L O D Z U N I V E R S I T Y O F T E C H N O L O G Y
No. 1(1)/2020 JOURNAL OF MANAGEMENT CHALLENGES, Vol. 01 2020

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THE DETERMINANTS OF BIOTECHNOLOGY DEVELOPMENT BY ACADEMIC ENTREPRENEURSHIP AND SPIN-OFF COMPANIES IN THE COMMERCIALIZATION PROCESS OF SCIENTIFIC RESEARCH RESULTS IN POLAND

1. Academic entrepreneurship in biotechnology

Innovative sectors of high technology are considered as one of the most important elements of the modern economy. The biotechnology industry perfectly fulfills the criteria of belonging to sectors of this type, and by some researchers [1] its development is considered indispensable for the functioning of modern economy. In technologically advanced industries, progress is impossible without access to knowledge and innovation, the most important source of which are research and development (R&D) institutions – both parts of companies and state research and educational entities (higher education institutions).

In the biotechnology sector, unlike any other industries related to innovation, the majority of innovations are created in dedicated research units – mainly universities [2]. Therefore, the basis for the development of this sector is an efficient knowledge dissemination process, enabling rapid penetration of the latest innovations in the economy. Landry et al. [3] distinguish three main diffusion paths in this case: fairs and conferences, the educational process of qualified employees and commercialization knowledge, skills. Commercialization takes place through: consulting services, research contracting, patenting (and subsequent sale of patents) and creating companies type of spin-off. The last one is the most important in the biotechnology industry forms [3].

Academic spin-off companies, which are the most important element of the biotechnology sector development, are in Poland at an initial stage of advancement. Activity of this type of endeavors remained unnoticed by the authorities and

business support organizations almost until the middle of the first decade of the 21st century. It was only the inflow of European Union funds focused on the development of innovative enterprises and a specific "fashion for innovation" resulted in increased interest in spin-offs (the first publication dedicated to spin-off companies in the high technology sectors, financed by Polish Agency for Enterprise Development – PARP, was issued in 2006).

International experience, especially American, indicates the extension of entrepreneurship education, which has been present in business school programs for years, also for didactic offers of technical universities and exact sciences at universities. Research shows that especially students of technical faculties, enriched with knowledge in the field of starting a new business, have a better chance of success than graduates of economic studies. The leaders in academic entrepreneurship are such universities as the Massachusetts Institute of Technology (MIT) and Stanford University, which has developed specialized didactic programs in the field of technology entrepreneurship, widely used in academic centers around the world [4].

The entrepreneurial competences and the ability to create innovations and research are crucial in the development of academic entrepreneurship [5]. Universities and Research Institutes should seek to transfer technology to the private sector, and therefore capture the benefits of commercialization of their innovation and intellectual property rights (IPR), through a number of different mechanisms. Thus, academic entrepreneurship can be defined as the involvement of scientific institutions and people associated with them, which "have the ability to create and visualize opportunities, take control over the possibilities, absorb and organize the necessary resources leading to the creation of new goods" [6] and they have the ability to create innovative solutions, which develop or implement new or improved products, services, production processes, technologies, organizational processes and marketing techniques [7]. Academic entrepreneurship is inextricably linked to scientific research and commercialization of technology and knowledge. One of the instruments used to transfer knowledge and technologies to build academic entrepreneurship are spin-offs [8].

2. Spin-off entities

A key element of the definition is the existence of commercialization based on intellectual property created at the parent university. On the other hand, forms of economic activity of scientific employees, in the case of which there are no intellectual property issues, are not treated as manifestations of academic entrepreneurship [9]. Matusiak [10] understands academic entrepreneurship much more broadly, as "all kinds of engagement of scientific institutions, auxiliary and administrative staff, PhD students and students in business" [11]. We deal with

widely understood manifestations of entrepreneurial activity of academic staff in various areas of cooperation between universities and business practice, the result of which is comer-cialization of research results, including cooperative forms of technology transfer based on licensing agreements, conducting research commissioned by industry, joint implementations, etc. [9].

According to a leading American researcher on academic entrepreneurship S. Shane [12], spin-offs are new companies created by members of the academic community in order to commercialize technology as an element of intellectual property created in the parent institution.

According to the STI Review, the scope of the term "spin-off" varies between countries. In the United States, a spin-off is any new company that employs a public or university employee; or a student or graduate as one of the founders; which licenses technology from a university or public research center [13]. But also every new company that started operations in an incubator or technology park linked to the university or public sector, or in which a university or research institute made an investment. However, in Germany there is a narrower deficit of the spin-off type, namely every new company that includes a public sector or university employee; or a graduate student as one of the founders, and in which the university or research institute made the investment.

The most important spatial feature of the spin-off type, highlighted by many authors (including [14], [15], [16], [17], [18]), there is a tendency to locate it near the mother institution. There are two explanation of this trend. The first one refers to "hard" location factors – presence of a mother institution, usually a large-sized economic entity or scientific, contributes to the benefits of agglomeration, used by start-ups [15]. A tailored labor market, the presence of specialized business environment institutions or potential partners creates favorable conditions for spin-off companies in the initial phase of development [14]. The second explanation of the phenomenon emphasizes the role of "soft" factors, and in particular participation of new spin-off entrepreneurs in local social networks, which is related to their previous work in the mother institution. Sorenson [18] recognizes local social networks as the most important channel of knowledge flows, and also distinguishes two their types: related to the flows of specialist knowledge and based on the exchange of information about the local business environment. Specialist knowledge, especially hidden knowledge (tacit knowledge), referring to personal, practical experiences from work in a given industry, it flows mainly through informal channels, in personal time meetings of employees in a specific sector. Hence the strong local rooting of her flows [19]. Flows of the second type of knowledge are similar channels – mainly through informal meetings, groups and social ties. That is why the start-up entrepreneurs have the best information about the undeveloped market niches and the resources necessary to conduct profitable

activities, if their new company operates in the industry in which they worked earlier and is located in a place with a known business environment.

3. Potential of biotechnology in Poland

The definition of "biotechnology" presented by the Organization for Economic Cooperation and Development (OECD) is divided into two parts: a simple description of what biotechnology is and the list of techniques that are used in it. According to the Polish equivalent of the OECD definition, proposed by the Interdisciplinary Team for Bioeconomy Development within the Ministry of Science and Higher Education, "biotechnology is an interdisciplinary field of science and technology dealing with the change of living and non-living matter through the use of living organisms, their parts or derived from them products, as well as models of biological processes to create knowledge, goods and services" [20]. According to the list of techniques used in biotechnology, below areas should be distinguished:

- DNA / RNA: genomics, pharmacogenomics, DNA probes, genetic engineering, sequencing / synthesis / DNA / RNA amplification, gene expression, antisense technology.
- Proteins and other molecules: sequencing / synthesis / engineering of proteins and peptides, improved methods of transporting large molecules of drugs, proteomics, isolation and purification, signal transduction, identification of cellular receptors.
- Cells, cell cultures and cell engineering: cell and tissue cultures, tissue engineering, cell fusion, vaccines and immunization, embryo manipulation.
- Genes and RNA vectors: gene therapy, viral vectors.
- Techniques of biotechnological processes: biosynthesis with the use of bio-reactors, bioengineering, biocatalysis, bioprocessing, bioleaching, biospulization, bleaching with biological agents, bioresprinking, bioremediation, biofiltration.
- Bioinformatics: creation of genomic / protein databases, modeling of complex biological processes, system biology.
- Nanobiotechnology: application of nano / micro-products tools and processes for the construction of devices for biosystems research and in drug transport, improvement of diagnostics, etc.

The association of biotechnology industry activists – the European Association of Biotechnology Industries EuropeBio (The European Association for Bioindustries) proposed the distinction within biotechnology of three departments (biotechnology colors) to facilitate monitoring and determine the directions and speed of biotechnology development [21]. The proposed approach

has been accepted by the OECD and is now widely used by European countries. "Colors" of biotechnology means: red – biotechnology related to medicine and health protection, used in molecular diagnostics, for the production of medicines – biopharmaceuticals and vaccines, includes gene and cell therapies and tissue engineering; white – industrial and environmental biotechnology; green – biotechnology related to agriculture, including the use of genetic engineering methods to improve plant and animal production. In addition, there are two additional "colors": blue – biotechnology of waters, dealing with the protection of the water environment of rivers, lakes, seas and oceans; violet – deals with social, legal and ethical issues related to biotechnology, including food-related issues genetically modified (GMO) or research on cell cultures, as well as issues of patents and protection of intellectual property.

The research potential in the field of biotechnology and pharmacy in Poland is created by over 2800 scientists specializing in "life science" (a group of science fields that by definition relate to living organisms, including humans, animals and plants) and medical sciences, employed in universities and research institutes and also over 8,000 biotechnology students studying at 50 universities with biotechnology specialization (93 faculties).

Research and development projects concerning biotechnology and the pharmaceutical industry are conducted in over 100 scientific institutions. The majority of implemented R&D projects in Poland, including over 70% of all biotechnology R&D projects, concern the development of innovative products. Poland ranks 10th in the world in terms of the number of centers involved in conducting clinical trials and the first among the so-called emerging markets (1.6% involved in the world).

Noteworthy, the Central and Eastern Europe is the largest market for clinical trials. The country's attractiveness for clinical research and location of R&D activity is determined by: large population of patients, relatively low operating costs and cost effectiveness of production, well-prepared staff, significant know-how in improving generics, great potential for conducting clinical trials and growing experience in this area [22]. The scale of market development is also evidenced by the fact that business expenses for R&D in Poland have been steadily growing for several years [23]. The structure of external expenditures of biotechnology companies on research and development activities is also changing. In 2011, enterprises allocated almost the entire external expenditure (96.8%) to payments to government sector entities, while in 2017 external outlays for R&D were directed to entities from all parts of the sector, including the largest part of the enterprise sector (50% of external expenditure) [24]. In 2012, internal expenditure on activities in the field of biotechnology in enterprises increased by 37% compared to the previous year, including R&D increased by 73%. The structure of expenditures on biotechnology is changing significantly according to the conducted activity. Every tenth Polish zloty spent on biotechnology in

enterprises was allocated to research and development in 2016, and in 2017 – more than every fourth.

4. Determinants of the development of biotechnology spin-offs in Poland

Currently, biotechnology in Poland is in the early stages of development, and the biotechnology market is growing slowly. Despite the huge scientific potential, there is no efficient transfer system of the developed solutions to the market. The innovation of the biotechnology industry is associated with its high capital intensity and high risk, which hinders its development. According to the Central Statistical Office (CSO) data, only 184 enterprises operate in the field of biotechnology (Fig. 1). Their number, however, grows by leaps and bounds and increased by 27% during the year (Fig. 2). Poland has a good scientific base to become one of the leaders in this sector in the future, however, representatives of biotechnology companies pay attention to the fact that access to capital and the regulatory environment remain the main barrier. In 2016, the R&D field of biotechnology was conducted by a comparable number of entities from the enterprise sector (33.5%), the government sector and private non-profit institutions (33.4%), and the higher education sector (31.1%), although the dominant internal expenditure on R&D (42.4%) was generated by the government sector and private non-profit institutions, and the smallest enterprise sector (22.9%). The highest percentage of R&D personnel was employed in the higher education sector (48%). There is a greater concentration on basic research than in the government sector and private non-profit institutions, with low expenditures on applied research being the basis for cooperation with the industry [25]. The main source of funding for all research and development in the field of biotechnology in Poland are funds from the government sector (57-62%, well above the average level in the EU). Funds from abroad financed 31.5% of R&D in the field of biotechnology, almost 2.5 times more than their share in total R&D in Poland. The funds from the enterprise sector constituted only 10.8% of total R&D expenditure in the field of biotechnology. The activity in the scope of patent protection was attended by only a part of the surveyed entities, as inventions for patent protection in 2015 were filed by 35% of entities, and patent protection was obtained by 23% of entities [25]. An important limitation of the development of the biotechnology sector is the low availability of experienced entrepreneurs and members of the scientific and research team who understand what is necessary to establish and develop a successful company in the field of biotechnology [26].

For the development of Polish biotechnology spin-offs and start-ups in the conditions of global competition, the overall innovation of the economy, processes of developing a knowledge-based economy and conditions for the commercialization of scientific research in Poland are important. Poland scored 68.16 points out of 100 on the 2018 Global Competitiveness Report published by the World Economic Forum. Competitiveness Index in Poland averaged 15.02 Points from 2007 until 2018, reaching an all-time high of 68.16 points in 2018 and a record low of 4.28 Points in 2008. The value obtained in the Innovation pillar assessing the environment conducive to innovative activity places Poland in the 37th position on the 140 countries studied [27].

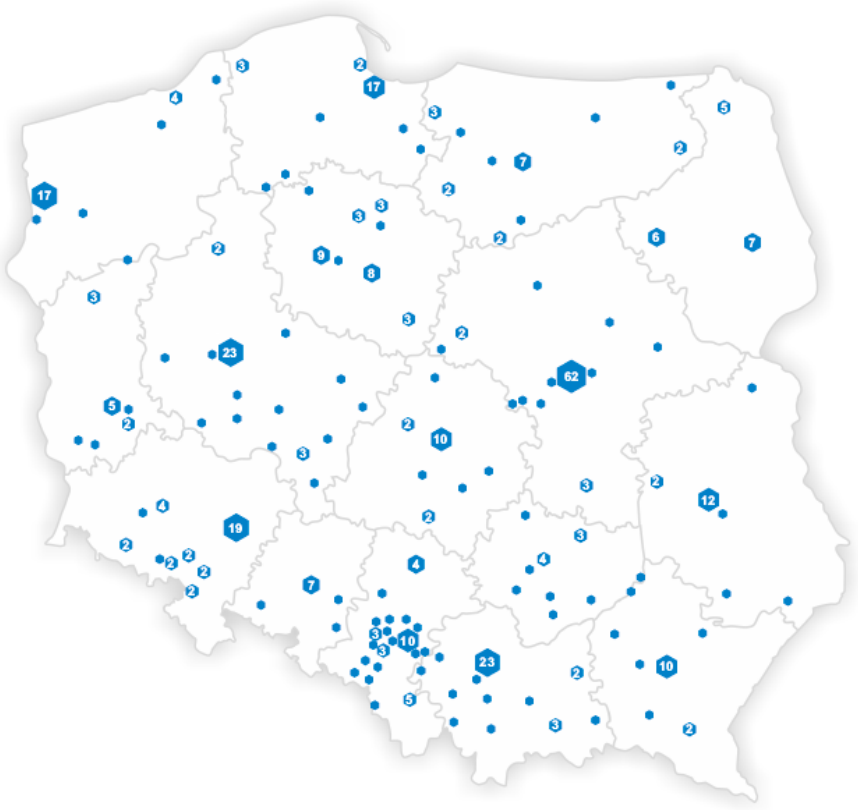

Fig. 1. Innovation and entrepreneurship centers
in Poland in 2017 (leading institutions)

Source: own elaboration based on Beauchamp M., Kowalczyk A., Skala A., Polish Startups Report, Warszawa, 2017.

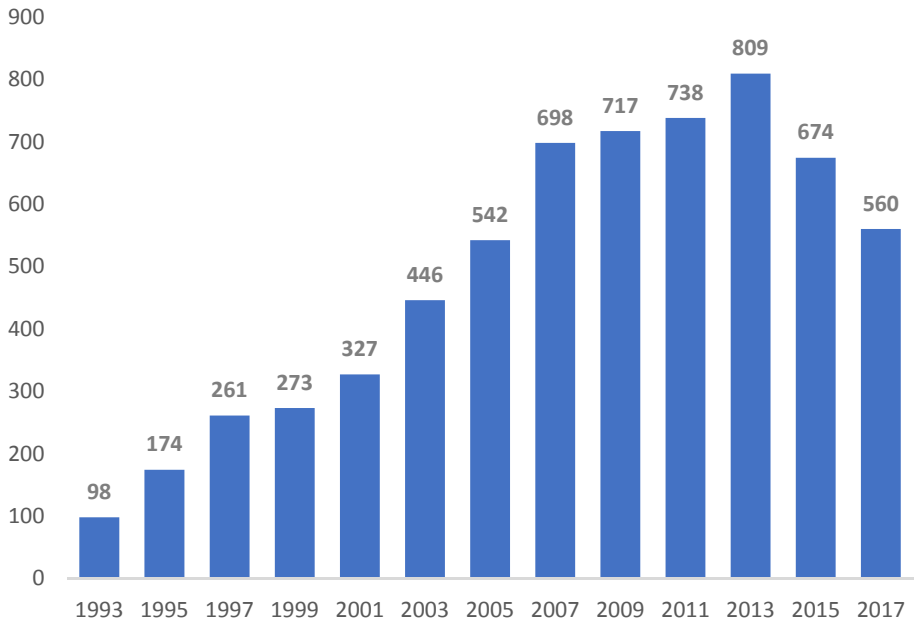

Fig. 2. Innovation and entrepreneurship centers
in Poland between 1993 and 2017

Source: own elaboration based on Bąkowski A., Marzewska M., Ośrodki innowacji i przedsiębiorczości w Polsce. Raport 2018, Poznań-Warszawa 2018, s. 9.

5. Commercialization of scientific research

The market (commercialization) of scientific research consists of four areas: the supply side (manufacture of inventions by inventors and universities and research institutes), the demand side (demand for innovation from entrepreneurs and investors), transmission mechanism (matching demand with supply, i.e. commercialization of inventions) and market regulation policy (legal regulations, scientific policy and innovation support) (Fig. 3).

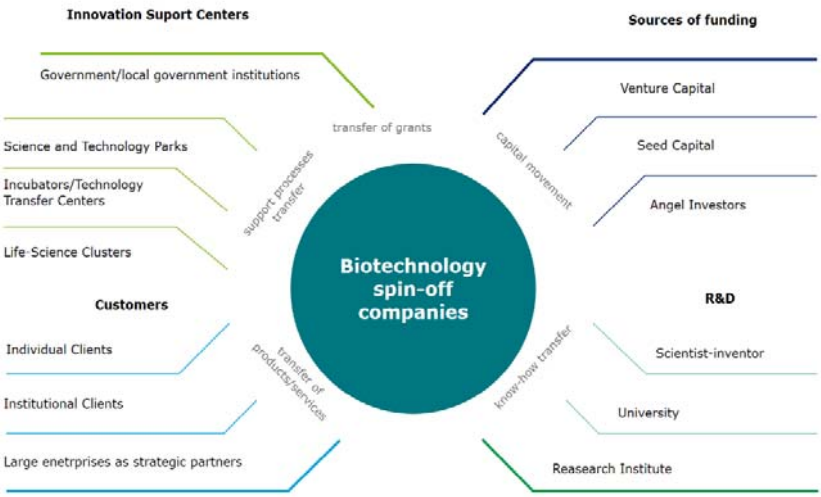

Fig. 3. The market of commercialization
of scientific researchfor biotechnology spin-offs

Source: own elaboration based on Białek-Jaworska A., Gabryelczyk R., Perspektywy rozwoju przedsiębiorczości akademickiej w branży biotechnologicznej, Warszawa 2014, s. 30.

Observed in OECD countries trends in the development of the research market point to the increasingly important role of proper regulation of intellectual property problems, the need to build a culture of innovation and the elimination of barriers to entrepreneurship and change the direction of direct research support by supporting cooperation between universities, institutes research – entrepreneurs, development of start-up companies and increase of venture capital support. It seems that the development of the Polish research market in this direction will accelerate the development of biotechnology spin-offs, and above all will make the process of R&D commercialization more effective and reachable. The most important barriers for the commercialization of research results in Poland, also in the field of biotechnology, include: limited experience in cooperation between universities and scientific institutions with business, weakness of the transmission mechanism, insufficiently developed institutions or positions of innovation entrepreneurs (science). Additionally, Orłowski [28] mentions the lack of clear principles of settling costs and income from commercialization in scientific institutions, internal mechanisms blocking commercialization in scientific institutions, availability of basic research funding and lack of economic coercion for searching long-term commercialization revenues by scientific institutions, as well as lack of effective channels of information flow between the supply side and demand.

Building models of cooperation between universities and scientific institutions with business should be accompanied by the dissemination of best practices tested on the Polish market for this cooperation and the use of reference solutions used in countries (benchmarking) – innovation leaders. The Ministry of Science and Higher Education as part of the "Brokers of Innovation" program chose the first 30 people who perform the new brokerage of innovation on the Polish market [29]. Their task is to search for research results at universities that have market potential and their commercialization. As part of another ministerial program "Top 500 Innovators", young scientists from Polish universities have spent several months internships at the best universities in the United States, where they learned the best methods of commercialization of research results [29].

6. Summary

In summary, there is a large scientific potential in Poland and there is a significant development of the biotechnology sector and enterprises that focus on R&D and the creation of innovative solutions in the field of biotechnology. Innovation support institutions have also been established, such as technology transfer centers or science and technology parks with varying operational efficiencies. An obstacle to the even more dynamic development of the biotechnology industry seems generally low innovation of the Polish economy, whose roots lie in the improper functioning of the market for the commercialization of scientific research.

In order to strengthen the competitive position by increasing the innovativeness of the Polish biotechnology sector, it will be important to influence the growth of competences of R&D staff. This applies in particular to qualifications in the scope of protection of intellectual and industrial value, management of research projects and commercialization processes of research results.

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