THE ROLE OF BIOTECHNOLOGY IN THE DEVELOPMENT OF THE BIOECONOMY

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Abstract

This paper analyzes the steps of the strategic development and use of innovations in the field of biotechnology in the largest and most developed countries of the world. Support for applied recommendations for state-level fundamental provisions regarding initiatives to develop the capacity of the biotechnology sector and increase the level of an international, strategic and competitive industry is presented. The authors conducted a study and evaluated the further promising use of innovations in biotechnology on the example of the EU-15 and EU-13 countries. A regularity was revealed that the biotechnology of the EU countries (EU-15) is developed at a high national and international level. The overall results of our work have helped to define further strategic directions and presented potential prospects for innovation in the field of biotechnology, which will subsequently lead to increased investment in this area. Using the graphical method, a dynamic model of trade turnover in the bioeconomy of the EU-15 countries is presented, followed by the construction of a trend line. And also formulated and predicted the value of trade in the bioeconomy of the EU-13 for the next decade.

Keywords

bioeconomy; innovative opportunities; clusters; investments; strategic development; biotechnologies; ecosystem.

Introduction

The authors of the article, in the course of studying an array of scientific studies, determined that in recent decades, the biotechnology industry has attracted more and more attention from investors around the world, and according to the forecasts of financial experts, biotechnologies that improve human life or the body itself

can become one of the most dynamically developing and profitable businesses of the 21st century. The research problem posed by the authors is to analyze the prospects for the investment growth of biotechnology companies, to determine the impact of these companies on the formation and development of the bioeconomy. On the basis of the analysis, develop proposals for enhancing state initiatives for the development and implementation of innovations in biotechnology companies, which will allow in the future to create an investment-attractive and competitive industry in any country.

So, we first of all studied scientific approaches to the definition of the definition of "biotechnology" as follows. We believe that this is a multicomponent and at the same time complex of interconnected industries, which often includes three main areas: biomedicine, industrial biotechnologies and agrobiotechnologies. In the first direction, research and implementation of new/modernized drugs, vaccines, molecular diagnostics and cell technologies can be singled out. The next direction includes high-tech and industrial processes using biological reactors, processing of microbial waste, as well as the production of biofuels, biodegradable polymers, etc. (Table 1).

Table 1. Bioinnovation is occurring in three key arenas. Source: compiled by the authors.

Definitions	Biomolecules	les Biosystems Biomachine interfaces		Biocomputing		
Mapping	In the study of omics, the subject of action is cellular processes and the functions of measuring intracellular molecules (such as DNA, RNA, proteins, etc.)	Complex biological functions and processes, as well as interactions between cells	The nervous system of organisms - its structure and functions	Calculation of the output data of intracellular interactions under certain conditions		
Engineering	Intracellular molecules (in selected cases via genome editing)	Technologies of various levels - from cells, tissues, organs, to stem cells and their transplantation	The connection of the nervous system of the body and the machine in the form of a hybrid system	Selection, storage, processing and other actions of cells and their components for computing processes		
Examples	Gene therapy for monogenic diseases and/or pathologies	Production of laboratory-grown meat	Motor control of human limbs (robot, hybrid) using neuroprocessing	Data storage in strands of DNA		

For example, at the moment in the agricultural sector, one can observe the use of cultivation and soil reclamation, which improves pest resistance and plant fertility. In this case, we believe that this industry is attracting more and more attention over the last years of the 21st century, namely in the form of attracting investors at the international level. And if we rely on the opinion of well-known investment experts, then it is quite natural that at this stage of development, biotechnology should be considered the latest tool for improving human life due to the prospects for improving the quality of life, as well as the impact on the ecology of the whole world. The branch of our research, biotechnology, in comparison with other areas that are currently developing, but with difficulties, has a high popularity and necessity, as it affects almost all areas of human activity. In the conditions of modern risks, namely a general pandemic, many entrepreneurs, business entities, and, first of all, investors, are in no hurry to invest their funds with ambiguity in business structures [1,2]. Thus, if we consider the attention and influence of governments of various states, the media, society, medicine, scientific developments and other components of the search for drugs from COVID-19, it should be noted that there is a synergy of all of the above in the field of biotechnology, which has impressive prospects from the point of view investment perspective. In recent years, economic development during the worldwide COVID-19 pandemic has had a huge impact on the financial flows of most industries. It should be noted that few of them have recovered to the previous level, which distinguishes, on the contrary, biotechnologies, in which, after a short-term decline, there is a rapid improvement in indicators (Figure 1).

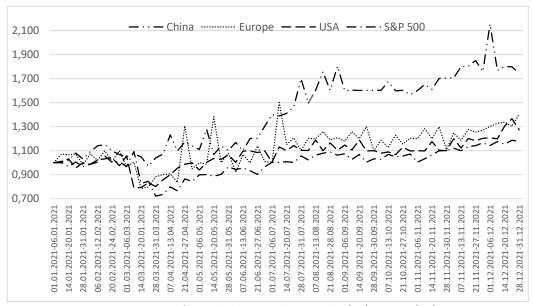
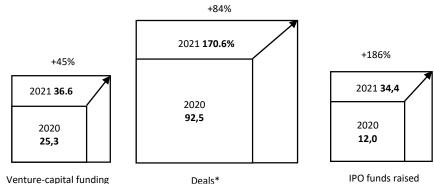


Figure 1. Recovery of biotechnologies in the period 01/01/2020 - 12/31/2021 Sourse: own processing based on [3].

From the above, we can summarize that in 2021, the average value of shares of biotech companies in the countries of the European Union and the United States of America has more than doubled compared to \$\$500. Accordingly, shares of Chinese companies increased by 106%, the United States and Europe by 39%, and the S&P 500 by 17%, that is, the increase in the first country increased by almost 6.5 times at an average price. In addition, it is biotechnologies that are advanced, even in comparison with other related and related companies, such as pharmaceuticals and virology [4–6]. In our opinion, these are obvious things, because modern conditions contribute to the close interaction of such areas in science and innovation as ecology, healthcare, sociology, as well as economics. These conditions of modernity form the radical changes that must be formed in Europe. Namely, it is necessary to form and change the approach to

the production, use, consumption, processing, disposal and storage of all possible biological resources [7]. Accordingly, it is realistic and expected that the bioeconomy has emerged as a representation of the latest direction in the field of science, technology and innovation. Its main direction is to minimize the harmful impact on the environment in the process of doing business, subject to the achievement of operational, operational, strategic goals of sustainable development [8,9].

Between 2020 and 2021, biotechnology saw an annual increase in VC fundraising and deals (partnerships, joint developments, joint ventures) (Figure 2)



^{*} Includes acquisitions, partnerships, co developments and ventures; covers only disclosed deal values (26% of deals in PharmaDeals)

Figure 2. Recovery of biotechnologies in the period 01/01/2020 - 12/31/2021 Sourse: own processing based on [10].

Venture activity in this area has increased by almost half over the past year, which has affected investments in this area, and at the time of mid-2021 the total amount was \$36.6 billion. From the point of view of assessing world leaders, the positions of the largest investments are distributed as follows - the USA, China, European countries. But it is worth noting that in the dynamics over the past year, the countries of the European Union (EU-15) in relative terms have more achievements in the development of investment in biotechnology. Thus, the volume of funding has more than doubled, and its growth rates are observed more rapidly than in the United States. But it is fashionable to consider China as the leader of relative indicators in this case, since its indicators have increased by 4 times, even in comparison with the EU-15 countries. Accordingly, it is China that at the moment should be considered the leader in venture activity in the field of biotechnology. Thus, having studied the opinion of venture investors, we can conclude that the field of biotechnology is now, more than ever, acceptable for deposits and has lower risks, compared to the period of the beginning of the 21st century. In contrast to this opinion, researchers of investment activity put forward their hypotheses that small contributions in the past affected the possible attractiveness in the present [11]. The other, third point of view, is more loyal and indicates that this activity in biotechnology is due only to the diversification of global investment portfolios. At the moment, the growth in investment activity is mainly due to quantitative growth in monetary terms in the United States. You can see the average amount of transactions doubled, and the total number increased by 25%. Among the EU-15 countries and China, rapid growth is also observed, but these rates are not supported by fundamental changes [12]. It is necessary to highlight the fact that the growth of investments in the bioeconomy is a strategically important indicator, which at the moment indicates growing financial benefits, and can also further increase the indicators of financial activity of related industries, which will form a new ecosystem. For example, some representatives of the strategic planning of large corporations expect to create and develop new enterprises not in urban areas, form import substitution of goods and services, and also strengthen the interaction between science and business [13]. In this direction, it should be noted that the bioeconomy has a direct impact even on such industries as biopolymers, fuel and its analogues, food additives and substitutes [14,15]. There is also a possibility of transformation, restructuring and formation of new processing processes [16,17] in the field of industrial biotechnology [13,18]. If we compare the development indicators of the bioeconomy five years ago, we can clearly see that in 2015 the indicator of 4.7% of the EU GDP accounted for this direction is very small. And in recent years, its development has stimulated representatives of science and entrepreneurs to deal with possible obstacles and risks. After we have studied a number of recent scientific studies in this industry, as well as the most popular theories and theorems [17,19–23] in the field of development of bioeconomics, it has been shown that the main direction regarding the development of this area is to reduce risks through the use of innovative systems at various levels - business, industry, state, international relations.

Development prospects will be possible through the use of knowledge, the use of new materials, the inclusion of modern technologies and artificial intelligence in the process, as well as through the formation of rules, strategies and sustainable development [24]. Also, one should not forget that life cycles of development remain acceptable for any industry. In this case, it is necessary to predict development declines and form scenarios for getting out of them. In addition, the inherently collective nature of innovation requires a certain degree of shared imagination [25] and collective responsibility for developing capabilities [26]. In the case of a pessimistic scenario, only further observation and forecasting is necessary. The purpose of the study is to develop practical recommendations for the main provisions of the state level regarding initiatives to develop the potential of the biotechnology sector and increase the level of an international, strategic and competitive industry.

To achieve the goal, the following tasks were solved:

- the steps of strategic development and use of innovations (scientific transformation) in the field of biotechnology in the largest and most developed countries of the world were analyzed;
- the perspective of using innovations in biotechnology on the example of the EU-15 and EU-13 countries is determined, due to the identification of patterns (drivers) that the biotechnology of the EU (EU-15) countries is developed at a high national and international level;
- a dynamic model of trade in the bioeconomy of the EU-15 countries is presented, followed by the construction of a trend line with a forecast of the value of trade in the bioeconomy of the EU-15 and EU-13 for the next decade;
- strategic directions and potential prospects (intensification of state development initiatives) for innovations in the field of biotechnology are proposed, which will subsequently lead to increased investments in this field, which will provide each country with competitive advantages in the world.

Methods

In the process of the research, reporting and analytical information and the information base of the Ministry of Education and Culture were used [1,2,11-20,3,21-25,27,4-10]. To conduct the research, the dialectical method was applied during the establishment of contradictions in methodological approaches regarding the determination of the features of strategic development and the use of innovations (scientific transformation) in the field of biotechnology in the largest and most developed countries of the world. Strategic directions and potential prospects for innovations in the field of biotechnology were proposed on the basis of the system-structural method based on the principle of a systematic study of socio-economic phenomena and processes, which will eventually lead to an increase in investments in this field. With the help of the historicallogical method during the study, the innovative drivers of development in biotechnology were singled out on the example of the EU-15 and EU-13 countries, due to the identification of patterns that the biotechnology of the EU (EU-15) countries is developed at a high national and international level. Based on the methods of quantitative and qualitative comparison, observation during the examination of patterns, resorting to the comparison of the state and structure of the compared indicators, the dynamics of turnover in the bioeconomy of the EU-15 countries was determined, followed by the construction of a trend line with the forecasting of the value of trade in the bioeconomy of the EU-15 and EU- 13 for the next decade. As a result of the search for representatives of the bioeconomy, it is necessary to initially determine the possible existing clusters in this industry. Their presence indicates that joint work is already underway in the direction of development, learning processes, which may indicate a potential readiness for innovation. Such synergistic alliances can facilitate interaction with them, considering territorial, national, ethnic and other characteristics. In the future, the construction of trusting relationships can form sustainable management in the cluster. The analysis of the regional model of high-tech clusters of the EU based on the assessment of the development of the bioeconomy on the example of the EU-15 and EU-13 proves that the biotechnological industry of the "old" countries of the European Union (EU-15) is developed at a powerful level, both nationally and internationally. All opportunities for doing business and attracting investors have been created. The state plays an active role in developing initiatives and creating favorable risk control conditions for international investors. The results of monitoring companies associated with biotechnology showed that it is typical for them to use the latest developments in science and technology most effectively. A big role is played by the developed infrastructure and technological progress achieved by the "old" EU countries. Over the past 10 years, the biotechnological industry has been one of the development priorities in the national strategies of the "old" EU countries. In the course of the study, we formed a dynamic model of changes in commodity circulation in the bioeconomy of the EU-15 countries using the same trend line. The choice of the empirical function was carried out on the basis of linear, polynomial, logarithmic, power and exponential functions. Calculations with five trend lines were carried out to forecast the turnover based on the series of dynamics. The R2 approximation reliability coefficient was used for the most optimal trend equation used in forecasting. If this coefficient approaches 1, then the trend equation can be a predictive model. The results of the forecast of changes in turnover in the EU-15 bioeconomy (Figure 3) showed optimistic results.

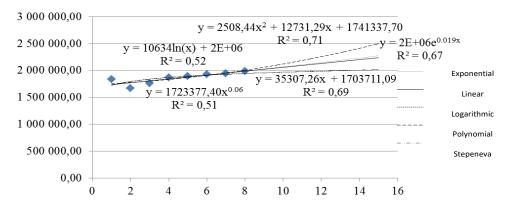


Figure 3. Forecast of changes in turnover in the EU-15 bioeconomy using the trend line. Sourse: developed by the authors.

The highest approximation reliability was shown by the exponential function, R2 is 0.71 (for polynomials of order 2). However, as the calculations showed, the reliability value of the approximation of all data / functions is disappointing. Carrying out calculations for polynomials of the 3rd order, we obtained the coefficient of determination coefficient R2 = 0.84, for polynomials of the 4th order, R2 = 0.97, and for polynomials of the 5th order, R2 = 0.997 - that is, we obtained the largest value of reliable approximation. But, as a rule, the results calculated using polynomials of such orders, when compared with real data, should be rejected because they are inaccurate.

So, the forecast values of turnover in the EU-15 bioeconomy for 7 years (2014-2021) are calculated using the obtained equations. The pessimistic forecast reflects the lower limit of the possible value of the indicator (due to the dominance of negative influencing factors), the optimistic one shows the upper limit of the possible value (due to the predominance of positive factors), and the probable one reflects the most optimal development scenario. For optimistic forecasting, the highest R2 (value of approximation reliability) was used -0.71, for probable forecasting a linear function with R2 - 0.69, and for pessimistic calculation R2 - 0.51 was chosen. It can be asserted that the turnover in the bioeconomy of the "old" EU-15 countries in 2022 will amount to no less than 2,027,430.00 and no more than 2,496,706.05 euros (Figure 4). Forecasting the change in 2022 compared to 2008 showed that, according to the probable forecast, the turnover volume will increase by 28%.

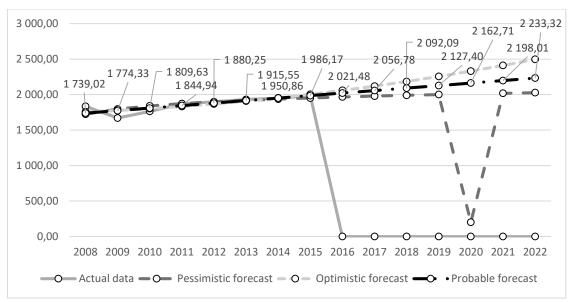


Figure 4. Optimistic, pessimistic, and probable/realistic scenarios of turnover growth in the EU-15 bioeconomy, 2008-2022 (thousand euros). *Source: calculated by the authors based on Data portal of agro-economics research: Bioeconomy.*

Thus, according to the optimistic forecast of turnover in the bioeconomy of the "old" EU-15 countries, it will increase by 42% by 2022 compared to 2008. To forecast the turnover in the bioeconomy of the "old" EU-15 countries, a linear dependence was used for each country, because it's the probability ratio is 0.69 and shows steady growth. Disappointing results were shown by Greece, because its turnover in the bioeconomy may decrease by 7% in 2022, and in Spain, an increase in turnover is observed by 5%. The best changes in turnover are reflected in Luxembourg with an increase of 58%, Belgium – 51% and Denmark – 50%. The results of the forecast of changes in turnover in the EU-13 bioeconomy (Figure 4) are also optimistic. However, the reliability value of the data/function approximation is low, as it is for the EU-15. That is, the R2 criteria is low-precision, which makes it difficult to predict. Shown in Figure 5 polynomial dependence shows that turnover in the EU-13 bioeconomy will increase.

Similarly, forecasting for the EU-13 was carried out as for the EU-15. From several functions, we choose the one that most likely approximates the dynamics of the indicator. For optimistic forecasting, the highest R2 (value of 95 confidence approximation) was used - 0.59, for probable forecasting a linear function with R2 - 0.57, and for pessimistic calculation R2 - 0.50 was chosen. It can be argued that the turnover in the bioeconomy of the "new" EU-13 countries in 2022 will be no less than 283,541.05 and no more than 399,672.26 euros (Figure 6). Forecasting the change in 2022 compared to 2008 showed that, according to the probable forecast, the turnover volume will increase by 40%. A polynomial model was used for the best regression analysis, and according to its forecast, turnover in the bioeconomy of the "new" EU-13 countries in 2022 may increase by 70%.

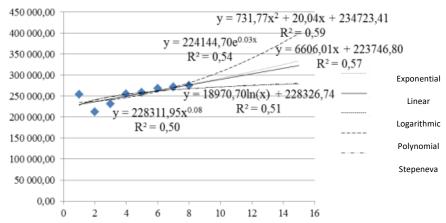


Figure 5. Forecast of changes in turnover in the EU-13 bioeconomy using the trend line. Sourse: developed by the authors.

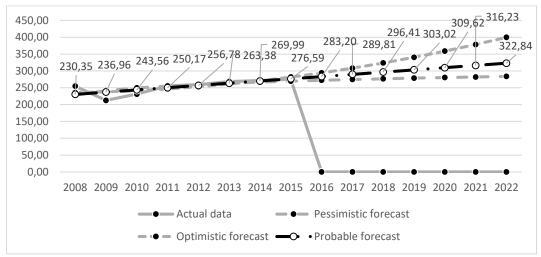


Figure 6. Optimistic, pessimistic, and probable/realistic scenarios of turnover growth in the EU-13 bioeconomy, 2008-2022 (thousand euros). Source: calculated by the authors based on Data portal of agro-economics research:

Bioeconomy.

Figure 7 presents the likely forecast of turnover in the bioeconomy of the "new" EU-13 countries. A negative trend is observed in 4 countries (Cyprus – 22%, Croatia – 19%, Slovenia – 5% and the Czech Republic – 6%). However, Cyprus is not a high-tech country, so these indicators are typical. Best forecasts in Estonia, Lithuania, Latvia and Poland. In the process of building forecast scenarios for the development of the bioeconomy in the EU-15 and EU-13, a second-order polynomial function was chosen, which has the most accurate results. The development of the optimistic scenario for the EU-15 is 42%, for the EU-13 – 70%, the onset of the pessimistic prognosis is 18% and 24%, respectively, for the EU-15 and EU-13 countries, which is unlikely. The most realistic is the forecast for the growth of turnover in the bioeconomy at the level of 28% and 40% for the EU-15 and EU-13 countries, respectively. Therefore, according to all forecast development scenarios, there is a further increase in turnover in the bioeconomy of the EU, which proves the increasing role and importance of the development of the bioeconomy and biotechnologies in the future.

Over the past ten years, the European Patent Organization received 1,807.65 thousand applications for obtaining patents in the field of biotechnology from EU countries (Figure 8). The presented data (Figure 8) of submitted applications for patents in the field of biotechnology were presented by such countries as Belgium, Bulgaria, the Czech Republic, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden, as well as Great Britain. The data for 2021 as a whole is the lowest for the period 2012 - 2021. The highest application activity was observed in 2015 - 3,053.99 thousand. The largest number of applications

came from Germany, France and Great Britain, which were the constant leading countries throughout 2012 - 2021. On the other hand, Malta, Cyprus and Bulgaria show the lowest activity.

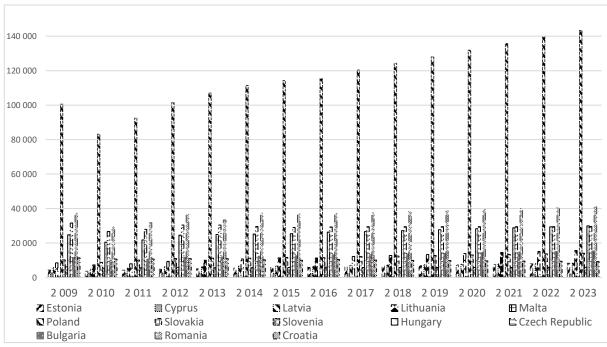


Figure 7. Dynamics of changes in the total trade turnover in the bioeconomy in the EU-13 countries, euro.

Source: calculated by the authors based on [28].

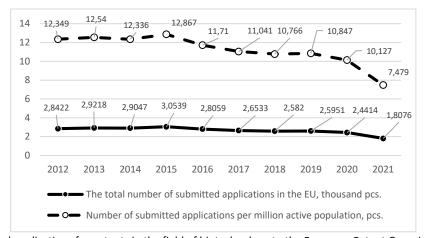


Figure 8. Submitted applications for patents in the field of biotechnology to the European Patent Organization, 2012-2021. Source: calculated by the authors based on Meta-network for public-to-public partnerships in the bioeconomy.

Results

At the moment, the total world volume of biotechnologies is estimated at more than 1 billion dollars, and its constant annual growth is also estimated at an average of 14% until 2030 inclusive (Figure 9). The ever-increasing influence of person-centered medicine and the increase in orphan formulations are opening up new opportunities for biotech applications and driving the influx of new and innovative biotech companies, which in turn further increases their market revenues.

In the conditions of modern economic relations and the construction of business structures, it can be confidently stated that the conditions of restrictions as a result of the spread of the pandemic around the world had a negative impact on the majority of business entities, but at the same time, improvement in the field of biotechnology and bioeconomy can be identified as a positive factor. Thus, as of 2021, more than 11 billion

doses of COVID-19 vaccines have been produced in the world, which made it possible, as a result of mass vaccination, to create conditions for the formation of herd immunity. Against this background, from an economic point of view, it is important to note that companies that produced vaccines are seeing sharp revenues from these industries. Industry leaders in the United States of America have revenues of almost \$31 billion in 2021 (Figure 9).

In many countries of the world, a regulatory and legal framework has been developed, in particular, strategic programs for the long-term and short-term perspective regarding the development of public-private partnerships (PPP) in the field of biotechnology. For example, the largest research and innovation program in EU countries to promote PPPs is Horizon 2020, the budget of which is almost 80 billion euros (from 2014 to 2020). Biotechnology in this program plays a leading role in the creation of industrial technologies (LEIT), which will develop in three directions:

- 1. advanced biotechnologies as a future driver of innovation growth to ensure leadership positions in the medium and long term;
- 2. biotechnologies based on industrial processes a driver of increased competitiveness and sustainability to maintain European leadership in the field of industrial biotechnologies;
- 3. innovative and competitive technology platforms for the development of new technology platforms related to biocatalysis and biodesign for industrial applications in a wide range of industries.

The number of biotechnological enterprises in EU countries is more than 1,700, of which 180 are public companies. To implement the Horizon 2020 program, a new institutionalized public-private partnership based on bio-industry (BBI) was created to overcome the "valley of death" on the way from research to market implementation. Projects on the creation of industrial biotechnologies in the "Horizon 2020" program (Table 2) are financed under three themes:

- 1. synthetic biology construction of organisms for new products and processes;
- 2. expansion of industrial application of enzymatic processes;
- 3. the following processes of unlocking biotechnological transformations.

From the above, it can be concluded that projects for the creation of industrial biotechnologies in the EU countries are mainly focused on: the application of modern synthetic biology to fill the main technical and scientific gaps in the biotechnological industry of Europe; expansion of the industrial use of robust oxidation biocatalysts for the conversion and production of alcohols; creation of interdisciplinary and interdisciplinary consortia as a powerful synergistic tool for promoting innovations in the field of formation of biocatalytic platforms in order to ensure the competitiveness of the European chemical and pharmaceutical industry; development of prophylactic vaccines with a low production cost, which will combine nano- and bioinnovations.

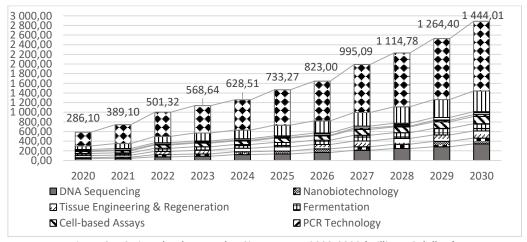


Figure 9. US Biotechnology Market Size Forecast 2020-2030 (million US dollars).

Source: calculated by the authors based on Meta-network for public-to-public partnerships in the bioeconomy.

Table 2. Projects on the creation of industrial biotechnologies in the Horizon 2020 program on the basis of PPP. Source: systematized by the author based on [29].

Project name	Task	Cost, thousand €	Deadline	Participants	
Biology is the con	Istruction of organisms for new products and processes	ı	1	1	
EmPowerPutida	The development of three main factors in the field of biotechnology: 1 — enables the transition from petrochemistry to bioeconomy; 2 — diversification of new products, processes and markets; 3 — provision of a strong, high-level platform for new industrial enterprises that find it too burdensome to implement new technologies	6 839	01.05.2015 – 30.04.2019	Industrial enterprises, scientific organizations of Germany, Spain, Switzerland, Portugal, Great Britain	
MycoSynVac	Development of a universal Mycoplasma chassis that could be used to vaccinate animals against various types of mycoplasmas. Expected results of the project: 1 — decrease in the level of infection caused by mycoplasmas; 2 — improvement of animal safety; 3 — cost-effective vaccines; 4 — protection against new pathogenic microorganisms; 5 — protection from the first time of use	8 057	01.04.2015 – 31.03.2020	Industrial enterprises, scientific organizations of the Netherlands, France, Great Britain, Germany, Austria, Denmark	
P4SB	Biotransformation of plastic waste (e.g., polyethylene terephthalate and polyurethane) into alternative materials such as biodegradable plastic polyhydroxyalkanoates	7 057	01.04.2015 – 31.03.2019	Industrial enterprises, scientific organizations of Germany, Spain, Ireland, Great Britain, France	
Diversification of	new products, processes and markets		•		
ROBOX	Demonstration of the technical and economic viability of biological transformations of four types of stable oxidizing enzymes: monooxygenase (450), Bayer-Villiger monooxygenase (BVMOs), alcohol dehydrogenase (ADH) and alcohol oxidase (AOX), whose reactions have already been tested in laboratory conditions in the pharmaceutical, food industry, etc Implementation of ROBOX bio-oxidation processes is expected to result in significant reductions in cost (up to -50%), energy use (-60%), chemicals (-16%) and GHG emissions (-50%)	11 389	01.04.2015 — 31.03.201	Industrial enterprises, scientific and educational institutions of Switzerland, Belgium, the Netherlands, Germany, the Czech Republic, Austria, Italy, Spain, Great Britain	
CARBAZYMES	Creation of an interdisciplinary and interdisciplinary consortium. The interdisciplinary approach will include: 1 — a broad platform of 4 types of unique C-C bond forming enzymes; 2 — the ability to quickly develop, work in industrial conditions with the help of new enzyme panels and massive screening methods; 3 — application of microreactor technologies for biotechnological characteristics; 4 — demonstration activities	9 251	01.04.2015 — 31.03.2019	Industrial enterprises, scientific and educational institutions in Spain, Germany, the Netherlands, Croatia, Great Britain	
	cking biotechnological transformations	7.622	04.02.2245	I to do and a land	
DiViNe	Development of preventive vaccines of various nature, which will combine nano- and bioinnovations: glycoconjugates, protein antigens and enveloped viruses	7 632	01.03.2015 – 29.02.2020	Industrial enterprises of France, Denmark, Germany, Portugal, Italy	
NextBio PharmaDSP	Implementation of an integrated manufacturing platform for biosimilar monoclonal antibodies based on continuous chromatography combined with SingleUse methods for all single DSP sequencing operations together with state-of-the-art analytical tools	10 570	01.03.2015 – 28.02.2019	Industrial enterprises, scientific and educational institutions of France, Austria, Germany, Slovenia, and Italy	

Discussion

Modern biotechnology and bioeconomics are closely intertwined with other areas such as agriculture. After all, it is obvious to introduce the latest technologies in this direction, namely in the processes of reproduction of flora and fauna at the micro and molecular levels, selection and crossing of various plant species for the purpose of their cultivation, transformation of wild plants, and so on. This kind of synergy allows plants to be more resistant to pests, use less herbicides, and improve their growth and productivity. At the moment, they already have positive results of introducing biotechnologies into the processes of growing bananas and rice in the countries of Asia and Africa. Against this background, clinical trials are constantly taking place, which also has good funding and stimulates the development of science and technology. According to the results of the total number of investments for 2020, they are estimated at \$19 billion, in 2021 this figure increased to \$23.1 billion, which is 16% more. The leader of such indicators is the company Intellia Therapeutics and Regeneron, which has produced the largest number of successful clinical trials. Such an example is a stimulating factor for increasing activity for other market representatives and the formation of a new range of drugs for currently incurable diseases (cancer, diabetes, etc.).

It is expected that such studies will stimulate further research in this area and stimulate the market. In the past few years, biotechnological methods have gained popularity, including stem cell technology, DNA fingerprinting, and genetic engineering (Figure 10).

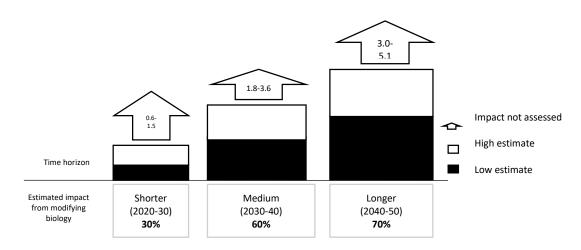


Figure 10. Estimated impact from modifying biology. Source: compiled by the authors based on [30].

It should also be noted that more than half of biotechnological innovations are outside healthcare in agriculture, consumer and other areas (Figure 11). Thus, the development of biotechnologies has a direct impact on the spheres of science, life and healthcare, which forms new clusters of the economic space. Thus, the development of biotechnology has a direct impact on the spheres of science, life and healthcare, which forms new clusters of economic space. Accordingly, it is worth assuming that the bioeconomy combines many elements on the basis of production, using modern, innovative and progressive biotechnologies, while providing for the needs of the population. In this case, further discussion of possible discussion issues regarding the social impact of the bioeconomy is considered through food security, access to land plots and land use, employment, household income, lost working days due to injury, quality of life of the population in general, etc. At the current stage, the comparative analysis of countries is relevant to research with the help of the global innovation index. The Global Innovation Index was compiled by the World Intellectual Property Organization of Cornell University and the international business school "Insead". 143 countries of the world are represented in the rating. The structure of the index includes 7 indicators and their components. For the analysis of the countries of the European Union, information on their indicators for 2021 is presented (Table 3). The global innovation index reflects the main components of the country's innovation potential, so the index is a generalized assessment. There is a trend that the higher the country's position in the rating, the higher the development of high-tech industries, including biotechnology. Stock markets are also an important condition in the development of biotech companies for obtaining additional capital. Great optimism and new signs of confidence are observed in 2021, because 233 European biotechnology companies received 5.09 billion euros in financial resources, which

is 54% more than in 2016 (3.30 billion euros). In 2021, investors show increased interest in European biotechnology companies compared to 2020. By the end of 2021, 4.27 billion euros were allocated to biotechnology companies for follow-on offering, which is 56% higher in comparison with a similar period in 2020 – 2.75 billion euros. In 2021, according to analysts' forecasts, interest in the volume of initial public offerings (IPOs) in the European biotech sector on the stock market has improved compared to the previous year. The total amount of initial public offering of shares amounted to EUR 814.7 million, which shows an increase of 47% compared to 2020. Volumes of initial public offering of shares (IPOs), as well as their subsequent financing, increased, in particular, due to the upward trend on the NASDAQ stock exchange. An initial public offering of shares is increasingly becoming one of the financing options aimed at strengthening the future growth of business in the European biotech sector, because it involves the shares being offered to a wide range of investors for the first time and the company receiving a listing on the stock exchange. As a result of the search for representatives of the bioeconomy, existing clusters in this direction were identified, which emphasizes the formation and development of this industry. The authors set a goal to show the strategic directions and potential prospects of innovations in the field of biotechnology based on the system-structural method based on the principle of systematic study of socio-economic phenomena and processes [9–11]. Thanks to this, a dynamic model of changes in turnover in the bioeconomy of the EU-15 and EU-13 countries was formed along the trend line. In the future, calculations with five trend lines were carried out to forecast the turnover based on a series of dynamics. The R2 approximation reliability coefficient was used for the most optimal trend equation used in forecasting. If this coefficient approaches 1, then the trend equation can be a predictive model. It seems that the presented method of forecasting the turnover for building the strategic development of the bioeconomy contradicts the claims of research [8,10,13,14] about too much formalization and systematization of processes. The implementation of the authors' initiatives can be supported by efficient and effective communication channels, and the collection of results is automated in the bioeconomy company's IT systems. On the other hand, this confirms the statement of R. Bosman et al. [19] about the positive relationship between linear, polynomial, logarithmic, power, and exponential functions.

When analyzing the assumptions regarding the construction of the turnover strategy of bioeconomy companies in the EU countries, as well as the assumptions and the construction of five trend lines, a positive connection between them is visible, which turns into measurable advantages for the organization of clusters. A significant limitation of the research at this stage is the low level of knowledge regarding the future use of the main natural resources in the EU countries, considering the deterioration of the political situation. According to the authors, unfavorable conditions can delay positive forecast data for the sustainable development of trade in the field of bioeconomy.

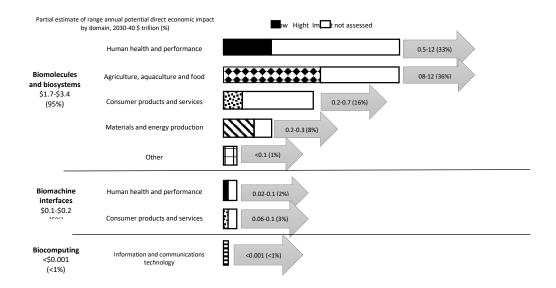


Figure 11. Partial estimate of range annual potential direct economic impact by domain, 2030-40 \$ trillion (%). Source: compiled by the authors based on [30].

Table 3. Global innovation index of EU countries, 2021. Source: systematized by the author based on [31].

Country	Place in the rating	Global Innovation Index	Institutional environment	Human capital and research	Infrastructure	Market experience	Business experience	Acquired knowledge and scientific and practical results	Results of creative activity
Sweden	2	68	88.3	63.7	69.1	64.9	62.6	62.5	53.3
Netherlands	3	63.4	88.2	54.7	63.3	63.3	59.0	62.9	59.0
Great Britain	5	60.9	88.4	63.3	67.1	70.2	52.2	46.5	60.5
Denmark	6	58.7	91.4	66.1	63.2	70.2	52.5	43.9	53.5
Finland	8	58.5	92.2	66.4	64.4	61.6	60.1	48.8	47.3
Germany	9	58.4	83.5	60.1	61.5	60.0	51.4	51.1	55.9
Ireland	10	58.1	87.6	55.1	62.1	55.0	54.5	55.9	50.9
Luxembourg	12	56.4	82.6	42.9	60.1	43.4	57.8	45.0	65.8
France	15	54.2	80.7	58.1	63.4	64.3	50.6	38.5	51.4
Austria	20	53.1	87.1	61.0	63.0	53.1	50.3	38.2	48.3
Czech Republic	24	51.0	77.6	47.6	57.3	50.2	45.9	45.8	46.7
Estonia	25	50.9	81.1	41.5	63.9	55.0	43.4	36.1	53.6
Malta	26	50.6	77.6	41.9	60.6	45.4	49.0	36.6	56.0
Belgium	27	49.9	80.5	59.7	57.2	51.8	48.5	33.2	47.1
Spain	28	48.8	75.9	48.9	64.3	59.0	38.4	36.3	44.4
Italy	29	47.0	71.9	46.3	61.8	52.6	39.6	36.1	42.9
Cyprus	30	46.8	81.0	39.9	48.1	57.9	42.7	41.3	38.2
Portugal	31	46.1	80.8	47.6	54.0	51.1	35.4	29.9	46.7
Slovenia	32	45.8	80.9	49.2	55.4	43.1	43.4	28.0	46.4
Latvia	33	44.6	77.8	35.2	53.1	52.1	38.2	26.5	49.4
Slovakia	34	43.4	74.5	34.4	55.3	45.8	38.3	33.5	40.8
Bulgaria	36	42.8	67.1	33.7	51.9	43.9	41.4	32.0	44.1
Poland	38	42	75.6	36.5	53.3	48.2	37.4	27.9	39.7
Hungary	39	41.7	70.7	39.5	52.3	41.5	37.8	32.3	37.9
Lithuania	40	41.2	74.1	37.5	57.2	53.0	37.8	21.3	39.6
Croatia	41	39.8	69.3	37.4	55.9	42.1	35.1	25.4	37.9
Romania	42	39.2	69.0	30.5	55.1	44.2	33.0	31.0	32.9
Greece	44	38.8	65.2	56.4	48.2	50.2	28.8	20.4	35.5

Impact

Regarding the impact of biotechnology on the development of the bioeconomy in different countries of the world, it is worth noting the rapid development and prospects. For example, systematic work on the development of biotechnology is already being carried out in the EU countries, with the main emphasis being placed on such a tool as strategic program documents for the medium and long term. Separately, each country strives to provide support for the development of this sector of the economy, creating quite powerful national strategic programs. For example, in Hungary there is a "National Research and Innovation Strategy - Investments in the Future" (2013-2020), in Slovakia - a "Strategy for Research and Innovation Development within Smart Specialization" (2014-2020), in Slovenia - "Road and research infrastructure" (2012-2020), in South Africa - "Tenyear innovation plan" (2008-2018), which allow to improve the well-being and quality of life of society. As you can see, most of them have already expired, but this does not mean that these programs will not be continued. In the future, the implementation of these programs ensures a reduction in the cost of food industry and agriculture products, allows to significantly improve and improve the field of environmental protection,

leads to the development of biomedicine and the emergence of new effective and affordable biopharmaceuticals, etc. At the same time, the analysis of the main ways of supporting the biotechnological sphere will allow to create a scientific basis for borrowing the best world experience in the conditions of Ukrainian realities.

Considering the joint efforts of scientific and governmental structures in increasing the share of the national biotechnology sector in the structure of the world, the leading player remains the USA. According to preliminary estimates, the total market value of the biotechnology sector is more than 360 billion dollars. In the USA, the total revenue provided by the biotechnology sector is about 60 billion dollars. USA and provides jobs for more than 100,000 workers. One of the ways to achieve such success, even during the financial crisis, is a number of programs to support the development of scientific, technological and innovative activities. According to experts of the international auditing company "EY" ("Ernst & Young"), the revenues of the biotechnology industry of public companies based in the USA amount to 71.9 billion dollars. USA per year. In relation to 2020, the revenues of the leaders of the biotech sphere in the USA increased by 15%, and expenses - by 25%, while in Europe - by only 3%. The market capitalization of these companies in 2021 exceeded 400 billion dollars. of the USA (increased by more than 74% compared to the previous year), which indicates the efficiency of using own resources, strengthening and expansion of business, financial stability. According to the Financial Times Global 500 world ranking for 2021, the ranking of the Top 10 biological and pharmaceutical companies is distinguished by the indicators of the net profit obtained. In this rating, the 1st, 2nd, 7th, 8th, 10th places were occupied by US companies ("Pfizer" with a net profit of 22 billion USD; "Johnson & Johnson" - 13.8 billion USD; "Amgem" - 5 .1 billion USD; "Eli Lilly" - 4.7 billion USD; "Merck" - 4.4 billion USD). According to the rating conducted by the American magazine "Forbes", where experts evaluated companies not only by indicators such as annual sales growth and total revenue over 5 years, but also by the so-called "innovation premium", in 2021, to the Top 100 the most innovative companies in the world included 8 companies represented in the field of pharmacy and biotechnology.

Conclusions

In the conditions of constant complication of biotechnological processes, their dynamics and innovative renewal, the determinants of further development of the main subsectors, which include intensive generation of knowledge, access to poststructuralist sources of financing, constant renewal of scientific and production infrastructure, creation of collaborative networks, a high degree of entrepreneurial culture, become extremely important. partnerships between government, business and universities, commercialization of existing and promising developments, and the creation of a new type of bio-based companies. Summarizing what has been said, for the perspective development and implementation of biotechnology innovations in the countries, it would be advisable to:

- prepare strategic program documents for the medium and long term to ensure effective legal regulation, in particular: management and protection of intellectual property; attraction of foreign investments for R&D, commercialization of their results, creation of competitive biotechnological clusters, etc.;
- 2. develop a state program for the training, retraining and internship of specialists abroad in the field of biotechnology to ensure the acquisition of knowledge and experience of the future specialist in law-making activities, project management and scientific and technical activities;
- 3. to initiate the development of measures to stimulate research and development works in the field of biotechnology with the aim of commercialization and development of innovations and ideas in various sectors of industry. Within the framework of this program, conduct various competitions with the payment of rewards for scientific and technical achievements in the field of biotechnology, etc.;
- 4. promote, with the participation of the state and economic entities, the creation of organizational and institutional structures for the development of the biotechnological sphere, which will deal with the support of scientific and technical developments and the commercialization of their results, paying special attention to the current needs of the introduction of biotechnology in various sectors of the economy;
- 5. to activate the participation of domestic specialists in international programs and projects of the biotechnological sphere, in particular, to involve domestic scientists as experts based on the results of international programs and projects, which will allow a more comprehensive consideration of the possibilities of creating innovative products (for example, biomedical products) as responses to the current challenges of modernity simultaneous reduction of the consequences of adverse impact on the environment;

- 6. create a state system of registration and accounting of scientific and technical research and development in the field of pharmaceuticals and biotechnology for the informatization of business entities, which will lead to the acceleration of their commercialization;
- 7. expand public-private partnership by intensifying the development of innovative infrastructure through the creation of industrial parks, bio incubators, innovation towns, etc.;
- 8. to concentrate efforts on the development of innovative medicinal products, with the involvement of talented students, postgraduates, scientists from both the state and corporate sectors, intended for the treatment of rare diseases, which will allow manufacturers to be competitive on the domestic and foreign markets in the long term.

The above proposals for the activation of state development initiatives and the introduction of biotechnological innovations will allow in the long run to create an investment-attractive and competitive industry that will provide competitive advantages in the world of each country.

Conflict of interest

There are no conflicts to declare.

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