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研究課題名（和文）A Global Business History of the Medical Device Industry Since 1945: Coevolution of Global Firms, SMEs & Science

研究課題名（英文）A Global Business History of the Medical Device Industry Since 1945: Coevolution of Global Firms, SMEs & Science

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研究成果の概要（和文）：本研究は、1960年代から現在に至るまでの世界の医療機器産業のダイナミクスを、経営史と産業史のアプローチを用いて分析したものである。ユニークな特徴は二つがある。第一に、世界および主要な国（米国、日本、ドイツ、スイス、フランス、中国）における医療技術ビジネスの形成と発展について考察している。第二に、個人起業家から、家族企業、国籍企業、さらには大学や研究所まで、幅広い関係者と組織を取り上げている。したがって、本研究の最も重要な貢献は、世界における医療技術産業の形成と変容に関する一般的な理解を提供することである。

研究成果の学術的意義や社会的意義
この研究は、学術的に3つの大きな意味を持つ。第一に、1960年代の形成期から今日に至るまで、世界の医療技術産業のダイナミクスを調査した初めてのプロジェクトである。第二に、産業研究の分野への重要な貢献である。本書は、主に1970年代から1980年代にかけて、製品の多様化とM&Aという二重のプロセスを通じて、新しい産業（メドテック産業）がどのような状況で出現し、形成されたかを明らかにした。第三に、多国籍医企業のグローバルなプレゼンスが、世界的な医療の標準化に影響を与えることを示した。このような観点からの企業のインパクトは、医療経済学者やグローバルヘルス研究者からは軽視されがちである。

研究成果の概要（英文）：This research offers an analysis of the dynamics of the global medical device (medtech) industry from the 1960s until the present, using the approaches of business history and industry studies. While most of the publications in the corresponding field have focused on particular countries/regions or actors, this research is unique in its scope. First, it explores the formation and development of medtech business both globally and in the major countries engaged in this industry (the United States, Japan, Germany, Switzerland, France, and China). Second, it tackles a broad range of actors and organizations, from individual entrepreneurs, medical doctors, and engineers to small family firms, start-ups, and large multinationals, as well as universities and research centers. Hence, the most important contribution of this research is to provide a general understanding of the formation and transformation of the medtech industry throughout the world.

研究分野：経営史

キーワード：医療機器　Medtech　経営史　グローバル経営史　医療技術　スタートアップ

１．研究開始当初の背景

This industrial transformation and the dynamics of the global medical device industry have not been researched by scholars in business history, management or health economics. One of the rare works was carried out by Gelijns & Rosenberg (1999), who analyzed the global diagnostic device industry until the 1990s, with cases in the US, Europe and Japan. They argue that firm-specific capabilities were the driving force of growth and competitiveness; but this view obviously results from the characteristics of the sector they focused on (radiology, dominated by MNEs. Yet, even if MNEs (from radiology and from other sectors) dominate the general medical device industry presently, the position of SMEs and their relation with large enterprises has not been addressed.

Moreover, a second missing point is the relationship between medical device producers (MNEs and SMEs) and medical doctors and scientists to discuss how innovation and R&D are carried out in this industry. Works focusing on the pre-WWII period have shown that the geographical closeness between hospitals and doctors, on the one hand, and artisans and technicians, on the other hand, led to the emergence of clusters of specialized SMEs in large cities, particularly in Germany and in Japan (Takeuchi 1974, Schlich 2002). From the period after 1945, nearly all the works that addressed this issue were realized by scholars of history and sociology of technology. They emphasized the importance of medical doctors as innovators (Schlich 2010), the role played by social networks for the diffusion of innovation (Blume 1992, Anderson, Neary & Pickstone 2007), and the regulation of medical technology (Schlich & Tröhler 2006, Altenstetter 2014). However, these works neglected the economic dimension and give no clues for understanding the dynamics of the medical device industry after 1945.

Finally, a third major issue is the process or growth and internationalization (internal growth; greenfield investment; cross-border M&A) for both MNEs and SMEs. Here, the only sector to have been investigated was radiology, and only within the general context of the globalization of MNEs like General Electric and Siemens (Donzé 2014).

２．研究の目的

The main objective of this research project was to analyze the formation and growth of the medtech around the world since 1945. Using the concept of “coevolution”, this research tackled MNEs, SMEs and scientists (including medical doctors) (Nelson. 1994; Murmann, 2003). Firms (large and small) must innovate to develop and market new devices. Yet, there are various sources of knowledge and innovation (Universities, hospitals, medical doctors, scientists), and one must analyze the way firms access this knowledge (scientists founding startups and SMEs, MNEs merging SMEs, in-house R&D, purchasing patents, etc.) and understand how these changes over time. Moreover, the legal (national health regulation) and financial (access to capital) environment also

has a major impact and must be included in the analysis.

Consequently, the major research question addressed in this research is: Why has the global medical device industry been characterized by the coexistence of large MNEs and resilient SMEs since 1945? Secondary research questions include: How did the global medical device industry transform (change of industrial organization)? How did companies cooperate with medical doctors to innovate? What was the growth strategy of the dominant actors (M&A or internal growth)? What are the driving forces of the resilience of SMEs in this industry (R&D with hospitals, startups by scientists, spinoffs from large companies, etc.)?

３．研究の方法

This research follows the methodology of business history and of industry studies. For business history, I use the classical approach developed most notably by Chandler (1990), which involves identifying the main enterprises in an industry and explaining the development of their competitive advantages over the years. The discussion is consequently focused on the main firms, as the objective is to offer an understanding about the general dynamics of this global industry—not to identify and explain exceptional cases. As for industry studies, my work builds on the conceptual model proposed by Kurosawa (2018), which demonstrated that each industry has its own specificities that impact on the conditions of firms' competitiveness. In the case of the medtech industry, one can emphasize first the broad variety of products for which the common point is supporting healthcare; second, the fast expansion of markets due to the ageing population and increasing healthcare expenses; and, third, the importance of R&D and innovation. These characteristics explain the growth of firms through acquisitions and in-house research, which is driven by a growing demand. In particular, this research discusses the formation of medtech as an industry to understand the competitive advantages of the firms that dominate this sector in the 21st Century. In the case of the industrial gases industry, Stokes and Banken (2016) demonstrated that innovation and mergers led small firms not only to become larger, but also to move out of their original fields of specialization and to encounter competitors. This process led to the formation of a new industry, based on several companies competing with each other. This model can be applied to explain the formation of the medtech industry.

The research focuses on six main countries (USA, Germany, Japan, Switzerland, France and China). It follows both with a quantitative (analysis of export and production statistics, FDI and patents) and a qualitative (case studies) approach.

４．研究成果

This research has demonstrated that a process of diversification led to the emergence of large companies, mostly in the US, but also to some extent in Japan and Germany. These firms have dominated the world market since the early 21st Century.

The medtech industry did not exist in the 1960s. A broad variety of companies developed, manufactured, and distributed a diverse range of equipment, devices and instruments, all of which had been used by medical doctors and hospitals for healthcare purposes. These companies were usually focused on specific goods such as surgical instruments, equipment for dentists, hearing aids, patient monitoring devices, and orthopedic appliances. Innovation by doctors and engineers led to the creation of new companies for the production and marketing of these goods. This was the case for Medtronic, for example, with its pacemakers in the US, as well as for Terumo with its thermometers in Japan. The market of all these firms was originally national, and even local. Several of them grew via export, which created competitiveness with other firms worldwide, such as the Swiss manufacturers of implants and orthopedic appliances, and German endoscope manufacturers.

The only large-scale MNEs engaged in the medical devices market were companies in the electrical appliance and pharmaceutical industries. The first of these included GE, Siemens, Toshiba and Philips. They established a competitive advantage for themselves in their development of X-ray machines during the interwar years and maintained it through substantial R&D expenditure toward improving their goods. This was in addition to their development of CT scanners in the 1970s and MRI equipment in the 1980s. Despite medical imaging being their core competence, they diversified into neighboring fields, applying electronic technology to develop patient monitoring devices. As for pharmaceutical companies, several of them (e.g., Abbott, Baxter and Roche) developed divisions that specialized in diagnostic devices and patient monitoring, essentially as activities related to the development of diagnostic agents.

The growth of diversified medtech companies co-occurred with the globalization of their organization. Although export continues to represent an important driver of the internationalization of markets, cross-border M&A enabled firms to strengthen their competitive advantage. Since the 1990s, takeovers have developed dramatically. Some companies took over firms and founded joint ventures worldwide to access the local knowledge necessary to adapt their equipment to some countries. This was the case for GE, whose investments in Japan, and later on in China, were made to develop new generations of CT scanners. Other companies, such as the US orthopedic appliance manufacturers Stryker and Zimmer, maintained a focus on their core technology and acquired firms around the world to access local markets (like in France), or to internalize R&D capabilities (like in Switzerland). Finally, companies like Siemens used cross-border M&A to diversify and acquire new technologies related to digitalization and ICT.

The globalization of the medtech industry challenges the conventional national-based approach. The overwhelming majority of scholarly works on this sector has tackled national cases (see Introduction). The existence of SME clusters, of university-industry relations, and of localized knowledge has often been stressed as a major reason for the development of national medtech industries. I have shown that, although local knowledge is important and SMEs continue to be competitive (notably in Germany and

Switzerland), large MNEs established themselves as dominant actors in the medtech industry. The different chapters in this research based on national medtech industries emphasize a variety of trajectories regarding the formation and growth of a global medtech industry. The US appears as a special case, as the home country of the majority of the most powerful firms in this industry and of the constant creation of startups thanks to innovative universities and the presence of a developed financial market for capital risk. In other countries, medtech companies were able to continue their growth where they benefited from established competitive advantages in specific fields, such as electronics (Japan), micromechanics (Germany and Switzerland), optical technology (Germany and Japan), and orthopedic appliances (Switzerland).

Beyond the specific case of the medtech industry, this research contributes to literature in the fields of industry studies and industrial history. Considering "industry" the "fundamental arena in which competition occurs" (Porter, 1985, p. 1), the analysis confirms the model proposed by Stokes and Blanken (2016) in their work on the industrial gas industry. They demonstrated that "industry" is the consequence of the action of firms, which began to invest outside of their core business and consequently began to encounter competitors. A new arena for competition can then result from this process and lead to the formation of a new industry. Its definition and boundaries, however, evolve over time (Stokes & Blanken, 2015). The current medtech industry is the outcome of a process of diversification and consolidation of companies engaged in the development, manufacturing and sales of devices used by medical doctors and hospitals. The limits of this industry, however, are not fixed forever. Technological innovation and the transformation of markets—for example, a growing integration between medtech, biotechnology and life sciences—will impact the nature of this industry in the future.

Another important contribution is to the field of global health and the global history of medicine. Although some medtech firms based their international expansion on the localization of their equipment, like some medical imaging devices, one can argue that the result of the formation of a global medtech industry is the existence of standardized medical equipment worldwide. Companies offer similar devices to doctors and hospitals throughout the world. They contribute deeply, therefore, to the globalization of medicine, like the pharmaceutical industry or medical science itself. A proper understanding of the dynamics of the global healthcare system would require, however, more of a focus on factors that lead to divergence between nations. The role of governments and regulation, the varieties of health insurance systems, as well as demographic and geographic specificities should be taken into consideration to offer a more balanced view. Despite the globalization of medtech equipment, the practice of healthcare and of medicine differs between nations. Providing a narrative of the historical development of the global healthcare system that integrates global actors, such as medtech companies, and local specificities is the next major step of my research.

５．主な発表論文等

〔雑誌論文〕　計4件（うち査読付論文　3件／うち国際共著　3件／うちオープンアクセス　1件）

１．著者名 Pierre Yves Donze, Raphael Imer	４．巻 69
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３．雑誌名 Osaka Economic Papers	６．最初と最後の頁 18-42
掲載論文のDOI（デジタルオブジェクト識別子） 10.18910/75484	査読の有無 無
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２．論文標題 Global competition and cooperation in the electronics industry: the case of X-ray equipment, 1900-1970	５．発行年 2019年
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オープンアクセス オープンアクセスではない、又はオープンアクセスが困難	国際共著 該当する

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３．書名 8.Medtech: The Formation and Growth of a Global Industry, 1960-2020	

〔産業財産権〕

〔その他〕

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６．研究組織

	氏名 （ローマ字氏名） （研究者番号）	所属研究機関・部局・職 （機関番号）	備考

７．科研費を使用して開催した国際研究集会

〔国際研究集会〕　計0件

８．本研究に関連して実施した国際共同研究の実施状況

共同研究相手国	相手方研究機関