**Cuban Journal of Public and Business Administration**
ISSN 2664-0856 RNPS 2458 / Vol. 6 No. 2 / May-August (2022) / e220
Available in: https://apye.esceg.cu/index.php/apye/article/view/220

Original article

# INDUSTRIAL PROPERTY MANAGEMENT OF THE PRODUCT/PROJECT LIFE CYCLE IN A CUBAN BIOPHARMACEUTICALS COMPANY

# GESTIÓN DE PROPIEDAD INDUSTRIAL DEL CICLO DE VIDA DEL PRODUCTO/PROYECTO EN UNA EMPRESA BIOFARMACÉUTICA CUBANA

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Classification JEL: D21, D23, D24

DOI: https://doi.org/10.5281/zenodo.6940981

*Received: 16/02/2022*
*Accepted: 18/05/2022*

## Abstract

The Center for Research and Development of Medicines (CIDEM) is a company of the Group of Biotechnological and Pharmaceutical Industries of Cuba (BioCubaFarma) that is dedicated to the research and development of generic, innovative medicines and natural products, at different stages of their development. development to industrial scale and commercialization. The objective of the article is to characterize CIDEM's industrial property management in relation to the stages of the project/product life cycle. These stages are divided into R&D, registration and transfers. Finally, the strategies of industrial property are shown.

**Keywords:** management, industrial property, strategy, pharmaceutical industry, R&D life cycle

Published by Superior School of State and Government Cadres, Havana, Cuba



Escuela Superior de Cuadros del Estado y del Gobierno

## Resumen

El Centro de Investigación y Desarrollo de Medicamentos (CIDEM) es una empresa del Grupo de las Industrias Biotecnológica y Farmacéutica de Cuba (BioCubaFarma) que se dedica a la investigación y desarrollo de medicamentos genéricos, innovadores y de productos naturales, en diferentes etapas de su desarrollo hasta su escala industrial y la comercialización. El objetivo del artículo es caracterizar la gestión de la propiedad industrial del CIDEM en relación a las etapas del ciclo de vida del proyecto/producto. Estas etapas se dividen en I+D, registro y transferencias. Finalmente se muestran las estrategias de la propiedad industrial.

**Palabras clave:** gestión, propiedad industrial, estrategia, industria farmacéutica, ciclo de vida de I+D

## Introduction

In Cuba, the Industrial Property System, made up of the Cuban Industrial Property Office, as the governing body and the actors of the System, constitutes the set of functional relationships for the management of industrial property in the country and with other markets of interest, it is based on the principles of policy, national regulations, treaties and international agreements on the matter.[1] In the Cuban pharmaceutical industrial infrastructure[2] industrial property plays a relevant role. This sector has well-structured industrial property systems, among the largest generators of invention patents. As an annual average, Biotechnology represents 25%, Chemistry and Pharmacy, 33%, and between the three branches they add up to 58% of the country's current patents.

Cuban medical assistance occupies one of the first places in Latin America, recognized by the Pan American Health Organization (PAHO), the United Nations Specialized Organization for Children (UNICEF) and the World Health Organization (WHO).[3-7] These results are possible due to the construction of a socialist society, which conceives health as an essential human right, a main component of the quality of life and a strategic objective in the development of the country.[8-10]

On the other hand, BioCubaFarma (BCF) emerged in 2012 with more than 30 companies that supply 70% of the medicines in the Basic Table of Medicines (CBM) and import substitution. The Drug Research and Development Center (CIDEM) is one of its companies that has played a decisive role through the development and registration of approximately 500 products that meet medical needs from the Basic Table of Medicines (CBM). This company has 50 years of experience in the biopharmaceutical sector, if the creation of the first laboratories is considered, moving towards a consolidated R&D center. Its strategy has been aimed at developing technologies for the production of generic medicines of natural origin and nutritional supplements to cover or complement therapeutic products.

In relation to intellectual property (IP), patents, trademarks and trade secrets are assets that increase the value of a business[11] and the strategy is formulated taking into account not only the internal environment where it operates, but also the external one. Pharmaceutical companies in particular are facing challenges with patent expiration and declining R&D productivity. Among the strategies is the specialization of the business portfolio in order to maintain and strengthen its position in a given field, which faces greater risks; On the other hand, diversification may have the objective of compensating for a decrease in sales in mature fields and the risks are due to the effect of distribution.[12] For example, in high-tech

BioCubaFarma companies, a strategy followed is the continuous renewal of the sanitary registration , the consolidation and generation of new patents,[13] with the performance of new clinical trials in high-standard markets.[14] IP management is an important issue, since it allows and/or restricts research, and contributes to the results and impacts on the competitiveness of technology-based companies.

The objective of the article is to characterize the industrial property management of the Drug Development Research Center (CIDEM) as a company of the Cuban Biotechnological and Pharmaceutical Industries Group (BioCubaFarma). For this, the life cycle of a CIDEM project/product is analyzed in relation to the management of industrial property. Finally, the Industrial Property Strategy adopted in this institution is shown, which has a varied line of closed-cycle research-development (R&D) with a relevant role in the generation of generic drugs and innovative products in the country.

## Materials and methods

The life cycle of a medicine must be managed effectively to guarantee sustained development through commercialization.[15] Thus, the method used in the management of industrial property at CIDEM has been established according to the life cycle of the project/product, which operates in a closed cycle due to its potential in technological infrastructure and analytical services. The analysis of intellectual property management required starting from the research-development-innovation (R&D&i) cycle, up to industrial scale-up, registration and industrial introduction of biopharmaceutical products, as shown in **Figure 1**. As can be seen in figure 1, IP management at CIDEM according to the life cycle of the CIDEM project/product is structured in the stages: R&D, Registration and Transfers. Transversely to all stages, IP strategies are drawn up to be deployed in the institution.

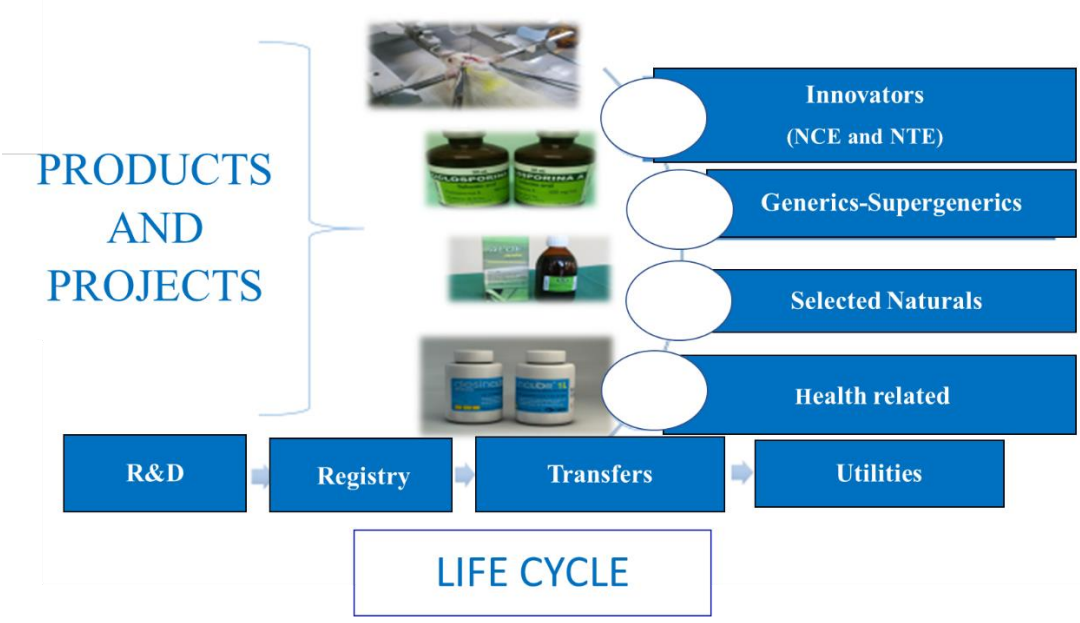


**Figure 1**. Life cycle of a CIDEM project/product
**Source**: self made
Note: NCE (New Chemical Entity) and NTE (New Therapeutic Entity)

## Results and Discussion

Research and Development (R&D) of CIDEM

The insertion of CIDEM in the BCF business group strategically contributes the experience acquired in the development of generic products, allowing the expansion of the number of therapeutic products of the National Health System, with a positive effect on the country's economy.[16] The experience of more than 25 years in the research and development of generic, innovative medicines and natural products, at different stages of their development up to their industrial scale and commercialization in this center confirms the maturity reached in industrial property.

On the other hand, in recent years this institution has successfully begun to venture into the development of innovative drugs, establishing as a work scheme the management of research lines that include research areas in orphan diseases, not satisfied within the therapeutics to global level, thus conforming the portfolio shown in **Figure 2**.

Based on the strategic projection of CIDEM, the introduction of new research-development lines was envisaged, pursuing the objectives of producing new forms of pharmaceutical product presentation, improving product quality, import substitution, creating the basis for boosting exports and improving scientific-technical health services.

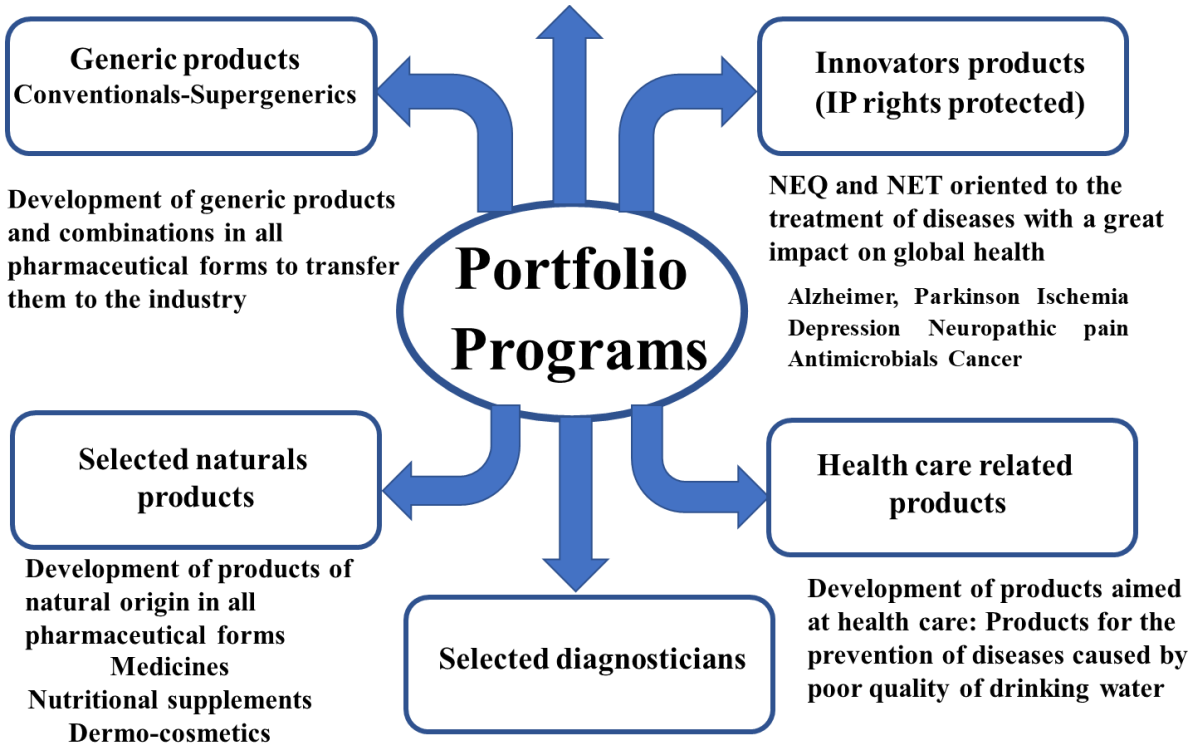


**Figure 2**. Portfolio of CIDEM Research + Development (R&D) lines
**Source**: self-made

CIDEM's R&D lines, like other BCF companies, are fundamentally focused on research into natural products, conventional generics, diagnostics, health-related and innovative products, as can be seen in **Table 1**.

**Table 1.** Types of products investigated at CIDEM and their evolution before and after 2018

| **Products** | **Until 2018** | **After 2018** |
|---|---|---|
| Natural | Natural products with a great impact on the population due to their easy handling, without relevant adverse effects | Selected natural products of small volumes and great added value |
| Traditional Generics | Products that substitute imports | Depending on the business model established. It can be transfer, cession of the production technology of traditional products to other BCF companies, or other. |
| High value-added generics | Products demanded by the National Health System | Products of small volumes and high added value |
| Diagnosticians | Development of projects with little business vision. | Selected products consisting of a reagent, reagent set, system, calibrator, controller or culture medium, intended for use in vitro in the study of samples |
| Health related products | Other products that solve health problems, despite not being medicines, contribute to raising the quality of life of the population, as is the case of water or surface disinfection products | Development of new formulations demanded by the market. |
| Innovators | Development of projects with little business vision. | Oriented to national treatment, to the treatment of diseases with a great impact on global health, such as Alzheimer's, Parkinson's, Ischemia, neuropathic pain, infectious diseases, Depression and Cancer, as well as to export |

**Source**: self-made

Especially in the last two decades, the diversification strategy and the specific way in which it is applied have become key factors in creating and consolidating competitive advantages in the pharmaceutical industry. This industry is extremely complex and the technologies that lead to drug R&D expand the limits of human knowledge, which has also been implemented at CIDEM. It is worth noting that in this industry, innovation activities face high levels of variation and uncertainty, especially during the initial creative phases; they are exploratory and characterized by searching, experimentation and learning. As the process progresses, knowledge is gained and uncertainty is reduced. On the one hand, the large size of companies, the complexity of their processes and technologies are organizational and management challenges.

On the other hand, the development and coordination of the distribution system implies large investments in its management. For example, companies like Pfizer are continually concerned about bringing new

drugs to market in other therapeutic areas, such as breast and kidney cancer and Parkinson's disease. Thus, CIDEM has also oriented its strategy to the R&D of value-added products for the treatment of diseases with a great impact on global health, such as Alzheimer's, Parkinson's, ischemia, neuropathic pain, infectious diseases, depression and cancer.[17,18]

In this center, Research management is carried out through the interrelation between the Research Management Offices and the Development Directorate, with which the inclusion of research projects in the programs with the greatest impact at the national level is achieved.

Registry

The Sanitary Registry of a product is the authorization issued by the regulatory agency, which empowers its Holder to produce and market a certain product, during a period of time and under specific conditions. At CIDEM, the fundamental mission is to research and develop generic drugs, complexes, innovative products, natural products and health-related products, which are finally registered with the regulatory agencies according to the purposes. Natural products, cosmetic and hygiene products are registered in the National Institute of Hygiene, Epidemiology and Microbiology (INHEM) and medicines in the National Regulatory Agency: Center for the State Control of Medicines, Medical Equipment and Devices (CECMED).

Currently the CIDEM Company is the owner of 4 products registered in the CECMED and 23 in the INHEM for which it closes the R&D, production and marketing. Throughout the history of CIDEM, it has developed approximately 500 products, which it has registered and transferred to the industry and which are currently part of the Basic Table of Medications. This situation has been reversed as of 2018 since the products, once developed, are transferred to other companies of the BCF group, and CIDEM only continues to produce those of low demand and those related to health due to the type of technology.

**Transfers**

CIDEM is linked with BCF companies through technology transfer of their products, both for marketing at the national level and for export. The values of technology transfers to production companies are shown in **Table 2** (licences) and **Table 3** (transfers).

**Table 2.** Inventory of technology transfers (total licenses)

| TOTALS per YEAR in CUP (Cuban peso) | | | | |
|---|---|---|---|---|
| 2016 | 2017 | 2018 | 2019 | 2020 |
| $430,250.00 | $24,457.00 | $2,790,604.67 | $98,788.66 | $748,798.15 |
| TOTAL $4 092 898,48 | | | | |

**Source:** self-made

In recent years, CIDEM's strategy has been transformed and has gone from developing and delivering product files to the manufacturing industry to earning income for these concepts, such is the case of

license contracts with manufacturing companies of organizations such as MEDSOL, AICA, March 8, MEDILIP, Roberto Escudero and others, with economic income for this concept.

**Table 3.** Inventory of technology transfers (total transfers)

| TOTALS per YEAR in CUP (Cuban peso) | | | | |
|---|---|---|---|---|
| 2016 | 2017 | 2018 | 2019 | 2020 |
| $0.00 | $0.00 | $20,410,375.39 | $904,001.98 | $11,650,104.75 |
| TOTAL $32 964 482,12 | | | | |

**Source:** self-made

Despite the fact that in commercial practice there are technology transfer contracts by way of assignments, it is not a positive experience for CIDEM, by receiving an amount at the time of signing the contract, autonomy over said technology is lost and other successive income is received. Such is the case of the contracts signed with some BCF companies that today receive income in USD from the exports of products developed by CIDEM, which only obtained income in CUP.

CIDEM Industrial Property (IP) management strategy

Intellectual property management includes activities related to the management of intangible assets generated or to be generated. The identification of the intangible, its assurance, protection, negotiation, possible exploitation, transfer and defense are relevant. Among the activities to be developed in the intellectual property management strategy of each of the intangible assets, the following must be considered:

- Identify that a creation is susceptible to protection through one of the mechanisms provided by intellectual property.
- Generate a regulation for the use of intellectual property within an institution, which includes, for example, the benefits or remuneration to the creator of the intangible asset.
- Deciding to patent a technology not for the purposes of its exploitation, but to block possible competitors.
- Deciding to patent in order to have greater negotiating power regarding the technology.
- Decide to file a lawsuit for infringement of rights.

This IP strategy of CIDEM has been evolving within the entity to carry out its objectives. The cycle of the company includes from the conception of research to industrial escalations, registration, technology transfer and the negotiation of projects that are in different stages of development, with a quality system that harmoniously intertwines the organization, the qualified personnel and resources, thus contributing to raising the health levels of the population, as well as the scientific and socioeconomic development of the country.

Within its business strategy, it contemplates the management and administration of the protection of these results through IP rights, for which it undertakes strategic actions whose main objective is to obtain economic benefits. The main actions include the following:

- The IP generated is considered the most valuable asset of the company that gives it bargaining power; and in this sense, it constitutes a fundamental tool in its growth, in order to fulfill its institutional mission.
- The IP strategy is harmoniously combined and integrated into the company's R&D strategy. Every Research Project considers an IP management strategy from the very early stages of the research, until the finished product is placed on the market, which maximizes the commercial benefits derived from the R&D&i activity.
- Applied research processes are promoted in the Company, which seeks to ensure that R&D activities always yield marketable products, technologies or services.
- The strategy considers the protection of the results through any of the IP modalities, where the most used are invention patents, undisclosed information and trademarks.
- IP is seen as adding value at each stage within the chain in order to bring a new, superior and cheaper product or service to market. So, according to the stage in which the R&D project is, actions are considered within its IP strategy.
- A working approach is adopted aimed at the quality of IP and that the quality of IP rights, is consistent with or exceeds its quantity. The number of IP rights, their strength and competitiveness are valued as more important; which confers temporary advantages.
- The IP strategy of each project considers, prior to the start of a new research topic that may lead to the development of a new product, ensuring that it is not infringing the rights of third parties by conducting patent information searches, including analysis of freedom of operation.
- Control is exercised over the disclosure of scientific results, preventing it from undermining the entity's assets. The IP strategy of each project establishes the moment in which the dissemination of the scientific results of the project may be carried out, either by publication in scientific journals, or oral, written or other means.
- The management of IP rights contemplates the effective use of different legal documents to establish binding agreements with other parties, in which the inclusion of clause related to IP is always valued. These documents include different forms of contribution to R&D projects (risk financing, contribution of know-how and pre-existing IP, logistical support, contributions in conducting certain R&D tasks); different types of contracts to undertake R&D activities (framework and specific collaboration contracts; scientific-technical service contracts; research contracts); different forms of measuring the progress of R&D projects (fulfillment of milestones) and different forms of distribution of risks, benefits (pre-commercial payments, royalties) and ownership of the R&D results.

**Table 4** shows some of the main actions of CIDEM for the integration of IP into the R&D&i strategy in each of its stages.

**Table 4**. Integration actions of the IP strategy to the R&D&i strategy of CIDEM

| Project Stages | | |
|---|---|---|
| Research | Development | Commercialization |
| - Review of the state of the art<br>- Identification of third-party rights | - Revision of the state of the art again and third-party rights<br>- Negotiation with third parties when necessary | - Maintenance of IP rights<br>- Surveillance of rights infringers<br>- Competitor monitoring |

| | | |
|---|---|---|
| - Decision whether to make or acquire the technology that is needed<br>- Protection of the results as they arise in the project | - Review of IP protection strategies<br>- Sanitary registration | |

**Source:** self-made

CIDEM directs its efforts towards a High Technology Company, combining the scientific potential of its workers, experience in research-development activity in the biopharmaceutical industry and the development of complex production processes. Among the BCF companies that have registered the largest number of patents in recent years are the Center for Molecular Immunology (CIM), the Center for Genetic Engineering and Biotechnology (CIGB), the National Center for Scientific Research (CNIC) and the CIDEM, thus generating knowledge of high added value in the field of the Pharmaceutical Industry.[19,20]

As is known, one of the objectives of patents is to achieve market exclusivity. The main pharmaceutical markets are known to be in the US, Europe and Japan. Although Cuba still has limited access to these highly regulated markets, having patents in these regions is very important for the IP strategy. The limitations are related, among other causes, to the lack of financial and organizational resources, difficulties in attracting investments for the commercialization of IP, high costs and length of IP registration procedures.[21]

In CIDEM, a marked growth in registrations has been observed in recent years (See **Table 5**). Thus, in the 2016-2021 period, seven new objects of invention (1.16 per year) have been submitted to the Cuban Industrial Property Office (OCPI). The company's strategy in this sense is to initially present in Cuba as legally established, always with the subsequent vision of going abroad to guarantee the exploitation actions of said objects of invention.

**Table 5**. Registration activity of new objects of invention of CIDEM from 2016 to 2021

| Year | National Registry of Patents | International registry | | | | Exploited patents as an intangible asset |
|---|---|---|---|---|---|---|
| | | Active Patents | Granted Patents | Requested Patents | Number of countries with granted patents | |
| 2016 | 2 | 5 | 5 | 13 | 4 | 0 |
| 2017 | 0 | 5 | 6 | 21 | 5 | 0 |
| 2018 | 1 | 5 | 22 | 66 | 14 | 0 |
| 2019 | 3 | 6 | 22 | 66 | 14 | 4 |
| 2020 | 1 | 10 | 26 | 62 | 15 | 1 |
| 2021 | 0 | 10 | 60 | 47 | 31 | 0 |

**Source**: safe-made

IP protection is very important in the field of business and services, but only with the increase in the number of inventions will there be opportunities to attract technologies that contribute to the country's

progress. The innovation boom, particularly start-ups, benefit from the possibility of obtaining patent protection, which attracts the necessary capital.[22]

The intangibles generated are also protected by means of patent rights and their subsequent negotiation with the modality of patent license and co-development of the project, which encompasses the negotiation strategy of intangibles with high added value, without ruling out other modalities of PI. These modalities can be seen in **Figure 3**.

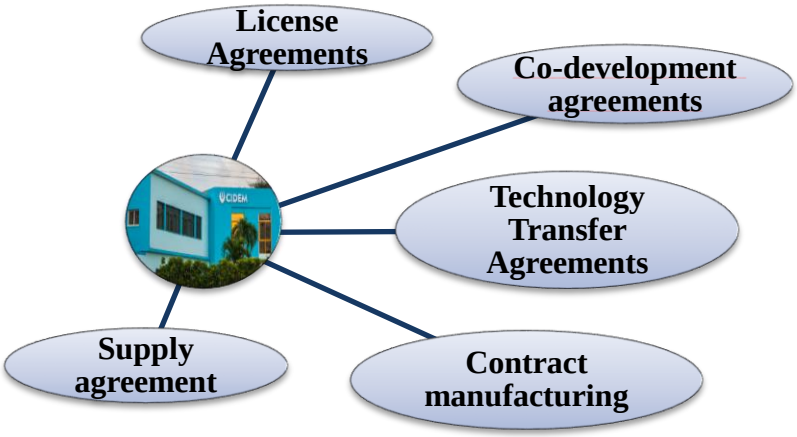


**Figure 3.** Different modalities to consider in business strategies
**Source:** self-made

In recent years, CIDEM has established strategic alliances with companies at a national and international level, providing IP assets that support innovative projects and products under development. Likewise, the main achievements and results are timely published in scientific journals with a High Impact Factor, which places the company in the visibility of the national and international scientific community with very positive indicators within the organization.

In this way, priority is given to the University-Business relationship, with the vision of achieving synergies in the R&D activity and contributing to the economic and social development of the country. Universities are an integral part of the supply chain to contribute to skills and business innovation. However, this supply chain is not a simple linear transaction between supplier and buyer, it is not the acquisition of a single product or service, it is multidimensional, it has to be sustainable and have quality, strength and resilience. These attributes can only be ensured through close collaboration, partnership and understanding between companies and universities.[23]

In terms of Industrial Property management, cooperation mechanisms between research institutions and/or companies in which each one agrees to have and apply certain common policies to all members and even share some services, has the objective of supporting researchers in the process, prior to the request for protection and exploitation of the results of their investigations and train the personnel of each sector in matters related to Intellectual Property to enhance their skills and strengthen both the sector and the system in all its areas.

University-business collaboration is key in the innovation process,[24] an example of this is the creation of the Chemical Synthesis Laboratory at the University of Havana, a joint project between BioCubaFarma and the higher education institution, coordinated by CIDEM since its foundation. in 2018.[25] Likewise, alliances have been achieved with international companies such as the Russian company NEYROS for the co-development of an innovative molecule for the treatment of Parkinson's disease; the technology transfer of different natural products to the MEDILIP company, belonging to the BCF-Cuba group; the CIDEM 113 license to the Guanky-Fukang company in China, among others.

In keeping with this theme, in the international arena, for example, Merck has developed a series of cooperations with other companies, such as research institutes and universities (University of Dundee, University of Edinburgh) for research activity, and this led to the discovery and development of new drugs. Market mechanisms play a central role in the diffusion of technology,[26] as well as strategies to extend patent protection for products under development.[27] The use of the methodology for generating knowledge[27] based on surveillance[28] and intelligence[29] and applied to the health sector through concept maps.[30]

The wide variety of legal contracts corresponds to the business models previously described in **Figure 3**. With respect to the exploitation of IP rights, the possibility of different forms of exploitation in different territories from the same object of ownership is considered. invention. In this way, the Portfolio of Business Opportunities is formed, which includes several modalities for its main research projects, such as:

- Different models are established for the transfer of technology, to always value the IP license as the first option.
- The exploitation and negotiation of the technology generated by the company is directed towards the transfer of bundles of IP rights.
- The possibility of creating joint ventures or start-up companies based on the IP generated by projects is considered.
- Scientific-technical collaboration work with other institutions is promoted, ensuring proper administration of the resulting IP.
- Domestic patent processing management is carried out (not outsourced to third parties): presentation of new applications, processing and maintenance, studies of patent trends, litigation.
- Periodic evaluation of the results of research projects is carried out to determine the right time to present patents (proof of concept).
- Work is being done on the development of an IP portfolio. The intention is the creation of patent networks for exclusively commercial purposes, around the most promising intangibles generated by the company.
- The presentation of applications and the necessary financing for their protection are administered, fundamentally abroad, in a justified manner and that respond to commercial objectives.
- The IP strategy. of CIDEM contemplates the attraction of foreign counterparts that provide us with funds to achieve the maintenance of IP rights.
- An analysis of the patentability of inventions generated by R&D is carried out and their commercial potential is evaluated.
- An assessment is made of the scope of protection of patent claims, case by case. Obtaining strong patents is considered to be crucial to make our products and projects attractive in establishing negotiations.

- Special attention is paid to the identification and protection of undisclosed information.
- The development of platform technologies is promoted, over the development of isolated products.
- The Patent Cooperation Treaty (PCT) route is used, as well as other international agreements that favor savings in the processing of patents.
- The process of designation of territorial coverage of patents is carried out collegiately with the entity's business group.
- Periodic evaluation of the feasibility of maintaining active patent files within the company's portfolio is carried out.
- The use of information contained in patents is promoted as a driving force for R&D&i processes.
- The negotiation of projects is promoted to achieve CODEVELOPMENT, in exchange for geographically limited commercial rights.
- The negotiation of all R&D results is promoted, since this will allow raising research standards (sources of financing, sharing risks, gaining knowledge, experience, knowledge of the regional market, regulatory standards, clinical trials abroad).
- The co-ownership of patents is valued as the best variant in those cases in which the contribution of resources by the partner has contributed to obtaining the object of the invention.
- Priority is given to obtaining patents related to the generation of a new molecule that would give rise to a new product rather than patents related to the generation of new processes, equipment or devices.

## Conclusions

CIDEM gradually transformed from a research-development center to a company that diversifies its products, with the purpose of substituting imports. This diversification is strategically focused on the management of industrial property throughout the product development cycle with the aim of diversifying its markets from innovative products, but without stopping developing, producing and marketing other products with great economic impact and for health, as well as achieving improvements in existing medicines.

CIDEM's business strategy prioritizes the management and administration of IP through qualitative and quantitative indicators. In this sense, a sustained growth is observed not only in the number of objects of invention and the countries in which they are patented, but also in the potential to promote the interest of partners in the co-development of their innovative products.

CIDEM intends to expand and diversify strategic alliances in Cuba and with other countries, particularly with innovation centers, which will allow it to generate and exploit its portfolio of products and projects with greater speed and impact, becoming a high-tech company.

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**Conflict of interests**

The authors declare no conflicts of interest

**Authors contribution**

- Amarilys Casalis Viamontes: Idea, design, analysis and interpretation of the results, drafting and critical review.
- Mercedes Delgado Fernández: Idea, design, analysis and interpretation of the results, drafting and critical review.
- Idania Caballero Torres: Idea, design, analysis and interpretation of the results, drafting and critical review.
- Adolfo José Castillo Vitlloch: Idea, design, analysis and interpretation of the results, drafting and critical review.