The Strategic Role of Sino-U.S. Bilateral Investments in China's Advance in the Field of Biotechnologies

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Abstract: Recognizing from a very early stage the capacity of advanced technologies (and of biotechnologies in particular) to fundamentally change the economy, the geopolitics, and the society of the 21st century, Chinese authorities placed the development of the biotechnology sector among the top national priorities and, as a result, adopted political strategies and programmes meant to help achieving this goal. In the context of the "Made in China 2025" Strategy, which, among others, sets out China's goal of becoming a world leader in the field of life sciences and of reducing the country's technological dependency, our article sets out to present the evolution of the Chinese investment policy over the recent years, which was focused on finding an optimum synergy between guiding foreign direct investment (FDI) in line with the country's own sectoral modernisation plans, and targeting its own outward direct investment (ODI) in accordance with the same interests. With the U.S. being the global biotechnology leader and, as a result, China's main competitor in the race for global supremacy in the field, our analysis will focus on highlighting the role and importance of bilateral China-U.S. investment flows for the development of the Chinese biotechnology sector.

Keywords: biotechnologies, China, U.S., foreign direct investment (FDI), outward direct investment (ODI)

JEL classification: L65, O30, O33

1 Introduction

The spectacular achievements seen by the scientific world over the last half of a century – resulting from the unprecedented international progresses in a series of fundamental fields (e.g., genetics, molecular biology, biochemistry, embryology, cellular biology, enzymology, etc.) – and their subsequent transformation into productive processes[1] are among the essential factors that revolutionised modern-era biotechnology. As such, a succession of considerable scientific discoveries – among which, for example, the decoding and editing of the genetic code of live organisms and the subsequent remarkable applications that enabled the creation of synthetic genome organisms – crucially changed the perspectives on the applicability of the results of life science research and on the degree of complexity of the generated products, favouring a worldwide transition to a higher level of knowledge in the field of bioeconomy[2].

Once the immense potential and the transforming capacity of 21st century biotechnology for economic development and for geopolitical and societal evolution were globally recognized, government authorities and national leaders began approaching this field as a vital tool for the optimum implementation of processes such as: i) the combatting and eradication of diseases; ii) the modernisation of agricultural practices and of the food industry; iii) the strengthening of capacity for non-conventional energy generation and improved environmental protection; iv) the strengthening of military power (Greenwood, 2013). As a result, given the relevance of contemporary biotechnologies for the development of individual economies, for the preservation of the population's optimum health and increased wellbeing, for the improvement of food supply chains and for perfecting the use of renewable energy sources, all the countries of the world adopted and implemented ample national programmes that sought to create a robust internal biotechnology sector capable of supporting the

[1] As a result of the interconnections established at an interdisciplinary level with other scientific branches with practical applicability, such as chemical engineering, computer science, robotics, information sciences, etc.

[2] Bioeconomy brings together economic activities that are based on the results of research and innovation in the field of life sciences and biotechnology which became possible due to technological progresses made in related fields such engineering and information sciences (US National Academies of Sciences, Engineering, and Medicine, 2020).

increased dynamics of the medical and related sectors, as well as of local agriculture and industries (Dahms, 2004; Martin, et al., 2021).

Although a relatively late entry on the global science and technology (S&T) stage, and initially seeking merely to equal the performances that Western economies had already demonstrated in the field, China understood from a very early stage the stringent need to accumulate a knowledge capital that could enable it to achieve sustainable economic growth based mainly on innovation. As a consequence, Chinese decision-makers prioritized innovation in the national development plans and, in time, gradually consolidated this goal by including increasingly ambitious objectives which, during the recent years, culminated in assuming more and more complex targets that were meant to reduce the country's technological dependency on advanced countries (towards year 2035) and to achieve global supremacy in the field of science, technology and innovation (S&T&I) by mid this century (Cao, 2012; Xi Jinping [2015], quoted by Atkinson, [2015]).

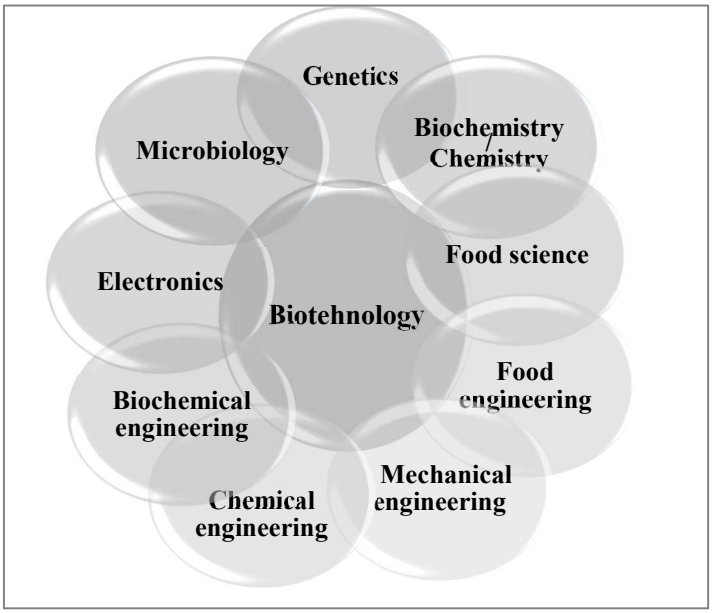
Having recognised the strategic importance of the biotechnological field for the prosperity of the national economy, and having placed it at the heart of the ample industrial development plan *Made in China 2025* (MIC 2025; of 2015) and of all the subsequent programmes. Hence Chinese government authorities undertook complex actions that sought, among others, to increase the degree of local innovation and to reach internal technological self-sufficiency, as first steps towards a future global domination in the biotechnological field.

China's quick transformation into an important player in the field of biotechnology, but also a series of policies applied for achieving the intended goals – including the national investment policy – are seen as real challenges for many of the industrialized countries (Amighini, 2019), in particular for the U.S., the traditional global leader in this sector.

The definition of the working notions

As we stated, biotechnology is not founded on one single scientific development, but it rather represents the result of the coming of age of several branches launched decades (and even centuries) ago or, as Smith J. E. noted (1996), it represents "*the industry specific for the 21st century, as the industries based on physics and chemistry characterised the 20th century*". We can therefore conclude that biotechnology does not capture one individual activity, emerging instead from the interaction of a spectrum of scientific disciplines (Figure 1). Its complexity derives from its very multidisciplinary nature, which results from the integrating use of biochemistry, microbiology and engineering sciences in order to obtain technological applications for the production and service sector (US Congress - Office of Technology Assessment (OTA), 1984; Bu'Lock & Kristiansen, 1987; Bhatia, 2018).

Figure 1: The interdisciplinary nature of biotechnology



Source: Author's graphical processing based on Smith J. E. (1996).

To be able to better understand the degree of complexity we refer to, as well as the fields of application and the scope of the biotechnological sector, we found it useful to provide a brief overview of some of the most representative definitions that were given to biotechnology, as that there is no unanimously accepted definition at international level (Box 1).

Box 1: Compendium of biotechnology definitions

⇒ *"Biotechnology combines natural and engineering sciences to develop applications that use biological systems – e.g. microbial, vegetal, animal cells and parts thereof, or molecular analogues – in bioindustries, in order to obtain goods and services"* (European Federation of Biotechnology [EFB], 1999, p. 1).
⇒ *"Biotechnology is the application of scientific and engineering principles in the processing of materials under the action of biological agents, in order to produce goods and services"* (OCDE, 1999) (the initial OECD definition); *"Biotechnology is the application of scientific technology on living organisms and on parts, products and models thereof in order to modify living or non-living materials for the purposes of obtaining knowledge, goods and services"* (OCDE, 2001)[3] (the basic OECD definition);
⇒ **As for the definitions of biotechnology used in China**, to a large extent they took explanatory elements from the universally accepted definitions provided by the international organisations or by the relevant authorities in the field in developed countries and adapted them to the specific national pragmatism (Zhe, Lifeng, & Xingua, 2009). As exemplified by Zhe, Lifeng and Xingua (2009), biotechnology research reports prepared by the bodies subordinated to the Chinese central government use two definitions which are considered to be representative at national level: a) *the first* of these, proposed by the *National Development and Reform Commission (NDRC),* describes modern biotechnology as "*[…]the result of all the activities that are based on the progresses made in the field of molecular biology, which includes genetic engineering, protein engineering, cellular engineering and zymotic engineering (zymotechnics)"* (the NDRC Department for High-Tech Industries, 2004); b) *the second,* proposed by the Ministry of Science and Technology (MOST), considers biotechnology as *"a complex system that uses individual cellular and molecular biocomponents" to "[…] solve existential problems or generate products that are useful for achieving this objective, to transfer/reconstruct the specific characteristics/properties of plants, animals and microorganisms, as well as to produce goods and services".*

Source: Author's selection based on the bibliography quoted in the box

Brief overview of the role and importance of biotechnologies in the contemporary era

After the end of World War II, which was a major obstacle for scientific research and discoveries, once the structural model of the human DNA was deciphered, it was possible to proceed to the modern stage of biotechnology, which has unlimited applications and an enormous potential for mankind's wellbeing, in a multitude of fields (Box 2).

Box 2: Applications of modern biotechnology (synthesis)

"Green" biotechnology (with applications in agricultural processes)	• A sub-field that comprises the development of certain genetically modified (trans-genic) plants or animals, activities pertaining to the genetic engineering of plants, the manipulation and use of microorganisms in order to facilitate crop growth, the production of fertile and resilient seeds, etc.
"Red" biotechnology (with applications in the medical field)	• A segment that includes complex medical procedures: the use of organisms to manufacture new medicines or the use of stem cells to replace/regenerate deteriorated tissues or regenerate certain organs.
"Blue" biotechnology (with applications in the field of aquatic and marine biology field)	• An area of biotechnology that uses the diversity found in marine environments, including the form, structure, physiology and chemistry of marine animals. It is a field that uses marine bio-resources as a source for biological applications.
"White" (or "grey") biotechnology (with applications in industrial processes)	• It entails the use of enzymes or microorganisms in various industries in order to obtain chemical and pharmaceutical products, food ingredients, energy, paper and renewable biofuels.

Source: Author's synthesis based on Bhatia (2018).

[3] Although in 2018, the OECD updated the list of biotechnology sub-fields to include the latest progresses in the field, the basic definition of biotechnology was not revised (Friedrichs & van Beuzekom, 2018).

2 Foreign direct investment – strategic instruments for the development of China's biotechnology sector

The propagation of technology transfer through guided inward direct investment

In light of the transforming policies adopted by China over the recent years and of the change determined in the country's development direction by the strategic guiding principles they contained, ample dissentions emerged on the international stage in relation to how Chinese national authorities treated foreign investing companies. As such, several analysis reports published by the U.S. and European bodies entrusted with monitoring global investment flows [e.g. European Commission, (2019); U.S. Trade Representative (2018); White House (2018)] note that there are regulations and barriers that restrict the access of foreign direct investment (FDI) on the Chinese market – e.g. insufficient protection of intellectual property rights (IPR) in the advanced technological industries (including in the case of biotechnologies), quasi-monopolies of large state-owned enterprises in the strategically important sectors, discriminatory public procurement procedures in the state-controlled fields, etc. –, and that these are used to guide the transfer of new technologies on the internal market in accordance with China's national interests.

As shown by the analyses referred to above, the main instruments on which the Chinese authorities rely to better direct FDI flows in the sectors of national interest, or to boost the transfer of new technologies to these sectors may take several forms, varying from *i)* restrictions on the share of foreign participation in joint ventures, and up to *ii)* imposing barriers and administrative burdens in the investment authorisation and approval process. These two aspects show the non-transparent and discretionary nature of China's foreign investment approval regime, which goes against the international practices agreed upon with the WTO.

To meet the criticism expressed in the international environment and the concerns raised by foreign governments and companies in relation to the opaqueness of the Chinese investment framework and the excessive rules applied to FDI, in 2019, the Chinese central authorities adopted a new *Foreign investment Law*[4] *(FIL*), which expressly prohibited actions that could lead to a "forced" transfer of technology, and promoted: *a)* technological cooperation based on the free will of investing companies; *b)* enhanced IPR protection; *c)* equal and non-differentiated treatment of foreign capital companies[5] (Standarder Trade Portal, 2021). Nevertheless, international analysts highlight that FIL continues to use a vague wording which leaves room for interpretation – in particular with respect to aspects related to "forced" technology transfers – and presents a series of loopholes when it comes to its implementing regulations, which do not contain details on how the legitimate rights and interests of foreign investors can be protected (Elen, 2020).

Also, despite the gradual liberalisation of the regime allowing for foreign direct investment inflows, which was implemented over the recent years, China still maintains a detailed FDI monitoring, control and management system, in which the *Catalogue for the guidance of foreign direct investment* plays a central role. Depending on the potential receiving industries, the Catalogue divides FDI into three groups (encouraged, restricted and prohibited), which determines both different degrees of examination when approving investments, and different levels of investment conditioning or investment regulation. From the time it was prepared until its last annual review (2020), the document has continued to specify the fields in which foreign partnerships (such as joint ventures) can be created and the shares of participation permitted to foreign companies, so that the Chinese party may have control over the newly created entities.

In light of the provisions of the *12th Five-Year Plan* (2011) and of the *Five-Year Plan on Foreign Capital* adopted later (in 2012) by the National Development and Reform Commission – which anticipated the launch of the new *MIC 2025 Strategy* –, Chinese authorities started paying increased attention to the promotion of FDI inflows in the emerging branches of the national economy, expressly referring to a need to stimulate the absorption of foreign capital in biotechnology industries (Edelberg, 2017). Given the importance of FDI absorption for accelerating innovation by national companies[6] and the fact that decision-makers were aware of the significant importance this absorption has for the development of local industries related to life sciences[7], the

[4] Adopted at the 13th Congress of China's CCP of 13 March 2019, the law entered into force at the beginning of 2020.

[5] For example, when licences are granted or when participating in public procurement calls.

[6] On the one hand, resulting directly from advanced technologies and the sharing of the know-how of foreign companies and, on the other hand, as a result of the reduction of the cost of innovation for national companies (an indirect consequence of the demonstration effect, workforce mobility, shared use of suppliers, etc.).

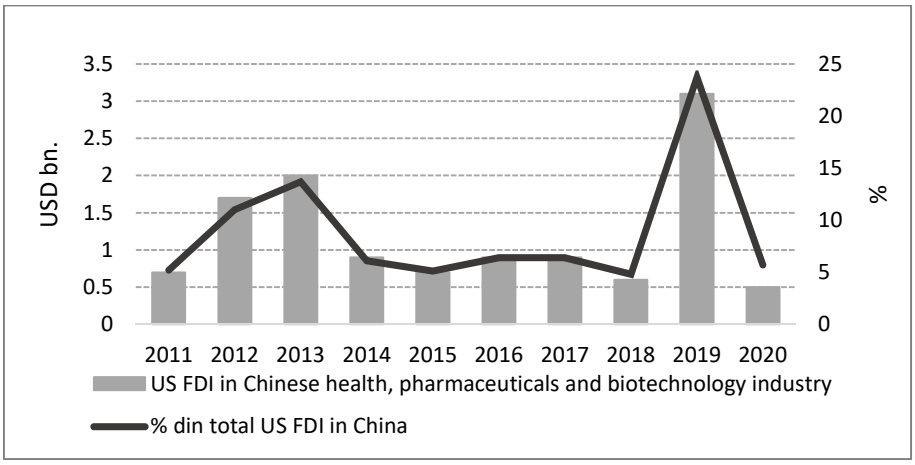
[7] Out of all the channels that can be used for technology transfer, FDI has the largest contribution to the development of the national biotechnological industry, because with the capital intended for the creation of new local facilities, foreign

Catalogue issues of the recent years not only extended the biotechnology sub-fields in which the authorities seek to encourage the inflow of foreign direct investment, but they also gradually optimised the measures intended to stimulate them. As such, depending on a series of well-delineated criteria (which are related, among others, to the specific particularities of the sub-branch towards which the investments are directed, the amount thereof, etc.), based on the recent regulatory rules, the investors in the field are granted a wide range of incentives, such as tax reliefs, lower customs duties, preferential rights on the use of land, etc.

Against this background that we described, U.S. FDI flows in the Chinese medical sector and in the pharmaceutical and biotechnology industry evolved without major fluctuations during the last decade – with the exception of 2019, when they reached an absolute maximum –, particularly fuelled by financial motivations, stimulated by the ample modernisation of the local medical system in the context of an increased population ageing (Rhodium Group, 2021).

During the period analysed (2011-2020), U.S. investments in this sector amounted overall to around USD 12 billion, which corresponds to a share of approximately 9% of the total U.S. investments in China. From this perspective, the year 2019 marked an unprecedented performance in this regard, with this share reaching a historical "peak" of 24% (Graph 1), also due to a major individual purchase worth USD 2.7 billion: the takeover of the Chinese pharmaceutical company *BeiGene*, specialising in the manufacture of cancer medication, by the American group *Amgen* (Hanemann, et al., 2021).

Graph 1: U.S. FDI in the Chinese medical sector*, the pharmaceutical and biotechnology industry, 2011-2020



Note: * Including investment in medical technologies.
Source: Author's calculations and processing based on the data published by Rhodium Group-China Investment Monitor (2021): https://www.us-china-investment.org/fdi-data.

In 2020, as a result of the negative effects of the Covid-19 pandemic – which diminished the investment appetite of U.S. companies – and because of intensified U.S.-China frictions, the value of U.S. FDI in the biotechnology sector and the related areas decreased by around USD 2.5 billion, the only significant transactions this year being the purchase of *Cstone Pharmaceuticals* by *Pfizer* (USD 200 million), and the takeover of the *Shenzhen Hepalink* pharma group by *GGV Capital* (USD 50 million).

Although at the level of the overall interval under analysis the main way in which U.S. companies chose to enter the Chinese biotechnology market was represented by aquisitions (with a share of 58% of all investment) (Box 3), at sub-sector level there were a series of differences, mainly resulting from the motivations that underpinned the decision-making process.

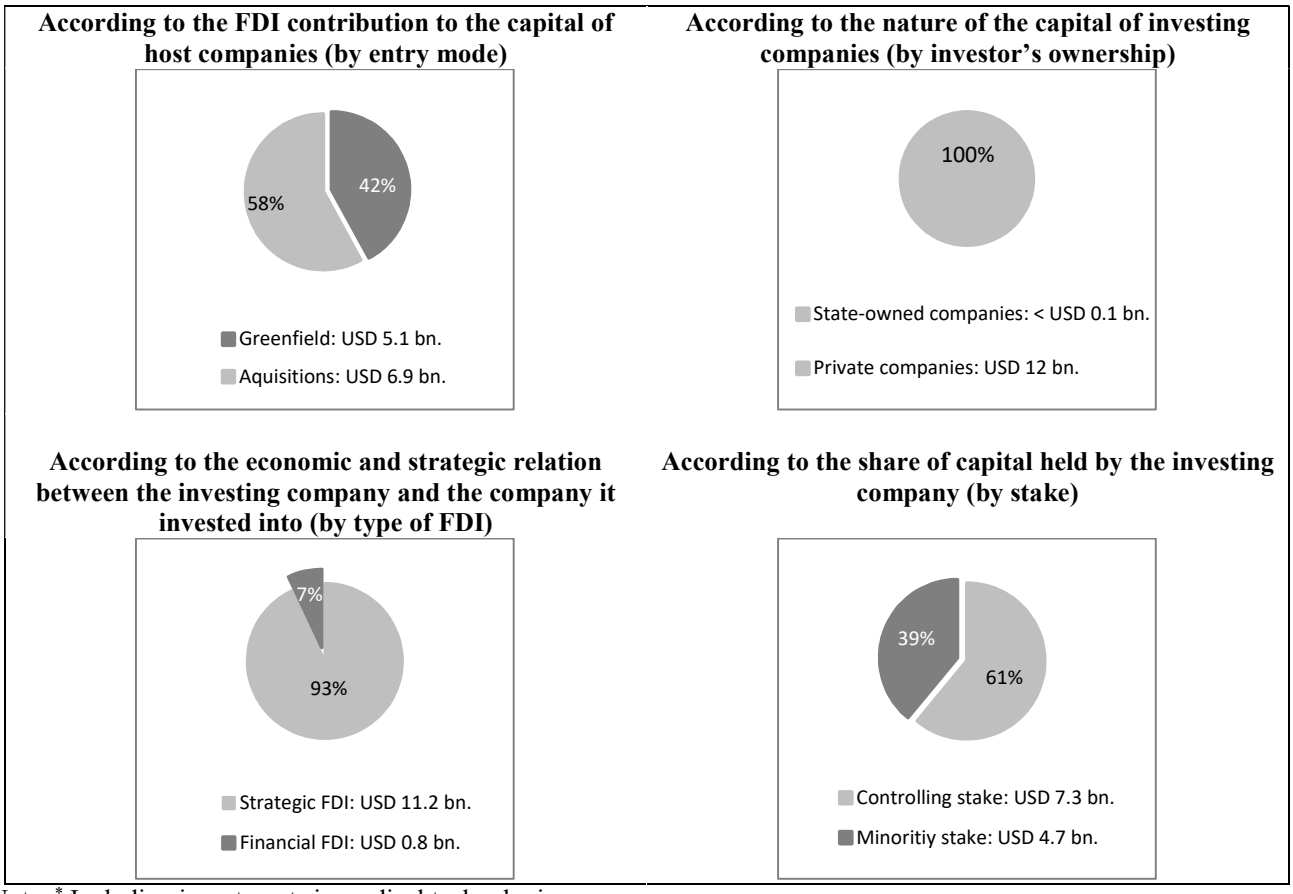
As is the case with the medical technology development and production branch, U.S. FDI sought both to benefit from China's lower production costs, and to increase their market share, which is why investments in these industries were mainly "greenfield" investments (e.g., the creation of production subsidiaries in Suzhou by the companies *Becton Dickinson* and *Johnson & Johnson*).

companies transfer IPR, expertise and good practice in the field, at the same time facilitating the integration in the global supply chains.

In the same period, U.S. companies also made a series of purchases of local companies. Several illustrative examples in this regard are: a) the acquisition of the orthopaedic implant manufacturer *China Kanghui* by the U.S. company *Medtronic* (in 2012), at a transaction value of USD 816 million; b) the acquisition of the medical device manufacturer *Trauson* by the *Stryker* group (2013) at a value of USD 764 million.

As regards FDI in the pharmaceutical and biotechnological industry, which is the most attractive investment segment for U.S. companies in the field (with a total share of around 70% in the interval analysed), the main motivations underpinning the investment decision were determined by *i)* advantages related to production costs; *ii)* the prospects of accessing a larger and dynamic market (market-seeking investments); *iii)* the opportunities related to distribution and other downstream activities, and the setting up of production facilities mainly took place via acquisitions.

Box 3: Synoptic table of the classification of U.S. FDI in the Chinese medical sector*, the pharmaceutical and biotechnological industry, 2011-2020 (cumulated values)



Note: * Including investments in medical technologies.
Source: Author's calculations and processing based on the data published by Rhodium Group-China Investment Monitor (2021): https://www.us-china-investment.org/fdi-data.

Although it presents attractive investment prospects for U.S. companies in the field, the healthcare services sector still maintains a series of formal and informal restrictions – deriving from how the functioning of hospitals and healthcare centres is regulated –, which on the one hand determined a low share of U.S. FDI in the field (5% of the overall total in the sector), and on the other hand provided the option to access the market by setting up joint ventures with Chinese participation.

Directing Chinese outward investment to increase the biotechnological intake

The upward trend of Chinese outward direct investment (ODI) in developed countries (the U.S. in particular[8]) – increasingly visible during the last decade – triggered an international need to study the determining factors of this trend. The conclusions of recently carried out analyses (Huang & Zhang, 2017) showed that since local transnational companies do not (at present) possess technological resources similar to those in highly industrialised economies – thus ruling out the exploitation of competitive advantages on external markets as a motivation for the internationalization of their activities (which would have been in line with classical investment theories) –, the main reason underlying their decision to invest abroad is that of obtaining strategic assets. As such, to acquire *know how*, Chinese companies invest in economies that are rich in technological resources, where they purchase strategic assets which they take over and then use on the national market (a phenomenon that is known as a reverse technology transfer).

Implicitly, and in order to develop its domestic biotechnology sector, China also relies to a great extent on the interaction with relevant companies in technologically advanced countries, and in this case its investments and acquisitions abroad seek to secure new research, development and innovation skills and competencies in the field, which could contribute to the strengthening of the existing national capacity (Kazmierczak, et al., 2019). With the launch of the *Made in China 2025* industrial development plan that designated the biotechnology sector as a strategic emerging branch of national interest and one which was eligible for increased government support, followed by the implementation – as a result – of a program for the reform of the internal regulatory framework in the field and the implementation of a set of measures meant to increase control over how outward investment could be directed, China's investment policy became an *"aggressive one […], based on innovation mercantilism"* (Atkinson, 2019, p. 2). As such, by establishing clear and well "targeted" goals, the new internationalisation strategy seeks to secure competitive advantages that could enable China's transition towards a new stage of industrial transformation – from a follower to a future leader in the field of biotechnologies and innovation –, which entails achieving supremacy over the U.S., the traditional holder of the dominant position in the life sciences industry.

Although the U.S. policy usually focused on the active promotion and attraction of foreign direct investment from China, the recent emergence of certain increasingly higher geopolitical and geoeconomic ambitions on China's part generated a series of concerns among U.S. decision-makers with regard to: *a)* the unilateral transfer of technological and business expertise, in the conditions in which Chinese ODI in R&D mainly seeks to bridge the national technological gap; *b)* the unfair competitive advantage over U.S. companies as a result of the government support received by Chinese companies[9]; *c)* the danger of a leak of sensitive information (Box 4).

Box 4: Examples that illustrate how, through ODI, China gained access to U.S. citizens' sensitive data

✓ In addition to the financial interests which, in accordance with the classical theories, each and every investment, as well as to the motivations related to acquiring high technologies and *know-how*, which we illustrated in this analysis, the accessing of the U.S. markets by Chinese companies involved in the conduct of activities in the field of life sciences can provide them with access to sensitive information and data bases on the medical history and state of health of U.S. citizens.

✓ Because based on the government support they benefit from Chinese companies ODI are able to provide services at much more affordable prices than national actors, they are often selected to the detriment of local companies to carry out research and tests in the medical field, in genetics, etc. For ample, in 2019, 23 companies associated with China were authorised to carry out genetic tests on the U.S. territory (Kazmierczak, et al., 2019).

✓ Following the onset of the Covid-19 epidemic, the U.S. further liberalized the access on the U.S. market of Chinese medical companies which collected sensitive data. As a result, in 2020, the *U.S. Food and Drug Administration (FDA)* authorized under an emergency procedure the use of Covid-19 test kits manufactured by the U.S. subsidiary of the Chinese company *BGI Genomics* (a supplier of medical devices and genome sequencing services), a premiere in terms of authorisation of medical devices manufactured in China (later, *Genetron Health*, another Chinese company specialising in high-precision medicine received the FDA green light).

[8] From the very first stage of the opening towards the exterior of the Chinese economy – launched at the beginning of the 2000, in order to support the internationalization of the activity of local companies –, the U.S. was always the main destination of China's outward direct investment (China Power, 2021).

[9] Because companies accessing external market usually benefit from government subsidies, they have a competitive advantage compared to local companies (for example, in the merger and acquisition call for tenders).

✓ By mid-2020, *BGI* had sold around 35 million tests in over 180 countries, including the U.S. Moreover, the same Chinese companies set up their own laboratories dedicated (apparently) to supporting the processing and interpretation of the data collected from the tested persons, thus fuelling international fears that by doing this, China is actually trying to collect heterogeneous genetic information the research of which could help China's interests of dominating the global biotechnology market (Needham, 2020).
✓ Unlike in other federal states, the U.S. legislative system has no regulations that could ensure a nationwide approach of data collection and management; it only has state laws on the management of information from certain sectors. For the medical sector, the *Health Insurance Portability and Accountability Act (HIPPA)* provides the legal framework, defines the aspect related to the protection of health information and establishes the conditions in which the disclosure of such information is permitted. Nevertheless, the HIPPA provisions do not cover all the cases in which personal data are collected, nor does it apply in situations in which patient data are anonymised.

Source: Author's synthesis based on US-China Economic and Security Review Commission (2020).

In these conditions, because the biotechnological sector is considered essential for U.S. national security, the Department of Trade raised concerns with the U.S. federal government on the risks posed by China's illegitimate actions that seek an accelerated and "forceful" technology absorption[10], and at the same time pleaded for the need to adopt measures that could confer a higher degree of protection for intellectual property and limit the transfers of *know how* to Chinese companies (Ono & Cabot, 2019).

As a consequence, in 2018, the *Committee on Foreign Investment in the US (CFIUS)* within the U.S. Department of Trade adopted the *Foreign Investment Risk Review Modernization Act (FIRRMA)*, which consolidates the system for the monitoring and mitigation of the risks that certain FDI may pose to the critical infrastructure, as they enable the access to sensitive information and/or key technologies within several industries of national interest, including those related to life sciences (Box 5).

Box 5: Synthetic overview of the recent changes in the Chinese and U.S. investment regulatory frameworks

CHINA

Beginning in 2016, the Chinese government implemented a series of measures aimed at increasing the control and surveillance of outward investments of national companies:
✓ The State Council issued (in 2016) the *Guiding opinions on the promotion and regulation of the development of applications using big data in the medical field*, which it designated as "fundamental national resources", encouraging outward investment in this sector (particularly in in the U.S.)[11] (U.S.-China Economic and Security Review Commission, 2020).
✓ In 2017, the *State Administration of Foreign Exchange (SAFE)* adopted a set of internal rules whereby it required national banks to report any transfer made abroad by Chinese-based companies which exceeded the USD 5 million ceiling. This regulation not only restricts ODI flows of Chinese companies, but it also limits the transfer of funds between the mother company and the subsidiaries abroad.
✓ In 2017, the Chinese authorities published a new package of administrative measure applicable to national companies accessing the foreign market, the purpose of which was both to restrict certain fields (by introducing blacklists), and to regulate the companies' activities in the post-investment stage. These special administrative measures were revised on several occasions (during the years 2017/2018), in order to reduce "irrational" investments[12] and redirect ODI towards technologically-intensive fields that could favour China's repositioning within global value chains. At the same time, the government sought to correlate the investment process with the development goals proposed at national level and transform the internationalization policy into an essential component of the country's economic transformation and modernisation process.

[10] Among the unfair practices employed by the Chinese companies in order to accelerate learning/the development of new skills and competencies are: the takeover of intellectual property rights, the application of opaque, discretionary measures in the investment approval process, state subsidies for acquisitions/investments in companies that own high-end technology, the relocation to China of the company's activity after the acquisition and the technology transfer are completed etc. (White House Office of Trade and Manufacturing Policy (OTMP), 2018).
[11] Although it is unlikely that the data included in individual medical records may lead to the development of new treatments, their aggregation in case of countries with large populations could facilitate medical discoveries with a high commercial value. Because of the ethnic diversity of the U.S. population, U.S. medical data are particularly valuable in this regard.
[12] Namely, investments in real estate, the hotel and entertainment industry, which have been considerable during the recent years.

The National Development and Reform Commission, by Order no. 11/2017, extended the process for the analysis and approval of the national companies' outward investments. As a result, for investments exceeding the USD 300 million ceiling, investors are required to submit additional supporting documentation at the NDRC branch of the company's province of origin. This rule does not apply to Chinese companies that fully take over the control of the company located on the foreign market (nevertheless, even these companies are subject the SAFE regulations on the international transfer of funds). Although so far the biotechnology sector has not been included on the list of sensitive industries subject to Order 11 restrictions, it remains to be seen how the Chinese authorities will choose to respond to the commercial and investment policies recently adopted by the U.S.

U.S.

- The implementation of FIRRMA led to an extension of the jurisdiction of the Committee on Foreign Direct Investment in the U.S., through the launch of a pilot-programme that sets out an obligation to report all foreign investments related to critical technologies and those directed at the collection of data that are sensitive for U.S. citizens, even in cases where the foreign companies are not the majority shareholders (which would enable them to take direct control over the newly established company[13]) (Lenvine & Paretzky, 2019). R&D activities in biotechnology are also among the 27 critical fields identified. The actions that CFIUS can take in the event of a failure to comply with the investment registration requirements and/or in the event that sensitive assets are excluded from the statements include, among others, the application of penalties of up to the value of the transaction Also, the pilot-programme forced U.S. companies to pay increased attention to permanently checking the compliance of the classification of the products, services and technologies resulting from foreign investment, in particular with the provisions of the *Export Control Act* (which is constantly changing).
- The promulgation in 2018 by President Donald Trump a of the *National Defence Authorization Act (NDAA*), the key-objectives of which being to protect U.S. technological advances through a closer monitoring of technology transfer to foreign entities. In addition to the provisions of the *Foreign Investment Risk Review Modernization Act*, NDAA includes the *Export Control Reform Act (ECRA)*, which brought significant changes in the control of emerging and fundamental technology exports, imposing additional restrictions for this transfer. As such, the ECRA extended the jurisdictional scope of export controls and tightened the restrictions, by adopting a set of measures with significant impact on cross-border transactions (Leiter, 2018):
  - the setting up of an ample documentation review process in order to identify fundamental emerging technologies and impose adequate export controls;
  - the conditioning of the granting of export licences for joint ventures on the declaration of "significant foreign ownership";
  - the call for an immediate review of the restrictions and conditions for the granting of licences for the export of U.S. products to countries under embargo (including China).

The adoption of the *Fair Trade with China Enforcement Act* (May 2019) brought additional restrictions on Chinese investments in U.S. companies in several industries designated as being of strategic importance, including in the field of biotechnologies.

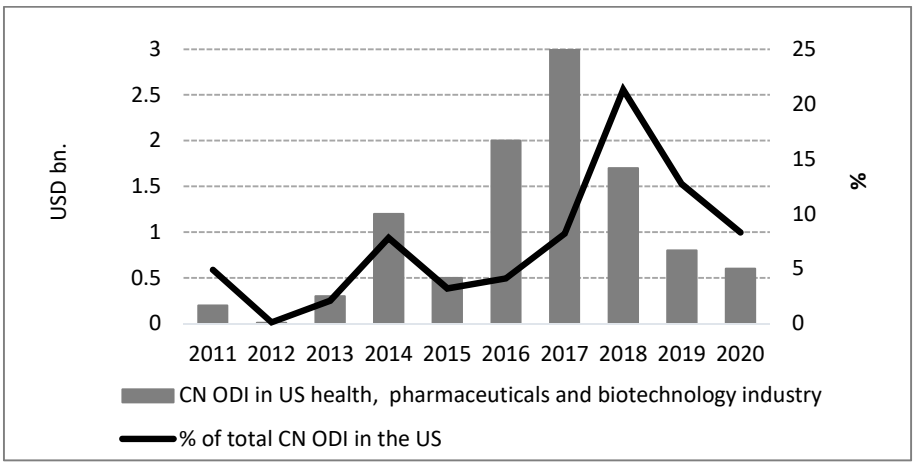
Source: Author's synthesis based on Brookfield (2019); Ono & Cabot (2019), as well as on the bibliographical sources quoted in the box above.

As regards the evolution of Chinese ODI flows directed to the U.S. medical, pharmaceutical and biotechnological sector, although the cumulated value over the last decade was relatively low (of around USD 10.2 billion; Graph 2 and Box 5), the investment activity saw a rapid increase beginning in 2016 and until the second half of 2018, when the tensions between countries began in relation to China's outward investment policy and practices[14].

[13] Until 2018, for these companies, the submission of supporting documents for investments on the U.S. territory was generally optional.

[14] As we stated, these dissensions began in 2018, based on the accusations issued by the U.S. government, according to which, the policies adopted by China in the field of investments are mainly directed to the support of priority industries and favour "large national champions", and aimed at the same time at a technological advance, by purchasing and re-innovating foreign technologies (Atkinson & Foote, 2019).

Graph 2: Chinese ODI in the U.S. medical sector*, the pharmaceutical and biotechnology industry, 2011-2020



Note: * Including investments in medical technologies.
Source: Author's calculations and processing based on the data published by Rhodium Group-China Investment Monitor (2021): https://www.us-china-investment.org/fdi-data.

Also, in accordance with the conclusions put forward by a series of reports prepared at national and international level (Deloitte China, 2018; Hanemann, et al., 2021), during the entire interval analysed and referred to above, the main factors that motivated Chinese ODI in U.S. industries pertaining to the biotechnology field were based on: *i)* the initiative of modernizing China's internal technological capacity and the related assets, in order to achieve the degree of progress set out in the MIC 2025 strategy and in the later programme documents; *ii)* the creation and/or consolidation of supply chains; *iii)* the use of the U.S. talent pool to expand R&D activities in the field.

As shown by the data presented, despite the increase in value visible at the level of Chinese investment flows dedicated to the U.S. healthcare, pharmaceutical and biotechnology sector, in the investment boom period (2016-2017), the share of this sector in total ODI from China remained relatively low (around 4% in 2016, and approximately 8% in 2017), a trend that was reversed beginning in 2018.

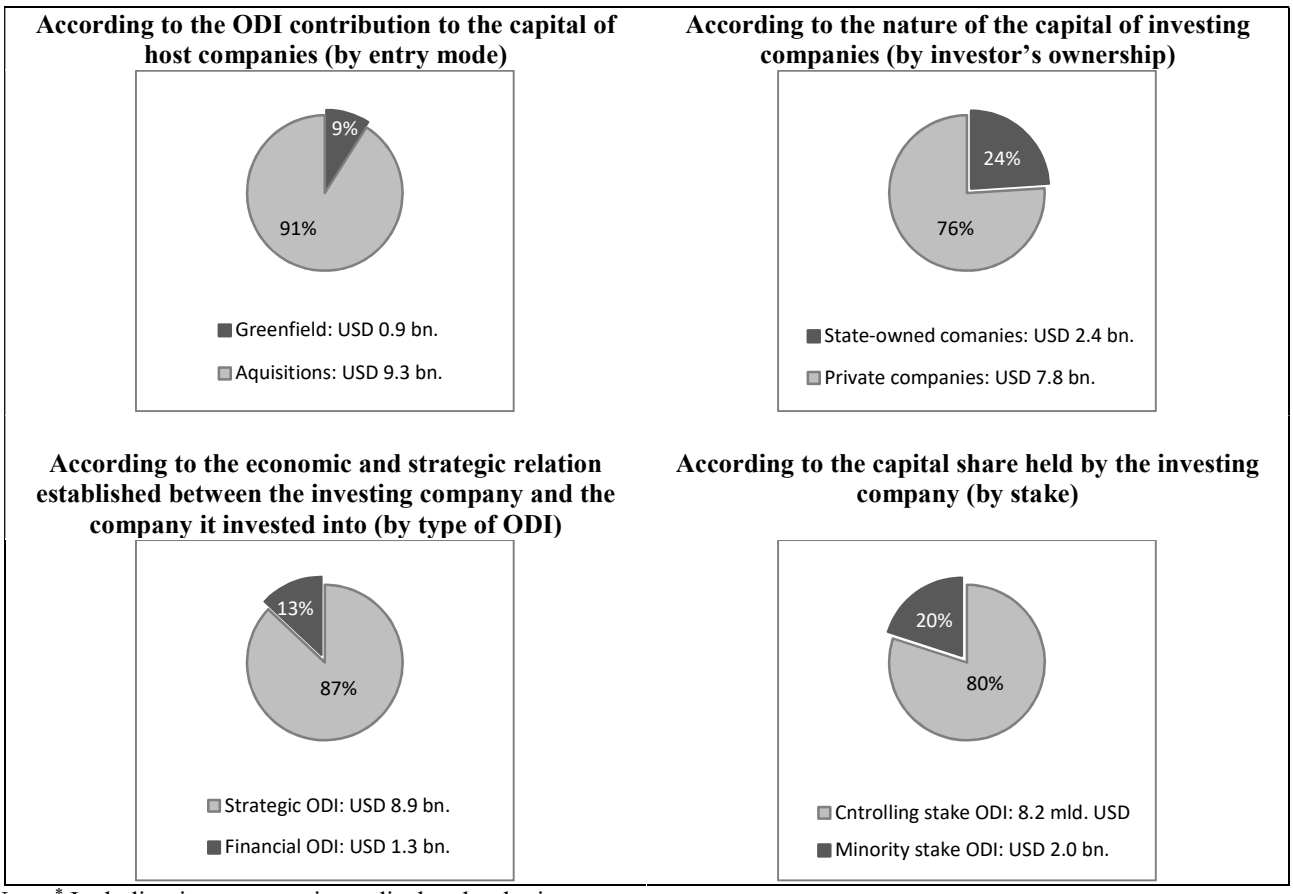
As such, in 2019, against the background of an intensified examination and monitoring of Chinese investments falling within the scope of FIRRMA and of the divestiture provisions applied (e.g. in the case of *iCarbonX*, the amount of ODI in the field of life sciences saw its first contraction after 2015 and at the same time a major decrease compared to the level seen in the preceding year (of around 50%).

As the pandemic accelerated and the tensions between the U.S. and China intensified, this declining trend continued in 2020 as well, when Chinese ODI in the biotechnological and pharmaceutical industry marked a new decrease in annual terms (of approximately 20%), although this sector ranked third among the preferences of Chinese investors[15] (Hanemann, et al., 2021). The most significant purchase contracts concluded in 2020 are: the takeover of *Absorption Systems* (by the Chinese group *Pharmaron*) and of the U.S company *Red Realty LLC* (by the *Fuan* pharmaceutical group), which totalled USD 2011 million. Also, the value of "greenfield" projects with only Chinese capital was relatively low, given that the main investments in start-ups were made by: *a) Beijing Gan & Lee Biotechnology* (USD 67 million); *b) Shanghai Henlius Biotech* (USD 65 million).

Since the main goal of Chinese ODI was always to absorb new technological skills and competencies, the preferred ways of accessing U.S. markets were mergers and acquisitions involving existing companies in the field. As a result, during the last decade, the cumulated share of acquisitions in total Chinese sectoral investments in the U.S. was of over 90%, while "grassroot" investment projects were insignificant in share (Box 6).

[15] After the entertainment industry and the consumer product services sector.

Box 6: Synoptic table of the classification of Chinese ODI in the U.S. medical sector*, the pharmaceutical and biotechnological industry in 2011-2020 (cumulated values)



Note: * Including investments in medical technologies.
Source: Author's calculation and processing based on the data published by Rhodium Group- China Investment Monitor (2021): https://www.us-china-investment.org/fdi-data.

As China's biotechnology sector is dominated by companies formed with mainly private participation[16], this was also reflected in the total investment flows targeting the U.S. in the last decade, during which only USD 2.4 million – corresponding to a share of 24% – came from state-owned companies. However, beyond the shareholding structure of the companies accessing a foreign market, the Chinese government authorities are able to influence the decisions of local companies by a variety of channels.

Among these, an important role is held by ODI monitoring, control and approval activities, whereby the authorities are able to direct investment flows in accordance with the objectives of the national industrial development policy. At the same time, another way of exercising government influence on local companies in the biotechnology field is the massive support granted by the state through direct investment flows aimed at the construction of industrial parks, the development of SMEs, or the attraction of foreign companies. In addition to these, Chinese companies also benefit from indirect financing received from state-owned industrial foundations and research centres managed by large national agencies (usually, MoST). Although the main objective of most of these funds is to finance the development of local activities, in certain cases they are also mandated to support the internationalization of relevant companies[17]. Also, the largest part of the capital of private companies comes from the large state-owned commercial banks which, in their turn, are subject to the rules imposed by the governmental regulatory authorities. Although it is difficult to measure the extent to which government control

[16] In accordance with the definition developed by the *State-owned Assets Supervision and Administration Commission of the State Council (SASAC),* private companies represent those entities in which the share of government participation is less than 20% (similarly, in state-owned companies, the government holds a share of more than 20%) (Kazmierczak, et al., 2019).
[17] For example, in 2017, in the Wuhan Donghu district, the local authorities created a special fund – amounting to USD 155 million –, intended for the increase of the degree of innovation of local high-tech companies with a view to their global expansion.

is exercised by resorting to coercion in relation to any of the aspects referred to, the Chinese authorities are at all times able to directly intervene in the transactions of individual companies, because those companies do not have the legal means to appeal against government interference.

3 Conclusions

As a result of the political measures adopted from a very early stage by the Chinese central authorities in order to regulate and guide foreign direct investment in accordance with the country's own strategies for the modernisation of the biotechnological sector and, later on, direct Chinese outward direct investment in accordance with the same national interests, correlated with the sustained efforts made over the recent years for the creation of a knowledge-based economy, China gradually reduced the gap that was separating it from the technological frontier, and became one of the main competitors in the race for global supremacy in the field of biotechnology. As such, in addition to an ample direct support for research programmes and initiatives in the field, the Chinese government applied a sustained and gradual policy seeking to encourage the entry on the Chinese market of large transnational biotech corporations (U.S. companies in particular) and the relocation of their production on the local market, coupled with the adoption of measures meant to stimulate national companies to merge with and acquire U.S. companies in the field.

Over the recent years, the competition between China and the U.S. in the field of biotechnology has become fierce, and the U.S. officials are not sparing any efforts in claiming China's advance with regard to the development of emerging technologies in critical sectors. This may be true in certain fields, but not in the biotechnology sector, for now. Certainly, Chinese biotechnological industries are evolving at an accelerated pace, and some companies become leaders on certain market sub-segments (e.g. cancer treatment), but nevertheless, the U.S. holds the dominant position in the research-development-marketing activities based on the significant results assimilated in a period of over a decade (2000-2013) in which they held almost half of the total number of patents submitted in the field of biotechnology worldwide.

Biotechnology is a critical aspect in the technological competition between the U.S. and China, because based on its complexity and multidisciplinary nature, this sophisticated discipline has the capacity to transform in an interchanging way two essential fields: medicine applications and uses that are generally the prerogative of a military power. To exemplify more clearly, as shown by the history of the 20th century, the evolution of discoveries in physics enabled the understanding and use of nuclear reactions to produce energy; however, the same scientific principles were later used for the production of nuclear weapons. Biotechnology offers a similar mix of promises and dangers. For example, the discovery of the CRISPR-Cas9 enzyme system (which was awarded the Nobel Prize in 2020) enables the highly precise encryption of a body's genome, which makes it a transforming discovery. However, while CRISPR is very promising for the development of innovating treatments for certain conditions that have long been considered untreatable, it could also lead to the production of a new generation of lethal biological weapons.

China's determination to become a global power in the field of biotechnology is reflected in the unequalled level of government support, in the minute development of roadmaps for each stage of evolution, in the design of policies for incentivising the attraction of high-quality talents (regardless of nationality), as well as in the creation of a national ecosystem that favours innovation.

Since the period when Deng Xiaoping was leading the country, China has started an ample transition process which enabled it to shift from the status of an "imitator" of developed nations to that of an innovating country. Concomitantly with this transition, biotechnology applications extended to extremely diverse fields such as: medicine, industry, agriculture, energy and environmental protection. Despite the persistent delays noted in the production of medical devices, China has reached its goal being today among the world leaders in the field of genome editing, immune therapy, cell therapy and the integration of information technology in medicine.

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