

Analysis of the Internationalization Pathways of Chinese Medical Device Enterprises-Taking Mindray Medical as an Example

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Abstract. With the rapid development of China’s medical device industry and the continuous expansion of its export scale, corporate internationalization has become a focal point of attention for both academia and the industry. This paper uses Mindray Medical as a representative case study. By integrating the Uppsala internationalization model, the resource-based view, dynamic capability theory, and global value chain analysis, it explores how Chinese enterprises can enter institutional markets and achieve capability building. Research findings indicate that Mindray Medical has adopted a progressive path of “entering emerging markets-building compliance capabilities-achieving breakthroughs in high-end markets.” Through compliance adaptation, dynamic capability accumulation, and M&A integration, the company has transformed from a low-cost manufacturer into a global solutions provider. Mindray Medical has enhanced its regulatory compliance by adhering to EU Medical Device Regulation (MDR) and Food and Drug Administration (FDA) standards, while simultaneously upgrading its value chain from single-device manufacturing to ecosystem-based services. This pathway not only reveals the dual role of the institutional environment as both a constraint and a catalyst but also underscores the importance of localized services and strategic patent positioning. This paper provides case support for understanding the catch-up logic of emerging market enterprises and offers insights for the internationalization practices and policy formulation of Chinese medical device companies.

Keywords: Medical devices; internationalization path; Mindray medical; dynamic capability; global value chain.

1. Introduction

In recent years, the global medical device industry has entered a phase of rapid development. Driven by population aging, the high prevalence of chronic diseases, and the application of technologies such as artificial intelligence and digitalization, the medical device market continues to expand, exhibiting trends toward high-end, intelligent, and platform-based solutions [1]. Through this process, multinational corporations from developed countries such as GE Healthcare, Philips, and Siemens Healthiness have long dominated the high-end market by leveraging their technological and brand advantages, thereby establishing formidable competitive barriers. However, with the rise of enterprises from emerging market nations, the competitive landscape of the global medical device industry is undergoing significant changes [2].

AS a major manufacturing powerhouse, China’s medical device industry has achieved rapid development over the past decade. In 2024, China’s medical device exports reached US\$48.75 billion, marking a 7.3% year-on-year increase and demonstrating the industry’s competitive potential in the international market [3]. Among them, Mindray Medical, as a leading Chinese medical device company, has seen its overseas revenue exceed 40% of total sales. Its products are distributed across more than 190 countries and regions, and the company has gradually grown into a key player in major international markets [4]. However, Chinese enterprises face formidable challenges in their internationalization process, including stringent compliance regulations in Europe and the United States(such as FDA 510(k) and EU MDR0,inadequate overseas intellectual property protection, underdeveloped localized service systems, and intensifying global competition. These challenges compel Chinese enterprises to move beyond the initial question of “market entry feasibility” and

delve deeper into the fundamental issue of “how to achieve legitimacy and sustainable competitiveness within the regulatory environment” [5].

Academic research on internationalization pathways has predominantly focused on multinational corporations from developed economies, with limited attention given to how emerging market firms navigate institutional barriers and build capabilities. Existing studies indicate that entering institutional markets is not merely a process of market expansion but also a test of firms' dynamic capabilities and resource allocation [6]. Cross-national comparative studies reveal that emerging market enterprises in China, India, and South Korea exhibit differences in their path selection and capability building. However, they share a common imperative: achieving breakthroughs through value chain upgrading and compliance adaptation [7]. In the medical device sector, the regulatory environment serves as both an obstacle and a catalyst. The ability of companies to transform compliance pressures into capacity enhancements through dynamic learning is pivotal to the success or failure of their internationalization efforts [8].

Against this backdrop, this paper examines Mindray Medical as a case study. Mindray Medical has not only entered emerging markets through independent R&D and cost advantages but has also gradually penetrated high-end markets in Europe and the United States through cross-border M&A and technological innovation [9]. Its internationalization path can be described as “testing the waters in emerging markets—accumulating compliance capabilities—breaking through in high-end markets,” which is in line with the logic of phased expansion of Uppsala internationalization model. Meanwhile, Mindray constructed its dynamic capabilities to enhance technological R&D capability and compliance adaptation under influence of institutional pressures. Finally, through upgrading its value chain, the company changed its image from being a manufacturer to a solution provider. This case provides an important reference for studying how Chinese enterprises change from “manufacturing advantages” to “institutional legitimacy” [10].

This study focuses on how Chinese medical device enterprises obtain competitive advantages in the world by gaining legitimacy and developing dynamic capabilities and upgrading their value chain in the process of internationalization. The academic research value of this study is reflected in the following three aspects: First, academic value. Taking Mindray as an example, this study enriches the literature on internationalization paths of emerging market enterprises. It reveals the logic of latecomer catch-up under the interaction between institutional environments and dynamic capabilities, which has theoretical value for international business and strategic management studies [6,7]. Second, practical Significance. Mindray's experience offers actionable insights for Chinese medical device companies, such as how to mitigate risks through proactive compliance, accelerate entry into high-end markets via cross-border M&A, and enhance customer loyalty through localized services [9]. Third, policy implications. The internationalization of China's medical device industry represents not only a strategic choice for enterprises but also a vital component of national industrial upgrading. Mindray's trajectory suggests that policymakers should establish institutional safeguards in intellectual property protection, international certification support, talent development, and international cooperation mechanisms to propel the Chinese medical device sector toward high-quality globalization [2,5].

In summary, this paper aims to systematically analyze the evolution of internationalization pathways and capability development among Chinese medical device enterprises through a case study of Mindray Medical, integrating the Uppsala Internationalization Model, Resource-Based View, Dynamic Capabilities Theory, and Global Value Chain Theory. The article is structured as follows: Section II analyzes Mindray Medical's core internationalization pathway, focusing on the processes of institutional adaptation and dynamic capability enhancement; Section III explores the external and internal challenges Mindray faced during internationalization; Section IV summarizes insights for Chinese medical device enterprises' internationalization; Section V presents research conclusions and future directions. Through this research design, this paper aims to provide references for academic research and practical exploration of internationalization among emerging market enterprises.

2. Core Pathways for Mindray Medical's Internationalization

The internationalization process of medical device companies is not a gradual one, but a continuous process of adaptation between regulatory pressures, market opportunities and corporate capabilities. According to the analysis of Mindray experience, internationalization is not a simple process of “market expansion”, but an evolutionary process of “learning and rebuilding regulatory capacity” while “gradually upgrading value chain in competition”.

In order to enter into regulated market, Mindray adopted a step-by-step entry approach, entering easy-entry market before entering difficult-entry market. Instead of facing directly the entry conditions of Europe and United States, Mindray first entered into emerging market. It's not an evasion, but a strategy of “entering these markets gradually by building regulatory compliance and certification experiences in areas with less strict regulation”. So that later it could enter into Europe and America with its entry conditions. When entering Europe and America, it had relatively mature process and team internally. It could turn the regulatory pressure into an opportunity to upgrade its own process. In this process, the regulatory environment did not play the role of barrier simply but played the role of promoting the company to build capability.

The process of adapting to the institutional environment and building capability need the support of dynamic capability. The success of Mindray does not lie in its technological breakthrough, but in its ability of “learning and rebuilding” when facing the change of environment. For example, when facing the challenge brought by EU MDR, it quickly adjusted its compliance team, adjusted its technical documents, and revised its plan of clinical trial. This “integration-learning-reconstruction” process is the long-term accumulation of dynamic capability. What is more important, this kind of capability is not only reflected in the face of regulatory pressure, but also in the advancement of technology. The R&D and compliance function of Mindray are not isolated, but through the internalization of dynamic capability, they become two driving forces of technology advancement and institutional adaptation.

When the institutional legitimacy and dynamic capability of enterprises continue to improve, the internationalization process of these enterprises will show more characteristics of upgrading value chain. Enterprises no longer rely on the comparative advantage of low-cost manufacturing, but gradually master core technology in the process of R&D and acquisition and even provide solution-based service and platform-based service. In the business of in vitro diagnosis, Mindray is not only a supplier of individual devices, but also an enterprise that builds ecosystem solutions. It has built a chain from product to platform, and then to ecosystem. Not only does it improve added value, but it also improves the bargaining power of the enterprise in the global market. In other words, the upgrading of the value chain is not achieved through isolated breakthroughs, but the result of the joint effects of institutional adaptation and capability restructuring.

Compared with other Chinese and emerging market companies, this company is different from the rest. United Imaging pursues independent R&D; Micro Porl pursues small segments. Indian companies pursue costs; Korean companies pursue institutions and brands. Mindray has invented its own road of “innovation + M&A + localization.” It is catch-up with technological innovation; it swallows channels and resources through M&As; it mitigates its late-mover position with localized services. Its multidimensional road enables Mindray to maintain a balance between dynamic capabilities and institutional legitimacy.

Therefore, Mindray Medical's internationalization is not just an issue of entering foreign markets, but a cycle of cultivating capabilities under institutional constraints and creating upgrades of value chains through capability growth. It reveals the logic by which Chinese medical device companies transcend manufacturing advantages and gain institutional legitimacy and offers valuable suggestions for emerging market enterprises to make breakthroughs in global competition.

3. Challenges and Insights in Mindray Medical's Internationalization

In the face of rapid globalization, Chinese medical device enterprises confront opportunities and challenges when they seek to enter the international market. As a representative company, the internationalization experience of Mindray Medical shows not only the development path of Chinese medical device enterprises but also the structural problems that Chinese device companies meet when they enter the international market. People can have a better understanding of the external institutional environment and the internal capacity building that Chinese medical device enterprises face by analyzing the experience of Mindray Medical. And then people can draw some generalizable insights.

The most obvious problem existing in the external environment is compliance and regulation complexity. The certification system for medical device product in European and American market is very strict, and it has high requirement on medical device company in each process from clinical trial to the production standard and risk management. And the process of FDA and EU MDR certification will take up lots of time and cost. It's also a huge entry barrier that can't be ignored by Chinese company even they have advantages in the domestic market. When they want to enter in European and American market, Chinese company must spend a lot of money and energy to set up compliance department, and they also need to adjust their R&D process and production process to meet the institutional requirements of developed market [5]. The huge time cost and high entry cost brought by certification also slow down the speed that Chinese company can bring their product to the market.

Besides, IP barrier is another problem. Multinational giants own the core patent in medical device industry, and they can dominate the market by litigating with their patent portfolio. When Chinese company enters in the overseas market, they will also face the problem of patent litigation or they will pay licensing fee for every unit they sell, which brings a big challenge to the sustainability of their internationalization process [6]. And it's not only the high-end equipment but also the middle range market like patient monitor and ultrasound enter in the overseas market, and the limitation of the speed of Chinese company enters in the international market is also caused by the asymmetry of IP right.

Another problem existing in the external environment is brand recognition. It's also a challenge that Chinese enterprise can't avoid when they internationalize. Even if their product is better than other competitors in technology and price-performance, some international clients still think that Chinese medical device company is an inferior supplier. Compared with Siemens Healthineers and GE Healthcare, Chinese brand has no long-term technology accumulation and market influence to support their brand image. When Mindray Medical centers in the overseas market, although they have certain recognition in the emerging market, there's still a gap between their brand image and technology in the high-end market like Europe and America, and they also need to put more efforts to win the tender and do marketing in order to gain the trust of the customer [7].

Furthermore, the globalization of competitive entities has increased uncertainty. When Chinese companies compete with MNCs from developed countries, they also face pressures from other developing countries. Indian companies occupy a certain proportion of the market in some developing countries with a low-cost strategy; South Korean companies gradually capture the mid- and high-end markets with government support. The above-mentioned competitive entities have converged, and the position of Chinese enterprises in the value chain has become more uncertain. Therefore, Chinese enterprises become more cautious in their strategic decisions [7,8].

In terms of corporate internal capability, the development of Mindray Medical also reflects the limitations faced by Chinese enterprises. The most prominent problem is the shortage of talent. Internationalization does not only require talents in R&D and manufacturing, but also versatile talents who are familiar with compliance, market marketing, and cross-cultural management. However, the reserve of such talents in China medical device industry is very weak. Although Mindray can partially solve the problem by establishing foreign subsidiaries and R&D centers, the reserve of talents in the

whole medical device industry is still very weak. The shortage of talents will cause execution and implementation problems in the process of implementing global strategies [9].

M&As are important ways for Chinese enterprises to realize rapid internationalization. However, it should be noted that the integration after M&As is not an easy task. Due to the differences in management systems and institutional arrangements, there will be conflicts. For example, Western companies are decentralized and flexible, while Chinese companies are used to centralized decision-making. These differences will affect the realization of synergies after M&As. Mindray Medical also has encountered management and cultural conflicts in the process of M&As and needs to communicate and adjust continuously to solve them [9].

The shortage of service systems also affects the depth of corporate internationalization. Competition in medical device products is not only for the product performance in hardware, but also the performance in after-sales service, training, and maintenance. Multinational giants leverage mature service systems to provide high-quality services for customers, while Chinese enterprises invest less in this field. Although Mindray Medical has established local teams in some markets, its service level still needs to catch up with multinational giants in order to provide customers with long-term trust in the brand [4,10].

Improving R&D strength is another challenge. Although Mindray Medical and other leaders in the industry continue to increase investment in R&D, the entire industry still faces the problems of insufficient innovation and serious product homogenization. Most companies focus on making small improvements on existing products rather than making real original innovation. This situation makes Chinese enterprises face the challenge brought by the new technological revolution and regulatory requirements [3].

These cases jointly show that internationalization of Chinese medical device company is a long-term and difficult process. And Mindray's experiences are interesting for others. First, differentiation strategy is an important way to breakthrough. The Chinese companies should avoid competing with international big brands in the core areas and then open up in the niche areas and create differentiation advantages through technology and service [3]. Second, a combination of phased entry strategy and M&As is a feasible way to help Chinese enterprises to enter the target markets with integration capability. And the target companies could minimize the uncertainties brought by M&As through the cooperation in culture building and institution innovation [9]. Third, the effort of compliance should be front-loaded. Companies should integrate international standards into their strategic planning from the very beginning and avoid making up for losses after entering the market. This way not only could it minimize the compliance cost but also improved the company's adaptability in regulatory environment [5,7]. Finally, localization service and cultivation of international talents are also important ways to achieve sustainable competitiveness. The two companies established a service network all over the world and cross-cultural teams and then enhanced the satisfaction of customers and loyalty of brand and at last gained an important place in the global market.

In the aspect of policy, as for the government, it also does something meaningful. If the protection of intellectual property strengthened, the risk of intellectual property lawsuit in local market would be reduced. And if the team certification support system could be more reasonable, the time to enter developed market would be shortened. Then, cultivating international talents could make up for the lack of industry development. And if the international cooperation platform like the Belt and Road Strategy was established, the government could help Chinese enterprise enter emerging market better and get more institution support in the global industrial division of labor [1,2,6].

In short, Mindray Medical internationalization experience not only shows together that internationalization of Chinese enterprises meets with multi-dimensional challenges in the process of global expansion but also gives reference for industry development. The Chinese companies should keep exploring in the aspect of differentiation strategy, proactive compliance, localization service and international talents. And then, by making use of policy support to overcome institution restrictions, they could achieve sustainable development in the fierce international competition.

4. Conclusion

This paper uses case study method based on Mindray Medical. Taking path of internationalization of Chinese medical device enterprises as research object, entering emerging market, European and American market, cross-border M & A and localized service as representative, this paper finds that Chinese medical device enterprises have internationalization logic of “incremental entry – dynamic capability – value chain upgrading”. This paper explains how Chinese medical device enterprises improve compliance management and R&D capability based on external regulations and differences, and how Chinese medical device enterprises seek market advantages and service advantages different from multinational giants in competition with Western giants. This shows that: First, the internationalization path of Chinese medical device enterprises displays a step-by-step characteristic. Second, cultivating dynamic capabilities become key to overcoming institutional differences. Third, value chain upgrading becomes a key path to enterprises’ sustainable competitive advantages. Based on this analysis, this paper offers several recommendations. For enterprises, it is advisable to increase investment in R&D and patents, focus on differentiated niche markets, gradually advance localized operations, and incorporate compliance adaptation into strategic budgets to mitigate passive risks. For policymakers, stronger institutional safeguards should be established in areas such as intellectual property protection, international certification support, global talent development, and the establishment of international cooperation platforms to foster a favorable environment for enterprises

Future research can be deepened in two directions: First, cross-case comparisons to systematically summarize the internationalization models of different Chinese medical device enterprises; second, cross-country comparisons that integrate experiences from emerging markets such as India and South Korea to reveal how institutional differences influence corporate path selection. This will enrich theoretical research on the internationalization of emerging market enterprises and provide more universally applicable references for the globalization strategies of China's medical device industry.

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