of that problem, discussions with affected companies were the only way to go.

4.5 Interview method

In-depth interviews were used in the thesis to collect primary data. This enabled access to more detailed information and the ability to adjust the questions and adding questions during the interviews (Bryman, 2004). This thesis employed semi-structured interviews since it was important not to limit the interviewee in case he or she felt that there were other obstacles to trade to be discussed. The assumption after the first interview was that it was the length of the registration process that was the major obstacle but to make sure that it was a general opinion open-ended questions were used. In that way the interviewee was given the opportunity to bring up that obstacle or other obstacles in case he or she felt that they were more important. Besides, the interviews mainly encompassed the same questions but modifications were made during the interviews to stay flexible and follow the interviewees' line of argument. Moreover the interviews acknowledged the different problems in the registration process the companies experienced when applying for Chinese market approval no matter if they were trivial or significant in nature.

4.5.1 Choice of Interview Objects

The two initial interviews conducted took place in Shanghai, China. The intention was to conduct all of the interviews in China and the purpose was to interview international medical device companies with operation in China. Since the field work course was held in Shanghai

during the Western Christmas season, and since most of the company representatives that were contacted (21 out of 23) were on holiday leave overseas, it was extremely difficult to conduct the number of interviews originally intended. Hence, the non-response proportion was very high (Bryman, 2004).

The new strategy became to interview Swedish-based medical device companies based in the region of Scania. The region was chosen because of its proximity to the author's residence but also because the region is one of the World's leading life science cluster and consequently a hub for medical device companies in Sweden (www.mediconvalley.se, 2010). The sample was in addition not selected randomly if looking at the whole population of medical device companies in Sweden and the sample method used is thus termed non-probability sampling (Bryman, 2004).

However, the sample within the population that at last was interviewed was selected randomly. Each medical device company in the region had presumably a known chance of being selected since every listed medical device company in the region were identified and contacted by the use of www.mediconvalley.se and www.eniro.se (www.mediconvalley.se, 2010) (www.eniro.se, 2010). 42 medical device companies were identified and contacted through e-mail. Seven of them responded to the questions. Hence, all in all 9 out of 65 companies replied and answered the questions.

All of the participating companies, except for one, wish to remain anonymous in the thesis and expressed their concern of being publicly exposed while talking about the obstacles they face. Of the nine interviews conducted seven of them were telephone interviews and two of them were face-to-face interviews. The face-to-face interviews took about forty-five minutes while the telephone interviews took about twenty minutes. In seven of the cases the CEO or the country manager answered the questions while the marketing manager replied in the other two cases. Only employees with the "correct" position at the company and knowledge about the subject matter were in addition chosen to answer the questions. This increased the validity and minimized fabricated answers.

The two interviews that took place in Shanghai were similar to the other ones but with some differences. The first difference was that the people I interviewed were more aware of and more deeply engaged in the registration process. They had more frequent contact with the people from SFDA and it seemed like they put more pressure on the agency

to speed up the process than what the Swedish based companies did. They knew which buttons to push and how hard they could push them. It was probably like this because of the proximity to the SFDA's location for these two companies and the Chinese staff the companies employed. Communicating with SFDA became in other words easier. If this had a noticeable effect on the length of the registration process was however not clear. The China-based offices had in addition a better knowledge of the Chinese regulatory environment. Having been based in China for a long time and employing Chinese staff gave them an advantage in that aspect. They did not experience any cultural shock, they know the business procedures in China, they had good knowledge regarding the legal procedures, and had previous first-hand experience with bureaucratic officials in China. Hence, they were self-confident regarding this, kept good control through the complete registration process, and didn't feel any stress. That was quite different compared to the Swedish-based offices who basically just followed the mandatory steps and then waited for an answer with none or very little follow up. Consequently, the information I got from the Chinese-based offices were deeper and I gained more insight from them.

4.6 Validity, Reliability, and Objectivity

4.6.1 Validity

Validity means to which extent you actually measure what you intended to measure. One way to increase the validity of the research, which also was applied in this study, is to ask clearly formulated and non-leading questions (Björklund & Paulsson, 2003). According to Yin there are three ways to increase construct validity; the usage of multiple sources of evidence, establishing a chain of evidence, and to have key informants review the draft report (Yin, 2003). To generate evidence a multiple of secondary sources have been used in this study in combination with interviews. A total of nine interviews were conducted to gather primary data. Efforts were in addition made to find the most suitable and knowledgeable respondents as possible for the interviews. The objective when choosing the people to interview was to talk to the person with insights in the Chinese registration process for respective company. The judgment was that only these people could provide the information sought after and thus give reliable answers. Moreover, to establish a chain of

evidence, references to all the sources from which evidence was collected have been made throughout the research. The draft report has finally been reviewed by the supervisors.

4.6.2 Reliability

Reliability is to what extent you will arrive at the same findings and conclusions if the research was repeated (Björklund & Paulsson, 2003). According to Bryman, researchers that primarily conduct qualitative research strategy tend to play down the importance of the issue of reliability. Then again, one aspect that remains significant for many qualitative researchers is the observable fact of generalizability. That is how a single case can be representative so that the findings can be applicable to other cases (Bryman, 2004).

Since Western medical device companies are faced with more or less the same registration processes, no matter if it is in Europe or the United States, the findings should accordingly be applicable to companies that come from these countries. What should be kept in mind though is that the reliability over the years probably may decrease as the objectives and business procedures may be changed. That means that the results of future studies with the same nature as this research might take another turn.

4.6.3 Objectivity

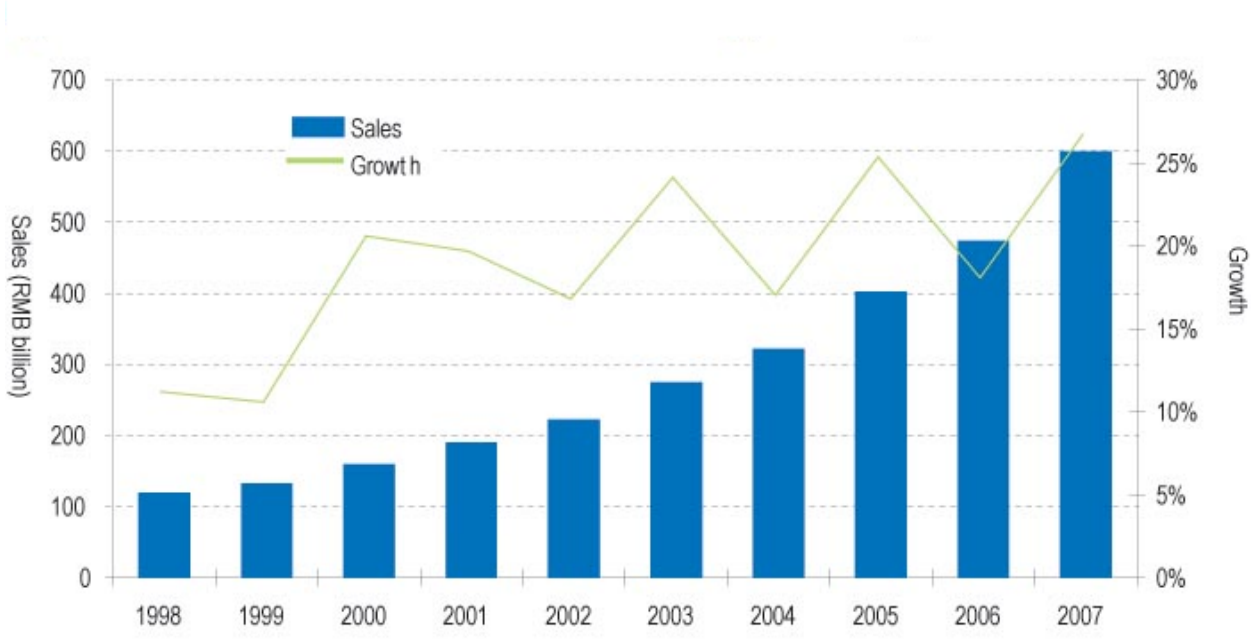
Two things should above all be kept in mind to increase the objectivity of the study; clarifying and motivating the choices that has been made, and to reproduce the content of the source correctly. This means that no factual errors or distorted factual basis can be reproduced. Moreover, interviews have probably the lowest objectivity since the interviewer affects the interviewee no matter how neutral that person tries to be (Björklund & Paulsson, 2003). Byron even goes as far as to say that complete objectivity is impossible in social research but that the researcher can be shown to have acted in good faith (Bryman, 2004). Theoretical inclinations and personal values have in that case been withheld. In this research the act of good faith was practiced during the interview sessions although, as mentioned earlier, a bias may have evolved as interview after interview were conducted. The bias may in that case be based on the increased knowledge gained during interviews. With more knowledge in the subject matter, conclusions can be drawn and it is these conclusions that unintentionally may have changed the attitude of the interviewer. Certain prejudices may vanish and new ones may instead evolve that changes the nature of how questions are being asked. That can of course affect the answer of the interviewee.

5 Empirics

5.1 The Pharmaceutical Industry in China

With an expanding middle class and a population of 1.3 billion people many business observers project China to become the fifth largest pharmaceutical market by 2010. Four pillars make up about 95 percent of the pharmaceutical market: chemical synthetic medicines, traditional Chinese medicines, biological products, and medical devices (Zhou, 2007). The sales of the pharmaceutical industry have experienced high growth numbers (Figure 1) since the reform in the 1970's.

Figure 1 – Sales of the pharmaceutical industry in China (1998-2007)



Source: National Development and Reform Commission, China Statistics Yearbook

As displayed in figure 1 the growth has been notably significant since year 2000 amounting to about RMB 600 billion in 2007 which would be the equivalent to USD 80 billion calculated using 2007 exchange values (www.x-rates.com, 2010) (China Data Online, 2010).

The expansion of the healthcare system by the government is expected to continue and in early 2009 a new health reform with the intention to provide accessible and affordable healthcare to the country's 1.3 billion people valued to RMB 850 billion was initiated. Apart from the health care reform, other drivers of the pharmaceutical industry are resident's increasing income, the urbanization level, and the aging population (Xiaohuo & Tian, 2009).

5.2 Medical Device Industry in China

5.2.1 The Market

The size of the medical device market in China is growing at a fast pace and it is a billion-dollar industry today that has a huge potential for further growth. One reason for that is because 75 percent of the country's medical devices used in medical and healthcare institutions in 2007 were produced before 1980. The estimated market size for medical devices in 2007 was USD 11.2 billion (PricewaterhouseCoopers, 2009). In 2005, this number was USD 7.0 billion making it the third biggest market after the United States and Japan (Zhou, 2007). The market is in other words huge and it will continue to develop as China's population becomes richer and richer. This has of course not passed unnoticed by the foreign medical device companies interviewed for this thesis and measures are taken to get a piece of the market.

The larger companies already have access to the Chinese market by means of other medical devices and thus have good knowledge of how the bureaucratic registration process works. Their knowledge of how to gain market access is therefore well developed and they know what to expect when entering with a new device. The situation is rather different for the small medical device companies. They are usually research based and receive money from private funds and investors. The people working at these companies are usually not market minded and are not used to trading and negotiations. In addition, they have none or very limited experience from exporting devices and do not know the procedures for that. Some of these companies have on the other hand recruited market oriented employees with previous knowledge of trade and export. In general though, the smaller companies lack previous knowledge of the Chinese registration process for medical devices and they lack previous knowledge of the Chinese market. The implications from this could be a more naïve and accepting attitude towards the process possibly resulting in that these companies put less pressure on accelerating the registration process. As a consequence less complaints will be put forward by these companies and less momentum can be built by the companies that are pushing for a change.

5.2.2 The Regulatory Environment in U.S. and Europe

As a reference regarding the registration process for new medical devices on the European and the U.S. market the average approval time is 6 months on the European market and 3 to

10 months on the U.S. market according to the International Trade Commission in the United States (International Trade Commission, United States, 2007). However, should a manufacturer, for instance, already have CE marking and later applies for FDA approval to the U.S. market that process will only take a few days, according to some of the manufacturers interviewed. It is this time that should be used as a reference since the Swedish companies at least have CE marking before applying for Chinese market approval.

5.3 Case Study: Swedish Based Medical Device Companies

5.3.1 Description

The nine companies were faced with the same main questions (See Appendix A for the main questions and Appendix B for a description of when and with whom the interviews were conducted). These included prior sales and marketing experience in the Chinese market, the main obstacles to trade they have faced previously and/or this time, average time span of the registration process, and the number of products they have launched on the Chinese market. Company specific questions, such as number of employees and sales turnover, were also asked. All of the companies answered the main questions while some of the companies did not chose to answer some of the more specific questions.

Six of the manufacturers are very small in size (1-5 employees) and only have one product on the market as of yet. These companies have normally started with one or two innovators that have developed a medical device to fill a gap in the market. After having received CE marking approval for the European market, and in some cases FDA market approval into the U.S. market, getting approval to the Chinese market has been the next step in the business plan for these companies.

The other three manufacturers are well established companies with five hundred or more employees. They have several medical devices in their product portfolio and already have established themselves in the Chinese market with other medical devices. They have experienced the Chinese registration process several times during a span of at least ten years and have established courses of action of how to make the registration process as smooth as possible. These companies have dedicated staff based in China or Hong Kong that operationally work with the registration process as part of their daily work. This includes filling out the forms and staying in touch with the legal and sales agents.

5.3.2 Present Situation with the Registration Process

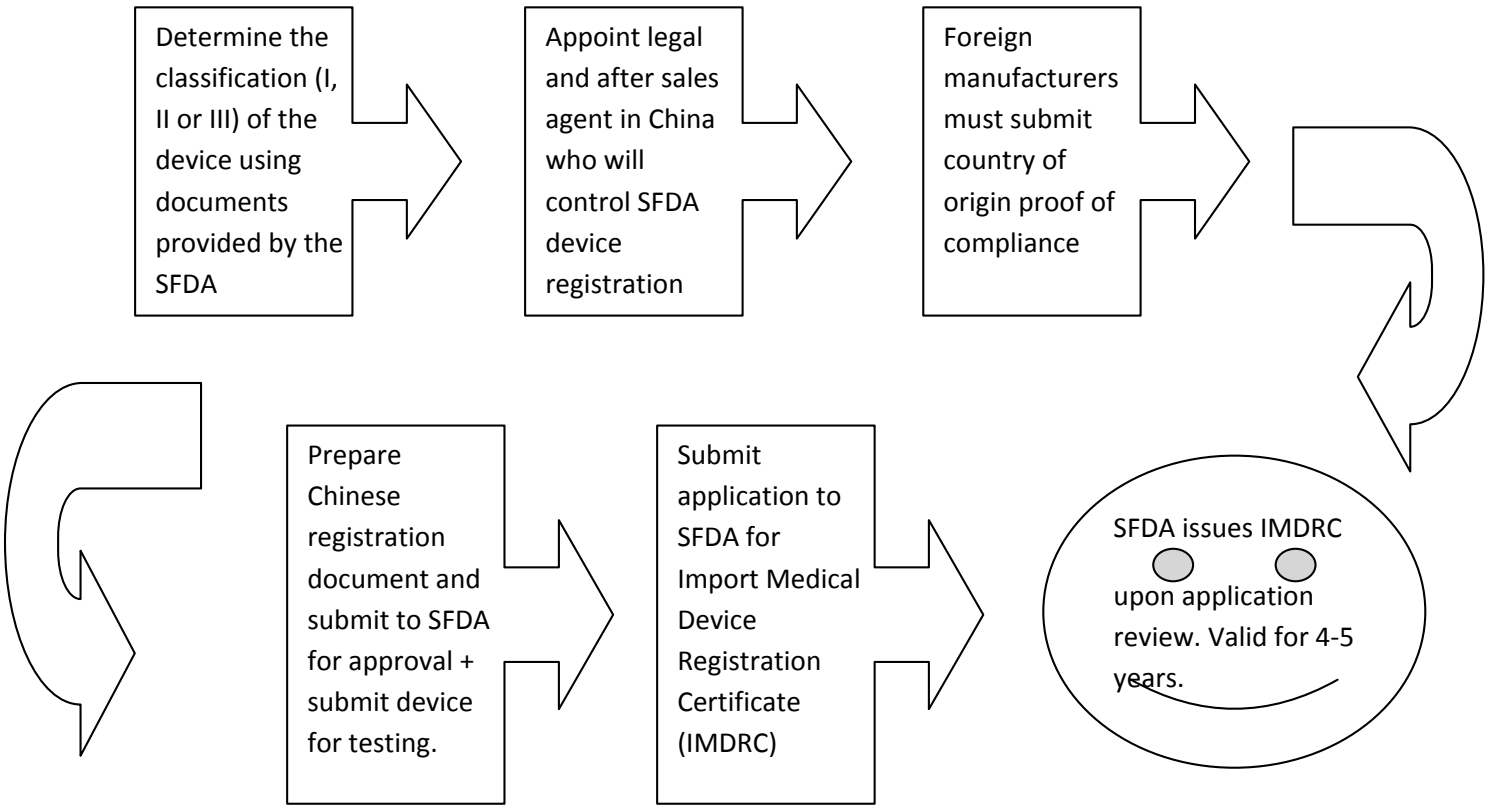
All of the manufacturers have medical devices that are waiting for market approval at the moment. The expected time to receive the market approval spans from 12-24 months according to information they have received from the State Food and Drug Administration (SFDA) in China. Two of the manufacturers find the waiting time acceptable while the rest find it unusually long; especially since the medical device already have market approval in either Europe or the United States, or both. The three larger manufacturers that previously have received market approval to the Chinese market with other medical devices and that in addition have substantial experience from the registration processes in Europe and the United States are not satisfied with the length of the registration process in China. The length for receiving market approval for products that had the country of origin market approval varied from 12 months to 24 months. As mentioned earlier the equivalent registration process in Europe or the United States, with the same conditions, does not take more than a week. What they in addition mentioned was that the approval time for domestic manufacturers and international medical device companies with production in China was significantly faster than the 12-24 months.

Experience does play a role here. The larger companies and four of the smaller ones find the waiting time to gain access to the market too long. The three larger companies have substantial experience not only from the registration process in China but also from the equivalent process in the United States and Europe. The four smaller companies have people employed that do have previous experience from the registration processes in China, the United States, and Europe. These seven companies find the registration process in China unacceptable. The two other smaller companies, on the other hand, are beginners in general and do not have a good understanding of how long a registration process should take to be acceptable. Thus, they are less frustrated with the length of the registration process and accept the long waiting time as long as they eventually get their medical device on the market. Expectations and previous experience of gaining access to the Chinese market therefore seems to be a decisive factor when the companies evaluate the time span of the registration process in China. What factors then does make the registration process in china unusually long? Let’s look at the factors affecting the process.

5.3.3 The Regulatory Environment in China

SFDA has made significant efforts to raise the quality of regulation in China, including cracking down on corruption, strengthening the supervision of medical device factories, and improving SFDA efficiency. As we will see, the registration process is nevertheless perceived as bureaucratic and lengthy for the foreign medical device manufacturers looking for Chinese market access. To get a basic understanding of the regulatory process for medical devices we will start by taking a look at a schedule describing the process built after a model by the Emergo group (Figure 2) (EmergoGroup, 2010).

Figure 2 – China's regulatory process for medical devices



5.3.3.1 Two Agencies – One Job

It is SFDA that reviews and approves domestic and international medical devices for the Chinese market (http://eng.sfda.gov.cn/eng/, 2010). To get a better understanding of what SFDA is, the equivalent in the United States would be the U.S. Food and Drug Administration (FDA) (www.fda.gov, 2010). While SFDA is the approving agency, the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) inspects and certifies medical devices in order for them to physically be imported into China. In other words, two agencies

have required very similar quality testing on medical devices before allowed into China. However, in late 2008 SFDA and AQSIQ joined forces and agreed upon one single testing process, without duplication of tests or fees (Gross & Minot, 2009). According to the three companies with experience from the Chinese market, the unification of the two instances have made the registration process less cumbersome, especially since they only have to deal with one and not two contact persons for every single question they have regarding the registration process. What they indicated, despite this, is that the length of the process hasn't decreased.

5.3.3.2 Country of Origin Requirement

Another bottleneck to export medical devices into China is the country of origin requirement. In short, it means that if a foreign manufacturer applies for marketing approval in both Europe and the U.S. and the product is approved in the U.S. before it is approved in Europe, the manufacturer has to wait for European approval before China even will review a marketing application. What this led to is that SFDA had a backlog of about 6,000 medical devices in 2008 that are accepted for review but are waiting to be approved in the country of origin. In some cases the backlog goes back 1.5 years (Mezo, 2008).

This is certainly a time- and cost-consuming obstacle for medical device companies that produce devices especially suited for the Chinese market and that is not intended for other markets. One of the larger companies have faced this with a device that were not intended for the Swedish market and therefore wasn't necessary to register in Sweden, if it wasn't for the Chinese requirements. Time and money was lost during the period, and other things that are harder to proof, such as similar devices or even copies released by Chinese manufacturers during the time the Swedish device was stalled, may have affected the success of the device. A similar and more hands-on case occurred in the PC-gaming industry in 2008. In that industry it takes about 12 months for a foreign produced PC-game to gain access to the Chinese market. The result of this is that pirated copies have reached and saturated the market before the original game is out on the market (Takahashi, 2009). Consequently the foreign company cannot export as much as it would have if it wasn't for the country of origin requirements. Time and money is lost, and the market share is as a result smaller than it probably would have been otherwise.

5.3.3.3 Re-registration

Re-registering medical devices has also been a time-consuming requirement in China. If a manufacturer has made any form of changes, from a design adjustment to product labeling revisions to updating the company address, the product more or less has to go through the complete registration process again. The same is true for products that have been on the market for four years or more. The device has to be re-registered by the manufacturer after that to be able to market it. Concessions have been made in the last years by SFDA and only products with "major" changes are still subject to the testing requirement (Mezo, 2008). Again, the larger companies have faced this in the past and again, time and money is lost. The analysis of this is that the foreign companies have been stalled in the market process and domestic producers have been able to gain market share and pick up technological know-how. The concession by the SFDA, in spite of not being put down on paper as of yet, was therefore welcoming. The question to raise is if they will be followed by SFDA.

5.3.3.4 SFDA under Government Control

After a number of product safety scandals in the Chinese medical device industry due to corruption in top-level management the SFDA lost its autonomy in 2008. The agency has now been put under direct command of the Ministry of Health (MOH) with the official purpose of restraining corruption. No matter how good the intentions are some people look at it as a way for the MOH to use its power to interfere in individual regulatory decision for political reasons (Gross & Minot, 2009).

Are the government officials less corrupt than the representatives working for SFDA and are they less prone to protect the local companies? This is the general comment from the companies interviewed. The main concern is with the political autonomy after the reform. Will the decisions the MOH takes be completely professional or will they be subject to strategies set up by top-level politicians whose absolute goal is to stimulate the development of domestic companies? None of the companies could give an answer to this since they haven't seen any noticeable changes yet. What is clear though is that the government after this change sits in a very deep-seated position to steer the events in a favorable way for the domestic medical device producers, if it wish to do so.

6 Theory

6.1 Protectionism

According to Merriam-Webster Online protectionism is “an advocate of government economic protection for domestic producers through restrictions on foreign competitors” (www.merriam-webster.com, 2010). The point here is to demonstrate that protectionism is a broad definition that covers many different aspects of a country’s strategy to grow its own economy by making it easier for domestic companies to prosper while at the same time limiting market access for foreign companies.

Protectionism can moreover take many different forms and the intention of this paper is to discuss the measures taken by the Chinese government to protect and develop its domestic medical device companies. Further, it is the lengthy registration process that above all will be discussed as it is that measure that creates most of the frustration among the companies interviewed. However, let’s start with some of the most common protectionist measures taken by governments that wish to favor domestic companies and develop its economy.

6.1.1 Tariffs

A tariff is a rate imposed by the government before the good has reached a country’s market. An additional sum of money, normally expressed as a percentage figure, is added to the good. The additional charge differs depending on the priority of the concerned industry and sometimes also on the exporting country (Bhagwati, 1988). As a protectionist measure, tariffs are less and less significant in the medical device industry in China. Since the country’s accession to the WTO in 2001, the government reduced the tariff rate for imported medical devices from 11% in 2001 to 3.9% in 2005 (Zhou, 2007). During the discussions with the foreign medical device companies none of them mentioned tariffs as an impediment to trade. They acknowledged the tariff but it was not causing any frustration and was not looked at as an obstacle to trade.

6.1.2 Non-Tariff Barriers and Administrative Guidance

Non-tariff Barriers (NTBs) include various bureaucratic or legal actions resulting in hindrances to trade. The NTBs are often referred to as guidance administered by the government and they typically do not imply legislative enactment of each act of protection. The restrictions are normally applied through institutions set up to regulate imports. Some

of the most common NTBs are import quotas, non-automatic licensing, countervailing duties, and anti-dumping provisions (Bhagwati, 1988).

Complicated bureaucratic procedures have most likely always been a burdensome barrier to trade, causing costly delays and heavy compliance costs. Lately, more and more attention has been put on this since traditional tariffs have decreased in importance. This is true also for China and especially since the accession to the World Trade Organization (WTO). Tariffs have more or less been dismantled with the most important trading partners around the World and new NTBs to protect the domestic companies have come into existence instead, in which the practice of administrative guidance has been a well-liked method (Messerlin & Zarrouk, 2004). An example of that is when Chinese officials employed non-tariff barriers on imports in the case with 118 tons of Evian mineral water in 2007. The shipload was sent back to France after failing a Shanghai customs inspection by having too much bacteria, although Danone claims that the bacteria occurs naturally in Evian and is safe. The background to this action was a legal dispute with partner Hangzhou Wahaha in which Danone accused the Chairman Zong Qinghou of selling products from their five joint ventures illegally via separate companies (Ying & Bauerova, 2007). In this case the Chinese government indirectly decided to protect the domestic company by shutting out the foreign company.

It is the content and the effects of the protectionist measures that are of relevance to the concerned companies. As professionals they claim, when asking them why the registration process takes such a long time, that the Chinese government has constructed different barriers to trade to make it harder for foreign companies to compete on the market and that it in particular is the long waiting time for market approval. Other potential administrative obstacles such as making the application forms more complicated than needed and getting in touch with officials are not seen as more problematical in China than in the Unites States or Europe. Two other obstacles to trade that used to be bottlenecks, the re-registration process and the practice of two agencies basically controlling the same thing prior to registration, have been streamlined and are not considered arduous when trying to get access to the Chinese market.

6.2 China's WTO Entry

"China will provide non-discriminatory treatment to all WTO members. All foreign individuals and enterprises, including those not invested or registered in China, will be accorded treatment no less favorable than that accorded to enterprises in China with respect to the right to trade."

Citation from the WTO agreement with China, 2001

6.2.1 Trade Liberalization in China

The citation above comes from the WTO agreement China signed when the country was granted membership to the World Trade Organization in 2001 (Khandke, 2007). The accession to the WTO gave way to a better trading climate for foreign nations with China. Tariffs in general were reduced after the accession and easier access to the Chinese market were as a consequence granted. Nonetheless, China had prior to the accession lowered its tariffs significantly and, as we can see in table 1, that process continued after the accession to the WTO (Rumbaugh & Blancher, 2004). By 1990 the average tariff rate was 40.3 percent and in 2005 it was down to 9.0 percent (Erixon, Messerlin, & Sally, 2008). The tariff rate for imported medical devices followed the same line and has been cut from 11 percent in 2001 to 3.9 percent in 2005 (Zhou, 2007).

Table 1. China: Tariffs, 1982–2005

	Unweighted Average (%)
1982	55.6
1986	38.1
1990	40.3
1995	22.4
2000	16.2
2005	9.0

Source: World Bank

Another effect of the trade liberalization in China was that it also had a positive impact on NTBs. They were down to about 7 percent at the time of accession to the WTO after having peaked in 1988-90 at about 23 percent (table 2) (Ibid, 2008).

Table 2. China: Non-tariff Barriers in Import Trade

	Unweighted Average (%)
1984-87	10.6
1988-90	23.2
1991-93	11.3
1997-2000	5.7
2001	7.6

Source: World Bank

6.2.2 Nurturing the Domestic Industry

Despite the accession to the WTO, lowered tariffs and NTBs, and the ease of access for foreign companies to the Chinese market, the number one priority of the Chinese government has nevertheless been to make sure that domestic companies kept control of the market in selected industries in relation to international competitors. The pharmaceutical market was included in this strategy. This would in part be undertaken by a massive reorganization of the state-owned enterprises (SOEs) through mergers, and privatization of state-supported medical research institutes. In addition, organizational restructuring took place within the SOEs to make them more competitive, both domestically and internationally (Minden & Dong, 2007).

What has happened after the entry to the WTO is that access to the market in some cases has become more open and China do follow a large part of the commitments in the agreement. There are nevertheless major complaints by the United States and other members and it is especially the Agreement on Trade-Related Investment Measures (TRIMS) that most of the criticism stems from. For example, China agreed not to make import and investment approval conditional on export-performance, local content, foreign-exchange balancing, and technology-transfer requirements. But officials keep on encouraging such measures without formally requiring them (Ibid, 2007). These are smart actions that circumvent the commitments to the WTO. So far the Chinese government also avoid being legally punished for it and are simultaneously keeping an edge for the domestic companies.

6.2.3 Soft Walls

While tariffs and border NTBs (i.e. quotas and investment limitations) on the one hand were reduced, so called "soft walls" on the other hand played an even more significant role in protecting the development of the domestic companies after the accession. The advantage of the soft walls was that they were not regulated by the agreement with the WTO (Minden & Dong, 2007).

The most important soft wall applicable to this thesis is the Chinese government's administrative system, which requires foreign manufacturers to negotiate a bureaucratic maze of political representatives to obtain the needed approvals to operate and market their products in China. These lengthy registration processes hindered foreign companies to operate freely and products that could have been sold on the Chinese market were instead waiting for government approval (Ibid, 2007). Erixon et al. agrees with this, claiming that signs of industrial policy interventions in the form of administrative guidance are rather common phenomenon in China, especially where SOEs and selected national champions operate. This is characterized in the science and technology sectors in which the medical device industry in turn is represented (Erixon, Messerlin, & Sally, 2008).

Despite the accession to the WTO it seems like getting access to the Chinese market has even so remained the same or even has taken a step back. When confronting the foreign medical device companies with this, only the three larger companies had the previous experience to give an answer. What they said is that the same amount of time and energy is put down into gaining access, although the focus is directed to different issues today. Previously it was predominantly focused on working with tariffs, quotas and investment limitations. Today, most of the workload is put down on NTBs of a less tangible nature and working out routines of how to deal with the complete registration process as smoothly as possible. The focus has in other words changed, but the time and energy spent on the registration process is basically the same. The goals WTO set up when inviting China to join has perhaps been achieved when referring to tariffs and quotas, but the problems of gaining market approval still remains.

6.3 Industrial policies

The grand objective of an industrial policy is to experience higher growth and prosperity for a country. An industrial policy, in general, contains a number of sector-specific industries in which the government acknowledges high growth potential. The domestic companies should

by this selection become more competitive internationally and in the end transform the country into a major partner and player in the global arena (Graham Jr, 1992). In other words, a significant aspect of an industrial policy is that it works as a foundation for the different protectionist measures the government sets up in order to develop the selected domestic industries.

Most of the East Asian economies, including China, were underdeveloped after World War II. Economic stagnation, political instability, and human capital shortcomings were prevalent in the nations and most of them still based their economy on agriculture. Manufacturing was moreover at its infant level. Japan, for instance, had suffered rigorously during the war, and Taiwan was threatened by mainland China. The resulting outcome was poor living standards and social discontent among the populations. As a consequence, these nations needed economic reform to turn around their economies. What they above all needed to reach the long-term goal of economical and political stability was investment in industry and management, and a strategy to achieve this (Khandke, 2007). This is the basic reason why the industrial policies were implemented in these countries.

6.3.1 Industrial Policy in Japan and Taiwan

What Japan and Taiwan did well was to separate the technocrats, that had been hand-picked to lead the economic reform, from the rest of the government. Consequently they were able to formulate and carry out national goals with little or no pressure from lobbyists, politicians, and interest groups (Khandke, 2007).

In Japan, the technocrats were represented by the Ministry of International Trade and Industry (MITI), which consisted of a highly educated group of people selected by the government to do what is necessary to grow the economy, become competitive in international trade, achieve economies of scale, take advantage of technological advancements, and to increase the productivity of the labor force. Early on, MITI declared that the market forces alone would never produce the desired shifts of energy and resources into new industries and economic activities. Industrial policies with state intervention were, accordingly, necessary to direct the path to economic growth (Johnson, 1982).

Likewise, Taiwan's openness and outward orientation has not been based on free trade in the past. Just like in Japan, the government has intervened in trade to promote certain sectors and to raise government revenue. The trade regime has in addition been

dualistic, in terms of that export-related production almost has been trade free while domestic market-related production has been protected with tariffs and NTBs. Hence, the government has been a gatekeeper for the national economy with the goal to develop it in the best possible way according to their belief (Wade, 2004).

6.3.2 Tools for Carrying out Industrial Policies

The tools used to implement the industrial policies in Japan and Taiwan altered over time because of changes in the national economies and in the global economy. The tools most relevant to the topic of this thesis that MITI applied to protect the domestic industry were discriminatory tariffs, certain import restrictions on products, and licensing of imported foreign technology. One concrete tool, The Foreign Capital Law, was for instance created to restrict the import of foreign technology in industries the Japanese government had classified as critical for the development of its domestic industries. What they yearned for was to separate the foreign technology from its foreign ownership, abolish patent rights for foreign companies, introduce know-how agreements, and put foreign managers in place on boards of directors in order to get access to the foreign technology and in the long-run improve the conditions for the domestic manufacturers. The consequence for the foreign companies that wanted access to the Japanese market were in particular bureaucratic procedures, insecure property rights, and decreased profit margins (Johnson, 1982).

On behalf of the Taiwanese government they used tariffs and non-tariff barriers with higher protection on final products than on raw materials and semi-conductors. Moreover, non-tariff barriers were open to interest groups in Taiwan and could be applied on foreign products if requested by the domestic interest group. Individual producers or industrial associations could consequently apply for non-tariff barrier protection to government agencies, such as the Board of Foreign Trade. The agency then forwarded the application with recommendations to a central committee where the final decisions were made, often with little changes. The purpose of this was to prevent foreign competitors from entering the Taiwanese market and simultaneously provide strong domestic demand for products manufactured by domestic industries which the government representatives considered to be important for the growth of the domestic economy (Wade, 2004).

Likewise, China's strategy before entering the WTO was to gradually open the market for foreign players in certain industries. In the pharmaceutical market for instance,

the foreign companies had restrictions imposed on them to enter the market by the Chinese government and local business networks. Getting access to the market was in other words difficult and in some cases not worth the effort. Yet, local pharmaceutical companies didn't have the necessary instruments or the know-how of how to capture the growing health care market in China that the foreign companies had acquired in the global market. This resulted in a wave of joint ventures between foreign and local Chinese companies. By the end of 1999 1,800 joint ventures had seen the light in the pharmaceutical industry in China amounting to approximately 40% of China's pharmaceutical companies (Minden & Dong, 2007). Just like Japan and Taiwan, China employed discriminatory actions to control the domestic market and were accordingly not willing to relinquish it to foreign companies that were stronger in terms of research and development, new product development, product quality, and business management. The joint venture solution was one way for foreign companies to get around this. The negative side of it was that they didn't have freedom to act as they would have wanted to in order to gain significant market share.

6.3.3 Balancing Trade Policy

Export promotion and import substitution are interrelated trade policies that are executed by a government to optimize the development of the selected domestic industries. They are not mutually exclusive but are on the contrary dependent on each other, and one policy is often used by a government to accelerate the other. Import substitution is in particular used to stimulate certain products manufactured for export. South Korea, for instance, needed foreign machinery and synthetic inputs early in their post-war developmental phase to drive exports. Consequently import tariffs on these products were almost zeroed and the exporting companies did get access to important tools for a very low price and without any obstacles. This in turn accelerated the manufacturing of products that later was exported and it was through actions like this that South Korea in the long run managed to become strongly competitive in the global arena (Kohli, 2004).

Alice Amsden also discusses this reciprocity concerning subsidies on strategically imported products allocated to make domestic manufacturing profitable in exchange for exporting these manufactured products. The purpose with this is to increase exports while only importing the necessary products needed for manufacturing and ultimately to get a positive trade balance. This in turn lead to capital accumulation which, in

combination with high private and industrial savings rates, lead to investments in human resource skills in the form of higher education and research and development. Consequently, this allowed China to rely less on borrowing foreign technology and foreign direct investment, and instead making it possible to develop its own knowledge-based assets. A situation which eventually will make the domestic companies more competitive in the global arena. Some of the state intervention that the Chinese government employed to carry out this are devaluation of the Yuan, tax breaks for exporters, preferential access to imported technology to large exporting firms, easy and cheap access to credit, and import tariffs and non-tariff barriers on competitive products (Amsden, 2001).

The foreign medical device companies are affected by this and it is in particular the policy of upholding non-tariff barriers on competitive foreign products that devaluate their possibility to compete on the same conditions. Since the medical devices are end products targeted towards the Chinese market and are not used to ease the export of Chinese products, they are consequently subject to the long registration process. Should the products have been used for facilitating Chinese exports the situation would, according to Amsden and Kohli, be different. In conclusion, it is the knowledge-based asset-building by the Chinese government and hence the will of the government to be less dependent on foreign knowledge and capital that has led them to take measures to let specific industries develop the global competitiveness. Foreign companies, like the ones studied in this thesis, have to pay the price for this by competing against state interventions and not the market forces.

6.3.4 Why Industrial Policies?

In short, the purpose of the industrial policies in Japan and Taiwan was to reform the economies with large investments in selected industries they believed to be vital for the development of the society. In order to be competitive in the selected industries on the global arena, discriminatory measures were taken in the form of tariffs and non-tariff barriers to protect the development of the domestic companies whereas exports were liberalized. The situation was similar in China when the nation started to liberalize in the late 1970s. The industrial policy was aimed at developing the competitiveness of the domestic companies by imposing trade barriers on imports while exports were encouraged by top-level policy makers (Naughton, 2007). According to an analysis by the World Bank in 1992,

51% of the imports were subject to one or more of four different non-tariff barriers (World Bank, 1994). Certain products that the government found essential or sectors that were prioritized were subject to both tariffs and non-tariff barriers. The non-tariff barriers included limited access to domestic marketing channels, requirements for technology transfers, bureaucratic procedures when entering the market, and sub-contracting to selected domestic companies as a price to pay for gaining market access (Nolan, 2002).

A majority of the interviewed companies do feel that they are subject to bureaucratic procedures when entering the Chinese market today. The major obstacle, as mentioned before, is the length of the registration process. This non-tariff barrier is part of China's import substitution policy and works as a hindrance for foreign establishment and the possibility to gain significant market share. As a consequence the Chinese medical device companies will benefit from this by having time to catch up on technological know-how, gain market share, and become more competitive. That will in the long-run benefit the Chinese economy as the Chinese devices will be competitive on a global scale.

The foreign companies, on the other hand, will lose their technological advantage and the benefit of being first with a new product on the market will also be exhausted. The potential market share will as a consequence be lower than if the market approval was attained at a standardized speed. An example of this is the registration process for international mining companies that are applying for Chinese market access. The Chinese government has in this case passed much of the approving process to provincial and municipal authorities, which in turn administer regulations according to their own interpretations. The problems occur on major projects, where approval in addition is needed from the National Development and Reform Commission. Having received approval from the provincial and municipal authorities, the central government then quite often declines to approve the project (Guerin, 2005). Hence, it seems like the phenomenon of trade obstacles exist in other industries as well and not only in the medical device industry, leading one to think that it is a systematic approach to protect certain industries the government find essential for the development of the nation.

7 Analysis

Based on the evidence and the facts presented in this thesis it is quite obvious that foreign medical device companies are discriminated against by the Chinese government. The Chinese government uses modern obstacles to trade in the form of soft non-tariff barriers. These barriers do not occur at the border but take place when the medical device company applies for market access. The registration process takes unreasonably long time and the companies lose time and money by that. The reasons behind this are manifold and they will be explained in the following section.

The market potential for the pharmaceutical industry in general and the medical device industry in particular is enormous. Furthermore, a majority of the medical device equipment used is old and outdated. The nation has moreover seen extremely strong growth numbers in GDP year after year since the reform in 1978 (Khandke, 2007). This has made the people wealthier and that, in turn, has made them demand better health care. The government has comprehended the huge potential in the industry and accordingly perceives it as an industry that can contribute to the growth of the domestic market. Job opportunities will be created along with the growth in the market and it is also a possibility for the nation to move away from low-tech production of semi-manufactured products to the development of more advanced high-tech products. Knowledge-based assets will be allocated through investments in the chosen companies and more people will be educated to a higher level. This will in turn make possible a new and more advanced phase in industrialization in which China can build strong, global brands. These are strong reasons why they want to protect the selected markets or at least make it difficult for foreign competitors to get a share of it. And that is also one reason why foreign medical device companies are facing difficulties in receiving market approval.

To protect the domestic market from foreign competition the Chinese government has employed industrial policies. This is a proven and successful tool that Japan and Taiwan employed during their strong period of development. Theirs were of course adapted to each nation's conditions just as China's is now. Choosing different industries to be developed and to be the drivers of the economy in certain phases is the gist of the policies. The policies are implemented systematically and operate as a good way to control the industries to be developed and to gain technological knowledge from foreign companies.

China's use of joint ventures before the accession to the WTO was a way to gain insights into how foreign companies conducted business and it was also a way to get access to new technology (Minden & Dong, 2007). After the accession China had to change strategy as the commitments to the WTO forced them to. Instead of using traditional tariffs and quotas, non-tariff barriers became a new way to control foreign competition and this is what the Swedish companies have faced when applying for market approval. The advantage with them is that they are not regulated in the agreement with the WTO and China can thus not as of yet be penalized for using them. Another advantage with them is that these non-tariff barriers easily can be applied to industries the government finds necessary to protect.

It is in particular the registration process that affects the course of action for foreign medical device companies operating in China. The experience and the expectations of the companies are decisive in the reaction over the long registration process. Experienced managers, which is the case in seven of the companies, do find the process unacceptable but they also realize that it is the only way to get access. The two other less experienced managers accept the waiting time as long as they finally get access. Compared to the time it takes to get access in either the United States or Europe the overall perception is that this is a case of protectionism. The evidence in the literature regarding industrial policies, import substitution and export promotion is backing this and it is through the use of the government's grand strategy of developing the domestic economy that this is possible and normalized. The international community with the WTO and perhaps the United States at the front will be the drivers that possibly can push China to soften its strategies and be more market oriented. But since the belief of the Chinese state is that the market itself can't carry out the necessary reforms that the nation needs to undertake to further develop, foreign companies will have to accept the obstacles to trade in the near future if they want to get access to the Chinese market. That includes foreign companies operating in the medical device industry.

This case study has contributed with a theoretical link between the usage of industrial policies in a developmental state to accelerate the domestic economy and consequently using non-tariff barriers to delay foreign establishment. It is quite clear that the central Chinese government has a plan with the protectionist actions taken and that nothing happens by chance. The lengthy registration process is not just implemented to

satisfy a few business leaders in the domestic medical device industry. Instead it is part of a bigger plan to make China and certain selected industries more competitive in a global perspective and in the long run to grow the domestic economy. The government does this by import substitution, export promotion, and employs non-tariff barriers as a control mechanisms. Easy and cheap access to imported machinery needed for manufacturing is an example of import substitution while exports for example are encouraged by establishing special economic zones (Wu, 1984). Finally, non-tariff barriers are used to regulate the domestic market and give domestic companies extra time to get catch up with foreign competitors.

Generally speaking, the problem with the long registration process for foreign medical device companies is in itself not a huge issue. Even though it takes longer than normal foreign companies do get access to the Chinese market and once they have received access they have a fair chance of marketing their products. However, looking beyond the medical device industry the issue with non-tariff barriers should be taken seriously. As demonstrated in the thesis it is not only the medical device industry that is facing problems with getting access to the Chinese market. Other large industries are also troubled with non-tariff barriers of different kinds and what this eventually leads to is a trade imbalance between China and its trade partners (The Economist, 2009). The point is that the trade obstacles a tiny medical device company are faced with when trying to get access to the Chinese market is relevant on both a macroeconomic level as well as on a business specific level. This is particularly interesting since the case study shows that it is very common for foreign medical device companies to be faced with these obstacles and that it in addition seems to be rather common in other industries as well. The consequences therefore goes far beyond the obstacles to trade that individual companies are facing, which should be of relevance to countries that are trading with China.

8 Conclusion

This thesis has concluded that foreign medical device companies that are looking for access to the Chinese market are faced with obstacles to trade. The essence of the problem is that the registration process takes longer time than needed compared to what is normal in developed nations. The trade obstacle in this case is a non-tariff barrier that informally is

supervised by the central government. Furthermore, Wade's and Johnson's theory regarding industrial policy can also be applied to this case. The fundamental strategy in that theory is to develop certain handpicked industries that will drive the economy and at the same time protect these industries from foreign competition. The medical device industry is such a chosen industry in China and the government is accordingly practicing industrial policies to develop the domestic medical device companies. The accession to the WTO has in addition changed the nature of the protectionist measures that China utilizes to protect its domestic companies. Tariffs and quotas are more or less outdated and soft non-tariff barriers are more in fashion these days. The lengthy registration process for foreign medical device companies is an example of a non-tariff barrier and in the case of foreign medical device companies it has functioned as an obstacle to trade.

The problem with the non-tariff barriers for the foreign companies is that they are not legally enacted in the WTO agreement. This means that the Chinese government basically can apply them without any repercussions. However, as this is a common and well-known phenomenon, memberstates of the WTO have started to put pressure on China regarding this which eventually may lead to a change of action. What has been apparent in the past though is that China has been very innovative and flexible when it comes to protecting the domestic industry. So even though non-tariff barriers of this kind will be banned in the future the likelihood that china comes up with other trade obstacles is rather big.

What in addition should be mentioned is that China's objective with the industrial policies is not primarily to hinder foreign companies to enter. Their main objective is to move from a developing state to a fully developed nation. What China needs to do to reach that goal is to be less dependent on foreign investment and know-how and instead develop its own savings and skills. Import substitution and export promotion have been practiced to fulfill this objective. Import substitution has enabled Chinese companies to import necessary instruments at favorable conditions in order to manufacture products that are demanded outside of China. This has eventually led to an overall positive trade balance and the excess capital has been invested in developing knowledge-based assets. This strategy has transformed China to become one of the biggest economies in the World and the nation is still growing at a rapid pace (Naughton, 2007). The negative side of this for the

foreign companies is that the market isn't free and that they thus are faced with one-sided game rules.

This has been a rather small case study of a few foreign medical device companies wishing to market their products in China. Can this be applied to other countries and to other industries? Yes and no. Yes to other medical device companies from other countries that have registered their device on either the US or the European market. The country of origin is a mandatory action that is needed prior to be tested in China and something that the Swedish companies in this study had to go through. When that has been accomplished the registration process looks more or less the same in China no matter if you are from the United States or Sweden. Yes also to memberstates of the WTO that comply with the registration process in either the United States or Europe, and that have the same trade agreement with China. These companies should at least in theory have the same conditions as the Swedish ones. Nevertheless, the study cannot be applied to companies from countries that do have a different domestic registration process than those in the United States or Europe. Hence, the scope of this study cannot declare if their registration processes to achieve country of origin status are equivalent to the ones in the United States and Europe. Furthermore, should a nation not be part of the WTO other trade agreements with China will most likely be the case and they are thus subject to other conditions.

9 Appendices

9.1 Appendix A - Main Interview Questions

The first criteria I established was whether the manufacturer was active or on the way to be active on the Chinese medical device market. If the answer was yes I continued with the following questions to start a discussion. If no, the interview was ended.

Questions regarding your experience on the Chinese market

- For how long have you been active on the Chinese medical device market?
- What kind of medical devices are you exporting to China?
- How many medical devices have you exported to China?
- Prior to applying for market approval in China was the medical device already market approved in the country of origin?

Questions regarding the registration process for medical devices in China

- How well does the registration process work in China mainly thinking of the process of getting it approved by the SFDA?
- How long did the registration process take or how long is it expected to take if the medical device are in the process of being approved?
- What do you think of the length of the time to get the product registered?
- Have you encountered any positive experiences during the registration process?
- Have you encountered any negative experiences during the registration process?

Company specific questions

- Number of employees?
- How would you define your company?
- Do you have operations in China?

9.2 Appendix B - Companies Interviewed

Company I

Date interviewed:	2009-12-30
Length of interview:	60 minutes
Title of respondent:	President

Company II

Date interviewed:	2010-01-02
Length of interview:	60 minutes
Title of respondent:	General Manager

Company III

Date interviewed:	2010-03-09
Length of interview:	45 minutes
Title of respondent:	Founder/CEO

Company IV

Date interviewed:	2010-03-10
Length of interview:	45 minutes
Title of respondent:	Marketing Manager

Company V

Date interviewed:	2010-03-12
Length of interview:	45 minutes
Title of respondent:	CEO

Company VI

Date interviewed:	2010-03-16
Length of interview:	45 minutes
Title of respondent:	Founder/ CEO

Company VII

Date interviewed:	2010-03-18
Length of interview:	35 minutes
Title of respondent:	Marketing Manager

Company VIII

Date interviewed:	2010-03-19
Length of interview:	45 minutes
Title of respondent:	Marketing Manager

Company VIIII

Date interviewed:	2010-03-19
Length of interview:	45 minutes
Title of respondent:	Marketing Manager

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