The Development of Cuba's Biotechnology: Mechanisms and Challenges

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Abstract: Cuba faces a dilemma between continuing its current portfolio of biotechnology drugs and vaccines with lower profitability or renewing its product portfolio with the associated costs and risks.

Introduction

The Cuban biotechnology experience is an indisputable success in product generation (biopharmaceuticals and vaccines), impact on public health, patent registration, and export weight. The sector, strategic for Cuba, has been developed on a solid scientific basis, meets high-quality standards, and has achieved high international prestige. Its strength and added value are derived from the 32 companies that make it up, 9 of them trading, 61 production lines, and the more than 20,000 workers that make it up.[1]

With more than 30 years of experience in research and compliance with Good Manufacturing Practices, clinical trials, and exports, the Cuban biopharmaceutical industry is a mature sector that benefits from the synergies between all its components. The Cuban Biotechnological and Pharmaceutical Industries Group (BioCubaFarma) manufactures and distributes more than 1,000 products, including 482 medicines from Cuba's Basic Drug List and an international presence reflected in more than 765 records.[2]

Such successes may seem unlikely in a socialist country with limited economic development, facing the weight of significant international sanctions. But it was not an accident. This article analyzes the mechanisms that allowed the development of Cuban biotechnology, arguing that the country knew how to transform typical distortions of socialist economies into comparative advantages while neutralizing the characteristic imperfections of market economies thanks to a strategic institutional design.

The main distortion that Cuban biotechnology took advantage of was the abundance of a highly qualified labor force and its low cost compared to that of more developed countries. The strong support of the state in the preparation of human resources, the massive training of medical personnel, and the centrality of health in public policies were salient characteristics of the Cuban Revolution. Therefore, it is not surprising that the development of biotechnology has been based from the beginning on having a highly qualified professional whose low salaries in international terms implied that Cuban products had low research or production costs per peso.

At the same time, the importance of knowledge in the added value of the pharmaceutical sector makes it vulnerable to imperfections typical of market economies. One is the lack of coordination between research, development, production, and marketing. Another is the lack of incentives to generate innovations with the characteristics of public goods. These imperfections may explain why other Latin American

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and Caribbean countries were only partially successful in developing their pharmaceutical sectors despite being non-socialist market economies.

The Cuban strategy for biotechnology development dealt with these imperfections using three mechanisms. First, regarding coordination, Cuba stands out as a state business model in which the industry is vertically integrated, with companies responsible for the entire innovation cycle, from basic science to preclinical and clinical trials, production, and marketing. This "closed cycle" strategy included a substantial state investment process that allowed the construction of dozens of Research and manufacturing centers.[3]

Second, in a low-wage country, significant incentives were created for biotechnology researchers. The Cuban state leads in the licensing and management of patents for the development of its pharmaceutical sector, but income from intellectual property rights is granted to inventors to promote research. Researchers are also offered work incentives, good working conditions, and the possibility of constant improvement in Cuba and abroad. These benefits have diminished today, but they were national ideas that were tested in practice.

Finally, licensing serves as a platform to attract foreign business partners who can strategically complement the local industry through financial resources, related patents, and marketing channels. In this sense, Cuba stands out as a state business model supported by international joint ventures, frequently operating under the legal regime of developed countries, such as the United Kingdom or Switzerland. This way of proceeding offers guarantees that foreign investors would not have if the resolution of commercial disputes depended on Cuban courts.

This combination of mechanisms gave rise to the successful development of Cuban biotechnology, as could be verified during the Covid-19 pandemic. During this period, new vaccines and highly effective treatments were introduced, on par with the most advanced countries. However, Cuba has a low internal demand for biotechnological products, which is insufficient to internalize the fixed costs of the research and development activity.

The export orientation is, therefore, an essential condition to achieve the economic viability of the Cuban model. Unfortunately, the tightening of trade sanctions against Cuba had dramatically affected the sector's ability to generate income, as was made clear during the Covid-19 pandemic, when international recognition of its vaccines was suspended due to difficulties in financing equipment and maintenance of production lines.

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Resources, Products, and Markets

After the 1959 revolution, Cuba created multiple educational programs and granted important budget items that made it possible to create the necessary

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Table 1
Leading Products of Cuban Biotechnology

Name	Therapeutic use
Heberon Alfa R	Human leukocyte clone produced by recombinant DNA technology for antiviral or antineoplastic use.
Heberprot-P	Treatment of diabetic foot ulcers and to reduce the risk of limb amputation.
HeberFERONR	Blends recombinant human Interferon alpha 2b with recombinant human Interferon-gamma in a single vial.
CIMAvax-EGF	Induces an autoimmune response, inactivating the mechanisms of cell proliferation in tumor cells.
CIMAher	Passive cancer immunotherapy against a target that manifests itself in tumors of epithelial origin.
Proctokinasa	Novel application of recombinant streptokinase for patients with acute hemorrhoidal disease.
EPOCIM 2000, 4000 and 10000	Increase hemoglobin and hematocrit, reducing complications from anemia and transfusions.
Biomodulina T	Natural biological extracted from bovine thymus that limits the severity of Covid-19.
UMELISA SARS-CoV-2-IgG	Detects IgG-type antibodies in serum or plasma samples and is used for mass diagnosis of Covid-19.
Itolizumab	Humanized monoclonal antibody that limits the severity of respiratory difficulties caused by Covid-19.
Jusvinza	Peptide that increases the immune response during viral infections and inflammatory physiological responses.

Source: BioCubaFarma, *available at* <https://www.biocubafarma.cu/productos/productos.php> (last visited September 12, 2023).

professional base for national science, a central objective of the new government. Among his first steps were the Literacy campaign (1961), the reactivation of the Cuban Academy of Sciences (1962), and the creation of different Public Health institutes.

The training of human resources and the development of scientific capacity were part of a broader effort to ensure universal and free public health at the state's expense. The number of doctors grew from less than one per thousand inhabitants in 1960 to almost six today. The vaccination campaigns made Cuba the first country in Latin America and the Caribbean to eliminate polio and made it possible to practically eliminate contagious diseases such as tetanus, diphtheria, and rubella. And maternal and prenatal care programs helped reduce infant mortality to a level similar to that of Canada.

The pharmaceutical industry was central to this strategy. The investments of the State budget in these areas of high technology were very significant and did not stop between 1990 and 1996 when Cuba went through a deep economic and social crisis known as the Special Period. Despite the disappearance of the socialist bloc, which provided the country with significant financial and material resources, large sums were allocated to equipment. In other words, the country sacrificed resources from other economic areas with the aim of promoting this industry, which could help reduce imports of vaccines and medicines.

In Cuba, biotechnological products have been concentrated in the area of human health and livestock, and agriculture. In the non-human area, investments were made to build an extensive bio-factory network to produce vitro-plants. Varieties more resistant to diseases and pests were achieved in crops such as sugar cane, potato, tobacco, banana, vegetables, and citrus. Then the obtaining of new-generation veterinary vaccines and the production of transgenic animals and plants were added.

However, the most salient feature of Cuban biotechnology is its specialization in locally produced pharmaceuticals for human use (table 1). Among them, vaccines stand out, particularly against hepatitis B, meningococcal disease, rabies, tetanus-toxoid, diphtheria-tetanus, diphtheria, tetanus and whooping cough (DTP), trivalent antileptospirosis, quadrivalent DTP-HB (TRivac-Hb), pentavalent heberpenta, typhoid, and Haemophilus Influenza type B. Until now, the Cuban immunization schedule includes thirteen vaccines. Of these, eight are already produced on the island.[4]

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A new therapeutic vaccine against chronic hepatitis B – HeberNasvac – has been recently developed. It has been shown to have higher levels of efficacy than the main registered treatments for this condition. It was one of the first vaccines in the world for therapeutic use and is applied nasally and subcutaneously. The first has two antigens of the hepatitis B virus, the surface antigen and the nucleocapsid of the virus.

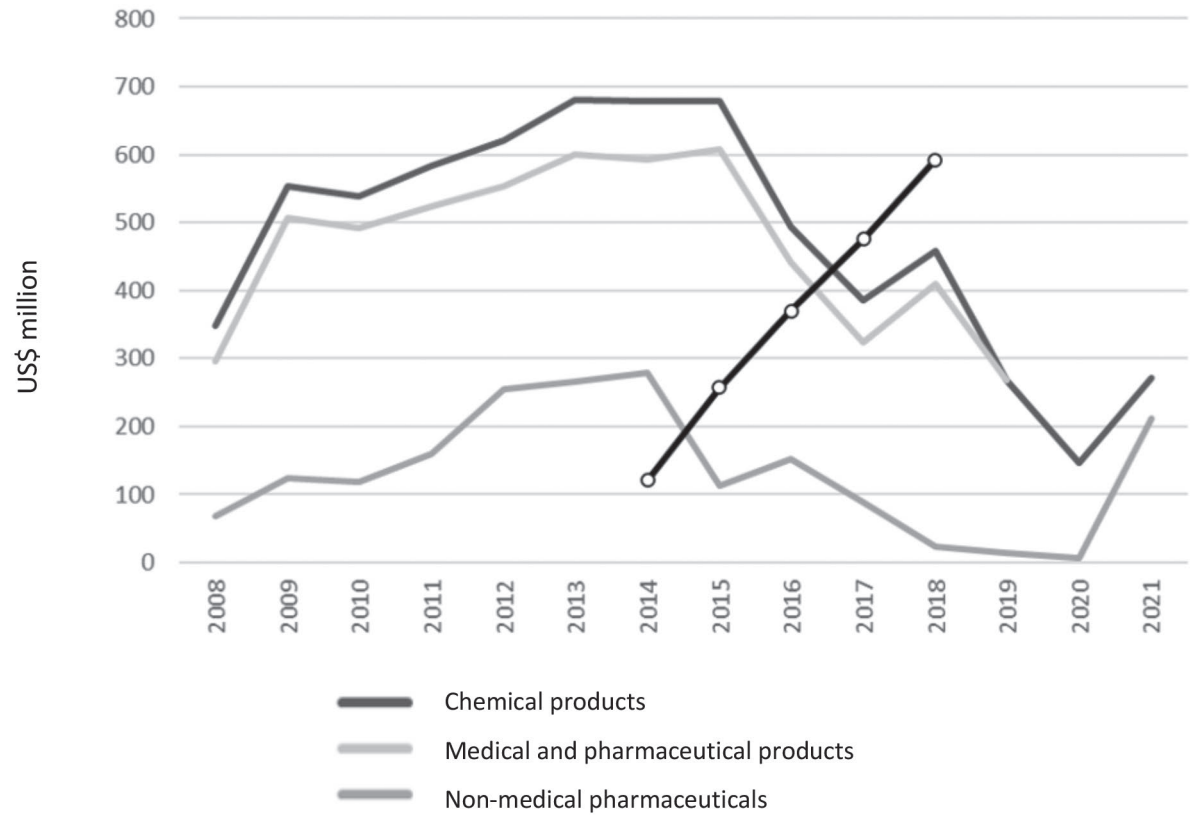
Technologies for the diagnosis of neural tube defects, dengue, pregnancy kits, vaccines against lung cancer, and drugs dedicated to combating viral diseases, myocardial infarction, and organ transplant rejection are also highlighted. Other therapeutic-type products delay the onset of AIDS in people already infected and preventive variants.

One of the leading products of Cuban biotechnology is Interferon alfa-2b, an antiviral or antineoplastic drug produced locally in recombinant human form in 1986. Internationally approved, this drug is used for a wide range of infections and cancers; Interferon alfa-2b is used for the treatment of hepatitis, leukemia, myeloma, and melanoma, among other diseases. A recent study showed that Covid-19 patients in Wuhan, China, who received interferon alfa-2b showed a significant reduction in the duration and intensity of inflammation.[5] Another highly recognized product is Heberprot-P, a unique medication in the world that has reduced the rate of amputations in patients with diabetic foot ulcers by up to 75%.[6]

In 2006, Cuban biotechnology exported 38 medicines to 40 countries, with revenues of more than 50 million dollars. And the island maintained joint ventures with South Africa, India, and China, technology transfer agreements with Brazil and Iran, and joint developments with several nations, including China, Venezuela, and Vietnam. In the following two years, there was a significant increase in exports, thanks to vaccines against meningitis B, hepatitis B and influenza, Interferon alfa-2b, and Heberprot P. By 2008, there were already more than 300 million dollars of

Figure 1

Exports of Chemical, Pharmaceutical, and Medicinal Products



Sources: WIPO 2023, Cuba Statistical Yearbook, 2021

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income and 58 countries. And from 2009 to 2013, exports of more than 50 biotechnology products reported income to the island worth 2,779 million dollars (figure 1).

However, since 2016, chemical and related products exports, including medicinal and pharmaceutical products, have declined. Currently, it can be estimated that exports of medicines would be around 244 million dollars per year. But it is not possible to isolate what part of that income corresponds specifically to products from the biotechnology sector. [7]

Institutional Arrangements

The leadership of the state in the development of the Cuban pharmaceutical industry was reflected in the creation of an institutional architecture capable of coordinating the different public actors and of integrating the research, production, and commercialization phases in a closed cycle. However, such architecture did not emerge overnight. It was rather the result of a gradual process of experimentation and learning.

The starting point was the inauguration in 1965 of the National Center for Scientific Research (CNIC), a pioneer of many investigations in the biotechnology field in Cuba. Subsequently, research-production centers, or full-cycle institutions, were established not only to meet national health needs but also to access export markets. This experience informed the strategy for developing biotechnology, articulated during the 1980s.

An important consequence of this new strategy was the creation, in 1981, of a biological front that included various scientific institutions. From there, they began to establish and found various institutions that were non-existent in Cuba until then. Among them were the Center for Biological Research, the Center for Genetic Engineering and Biotechnology (CIGB), the Center for the Production of Laboratory Animals (CENPALAB), the National Center for Biopreparations (BIOCEN), the Center for Immunoassay, the Center for Immunology Molecular (CIM), the Finlay Institute, the Center for Pharmaceutical Chemistry, the Cuban Center for Neurosciences (CNEURO), COMBIOMED Digital Medical Technology, the Center for Research and Development of Medicines (CIDEM), the Center for Placental Histotherapy Dr. Carlos Manuel Miyares Cao, NEURONIC — Medical Technology and AICA Pharmaceutical Laboratories Company.

Each of these institutions is organized following the principle of a closed-loop company that integrates all stages of product realization, from research to commercialization, to maximize the impact of its R&D programs in the biotechnology and pharmaceutical industry. During this phase, other centers were also built, and equipment was installed in different Cuban universities and provinces.

In 1992, the West Havana Scientific Pole was established, comprising more than fifty institutions and ten thousand workers.[8] And in December 2012, the biotechnological companies became part of BioCubaFarma, one of the 32 Higher Economic Management Organizations (OSDE) created at that time. Entities from the biotechnology sector previously belonging to the Ministry of Science, Technology, and Environment (CITMA) and those of the QUIMEFA Business Group, in charge of drug production, also joined the group.

The BioCubaFarma group was conceived as a business organization that researches, develops, produces, and markets medicines, diagnostic systems, medical equipment, and high-tech services based on technical and scientific development aimed at improving the health of the population, the generation of exportable goods and services and advanced technologies in food production.

BioCubaFarmal has establishments in the 15 provinces of Cuba and comprises 16 large producing companies, eight trading companies, eleven located abroad, and three service companies. The integration of the biotechnological industry with the pharmaceutical industry reported benefits for both in the case of high technology areas (for example, the manufacture of quadrivalent vaccines with high production rigors) and in other more basic ones (such as the production of analgesics).

The emergence of BioCubaFarma also made it possible for foreign capital to enter this area, especially in the construction of plants and in the Mariel Special Development Zone, where a production and research plant known as CIGB Mariel S.A. has already been built. However, the Cuban state was relatively averse to foreign investment in the research and production stages. Conversely, there are 19 entities abroad governed by BioCubaFarma, either as joint ventures or fully Cuban-owned.

Patents and Incentives

The institutional structure of Cuban biotechnology allowed all member organizations to have their own marketing company to facilitate the export process. Each of them thus began to function in a closed cycle where the resources obtained were reintroduced into the industry in the form of equipment, reagents, and other materials. At the same time, mechanisms were established for researchers to benefit from the economic performance of the organizations for which

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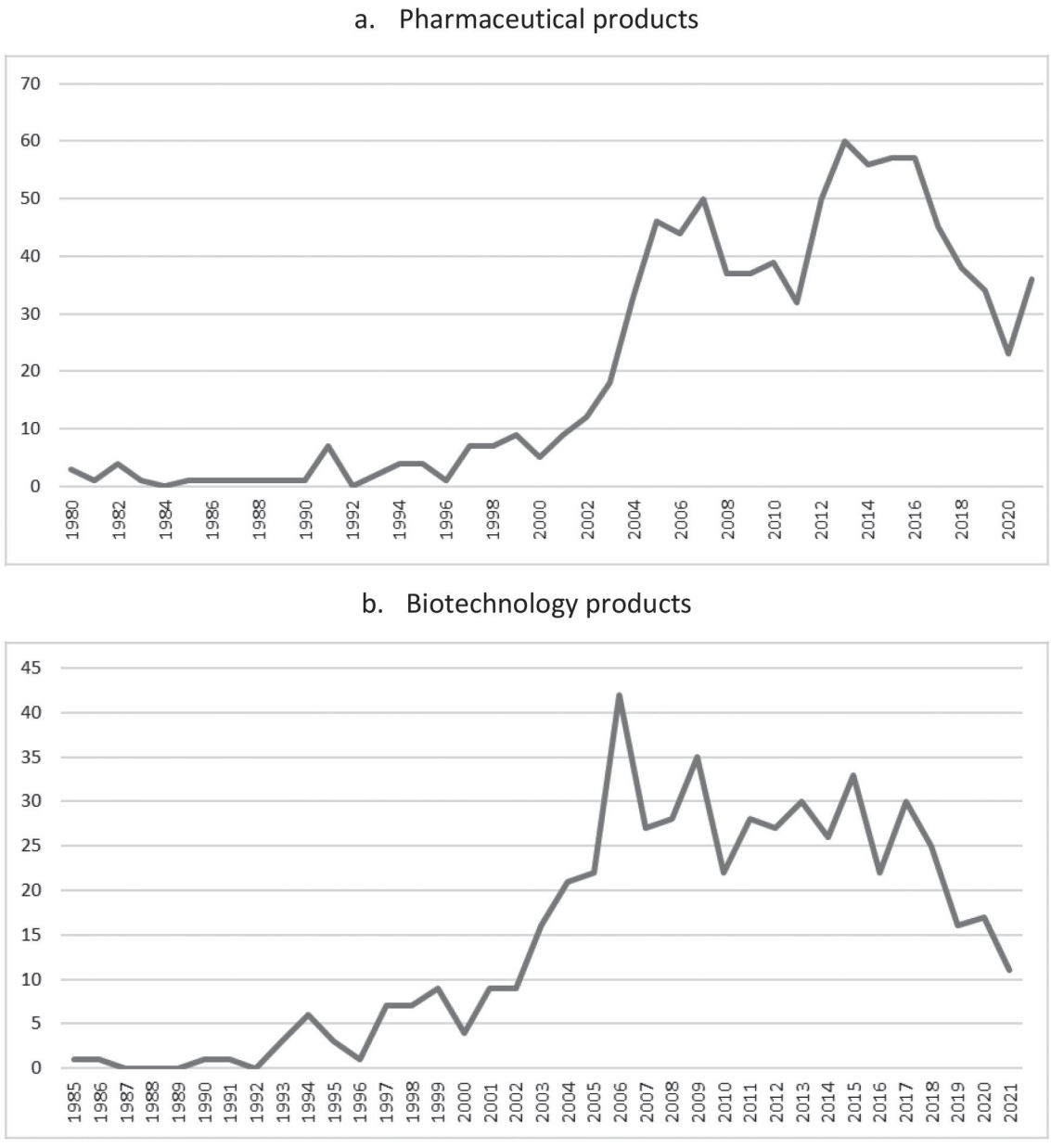
they worked. Commercial patents and individual incentives were thus the two mechanisms that made it possible to reconcile state ownership with high scientific and industrial productivity.

Indeed, the Cuban biotechnology system has been inserted to protect the technologies and inventions developed by our scientists and researchers. This will of the country in relation to the protection of research results both in Cuba and abroad is observed in its programmatic documents. Thus, among the Economic and Social Guidelines where, number 110 proposes "strengthening the capabilities of prospecting and technological surveillance, as well as the policy of pro-

Figure 2

Patents Granted in Cuba (Number)



Source: WIPO 2023

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tection of industrial property in Cuba and the main foreign markets."

The use of patents in the biotechnology sector was reinforced by the establishment of numerous legal instruments to support this practice, not only to protect intellectual property rights but also as a platform to align national practice with the guidelines governing trade. of this activity and promote access to markets.

To promote innovation and development of health technologies, the patent law was adapted based on the flexibilities of the Trade Related Aspects of Intellectual Property Rights (TRIPS). Several measures adopted between 2011 and 2018 have been particularly important for the population's access to medicines and health technologies.

Decree-Law No. 290, promulgated in 2011, repealed previous articles and stated that "the new legislation should make it possible to counteract the abusive exercise of the rights that are acquired or the recourse to practices that unjustifiably limit trade, as well as how to safeguard the rights that help the Republic of Cuba to adopt the necessary measures to protect public health and, in particular, the right to promote access to medicines.[9]

This decree and the National Policy of the Industrial Property System of the Republic of Cuba, approved in 2014, are the basis of the system currently in force in the country, allowing the adoption of measures to protect the public health and nutrition of the population, as well as safeguard the general interest around scientific-technological and socio-economic development. This management framework for legal and natural persons is included in sectoral development policies and is part of the work agendas of the different organizations involved.

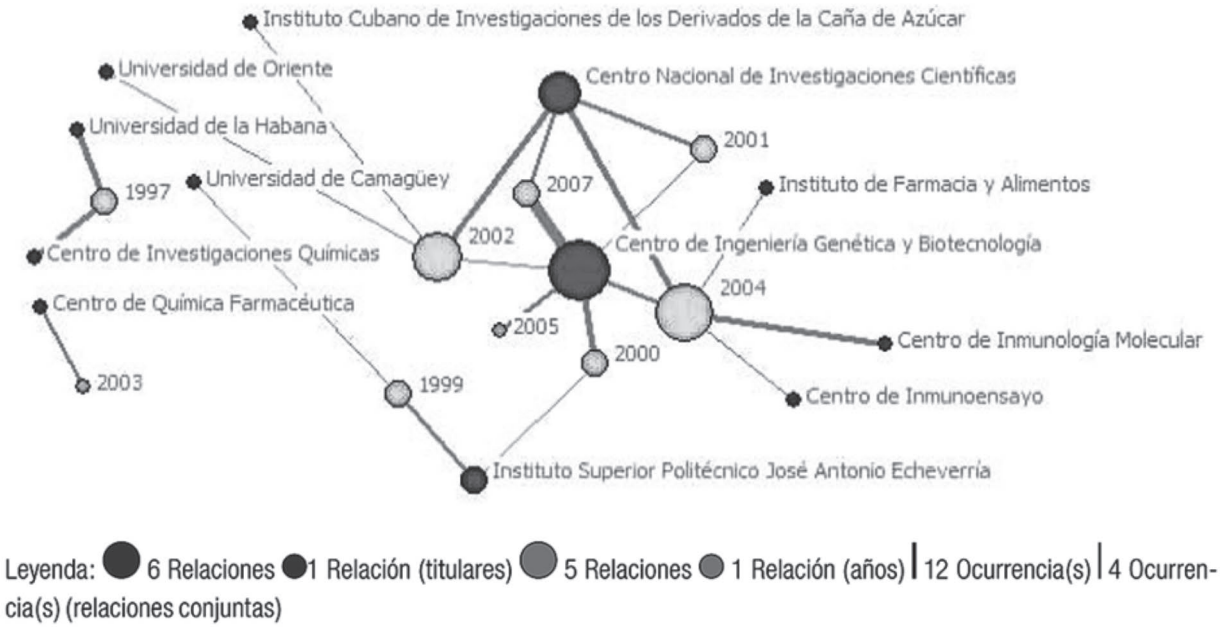
Subsequently, between 2016 and 2018, new decree laws and resolutions were adopted to perfect the existing legal system in this matter. Among them, Decree No. 342, "Regulation of Decree-Law No. 290 of inventions and industrial drawings and models" stands out.[10]

These legal changes are associated with a significant increase in the number of patents approved in Cuba for pharmaceutical products, reaching an average of practically 60 per year between 2013 and 2016 (figure 2. a). But this acceleration is part of an upward trend that was already clear since the beginning of the 2000s, especially in the case of biotechnological products (figure 2. b).[11] The new regulatory framework does not prevent a clear slowdown in the number of patents approved in recent years.

In the Cuban biotechnology industry, the ownership of patents does not lie directly with the inventors, sim-

Figure 3

Number of Patents by Holders and by Years



Source: Maidelyn Díaz Pérez, Raudel Giráldez Reyes, Humberto Andrés Carrillo-Calvet, 2017.

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ilar to most countries. The authors are recognized as inventors, while public institutions hold patent rights for new products. This arrangement has implications, and scientists must align their investigations with the goals and priorities established by their institutions. This stands in contrast to researchers in some other countries, where they have more autonomy to pursue scientific research according to their interests and preferences.[12]

between the institutions themselves (figure 3). The collaborations that are taking place in Cuba between universities and companies are also interesting, the result of a national science and technology policy that aims to articulate the financial resources destined for research, development and technological innovation based on the main problems of Cuban society.[15]

This growing international insertion has resulted not only in an increase in the commercial exchange of biotechnological products with a significant number of countries. It has also allowed the creation of joint ventures, the increase in Intergovernmental commissions on biotechnology, and a greater number of scientific exchange projects with world-renowned universities and companies. More indirect benefits include a notable increase in exchanges with high-level foreign political leaders, petitions to increase scientific ties, and international recognition of the country's achievements. Thus, biotechnology has become an integral part of Cuba's foreign policy with nations from different regions of the world.

However, researchers benefit greatly from a privileged salary scheme that completely separates them from the rest of the workers, even in the health sector itself. For example, they enjoy benefits from housing programs and others, specifically designed and implemented to meet their specific needs. And CITMA resolution No. 152, promulgated in 2018, stipulates a clear procedure for the remuneration of inventors based on their contributions to innovation.[13]

The basis for calculating the amount of the remuneration is the income obtained from the exploitation of the invention, after deducting the expenses incurred for the research, development, production and commercialization of the product, as well as for the protection, maintenance and defense of the patent. The group of inventors corresponds to 1 to 10% of this base, and 10 to 30% of the royalties or fixed payments for patent licenses. Within this total, each inventor corresponds to a fraction related to the individual contribution of each one in the creation of the patented invention.[14]

This incentive system not only stimulates individual productivity, but also favors collaboration between institutions. And since the inventors who work in these institutions are the same, they end up forming a dense network in which everyone collaborates with everyone else, which is later manifested in the links that exist

International Agreements

The patent rights granted to the Cuban biotechnological and pharmaceutical industry allow the protection of its results in the country and support access to medicines by the population. On the other hand, the rights acquired in other countries allow access to other markets, as well as the transfer of technologies that have industrial property rights incorporated, which becomes a source of resources for the development of new health technologies.

The recognition of Cuban patents by other countries, and in particular by the main export markets, is indeed essential to ensure the income of the pharmaceutical industry and offer incentives to its researchers. Aware of this need, the country signed an important number of international conventions, treaties, and agreements related to industrial property.

Since 1995, Cuba became a member of the World Trade Organization, therefore having to apply the TRIPS provisions. The norms of this agreement related to patents and industrial drawings and models led to the implementation of national legislation and the promulgation of new Decree-Laws.[16] Cuba also adhered to the Paris Convention for the Protection of Industrial Property and is one of the signatories of the Patent Cooperation Treaty.

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This strategy of protecting its innovative technologies and products, both in Cuba and abroad, has allowed BioCubaFarma to have an important portfolio of patents and trademarks around the world. The aforementioned portfolio is an expression of the outputs and the technological impact of the results obtained by the institutions belonging to this industry, which has industrial property rights on the five continents.

In 2008, 528 licenses or health medical records had been granted in 66 countries, of which almost 90% were related to biotechnological products (mainly vaccines and diagnostics). Similarly, a significant number of patents had been registered internationally.[17] But by 2022 BioCubaFarma already had 780 health registrations abroad, and more than 2,400 patent registrations internationally, actively exporting to more than 45 countries. Of particular significance are the patents granted to Cuban researchers in the United States (figure 4).

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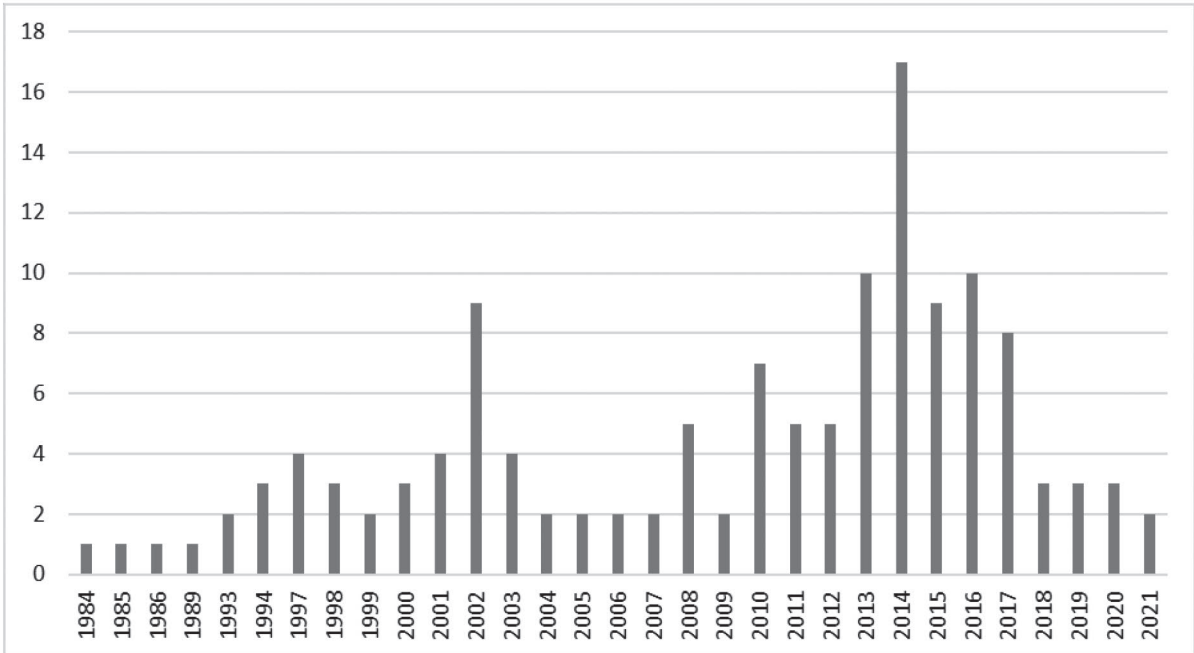
The Current Situation

The set of mechanisms established by the Cuban government to develop the pharmaceutical sector, and biotechnology in particular, has been successful if measured by the ability to generate innovative products that are internationally recognized. The Covid-19 crisis clearly illustrated the maturity reached by Cuban biotechnology, which was capable of generating new vaccines and effective treatments on a par with the most developed countries.

At the same time, the sustainability of the Cuban model crucially depends on the ability to export. Without income from abroad, their closed-loop companies

Figure 4

Patents Granted to Cuban Holders in the United States



Source: WIPO.

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lack the resources to develop new products and carry out the necessary clinical trials to be able to patent them internationally. The intensification in 2017 of the trade sanctions imposed by the United States has seriously affected Cuban exports. And the non-recognition of the Cuban vaccines against Covid-19 by the World Health Organization (WHO) cut off a unique income opportunity for the sector.

Cuban biotechnology demonstrated excellent results in dealing with the COVID-19 pandemic, especially the use of national resources and its own vaccines to immunize the entire population. In the protocols established by the Ministry of Health, most of the products used were national and were used effectively in serious and critical patients, as well as in certain risk groups.

In the beginning, recombinant Interferon alfa-2b, already in existence, was used and acceptable results were achieved.[19] But the BioCubaFarma group worked on 16 projects for new treatments and medical technologies to prevent and combat this disease. There were five vaccine candidates in different phases. The Soberana 02 and Abdala vaccines stood out, which were scaled up in large batches for mass vaccination of the population. The remaining vaccines were Soberana 01 and Mambisa.

Other Cuban products that were used successfully during the pandemic were Biomodulin T (a naturally occurring immunomodulator), Hebertrans (a transfer factor), Nasalferón (a nasal formulation of recombinant human Interferon alfa-2b), Hebrón (another interferon alfa-2b recombinant human), Heberferon R (combination of interferon alpha-2b and interferon gamma), Jusvinza (an immunomodulatory peptide), and Itolizumab (a monoclonal antibody).[20]

The quality of these products has been recognized internationally. For example, the prestigious journal Lancet Regional Health Americas published the results of the phase 3 clinical trial of Soberana 02 and its heterologous combination with Soberana Plus. As detailed, more than 44,000 subjects from 8 municipalities in Havana, in a complex epidemiological context with circulation of beta and delta variants, allowed us to demonstrate 92% efficacy in the prevention of symptomatic disease.[21] In addition the Abdala vaccine, underwent a phase III clinical trial with over 48,000 participants. The results of the trial demonstrated that the vaccine was safe, well tolerated, and highly effective in preventing symptomatic and severe cases of COVID-19. In addition to its efficacy, the Abdala vaccine offers other advantages. It has a convenient immunization schedule, and its storage conditions are favorable, making it easier to handle and distribute.[22]

Cuban vaccines against COVID-19 have several characteristics that distinguish them from others that have been developed. First, they have proven to be very safe. After tens of millions of doses applied, in Cuba and in other countries, it has been observed that adverse events are mild and with a very low frequency, even in the pediatric population from two to 18 years of age, a unique experience in the world to date. And second, they have high thermo-stability. Unlike other vaccines that require freezing temperatures, the Cuban ones can be stored between 2 and 8 degrees Celsius.[23]

By the end of 2022, more than 20 scientific articles had been published in high-impact magazines on Cuban vaccines against Covid-19. But the recognition by the WHO was not granted, despite the fact that the various steps were taken according to the established procedures. Many countries that could have been importers of Cuban vaccines preferred to access other options, such as Pfizer-BioNTech, Moderna, AstraZeneca, Janssen, Sinovac or Sputnik. Consequently, Cuban exports did not reach the expected sustained growth.

The WHO recognition was not granted due to the delay in evaluating the production facilities of the CIGB-Mariel biotechnological complex. Although the plant is active, the line in which the recombinant products are manufactured presents delays in its start-up. And the reason for this is that it has not been possible to make payments to the company in charge of commissioning the equipment and systems of that production line due to the refusal of several banks to carry out the transfer operation due to pressure from the US government and its blockade of Cuba.

More generally, the tightening of economic sanctions imposed by the United States, in 2017, is undermining the main sources of income for Cuban biotechnology, without which the mechanisms that generate the dynamism of the sector lose their effectiveness. In particular, the rule that prohibits ships from calling at US ports for 180 days after leaving a Cuban port makes exports more expensive. Thus, Cuba's medical instruments and pharmaceuticals have had trouble finding new markets. Foreign trade increasingly depends on few trading partners, generating great vulnerabilities. For example, Cuba's pharmaceutical exports dropped dramatically when Venezuela's economy collapsed.

The certain fact is that the proportion of investments in the health sector fell to 0.8% in 2021, while those destined for tourism activities reached 45.6%.[24] The result has been a cumulative slight reduction in budget spending on health, while at the same time the

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currency crisis has led to severe shortages of medicines, medical supplies and supplies.

Prospects and Challenges

Cuba has successfully entered an area dominated by some developed countries and few transnational corporations. However, for its competitive development this sector, which has a high degree of complexity, needs enormous financial resources for research, which the country lacks. While it is very profitable when successful, to get there you need to invest large sums and be willing to wait long periods before recouping the investment. Hence, the challenge consists of how to achieve their survival in the country's conditions in the short term.[25]

In this context, the diversification of the market in the export process becomes a necessity. Despite the fact that Cuban biotechnology products are exported today to several countries on all continents, there are still problems of concentration of these exports in terms of their value, a real limitation for competitiveness. This is not only a problem of volume, but also of the technological content of what is exported. True technological development always requires the ability to produce and export products with high added value and new over time.

The diversity of destinations with different regulatory environments and the increase in international regulations constitute a barrier to the entry of Cuban products in many economies. In each country of destination there are regulations in this regard, which requires permanent reinvestment to obtain high quality standards, a fundamental risk for the Cuban biotechnological sector, especially since the most restricted markets are those of developed countries, which have few companies. but monopolistic It is there that the greatest benefits can be obtained.

Productivity in the medium term will depend on penetrating new markets, but also on creating new products. Therefore, Cuba faces a dilemma between continuing to produce biotechnological products that require less effort, but are less profitable, or renewing its product portfolio, which entails greater investment and risk, given that no less than ten years are needed to develop a new biotechnological drug.

The success of Cuban biotechnology was due to the priority given to it, and the use of effective incentives to take advantage of the abundance of relatively low-cost, highly-skilled human resources. But the success was also due to the strong investments made in this area, and today the country is not in the same conditions to offer them, as it was during the takeoff of the 1980s. In addition, the sector has lacked autonomy in decision-making financial resources, which has prevented it from having capital at the necessary time and has turned the scarcity of financial resources into an even greater weakness.

However, biotechnology is a strategic sector in terms of the multidimensional notion that Cuban development will have in its horizon aspirations until 2030. Making it a reality is what it is up to economic policymakers.

Note

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