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Big Pharma in China—The Driving Forces behind Their Success—A Qualitative Analysis

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China has become a major player in the pharmaceutical industry within few years, leading the production and export of API worldwide and representing a double digit growth sector in terms of healthcare services needs in the next 5 to 10 years and predicted to be the largest Pharma market in 2020. To enter this market, Big Pharma companies have adopted different strategies to tackle the challenges specific to the country in terms of size, specific needs sales channels and logistics adjustments. In this paper we will discuss the market entry strategies adopted by big Pharma in China. Major Pharma players have opted for either the aggressive M&A approach to penetrate the Chinese market, gaining local insight through the acquisition of local Pharma manufacturers and the production of generic drugs in China; or for some others an innovation focused strategy through developing its R&D structure in the Mainland to capitalize on the local talent pool and the cheaper operating costs the country offers. For this paper, we have applied a various set of tools to gather data: personal observations used as primary data, reviewed secondary data: Government reports, Pharma reports, studies and related scholarly articles, press releases and specialized websites. We performed PEST analysis to demonstrate how the socio economic environment in the country and the other external factors characterizing the Mainland all contributed to the success of foreign multinational pharmaceutical companies in China.

Keywords: Big Pharma; Outsourcing; China; PEST Analysis

Current Outlook of the Global Pharmaceutical Industry

The pharmaceutical is a particular industry characterized by the high-risk/high-profit industry that reached its paroxysm in the 1990s with blockbuster drugs such as Plavix for Roche generating billions over the course of a decade. The research and development process that leads to a drug being available on the market, generally takes 8 years on average. The active ingredient first needs to be isolated and identified, and then this product needs to be tested for its chemical stability and toxicity on animals or pre-clinical phase, after that the drug is administrated to sane volunteers and lastly to ill patients (clinical trials phase I and II respectively). The final approval on whether or not that new drug is authorized in the market is upon regulatory bodies prerogatives such as FDA in the USA or SFDA in China or AFSSAPS in France.

The cost of these R&D efforts has been on the rising trend for the past years due to the increase in raw material products prices, tightened regulations for R&D protocols and manufacturing standards, inflation and currency instabilities and lastly to the rise in labor costs globally. Some experts qualified the industry as overregulated and point it as one of the potential major threats to the Pharma industry's players' competitive advantage and would eventually affect the core of the R&D model in the industry by failing to be flexible and reactive to these recent changes.

These conditions have been aggravated by the patent expiration wave that has hit several blockbuster drugs, these drugs represented the cash cow for the Big Pharma companies who produced using exclusive in-house expertise from drug screening up until its availability in the market. These "superstar" drugs have been developed back when few multinational drug manufacturers had the monopoly of drug developing and manufacturing thus charging a premium price for these highly innovative drugs, having unlimited access to virtually every market on a global level and protecting their products with a patent of 20 to 30 years during which every other Pharma company was legally prohibited to manufacture a drug with a similar active compound or using the same manufacturing process (DiMasi, 1991). This era is at its dawn now with the "patent cliff" looming ahead for the Big Pharma, which obliges them to rethink their business model as a whole to find a more suitable strategy that would ensure a more sustainable growth. The need for a shift from the classic drug development & marketing model is urgent. This business model on which Pharma MNCs used to rely on to yield profits is no longer relevant, especially with the emergence of new contenders in the industry. With India and China leading the pack with huge market growth potential, and also as new power houses for drug manufacturing and innovation in the biotechnology & Pharmaceutical sectors (Calo-Fernandez, 2012).

Big Pharma has to reshape their organization structure to be more flexible and reactive to the changes the industry is under-

going. The main industry players are now trying to palliate to the losses incurred by patent loss of their premium drugs, there is an urgent need for a new R&D model as the classical one becomes riskier yielding lower benefits. The main measures Big Pharma companies have applied so far include restructuring of their R&D facilities inducing massive layoffs in their Western plants: manufacturing facilities have been shut down in France, Germany, UK and the US to be outsourced in countries where labor costs are cheaper and in most cases the outsourcing destinations constituted major producers for raw materials used for the manufacture of these drugs, China being the first exporter of Active Pharmaceutical Ingredients in the world represents an R&D outsourcing destination of choice. So far the outsourcing strategy was reserved to the manufacturing of finished products, and where the major R&D efforts leading to the final product that would eventually be manufactured were in their majority performed in Western countries where the adequate infrastructure and qualified labor were readily available. The outsourcing destinations were not qualified to handle complicated and comprehensive research and development efforts within their soil (KPMG, 2011). This trend is set to change in a country like China, where Big Pharma companies do not only consider the opportunities arising from the huge market size and the potential benefits from selling their drugs to cater for the needs of the 1.5 billion people nation, where national healthcare coverage is a priority to be achieved by 2020. But also as a major R&D destination with consequent funds injected to modernize, integrate the previously fragmented Pharma & Biotech sector (Zhang, 2009). Foreign Pharma companies could benefit from the availability of local talent whether graduates from Chinese Universities (over 20,000 Science PhD degree holders) or returnees trained abroad in Western universities and Research Institutes. This local talent is a blessing for Foreign Pharma executives who can dispose of a local qualified talent pool cheaper to hire and retain in comparison with their Western counterparts even if the salary gap between the two is narrowing quickly. In this paper, we will analyze the various socio-economic, demographic, legal and political conditions that are making China become a premium R&D outsourcing destination compatible with new imperatives the Pharma MNCs have to abide by to remain competitive and profitable.

PEST Analysis of the Pharmaceutical Market in China

In this section, we are going to examine the different factors that favored the rapid growth of the pharmaceutical industry in China. The country represents now one of the most attractive destinations for big Pharma, not only as a market for their premium drugs or the manufacture of generic drugs, but above all as a major innovation hub that these enterprises are willing to bet on in order to speed up the drug discovery process, and also to be able to face the increasing global demand for better and more personalized healthcare solutions with less adverse effects. We will perform a scan of the different environmental factors that we believe are in line with the Pharma MNCs growth strategies in general to better understand the key drivers of the Pharmaceutical industry in China.

Political Factors in Favor of R&D Oriented Industries for an Innovative China

Chinese government is heavily involved in the Pharmaceutical industry that has been part of the 7 key industries in the latest 5-year plan designed by the government. This could be explained by two axes the government is trying to shift towards:

- Provide basic health coverage schemes for the entire Chinese population by 2020.
- Shift from low innovation products export driven economy to an innovation driven economy

The new party leader Xi Jinping is likely to favor the continuity of what has been implemented by his predecessor and the need for innovation is the main driver for the country and the policies that will be introduced will most likely be designed to favor the thrive of high technology industries and R&D oriented enterprises that will hence receive further support. The new communist party leader Xi Jinping emphasized the need to carry on with the reforms and opening the country up to face the various challenges already existing and the ones looming ahead. The new government in Charge is advocating the development of “Socialism with Chinese characteristics” through 5 Major axis, the following 3 are directly relevant to the Pharmaceutical industry:

- A sustainable Economic growth maintained with active fiscal policies and prudent monetary policies, also by enhancing organic energy and incentives.
- Strengthen the industrial sector by encouraging innovation and R&D efforts and also by stabilizing the external demand and expand the internal demand.
- Great emphasis on safeguarding & improving people’s livelihood

From all these directives foreign Pharma MNCs will still have a huge opportunity in China as the government supports the opening up approach for this R&D focused industry. Cooperation schemes and incentives would be at foreign companies hand especially the highly innovative enterprises. Healthcare will constitute a major concern for a government keen on cutting spending in the sector and improving the access to healthcare. This could be achieved through a strong emphasis on prevention and education of the increasing number of urban population, together with the isolated rural population that yet has little or no access to healthcare services.

Legal Environment in China Driving Innovation

The Pharma industry has been part of the 7 key industries in both the previous 11th and 12th five year plans of the Chinese government in place. The government has different objectives to achieve through a series of reform aimed to expand the healthcare coverage to the entire population by 2020. In order to achieve these goals a series of reforms have been reshaping the healthcare sector in China. The most recent one taking place in April 2009 called the: “Anhui model”.

The Anhui Model

This new set of laws and regulations compiled in the Anhui model represents an aggressive tendering system enforced by the Chinese government that resulted in the slash of drug prices by at least 30% of key drugs (part of the essential drugs list). The government enforced the broaden use of a new procurement method which leads to price reductions in order to trim the costs of caring for an aging population. Both Foreign Pharma MNCs and Chinese Pharma manufacturers frown upon this reform that threatens to cut their profit margins and they

are lobbying against it. United laboratories lost 2.5% in terms of value per share and so did Shineway Pharma by 5.8%.Both foreign and local pharma companies raise the concern of the government's attempt to cut prices through tendering to compete on prices and the resulting decrease in quality of the drugs produced to cut on manufacturing costs. Although this reform has resulted in the shrinkage of the profit margin of these companies they are still profitable and this reform would eventually be profitable in the long term for Foreign Pharma as it will drive demand up resulting in growth through the increase of sales volume.

Tax Law

In January 1st 2008 the new Company Income Tax Law and other regulations provided tax incentives to boost R&D and gave preferential income tax rates in addition to turnover tax exemptions for R&D centers providing research services to overseas companies. Pharma manufacturers eligible for reduced income tax rate if these enterprises qualify as "Advanced & new technology enterprise" which is in the same line as HNTE incentive standing for High New Technology Enterprise being taxed at the preferential rate of 15% instead of the standard 45%. These measure add up to the tax holidays of 2 years in the 5 special economic zones (SEZ: Shenzhen, Xiamen, Zhuhai, Hainan and Shantou). In addition to Shanghai Zhangjiang High Technology Park that favored the growth of Pharma and biotech industry in the country and Zhongguancun life science park in Beijing. Both are boosting the R&D sector and driving an innovation oriented Pharma industry up with a combination of local CROs, drug manufacturers and Multinational Pharma R&D centers located within these parks.

Intellectual Property Rights and Patent Protection

To many foreign companies, China remains attractive as the world's largest potential market for pharmaceutical products. As such products rely heavily on the protection of intellectual property rights, it is essential for foreign companies in this field to adopt a combination of IP protection methods to formulate a strategy for their products in China. To this end, China has established a relatively comprehensive legal system in relation to IPR protection where intellectual assets are protected by way of patents, trademarks, copyrights, and trade secrets (see **Table 1**).

Initially, as seen by the rampant counterfeiting and piracy of copyrights and trademarks, many Chinese businesses recognized only the value of intellectual property that belonged to foreign investors (Liu et al., 2009). Increasingly, however, Chinese businesses recognize the benefit to their own economic interest that can be gained through the use of intellectual property laws.

To see the effect of this trend, consider China's pharmaceutical industry. Price Waterhouse Coopers estimated that in 2000, China's pharmaceutical industry was worth $28.2 billion (approximately 2.8 percent of GDP). In 2002, China's pharmaceutical industry experienced a 15.5 percent rate of growth, with a 22 percent growth in profits. The central government is currently putting money into the pharmaceutical industry, specifically to encourage domestic research and development. With increasing profits and opportunity at stake, the Chinese drug companies that once built businesses around pirating foreign owned Pharmaceutical companies are now beginning to use intellectual property laws as a strategic tool. This shift in business practice is significant because it demonstrates that the enforcement of IPRs can provide a profitable business environment for Chinese businesses. A recent example of this shift is the well-publicized invalidation of Pfizer's Chinese patent on Viagra by SIPO. While criticized extensively by US businesses and the US trade officials as a sign that China lacks the interest in enforcing intellectual property laws and in complying with TRIPS, the case really provides an important example of the growing acceptance of IPRs in Chinese business culture.

Table 1.
Evolution of China's intellectual property protection for drugs (source: author).

Phase	Patent law amendment date	IP protection for drugs
Pure imitation (1949-1985)	N/A	N/A
Innovative imitation (1984-1993)	March 12, 1984	Protection of the synthesis and dosage form manufacturing processes of pharmaceuticals only
Imitative innovation (1992-2008)	September 4, 1992	Patent protection of drugs
Independent innovation (2008-)	December 27, 2008	Patent exemption for drugs trail compulsory licensing and parallel import of patent drugs

Labor Law

China has been and still is a very attractive outsourcing country mainly due to cheap labor costs compared to the West. Foreign companies can still benefit from the affordable labor force available in the country since the liberalization of the labor market in 1994 that resulted in the creation of the biggest manufacturing center in the world in Guangdong province due to massive capital influx from Chinese and Hong Kong entrepreneurs. The minimum wage varies with the geographical location, in Shanghai it is 1.120 RMB while it reaches 870 RMB/month in Chongqing. As for factory workers, the same pattern applies for skilled factory worker the average salary would be around 500 USD per month which is 3 times more than what he could earn working in Jiangxi province. However, the current trend is the rise of labor costs all over China especially since the 2010 labor strikes following the Foxcon scandal and it resulted in 20% increase in the minimum wage in Shenzhen starting from March 2011 and doubled the amount of the minimum wage in Beijing within a 6 months period. Overall, the wages are increasing fast in the country where enterprises struggle now to retain their employees. Multinational Pharma companies have started a fierce battle to attract and retain the growing yet still insufficient talent pool in China where highly skilled employees in the field are still lacking but cheaper to hire than their Western counterpart due to the costs of living in China being still lower than in Europe or the US for example.

Economic Environment—The Domestic Market's Crucial Role

The 2nd world's largest economy is set to have a rather optimistic 2013 economic outlook. Analysts project the growth

rate to be around 7.7% for the year 2013 or even reaching 8.2% in the case of a good management of the fiscal cliff risk in the US and its consequences on the global market and also the recovery pace in the Euro zone dealing with the financial crisis. The emphasis would likely to be put on economic reforms and the optimization of China's economic structure and growth pattern. Another main axis for the year 2013 is to intensify the proactive fiscal policy next year by "appropriately" expanding the fiscal deficit and cut taxes to stimulate local consumption. The government is also keen on allowing more market-determined pricing of resource products and expanding Value added taxes reforms. The Chinese government will maintain control of the important real estate sector to avoid the real estate bubble from bursting along with allowing reforms with state firms. The Chinese economy will show the first signs of recovery after enduring a slowdown 7 quarters in a row. One of the most encouraging sign is the pace at which the manufacturing sector constituting the backbone of the country's economy has displayed an accelerating growth pace in the last quarter of 2012 and despite of an inflation rate of 3% predicted for the upcoming year the Chinese government remains cautiously optimistic for the year 2013. It is likely to be rejuvenated by a stronger local demand, the acceleration of the reform pace especially for taxes such as the trial tax reform in Shanghai that has been successfully applied through the replacement of business tax with Value added tax for the transportation and services industries Since then the reform has been successfully applied in several other provinces across the middle kingdom. As China joins the World Trade Organization (WTO), it will need to integrate more completely into the global economy. The international competition will place an intense pressure on the Chinese pharmaceutical industry. Accession to the WTO will bind China by fundamental WTO principles, such as improved transparency and the strengthening of commercial legal procedures. China's WTO commitments include the tightening of rules on intellectual property, tariff concessions, and market access of non-Chinese service suppliers engaging in the distribution of pharmaceuticals. Investment conditions in China have improved due to the vast consumer demand for pharmaceuticals, the lower labor costs and the changes resulting from economic reform. Changes to the patenting laws in full compliance with the requirement of the Agreement on Trade-Related Aspects of Intellectual Property Rights (or "TRIPS Agreement") and the lack of Chinese pharmaceutical R&D have also left gaps in the market. These gaps are currently filled by Foreign Pharma companies, where the local demand stimulation drives Pharma growth as China still suffers from an important shortage in healthcare facilities and solutions for an ageing population that requires a better allocation of healthcare resources.

Social Environment-The Consequences of Urbanization on the Chinese Population

The demographic component in China will play a crucial role in determining the market size for Pharmaceutical firms, the combination of rapid urbanization with the fast pace at which the Chinese population is ageing also helps driving the growth of Pharmaceutical companies in the Mainland. These two factors generate a number of healthcare issues such as the increasing burden of diabetes, cardio-vascular diseases related to obesity and sedentary lifestyles of a rising number of Urban Chinese population. In addition, the ageing population also means a rise in degenerative diseases such as dementia, Alzheimer … etc. China will also have to deal with the consequences of their astonishing growth rate in the last two decades by dealing with the effects of this development on the environment and its devastating consequences on public health, most prominently the appearance of "Cancer villages" throughout the mainland with an alarming rate of cancer incidence where heavy polluting industries are concentrated.

One Child Policy Aftermath

The one child policy implemented in the 1970 to control the population's growth and now will have disastrous effects on the country's demographics.

China's demographic transition will create opportunities as well as challenges. Population aging and the growing pile of pension funds are already forcing changes in the capital market and financial services sector. An aging society will require a more sophisticated investment sector, thereby presenting new opportunities for financial managers and investment services. Another big growth area will be health care. Establishing better long-term insurance plans will be critical in a country with few young family members to care and provide for the old. Currently over 40% of all middle-aged Chinese couples have only one child, a figure that rises to two-thirds in cities. A sound social safety net needs to be put in place before the economy feels the full force of deteriorating demographics. That means extending and improving the fledgling national pension scheme, and creating a universal medical insurance program that is portable across regions. Reforming the health care system is a daunting challenge. Over the past decade China made important strides to extend health care coverage across the population—yet serious challenges remain. For individuals, the two big issues are lack of access to decent treatment and paying for its often exorbitant cost. For the government, the major challenge is creating a fiscally sustainable public health care system. Funding remains a significant issue, but the system also suffers from the inefficiencies of bureaucratic control and price distortions, which set the cost of labor artificially low. As a consequence, hospitals routinely attempt to profit by over-prescribing medicine. Since elderly people account for the largest share of health care costs, getting these reforms right has important economic implications. An increasingly aging population is creating a heavy burden on the government's health expenses as the society itself is transforming whist used to assign the responsibility of taking care of the elders by their offspring to a more modern and individualistic society where children no longer are assigned with this duty but rather make it become a governmental one. Another important factor playing in favor of Pharma companies such as Novo Nordisk is that the type II diabetes is widespread amongst the elderly and not the young overweight generations like in other developing countries where the diabetes pandemic is present. The combination of this ageing population and the widespread of diabetes among this fringe of the population make China one of the most promising market for diabetes drugs and other diseases affecting the elder generations such as neurodegenerative diseases: Alzheimer, dementia, etc. The demand for these drugs is going to know a steady increase in the next 5 - 10 years as part of the government's efforts to widen the access for healthcare services to their population whether in urban or in remote rural areas and it made it a national priority within their 13th 5-year plan.

Urbanization in China and Its Consequences

The Chinese territory has witnessed a drastic urbanization plan since the 1990's where it witnessed construction frenzy especially in the Yangtze River delta in provinces like Hubei, Chongqing and Jiangsu. In addition to the expansion in Zhejiang province and Shanghai municipality in the Eastern part of China, the urban population is now estimated to not less than 47% of the total population and expanding at a rate of 2.3% per year (Wang et al., 2012). The urbanization of China has transformed its population lifestyle in a radical manner, urban population tend to work in offices, thus working in less physically constringent environment with a wider and richer choice for food and easier access to it. Urbanization also transforms how people eat, as the study shows urban people have less time per meal on average than in rural areas and tend to have a highly carbohydrate diets combined with a sedentary lifestyle due to the abundance of services and urban transportation (buses, subways, taxis) that decrease the physical activity of the urban population. the introduction of the American fast food giants such as Mc Donald's, Yum! Brand's KFC and others in the 1990s have greatly impacted the Chinese population's food habits by offering more affordable "Western" food options affecting especially the younger generation with a profusion of calories in their meals. Conveniently located in malls, railway stations, around campuses and schools this helped them become the favorite dining option for these young consumers (Gu et al., 2013). Add to that the explosion of the local food industry manufacturing attractive food items conveniently packaged designed for that fringe of the population who can now afford a wide range of products due to a rising buying power. Indeed, the rapid development of the middle-kingdom resulted in the rise of a middle-class that is transforming the whole country's structure. This middle-class is usually urban, well-educated individuals with full-time jobs within both local and international companies at different levels. This class has witnessed an increasing buying power through the gradual wages increase in the country. It had transformed China from an export-oriented economy that manufactures low-end products to the world to a domestically focused economy that manufactures products for this middle-class that has now a sufficient economy to sustain the growth of the Chinese and International companies doing business in China. One of the major indicators of this trend is a rising number of multinational companies who have changed their strategy from enforcing Western products to China to a more "Glocal" approach (Go global but act local) and one of the most striking examples is KFC's strategy in China who adapted their product line and tailored it to the Chinese taste by introducing Congee and Youtiao two typical Chinese food items for their breakfast menus in the mainland and Rice beef meals for lunch. It is now reaping a great success from this winning strategy. This middle-class is now increasingly aware of the health risks them and their children are exposed to, that is why research has shown that for health products this population tends to spend more and more on internationally recognized brands especially after the numerous food scandals of contaminated baby milk powder in 2008. This creates a major opportunity for multinational companies such as Pharma companies who entered the Chinese market as they are known for the safety and high-quality of their products. Therefore, this class tries to select carefully the products they consume and are quickly reactive to the health problems they are facing and are ready to take the necessary measures to counteract the disease. For diabetes for example, this urban middle-class is more receptive to preventive measures and more likely to be diagnosed at earlier stages to be able to manage the disease and the treatment in an optimal manner.

Technological Environment

Local Talent Pool

China's current leadership views talent, along with science and education, as the key to building a harmonious and comprehensive well-off society, to solving the nation's emerging problems in environment, energy, urban-rural and regional development gap, social inequality, aging population, and national security. For the Chinese leadership, the effective training, development and utilization of talent is the key to transforming China into an innovative society by 2020. In proposing to leapfrog stages in their own S&T development and become a so-called "innovative nation," the final plan suggested that China should focus on the structural adjustment of its talent pool, raising talent's innovative capabilities, and achieving better utilization of the existing talent ranks, while at the same time maintaining a suitable quantitative growth rate. In 2004, China turned out 2.4 million undergraduate students and 151,000 graduate students (masters and PhDs). The graduates are the chief source of talent supply to support China's economic and social development as well as scientific and educational enterprises. China awarded 23,500 doctorates in 2004, of which some 70% went to students in science, engineering, agriculture, and medicine. These students are largely deployed in universities as well as think tanks such as the Chinese Academy of Sciences. Still, the investment in the upgrading of Chinese universities has been substantial by domestic standards, with universities now becoming a more central player in the R&D system instead just being primarily teaching institutions. New facilities have been built throughout the country, many with advanced equipment and research space to spur the growth of innovative technologies in an in-house setting.

In addition, the Chinese Diaspora is a potential source of "brain gain," a reverse migration or return of overseas Chinese. China's efforts to lure their native sons and daughters back home after they have been trained overseas, including various programs targeting overseas Chinese mentioned above, has had some success. For example, the sitting number of university presidents and professors in Chinese universities are overwhelmingly returnees, though they are most likely to have been short-term visiting scholars rather than degree-holders (Li, 2009). An increase in the number of returnees would counteract, to some extent, the tendency for Chinese "high fliers" in research and other professions to go and remain overseas. But, it still remains to be seen whether more high-level talent will make a permanent move back to China. In summary, China's indigenous S&T initiatives as measured by increasing spending on S&T, R&D, and education will drive the growing demand for S&Es and innovation, while the structural changes in FDI will "super-charge" the thrust of demand. The growing connectivity of the Chinese society and the growth of the domestic high-end market mainly will serve as the key intervening factors—fostered and shaped by the changing face of FDI and indigenous innovation efforts. The domestic market also will become a more important force underlying the growth in demand, especially when the supply-demand gap becomes narrower. All these factors point towards a heavy makeover of the

R&D landscape for Pharma companies, as China is increasingly present on the innovation front thanks to government support through investment in enterprises supporting technologies and innovation and substantial funds allocated to attract & retain local and overseas talents within their academic institutions (Simon et al., 2011).

R&D Capabilities of China Pharmaceutical Industry

China's pharmaceutical industry has witnessed core changes in its structure, from a traditionally orientated industry it is set to become one of the key players in Asia alongside India. It already is the world's leading API (Active Pharmaceutical Ingredients) Manufacturer supplying the main Pharma companies around the world with high quality ingredients. It has since modernized its infrastructures by building Pharma incubators for young Chinese biotech and Pharma companies such as Zhangjiang Park in Shanghai and Zhongguancun Park in Beijing to help these enterprises in their innovation endeavors by being in contact with major Pharma companies such as Eli Lily and Novo Nordisk who also established their R&D headquarters in Mainland in these cities. The growing interest of Big Pharma shows in the R&D investments they are making and the partnerships they are forming with promising local firms to help offset the consequences of their own pipelines drought. The Chinese government has classified the Pharma industry as a key industry to be developed and nurtured in the 13th 5-year plan as it represents an innovation driven industry, has a great growth potential and would benefit the nation's growing needs in terms of healthcare services (Eggelston et al., 2008). Another major card the Chinese Pharma industry can play is the modernization of its world-famous traditional medicine. In the recent years, there has been a constant flow of investments to modernize the TCM practices and use them to speed up drug discovery process whether by local or International Pharma manufacturers who acknowledge the tremendous amount of resources and research areas the TCM could offer combined with Western techniques and was called Integrative medicine. China's growing market for traditional drugs estimated by McKinsey at $13 billion in 2011 and expected to grow at 14% yearly increase for the next five years, is attracting the world's largest drug makers. GlaxoSmithKline is testing a cure for immune disorders from botanical extract compounds, Sanofi is searching for alternative diabetes and cancer therapies from traditional Chinese medicines and Nestle in partnership with billionaire Li Ka-Shing plans to develop a drug for inflammatory bowel disease from old Chinese remedies. The growth for this market would be leveraged by the Big Pharma's abilities to capture the value of traditional and/or herbal medicine to address unmet medicinal needs for patients who, especially in Asia, believe in the power of traditional Medicine, which would be combined with the Big Pharma's drugs reputation in terms of safety and efficacy to create innovative treatment solutions. This would most likely help foster the growth of TCM utilization and integration and thus increase its share in the global drug market over the next 5 to 10 years. GlaxoSmithKline is cheaper than Sanofi based on its lower price-to-earnings ratio and its lower price-to-sales ratio. It also has a higher estimated earnings growth according to analysts. Future earnings might benefit from their ventures into traditional Eastern medicines. Based on these price multiples, GlaxoSmithKline is a better investment candidate. Its pipeline could be bolstered by these new medicines and it trades at attractive price multiples. Hence the growth opportunities, there are currently various projects in the Mainland aiming at the utilization of TCM potential to find new therapeutic approaches for a given affection such as the research efforts carried out for the eradication of Tuberculosis in Shanghai Research Center jointly with the British giant GSK. The new R&D model in the Pharma industry has helped seal a great deal of strategic partnerships between academia and private Pharma companies. In an effort to combine efforts in drug research using local talent whether educated in China or returning from overseas Chinese who are in charge of R&D in Pharma laboratories across the country. This helps nurture the local talent pool, by having access to the latest technologies that multinational Pharma companies offer, along with the biotech incubators across the country in biotech parks in Shanghai, Beijing or more recently in Tianjin. In addition, Chinese government in a effort to modernize the sector has introduced a series of strict reforms for the local firms to comply with International GMP and GLP standards worldwide which has led to the disappearance of small Pharma firms that couldn't afford the upgrade. These drastic upgrade measures enforced by the Chinese government, have reshaped the industry's structure in the country with: the emergence of high technology reliant Pharma manufacturers with state of the art facilities to manufacture high-end Pharma products rather than small, local fragmented manufacturers of low end pharmaceutical products. This is how China has become one of the biggest players in the API ingredients worldwide such as Heparin and an increasing number of big Pharma is moving its API production or purchase to Mainland. In 2009, Astra Zenneca the UK Pharma giant has relocated its API production to China as it sees it now as a favorable destination for these activities in terms of technology advancement and production facilities compliance with the global standards applied to the industry. According to Deloitte's latest report China M&A scale records largest over 6 years in 2012. And one of the hottest sector for these activities is represented by Pharma with a series of buyouts, consolidation through merger and a restructuration of the fragmented market which characterized the Pharma industry's landscape in China until these recent years (Zhang, 2009). For instance, Sinopharm (China National Pharmaceutical Group) and China Development Bank recently signed a 40 billion RMB ($6.4 billion) agreement that will help Sinopharm—and China's pharma industry as a whole—develop on several fronts. CDB will supply the investment in a combination of investment, loans, debt, rent and other financial services (Deloitte, 2013). With the new capital, Sinopharm will seek to advance its R&D and manufacturing, while it also aims at the internationalization of the firm to seek growth opportunities outside the Mainland.

Environmental Factors

China's rapid economic growth and its early and heavy focus on manufacturing have led to the deterioration of the environment within the mainland. Air and water pollution have been recognized as a clear threat to China's future prosperity, Street-level anger over the air pollution that blanketed many northern cities this winter has spilled over into online appeals for Beijing to clean water supplies as well (Li et al., 2012). The Chinese Prime Minister Li Keqiang has publicly expressed his concern about the pollution and the threat it poses to the country and its population, he encouraged increased public participation in cleaning China's water, soil and air. The rapid economic development of the middle kingdom in addition to urbanization

and industrialization all had a boomerang effect on the environment and affected durably the quality of the air, soil and water constituting a serious to the Chinese population health state and became now a heavier load for the government in terms of loss of productivity and increased healthcare costs. In China today approximately 700 million people—over half the population—consume drinking water contaminated with levels of animal and human excreta that exceed maximum permissible levels by as much as 86% in rural areas and 28% in urban areas. By the year 2000, the volume of wastewater produced could double from 1990 levels to almost 78 billion tons (Harada, 1996). These are alarming trends with potentially serious consequences for human health. First, the critical deficits in basic water supply and sewage treatment infrastructure have increased the risk of exposure to infectious and parasitic disease and to a growing volume of industrial chemicals, heavy metals, and algal toxins. Second, the lack of coordination between environmental and public health objectives, a complex and fragmented system to manage water resources, and the general treatment of water as a common property resource mean that the water quality and quantity problems observed as well as the health threats identified are likely to become more acute (Wu et al., 1999).

- Environmental risk factors

Air and water pollution, are a major source of morbidity and mortality in China. Biomass fuel and coal are burned for cooking and heating in almost all rural and many urban households, resulting in severe indoor air pollution that contributes greatly to the burden of disease. Many communities lack access to safe drinking water and sanitation, and thus the risk of waterborne disease in many regions is high (Zhang, 2007). At the same time, China is rapidly industrializing with associated increases in energy use and industrial waste. Although economic growth from industrialization has improved health and quality of life indicators, it has also increased the release of chemical toxins into the environment and the rate of environmental disasters, with severe effects on health. Although its ambient air quality has improved substantially, China is still facing the worst air pollution problem in the world. Outdoor air pollution has become a major concern for public health. It has been estimated that the total health cost associated with outdoor air pollution in urban areas of China in 2003 was between 157 and 520 billion Chinese Yuan, accounting for 1.2% - 3.3% of China's gross domestic product. Health end points studied in China in association with air pollution include all-cause mortality, mortality and morbidity due to cardiopulmonary disease, and numbers of outpatient and emergency department visits (Chen et al., 2004). Changes in respiratory and other clinical symptoms, lung function, and immune function are also studied.

- Cancer villages in China—a national concern

The incidence of esophageal squamous cell carcinoma (ESCC), which is the eighth most common malignancy worldwide, is highest in China. The incidence of ESCC is high in Shexian county, China and environmental factors, particularly nitrogen-contaminated drinking water, are the main suspected risk factors. Another recent study on the association between pollution and cancer incidence in Guangdong province have demonstrated the correlation between long-term environmental exposure to both cadmium and lead and an increased risk of mortality from all cancer, as well as from stomach, esophageal and lung-cancers. This is only one of many studies showing the clear association between water, soil or air contamination with pollutants such as heavy metals toxins or bacteria pose a serious threat in the long-term by considerably increasing the cancer exposure for the population in addition to genetic malformations for new born and other pollution related affections such as Asthma.

The government estimates to roughly 400 cancer villages throughout the Chinese territory and has recently acknowledged the need for an urgent and effective strategy to control the phenomenon. China's toll from pollution was the loss of 25 million healthy years of life from the population. The data on which the analysis is based was first presented in the ambitious 2010 Global Burden of Disease Study, which was published in December 2012 in The Lancet Journal. What the researchers called "ambient particulate matter pollution" was the fourth-leading risk factor for deaths in China in 2010, behind dietary risks, high blood pressure and smoking. Air pollution ranked seventh on the worldwide list of risk factors, contributing to 3.2 million deaths in 2010 (World Bank, 2011). The environment deterioration is likely to create new opportunities for the Pharma industry and the most profitable sectors would be the research & development, manufacturing and marketing for drugs set to cure or alleviate pollution related diseases symptoms. Sectors such as Oncology drugs already represent one of the most promising market segments in China. The Chinese gastric cancer drug market will grow from $250 million in 2010 to $469 million in 2015. According to the Emerging Markets report, Gastric Cancer in China, market growth will be driven by expansion of the diagnosed and drug treated population, greater access to chemotherapy agents used to treat gastric cancer, increased use of targeted therapies and improved patient spending power. Also, China's demand for lung cancer treatment drugs has grown at a fast pace in the past decade. In the next five years, both production and demand will continue to grow. This shows the clear correlation between pollution and increased market share for Pharma MNCs producing drugs set to cure or limit the consequences this pollution has on human health.

Findings

Taking into account the current global Pharmaceutical industry situation and the macro environment in China, we can easily demonstrate how the latter influences the growth of Big Pharma in the country.

From **Figure 1**, we can see that a set of prerequisites for the growth of the Pharmaceutical companies in China is made available thanks to various conditions. The 12th five-year plan heavily emphasized the need for healthcare coverage for the Chinese population, close the gap between urban and rural healthcare services and also take action against the diseases threatening the population and impacting China's sustainable growth plans such as air & Water related pollution which costs an estimated 4.8% f the country's GDP of which 4.3% incurred health related costs. This will boost health related industries such as insurance services, according to a report by Swiss Re, health insurance was the fastest-growing sector in China's life insurance sector last year, and the trend will continue this year. According to the experts, the current Chinese macro environment is favorable for foreign investment in healthcare including Insurance and Pharmaceutical& Biotech sectors. By setting the goal of national healthcare coverage of the Chinese population by 2020, this positions the Pharmaceutical industry as a major

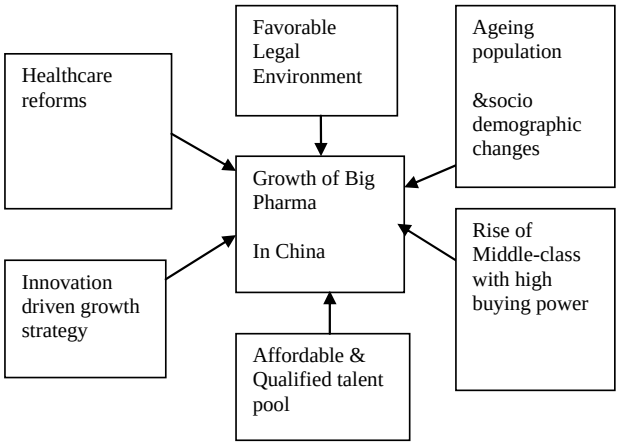

Figure 1.
The key drivers of Big Pharma growth in China (source: author).

player in order to achieve this goal by making readily available the drugs for the different health conditions the Chinese population is and will face in the future. The core changes the Chinese society witnessed in that last two decades in terms of diet habits and physical activity patterns in urban zones caused by the rise of middle-class consumers and the boom of the food industry have resulted in the spread of metabolic diseases such as diabetes, cardiovascular diseases Hypertension and other lifestyle-related affections. In addition, Pharmaceutical industry will benefit from various tax incentives when entering the Chinese Market to cater for the country's needs in OTC and prescribed drugs. Being a highly innovative oriented industry and one of the 7 key industries mentioned in the 5-year governmental plan, Pharma industry players are highly encouraged to not only set their manufacturing facilities in the mainland but also use it as major R&D hub in the Asia Pacific region and on a global level. This is being achieved by the creation of several biotech parks throughout the Chinese territory in Beijing, Tianjin and Shanghai to encourage the thrive of research in the Pharmaceutical industry and facilitate the collaboration and technology transfer with local manufacturers and CROs in a low tax environment designed to attract the Pharma MNCs to the Mainland. The establishment of R&D headquarters for an increasing number of Pharmaceutical companies is taking advantage of the favorable tax environment offered by the Chinese government. Unlike India, China benefits from a relatively favorable legal environment that ensures the patent protection for the different research initiatives performed in the Chinese soil. The government has indeed, introduced a series of measures to secure a healthy R&D development by ratifying the WTO and abiding by its regulations for IPR and Patent protection. Nevertheless, there is a dark cloud looming ahead of the Big Pharma's blue sky in China as the Chinese government has officially amended its patent laws to allow drug companies to reproduce generic, low-cost versions of expensive, patented drugs, a daring move that is sure to shake up the pharmaceutical industry. Yet, China still stand ahead in terms of patent protection and IPR preservation in comparison with its Indian counterparts and it has been proven by the number of Big Pharma opting for China instead of India when setting up their R&D headquarters in Asia. In addition, they fully benefit from the skilled talent pool found in the country composed by locally trained scientists benefiting from highly technological facilities instituted by the government in the universities across the country and in partnership with private Pharma firms, and by Chinese returnees from prestigious institutions in the US, Canada and Europe attracted by the dynamism of research and growth the industry is witnessing in the APAC region in general and China in particular. The tax incentives and local affordable talent pool in comparison with their Western counterparts account for the main drivers of Pharma industry in China. The country highly encourages the sector as part of long-term strategy aiming at the transition from a cheap manufacturing destination into an innovation driven economy highly invested in high-technology and sciences to ensure a sustainable growth and manufacture high-end products with a greater added-value. There will be an increased emphasis on the R&D sectors and an involvement of Chinese enterprises at an earlier stage in the value chain for a wide range of products. As the country possesses now a more adequate infrastructure to achieve such efforts. Even though the country has witnessed a slow-down in its growth in 2012 for the first time since 2008, China's growth is set to continue to surpass the 6% in the next 5 years with a shift from the manufacturing sector focus to the high end products in Pharma, Biothech, electronics, ... etc. The 1.5 billion population makes a huge untapped domestic market, with increasing buying power and needs in healthcare and various services constitute the promise land the Foreign enterprises such as the Big Pharma which were looking for to leverage its growth capabilities and face the various challenges it is put up against with a drying pipeline, patent cliff consequences and rising of R&D costs and increasing difficulties to attract and retain talents. The scan of these various macro environment conditions that the Middle Kingdom is offering shows that innovation driven industries such as Pharma are poised for the giant leap in China and will find in the country all the conditions necessary to ensure sustainable growth.

Conclusion and Future Research

The Pharmaceutical sector is undergoing changes to its core, the patent cliff underway for many of the Pharmaceutical big players illustrates the end of the "blockbuster drug" golden era for the industry. The need for a new sustainable growth strategy is crucial for many Big Pharma companies. This resulted in a series of restructuring, outsourcing, M&A in addition to new cost-efficient R&D models and finally the search for new growth territories. Big Pharma has set her eyes on China, first as a colossal market for its blockbuster drugs and also licensed generic drugs manufactured locally. The healthcare reform enforced in 2009, in addition to the government's commitment to offer a better healthcare service to both its urban and rural population all will positively affect Big Pharma sales growth in the Mainland through an increase in their sales volume which offset the possible price adjustments introduced by the government such as the Anhui model. The outlook is positive for Big Pharma in China, especially for the ones willing to set up R&D activities in China. The government has clearly indicated his intention of transforming China into an innovative nation with support for high-tech and R&D oriented industries. The Pharmaceutical industry is likely to reap the benefits of this governmental policy that favors innovation driven enterprises with tax incentives and government support through the creation of biotech hubs spread across the Mainland. Pharmaceutical Multinationals then could rely on a growing talent pool of scientists

and researchers. The government has made consequent investments to spur the development of local expertise. According to the ministry, in 2011, central and local governments at all levels budgeted 1.68 trillion Yuan in education, up 24.57 percent from 2010. That represents 3.69% of the country's GDP in 2011. This considerably lowers the Big Pharma spending in talent attraction and retention in China, by hiring local talent in the Mainland where the labor costs are still lower than their Western counterparts even though this gap is quickly narrowing due to the inflation and increase in salary rates for Chinese employees in the last 5 years. Socio-demographic factors are also in favor of the rapid development of Big Pharma in China with the ageing population and its related diseases: Neuro degenerative diseases such as Dementia or Parkinson, in addition to environment related affections: pollution related such as cancer, asthma, infections or to the rapid urbanization and change in lifestyle and food consumption patterns of a population who is now under the threat of "developed countries illnesses": diabetes and metabolic disorders, cardio-vascular diseases, … etc. Throughout this paper, we have identified the key drivers that Big Pharma could take advantage of in order to expand its presence in China and generally in Asia to ensure a sustainable growth in the upcoming years. A change in one or many of these political, economic, social, technological or environmental factors will definitely affect Big Pharma strategy in the country and on a global level, which is why a close monitoring of these factors could reveal itself essential when deciding for a growth plan in the Mainland. For Pharma MNCs there will be a growing need to keep up with the fast pace at which this country is constantly changing; offering growth opportunities for some and threatening the survival of others in the industry who would fail to fully comprehend the complexity of the Chinese environment and its implication for their global growth strategy.

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