Research Policy 52 (2023) 104787

Contents lists available at ScienceDirect

Research Policy

journal homepage: www.elsevier.com/locate/respol

Market for technology 2.0? Reassessing the role of complementary assets on licensing decisions

Solon Moreira [a,1], Thomas Maximilian Klueter [b,*,1], Aman Asija [c,1]

[a] Fox School of Business, Temple University, Philadelphia, PA 19122, United States of America
[b] IESE Business School, Barcelona 08034, Spain
[c] Nova School of Business and Economics, Universidade NOVA de Lisboa, Campus de Carcavelos, 2775-405 Carcavelos, Portugal

ARTICLE INFO

Keywords:
Complementary Assets
Technology Licensing
Contract Development & Manufacturing Organizations
Markets for Technology

ABSTRACT

The ability to access specialized complementary assets has been key to explaining how firms benefit from their technological innovations. When firms lack complementary assets the more likely they have to rely on markets for technology to profit from their R&D investments. We extend this view documenting the emergence of a new type of industry intermediary, Contract Development & Manufacturing Organizations (CDMOs), which provide access to complementary assets on a per-use basis. CDMOs allow firms to contract for complementary assets at variable costs without the need to invest in such assets internally. This opens up new product development paths, in which firms do not out-license their products to firms with complementary assets but sustain their development in-house using CDMOs. We highlight that the expansion of services offered by CDMOs changes the nature of the industry's source of competitive advantage and provide empirical evidence that the expansion of CDMOs is associated with a decline in the number of out-licensing deals among US biopharmaceutical firms. In so doing, the study explains how innovation intermediaries like CDMOs can have a profound effect on an industry's specialized complementary assets and the market for technology.

1. Introduction

The importance of complementary assets in shaping an innovator's profit strategy has long captivated strategy scholars (Gans and Stern, 2003; Teece, 1986). The successful commercialization of innovation requires technological know-how in conjunction with specialized complementary assets oriented towards product markets (Bercovitz and Feldman, 2007; Colombo et al., 2006). Without access to the complementary assets required to push a technology through the development funnel, the most common strategy for innovators is to offer that technology for licensing in the upstream markets to other industry players (Moreira et al., 2019; Joshi and Nerkar, 2011; Arora et al., 2001; Gans et al., 2002).

Research has highlighted that accessing specialized complementary assets is problematic for innovators, as in most cases these assets cannot be simply "contracted," and acquiring or building them is costly and time-consuming (e.g., Arora and Ceccagnoli, 2006; Teece, 1986). More recent studies have shown that firms can access complementary assets through partnerships when commercializing disruptive technologies (Marx et al., 2014; Marx and Hsu, 2015) and in the nascency of industry emergence (Higgins and Rodriguez, 2006; Moeen and Mitchell, 2020). Still, the typical assumption is that firms must either relinquish the rights to their technologies to a larger partner or internalize the necessary complementary assets to develop and commercialize them (Teece, 2018).

This study outlines an alternative path to technology commercialization due to the emergence of a new type of industry actor that allows firms to contract for specialized complementary assets on a *per-use and, thus, variable cost basis.* These asset providers occupy an intermediary position in the R&D value chain as they neither focus on upstream research nor on directly selling products in the downstream markets. Instead, they make significant capital expenditures on specialized complementary assets, which they make accessible to other firms (Macher and Boerner, 2012). We argue that the emergence of such

* Corresponding author.
E-mail addresses: solon.moreira@temple.edu (S. Moreira), TMKlueter@iese.edu (T.M. Klueter), aman.asija@novasbe.pt (A. Asija).
[1] All three authors contributed equally.

https://doi.org/10.1016/j.respol.2023.104787
Received 16 March 2022; Received in revised form 9 April 2023; Accepted 12 April 2023
Available online 23 May 2023

intermediaries has direct implications for the organization of R&D activities in an industry and consequently on the functioning of the markets for technology. More specifically, we focus on the emergence of Contract Development and Manufacturing Organizations (CDMOs)[2] in the context of the biopharmaceutical industry. CDMOs make large-scale investments to offer biopharmaceutical firms a comprehensive range of development and manufacturing services (Miller, 2017). Between 1995 and 2015, the CDMOs in our sample made substantial investments in assets to serve the biopharmaceutical industry (reaching over USD 80.000 mm) and have experienced a growth in sales over 572,32 %. CDMOs support the execution of clinical trials as well as the development and mass manufacturing of new drugs and treatments, allowing for the externalization of highly specialized complementary assets through market contracting (Gupta and Wang, 2007). This has alleviated constraints concerning access to complementary assets, particularly for those firms that do not have the means to support the development and scale manufacturing of new technologies in-house.

We document several important patterns in the biopharmaceutical industry during the period in which CDMOs emerged and expanded. First, the total number of out-licensing deals has been in relative decline over the last 15 years, particularly those initiated by smaller R&D-intensive firms. This decline is intriguing because specialized complementary assets continued to be highly valuable in the industry and overall R&D investments continued to increase over this period. Second, while the launch of new drugs was previously almost entirely dominated by the large pharmaceutical firms, we observe a gradual shift from big pharma to smaller industry players, with the latter reaching up to 60 % of the FDA approvals in recent years. These changes are parallel to the expansion and increasingly widespread use of CDMO services in the industry. Thus, we note that CDMOs may have enabled firms to move their discoveries further downstream in the R&D funnel instead of out-licensing them early on.

We go beyond industry-wide patterns to examine the association between the emergence of CDMOs and the R&D strategy of biopharmaceutical firms, specifically examining how the growth of CDMOs and a firm's reliance on CDMO services impacted technology licensing. First, we collected qualitative data through five interviews with executives from biopharmaceutical companies and/or CDMOs. We used the interviews to document the value proposition of the activities performed by CDMOs for biopharmaceutical firms and how the services offered by CDMOs affect the nature of R&D activities and competitive advantages in the biopharmaceutical industry. Our qualitative analysis also helps document the global nature of the emergence of CDMO phenomenon. We explicate how the majority of R&D activities in the biopharmaceutical industry remaining concentrated in the United States, CDMOs services are much more equally distributed around the globe (PWC report, 2019)[3] as key CDMO capabilities such as engineering and low-cost production are more cheaply found abroad.

We supplemented our inquiry with archival data collected from companies' SEC filings and other sources such as *Compustat*, *Pharmaprojects,* among others. This allowed us to collect a sample of 787 unique biopharmaceutical firms from 1995 to 2015 to explore how CDMOs shape the R&D strategy in the industry. The results of the firm-level analysis are in sync with the industry-wide trends: with the growth of CDMOs and firms' use of CDMO services, we observe a reduction in firms' out-licensing offerings and realized deals.

Our findings make several contributions to the literature on technology commercialization. To the best of our knowledge, this is one of the first studies to document the emergence of CDMOs as innovation intermediaries that have profound effects on the organization of R&D activities in the biopharmaceutical industry. Prior studies have noted innovation intermediaries in the form of early-stage incubators, capital providers, professional service organizations, or online technology marketplaces (Dushnitsky and Klueter, 2017), but these studies have not explicated the role of intermediaries such as CDMOs in providing access to complementary assets to help facilitate bringing technologies to downstream product markets. We go beyond describing how CDMOs emerged and expanded over time in identifying a set of CDMOs serving biopharmaceutical firms, and provide metrics related to their emergence that can be used in future studies.

This study also extends research on the importance of specialized complementary assets in profiting from innovation (e.g., Arora and Ceccagnoli, 2006; Bercovitz and Feldman, 2007; Gans and Stern, 2010). It adds a dynamic perspective to Teece's original framework (1986) as we show that access to complementary assets can change over time and consequently the value they provide for a firm's competitive advantage. Indeed, Teece's seminal framework defines the control over complementary assets as the main determinant of a firm's capacity to profit from their innovation. In the biopharmaceutical industry successful product development and commercialization of new drugs dependent on achieving scale in manufacturing and testing in clinical trials, which has been traditionally the role by established pharmaceutical firms (Rothaermel, 2001). However, we document a change as CDMOs are now offering access to these capabilities. Overall, this suggests a change in the nature of the industry's competitive advantage (Rothaermel and Boeker, 2008), as complementary assets and development capabilities become available to a broader range of firms. The paper, thus, calls for a reconceptualization for the role of complementary assets as a source of competitive advantage in the biopharmaceutical industry.

The study further shows that the emergence of CDMOs also has implications for markets for technology and the division of innovative labor among biopharma firms. The finding that the emergence of CDMOs is associated with a decline in technology licensing adds to the conversation as to when firms use out-licensing in the first place (Laursen et al., 2017; Moreira et al., 2019). We reveal an important emerging alternative route of technology commercialization that subjugates the perceived dependencies of firms lacking complementary assets having to partner with firms in possession of such assets. While, historically, smaller biotech firms have been "relegated" to the development of innovative early-stage discoveries, this pattern has gradually changed, with these firms becoming increasingly able to develop a larger share of new therapies in-house (Cockburn et al., 2000). These contributions are expanded throughout the paper.

2. Licensing in the markets for technology 1.0

While markets for technology can encompass several means of technology exchange, one of the most prevalent is technology licensing, wherein a technology holder (i.e., the licensor) agrees to sell the rights to exploit a technology to another firm (i.e., the licensee) in exchange for financial remuneration (Conti et al., 2013). Such contracts are typically structured around two main components: the rights and conditions regarding the use of the licensed technology and the remuneration structure of the contract, including its royalties and/or upfront payments (Anand and Khanna, 2000; Sakakibara, 2010). Licensing allows licensors to profit from their R&D investments by transferring know-how and intellectual property related to a technology to the licensee (Moreira et al., 2020; Joshi and Nerkar, 2011; Moreira et al., 2018). Therefore, licensing involves the transfer of existing technologies taking the form of *patents*, *tacit knowledge* as well as *development and commercialization rights* (e.g., ownership rights over drugs in the biopharmaceutical industry). Typically, such licensing deals entail technologies still under development that are used by the licensee to complement

[2] This study focuses on CDMOs (Contract Development and Manufacturing Organizations), which are different from CMOs (Contract Manufacturing Organizations). While CDMOs are involved in both the development and manufacturing of a drug, CMOs focus on manufacturing of already approved drugs.

[3] Source: https://www.pwc.de/de/gesundheitswesen-und-pharma/studie-pharma-cdmo-market.pdf.

internal R&D efforts (Moreira et al., 2020; Moreira et al., 2018).

Technology licensing is an important part of a firm's R&D strategy. It is sometimes the only viable route to profit from R&D, as many firms lack access to specialized complementary assets needed to fully develop and commercialize a technology in-house (Gans and Stern, 2003; Teece, 1986). In the absence of in-house control over specialized complementary assets, firms often opt for licensing to generate revenues in upstream markets and leave the further development and commercialization of a technology to the licensee. For example, Arora, Fosfuri and Gambardella (2001, p. 430) argue that the licensing decisions depend on whether "[…] *the firm lacks the complementary assets, it may consider selling or licensing the technology*." Several studies have corroborated this pattern (e.g., Arora and Ceccagnoli, 2006; Moreira et al., 2019; Rothaermel, 2001). The result is a division of "innovative labor" wherein some firms focus primarily on early-stage R&D while others license-in these technologies to develop and commercialize them in the downstream product markets (Arora and Gambardella, 1994; Pisano, 1991). Consequently, one should expect technology licensing to be more prevalent in industries where complementary assets tend to be prohibitively expensive or difficult to access (Ceccagnoli and Hicks, 2013).

While there are benefits to technology licensing, innovators must also deal with the disadvantages of licensing technologies at early stages. Arora et al. (2001, p. 430) note that "[…] *If the firm has superior access to the complementary assets as compared to its rivals, in-house exploitation is clearly an attractive strategy."* Most importantly, there are long-term competitive implications as out-licensing limits the possible upside of the profits from R&D investments compared to exploiting technologies in-house (Moreira et al., 2019). Reaching the product markets through in-house development can be significantly more attractive financially as the innovator firm can accrue entire proceeds (Choi, 2002). Potential competitors can also use the newly acquired technology to move into the innovator product-market space, leading to rent dissipation (Laursen et al., 2017; Fosfuri, 2006).

Given these challenges, there may be circumstances in which keeping a technology in-house could be more attractive for the innovator firm. Yet, even when in-house development is the most desirable option, the lack of access to complementary assets and lack of resources to build complementary resources remain significant constraints. Therefore, control over complementary assets is at the core of the industry dynamics related to R&D activities and technology licensing (Teece, 1986; Ceccagnoli and Hicks, 2013). Next, we illustrate and discuss these patterns in the context of the markets for technology in the biopharmaceutical industry.

3. Markets for technology in the biopharmaceutical industry

The biopharmaceutical industry is known for its well-functioning markets for technology. Technology licensing has been at the core of this industry's R&D dynamics as technology suppliers and buyers can readily connect due to a large number of market participants (Pisano, 1991; Moreira et al., 2020). On one side of the market, the larger firms possess highly specialized complementary assets related to the development and manufacturing of drugs and new therapies, which are costly to build, resulting in uneven distribution of such assets among industry participants (Melchner von Dydiowa et al., 2021; Rothaermel, 2001; Rothaermel and Alexandre, 2008). On the other side, research-active biotechnology firms possess strong capabilities to create novel technologies (Gittelman and Kogut, 2003). The prevailing view is that these smaller firms will focus almost *exclusively* on developing early-stage technologies and treatments, while large pharmaceutical firms will license-in promising technologies and continue developing them until they reach downstream product markets (Arora and Gambardella, 1994; Klueter et al., 2017).

A case in point is the emergence of biotechnology in the late 1970s. Biotechnology is considered a highly novel and disruptive change for the whole industry as it provides ample opportunities for technological innovations by smaller and specialized firms (Kapoor and Klueter, 2015). Yet, large pharmaceutical firms sustained competitive advantages by controlling specialized complementary assets necessary for technology development and commercialization (Roberts, 1999; Rothaermel, 2001). Those firms had made substantial investments to move technologies through large-scale clinical trials to mass market production (Nerkar and Roberts, 2004). Thus, to commercialize technologies, smaller biotechnology had to rely on accessing complementary assets from larger pharmaceutical firms (Ghosh and Klueter, 2022).

As an illustrative example, the first biotechnology-based treatment, Humulin, a genetically engineered insulin, was approved in 1982 and manufactured by Eli Lilly. However, the technology used was in-sourced through a licensing agreement with Genentech, which had discovered the new treatment (Rothaermel, 2001). During the 1980s, Eli Lilly made substantial investments in manufacturing capacities, with several plants costing more than $100 mm, capital outlays which would have been impossible for Genentech (Riggs, 2020). This case illustrates how complementary assets in the biopharmaceutical industry, including manufacturing capacities, are costly to build and control in-house – an important reason for such assets to have been concentrated among the largest industry players. At the same time, the example shows the substantial upside of in-house development, which Genentech missed as Humulin became a "blockbuster drug" for Eli Lilly, with $1bn sales annually (Chan et al., 2007; Hoang and Rothaermel, 2010), of which Genentech only received a minimal amount through royalties. The case of Humulin involves a specialized technology but constructing and sustaining a production plant for more general technologies can also be prohibitively expensive for many firms. For example, the development of cell cultures, one of the major tools used in cellular and molecular biology, can range from $10 million for a minimal production capacity of 100 L,[4] with firms that lack the production scale to benefit from operating leverage being unable to easily absorb these costs into their development and manufacturing processes. While the example shows that for products in development such as Humulin out-licensing was of pivotal importance for Genentech licensing equally was important for firms working further upstream in R&D. For example, Human Genome Sciences provided gene sequencing algorithms and other technologies to established pharmaceutical firms, and, initially had limited ability to apply its technologies further downstream as they lacked complementary assets (Teece, 1986). Other examples of technologies regularly out-licensed in the industry include *bioinformatic* and *precision medicine tools*, as well as *unique materials* or *biological samples* with value for upstream development.

The hesitation to internalize complementary assets is not only due to the prohibitive costs to develop or acquire these capabilities, but also about the minimum scale and scope of operations required to benefit from them (Cockburn et al., 2000). Larger integrated biopharma firms with a portfolio of R&D projects can better spread the fixed costs of owning specialized and general facilities by quickly exploiting economies of scale and scope through that portfolio (Henderson and Cockburn, 1996; Pisano, 1991). Conversely, smaller firms tend to specialize in a narrower set of technologies and therapies, and any investment in manufacturing or scaling capabilities is prohibitively expensive and fraught with operational risks (Gittelman and Kogut, 2003). The result has been a strong division between upstream R&D and downstream market activities, starting with the emergence of new biotechnology players in the early 1980s (Rothaermel, 2001).

The division of innovative labor in the industry also is facilitated by a strong appropriation regime underlying the industry. The ability to protect and enforce IP is the second important dimension in Teece's seminal "Profiting from Innovation" framework (Teece, 1986).

[4] Source: bioprocessintl.com/manufacturing/manufacturing-contract-services/worldwide-biopharmaceutical-cmo-capacity-analysis/.

Licensing only is a viable option for firm if they have lower that the licensee can expropriate the licensor (Laursen et al., 2017). The biopharmaceutical industry is characterized by a very strong appropriation regime compared to other industries (Arora et al., 2001; Klevorick et al., 1995), which sets an important boundary condition for the division of innovative labor.

This division is visible through the number of realized out-licensing deals for *publicly listed US biopharma firms* starting from the mid-90s in Fig. 1,[5] which depicts a gradual increase in the total number of licensing deals until 2006, followed by a decline. To understand how these patterns differ by a firm's control over assets, we split the number of deals according to the total assets of firms in a given year: *below USD 100 million in assets* (blue line), *between USD 100 million and 500 million in assets* (red line) and *above 500 million in assets* (green line). For the period covered in our sample, the first group shows a total of 2260 (49 %) out-licensing deals, the second one, 1069 (23 %) deals, and the third, 1305 (28 %) deals.

It is also important to note the changes in the characteristics of industry licensors over time. Fig. 1 shows that out-licensing deals were almost entirely performed by the smaller licensors (those with less than USD 100 million in assets) in the initial years of the sampling period. Indeed, smaller firms represented >80 % of all the licensing deals observed in 1995. This pattern is well-aligned with seminal studies (e.g., Arora and Gambardella, 1994) that examined the role of complementary assets in shaping R&D activities and technology commercialization in the biopharmaceutical industry during the 1990s. However, Fig. 1 also suggests that the relative prevalence of smaller licensors has significantly reduced in recent years, with this group of firms engaging in 34 % of the out-licensing deals in 2015. The firms below 100 million in assets were those who most often out-licensed in the initial period; however, from 2006, the number of deals by this group of firms seems to have shrunk severely. We checked if the decline in-licensing by those smaller firms could be explained by publicly listed US biopharma *firms* in-licensing relative more technologies from public research organizations, which could serve as substitute for the smaller industry players. However, examining the licensing deals from public research organizations in the US (including universities, research institutes etc.) vs. all licensing deals, we observe that the ratio of deals involving those organizations has not increased.[6]

The decline in licensing deals by biopharmaceutical firms suggests gradual changes in the dynamics of markets for technology in the biopharmaceutical industry. Overall, between 2006 and 2015, the number of out-licensing deals declined by 62.01 %, which is particularly intriguing considering that the total amount of R&D expenditure for this sample of biopharmaceutical firms increased by 31.52 % in the same period. While these are only patterns without a counterfactual allowing us to understand deviations from an expected trajectory, the contrast between out-licensing numbers and R&D investments does not seem to reconcile with what one might expect in terms of technology commercialization. Although biopharmaceutical firms have been expanding their R&D activities, out-licensing in the industry is not following a similar trajectory. Next, we investigate these changes more thoroughly.

4. Changes in biopharmaceutical markets for technology

We examine whether the decline in licensing deals, as shown in Fig. 1, occurred due to a lack of demand in the downstream product markets (Rothaermel, 2001) or because of structural changes in upstream technology markets (Moreira et al., 2020; Moreira et al., 2019). Based on sales data obtained from *Compustat*, one can observe that the total amount of sales in the industry has climbed from $200.000 (million) in 1995 to well over $600.000 (million) in 2015. This pattern suggests that the changes in the number of licensing deals is unlikely to be associated with changes in the demand for new drugs and therapies as the sales for biopharmaceutical firms have been steadily expanding throughout the years.

We then investigate the role of firms' possession of in-house complementary assets by focusing on companies' ratio between *Property, Plant, and Equipment* (PPE) and total assets. As firm PPE consists of highly specialized physical assets that cannot be readily liquidated or sold (e.g., buildings and machinery), they tend to be associated with long-term investments (Cleary, 1999; Souder and Bromiley, 2012). Importantly, these assets represent the investments made by firms to build capabilities for developing and manufacturing drugs and therapies in-house. Interestingly, we observe a sharp reduction in the industry's physical assets intensity, with this ratio dropping *more than half* between 1995 and 2015. Examining sales and PPE together, we observe that biopharma firms are investing less in complementary assets related to the development and manufacturing of drugs, despite steady increases in sales.

To further probe into the overall decline in realized licensing deals, we assess which industry participants were ultimately responsible for launching products in the downstream markets (Khanna et al., 2016). Using the applications for drug approvals in the *FDA Orange Book*, Fig. 2 shows that new product commercialization is no longer under the purview of large firms, with firms outside the Top 50 in global sales (Source: *Pharmaceutical Executive*) being increasingly responsible for the applications for drug approvals at the US FDA. Considering the traditional markets for technology, we would expect such firms to essentially become technology suppliers as they lack complementary assets and license their technologies to larger firms. However, between 2006 and 2015, 41 % of all drugs approved by US regulatory authorities were submitted by these smaller industry players, which are likely endowed with far fewer complementary assets than are the traditional industry incumbents.

The pattern above is also corroborated if we separate traditional pharma firms founded before the biotechnology revolution (i.e., 1976, with the founding of Genentech) and the biotechnology players (i.e., founded later). Fig. 2 shows that the non-traditional pharma firms were responsible for almost 60 % of all new FDA submissions in recent years.[7] This pattern suggests that smaller firms, even when they are not yet dominant in sales and likely do not possess the same level of complementary assets as their larger peers, have become major players in the commercialization of new technologies. It also indicates that the smaller firms have achieved commercialization without relinquishing the rights to their intellectual property early to the traditional industry incumbents and without making equivalent investments in complementary assets.

Given the need for specialized complementary assets to develop and commercialize new drugs (Martin et al., 2017), we ask the critical question: How have firms accessed these assets without having developed them internally? We next provide one possible explanation for these patterns by exploring whether complementary assets can be "contracted" from other players in the industry.

5. Emergence of CDMOs

We noted that our traditional understanding of the market for technology traditional pharmaceutical firms and emerging biotechnology entrants does not seem to reconcile with the more recent patterns related to the number of out-licensing deals, the investments made in

[5] This information was compiled based on licensing deals reported in Recap using as a sample all public firms listed in North America Compustat, excluding universities.

[6] Public research organizations remained consistently between 14 and 20 % of all deals in the last two decades.

[7] Data from the European Medicines Agency (EMA) shows a remarkably similar pattern to the one observed in the US, with non-traditional pharma firms reaching a peak of around 50 % of the submissions.

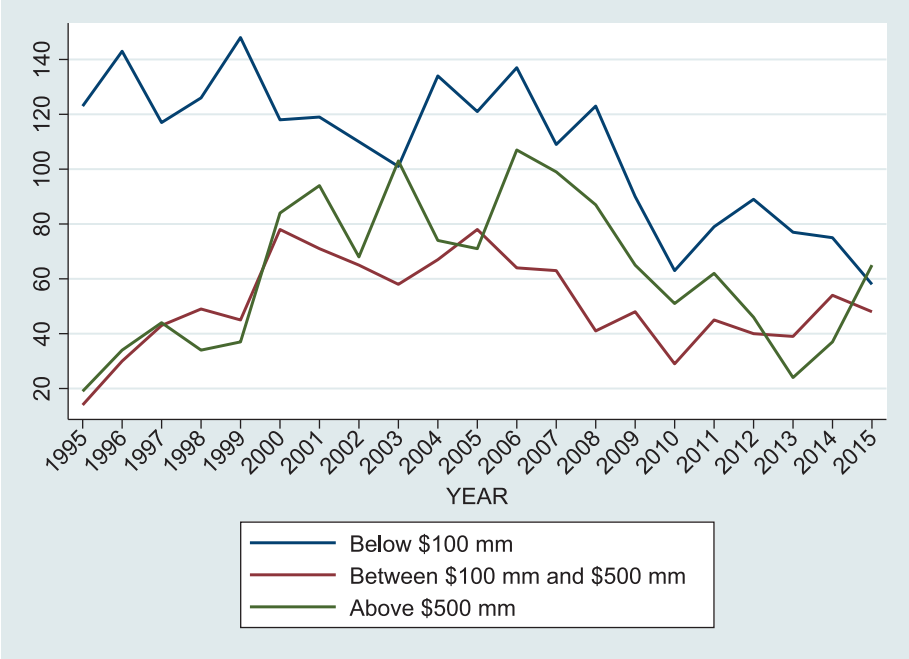

Fig. 1. Number of *out-licensing deals* in the biopharmaceutical industry.
Data: Recombinant Capital Biotech Alliance Database (Recap).

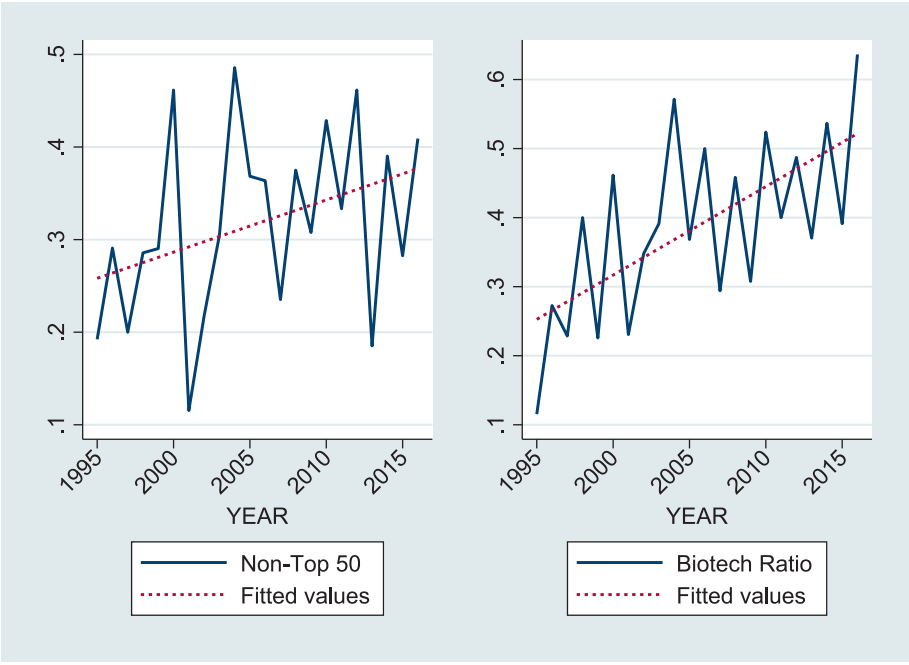

Fig. 2. FDA ratio for *new molecular entity approvals.*
Source: FDA Orange Book.

complementary assets, and the players ultimately responsible for launching new drugs documented above. Therefore, we suggest that an explanation may lie in the emergence of a new type of industry actor, Contract Development & Manufacturing Organizations (CDMOs), which have grown in importance since the mid-90s, and which, we argue, have profoundly shaped the industry. Indeed, between 1995 and 2015 CDMOs in our sample grew sales dramatically by over 500 %.

The origins for CDMOs come from API (active pharmaceutical ingredient) and GMP (good manufacturing practice) intermediate manufacturing typically provided by the fine-chemical industry as a smaller part of its business (Miller, 2017). As new technologies and therapeutic solutions in biotechnology (such as monoclonal antibodies or stem cells) emerged, firms began to become CDMOs and developed manufacturing capacity to produce therapies at scale for clinical trials. These firms provide comprehensive services ranging from the support and execution of clinical trials for drug development to drug manufacturing (see more examples of their services below). Their basic value proposition is to serve other firms in the biopharmaceutical industry on a *contract-fee basis*, offering a complete range of services to assist in every aspect of drug development. Thus, CDMOs allow the

externalization and in-sourcing of complementary assets on a "*per-use*" basis for firms investing in R&D upstream development. CDMOs typically do not perform upstream research or sell drugs downstream on the market, acting solely as contract service intermediaries using a contract-fee basis model to provide specialized assets to smaller and larger industry participants engaged in upstream drug development (Gupta and Wang, 2007). Small firms might be incapable of building or might lack the resources to develop complementary assets internally in the first place. Large firms may require adaptations in existing competencies in manufacturing and scale-up processes for emerging technologies (Gupta and Wang, 2007).

To support our exposition on the emergence of CDMOs and their value proposition we conducted five interviews, two involving executives of CDMOs and three of biopharma firms that actively use CDMOs for their clinical trials. Table 1 provides information about the interviewees.

We learnt from the CDMO executives that manufacturing drugs at scale for clinical trials requires competencies that are distinct from creating and innovating new therapies. As one CDMO CEO (*ID Number 3*) put it: "*CDMOs have an industrial and optimization mindset and aim for the fast delivery of results. When R&D personnel think of grams we think of many kilograms to be used in clinical trials.*" This suggests that efficient engineering and optimization as well as scale in the production process are the key capabilities deployed by CDMOs.

While in principle CDMOs have a focus on efficiency and scale in drug manufacturing there is also specialization in their activities. As an example, CEOs noted that CDMOs can specialize in managing the delivery of highly toxic compounds (*ID Number2, 5*), where they must adhere to strict regulation and environmental standards.

5.1. The value proposition of CDMOS for Biopharmaceutical firms

The growth of CDMOs provides flexibility for biopharma firms in terms of their commercialization strategies; rather than relying on out-licensing strategies of early-stage technology, firms can readily tap into the assets of CDMOs, and contract services such as manufacturing for the development and commercialization of new therapies.

In our interviews, executives from CDMOs and biotechnology firms alike stressed several value propositions in the development and commercialization of new therapies (*ID Number 1,3,4*). As clinical trials for treatments often require thousands of patients, many inventing firms would not have the means to manufacture their drug candidates in such quantities. Even if firms are venture backed or have IPOed, they may not want to make large idiosyncratic capital expenditures towards internal manufacturing capacity to conduct the clinical trials, given that the treatments have not yet been approved for commercial markets. Thus, CDMOs offer a set of integrated services that allow biopharma firms to outsource a large portion, or even their entire development and production process activities, that are downstream from early-stage R&D process.

Furthermore, CDMOs noted how they can improve efficiency in terms of time and costs. For example, CDMO *Albany Molecular Research Inc.,* highlights how its service offerings allow "reducing the time and cost involved in bringing these compounds from concept to market." (Albany_Molecular_Research_Inc., 2010, 10 K)." A key insight is that CDMO allow firms developing new drugs through a model of variable costs (through a fee for service model) without need to invest substantial capital into manufacturing capacity. *Syneos*, another CDMO, makes this clear "Our service offerings focus on optimizing the development, enhancing returns on their research and development, or R&D, investments, and reducing their overhead by offering an attractive variable cost alternative to fixed cost, in-house resources" (Syneos_Health, 2014, 10-K).

The cost advantages of CDMOs come from the synergies from offering engineering services to many firms in the industry, thus exploiting economies of scale. CDMOs leverage their assets over a broad range of contracting participants, thus increasing efficiencies. Yet, the interviews with biopharmaceutical firm executives (*ID Number 2, 3*) emphasized another value proposition of CDMOs as they help firms to build and devise scale-up plans of the manufacturing process beyond clinical trials. This allows firms to demonstrate that once their product is approved commercially, they have a plan how manufacturing could be scaled for commercialization (See *Appendix 1* for a detailed description of how CDMOs help biopharma firms scale on a global level).

The benefits of accessing complementary assets to contract through CDMOs clearly holds value for firms but may raise the concern of expropriation. However, both CDMOs and biopharmaceutical firm executives in our interviews stressed that ownership of IP of what is manufactured tends to remain with the firm contracting for services from CDMOs (*ID Number 1,2,3*). They also stressed that the IP management and IP rights of inventions created around the manufacturing process of the therapy are agreed upon ex-ante in the contract or as one of the CDMO executive noted (ID3) "Firms working with CDMOs wrap their IP with layers and layers of protection." Furthermore, CDMOs are focused on providing the support for clinical trials and manufacturing of new drugs and therapies. Those processes are not likely to add technical knowledge to the initial science and research developed by the contractor (i.e., biotech or pharma) so the important point is to protect existing IP.

5.2. Implications of CDMOs on competitive advantage and the market for technology within the biopharmaceutical industry

One of the fundamental questions raised with the emergence of CDMOs in the biopharmaceutical industry concerns how it affects the distribution of competitive advantages across firms (Porter, 2008). Teece's seminal framework (1986) emphasizes the importance of possessing complementary assets as a key determinant of biopharmaceutical firm's capacity to profit from their innovation. In detail, Teece noted that "*The successful commercialization of innovations requires that the know-how in question be utilized in conjunction with other capabilities or assets*" (1986, p. 288). In the case of the biopharmaceutical industry, successful product development and commercialization is dependent to scaling in manufacturing and the ability of mass testing in clinical trials, which typically was the turf of established pharmaceutical firms (Rothaermel, 2001).

CDMOs offer access to the capabilities and equipment that were historically concentrated on those small number of larger firms. In principle, they make highly specialized complementary assets available for rent on *per-use basis* for every industry player. This means that complementary assets and development capabilities continue to be specialized but are now available to any firms to access, which changes the nature of the industry's competitive advantage (Rothaermel and Boeker, 2008). Interestingly, even if Teece's original framework did not emphasize an external contracting for complementary assets, he acknowledged that "[…] *when the innovation is systemic, the complementary assets may be other parts of a system*" (Teece, 1986, p. 288). Thus, the emergence of CDMOs calls for a reconceptualization of the role of complementary assets in shaping competitive advantage, R&D strategies, and performance in the biopharmaceutical industry.

CDMOs have implications for all market players in the biopharmaceutical industry. For biopharmaceutical firms with business models focused on extensive R&D investments the underlying technologies will be the differentiating factors so that scientific capabilities will grow in importance in defining profitability. With CDMOs, these R&D focused firms have an alternative development and commercialization strategy as they could mature their products to a point further downstream in-house but without investing in their own internal complementary assets for development. This suggests scientific capabilities underlying the biotechnology firms will play an even larger role in determining their competitive advantage as the risk of development will be fully assumed by these firms.

Table 1
Interviews with CDMOs and biopharmaceutical representatives.*

ID Number	Position	Sector	Technological Areas	Geographic Scope	Duration
1	CEO	CDMO	R&D services and manufacturing for broad chemical reactions and products	North America, Europe	50 min
2	CEO	Biopharma	Therapeutics that cross blood-brain barrier	Europe	40 min
3	CEO Board Member	Biopharma CDMO	Biotech: Skin Cancer Therapy CDMO: Injectable drugs (parenteral medications)	Europe Global	50 min
4	Board Member and Investor	Biopharma	CAR-T candidates for the treatment leukemia	Europe	45 min
5	Senior Business Development Executive	Biopharma	Radiotherapeutics for cancer treatments	Europe	30 min

*All intervies have been transcribed and coded.

For firms engaged in upstream R&D, CDMOs should also affect the payoff structures of out-licensing vs. keeping drugs in-house for further maturation. Through licensing firms can obtain short-term revenues (e.g., upfront fees and milestone payments), even when the development of their drugs is still "work-in-progress" (Anand and Khanna, 2000; Choi, 2002; Moreira et al., 2020). The extreme alternative is to develop the drug in-house, building complementary assets in-house and when the drug eventually reaches downstream product markets capturing the larger (yet riskier) revenue upside (Choi, 2002; Jensen and Thursby, 2001; Kotha et al., 2018). CDMOs provide a more cost-effective approach as firms, in principle, do not have to invest in complementary assets for development but also do not have to relinquish control to more established industry players at an early stage.

The possibility of capturing a larger upside using CDMOs was reflected by our interviewees. They emphasized that due to their venture funding they, in principle, had enough cash at hand to involve and contract CDMOs for clinical development. As one biotechnology CEO noted: "*Moving from animal studies to one with 1,000 people and demonstrating an effect: The value of the clinical study is much, much higher and the payback is enormous*" (*ID Number 3*). Interestingly, catching such possible revenue upside, also, syncs with investors putting money in biotechnology firms. According to our biotechnology firm interviewees (*ID Number 4*), investors "*…take the risk because the payback is very high and they know some companies will fail and some will win. And for the winners the price is huge*." Moreover, investors prefer the variable costs aspect of CDMOs as building and maintaining complementary assets in-house would be an enormous capital expenditure for their portfolio firms.

Overall, this suggests an alternative development and commercialization strategy for biopharmaceutical firms as they can focus on their scientific capabilities, mature their products to a point further downstream in-house and neither out-license their technologies to firms in possession of complementary assets at an early stage, nor invest in internal manufacturing capacity for clinical development. This syncs with the patterns we documented previously, in which we observed relatively fewer upstream licensing deals coming from smaller firms and more drugs pushed to commercial markets by those firms. It is important to note though that despite these possible benefits, CDMOs are not a panacea, as clinical trials continue to have a low probability of succeeding. As R&D intensive firms now take on the maturation and commercialization by themselves it also takes out an important quality filter in terms of what drugs get pushed towards development. This may, ultimately and adversely affect the quality of drugs moved towards commercialization.

The changes in the competitive advantage in the industry also affects larger biopharmaceutical firms. In terms of development, they now own complementary assets that are not as unique anymore in the industry, which reduces their ability to sustain an advantage in terms of the development of new drugs (Ceccagnoli et al., 2010). This should push larger firms to increase their internal capabilities to match the capacity of specialized small biotech companies to develop more novel solutions. Alternatively, larger biopharmaceutical firm may look beyond development and try to differentiate themselves further downstream in commercial markets. Large biopharma firms often have a global distribution network and can help smaller firms at or post commercial approval to speed delivering drugs to actual patients on a global scale.

5.3. Moderna and Inovio – using CDMOs to develop and commercialize global vaccines

To showcase the role of CDMOs in drug development, we present two cases, Moderna and Inovio Pharmaceuticals, which were active in developing vaccines against Covid19 in 2020. Moderna worked on mRNA vaccines prior to Covid and, from the start, relied on using CDMO services. One of the first agreements was with GenIbet Biopharmaceuticals to take the very first Moderna mRNA vaccine in the clinic at the end of 2015. In 2015, GenIbet started to scale up and produce batches of mRNA, to develop better ways to stabilize large amounts of mRNA in a way that Moderna could use it in various clinical trials. At that time, Moderna did not have the capacity to produce mRNA batches at scale.[8]

Moderna also signed a 2016 deal with CordenPharma (Switzerland), which was then expanded in 2020 to manufacture large-scale volumes of Moderna's lipid excipients to be used in the manufacture of Moderna's vaccine candidate (mRNA-1273) against the novel coronavirus. CordenPharma had a long-standing reputation as a leader in specialized lipid manufacturing. As Moderna's CTO noted "This expansion will increase supply of lipid excipients used to manufacture our mRNA products. We appreciate CordenPharma's global presence and CDMO expertise as we scale manufacturing of mRNA-1273."[9]

In 2020, Moderna signed additional deals with CDMOs Lonza and Recipharm to help prepare for mass scaling in both clinical trials and, potentially, a commercial launch.[10] This syncs with insights from our interviews with the biotechnology firm executives (*ID Number 3, 5*) that CDMO services can go beyond clinical trials as they help demonstrate that a products can be produced at scale once commercial approval has been attainted. This was particularly important for Covid 19 vaccines such as the one from Moderna, which was expected to, if approved, be commercialized globally immediately.

The Moderna case is in stark contrast with the points we describe in the MFT 1.0. Indeed, Moderna was able to commercialize a product with a global rollout at scale without the help of a major biopharmaceutical firm. It is very likely that in the absence of CDMO helping with the manufacturing for clinical trials and the commercial manufacturing after approval, Moderna would have had to rely on the development and manufacturing capabilities of a larger pharmaceutical partner.

[8] Source: https://www.oeirasvalley.com/en/at-ibet-we-have-research-projects-with-major-international-partners/.

[9] Source: https://www.prnewswire.com/news-releases/cordenpharma–moderna-extend-strategic-manufacturing-services-agreement-for-the-supply-of-lipid-excipients-to-be-used-in-modernas-vaccine-mrna-1273-against-the-novel-coronavirus-sars-cov-2-301066688.html.

[10] Source: https://www.fiercepharma.com/pharma/moderna-clinches-fourth-vaccine-manufacturing-tie-up-sweden-s-recipharm.

Despite the successful example of Modena, drug development remains risky and firms, despite using CDMO, may ultimately not achieve commercial approval. A case in point is Inovio, a small biotech firm (USD 5.6 million total revenue in 2020), which specializes in the development of DNA vaccines, and in 2020, possessed almost no downstream capabilities. Inovio's DNA technology was believed to have potential for a Covid vaccine in 2020. Consequently, Inovio revealed a strategy to partner with Thermo Fisher among others in late 2020 when it announced the manufacturing plans of its COVID DNA vaccine:

> "**With its consortium of third-party manufacturers**, INOVIO plans to have 100 million doses of INO-4800 manufactured in 2021, subject to FDA approval of INO-4800 for use as a COVID-19 vaccine. **Thermo Fisher plans to manufacture INO-4800 drug substance as well as perform fill and finish of INO-4800 drug product at its commercial facilities in the US**."
>
> (Inovio, 2020)

The development and production of DNA vaccines required a new set of highly specialized complementary assets, likely lacked by even established industry players at the time. Building and maintaining these complementary assets would be an enormous task for any firm; CDMOs were able to bridge this gap by exploiting the increased demand for such highly specialized technologies while serving a variety of industry players. Ultimately, however, Inovio's technology did not pass the clinical endpoints and despite having the manufacturing through CDMOs available and being ready for commercial scaling the vaccine never reached the market. Inovio's case is a good example of how the emergence of CDMOs are shifting the source of competitive advantage in this industry upstream. Indeed, this company was successful in mobilizing a consortium of CDMOs to support clinical trial development and manufacturing of highly specificized raw materials required for this vaccine, but the technology development was not successful.

5.4. Empirically identifying CDMOs

Next, we systematically identify CDMOs to more clearly understand their impact on markets for technology. To alleviate concerns emerging from the international context and regulatory differences in which CDMOs operate, we opted to focus in our empirical exploration on actors located in the United States, which has two important advantages. First, as we out-lined the demand for CDMOs still predominantly emerges from the US, so tracking US based biopharmaceutical firms captures >50 % of demand for CDMO services – in particular in terms of advancing therapies through clinical trials for their initial approval. Second, focusing on CDMOs located in the US resolves issues of comparability in terms of regulatory differences and differences in IP rights across countries. The US is considered a country with the strongest intellectual property regime, which allows us to keep IP rights fixed as important boundary condition for our analysis. Thus, we allow a key dimension in the form of complementary assets to shift based on the emergence of CDMOs, while keeping the appropriation regime constant.

Despite the importance of CDMOs, there is no existing directory of these firms that allows one to examine their influence on the biopharmaceutical industry. Therefore, using several data sources, we built a dataset that identifies and maps CDMOs. The initial set was identified based on the firms listed in the Standard Industrial Classification (SIC) code *8731: Commercial Physical and Biological Research Establishments*. These firms primarily engage in commercial physical and biological research and development on a *contract or fee basis.* We used *Compustat* to identify all firms reported in this SIC between 1995 and 2015 as this is the period for which the data on technology licensing is available. These initial criteria led to a set of 101 unique firms. However, within this SIC are firms that provide services unrelated to the biopharma industry. For example, some firms are engineering contractors providing precision instruments to operate laboratories, supporting activities such as superconductive wireless systems, or helping to optimize industrial processes. Thus, based on the business descriptions in 10-K reports, as available on EDGAR, we verified whether these firms offer development and manufacturing services on a contract or fee basis to biopharmaceutical firms.[11] The 10-K fillings supply extensive business descriptions that, per the Securities and Exchange Commission (SEC) regulations, must include a clear explanation of the firms' products and services (Hoberg and Phillips, 2016). This allowed us to identify and validate the CDMOs operating in the biopharmaceutical industry, which ultimately yielded 32 unique CDMO firms.

Since firms may be listed in different SIC codes, but still work as contractors within the biopharmaceutical industry, we identified a second set of firms by searching for CDMO activities through *Mergent*. *Mergent* is acknowledged as one of the most comprehensive sources for in-depth business and financial research for firms based in the US. It complies a firm's information based on the required SEC filings, news articles, trade publications, and company websites. Using that information, we performed textual searches on the *Business Description* field for US firms (active and inactive). The Business field description in *Mergent* provides a detailed and accurate categorization of the main activities performed by firms.

We started our search using three broad keywords characterizing CDMOs activities: "*Contract Development,*" "*Contract Manufacturing*" and "*Contract Research.*" As expected, this led to a broad set of firms not restricted to CDMOs servicing the biopharma industry. Once more, we scrutinized each firm individually to ensure that we only included actual CDMOs. For that, we not only relied on the *Business Segment* description provided by *Mergent*, but also used the same approach based on 10-K fillings. This search provided us with an additional 34 CDMOs.

Given that 10-K filings critical to identifying CDMOs are only available for online searches from 1994 Q3 (third quarter), we chose 1995 as the starting year of our analyses.[12] Additionally, due to data availability related to out-licensing deals and licensing offerings, the last year in our sample is 2015. Therefore, combining the set of CDMOs extracted from *Compustat* and *Mergent*, and subsequently confirmed through 10-K filings, resulted in 66 unique public firms active between 1995 and 2015 that serviced the biopharmaceutical industry, leading to 834 unique CDMO-year combinations.

One limitation to this approach is that our analysis is restricted to publicly listed CDMOs. We chose this set of firms because it provides us with ample access to financial information regarding these firms, which will be necessary to compute some of the main variables used in our estimations. However, we expect that our sampling criteria will lead to an underestimation of the effect that these organizations have on the biopharmaceutical industry. Nevertheless, later in this paper, we also provide additional analysis in which our estimations do not rely strictly on publicly listed CDMOs.

6. Testing the effect of CDMOS on the market for technology

We followed prior studies and compiled a sample of biopharmaceutical firms using the *SICs 2834: Pharmaceutical Preparations* and *2836: Biological Products, Except Diagnostic Substances* (Moreira et al., 2020; Simeth and Cincera, 2016). Once more, we restricted our sample to firms which were headquartered and incorporated in the US. We also restricted our sample to firms that actively develop new drugs and therapies while excluding those that did not initiate at least one preclinical or clinical trial in the decade prior to a focal year. Therefore, this sample comprises firms that are most relevant in terms of R&D investments and the development of new drugs, treatments, and therapies.

[11] Accessible at www.sec.gov.

[12] We opted to use this window to keep the data consistent throughout the paper. However, starting the analyses from 1990, using data sources other than those relying on EDGAR filings provided comparable results to those we report here.

They are also the most important clients for services provided by CDMOs. Furthermore, they are the firms that actively engage in markets for technology by either out-licensing or in-licensing technologies. Based on *Compustat* and clinical trial information, we were able to identify 787 unique firms for the sampling period.

We screened the10-K filings of firms in this sample for mentions of the names of the *66 unique* CDMOs that we identified previously. It is likely that the more biopharmaceutical firms use the names of the CDMOs in their filings, the more they rely on their services. Because 10-Ks tend to be very specific in terms of R&D activities and strategy for biopharma firms, they would mention the name of the CDMO, for example, when they rely on a contract with a CDMO partner. Thus, CDMO mentions in the 10-Ks indicate the degree to which biopharmaceutical firms are reliant on the CDMOs' services.

Fig. 3 shows that, in the mid-90s, the biopharmaceutical firms barely mentioned any of the 66 CDMOs in their 10-K reports. Similar to the longitudinal patterns that we reported regarding the emergence of CDMOs, this figure also suggests a substantial ramp-up in the use of contracting organizations by the late-90s. Fig. 3 shows that the number of 10-K mentions to CDMOs increased. The number of biopharmaceutical firms citing at least one CDMO in their reports followed the same pattern, suggesting widespread use of CDMOs contracting. The expansion of CMDOs, thus, provides a potential explanation for how firms with fewer assets are able to commercialize new products, despite a decline in overall industry investments in complementary assets.

To examine how the emergence of CDMOs has affected a firm's participation in the markets for technology, we, next, conduct firm-level analysis. Our goal is to go beyond descriptive patterns and empirically examine how the markets for technology have changed because of the emergence and expansion of CDMOs. In particular, we address the following question: Does the emergence of CDMOs shape a biopharma firm's R&D strategies including out-licensing and drug development?

6.1. Sample and databases

We collected longitudinal information for the identified biopharmaceutical firms (discussed above). We then matched these firms with *Pharmaprojects*, a database widely used by researchers to capture drug development (Adams and Brantner, 2006; Kapoor and Klueter, 2015). A unique advantage of this database is that it documents whether a biotechnology firm has offered a technology in drug development for licensing (but not necessarily licensed). *Pharmaprojects* highlights the technology available for licensing and the corresponding year that the licensor made that technology available to potential licensees. We use this information to capture biopharmaceutical firms' offerings to out-license their technologies while also matching the biotechnology firms with the Recombinant Capital Biotech Alliance Database (Recap). This allowed us to access detailed information regarding *realized licensing deals*, R&D collaborations, Merger and Acquisitions (M&As), and manufacturing deals. Finally, we obtained patent information for our sampled firms using data from the *United States Patent and Trademark Office* (USPTO), accessed from *PatentsView*. The final sample consists of 6062 observations regarding 787 unique firms, with each firm appearing 7.7 times on average over the period 1995 and 2015.

6.2. Dependent variables

We use two different dependent variables to capture the effect of the emergence of CDMOs on upstream markets for technology. First, we perform our analysis using *Out-Licensing Offerings* as a dependent variable. This variable captures the technologies that the biopharma firms have communicated as being available for out-licensing, regardless of a deal being realized. This information on out-licensing offerings is extracted from *Pharmaprojects*, where licensors can indicate to potential licensees that they have a technology available for licensing. We focus on new drug development projects, i.e., those drugs in preclinical or clinical development. For those projects, we extracted the year they were flagged as licensing opportunities in *Pharmaprojects*. To create the variable *Out-Licensing Offerings*, we counted the number of licensing opportunities for each sampled licensor firm I within year $t + 1$ *and* $t + 2$.[13] Finally, to deal with skewness, we take a logarithm of this variable. Second, we also use as a dependent variable the number of *Realized Out-Licensing Deals* to see if the results remain consistent with those reported using *Out-Licensing Offerings*. The information on realized licensing deals was obtained using *Recap*, which lists the deals in which a licensor was able to successfully find a licensee. We used the same time window as described for licensing offerings and took the logarithm of this alternative dependent variable.

6.3. Explanatory variables

As this is one of the first studies to estimate the effect of CDMOs on firms' out-licensing offerings, we computed two sets of explanatory variables – firm-level and sector-level variables.

Firm level explanatory variable

Using CDMOs Services. A key indication of the usage of CDMO services is the mention of CDMOs in a firm's regulatory filing, in which firms disclose important transactions and strategies; for example, firms that engage with a CDMO regarding clinical development tend to disclose such activities in their filings. We searched within each biopharmaceutical firm's 10-K reports for the names of the identified CDMO. We counted the number of times a biopharmaceutical firm i mentions the identified CDMOs in its 10-K in year t. Because firm size may have a significant effect on both the number of mentions to CDMOs in 10-K reports and out-licensing offerings, we normalize this variable by using a focal firm's sales in the same year.[14]

CDMOs sector level explanatory variable

CDMOs Property, Plant, and Equipment. This variable captures the long-term investments made by CDMOs, to service biopharmaceutical firms measured as the total investments in the *Property, Plant, and Equipment of the CDMOs* serving the biopharma industry in a given year.

6.4. Control variables

Total Assets. We control for firm size using the logarithm of the Total Assets that firm i reported in a given year t.[15]

Downstream Commercial Capabilities. We control for the ratio between Selling, General & Administrative Expense and Assets. This variable captures the relative amount of investments that biopharmaceutical firms have allocated in sales and administrative efforts (Rothaermel, 2001).

R&D Intensity. To account for heterogeneity regarding the relative amount of R&D invested by each firm in our biopharma sample, we use the ratio between R&D expenditure to assets firm i incurred in year t (Cohen et al., 2000).

Financial Slack. We also control for the potential confounding effect that the amount of financial slack may have on firms' out-licensing offerings. This variable is based on the relationship between Debt in

[13] Although we prefer to use this variable based on the cumulative number of out-licensing offerings within t + 1 and t + 2, using only the first period provides results similar to those reported in our main analyses.

[14] The non-normalized version of the variable provides estimates comparable to those reported in our main estimations.

[15] Using a control for size, either firms' Total Assets or Property, Plant and Equipment or Total Sales provide the same results as those reported in the paper.

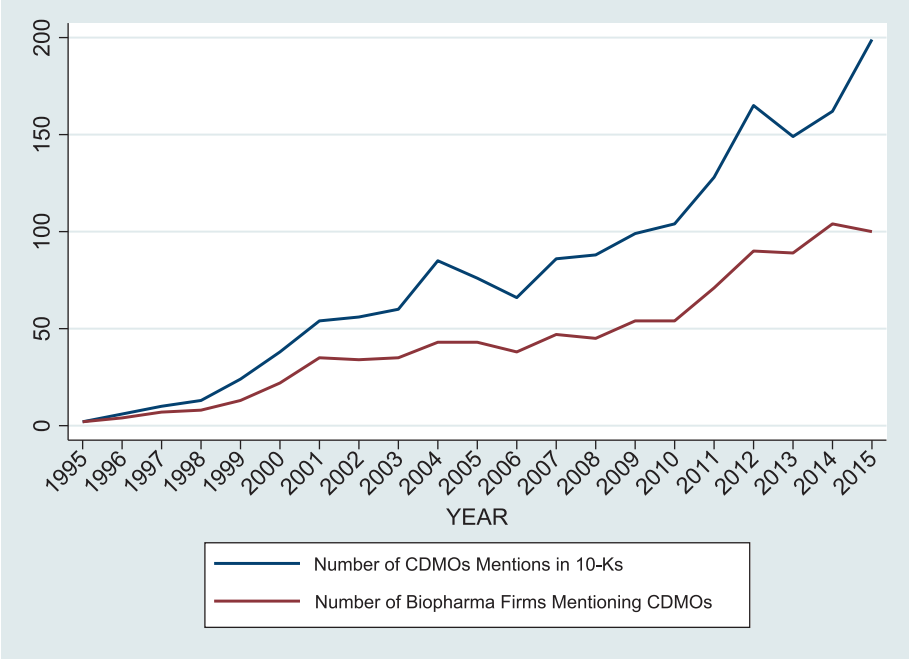

Fig. 3. Number of *CDMOs mentions* in biopharmaceutical firm 10-Ks.
Data: Wharton research data services.

Current Liabilities to Assets firm *i* reported in year *t* (Bourgeois, 1981).

R&D Collaboration. We control for the number of cumulative R&D collaborations that a firm has entered within 6 years from the focal year *t* (Klueter et al., 2017).

Realized Licensing Deals. To control for the effect of prior licensing on a firm's willingness to out-license its technologies, we use Recap to compute the cumulative number of realized licensing deals that the focal firm i has entered within the six years prior to the focal year *t* (Moreira et al., 2019).

Number of Acquisitions. To control for the effect that a firm's acquisition strategy may have on its out-licensing offerings, we control for the number of acquisitions that a focal firm entered as the acquiror within a given year (Moeller et al., 2004).

Government Funding. We also account for the importance of US Government funding received by the firms in our sample (Hemmatian et al., 2022). To compute this variable, we rely on Recap to identify the cumulative number of contracts a focal firm i had with the major US funding agencies (e.g., NIH, NSF, DoD, USDA, DoE) within the three years prior to the focal year *t*.

R&D Pipeline. Because firms with a larger number of drugs under development are also more likely to out-license, we also extracted from *Pharmaprojects* the number of current drugs under development in a focal firm *i's* pipeline. Accordingly, this variable is based on the count of ongoing internal R&D initiatives (Ceccagnoli et al., 2018).

Patent Stock. We control for the number of patents a focal firm *i* has accumulated for the four-year window prior to year *t*.[16]

Product Market Competition. We also control for the intensity of competition in downstream product markets by using a Herfindahl index based on the sales reported by the biopharmaceutical firms in our sample in a given year *t* (Moreira et al., 2019).

6.5. Econometric specifications

Taking advantage of the longitudinal structure of our data, we opted to use (within) firm-fixed effects ordinary least squares estimations to account for time invariant characteristics of firms in our sample. We also included year-fixed effects to account for overall temporal trends. Further, we used robust standard errors by biopharma firms to correct for potential bias emerging from heteroskedasticity. Finally, we used one year-lag structures between our dependent and independent variables to minimize concerns related to reverse causality. We are mindful that, with this process, we are not able to test causal relationships; nevertheless, we do our best to examine the relationship between the use of CDMOs and in out-licensing decisions of biopharmaceutical firms.

6.6. Results

Table 2 reports the descriptive statistics and the pairwise correlations of all variables used in our models. The descriptive statistics did not indicate the existence of any potential multicollinearity issues. Additionally, the average VIF among our explanatory variables is 5.67, with no individual variable showing values above a threshold of 10.

Table 3 reports the results of our firm fixed-effects estimations predicting *Out-Licensing Offerings*. Model I includes only the control variables. Model II introduces our first explanatory variable, *Using CDMOs Services*, which is negative and significant associated with our dependent variable ($p < 0.001$). Model III reports CDMOs Property, Plant and Equipment with a negative and statistically significant effect ($p < 0.001$). Model IV enters both variables, with the coefficients remaining very stable in terms of significance and direction. Finally, because CDMOs Property, Plant and Equipment only varies longitudinally, we estimated Model V and Model VI without year-fixed effects to verify the stability of the coefficients for our explanatory variables.[17] As can be seen in these two models, the estimations remained similar to those

[16] Alternatively, we used as a control the count of patents with priority in foreign countries. The results remained the same as those reported in the paper using the original *Patent Stock* variable.

[17] When these models are estimated with year-fixed effects, one additional dummy (in addition to the baseline) is automatically omitted from the estimation to avoid the so-called "dummy variable trap" (Blackwell III, 2005).

Table 2
Descriptive statistics and pairwise correlations.

	Variables	Mean	S.D.	[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]
[1]	Out-licensing offerings	0.23	0.45	1							
[2]	Realized out-licensing deals	1.49	2.48	0.16	1						
[3]	Using CDMOs services	0.63	2.89	−0.02	0.03	1					
[4]	CDMOs property, plant and equipment	6.29	1.98	−0.14	−0.21	0.1	1				
[5]	Current assets	3.69	1.98	0.01	0.28	0.09	0.01	1			
[6]	Downstream commercial capabilities	0.02	0.35	−0.02	−0.03	−0.01	0.03	−0.09	1		
[7]	R&D intensity	2.75	81.48	0.00	−0.01	−0.01	0.02	−0.05	0.67	1	
[8]	Financial slack	0.02	0.46	0.02	−0.01	−0.01	−0.02	−0.07	0.23	0.16	1
[9]	R&D collaboration	1.1	2.12	0.11	0.43	0.12	−0.01	0.21	−0.01	0.00	−0.02
[10]	Realized licensing deals	3.36	4.92	0.12	0.67	0.12	−0.09	0.38	−0.03	−0.02	−0.02
[11]	Number of acquisitions	0.01	0.12	−0.02	0.01	0.00	−0.01	0.07	0.00	0.00	0.00
[12]	Government funding	0.34	0.87	0.03	0.12	−0.03	−0.05	0.11	−0.02	0.00	0.02
[13]	R&D pipeline	8.52	16.95	0.07	0.36	0.02	−0.03	0.53	−0.02	−0.01	−0.01
[14]	Patent stock	7.3	23.91	0.01	0.31	0.02	−0.08	0.53	−0.02	−0.01	−0.01
[15]	Product market competition	0.88	0.06	−0.02	−0.06	0.04	0.23	0.17	−0.01	−0.01	−0.04

	Variables	Mean	S.D.	[9]	[10]	[11]	[12]	[13]	[14]	[15]
[9]	R&D collaboration	1.1	2.12	1						
[10]	Realized licensing deals	3.36	4.92	0.71	1					
[11]	Number of acquisitions	0.01	0.12	0.01	0.04	1				
[12]	Government funding	0.34	0.87	0.06	0.1	0.00	1			
[13]	R&D pipeline	8.52	16.95	0.21	0.4	0.02	0.28	1		
[14]	Patent stock	7.3	23.91	0.1	0.29	0.06	0.21	0.62	1	
[15]	Product market competition	0.88	0.06	−0.05	0.00	0.03	−0.05	0.12	0.13	1

Table 3
Fixed effects estimations predicting *out-licensing offerings*.

Variables	Model I	Model II	Model III	Model IV	Model V	Model VI
Using CDMOs Services		−0.031***		−0.031***		−0.045***
		(0.003)		(0.003)		(0.003)
CDMOs Property, Plant and Equipment			−0.064***	−0.064***	−0.028***	−0.028***
			(0.011)	(0.011)	(0.007)	(0.007)
Total Assets	0.019†	0.019†	0.019†	0.019†	0.010	0.010
	(0.010)	(0.010)	(0.010)	(0.010)	(0.009)	(0.009)
Downstream Commercial Capabilities	−0.020*	−0.020*	−0.020*	−0.020*	−0.025***	−0.025***
	(0.009)	(0.009)	(0.009)	(0.009)	(0.006)	(0.006)
R&D Intensity	0.000*	0.000*	0.000*	0.000*	0.000***	0.000***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Financial Slack	0.025***	0.025***	0.025***	0.025***	0.022***	0.022***
	(0.004)	(0.004)	(0.004)	(0.004)	(0.004)	(0.004)
R&D Collaboration	0.008	0.008	0.008	0.008	0.012	0.012
	(0.010)	(0.010)	(0.010)	(0.010)	(0.010)	(0.010)
Realized Licensing Deals	−0.009†	−0.009†	−0.009†	−0.009†	−0.008†	−0.008†
	(0.005)	(0.005)	(0.005)	(0.005)	(0.005)	(0.005)
Number of Acquisitions	−0.079†	−0.079†	−0.079†	−0.079†	−0.082†	−0.082†
	(0.044)	(0.044)	(0.044)	(0.044)	(0.043)	(0.043)
Government Funding	0.029	0.030	0.029	0.030	0.052	0.052
	(0.040)	(0.040)	(0.040)	(0.040)	(0.040)	(0.040)
R&D Pipeline	0.003*	0.003*	0.003*	0.003*	0.003*	0.003*
	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)
Patent Stock	−0.000	−0.000	−0.000	−0.000	−0.000	−0.000
	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)
Product Market Competition	0.340	0.344	0.340	0.344	0.034	0.036
	(0.389)	(0.389)	(0.389)	(0.389)	(0.339)	(0.339)
Constant	0.014	0.010	0.153	0.149	0.321	0.318
	(0.315)	(0.315)	(0.304)	(0.304)	(0.280)	(0.280)
Firm Fixed Effects	YES	YES	YES	YES	YES	YES
Year Fixed Effects	YES	YES	YES	YES	NO	NO
Number of Observations	6.062	6.062	6.062	6.062	6.062	6.062
Log-Likelihood	−2702.405	−2701.699	−2702.405	−2701.699	−2813.338	−2811.873

Note. Two-tailed tests for all variables; standard errors are in parentheses.
† 0.1 * 0.05 ** 0.01 *** 0.001.

including year-fixed effects.

Next, we extend our analysis by determining whether the use of realized deals as a dependent variable provides results similar to the ones obtained with offerings. The results reported on Table 4 show that that *Using CDMOs Services* ($p < 0.001$) and *CDMOs Property, Plant and Equipment* ($p < 0.001$) are also negative and statistically significant predicting this dependent variable. These patterns indicate that, overall, the results are remarkably similar when we compare out-licensing deals and offerings, both coming from different data sources. It is also worth noting that *out-licensing offerings* and *out-licensing realized deals* come

Table 4
Fixed effects estimations predicting *realized out-licensing deals*.

Variables	Model I	Model II	Model III	Model IV	Model V	Model VI
Using CDMOs Services		−0.100***		−0.100***		−0.162***
		(0.019)		(0.019)		(0.022)
CDMOs Property, Plant and Equipment			−0.146**	−0.145**	−0.146***	−0.146***
			(0.051)	(0.051)	(0.038)	(0.038)
Total Assets	−0.102**	−0.102**	−0.102**	−0.102**	−0.143***	−0.142***
	(0.038)	(0.038)	(0.038)	(0.038)	(0.037)	(0.037)
Downstream Commercial Capabilities	−0.027	−0.027	−0.027	−0.027	−0.031	−0.031
	(0.026)	(0.027)	(0.026)	(0.027)	(0.033)	(0.033)
R&D Intensity	0.000	0.000	0.000	0.000	0.000	0.000
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Financial Slack	−0.005	−0.005	−0.005	−0.005	−0.022	−0.022
	(0.015)	(0.015)	(0.015)	(0.015)	(0.015)	(0.015)
R&D Collaboration	−0.217*	−0.217*	−0.217*	−0.217*	−0.204*	−0.204*
	(0.097)	(0.097)	(0.097)	(0.097)	(0.099)	(0.099)
Realized Licensing Deals	0.114**	0.114**	0.114**	0.114**	0.124**	0.124**
	(0.038)	(0.038)	(0.038)	(0.038)	(0.038)	(0.038)
Number of Acquisitions	−0.497†	−0.497†	−0.497†	−0.497†	−0.526†	−0.526†
	(0.300)	(0.300)	(0.300)	(0.300)	(0.301)	(0.301)
Government Funding	0.331	0.332	0.331	0.332	0.514	0.515
	(0.319)	(0.320)	(0.319)	(0.320)	(0.324)	(0.324)
R&D Pipeline	0.033*	0.033*	0.033*	0.033*	0.031*	0.031*
	(0.014)	(0.014)	(0.014)	(0.014)	(0.015)	(0.015)
Patent Stock	0.007	0.007	0.007	0.007	0.007	0.007
	(0.008)	(0.008)	(0.008)	(0.008)	(0.008)	(0.008)
Product Market Competition	−6.120**	−6.107**	−6.120**	−6.107**	−2.701	−2.693
	(2.123)	(2.124)	(2.123)	(2.124)	(1.982)	(1.983)
Constant	6.523***	6.512***	6.842***	6.829***	4.635**	4.627**
	(1.677)	(1.678)	(1.615)	(1.615)	(1.568)	(1.568)
Firm Fixed Effects	YES	YES	YES	YES	YES	YES
Year Fixed Effects	YES	YES	YES	YES	NO	NO
Number of Observations	6.062	6.062	6.062	6.062	6.062	6.062
Log-Likelihood	−10,935.607	−10,935.102	−10,935.607	−10,935.102	−11,030.192	−11,028.906

Note. Two-tailed tests for all variables; standard errors are in parentheses.
† 0.1 * 0.05 ** 0.01 *** 0.001.

from different data sources, *PharmaProjects* and *Recap* respectively, and show similar patterns in terms of firms' licensing strategy when used as dependent variables.

We also computed the marginal effects for the variables of interest reported in Table 3 to estimate the *economic significance* of our findings. First, for all variables, we estimated how an increase of one standard deviation from their mean is associated with changes in our dependent variable. For the variable, *Using CDMOs Services*, we find that an increase of a standard deviation is significantly ($p < 0.001$) associated with a decrease of 11 % in the predicted values for the number out-licensing offerings. Additionally, the marginal effect for CDMOs Property, Plant and Equipment seems to have the strongest association with our dependent variable, with increasing values in this variable leading to a reduction of 23 % in the predicted values for the number of Out-Licensing offerings ($p < 0.001$).

While our research interest lies in the effect of CDMOs on the Market for Technology, we also document some of the performance consequences of using CDMO services for firms in the biopharmaceutical industry. Namely, in *Appendix 2* we show that consistent with our theorizing that CDMOs can help firms mature their product development pipeline and discuss the effect of CDMOs on other performance outcomes for firms.

6.7. Additional analyses

We performed several additional tests to increase our understanding of the effects that CDMOs will have on the dynamics of the biopharmaceutical industry. First, we used two alternative metrics for our two main explanatory variables. As an alternative to *Using CDMOs Services*, we used information from Recap to identify the cumulative number of manufacturing deals that a focal firm *i* entered within three years prior to the focal year *t*. These manufacturing deals are made between biopharma firms and service providers that will use their assets to manufacture a drug. As the alternative to CDMOs Property, Plant and Equipment, we computed the total sales reported by the identified CDMO firms. The variable is also aggregated at the CDMO sector level and changes longitudinally. Both variables provided negative and statically significant coefficients when use to estimate *Out-Licensing Offering*, as well as *Realized Out-Licensing Deals* ($p < 0.001$).

Second, while we used firm-fixed effects in all our estimations, we checked if there were differences in our predictors between biotech and pharma firms. For that, we created a dummy that takes value 1 if a focal firm reports its main activity in the SIC *2836- Biological Products, Except Diagnostic Substances* and value 0 if a firm reports its main SIC as being *2834- Pharmaceutical Preparations*. We interacted this dummy with the five CDMOs explanatory variables used in our main analysis while continue to control confounding effects such as firm size and R&D intensity. Based on the results reported in Table 5, we observed that none of the interaction terms were significant[18] ($p > 0.1$). In line with the qualitative evidence found regarding CDMO activities, the scope of the services that they provide is not specific to biotech firms but is also shaping other industry players.

Third, when we constructed the variable, *Using CDMOs Services*, we scrutinized the 10-K files of biopharmaceutical firms using a comprehensive list of CDMOs that we identified through our search. However, this list is limited to public CDMOs. While we expect that this led to an underestimation of this phenomenon, as expanding this analysis to non-public firms would likely result in a significantly larger number, we also performed our estimations with a broader sample. More precisely, we counted the number of times that the following expressions appeared in

[18] The direct effect of the dummy is absorbed by firm-fixed effects, so this interpretation is based on the interaction with the explanatory variables.

Table 5
Fixed effects estimations.

Variables	*Out-Licensing Offerings*			*Realized Licensing Deals*		
	Model I	Model II	Model III	Model IV	Model V	Model VI
Reliance on CDMOs Services X Biotech Dummy	0.002		0.001	−0.183		−0.178
	(0.015)		(0.015)	(0.479)		(0.479)
CDMOs Property, Plant and Equipment X Biotech Dummy		0.015	0.016		−0.065	−0.064
		(0.016)	(0.016)		(0.047)	(0.047)
Using CDMOs Services	−0.033*		−0.032*	0.073		0.069
	(0.015)		(0.015)	(0.466)		(0.466)
CDMOs Property, Plant and Equipment		−0.065***	−0.065***		−0.140***	−0.139***
		(0.011)	(0.011)		(0.035)	(0.035)
Firm & Year Fixed Effects	YES	YES	YES	YES	YES	YES
Number of Observations	6.062	6.062	6.062	6.062	6.062	6.062
Log-Likelihood	−2702	−2701	−2701	−10,935	−10,935	−109,345

Note. Two-tailed tests for all variables; standard errors are in parentheses. All controls included.
† 0.1 * 0.05 ** 0.01 *** 0.001.

the 10-K reports of the biopharmaceutical firms in our sample: "*Contract Manufacturing Organization*", "*Contract Research Organization*" and "*Contract Development and Manufacturing Organization.*" This allowed us to develop a variable not tied to specific CDMOs, but that generally captures reliance on this category of firms. We performed the same process as was reported for Model II in Table 3 using this alternative variable. The result is remarkably consistent with those reported in our main estimations, with a negative ($p < 0.001$) and statistically significant effect for a predictor based on a broader CDMO sample.

7. Discussion and implications

Ease of access to specialized complementary assets is key to explaining an innovator's profit strategy. Prior research has advanced our knowledge on when firms are more likely to develop and exploit technologies in-house and when they are likely to seek the upstream commercialization route of profiting from their R&D investments (Gans and Stern, 2003; Teece, 1986; Teece, 2006). The resulting framework has been widely used to examine the organization of R&D activities across different industries, including biopharmaceuticals, and have proven immensely helpful in understanding technology licensing between firms creating new technologies and those possessing complementary assets that further develop licensed technologies for product markets (Arora et al., 2001; Gans et al., 2002).

While the possession of specialized complementary assets is still critical to profiting from innovation, technology licensing between the market participants has shown a relative decline. We explain that among the two important dimensions of Teece's (1986) "profiting from innovation framework" the appropriation regime remained stable, but the availability of complementary assets changed in the industry. Namely, biopharmaceutical firms have begun to access specialized complementary assets through market contracting due to the emergence and growth of CDMOs (Gupta and Wang, 2007). These organizations offer opportunities to firms positioned upstream of the R&D value chain to contract specialized complementary assets related to the development and manufacturing of new drugs and therapies (Miller, 2017). We systematically study the emergence of CDMOs, how they change the value of complementary assets for development in the industry and how this has influenced firm's R&D strategies such as out-licensing.

By examining both industry patterns and firm-level R&D strategy, we showcased an association of CDMOs with firms' intensity to offer their technologies of out-licensing and engage in out-licensing deals in the US. Moreover, firms that do not represent the top biopharmaceutical players are increasingly becoming sponsors for drugs reaching the market. These findings, along with our qualitative insights, have important implications for the role of complementary assets and the market for technology in the biopharmaceutical industry. We note, with the emergence of CDMOs, access to complementary assets does not require a relationship with larger firms in the industry early on or building such assets in-house. Instead, CDMOs allow the externalization and in-sourcing of complementary assets on a "*per use*" basis. This has direct consequences for those who owns complementary assets in the industry. While such ownership was previously concentrated among incumbent industry players (Arora and Ceccagnoli, 2006; Hermosilla and Wu, 2018; Rothaermel, 2001), CDMOs have now become major accumulators of complementary assets and can be accessed by any industry player.

There are also implications as to costs; previously, firms either had to relinquish the rights to their technologies (e.g., through out-licensing) or invest substantial capital expenditures to build them internally (Conti et al., 2013; Teece, 1986). In the presence of CDMOs, the costs are lower as firms pay them on a per-use basis, converting drug development to a variable cost. Thus, firms do not have to make substantial capital commitments upfront and, in general, need to invest less in building complementary assets in-house. This has important implications on the competitive advantage for both smaller and larger biopharmaceutical firms, as both scientific capabilities and access to post approval global distribution networks may increase in importance.

Beyond implications for private firms the study also provides insights for public policy. The value added for publicly listed firms could equally apply to promoting the development of products from non-listed firms and even research organizations that have typically no in-house complementary assets. Prior research has discussed that universities typically rely on technology licensing and equity partnerships as the primary modes for commercializing (Bercovitz and Feldman, 2007; Moreira and Soares, 2020). The opportunity to contract development and manufacturing services to the CDMOs would present universities with an alternative mechanism to mature their inventions. Moreover, for public research organizations there may be more opportunities to now work directly with established pharmaceutical firms further downstream in R&D. Some initial vaccine initiatives during COVID 19 between the AstraZeneca and the University of Oxford have shown that direct collaboration can be an important new route in the development of new treatments.

However, there are also important risks that need to be considered from a public policy perspective. We noted that the maturation of assets in smaller firms not necessarily guarantees success in terms of bringing more products to market. If smaller firms take more of the onus of developing and commercializing their treatments it is important to monitor the quality of compounds that are pushed towards clinical development, a quality check often done by larger firms prior to in-licensing. A final public policy implication is associated with the risks of the value chain in the biopharmaceutical industry becoming more global (Lang and Siribaddana, 2012). We know that CDMOs are a global phenomenon that can support an increasing number of global clinical trials. As we noted in Appendix 1, this raises concerns about regulatory

arbitrage as well as ethical concerns (Glickman et al., 2009; Singh and Wang, 2013).

8. Limitations and avenues for future research

This study has only scratched the surface as to how CDMOs emerged and have grown over the last decades. Future studies could focus on a more comprehensive exploration of the genesis of CDMOs within the biopharma industry. This could shed light on the life cycle and evolution of industry's access to specialized complementary assets. In this context, it would be interesting to examine how the value proposition of CDMOs applies to specific technologies or therapeutic diseases such as addressed by orphan drugs. We also need to learn more on the commercial outcomes (i.e., post development) when using CDMOs. We noted that a possible quality filter in the form of finding a licensee has been removed through CDMOs as firms can develop their therapies internally longer. While the regulatory scrutiny should remain the same, it would be interesting to examine if we observe quality differences in terms of commercial success and withdrawals of drugs that were developed with the help of CDMOs.

Further, the generalizability of our results may be affected by contextual differences. Our investigation is based on publicly listed CDMOs in the US. However, as we noted the emergence of CDMOs is a global phenomenon. Future studies could more thoroughly document the overall activity of the CDMO sector and how they interact with biopharmaceutical firms around the globe. This is important as by focusing on the US, we kept the IP regime constant in our analysis. However, in countries like India or China, CDMOs are highly active but these countries represent different jurisdictions and differ in their rules for IP. Hence, documenting the global aspects of CDMOs and how they shape global drug development would be an important avenue for future research.

Second, while established firms play a role in our theoretical framework, as they possessed complementary assets for the industry, we have not systematically documented how their R&D strategies change with the presence of CDMOs. Future work could determine if increased access to CDMOs also influences the R&D strategy of large biopharmaceutical firms. We noted that the competitive advantage of more established firms remains unchallenged in commercial markets as they possess global distribution, marketing, and relationship with core customers (typically sales teams that have built strong relationship with medical doctors). It would be interesting what intermediaries could further support the commercialization of drugs post development and approval and if smaller firms in the future will file for more commercial assets including trademarks or invest in building commercial brands.

While we provide a holistic overview of the emergence of CDMOs and their impact on markets for technology, it is important to note that their effect on such markets in the biopharmaceutical industry is still in its infancy. We expect CDMOs to continue having important implications for the R&D strategy of firms that might ultimately impact both invention and innovation in the industry. As CDMOs expand and further consolidate, the development of new technologies might even become more disseminated across biopharma firms. While there has always been a substantial spread of inventive activities (Cockburn et al., 2016), the development and commercialization stages for new drugs were largely under the purview of large firms (Melchner von Dydiowa et al., 2021). However, with the growing presence of CDMOs, smaller firms are enabled to develop their R&D initiatives and may increasingly become the ultimate sponsors for new drug approval applications. This change may further reduce the number of realized licensing deals that we observed over the years, or at least enable firms to delay licensing until later stages of development.

Credit authorship contribution statement

Aman Asija, Thomas Klueter and Solon Moreira: Conceptualization, Writing- Original draft, Methodology, Data Collection.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The authors do not have permission to share data.

Acknowledgements

T. Klueter acknowledges the research support provided by the Mack Institute for Innovation Management at The Wharton School and financial support from the AEI. PID2020-112957RA-I00 / AEI / 10.13039/501100011033.

A. Asija acknowledges the financial support from the Fundação para a Ciência e a Tecnologia (UIDB/00124/2020, UIDP/00124/2020 and Social Sciences DataLab - PINFRA/22209/2016), POR Lisboa and POR Norte (Social Sciences DataLab, PINFRA/22209/2016).

Appendix 1 and Appendix 2. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.respol.2023.104787.

References

Adams, C.P., Brantner, V.V., 2006. Estimating the cost of new drug development: is it really $802 million? Health Aff. 25 (2), 420–428.
Albany_Molecular_Research_Inc., 2010. Form 10-K 2010. Retrieved from SEC EDGAR.
Anand, B.N., Khanna, T., 2000. The structure of licensing contracts. J. Ind. Econ. 48 (1), 103–135.
Arora, A., Ceccagnoli, M., 2006. Patent protection, complementary assets, and firms' incentives for technology licensing. Manag. Sci. 52 (2), 293–308.
Arora, A., Gambardella, A., 1994. The changing technology of technological change: general and abstract knowledge and the division of innovative labour. Res. Policy 23 (5), 523–532.
Arora, A., Fosfuri, A., Gambardella, A., 2001. Markets for technology and their implications for corporate strategy. Ind.Corp.Chang. 10 (2), 419–451.
Bercovitz, J.E., Feldman, M.P., 2007. Fishing upstream: firm innovation strategy and university research alliances. Res. Policy 36 (7), 930–948.
Bourgeois III, L.J., 1981. On the measurement of organizational slack. Acad.Manag.Rev. 6 (1), 29–39.
Ceccagnoli, M., Hicks, D., 2013. Complementary assets and the choice of organizational governance: empirical evidence from a large sample of U.S. technology-based firms. IEEE Trans. Eng. Manag. 60 (1), 99–112.
Ceccagnoli, M., Graham, S.J., Higgins, M.J., Lee, J., 2010. Productivity and the role of complementary assets in firms' demand for technology innovations. Ind. Corp. Chang. 19 (3), 839–869.
Ceccagnoli, M., Higgins, M.J., Kang, H.D., 2018. Corporate venture capital as a real option in the markets for technology. Strateg. Manag. J. 39 (13), 3355–3381.
Chan, T., Nickerson, J.A., Owan, H., 2007. Strategic management of R&D pipelines with cospecialized investments and technology markets. Manag. Sci. 53 (4), 667.
Choi, J.P., 2002. A dynamic analysis of licensing: the "boomerang" effect and grant-back clauses. Int. Econ. Rev. 43 (3), 803–829.
Cleary, S., 1999. The relationship between firm investment and financial status. J. Financ. 54 (2), 673–692.
Cockburn, I.M., Henderson, R.M., Stern, S., 2000. Untangling the origins of competitive advantage. Strateg. Manag. J. 21 (10–11), 1123–1145.
Cockburn, I.M., Lanjouw, J.O., Schankerman, M., 2016. Patents and the global diffusion of new drugs. Am. Econ. Rev. 106 (1), 136–164.
Cohen, W.M., Nelson, R.R., Walsh, J.P., 2000. Protecting Their Intellectual Assets: Appropriability Conditions And Why U.S. Manufacturing Firms Patent (Or Not). In: NBER Working Paper Series, 7552.
Colombo, M.G., Grilli, L., Piva, E., 2006. In search of complementary assets: the determinants of alliance formation of high-tech start-ups. Res. Policy 35 (8), 1166–1199.
Conti, R., Gambardella, A., Novelli, E., 2013. Research on markets for inventions and implications for R&D allocation strategies. Acad. Manag. Ann. 7 (1), 717–774.
Dushnitsky, G., Klueter, T., 2017. Which industries are served by online marketplaces for technology? Res. Policy 46 (3), 651–666.
Fosfuri, A., 2006. The licensing dilemma: understanding the determinants of the rate of technology licensing. Strateg. Manag. J. 27 (12), 1141–1158.

Gans, J.S., Stern, S., 2003. The product market and the market for "ideas": commercialization strategies for technology entrepreneurs. Res. Policy 32 (2), 333–350.
Gans, J.S., Stern, S., 2010. Is there a market for ideas? Ind. Corp. Chang. 19 (3), 805–837.
Gans, J.S., Hsu, D.H., Stern, S., 2002. When does start-up innovations spur the gale of creative destruction? RAND J. Econ. 33 (4), 571–586.
Ghosh, A., Klueter, T., 2022. The role of frictions due to top management in alliance termination decisions: insights from established bio-pharmaceutical firms. J. Manag. Stud. 59 (5), 1315–1353.
Gittelman, M., Kogut, B., 2003. Does good science lead to valuable knowledge? Biotechnology firms and the evolutionary logic of citation patterns. Manag. Sci. 49 (4), 366–382.
Glickman, S.W., McHutchison, J.G., Peterson, E.D., Cairns, C.B., Harrington, R.A., Califf, R.M., Schulman, K.A., 2009. Ethical and scientific implications of the globalization of clinical research. N. Engl. J. Med. 360 (8), 816–823.
Gupta, D., Wang, L., 2007. Capacity management for contract manufacturing. Oper. Res. 55 (2), 367–377.
Hemmatian, I., Ponzio, T.A., Joshi, A.M., 2022. Exploring the role of R&D collaborations and non-patent IP policies in government technology transfer performance: Evidence from US federal agencies (1999–2016). Plos one 17 (5).
Henderson, R., Cockburn, I.M., 1996. Scale, scope and spillovers: the determinants of research productivity in the pharmaceutical industry. RAND J. Econ. 27 (1), 32–59.
Hermosilla, M., Wu, Y., 2018. Market size and innovation: the intermediary role of technology licensing. Res. Policy 47 (5), 980–991.
Higgins, M.J., Rodriguez, D., 2006. The outsourcing of R&D through acquisitions in the pharmaceutical industry. J. Financ. Econ. 80 (2), 351–383.
Hoang, H., Rothaermel, F.T., 2010. Leveraging internal and external experience: exploration, exploitation, and R&D project performance. Strateg. Manag. J. 31 (7).
Hoberg, G., Phillips, G., 2016. Text-based network industries and endogenous product differentiation. J. Polit. Econ. 124 (5), 1423–1465.
Inovio, 2020. INOVIO adds Thermo Fisher Scientific to Global Manufacturing Consortium. https://www.nasdaq.com/press-release/inovio-adds-thermo-fisher-scientific-to-global-manufacturing-consortium-2020-09-08.
Jensen, R., Thursby, M., 2001. Proofs and prototypes for sale: the licensing of university inventions. Am. Econ. Rev. 91 (1), 240–259.
Joshi, A.M., Nerkar, A., 2011. When do strategic alliances inhibit innovation by firms? Evidence from patent pools in the global optical disc industry. Strateg. Manag. J. 32 (11), 1139–1160.
Kapoor, R., Klueter, T., 2015. Decoding the adaptability-rigidity puzzle: evidence from pharmaceutical incumbents' pursuit of gene therapy and monoclonal antibodies. Acad. Manag. J. 58 (4), 1180–1207.
Khanna, R., Guler, I., Nerkar, A., 2016. Fail often, fail big, and fail fast? Learning from small failures and R&D performance in the pharmaceutical industry. Acad. Manag. J. 59 (2), 436–459.
Klevorick, A.K., Levin, R.C., Nelson, R.R., Winter, S.G., 1995. On the sources and significance of interindustry differences in technological opportunities. Res. Policy 24 (2), 185–205.
Klueter, T., Monteiro, L.F., Dunlap, D.R., 2017. Standard vs. partnership-embedded licensing: attention and the relationship between licensing and product innovations. Res. Policy 46 (9), 1629–1643.
Kotha, R., Crama, P., Kim, P.H., 2018. Experience and signaling value in technology licensing contract payment structures. Acad. Manag. J. 61 (4), 1307–1342.
Lang, T., Siribaddana, S., 2012. Clinical trials have gone global: is this a good thing? PLoS Med. 9 (6), e1001228.
Laursen, K., Moreira, S., Reichstein, T., Leone, M.I., 2017. Evading the boomerang effect: using the grant-back clause to further generative appropriability from technology licensing deals. Organ. Sci. 28 (3), 514–530.
Macher, J.T., Boerner, C., 2012. Technological development at the boundaries of the firm: a knowledge-based examination in drug development. Strateg. Manag. J. 33 (9), 1016–1036.
Martin, L., Hutchens, M., Hawkins, C., Radnov, A., 2017. How much do clinical trials cost? Nat. Rev. Drug Discov. 16 (6), 381–382.
Marx, M., Hsu, D.H., 2015. Strategic switchbacks: dynamic commercialization strategies for technology entrepreneurs. Res. Policy 44 (10), 1815–1826.
Marx, M., Gans, J.S., Hsu, D.H., 2014. Dynamic commercialization strategies for disruptive technologies: evidence from the speech recognition industry. Manag. Sci. 60 (12), 3103–3123.
Melchner von Dydiowa, G., van Deventer, S., Couto, D.S., 2021. How large pharma impacts biotechnology startup success. Nat. Biotechnol. 39 (3), 266–269.
Miller, J., 2017. Contract manufacturing through the years. Pharm. Technol. 41 (7), 76–78.
Moeen, M., Mitchell, W., 2020. How do pre-entrants to the industry incubation stage choose between alliances and acquisitions for technical capabilities and specialized complementary assets? Strateg. Manag. J. 41 (8), 1450–1489.
Moeller, S.B., Schlingemann, F.P., Stulz, R.M., 2004. Firm size and the gains from acquisitions. J. Financ. Econ. 73 (2), 201–228.
Moreira, S., Soares, T.J., 2020. Academic spill-ins or spill-outs? Examining knowledge spillovers of university patents. Ind. Corp. Chang. 29 (5), 1145–1165.
Moreira, S., Markus, A., Laursen, K., 2018. Knowledge diversity and coordination: the effect of intrafirm inventor task networks on absorption speed. Strateg. Manag. J. 39 (9), 2517–2546.
Moreira, S., Cabaleiro, G., Reichstein, T., 2019. Licensing decision: a rent dissipation lens applied to product market competition, openness to external knowledge and exogenous sunk costs. Ind. Corp. Chang. 28 (4), 773–792.
Moreira, S., Klueter, T.M., Tasselli, S., 2020. Competition, technology licensing-in, and innovation. Organ. Sci. 31 (4), 1012–1036.
Nerkar, A., Roberts, P.W., 2004. Technological and product-market experience and the success of new product introductions in the pharmaceutical industry. Strateg. Manag. J. 25 (8–9), 779–799.
Pisano, G.P., 1991. The governance of innovation: vertical integration and collaborative arrangements in the biotechnology industry. Res.Policy 20 (3), 237–249.
Porter, M.E., 2008. On Competition. Harvard Business Press.
Riggs, A.D., 2020. Making, cloning, and the expression of human insulin genes in bacteria: the path to Humulin. Endocr.Rev. 42 (3), 374–380.
Roberts, P.W., 1999. Product innovation, product-market competition and persistent profitability in the U.S. Strateg. Manag. J. 20 (7), 655–670.
Rothaermel, F.T., 2001. Complementary assets, strategic alliances, and the incumbent's advantage: an empirical study of industry and firm effects in the biopharmaceutical industry. Res. Policy 30 (8), 1235–1251.
Rothaermel, F.T., Alexandre, M.T., 2008. Ambidexterity in technology sourcing: the moderating role of absorptive capacity. Organ. Sci. 20 (4), 759–780.
Rothaermel, F.T., Boeker, W., 2008. Old technology meets new technology: complementarities, similarities, and alliance formation. Strateg. Manag. J. 29 (1), 47–77.
Sakakibara, M., 2010. An empirical analysis of pricing in patent licensing contracts. Ind. Corp. Chang. 19 (3), 927–945.
Simeth, M., Cincera, M., 2016. Corporate science, innovation, and firm value. Manag. Sci. 62 (7), 1970–1981.
Singh, R., Wang, O., 2013. Clinical trials in "emerging markets": regulatory considerations and other factors. Contemp.Clin.Trials 36 (2), 711–718.
Souder, D., Bromiley, P., 2012. Explaining temporal orientation: evidence from the durability of firms' capital investments. Strateg. Manag. J. 33 (5), 550–569.
Syneos_Health, 2014. Form 10-K 2014. Retrieved from SEC EDGAR.
Teece, D.J., 1986. Profiting from technological innovation: implications for integration, collaboration, licensing and public policy. Res. Policy 15 (6), 285–305.
Teece, D.J., 2006. Reflections on "profiting from innovation". Res. Policy 35 (8), 1131–1146.
Teece, D.J., 2018. Profiting from innovation in the digital economy: enabling technologies, standards, and licensing models in the wireless world. Res. Policy 47 (8), 1367–1387.