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Dominant business models in the global pharmaceutical industry

Abstract
The research is dedicated to the analyses of existing business models in pharmaceutical industry, their strength and weaknesses. The first generation of corporate business models in the global pharmaceutical sector are the traditional closed business models based on vertical integration within one company of all units of research, commercialization and market launch of blockbuster medicines. Specialization of companies within the Pharma 1.0 paradigm, characterized by the comprehensive development of pharmaceutical R&D and biotechnology at the expense of both its own sources and support of venture funding.

Despite the significant competitive advantages of closed business models of pharmaceutical companies in the monopolization of entire areas of scientific and technological and innovative progress, in terms of techno globalism, they reach their limits. This is manifested in a significant decrease in the productivity of corporate research and development, the inability of firms to perform productive scientific research in all innovative areas, their inability to generate sufficient to compensate for lost revenue from the expiration of patents, the number of innovative developments, as well as a significant increase in the duration of the second and third-party development. This is the reason for the radical reorganization of traditional business models by pharmaceutical industry leaders and the implementation of qualitatively new types of models based on the implementation of open business models in the Pharma 2.0 paradigm. It involves the presence of a large number of independent pharmaceutical and biotechnology firms which, in partnership with various large and medium-sized companies, diversify their product portfolio and operating systems for managing operational processes.

Keywords
pharmaceutical sector, business model, biotechnology, innovation

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1 Statement of the problem

The intensification of the global market environment, a significant exacerbation of international competition, significant complication of the development and launch of new types of drugs, systematic digitalization of production processes – here the main factors that force MNE from pharmaceutical sector to radically modernize their corporate strategies and business models.

2 Latest scientific progress and publications review

Theoretical arsenal of research of the processes of transnationalization of business activity was most developed only in the second half of the twentieth century. in theories of international business. The first fundamental works on the problem of transnationalization of business activity and placement of companies (geography of enterprise) belong to R. Aliber, J. Dunning, S. Geimer, D. Stopford, A. Chandler. At the same time, the complex and multifaceted impact of global imperatives on transnational activity causes a constant evolution and enrichment of its theoretical arsenal in order to more fully methodologically and conceptually reflect qualitatively new trends in international MNE activity. Pharmaceutical industry, being closely associated with high-tech manufacturing,

is always among the first to respond to the smallest changes in the structural dynamics of the world innovation shifts and is characterized by a high level of profitability of financial and economic operations of economic entities.

3 The purpose and problem of research

Existing business models are undergoing profound transformational changes in accordance with the needs of their maximum adaptation to the turbulent conditions of financial and economic activity of pharmaceutical companies and its networkization, expansion of marketing opportunities, the development of effective marketing and logistics complexes and the achievement of other strategic goals related to improving the strategic effectiveness of strategic , tactical and operational activities of companies. The purpose of the research is to identify the main drivers of these changes and to define the prospects of their future development.

4 Results of the research

The global environment for pharmaceutical companies determines the dramatic qualitative and quantitative changes in their operations, deepening the corporate business models and competitive leadership strategies at a structural level. It should be noted that the strategic development of pharmaceutical companies in the global era is characterized by a certain dualism. Thus, on the one hand, even in the most competitive and dynamic MNE, elements of business models, which are connected with the natural character of the flow of technological and operational processes that form the basis of pharmaceutical production, remain quite inert. First of all, these are scientific, technical and innovative activities, organizational and managerial culture, which were formed in the period of the industry's birth in the last quarter of the XIX century, and therefore - are difficult to be influenced by exogenous factors [1].

On the other hand, add-on relationships in the pharmaceutical industry - marketing and marketing tools, logistics, relations with partners and clients, organizational and economic forms of innovation processes, investing in infrastructure projects and more are becoming more dynamic and "sensitive" to global changes.

As a set of principles for the development and market promotion of pharmaceuticals, mechanisms and levers of corporate governance, the global pharmaceutical industry's business models are a major driving force behind the dynamic scaling and segmentation of the global drug market through the channels of companies' influence on their consumers through the use of a set of appropriate marketing tools. In other words, business models reflect how pharmaceutical companies generate consumer value for their clients, and therefore are one of the most important factors in ensuring their international competitiveness and market share. t should be emphasized that since the second half of the 1950s, typical corporate business models have been formed in the activities of pharmaceutical companies [2]. They differed from each other both by the specifics of the organization of their business processes and the availability of external financing for their business activities and also by their peculiarities of innovations patenting and management of intellectual property rights. It should be added that the choice of pharmaceutical companies of certain business models is also based on the therapeutic sphere of their business entities and the orientation of firms on closed, open or network forms of interaction with their partners.

Thus, the first generation of corporate business models in the global pharmaceutical sector has become traditional closed business models based on vertical integration. In this case research, commercialization and launch of blockbuster drugs were all done in one unit. By their organizational and economic nature, they represent the strategies of product specialization of companies within the Pharma 1.0 paradigm, which is characterized by the comprehensive development of pharmaceutical R&D and biotechnology at the expense of both its own sources and support of venture financing [3]. Despite the short-term nature of venture capital, they remain critical in the global context of the pharmaceutical industry. As a prove we can declare the fact that the total venture funding of the Top 10 world medical technologies (Figure 1) in 2018 amounted to about $ 2.1 billion [4].

Therefore, in a global environment, small-scale pharmaceutical companies are experiencing significant risks of entering the market and being absorbed by giants of this sector of the world economy.

Closed business models of pharmaceutical corporations are characterized by a rather wide range of instrumental arsenal of realization of their business operations within the framework of product-oriented, technological-platform and hybrid models. Fully integrated pharmaceutical company – FIPCO model has received almost the greatest support from investors because of its competitive advantages, such as the orientation of pharmaceutical companies to complete a closed cycle of development and launch of medicines, obtaining on this basis huge revenues from the sale of blockbuster drugs, as well as coverage of the whole spectrum of property rights - from the invention to its introduction into mass production and subsequent marketing of the medicinal product. The institutional format of a fully

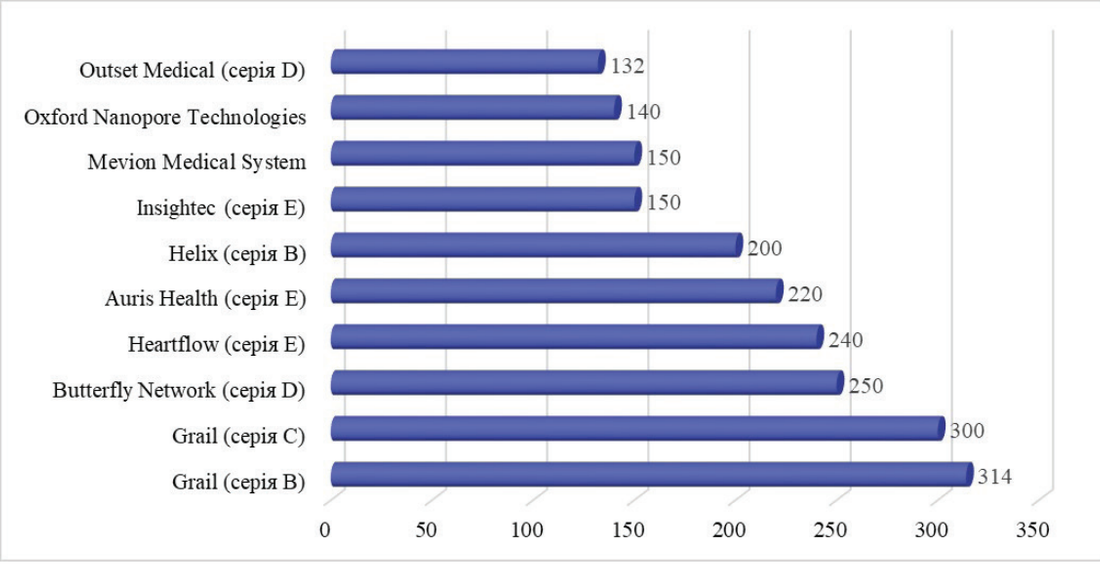

Figure 1 Venture Financing The Top 10 Worldwide Medical Technologies in 2018, $ million USA
Sourse: Value of top 10 medical technology venture financing rounds worldwide in 2018 (in million U.S. dollars). – Statista. – The Statistics Portal. URL: https://www.statista.com/statistics/334261/value-of-top-ten-medtech-venture-financing-venture-deals/

integrated pharmaceutical company is essentially a vertically integrated business model that focuses on generating revenue for firms from all levels of the social reproduction process. Understandably, the implementation of this business model requires large capital resources that are invested in all stages of drug development, clinical trials, regulatory approvals and marketing. Thus, the risks and the aggregate costs of their R&D and commercialization on the basis of their own brands are significantly increasing, which to some extent leads to resources withdrawal from production funds. There is every reason to believe that a fully integrated pharmaceutical company is objectively doomed to own numerous foreign manufacturing, marketing and research units formed in the process of consolidation of corporate assets and internationalization of companies [5].

In recent decades, these models have become the main driver of increasing the revenue generated by the pharmaceutical corporate sector, maximizing profits and increasing the profitability of business operations, both through the diversification of the product line of patented medicines and by entering new regional and product segments of the global corporate market. It is this strategic orientation of pharmaceutical companies in the global era that determines their well-established motivation to buy other companies along with all their productive assets and innovative developments, as well as expanding international operations to maintain operating profitability targets.

Technology-platform business models by their architecture belong to the horizontally integrated, within which the firm produces a unique medicinal product for its further sale to its partner companies or licensing within the single value chain. This business model, enables companies to develop and license integrated technology solutions, is implemented mainly on the early stages of developing new types of drugs (or molecules of active substances) and relies on the transfer of licensed technologies to companies located on the lower innovative stages of the world pharmaceutical chain. From the second half of the twentieth century technology-platform business models have become the most widespread in biotechnology, where corporations can generate significant revenue streams based on licensing revenue over a long period of time, thanks to the uniqueness of the product [6]. This is evidenced by the data in Table 1, that demonstrates that in 2012-2016 alone, total revenues of the Top 10 largest biotech companies in the United States increased from $ 65.9 to 120.3 billion. USA; and their net income rose from 17 to 35.3 billion, respectively [7].

At the same time, in almost all companies in this rating (except Vertex Pharmaceuticals Inc. and Biomarin Pharmaceutical Inc.), the net profit margin increased by almost one and a half times, which is an evidence of a significant increase in the profitability of firms' operations and improvement of corporate cost management systems.

Among powerful advantages of technological platform business models are dispersion of risks of production and innovative activity, practical reduction of the need of firms in venture financing, formation by the company of "scientific core of competences" that can be effectively integrated into the production of new generations of therapeutic and diagnostic drugs. In other words, technology-platform business models enable

TABLE 1 Key Financial Performance of the Top 10 Largest US Biotechnology Companies in 2012-2016 [8]

No.	Biotech company	Revenues, $ billion.		Net income, $ billion.		Net profit Margin, %	
		2012	2016	2012	2016	2012	2016
1	Gilead Sciences Inc.	9,7	30,4	2,6	13,5	26,7	44,4
2	Abbvie Inc.	18,4	25,6	5,3	6,0	28,7	23,2
3	Amgen Inc.	17,3	23,0	4,3	7,7	25,2	33,6
4	Biogen Inc.	5,5	11,4	1,4	3,7	25,0	32,3
5	Celgene Corp.	5,5	11,2	1,5	2,0	26,4	17,8
6	Regeneron Pharmaceuticals Inc.	5,5	11,2	1,5	2,0	26,4	17,8
7	Alexion Pharmaceuticals Inc.	1,1	3,1	0,3	0,4	22,5	12,9
8	Vertex Pharmaceuticals Inc.	1,5	1,7	-0,1	-0,1	-7,0	-6,6
9	United Therapeutics Corp.	0,9	1,6	0,3	0,7	33,2	44,6
10	Biomarin Pharmaceutical Inc.	0,5	1,1	-0,1	-0,6	-22,8	-56,4
	Total	65,9	120,3	17,0	35,3	X	X

pharmaceutical companies to focus as much as possible on their key technologies (discovery platforms) while developing unique approaches for each partner to transfer their technological developments and commercialize them [9].

Hybrid business models of pharmaceutical companies organically combine separate elements of models of product-oriented and technology-platform types. First of all, their strategic focus is on the technological transfer of innovative developments from biotechnology companies to pharmaceutical firms based on partnerships (in the format of strategic alliances) and the development of their own innovative projects, the results of which are subsequently marketed in partnership with commercial employees. The diversification of the product line is based on the additional licensing or access to the products of the technology portfolio of partner companies, which provides active involvement in the implementation of investor projects and the use of their own revenue stream for research and development of new types of medicines [10].

In the last decade, we have all witnessed the failure of the business model of a fully integrated pharmaceutical company based on the closed innovation paradigm to deliver steady growth in firms' innovative productivity and increase their competitive position in the global market. This is the reason for the radical reorganization of traditional business models by pharmaceutical industry leaders, as well as the implementation of qualitatively new types of them based on the introduction of a rather broad toolbox of companies' influence on the structuring of national and global pharmaceutical markets. This is manifested in the active transition of pharmaceutical companies to the implementation of open business models since the early 2000s. They reflect corporate diversified growth strategies, based on the Phare 2.0 paradigm and centered around a range assortment of medicines with little risk for research and marketing failure (generic group medicines, vaccines, over-the-counter medicines, medical technologies [11 p. 1], consumer goods, animal health products).

In research and development, the main focus of corporate strategies is shifting to the development of specialized therapies, and in financial activities, from Pharma 1.0's revenue management to Pharma 2.0's dominant cost and profit management, accelerating cash flow, outsourcing of unclassified operations, managing corporate balance and improving the return on investment.

We can say that open business models represent the second generation of models of organization of business operations of pharmaceutical companies, based mainly on the alliance mechanisms of their cooperation with partner organizations in the field of development and launch of new types of medicines. Pharmaceutical industry's functioning in the Pharma 2.0 paradigm involves the presence of a large number of independent pharmaceutical and biotechnology firms that, in partnership with various large and medium-sized companies, diversify their product portfolio and operating systems for managing operational processes. In spite of the contractual parties' differing (and sometimes diametrically opposite) economic interests and motivational goals for partnership, the Pharma 2.0 product portfolio management mechanisms ensure their effective convergence and increase the competitive advantages of pharmaceutical and biotechnology business structures [12].

Of the open business models of pharmaceutical corporations, in our opinion deserve the most attention the open innovation-based R&D model, virtually integrated pharmaceutical companies – VIPCO, IP-oriented business models, collaborative discovery business model [13].

Characterizing the most common business models of pharmaceutical industry corporations,

we cannot ignore the partnership models of cooperation with biotechnology companies (focused on the dispersion of costs and risks of pharmaceutical companies' business activities); biosimulation (generic) business models (aimed at maximizing the economic effects of the benefits of patent protection of branded blockbuster medicines); technology mediation models (aiming to use each other's client partner networks to expand their market segments); as well as business models of technological inheritance (aimed at the development by the pharmaceutical companies of molecules of active medicinal substances already on the market, but with qualitatively new therapeutic properties). All of them aim to maximize profits for pharmaceutical companies by expanding market volumes, generating additional revenue from the difference between individual and mid-industry costs for the manufacture of medicines, as well as comprehensive development of intra-company internationalization of production [14].

In the characteristic of the dominant business models of the global pharmaceutical industry, in addition to revealing the specifics of inter-corporate interaction, special attention is also paid to customer relationship management – CRM. Thus, as early as the early 2000s, large pharmaceutical corporations, possessing extensive B2C client bases and B2B partner networks, faced a huge production problem with international scaling of their databases while maintaining high quality standards for their management systems. As a result, a number of pharmaceutical MNE have resorted to active implementation of rather aggressive measures to develop extensive corporate customer interaction systems to expand partner bases, classified by specific criteria, and assigned to different business units to facilitate the ease of operation [15]. Today, pharmaceutical corporations are actively using not only CRM systems, but also various communication platforms. Together, they enable the streamlining and speeding up of electronic workflows and internal corporate communications, as well as ensure prompt decision-making in all areas of business operations. It is also important that in the context of increasing the pharmaceutical companies' international competitive position, they are improving a number of management processes, which fundamentally change the entire corporate management system. On the other hand, significant influence on the functioning and development of firms is also made by clients, who in this status can be attributed to stakeholders. One of the most pronounced trends of recent decades is the widespread adoption in pharmaceutical firms' systems of stakeholder relationship management – SRM [16]. In addition to clients, important stakeholder groups interested in the competitive development of modern pharmaceutical companies include internal stakeholders (employees, shareholders), patients (end users), medical companies (distributors and intermediaries), regulatory bodies, suppliers of reagents and funds.

It should be noted that the key areas of development of SRM systems in the global pharmaceutical business are also the active involvement of stakeholders in the management processes of companies (strategic planning and control systems) and information sharing; implementation of AA1000 standards in corporate governance; intensification of interaction of pharmaceutical companies with doctors to promote their products on the basis of agency sales, etc. [17].

5 Conclusions

Despite key trends in the modernization of pharmaceutical companies' business models and their strategic approaches to securing international competitive positions in global markets, the global pharmaceutical industry is, by its nature, more innovatively determined.

Therefore, the main trends of its organizational and institutional transformations stem from the objective need to increase the innovative competitiveness of firms, expand their implementation of the results of their R&D (even against the backdrop of their productivity), the transition from the production of traditional medicines to the creation of innovative biopharmaceutical drugs, the development of more effective pharmaceuticals and methods of drug delivery to human body, the merger of the pharmaceutical industry with modern information and genomic technologies, its complete moving to the personalized medicine. This requires the implementation of qualitatively new business models aimed at externalizing and aligning business activities, its networking and digitization, the establishment of cross-border clusters, regional integration markets and more.

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