

Bio-Pharmaceutical Industry Outbound Open Innovation

Subjects: Economics

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The nature of the bio-pharmaceutical industry is innovation as the main driving force behind its growth. To overcome the challenges that the industry has been facing for several years and to inflect stagnating Research and development (R&D) productivity, bio-pharmaceutical companies started to disclose their R&D results to external innovation [1]. The bio-pharmaceutical industry has distinguished features that make it a fertile ground for adopting open innovation and for studying its managerial and organizational implications. Due to the high risk in development process, the bio-pharmaceutical industry has transformed itself into an open innovation framework in order to overcome economic risk.

Keywords: outbound open innovation ; bio-pharmaceutical industry ; knowledge-based view(KBV) ; out-licensing

1. Background

Because of the complexity of the bio-pharmaceutical R&D process, soaring technology intensity ^[1], the importance of technology transfer ^[2], the intensity of relationships between bio-pharmaceutical firms, universities and research institutes ^[3], and the birth of a venture capital market specialized in supporting biotech ventures ^[4], several scholars argue that the traditional business model in the bio-pharmaceutical industry needs to evolve to solve the problem of a declining R&D productivity ^{[5][6]}. Without R&D productivity increase, bio-pharmaceutical industry cannot maintain sufficient innovation incentives to replace the decrease of revenues because of patent expirations ^[6]. Recently, the innovation strategies have been designed in considering an openness, while the processes for producing products and services have been extended across the boundaries of firms and industries because of the necessity of external knowledge to complement internal knowledge bases ^{[7][8]}.

“Open innovation” is one of the most frequently used keywords in management of technology field, and the management of intellectual property (IP) forms an inevitable component in this strategy for technology-based firms ^{[9][10]}. Open innovation is defined as “the use of purposive inflows and outflows of knowledge to accelerate internal innovation and expand the markets for external use of innovation” ^[9]. Alternatively, it is “systematically relying on a firm’s capabilities of internally and externally carrying out the major technology management tasks along the innovation process” ^{[11][12]}.

Bio-pharmaceutical firms need to explore improved commercialization opportunities and increasingly adopt a more proactive IP management strategy with additional values occurred in externally exploiting their IP ^[9]. Regarding the bio-pharmaceutical industry, increased complexity of new technologies and increased pressure on time and cost have accelerated the adoption of open innovation ^[13]. Today, multinational bio-pharmaceutical firms start to realize the potential of open innovation as they have begun to harness external sources of innovation by accessing ideas, technologies and the results of R&D projects. The bio-pharmaceutical industry has transformed itself into an open innovation ecosystem, and licensing strategy has become a core business model for biotechnology companies ^[14]. In the open innovation model, companies fill the gap of their internal product portfolio through licensing and acquisition of drug candidates ^[15]. In-licensing compound from a biotech company or a university allows the bio-pharmaceutical companies to avoid the full cost of development, decrease the early risk and selectively choose products that fit the firm’s business model. Companies can out-license abundant projects or technologies to cover high cost and to focus their efforts on a specific indication or technology ^[16].

The bio-pharmaceutical industry has a relatively high licensing propensity ^[17]. In the bio-pharmaceuticals industry, an IP is a means of appropriating rents from a technology, and thus the licensing propensity is quite higher. Research suggests that licensing out technologies is becoming more common ^[18]. Some firms have even made it a strategic priority to out-license technologies ^[19]. In the biotechnology industry, licensing is one of the most important strategies to overcome the economic crisis and is recognized as an exit strategy.

2. Characteristics of Bio-Pharmaceutical industry in Terms of Open Innovation

The main practices of open innovation in general are patent licensing, merge and acquisition (M&A), outsourcing, collaboration, and joint investment [20]. In particular, inbound open innovation based on absorptive capacity has been of interest to academia. However, the concept of knowledge flow with increased flexibility and the expectation to completely utilized technologies led outbound innovation to the academic attention. Knowledge such as the patent became the primary factor in innovation process, and knowledge transfer process including outside-in and inside-out innovation, beyond the organizational boundaries, is now emphasized in open innovation research [21][22].

The main practices of open innovation adopted in the bio-pharmaceutical industry are out-licensing in innovation and R&D process [23] and M&A [24]. Particularly, a product approved by authority can be competitive in the bio-pharmaceutical market by only charging a licensing fee to potential demand firms [20]. Currently, the open innovation framework and its methodologies are inevitable in bio-pharmaceutical industry [25], and most of empirical studies in bio-pharmaceutical area are approached by open innovation theory and constructs [20][23][26].

The bio-pharmaceutical industry in general has been through a lot of changes over the decades with mergers and down-sizing of R&D functions within companies [27]. Because of significant changes in the competitive situation such as globalized markets, extreme dynamics in technology development process [28] and a growing mobility of highly skilled people [29], closed innovation strategies become less viable and restrict interactions with the firms' environment [30]. Many firms have recognized the potential of disclosing their innovation processes and therefore they increasingly explore and share ideas out of their organizational boundaries [31].

The fact that only one of the 10,000 substances found during the research and development phase in the bio-pharmaceutical industry can be marketed [32] shows the significant risks these companies face with regard to the results of technological innovation. Bio-pharmaceutical firms have organized over time to exchange technologies and knowledge with different classes of external organizations (e.g., universities or competitors) along the different stages of the R&D process (e.g., drug discovery and drug development) [28]. They have changed their business models by consolidating other firms (M&A), increasing partnerships, outsourcing information technology and R&D functions, or reorganizing their entire R&D.

Since Chesbrough presented an "open innovation" concept [33], research interests have been increasing in many scholars, especially in the areas of management and innovation. A number of bio-pharmaceutical firms have announced that they have been doing an open innovation strategy and 55% of the top 20 bio-pharmaceutical companies of 2016 "open innovation opportunity" on their web pages [15].

Bio-pharmaceutical firms need to seek knowledge from multiple areas both inside and outside of firm boundaries. In the last decade the number of externally sourced drug programs in big pharma's pipeline have increased significantly. Drug development process has transformed into an open innovation ecosystem where small biotech companies are the innovators and where the large bio-pharmaceutical companies act as their commercialization partner [14].

3. Outbound Open Innovation with Knowledge Based View

3.1. Licensing as Outbound Open Innovation Strategies

Open innovation encompasses various activities, e.g., inbound, outbound, and coupled activities [20][22] with emphasis mainly on the inbound strategy [34], whereas the outbound strategy has received little attention. Outbound open innovation can have monetary and strategic advantages for firms exploiting their technological knowledge outside their boundaries or co-developing it with another organization [35]. Inside-out (outbound) process refers to one of key approaches focusing on the externalization of the firm's internal knowledge for bringing new ideas to commercialize faster than it can be done only through internal R&D. The outbound open innovation refers to "earning profits by bringing ideas to market, selling IP, and multiplying technology by transferring ideas to the outside environment" [21]. Lichtenthaler et al. find a relationship between inside-out activities (e.g., external technology commercialization) and firm performance [36].

Licensing is one of the practices of the outbound open innovation strategy. Firms now can commercialize their IP externally, out-license and sell patented technologies [37][38]. The importance of technology licensing has been emphasized by the previous literature on management of technology [39]. Licensing agreements is a commonly observed type of inter-firm alliances, especially in technology-intensive industries [40]. Patent licensing is an important strategy for technology transfer [41]. By licensing external technology, licensees can use it to fill technological or strategical gaps,

overcome blind spots, and complement their internal capabilities [42]. The patent licensing means the transfer of the right to use the patent from the licensor to the licensee. It refers that a patented technology owner can authorize another firm to use the technology in a certain way for a certain period of time, and the licensee should pay for it to the licensor [41].

In bio-pharmaceutical industry, a firm with relatively full of drug candidates at one clinical phase is likely to license out some of drug candidates at the same stage [43]. Out-licensing of IP involves selling or offering licenses or royalty agreements to other organizations so as to profit from licensor IP [31][44][45][46]. More competitions and faster product and technology life cycles have led firms to make a thorough evaluation of their technology bundles, considering licensing as a commercialization strategy to generate more revenues without additional cost. By out-licensing, firms can more fully leverage their investments in R&D, partnering with actors adept at bringing inventions to the marketplace [4]. Licensing-out requires firms to determine the value of IPs, contract with partners, and implement agreements that allow partners to use the patented knowledge [47].

Because drug development is expensive, time consuming, and risky, the importance of licensing deals between bio-pharmaceutical companies is highlighted. Because the licensor company lacks financial and physical resources to commercialize its technology, it seeks to create additional value through the out-licensing [48]. For small and medium-sized bio-pharmaceutical companies in partnership with Big Pharma, licensing is an essential element in business models. Therefore, in order to grow and succeed in industry, it is important for biotech companies to excel in licensing activities [14]. Licensing has been an essential part of bio-pharmaceutical industry [49].

The bio-pharmaceutical industry is a well-known as technology market has rapidly grown [50]. According to Cortellis, licensing accounted for 45% of all transactions in the bio-pharmaceutical industry in 2017 and 77% of companies participating in the 2018 Bio Convention were looking for licensing opportunities. Out-licensing allows firms to capture additional value from their technology [51][52].

3.2. Resource-Based View (RBV)

Resources are generally defined as “all assets, capabilities, organizational processes, firm attributes, information, knowledge, etc., controlled by a firm.” [53] Resources are valuable when they help improve the firm’s efficiency and effectiveness [53]. Firm performance may be an aggregated result of the different effects of different resources [54]. Resources can form the basis of exclusive value-creating strategies and their activity systems leading to competitive advantage [55].

Resources are at the center of the resource-based view (RBV). The RBV is one of the most widely accepted theoretical perspectives in the strategic management field [56][57]. It is an influential theoretical framework for understanding how competitive advantage is realized and how that advantage is maintained over time [58][59]. A firm consists of “a collection of productive resources.” [60] According to RBV, each firm even in the identical industry performs differently because they differ in terms of the resources they control [18][61]. RBV notes that the ability to use resources relevantly is the point to firms’ innovation and financial success [57][62] and the extent of innovation is decided by the resources of the organization.

RBV assumes that firms can be conceptually developed as an array of resources, that those resources are heterogeneously distributed across firms, and that differences of resource continue over time [18][63]. The RBV expands the knowledge of individual firm performance and helps understand of strategic management [57][63]. The RBV has been expanded to use corporate resources in a strategic way for the firm’s innovation [57][64].

3.3. Dynamic Capabilities

Teece et al. proposed the dynamic capabilities approach as an extension of the RBV [62]. Dynamic capabilities are developed over time through complex interactions between the firm’s resources [18]. The dynamic capability perspective extends the RBV by addressing how valuable, rare, and difficult to imitate and imperfectly compatible resources can be created and how the current stock of valuable resources can be improved in changing environments [23][65][66]. RBVs emphasize sustainable competitive advantage while dynamic capabilities focus on competitive survival issues that address today’s rapidly changing business climate. The dynamic capabilities, which refer to “the firm’s ability to integrate, build and reconfigure internal and external competencies to address rapidly changing environments” [62], has been used to explain the reason that firms in the same industry perform in a different way.

A dynamic capability is the capability of an organization to deliberately create, extend, or modify its resource base [67]. The emergence of dynamic capabilities has reinforced the RBV by suggesting the evolutionary nature of firm resources and capabilities in connection with environmental changes and enabling identification of firm-specific processes that are critical to firm innovation [68].

The effects of dynamic capabilities on firm performance are relatively complex. If a firm enhances its particular capabilities as directed by its strategic targets and if capability development and firm strategy are effectively coordinated, dynamic capabilities may lead the firm to have better performance. Dynamic capabilities are often steered by firm strategy [68]. This study extends the RBV to dynamic capabilities by combining it with open innovation theory.

3.4. Knowledge Based View (KBV)

The ratio of knowledge-based assets is increasing in terms of resource base of the organization [69][70]. Firms are repositories of knowledge. Knowledge is the most important firm resource which conceptualizes the firm as a unique bundle of distinguishable resources and capacities [60][71]. Knowledge creation fuels innovation. A dynamic and comprehensive view may strengthen “our understanding of knowledge strategies, their modification over time, and their effects on innovation performance” [72][73]. Evidences that firm performance is influenced by firms’ abilities to integrate, build, and reconfigure their knowledge, resources, and capabilities are increasing.

It is generally accepted that the KBV of the firm is an extension of the RBV because it considers that organizations are heterogeneous entities loaded with knowledge [74][75]. The KBV is the logical evolution of the RBV considering the temporal evolution of its resources and the capabilities that maintain the competitive advantage [76]. In comparison with the RBV, the KBV takes a more fine-grained and profound understanding of knowledge as its basis.

KBV is indirectly linked with firm performance to change a firm's portfolio of capacities, resources, which in turn affect economic performance. Companies need to develop “knowledge capabilities” to benefit from open innovation [9][77]. The KBV focuses on how knowledge capacities and resources are utilized and coordinated [78]. The resources and capabilities generate economic returns to the firm [18]. Now that the concepts of the KBV place substantial emphasis on firm financial performance, the research model of this study is divided into firm resources and firm capacities based on KBV.

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