The pharmaceutical CDMO industry is consolidating

Opportunities for current players and new entrants
September 2017
Winning strategies in the CDMO industry
1.1 The CDMO industry is heating up: consolidation and diversification

The pharmaceutical contract development and manufacturing organization (CDMO)1 industry is extremely active. In December 2016, Switzerland’s CDMO Lonza acquired Capsugel, a development and manufacturing specialist for gelatin capsules, for US$5.5b. This was one of the largest deals in the CDMO industry, aimed at building a vertically integrated solutions provider. Only five months later, in May 2017, life science company Thermo Fisher Scientific paid an even higher price to acquire Patheon, one of the leading global CDMOs, for US$7.2b. This deal allows Thermo Fisher Scientific to broaden its range of life science services significantly, taking the company closer to its goal of becoming a leading one-stop shop provider to the pharmaceutical industry. These two deals are remarkable in size and represent the largest premiums paid for CDMOs in more than five years: Thermo Fisher Scientific’s US$7.2b offer values Patheon at 16x to 17x its expected 2017 EBITDA, in line with Capsugel’s 16x multiple. Yet they constitute only the tip of the iceberg of the rising M&A activity in the CDMO industry. In addition to companies solely active in the CDMO industry, pharmaceutical companies have been growing their third-party manufacturing services, e.g., Pfizer’s CentreOne and Sanofi’s CEPIA. The search for attractive assets is not limited to the CDMO industry: global non-pharmaceutical players are entering the stage to diversify their portfolio, exemplified by the Thermo Fisher Scientific-Patheon deal or the creation of biopharmaceutical CDMO Samsung BioLogics. Given the continual need for outsourced manufacturing and the still fragmented vendor landscape, the CDMO industry is expected to remain a very attractive sector for M&A activity in the future.

1.2 A highly attractive industry for established players and new entrants

The CDMO industry started out decades ago as a niche service, offering additional manufacturing capacity or specialty services to pharmaceutical companies. The rise of the CDMOs was fueled by failure stories in the pharmaceutical industry. In the past, pharmaceutical companies often installed dedicated manufacturing capacities for innovative drugs in development, only to see them fail during phase III of clinical research trials. Thus, the additional manufacturing capacity for the specific drugs was no longer needed. To reduce the risk of expensive overcapacities, the demand for outsourced manufacturing has been rising continually. Constituting a US$62b market in 2016, the CDMO industry’s annual growth rate of 6% to 7% is slightly outpacing the growth of the pharmaceutical sector as a whole (5% to 6% compound annual growth rate (CAGR)), reflecting the ongoing shift toward increased outsourcing (see references 1 to 3). At a time when pharmaceutical companies face increasing price pressures around the globe from key payers, including public and government insurance systems, reducing operational expenses is a major driver of outsourcing pharmaceutical manufacturing to CDMOs. Also, an increasing number of pharmaceutical companies are refocusing on their core capabilities and strengths, leading to divestments of in-house manufacturing capacities in some areas and to a growing reliance on CDMOs in other areas. Furthermore, CDMOs play crucial roles in providing additional capacities to mitigate the risk of supply shortages, by offering additional sites for pharmaceutical companies with multisite supply strategies as well as backup capacities. Externalizing manufacturing may also be highly desirable to reduce time to market, in particular if internal expertise or capacities are limited. A lot is at stake for pharmaceutical companies when choosing a partner for their manufacturing outsourcing needs. Small biotechnology innovators rely on timely production to enter and proceed swiftly through clinical trials. Also, issues regarding the quality and documentation of the drug manufacturing processes surfacing during regulatory reviews can delay marketing authorization, which poses a significant risk to cash-restrained businesses. Therefore, for small and large pharmaceutical sponsors alike, proven reliability and impeccable quality standards are key to choosing a CDMO. Additionally, it is costly and time-consuming to switch the CDMO once a manufacturing process is established, in particular for biopharmaceuticals. Comprehensive due diligence is crucial in order to prevent potential production delays, revenue losses, damage to a company’s or brand’s reputation and, in the worst case, health risks for patients.

1 CDMOs are companies engaged in the manufacturing of pharmaceutical drugs on behalf of pharmaceutical companies.
1.3 The rules of the game

Industry segmentation
Choosing the right service offering and defining the ideal business model is key for every CDMO aiming for sustainable growth and attractive margins. Indeed, there are significant differences in CDMOs’ competitive strengths across the segments they are active in.

The segmentation of the pharmaceutical CDMO value chain follows three major categories: drug and process development, active pharmaceutical ingredient (API) production and finished dosage form (FDF) (Figure 1). Close to these CDMO core segments are drug discovery and development support, provided by contract research organizations (CROs) as well as contract packaging services, which are provided by CDMOs or specialized contract packaging organizations (CPOs).

Tasks outsourced to CDMOs by pharmaceutical companies cover the entire value chain of a drug’s life cycle, from drug development and preclinical and clinical trials to commercial production. While traditional CMO services were centered on their core competencies in API bulk manufacturing and formulation, CDMOs have also moved into adjacent segments along the manufacturing value chain. These tasks, which in the past have been covered by pharmaceutical companies themselves or by contract research organizations, include medical chemistry, support for preclinical in vitro and in vivo studies, and formulation and process analytics development.

CDMO business models
Although the CDMO industry itself is relatively mature, the advent of new production technologies, new types of pharmaceuticals and priority shifts in the pharmaceutical industry keep the pressure constantly high, causing CDMOs to evolve different business models that enable them to address their clients’ and stakeholders’ needs in the best possible way. Today’s CDMO business models are a result of historic developments combined with the CDMOs’ current strategic orientations. Three key business models can be distinguished: 1) the specialty or technology innovator; 2) the capacity consolidator; and 3) the vertical integrator (Figure 2).

Specialty CDMOs have an exclusive or very strong focus on one of the segments of the value chain (Figure 1), e.g., finished dose form, and often concentrate on a
Certain technology within this segment, such as sterile liquid fill and finish. This may lead to the development of a globally recognized brand through superior technological knowledge, long market presence and mastery of regulatory requirements in that specific area. Also, the focus on a core technology allows for targeted allocation of investments in R&D, which can result in a technological competitive edge that can become a unique selling point. Some of the most demanding CDMO services nowadays include high-potency API manufacturing, development and manufacturing of large molecules (biologics and biosimilars), sterile liquid formulations, and the emerging platforms of gene and cell therapies – for which specialty CDMOs bring competitive skills.

**Capacity consolidators** are companies seeking to expand the depth of their current service offerings. They have often grown inorganically in the past, acquiring assets that became available in the wake of big pharmaceuticals’ refocus on their core capabilities through business unit swaps, portfolio restructuring and divestment of noncore business units or manufacturing sites. Larger CDMO capacities are required for commercial manufacturing, and pharmaceutical partners aim to keep the number of CDMOs involved in manufacturing their APIs or drug products on a manageable level. Pharmaceutical companies may also seek CDMO partners in specific geographies to complement their existing multisite production strategy. Internally, larger capacities can also allow for better responsiveness to demand through more dynamic utilization planning across multiple contracts.

**Vertical integrators** originated as specialty CDMOs or big pharmaceutical carve-outs but have started to expand their scope into adjacent service segments since then. There are different reasons for offering a broader range of services, depending on the type of customer a specific CDMO serves. Small biotechnology innovator companies will contract CDMOs early on through preclinical and clinical phases. By contrast, by offering the entire value chain to big pharmaceutical companies, CDMOs mainly seek to establish a lock-in effect. This can be especially effective for biopharmaceuticals, an area in which replacing manufacturing partners is very time consuming and costly due to the impact of the manufacturing process on the final product. Vertical integration can go as far as creating a one-stop shop that covers all services, from retrieving marketing authorization to production of the packaged drug product – an important topic for many larger CDMOs.

All three business models address the market in different ways and aim to achieve growth and higher performance with different strategies. However, all three business models have, to a large degree, been enabled by M&A. Indeed, many of today’s CDMOs have been formed, and are still being formed, by this process. Our study of the CDMO ecosystem demonstrates that M&A activity and consolidation have been accelerating. It is therefore crucial for existing players and new entrants to the market to understand the underlying forces in order to define winning strategies.

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**Figure 2: CDMO business models**

<table>
<thead>
<tr>
<th>CDMO business model</th>
<th>Development</th>
<th>API production</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology innovator or specialty CDMO</td>
<td>Single use, continuous manufacturing, etc.</td>
<td>Special purpose solids, foams, extended release, etc.</td>
<td>Technological advance or specialization</td>
</tr>
<tr>
<td>Capacity consolidator</td>
<td>Horizontal growth (within segment):</td>
<td></td>
<td>Vertical growth (across value chain):</td>
</tr>
<tr>
<td>Vertical integrator</td>
<td>Integrated services</td>
<td>Conglomerate logic</td>
<td>Forward or backward integration</td>
</tr>
</tbody>
</table>

Overview of CDMO business models (top) across the CDMO value chain (left). Exemplary important trends are highlighted in green callouts.

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"The CDMO market is complex – there are lots of options for small and big players to position themselves."
CDMO M&A: global consolidation is accelerating
The pharmaceutical CDMO industry is still highly fragmented, with an estimated 600 global and local companies. One reason for the fragmentation is the fact that many players are privately held or are part of private equity firms’ portfolios. However, this is rapidly changing – the CDMO sector is receiving a lot of attention from large global strategic investors.

“We are in the middle of the consolidation of the CDMO industry.”

Since 2012, M&A activity within the CDMO industry has clearly been on the rise. The number of publicly announced CDMO deals increased by approximately 12% per year, with a slight cooldown in 2016 (Figure 3).

At the same time, the implied enterprise values (EV) of acquisition targets rose at an impressive 35% per year, thereby more than tripling the value of CDMO deals in only four years. These numbers reflect not only the increasing size of assets involved in deals but also, in some cases, the willingness to pay higher premiums for certain targets in more recent years. Interestingly, EVs have fluctuated between the regions, with European assets contributing less over the years, while Asia-Pacific and North American assets were highly appreciated.

2.1 Global and local M&A of CDMOs

North American targets of high interest for European buyers

More than US$23b worth of assets were acquired in North America between 2012 and 2016, with 43% representing domestic deals and the majority of the remainder involving European buyers (Figure 4). By contrast, other regions have seen much less cross-regional activity, with the majority of deals taking place within regions (76% for Europe and 86% for Asia-Pacific).

The US clearly leads the CDMO M&A table by number of deals and deal value, closely followed by China and India (Table 1). However, most of the deals in Asia take place within national borders, while the US and European countries – in particular Germany – attract significant interest from international investors.

Offshoring and reshoring as drivers of CDMO M&A

One important driver of M&A activity has been offshoring. Over the last decade, there has been a move to outsource manufacturing capabilities to CDMOs in Asia, particularly India. Among the key reasons for outsourcing are cost benefits due to lower labor costs and capital expenditures. India has established itself as a significant player, especially in solid dosage form manufacturing for the large-scale production of generics for global markets.
Concurrently, Indian generics companies, including Cipla, Sun Pharmaceutical Industries, Zydus Cadila and Dr. Reddy’s, have developed into top global generics players. Regional market access and supply chain considerations are additional reasons why global pharmaceutical companies have chosen Asian CDMOs. A striking example is the high volume of biosimilar production in India, which is driven by the global asymmetry of regulatory biosimilar approval. While more than 50 biosimilars have been approved in India, only 24 passed the regulatory hurdles in Europe and just 5 in the US. Due to its status as an early adopter, India became a hub for the development and manufacturing of biosimilars. Despite the continued importance of outsourcing to Asian countries, some manufacturing operations have been repatriated to North America and Europe as a result of supply chain security concerns, as well as pressure from regulators.

![Figure 4: Investment flows through M&A](image)

**Table 1: Country league table – targets of M&A**

<table>
<thead>
<tr>
<th>Rank</th>
<th>M&amp;A target HQ</th>
<th>Number of deals per country</th>
<th>Number of deals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>US</td>
<td>31</td>
<td>134</td>
</tr>
<tr>
<td>2</td>
<td>India</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>China</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>France</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>United Kingdom</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Germany</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Canada</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Spain</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Italy</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Australia</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Sweden</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Japan</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Belgium</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Ireland</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Switzerland</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

**EV (US$b)**

<table>
<thead>
<tr>
<th>Rank</th>
<th>M&amp;A target HQ</th>
<th>Sum of EVs per country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>US</td>
<td>21.1</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>7.1</td>
</tr>
<tr>
<td>3</td>
<td>India</td>
<td>3.5</td>
</tr>
<tr>
<td>4</td>
<td>Germany</td>
<td>2.8</td>
</tr>
<tr>
<td>5</td>
<td>Japan</td>
<td>2.5</td>
</tr>
<tr>
<td>6</td>
<td>Canada</td>
<td>2.4</td>
</tr>
<tr>
<td>7</td>
<td>Italy</td>
<td>2.0</td>
</tr>
<tr>
<td>8</td>
<td>United Kingdom</td>
<td>1.1</td>
</tr>
<tr>
<td>9</td>
<td>France</td>
<td>1.0</td>
</tr>
<tr>
<td>10</td>
<td>Switzerland</td>
<td>1.0</td>
</tr>
<tr>
<td>11</td>
<td>Norway</td>
<td>0.9</td>
</tr>
<tr>
<td>12</td>
<td>Poland</td>
<td>0.9</td>
</tr>
<tr>
<td>13</td>
<td>Turkey</td>
<td>0.7</td>
</tr>
<tr>
<td>14</td>
<td>Spain</td>
<td>0.6</td>
</tr>
<tr>
<td>15</td>
<td>Denmark</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Top 15 target countries for CDMO M&A transactions based on number of deals and EV involved in deals, 2012-16.
Consolidation of the CDMO industry: opportunities for current players and new entrants

This has led to a renewed need for production capacities, which will be filled in part by pharmaceutical companies’ in-house manufacturing facilities, but mainly provided by CDMOs.

CDMO M&A activity in Asia-Pacific has largely been within the region, as the number and volume of cross-border investments from North America or Europe have been mainly constant (Figure 5). On the other hand, there are some signs indicating increasing investments coming from Asia to Europe, as deal values have been rising from US$23m in 2012 to US$875m in 2016, potentially reflecting a stronger interest in European assets but also the rising firepower of some Asia-Pacific-based players, such as Piramal and Strides Shasun.

2.2 The CDMO landscape is changing

The majority of CDMO targets are privately owned – but for how long?

The large majority of companies in today’s fragmented CDMO vendor landscape are either privately owned strategic investors, often small family-run or mid-market companies, or assets of private equity funds. Private companies or their assets represented the vast majority of targets for CDMO acquisitions, with a total of 226 deals (56% of all CDMO deals from 2012 to 2016) (Figure 6). Interestingly, 22% of all M&A transactions involved the sale of investment firm assets (both private and public), making up almost 50% of the total

![Figure 5: M&A activity between Europe and Asia-Pacific](image)

Investments by European companies in Asia-Pacific through M&A have been on the rise.

![Figure 6: Targets of CDMO M&A activity](image)

Number of deals and EVs of publicly announced CDMO deals between 2012 and 2016.
value of CDMO deals. This suggests an interesting valuation difference depending on the target ownership, especially between assets of equity firms and assets of private or public strategic investors.

**Publicly traded strategic CDMOs are consolidating the industry**

The ownership distribution of CDMOs has changed significantly in recent years. M&A activity has altered the structure of the competitive CDMO landscape on a global scale. Fifty-seven percent of all assets involved in M&A were privately owned prior to the transaction - but only 47% of all assets remained or became private (Table 2). Similarly, assets owned by investment firms decreased from 22% to 12%. These numbers highlight a clear trend: private and publicly traded companies are consolidating the market, and private and public investors are selling in order to take advantage of the attractive premiums paid for well-managed companies.

**CDMO valuation: North American assets most expensive**

In this fast-changing environment, significant value differences exist between the regions. North American assets have recently captured the highest premiums, with median deal EV/last twelve months revenues around 3x and EV/LTM EBITDA approximately 15x. By contrast, European assets remained rather stable at median ~1.5x EV/LTM revenues and median ~10.4x EV/LTM EBITDA (Figure 7).

<table>
<thead>
<tr>
<th>Type of target</th>
<th>Ownership change matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>57% Private strategic</td>
<td>29%</td>
</tr>
<tr>
<td>21% Public strategic</td>
<td>12%</td>
</tr>
<tr>
<td>22% Asset of investment firm</td>
<td>6%</td>
</tr>
</tbody>
</table>

**Table 2: Ownership changes due to CDMO M&A activity**

Ownership changes during transactions in the CDMO sector between 2012 and 2016.

**Figure 7: Deal multiples**

Transaction multiples by region (median of deal multiples per region). Note: there are only a few data points for EV/LTM EBITDA for Asia-Pacific in 2013 and for North America in 2014.
2.3 The industry’s top consolidators

Figure 8: Top consolidators, 2012–16

Leading consolidators in the CDMO industry (by number of deals acting as acquirers).

Note: private equity (PE)

The overall trend of concentrating CDMOs into large publicly traded strategic players is demonstrated by Figure 8: out of 10 players, only 3 are currently privately owned (Aenova, Amatsigroup and WuXi PharmaTech). Recipharm is a good example of a capacity consolidator: its acquisitions of Italian CDMO Mitim and Indian CDMO Nitin Lifesciences expanded its formulation capabilities in sterile liquids and lyophilization, while its acquisition of OnTarget Chemistry signified a first step into the neighboring CRO space of preclinical development. Most of Recipharm’s transactions also extended its geographic footprint; the acquisition of Portugal’s Lusomedicamente is a case in point. Many of Recipharm’s peers, including AMRI and Aenova, aim to expand their offerings and increase their geographic reach. Most of the larger current CDMOs follow a hybrid strategy: they seek to extend their footprint across the value chain and expand capacities at the same time.

**One-stop shops on the rise: what is driving the top consolidators?**

Many CDMOs, such as Patheon, Lonza and Catalent, are aiming to extend their service offerings to areas adjacent to their core capabilities. M&A has been an important means to gain a larger footprint across the CDMO value chain efficiently and rapidly.

There are two important strategies for CDMOs: the specialist or the one-stop shop, covering all services that might be required by a pharmaceutical client, from drug development to FDF and packaging. One-stop shops can meet the need for whole process outsourcing. Key benefits for the pharmaceutical client include the convenience of dealing with fewer outsourcing partners and the opportunity to reduce time to market by coordinating all steps with only one partner. For CDMOs, a one-stop shop model allows cross-selling, stronger client relationships, client lock-in due to the client’s increased switching costs and a better marketing story. Currently, mainly CDMOs based in North America and Europe use the one-stop shop model, which also serves as a differentiator to lower-cost alternatives in Asia.

Clearly, many CDMOs view a business model focused on vertical integration as the primary path to value creation. This does not only apply to the major consolidators listed in Figure 8 but also...
to many of the other CDMOs that have executed one to three acquisitions, in many cases expanding their capabilities to neighboring spaces in the value chain.

Despite these seemingly obvious benefits, both for CDMOs and pharmaceutical clients, there has been some debate over the lack of uptake of one-stop shop offers. Although small pharmaceutical clients may prefer having one CDMO partner that provides all services, they may have concerns over higher prioritization of large pharmaceutical needs by their CDMO. From the perspective of larger clients, uptake is restrained because switching existing products from an established multiple-contractor supply chain to a single one-stop shop is difficult and time-consuming, and would need to be compensated by significant cost savings.

Therefore, the next years will show how much use pharmaceutical clients will make of one-stop shop CDMOs - and how much they will continue to rely on more specialized manufacturing companies. These CDMOs have relied on extension of scale through capacity consolidation in a specific segment or extended their technological know-how through internal R&D or smart add-on acquisitions, providing additional differentiation from competitors. Specialized CDMOs will continue to play an important role in the industry as technological innovators and experts providing demanding or smaller-volume services.

One-stop shop strategy most appealing to biologics CDMOs

The one-stop shop model is attractive for small molecule CDMOs, but it may actually be crucial for the commercial success of large molecule CDMOs that rely much more on winning projects early in the clinical development of biosimilars. By doing so, they can lock pharmaceutical partners in, since they will be hesitant to switch CDMOs once cell lines and processes are established. Therefore, CDMOs will need to build up their development capabilities and offer a seamlessly integrated portfolio ranging from the early stages all the way through to commercial production.

At the same time, there are potential risks associated with early involvement: significant revenues are only to be expected late in clinical and commercial production. Moreover, due to the complexities inherent to large molecule drug development and regulatory diligence, biosimilar candidates can fail before ever reaching the market - a situation very different from the development of generics. While biopharmaceutical CDMOs may have to extend their service offerings to win contracts, they have to establish highly specialized technologies at the same time. In particular, linked to the growth of biopharmaceuticals is the growing demand for sterile liquid dosage, a segment with relatively high barriers to entry due to the use of specialized delivery devices and the requirement for fill and finish equipment.

Conclusion and outlook

The consolidation of the CDMO market is accelerating, with many private companies selling to other publicly traded CDMOs or new entrants. CDMOs follow one of three business models to address the market needs and grow their businesses: specialty CDMOs rely on technological leadership and provide cutting-edge services for selected segments at limited scale; capacity consolidators aim to be regional or global leaders and preferred partners for large-volume production of certain product types; while vertical integrators seek to provide value by addressing a wide range of customer needs with integrated solutions, from development to packaging.

There is no clear view yet on whether a specialist or a one-stop shop model will prove to be the better strategy. However, an increasing number of companies follow the one-stop shop model, which seems especially well suited to biologics CDMOs. The establishment of large publicly traded players and interest from new entrants has increased the momentum in the CDMO market, supporting further consolidation. While private equity firms may consider selling assets due to attractive premiums, large publicly traded strategic investors will seek further acquisitions in order to establish global leadership across the value chain. At the same time, new mid-sized innovative players are likely to emerge through consolidation among hundreds of privately owned CDMOs, resulting in the arrival of new competitors and new potential acquisition targets. In order to create and grow a profitable business, market players should therefore clearly define their strategies and quickly pursue the right targets.

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3.2 Methodology

We define M&A activity as mergers and acquisitions in which the targets are acquired by buyers (more than 50% sought). Specifically, values and volumes used throughout this report are based on announced dates for transactions with a disclosed deal value, and supplemented by additional independent research - sometimes based on rumors stated in public sources. The sources used for the transaction analysis were S&P Capital IQ, Mergermarket, and company websites and press releases. Where mentioned within the text, specific sources were: (1) Global Pharmaceutical Contract Manufacturing Market 2016-2020, Technavio, 2016; (2) Myths and reality in the prescription market: Europe and Ireland, IMS Health, 2015; and (3) World Preview 2016, Outlook to 2022, EvaluatePharma, 2016. M&A activity was considered in this study if a CDMO participated as buyer, seller or target (or any combination thereof). Transaction values of deals with undisclosed values were estimated, if available, based on target LTM revenues and multiples of comparable transactions. We have used the annual average exchange rates from local currencies to US dollars for all conversions in this document.
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