Technological development and patent analysis: the case of biopharmacy in the world and in Latin America

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ABSTRACT
Pharmaceuticals, biotechnology, and technological advances are currently a new paradigm with ample potential to provide therapeutic solutions to multiple diseases. The purpose of this study was to survey granted patents related to biopharmaceutical products. The most important results show that most of these inventions are concentrated in the United States, and European and Asian countries, and that US companies are the clear leaders in this area of knowledge, reaffirming its position as one of the most important technological markets in the world. Additionally, the technological classes, established according to search criteria, that have shown the most progress over time has to do with medicinal preparations containing antigens or antibodies, as well as those associated with peptides. Finally, the role of the Latin American market is not relevant for the production of this group of technologies; consequently, it is important to define strategies for their inclusion in countries in the region and to promote cooperation in terms of research and development. This course of action will provide the region with the possibility of increasing technological capabilities that will allow it to innovate within the sector.

KEYWORDS
Biopharmaceutical; granted patents; patent families; IPC; applicants

Palavras-Chave
Biopfarmacêutico; concessão patentes; famílias de patentes; IPC; requerentes

Palabras Claves
Biofarmacéutica; patentes concedidas; patentes; familias de patentes; CIP; solicitantes

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conhecimento, o que reafirma a posição deste país como um dos mercados tecnológicos mais importantes do mundo. Além disso, as classes tecnológicas estabelecidas de acordo com critérios de pesquisa que mostraram mais progresso ao longo do tempo têm a ver com preparações medicinais contendo antígenos ou anticorpos, bem como as associadas a peptídeos. Finalmente, o papel do mercado latino-americano não é relevante para a produção deste grupo de tecnologias; consequentemente, é importante definir estratégias para a sua inclusão nos países da região e promover a cooperação em termos de investigação e desenvolvimento. Esta linha de acção proporcionará à região a possibilidade de aumentar as suas capacidades tecnológicas que lhe permitirão inovar dentro do sector.

Desarrollo tecnológico y análisis de patentes: El caso de la biofarmacia en el mundo y en América Latina

RESUMEN
Los productos farmacéuticos, la biotecnología y los avances tecnológicos constituyen actualmente un nuevo paradigma con un amplio potencial para aportar soluciones terapéuticas a múltiples enfermedades. El objetivo de este estudio fue realizar un estudio sobre las patentes concedidas relacionadas con productos biofarmacéuticos. Los resultados más importantes muestran que la mayor parte de estas invenciones se concentran en Estados Unidos, y en países europeos y asiáticos, y que las empresas Estadounidenses son las claras líderes en esta área de conocimiento, lo que reafirma la posición de este país como uno de los mercados tecnológicos más importantes del mundo. Además, las clases tecnológicas establecidas según los criterios de búsqueda que han mostrado un mayor avance en el tiempo tienen que ver con las preparaciones medicinales que contienen antígenos o anticuerpos, así como las asociadas a péptidos. Finalmente, el papel del mercado latinoamericano no es relevante para la producción de este grupo de tecnologías, por lo que es importante definir estrategias para su inclusión en los países de la región y promover la cooperación en materia de investigación y desarrollo. Esta forma de actuar proporcionará a la región la posibilidad de aumentar sus capacidades tecnológicas que le permitirán inovar dentro del sector.

1. Introduction
The construction of endogenous technological capacities and learning allows for sustained growth conditions, social development, and ad hoc national participation in the global market; in this context, education, science, technology, knowledge codification, investment in intangible assets, and increasing the pace of the innovation process represent sine qua non conditions (Cimoli 2010). In developing countries, however, policies have focused on manufacturing activities and favored the import of machinery and equipment to develop and produce resources in a context of institutional disadvantages relative to OECD member countries (Tybout 2000).
By contrast, industrial policy is defined as a series of actions usually involving incentives, investment, and support from the government. In the United States, for instance, employment creation and exporting potential have determined the country’s industrial policy. Unfortunately, the insertion of Latin America into the sector is still insufficient (Peres and Primi 2009). The concept of industrial policy is no longer the control and intervention mechanism preferred by the state to guide production and commercial activities: the concept is now focused on strengthening innovation dynamics and competencies for countries to insert themselves into an open economy (Bianchi and Labory 2006).

Latin American universities have a major role in the advancement of research and development (R&D) despite the low budget allocated to these activities; however, they employ most of the scientists in the region, and their scientific and technological productivity is remarkable in spite of their limitations (OCTS 2018). Thus, nurturing innovation clusters is a pressing need for the region’s innovation dynamics, but its degree of maturity is still limited, except for a few successful cases. As a consequence, conditions for the development of these clusters need to be implemented, such as the increased provision of venture capital and access to markets, as well as a more significant presence of stakeholders, among other actions (Bortagaray and Tiffin 2005).

On the other hand, given Latin America’s vast biodiversity, the development of phytomedicines is an important area of opportunity for biotechnology in the region. This activity has created association mechanisms between the local pharmaceutical industry and universities with the purpose of creating safe and effective products under adequate quality standards. In this context, however, it is still necessary to balance the multiple interests of the many actors involved regarding shared genetic and biological resources, and biodiversity must be protected by meeting existing relevant regulations, which can be further improved (Calixto 2005; Falkner 2000; Merson 2000; Spök et al. 2008). Therefore, the research question posed by the present study is: what are the current trends of granted patents on biopharmaceutical products in the world and in Latin America?

2. Biopharmacy, the market, collaboration, and intellectual property

Collaborative research and development (R&D) activities within the pharmaceutical industry have led to the creation of shared knowledge databases, sectoral growth, and rapid evolution of the network that supports liaison activities, in addition to a wide dissemination of research projects and techniques at different levels (Orsenigo, Pammolli, and Riccaboni 2001). As a result of its intensive use of biotechnology, the pharmaceutical industry has reoriented its structure and increased its investments in R&D activities (Cockburn 2004). It has also been necessary to introduce intensive technological management into these organizations.

Work carried out by biotechnological firms has two important features: networked dynamics and constant innovation. These two features allow for a better integration of the actors possessing key technologies. Nevertheless, R&D alliances among firms are heterogeneous, and together with the firms’ experience, alliances define the desired results of the creation of new products (Gay and Dousset 2005; Rothaermel and Deeds 2004). Alliances between new firms and firms already established and ready to tackle technological change are frequently observed. Another frequent organizational trend is the formation of...
of alliances between older pharmaceutical companies and younger biotechnological firms (Rothaermel and Boeker 2008).

For example, Deeds (2001) described a positive association between intensive use of R&D and technical and absorptive capacities and profit derived from highly specialized activities in the public pharmaceutical biotechnology sector. The same association has been observed in biopharmaceutical firms, where alliances favor the absorption of capabilities, knowledge, and innovation, as well as higher profits (George et al. 2001). For example, in the case of patents related to nanobiopharmacy, the innovation process is enhanced by the diversity, both geographical and organizational, of all participants, which can be reflected by technological diversification (Zhang and Tang 2018).

However, in the current context, the pharmaceutical industry faces strict regulations, environmental issues, and patent expiration, all of which force the sector to innovate by optimizing costs associated with R&D since, as it is in other technology-intensive sectors, patents play a fundamental role in their activities because costs are extremely high (e.g. development of new biotechnological molecules) (Paul et al. 2010; Grabowski 2002, 2003). In the case of the pharmaceutical industry, the possibility of leveraging R&D from other countries has been shown to depend on firms’ basic capacities to assimilate advancements (Penner-Hahn and Shaver 2005).

The dynamics of the pharmaceutical and biotechnological industries involve a fragmented market, and there is a need to develop a stock of innovative activities and to enter a technological paradigm in which competition is rethought and capacities are created to deal with products and companies traditionally present in the market (Malerba and Orsenigo 2002). It has also been argued that a favorable organizational development framework could be based on cooperation between firms and universities (George, Zahra, and Wood 2002).

The biopharmaceutical industry represents a strategic sector for knowledge-intensive economies, which invest heavily in research and development (R&D). These arguments are based on a paradigm of integration between biotechnology and pharmaceutical science. Moreover, biopharmacy relies heavily on scientific progress, and in countries such as the United States, it is an area of economic development that helps to compensate the country’s global competitiveness against other sectors in Europe and Asia (Sonmez 2017). In contrast, there are high-cost and important biopharmaceuticals that are not yet manufactured in economies as large as Brazil’s, but producing them could bring higher technological capabilities to Latin America. Hence, the importance of studying the actors and dynamics around this type of patents (Madeira, Borschiver, and Pereira Jr 2013).

The role of intellectual property (especially patents) has thus been recognized as a mechanism to drive innovation in the area of biopharmaceuticals, where a major challenge is how to accelerate the creation of innovative therapeutic solutions. In this regard, although there is a significant investment in R&D, the development of generic drugs is another challenge concerning prices and competition (Grabowski, DiMasi, and Long 2015). Although the role of patents in the biopharmaceutical industry is to encourage and guarantee the profitability of new inventions, the important role of regulatory bodies such as the US Food and Drug Administration (FDA) should not be overlooked if firms are to offer the market-safe and effective products while guaranteeing compliance with regulatory requirements to the population (Eisenberg 2003).
3. Biopharmacy in Latin America: what are the region’s challenges and opportunities?

In the case of Brazil, the most remarkable advancements have taken place in the health-care sector and have involved firms, the government, and institutions looking to innovate (Rezaie et al. 2008). In terms of safety and effectiveness, the production of biosimilar products in Latin America is challenging. Although these products are attractive due to their lower costs, they have been compared to innovator products, their regulation varies across countries, and the approval of some products has been diverted from the orthodox pathway; therefore, transparency must be increased, and the current efforts to build regulatory frameworks must move forward to a definitive stage (Mysler and Scheinberg 2012). In sum, the aim is to bring safe and effective products to the market.

The Mexican pharmaceutical market has grown rapidly, and it is the largest in Latin America (Hayden 2007). In the case of the biotechnological sector, Mexico is characterized by an intellectual property framework clearly in favor of transnational corporations. For its part, the industry is scientifically and technologically underdeveloped and is heavily dependent on imported scientific materials and equipment for their operations. It is also characterized by meager R&D investment and a lack of entrepreneurial incentives, as well as scant collaboration with the public sector (R&D institutions and universities). Concerning the pharmaceutical industry specifically, the market is dominated by large local groups and transnational corporations that often absorb local firms; these groups and corporations have no incentive to innovate in Latin America because their intangible assets are provided and managed by their headquarters in developed countries.

Although firms in the Mexican pharmaceutical biotechnology industry could complement their capabilities by cooperating with R&D institutions, this task is not easy due to their limited experience in the field of innovation. In addition, trade openness resulted in a loss of capabilities, knowledge, and skills, and the growth of the national pharmaceutical sector was consequently hampered. With some exceptions, there is an absence of a consolidated countrywide industry that can overcome the challenges of developing generic drugs and biosimilar products, and innovative therapies are specially scarce. In general, there is no evident interest in building technological capacities in the field of biotechnology. As a result, its role as one of the most advanced developing countries has largely depended on the creative imitation of biosimilars with the final goal of entering the pharmaceutical industry value chain (Stezano 2019).

Patents are a fundamental element of the pharmaceutical industry in developed countries. However, this model tends to elevate prices due to the considerable financing required to carry out the research and development (R&D) necessary to design new products. In some developing countries, the production of pharmaceuticals is considered essential, and the patenting of these products may not be seen as an appropriate mechanism. This situation has even led them to deny intellectual property protection for pharmaceutical products (Barton 2004). In fact, in the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreements, tensions are observed concerning patent protection within the framework of these agreements because the accessibility of medicines is considered a necessity in developing economies, despite the fact that...
under these agreements, there is the possibility of granting compulsory licenses that must be adequately compensated (Scherer and Watal 2002).

Understandably, the TRIPS responds to the interests of large corporations and developed economies. These actors influenced and lobbied even before the formalization of the agreements under the strong leadership of the United States and other industrialized economies. The large pharmaceutical firms were the main beneficiaries of this initiative, which was commercially disadvantageous for developing economies. Therefore, although intellectual property seeks to encourage the commercialization of inventions, generic drugs could generate schemes that translate into social value and could be a path for the inclusion of the most economically challenged population sectors (Sell 2007; Correa 2001; Smith, Correa, and Oh 2009). National governments and local companies in the region, together with all relevant actors, must converge to formulate public policies and comprehensive solutions to provide the best alternatives for the context and needs of each country.

Latin America has increased its scientific production in the field of biotechnology, but not as fast as Southeast Asia. On the other hand, the region is far from the frontier of knowledge in the field, which shows its lack of capacity to introduce innovative drugs into the market, except for a few cases. However, some Latin American countries do have the capacity to produce drugs that no longer have intellectual property rights. Three cases stand out in the region due to the size of their pharmaceutical industries: Argentina, a leader in biotechnology for human health; Brazil, which has made significant progress in the production of bioequivalent generics by combining the efforts of Brazilian and foreign companies; and Mexico, which has an important potential for the production of bioequivalent drugs based on a local manufacturing model. This allows for the construction of a scenario integrating both innovative products and those that imitate the original molecule, but always stressing innovation frameworks (Niosi, Bas, and Flores Amador 2013).

Globally, the market for biosimilars is becoming more important, and in Latin America, simplified regulatory frameworks are being worked out to promote the development of this sector, led by Brazil (Azevedo et al. 2012). Such arrangements are increasingly attractive because the market value of biosimilars is estimated at billions of dollars and there is a considerable number of patents that, when expired, can be used to manufacture these products; although, of course, it is necessary to continue working on the regulations required to guarantee safety, quality, and the comparability of the biosimilars with the innovative molecule (Ibarra-Cabrera et al. 2013). It is, therefore, necessary for developing economies such as Latin America’s to adequately plan for the continuous development of these products, but at the same time it is essential to invest more heavily in R&D to compete globally with innovative products produced in the region.

Similar to South Africa, China, and India, Brazil is seeking to enter the market of innovative biopharmaceutical products and has demonstrated progress in this direction (Rezaie et al. 2012). In the case of Mexico, despite its efforts toward the construction of scientific capacities and other actions for the advancement of biotechnology, poor results are observed in terms of accumulated technological capabilities and successful academy-industry linkages, which can be explained largely as a consequence of the inadequate execution of policies and programs for those purposes (Amaro Rosales and Natera Marín 2020). Nevertheless, the region’s biopharmaceutical sector does have success stories, such as Cuba’s whose population has enjoyed the benefits of these
technologies despite the country’s severe limitations (Arencibia-Jorge et al. 2016). However, the Latin American biosimilars market is undergoing significant development in terms of regulation. Alongside Brazil, Argentina and Mexico are the most relevant producers. The region’s biosimilars market value is expected to increase significantly in the near future, and governments and populations hope for a significant reduction in sales prices (Rathore and Bhargava 2021).

However, it should be borne in mind that Latin American countries are intensive users of foreign technology, and in general, the advanced economies and their companies are the main beneficiaries of the operation schemes contained in the TRIPS; therefore, the main purpose of strengthening intellectual property rights is to secure the market power of the advanced economies (Goretti and Salce 2020). Of course, the intellectual capital, knowledge, and learning linked to innovation are often associated with competitiveness, and these elements are necessary in a systemic analysis aimed at the formulation of policies designed to stimulate innovation and industrial development in a region (Solleiro and Castañón 2005; Solleiro, Gaona, and Castañón 2014). Finally, it is also clear that the link between intellectual property via medical patents and the human rights that guarantee access to health has to be discussed in more depth, and balanced actions with a greater emphasis on developing economies must be carried out (Cullet 2003).

4. Materials and methods

Patent search related to biopharmaceuticals was carried out using the Lens platform (2020). This database was chosen because of its pertinence for mapping innovation: it integrates the databases of the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), the World Intellectual Property Organization (WIPO), and IP Australia. Additionally, the platform has a technological structure that can be used to systematize patent searches and retrieve information efficiently.

As an open platform, it contributes to making the dynamics of knowledge generation transparent and promoting the inclusion of academic and economic communities in this process. Currently, its database includes more than 125 million patent registrations, as opposed to the 92 million patent documents contained in WIPO’s Patentscope. The patent search was based on the definition of the following variables, as well as their respective criteria, shown in Table 1.

The technical criterion used to search for patents considered the keyword and the patent classifiers as variables, and Boolean operators were used as follows:

\[(\text{biopharma}^* \text{ AND (classification ipcr:}(\text{A61K35/00}^* \text{ OR classification ipcr:}(\text{A61K38/00}^* \text{ OR classification ipcr:}(\text{A61K39/00}^* \text{ OR classification ipcr:}(\text{C07K14/00}^* \text{ OR classification ipcr:}(\text{C07K16/00}^*))\right)\big)

Table 1. Search variables for granted patents related to biopharmaceuticals.

| Variable            | Criterion                                                                 |
|---------------------|---------------------------------------------------------------------------|
| Keyword             | Biopharma* in all fields of the patent.                                   |
| Search period       | Application registration date: January 1, 2010 through June 1, 2020.       |
| Type of document    | Granted patents grouped by family.                                       |
| Patent classifiers (IPC) | A61K35/00, A61K38/00, A61K39/00, C07K14/00 and C07K16/00. |

Source: Elaborated by the authors.
Patents containing the biopharma lexeme were included in the search, including variants (such as singular and plural); another criterion was the possibility of the lexeme to be associated with any of the five classifiers that register inventions based on biopharmaceuticals. Concerning the search period, granted patents were considered according to their application date, which is the moment when the administrative and technical legal process is formally initiated until the patent is granted. In consideration to this criterion, the obtained results consider the evolution of the entire procedure and the evaluation over time based on application date.

Similarly, a patent application shows the country where the document is registered under the priority criterion. Based on this criterion, it is possible for the same document to be registered in different countries. This multiplicity of registries is what constitutes a patent family; therefore, the statistical multiplication of the same patent can be avoided if counting is carried out considering patent families. The country where the patent priority was registered and the applications in one or more other countries were also examined because priority registration is usually carried out in the country where the applicant develops their technological capabilities, whereas subsequent applications correspond to the registry in geographical areas where the patent owner identifies a commercial exploitation interest.

The report is based on geographical location, including priority date and subsequent registers, and it provides information on technological relevance and possible commercial activity in the territories where these processes take place. The search period (2010–2020) was selected because it has been the most dynamic in biopharmaceutical patenting activity, largely as a consequence of decreased productivity in pharmaceutical research in the late 1900s and early 2000s despite the enormous expenditure on research and development made by firms and policies aimed at merging companies as a mechanism to optimize resources and competition mechanisms and in view of the gradual growth of biotechnology within this field of knowledge within this period of time (Gassmann, Reepmeyer, and Von Zedtwitz 2010). Although the emergence of the biotechnology industry dates back to the 1970s, it is during the present century that it has become a converging field of knowledge together with other disciplinary areas of significant impact on national growth and development in several countries, configuring a development model known as bioeconomy (Rodríguez, Mondaini, and Hitschfeld 2017) where biopharmaceuticals represent a productive area of interest.

Patent classifications were defined based on those that, according to Friedrich and Van Beuzekon (2018), include biotechnology patents. This proposal is an update of the original one by the Organization for Economic Co-operation and Development (OECD) in 2005, when the organization formulated a structure for the compilation of biotechnology statistics based on the evolution of the activity itself. In this regard, the proposal based on the biotechnology patent report provides a more indicative than exhaustive taxonomy. This is due to the dynamism with which the biotechnology field evolves. Based on these considerations, we used the classifiers and definitions set forth by the WIPO (2020) for the review of biopharmaceutical patent statistics (see Table 2).

5. Results

Based on this search, we identified 1658 patents grouped by family. This study showed the behavior of patent activity over the course of one decade as follows: (a) the...
number of patent applications and publications; (b) countries where patents are registered under the criterion of priority and subsequent applications; and (c) patents, according to their main biopharmaceutical classifier.

### 5.1. Granted patents by year of application and publication

Figure 1 shows the number of biopharmaceutical patents granted during the period from January 1, 2010 to June 1, 2020, by application year. The annual number of patents is shown on the left (see Graphic a), whereas the cumulative amount for the period is shown on the right (see Graphic b). According to this information, an average of 213.7 patents applications were submitted per year from 2010 to 2016, and the sum of this documents during the period 2010-2016 represents 90.23% of the patents granted in the 2010-2019 period with information as of June 1, 2020.

It is important to mention that the patent document’s publication date corresponds to the year in which the first application was made public, so that only granted patents were reported; Figure 2 shows the increase in the state of the art over time as a function of granted patent publication date.

Graphic A shows the annual number of patent publications and graphic B their accumulated number. Remarkably, as of June 1, 2020, or halfway through the year, 167 granted patents had already been published; a total of around 400 patents could be

### Table 2. Biopharmaceutical patents according to the International Patent Classification (IPC).

| IPC Code | Description                                                                 |
|---------|-----------------------------------------------------------------------------|
| A61K    | “Preparations for medical, dental, or toilet purposes …”.                   |
| A61K35/00 | “Medicinal preparations containing materials or reaction products thereof with undetermined constitution …”. |
| A61K38/00 | “Medicinal preparations containing peptides …”.                            |
| A61K39/00 | “Medicinal preparations containing antigens or antibodies …”.             |
| A61K48/00 | “Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy …”. |
| C07K    | “Peptides …”.                                                             |
| C07K14/00 | “Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof …”. |
| C07K16/00 | “Immunoglobulins …”.                                                      |

Source: Authors’ elaboration based on WIPO (2020).

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![Figure 1](image1.png)

**Figure 1.** Patents granted related to biopharmaceuticals by application year. Source: Authors’ elaboration based on Lens (2020).
expected for the year if such a pace is maintained. Thus, between 2012 and 2019, the growth rate of patent publications increased 54.9% per year, which seems to indicate a period of expansion of the state of the art in biopharmaceuticals. With all this information, an accumulated number of 1891 granted patents could be expected by the end of 2020 for the period from 2011 to 2020.

5.2. Patents related to the production of biopharmaceuticals by country

Granted patents by country were grouped using two criteria: (1) patents by priority related to the first patent application filed in a specific office, which can be used to register applications in other countries and regions, and (2) patents registered with priority in one country and subsequent registrations form patent families; consequently, family counting is an adequate way to identify the number of granted patents because the family refers to the same invention. However, identifying the country of priority and subsequent patents helps recognize patterns of knowledge flows between countries.

In general, the country where the priority application is submitted corresponds to the geographical dimension in which the invention was made; therefore, subsequent applications correspond to markets where the invention manages to find a potential market in line with the innovative company’s commercial strategy. In this regard, the distinction between the two provides a way to understand the supply-demand dynamics of technological inventions, as in the case of biopharmaceuticals.

Figure 3 shows the distribution of patents granted by country of application. Graphic A shows the predominance of the United States in terms of biopharmaceutical technical capabilities; a little more than two thirds of all granted patents related to biopharmaceuticals were registered in that country under the criterion of priority. The motivation to commercially exploit patents in the United States is increasing (graphic b); patent applications applied for in a given country and then applied for in the United States account for 81.1% of the total number.

Figure 3 shows a second fact: capabilities are dispersed among the different countries, but they do not necessarily represent territories where biopharmaceuticals are sought to
be marketed in the same proportion. This is notably the case in countries from the European Union (EU) (Denmark, Sweden, and Germany) and the United Kingdom; graphic A shows them in the list of countries where most patents are registered under the priority criteria (11.6% of priority applications), but this is not the case when patent application data are disaggregated for countries after the priority application, as shown in graphic B (8.7% of applications after priority).

A third fact, derived from the previous information (Figure 3), is that while patent priority occurs in 30 countries, subsequent registration is limited to 15 countries. In other words, technological competence to develop patents related to biopharmaceuticals is observed in 30 countries, but in terms of patent families (the commercial appeal of protected inventions), they are concentrated in 15 countries.

**5.3. Patents related to biopharmaceutical products according to the CPI**

A patent can combine different technologies; therefore, it can be included in more than one classification. Thus, a total of 3340 records were obtained from the 1658 patents identified, which combine the different categories reviewed in this study. In fact, a patent was identified to fall within 115 categories and three of them fell within the proposed classifiers.

A total of 471 patents (28.4% of 1658 patents) were identified as having one of the main classifiers associated with biopharmaceuticals. Therefore, as can be observed in Table 3, five patents (0.3% of 1658) have category A61K35/00 as their first classifier; 179 (10.8%) correspond to classifier A61K38/00; 124 (7.5%) correspond to classifier A61K39/00; 40 (2.4%) to classifier C07K14/00, and a total of 123 (7.4%) to classifier C07K16/00.

As can be appreciated in Table 4, when considering combinations of classifiers identified for patents related to biopharmaceuticals, 40% of the patents contain classifier A61k39/00; 29.2% contain A61k38/00; 19.1% contain C07k16/00; 10.5% contain C07k14/00, and the remaining 1.3% contain A61k35/00. The present study shows that the development of biopharmaceuticals is strongly associated with the technological development of antigens, antibodies, peptides, peptide-containing drugs, and immunoglobulins.
Therefore, although A61K38/00 is the most important classifier among the five considered in this study, there are more patents related to biopharmaceuticals classified under A61K39/00. Thus, an alternative way to consider the weight of the classifiers in biopharmaceutical patents is to study their evolution over time since it shows the long-term behavior of this type of patent depending on its classifiers (see Figure 4).

In this way, it is possible to observe that the A61J38/00 classifier had accumulated the largest number of patents until 2016. However, as of 2017, the number of patents under classifier A61K39/00 increased significantly; as previously stated, the classifiers used for this search were combined 3340 times in the 1658 patents, and 43.1% of these

### Table 3. Patents by classifier.

| Classifier     | Total | Percentage of total |
|----------------|-------|---------------------|
| A61K35/00      | 5     | 0.3                 |
| A61K38/00      | 179   | 10.8                |
| A61K39/00      | 124   | 7.5                 |
| C07K14/00      | 40    | 2.4                 |
| C07K16/00      | 123   | 7.4                 |

Source: Authors’ elaboration based on Lens (2020).

### Table 4. Combinations of patent classifiers.

| Classifier     | First classifier | After the first classifier | Total | % of total |
|----------------|------------------|----------------------------|-------|------------|
| A61K35/00      | 5                | 20                         | 25    | 1.3        |
| A61K38/00      | 179              | 404                        | 583   | 29.2       |
| A61K39/00      | 124              | 676                        | 800   | 40.0       |
| C07K14/00      | 40               | 170                        | 210   | 10.5       |
| C07K16/00      | 123              | 259                        | 382   | 19.1       |

Source: Authors’ elaboration based on Lens (2020).

Therefore, although A61K38/00 is the most important classifier among the five considered in this study, there are more patents related to biopharmaceuticals classified under A61K39/00. Thus, an alternative way to consider the weight of the classifiers in biopharmaceutical patents is to study their evolution over time since it shows the long-term behavior of this type of patent depending on its classifiers (see Figure 4).

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![Figure 4. Evolution of IPC classifiers. Source: Authors’ elaboration based on Lens (2020).](image-url)
combinations corresponded to classifier A61K39/00. Oppositely, 1.3% corresponded to the A61K35/00 classification, which places it in the last position in this ranking.

6. Patents related to biopharmaceuticals by applicant and classifier

Table 5 shows the ten companies with the most patents related to the production of biopharmaceuticals. Of the total number of identified patents, 3.3% corresponds to Immatics, the company with the highest number of granted patents. Taken together, these 10 companies account for 17.9% of the 1658 identified patents. This percentage of accumulation indicates that, in the biopharmaceutical industry, research and development capabilities are distributed among multiple actors. Additionally, the Top Ten highlights that some companies have a pharmaceutical origin (Novartis and UCB Biopharma, whose incursion into the biopharmaceutical sector took place in the mid-1990s and the beginning of the twenty-first century), while the rest are companies that emerged from the bioeconomy paradigm (especially biotechnology with applications for health care using biopharmaceuticals). Among this group of companies, the strong leadership of the United States is remarkable because only four of them are from other countries: (1) Immatics Biotechnologies GmbH, from Germany, (2) UCB Biopharma Sprl, from Belgium, (3) Pangu Biopharma, from Hong Kong, as a subsidiary of Atyr Pharma, from the United States, and (4) Novartis, from Switzerland.

Additionally, as can be appreciated from this information, the principal patent applicants are companies although there are also universities and research institutions, most of them from the United States. Universities and research institutions account for 3.2% of granted patents, in most cases together with a pool of researchers and/or companies. Another aspect to consider from this information is the identification of technological capabilities among companies by classifier (see Table 6). The weight of Immatics Biotechnologies GmbH in three of the five classifiers is noteworthy. However, the category A61K35/00 represents a marginal competition for this organization because only one patent was found for this classifier. Companies present differences in terms of capabilities; while Immatics Biotechnologies GmbH has more patents from the A61K39/00 category, Abbvie does so in the C07K16/00 category and Atyr Pharma in A61K38/00.

6.1. Biopharmaceutical patents in Latin America

Of the original patent database (1658), four of them were granted in Latin America (LA), three in Mexico, and one in Nicaragua, which highlights the scarce protection

Table 5. Main holders of granted patents.

| Applicants                          | Grouped by family |
|-------------------------------------|-------------------|
| Immatics Biotechnologies GmbH       | 52                |
| Abbvie Inc                          | 38                |
| Alderbio Holdings Llc               | 35                |
| Genentech Inc                       | 33                |
| UCB Biopharma Sprl                  | 32                |
| Novartis Ag                         | 31                |
| Atyr Pharma Inc                     | 23                |
| Pangu Biopharma Ltd                 | 19                |
| Amgen Inc                           | 19                |
| Regeneron Pharma                    | 15                |

Source: Authors’ elaboration based on Lens (2020).
afforded to these inventions in Latin America. In fact, the four granted patents correspond to families whose parent patents were registered in the United States. Table 7 shows that granted patents correspond to inventions whose priority registration was awarded to American companies and that the registration was extended to Latin America as patent families during the technological commercialization process; these patents are related to cell production, use of trialkyl cationic lipids, and metabolic disorder treatment.

As can be appreciated in Table 7, except in the case of one patent, applications were first submitted in Latin American offices instead of other countries that award property status, such as Australia and Spain; therefore, in the case of the first (US 201462031063), third (US 201261602990), and fourth (US 201462073737) patents, the publication date is earlier (two patents in Mexico and one in Nicaragua) than in Australia (two patents) and Spain (one patent). Again, these results reveal the scarce interest of biopharmaceutical companies to patent in Latin America and, consequently, this may help to explain the low commercial interest of the region and scarce regional capabilities to develop and produce biopharmaceuticals.

We conducted a more rigorous complementary search of patenting activity in Latin America considering the following countries: Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Peru, Dominican Republic, and Uruguay. The original search formula was modified to include the option of identifying patents granted in English, Portuguese, or Spanish exclusively in the region. Therefore, the formula used in the platform was:

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((BIOPHARMACY OR (BIOFARMA*)) AND (classification_ipcr:(A61K35/00*) OR classification_ipcr:(A61K38/00*) OR classification_ipcr:(A61K39/00*) OR classification_ipcr:(C07K14/00*) OR classification_ipcr:(C07K16/00*))
```
Four patents were identified based on these criteria: two granted in Brazil, one in Mexico, and one in Cuba. These patents were related to the preparation of glycopeptide phosphonate derivatives, the use of trialkyl cationic lipids, glycopeptide compound (pharmaceutical composition), and macrocyclic inhibitors (hepatitis C virus replication). Patents granted in Brazil and Cuba correspond to inventions whose priority was requested before 2010 in the United States; these patents were thus not found in the original search. The one Mexican patent corresponds to the original patent database, and its applicant was Arbutus (see Table 8). Additionally, 22 patent applications were identified, 16 of them registered in Brazil; fourteen of these 22 applications corresponded to UCB Biopharma. These applications were awarded priority by the United Kingdom (11 registrations), the United States (8), European countries (two), and Korea (one).

### 7. Conclusions

The new paradigm represented by the integration of the pharmaceutical industry and biotechnology is a central element in the development of new therapeutic and prophylactic solutions and diagnostic applications that allow for innovative approaches and solutions to treat multiple diseases and ailments in which the pharmaceutical sector’s success has traditionally been limited. Remarkable scientific and technological advances have occurred over the past decades, and the transversality of biotechnology has allowed for a wide range of solutions in different areas such as health care, agriculture, food production, and environmental protection, among others. Additionally, advances in other disciplines such as microbiology, virology, genetics, and molecular biology, to name a few, have resulted in new medical applications based on the use of biotechnology that reveal important and unprecedented progress.

The development of molecules derived from biotechnological processes for the biopharmaceutical industry is focused on the design of innovative biological drugs, therapeutic options, and vaccines. It is also necessary to consider other sub-areas such as nanobiopharmaceuticals, which represent an alternative with important potential to provide cutting-edge solutions. In this regard, different issues related to intellectual property protection, sanitary regulation, biosecurity, standardization, and ethics must be addressed with the purpose of bringing effective and safe products into the market. As a consequence, developing countries must strengthen all of these functional elements in order to evaluate and verify the available technological supply, which comes mainly from developed economies; at the same time, it is necessary to guarantee that their endogenously generated developments can comply with all relevant requirements.

**Table 8. Patents granted in Latin America (part two).**

| Applicant                          | Priority data          | LA Publication data         |
|-----------------------------------|------------------------|-----------------------------|
| Theravance Biopharma Antibiotics  | 2001 US 31483101 P     | 2016 BR PI0211997 B1       |
| Arbutus Biopharma                 | 2012 US 201261602990 P | 2018 MX 356904 B           |
| Theravance Biopharma Antibiotics  | 2001 US 32888901 P     | 2018 BR PI0213154 B1       |
| Biopharma-Intermune Array         | 2005 US 70219505 P     | 2012 CU 23794 B7           |

Source: Authors’ elaboration based on Lens (2020).
According to the results of this study, the global biopharmaceutical industry is showing substantial progress. These technological developments are protected mainly in economies such as the United States, European and Asian countries, although it is of course necessary to extend this type of analysis to other databases and languages and use other search criteria depending on the desired specificity and depth of future studies. However, for Latin America, this first approach highlights the importance of working on strengthening R&D collaboration mechanisms, increasing technical and absorptive capacities and R&D investment, and defining an industrial policy for the region to take a competitive position within this market sector.

In particular, Latin America faces several challenges: it will be necessary to attract foreign investment in this sector and strengthen the development and absorption of technological capabilities, and these countries must take advantage of their biological richness and highly specialized human resources to seize opportunity areas such as the development of phytopharmaceuticals. This course of action will increase options in the region, which should continue developing in conjunction with the R&D of the most important technological advances (such as antigens, antibodies, peptides, and immunoglobulins) because these innovations have the highest market demand. It is also evident that this group of countries will have to continue working on the development of biosimilar products in order to increase the range of options at more competitive prices by trying to favor these economies and make them available to a larger part of the population and seize the benefits derived from these applications.

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