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HIGH REGULATION AND LOW CERTAINTY: MARKETING STRATEGY CHALLENGES FOR THE PHARMACEUTICAL INDUSTRY IN CHINA

ABSTRACT

The opening of China to foreign pharmaceutical companies created essentially a new market where the "rules of the game" were not previously established for the particular industrial setting. The regulations governing access to prescription drugs, the role of pharmaceuticals in providing funding for hospitals and clinics, and the low oversight of company practices resulted in a system of mutual corruption, high competition, and shifting regulatory and legal formalities. As the movement to open access to pharmaceuticals to non-hospital purveyors and the attention of Chinese authorities to certain industry practices has proceeded, the industry environment has changed significantly. Four possible new competitive models for pharmaceutical companies are evaluated.

Key Words: China, pharmaceuticals, competitive practices

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INTRODUCTION

It was once common belief that mature industries had fairly stable structures, operating rules, and standards. That view has been seriously undercut by the rise of international markets with vastly differing laws, regulations, practices, and situations (Porter, 2008). It is now common to find international companies struggling to maintain an internal strategic standard while navigating a very non-standard environment. Mature companies now are facing much of the same unpredictability that new firms in new industries face, but are, at the same time, far more constrained as they also operate in multiple stages of maturity environments, competing against both international and newly emerging firms.

Generally, as industries mature, the competitors are a known set within each industry grouping, while the distribution and pricing systems are well-established and understood. The past view was that industries tended toward stable predictability both internally and externally unless faced with unforeseen new technologies (Porter, 2008, 2011). However uncertainties facing mature multinational firms were expected to lessen as globalization erased the impact of local differences and the size and coverage of large firms would prune all but the most agile small firms from each industry. Any threats were felt to be largely external to the industry: new technologies, changing regulatory and economic situations, or unpredicted demographic shifts.

Recently, however, globalization has created in situations where both internal and external factors are unstable and local differences are making a difference. Therefore, effective universal strategies are hard to craft. These difficulties are particularly acute for firms in industries producing what are often regarded as public goods. What should firms in such an industry do?

THE STANDARD COMPETITIVE MODELS

Fleisher and Bensoussan (2003) presented the Nine Force Model as the basis for applications of various strategic intelligence tools. This combined the traditional 5 Forces of Porter (1998) with STEEP/PEST environmental forces. What this model shows are the forces but does not really explicitly look at interactive effects. It is acknowledged that government, for example, can have significant strategic impacts on some industries, *e.g.*, defense, but doesn't really capture the effects of mass mobilization, enhanced communication and social media plus the impact of technology and economics on the actual functioning and strategic necessities for all firms.

These shifts in the overall environment for everyone are just beginning to make themselves felt. The biggest weakness in these models, however, is the uneven effects of "partial" globalization: there are many international firms, media is increasingly global, and technology spreads swiftly. However, the internal conditions, particularly economic and regulatory, are still significantly different despite the impact of global economic trends and efforts to create a more uniform legal/regulatory environment. Examples of this are the differences in media outlets, distributive networks, demographic profiles, and infrastructure. Thus a national advantage (or regional one) that led to international competitiveness in a global sense may not yield advantage in particular markets. This is a key factor as nations attempt to compete as well as firms within industries.

The models also still separate consumers as a competitive force but fail to recognize "shadow" consumers—NGO and other organizations who can create significant cultural environment conditions which impact consumers and are difficult for firms/industries to counter. A good example is the separation of ecology in these models from social and government forces, although it is quite clearly one of the outcomes of social organizations affecting government and consumers resulting in programs (or at least media campaigns) illustrating sustainability efforts by international firms. International efforts regarding whole product categories are now a feature of the competitive environment: genetically modified foods or the availability of "life-necessary" products.

Much of Porter's (2008) work on national advantage and policy demonstrates the interactive effects of government, social demands, and economic opportunity in specific industries of particular countries. The challenge for the multinationals now is that they have to craft a strategy which is global and coherent, but adaptable in every tactical and communicative way to local conditions which may vary considerably. This challenges the very efficiency upon which the multinational firm advantage has been built. Never has some specific, difficult to replicate competence been more important and more difficult to achieve in the face of both external and internal competitive factors. This paper examines aspects of the modern pharmaceutical industry in China as an example of how these issues can affect both an industry and specific firms within an industry.

The Pharmaceutical Industry

The pharmaceutical industry is composed of a number of large multinational firms controlling most of the patented prescription medicines and branded OTCs, as well as large numbers of generic manufacturers and producers of traditional medicines, some international, but

most focused on domestic markets. There is also a complex mixture of supporting specialist service support firms as well as various organizations in the distribution system and in the payment system which interact with the producers of these products. The industry is also highly regulated and subject to fast changing regulatory and consumer movements.

The large international pharmaceutical companies emerged after World War II and the discovery of antibiotics. Since then, drug therapies have become a significant part of modern medical treatment. The strengthening of intellectual property protections and economic growth after the war in the major industrial countries made research investments potentially profitable. The expansion of IP protection for medical patents worldwide via Trade-Related Aspects of Intellectual Property Rights (TRIPS, www.wto.org) encouraged major company movement into developing markets, not just as sellers but also as direct investors in various aspects of the entire medicine creation and manufacture process. The saturation of developed markets and the short life of patented drugs made moves into major emerging markets necessary, but enhanced legal protections for expensively developed IP made such moves attractive as well (Thach and Marsnik, 2009). The signing of TRIPS by China combined with its encouragement of foreign investment in a huge market virtually untapped made China a magnet for pharmaceutical sales and the creation of China-based offices.

PHARMACEUTICALS IN CHINA—INDUSTRY RULE CREATION

When the economic reform program began in China, many international firms viewed this as an opportunity to enter a major market where their products had not been sold before nor where there equivalent domestic products or competitive firms. At the time of first entry, there were approximately 7,000 pharmaceutical manufacturers in China but all were small, making generics, copies, or traditional medicines (KPMG, 2011). While domestic firms in other emerging markets were similar in structure in Brazil and Turkey, many other basic industry structures in China were dissimilar to other major markets. There were no pharmacies selling either major over-the-counter drugs or prescription drugs.

The Chinese government had designated hospitals as the sole source for prescription medications although gradually various other outlets began to stock and sell OTC drugs, but largely in major coastal cities. The OTC were largely domestically produced and sold with generic labels; few international firm products were available. Thus, the international firms had to establish sales and distribution programs to service the hospitals for prescription medicines and use a complex distributional system for OTC (officially by prescription only and non-hospital prescription drugs) with approximately 10,000

government owned distributors (see Wei and Kang, 1998) for thorough review of the Chinese open market in the early stages).

The entrance of international firms and investments in the healthcare system gradually changed some aspects—pharmacies selling OTC, including international brands gradually opened in the major coastal cities. Consolidation and closure of many of the unproductive factories combined with new standards for quality control assisted in improving the distribution system, although the first tier distributors varied greatly in the formularies and OTC products so that regional differences in availability were large.

Although the Chinese government attempted to start a research based industry and had some success in getting drugs through the US patent system, there were still few products and producers capable of serving the domestic market nor able to compete with international firms. So the government designated Shanghai as the pharmaceutical center and a number of the leading international firm's established sales headquarters while some later expanded these offices to include research and development programs as well.

However, some peculiar features remained which restrained investment, distribution, and consumer confidence. Despite several efforts at drug pricing reform, intended to reduce both costs and the use of drugs as the primary medical intervention, the goals of the 1996 reform were largely unmet: reducing high and illegal discounts, the importance of drug sale revenue for hospital income, and the high prices of imported and joint venture products. Foreign firms had to cope with an unusual distribution system, work to reduce price controls, and adapt to the sales culture as it was rather than as it ought to be. The unreformed distribution system led to high costs, inefficiencies, and corruption as well as significant demographic disparities in coverage (Zhou, 2007; Yuanjia *et al.*, 2007).

One feature of working within the existing system was adapting to the sales system for pharmaceuticals. At first the international firms simply continued the payments and price fixing standards with hospitals; then payments to physicians who wrote the prescriptions. Eventually, they embarked on a variant of the old sales programs, offering physician and administrator "educational conferences" which initially made sense as the medicines, dosages, etc. were new to the system. They became luxurious vacations. Expansion of the health care system was not a priority in the initial phases of economic reform and modernization. Hospitals were often underfunded relative to services demand and so administrators viewed prescription drugs as a vehicle for earning money to offset other hospital costs. At the same time, these administrators and doctors expected "placement fees" from the various companies in order to stock or use the various products. As a consequence, patented prescription drugs are significantly more expensive in China

than in other Asian and developing countries (Shobert, 2013; Hirschler, Randall, and Kazunori, 2013; Yuanjia *et al.*, 2007).

Prior to the entrance of these international pharmaceutical companies into China, some of the Chinese manufacturers attempted to make copies of patented medicines and older, off-patent ones. However, most lacked the facilities to create credible copies. Additionally, supporting institutions such as testing and clinical trial firms did not exist, hampering the development of reliable generics as in India, Turkey, and Brazil. Many of these "generics" and copies were exported, but the quality and sometimes outright falsity of the drugs established a bad reputation for domestic Chinese drugs (this is a continuing problem, see Forster and Dinnes, 2013). Thus, the hospital source of drugs was seen by consumers as a guarantee of authenticity and quality, so the higher prices were not as significant a social issue as in other Asian countries. Rather, the prices were seen as a necessary part of the quality control process.

By the late 1990's, there was significant consolidation of Chinese firms in the Southern provinces. Distribution of drugs greatly increased, but nevertheless, China, with 20% of the world population accounted for only 1.5% of patented drug sales, with 80% of rural populations served almost exclusively with traditional medications.

The development of sales and distribution networks by international firms supplied the hospitals but there was significant opposition to moving *R&D* into China. With the Chinese accession to the TRIPS treaty and the establishment of a separate patents court to ensure fair and world standard treatment, there was a move toward treating the Chinese branches of international firms as more than sales offices. Seven of the 15 largest multinationals established research facilities and the Chinese government established an additional 13 centers for bio pharma research. Some of these are now joint venture operations.

INTERNAL CHANGE/EXTERNAL CHANGE

Recently, however, external changes have triggered changes within the industry as well, creating a "chaos" out of which new paradigms for action emerge. For the big pharmaceutical firms, this will require creativity and new investments, some particular to the China market and others more globally. The Chinese healthcare reform includes huge investments in rural outreach infrastructure, expansion of health insurance and basic care, and expansion of research efforts in biopharmaceuticals. Subsidies to domestic manufacturers and preference in sourcing for generics are also part of this endeavor. The

key issues, however, are drug pricing, drug sourcing, and the financing of hospitals and medical personnel Boynton, Ma, and Schmalzbach (2012).

First, the distribution system has been changed by changes in government regulation—prescription drugs may now be sold in pharmacies. Pharmacy chains may be established as well as stand- alone retailers. Initially, these pharmacies appeared in the large coastal cities, but may spread depending on shifts in other factors, such as consumer confidence, drug pricing and national purchasing and distribution. There will be considerable internal fighting with the pharmaceutical companies in the middle unless hospital funding changes. Alternatively, the pharmaceutical firms may become involved in the establishment of pharmacies and shift away from direct supply arrangements with hospitals.

Second, new health insurance programs have been announced by the government. It is not yet clear how this will affect the extent to which prescriptions will increase or decrease. Currently, the use of patented, prescription drugs is relatively high for those with medical access, in part because they are pushed by both doctors and hospitals. Widespread insurance may increase the number of people able to afford prescription drugs. Alternatively, regulation of OTC drugs may change with official rules on prescriptions and advertising relaxed. The introduction of government supplied basic drugs may increase pressure on margins and curbs on patenting protections for some categories.

Third, the anti-corruption campaign has affected large pharmaceutical firms and their sales programs. Tactics viewed as unethical in the West have nonetheless been quite common until now in China. Earlier this year, the government moved to indict several firms for corrupt practices accompanied by much publicity (Jack and Waldemeir, 2013; Howell, 2013). More than 50 firms are being investigated for price fixing, while Glaxo, Novartis and Eli Lilley have been charged with bribery of doctors and hospital administrators as part of their sales programs. Shobert (2013) among others noted that while these practices were contrary to international ethical standards, the drug companies involved did not create the system; the system developed given the incentives and financing of healthcare in China. It is also the case that no domestic firms have been indicted although the practice is "industry standard."

The healthcare reform that guarantees basic medicines to an aging population will require that drug prices decline drastically. Whether the campaign continues to target only foreign-owned firms and whether changes in medical continuing education and hospital funding accompany the crackdown will impact the direction and pace of change. There will be declines in the amount of value growth in big pharma drugs and use of prescription drugs

as a primary treatment. This may change the outlook for investment strategies and forecasts for the market.

Fourth, there are few new mass usage drugs in pharmaceutical pipelines even as patents on the current large earners end. This will spur generic manufacture but the strong government investment in small Chinese firms may prevent the large firms from adopting the tactics of mergers and takeovers as they did in India and Brazil. Conversely, the anti-corruption campaign may lead to further joint-venturing in both manufacture and sale in order to avoid disparate treatment.

Fifth, there is priority for bio pharma, internationally to be sure, but especially in China with large funding and infrastructure development. Whether the small partnerships in R&D will be allowed to expand is not clear nor is the ownership of medicines developed in these ways. There may be significant pressure to prescribe these new drugs in place of older drugs in order to support and encourage the growth of a domestic industry (Chu and Chun 2010).

Sixth, after initially adopting TRIPS, but supporting the Doha amendment to it, the Chinese patent courts were quite professional and followed the general international practice. However, the concern about drug prices and the successful challenge to patent protection and pricing by Thailand and India have led to indications of a possible shift in China policies, especially for drugs that treat long-term conditions such as AIDS and diabetes.

Seventh, China has strongly signaled a desire to become a major player in pharmaceuticals with a major exporting initiative. It is already causing concern among Asian pharmaceutical firms, particularly Japanese, Taiwanese and Indian. Thus far, lack of assured quality control and extensive counterfeiting has limited this initiative, but it remains a threat to purely international firms.

Eighth, Chinese consumers are changing. As the first wave of preference for foreign goods has passed, there is great uncertainty about how consumers will shop for non-traditional drugs. Whether pharmacies will be accepted as guarantors of drug quality and authenticity is one of many issues as Chinese consumers try to navigate between wanting to buy Chinese products and also wanting some certainty of safety and quality. If there develops a stronger preference for domestic drugs, particularly generics, the once anticipated profitability of Chinese investments by international pharmaceutical firms may disappear.

All these changes, occurring at once, will impact the strategies of the firms already invested in the Chinese market and those still contemplating significant investment. The

environmental forces have changed significantly, in ways all potentially negative for the international firms. These, in turn, have forced changes in the industry internal forces—strength of buyers (individually and governmental intermediaries), potential changes in supplier strength for manufacturing and distribution, and a change in the network of potential and actual domestic competitors all resulting from external change.

Firms, therefore, must create new strategies and tactics in the face of great uncertainty, essentially as if the industry were new. This occurs at a time when large pharma was already under pressure from expiring patents and few new mass market drugs on the horizon. Shifts to higher R&D expenditures with even higher costs and fewer commercially viable outcomes limit the financing necessary to cope with externally created change in industry operating structures.

POTENTIAL STRATEGIC DIRECTIONS AND RESPONSES

There are four good possible strategic options, but each must confront the uncertainty of policy changes within China. Further, any option chosen for China will impact operations in other countries. Just as international firms strive for consistency in order to achieve managerial and financial goals, so, too, governments are seeking more flexibility in international agreements and demanding more from multinationals. For many governments and their populations, drugs are a necessity and should be low in price to ensure availability. The low prices, on the other hand, will restrict potential investments in new drugs and enhancements of older ones.

Option One

Increase the extent of joint-ventures with Chinese firms. This will necessarily include loss of control over new drugs and distributive tactics, but may protect existing international products. There may be strong pressure to increase investment even as profits decline, but it may protect against regulatory and subsidy discrimination that would be more destructive to operations. The long-term benefits depend entirely on the ability to swiftly find, test, and commercialize new drugs. Although there is significant interest globally, and specific policy pressure in China, for bio pharma, the potential has yet to be realized. In the meantime, the companies will lose considerable independence.

Option Two

Attempt to control the market through mergers and takeovers as has been the case in other emerging markets. This may be difficult, however, given the probably government strategic

directions. Many of the firms which would be targeted are government owned, at least in part, and approval is quite uncertain. This may, in turn, lead to even more price controls and patent protection relaxation as part of the "price" for the mergers.

Option Three

Invest directly into distribution systems, creating vertically integrated systems with pharmacies. There would be strong opposition from existing firms, but the interest of the government in improving conditions for healthcare in rural areas might make this feasible, although not very profitable in the short term. The tangled current distribution system is a source of power and jobs; it has been highly resistant to change and consolidation although other aspects of the health delivery system have been made more efficient and effective. This does little to address the pricing and patent issues.

Option Four

Use the situation to develop the globally needed new industry system. The development of clinical trial facilities, patient tracing systems, R&D laboratories in many different locations, and various types of pharmaceutical contracting organizations have already started to shift the pharmaceutical industry toward the more diffuse, coordinating network model of other global industries. However, no multinational firm has yet explicitly adopted such a model which would result in networks not based in any particular country, but also creating a new set of international "rules" for development and distribution (see Cao and Wu, 2011; Huang, 2012). The chaotic nature of the Chinese experiment in reform may provide the opportunity to exploit the R&D collaborative potential, retain access to natural growth in drug usage and reduce dependence on an entirely domestically focused business model.

This global pattern will be perceived as less directly reacting to specific Chinese policy. It will also help overcome some of the known structural problems of data corruption, institutional research infrastructure inadequacies, and stiff competition for professional and managerial staff in China and elsewhere. It should also direct attention to new areas for development as there would be greater recognition of regional medical problems. This would create new submarkets for R&D as well as testing, new directions in medical research, and eventually regionally based sales tactics and distribution. This direction is already somewhat underway and mirrors the other global industries. It will be expensive, not all firms will survive as independents, and does not directly address the new drug pipeline issues in the near term.

CONCLUSIONS

There are some specific issues in the Chinese pharmaceutical market as outlined in this paper. Yet, the underlying pressures on the international pharmaceutical industry are not limited to China. In particular, the demands for lower cost drugs, decreasing patent protections, the limitations in scientific technology for new drugs, and the rise of new large firms and high quality supporting firms world-wide already change the external and internal forces operating on firms in the industry.

The radical reshaping of manufacturing based industries to value chain clusters can be viewed as an early revolution in the structure of industries and the firms in them. The particulars of intellectual property and service industries will lead to somewhat different organizational patterns and rules of operation, but the older models will not fit China, but not elsewhere either for long.

Finally, these patterns suggest that the dominant forces paradigm will require rethinking as the distinctions between external and internal forces are being blurred. The emergence international movements that shape policy, consumers, and firm policy add a new dimension to other factors affected by globalization.

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