COVID-19’s Impact on Transfer Pricing in the Life Sciences Industry

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In this article, the authors examine key trends affecting the life sciences industry in the COVID-19 pandemic and the associated transfer pricing considerations.

I. Overview

The COVID-19 pandemic continues to disrupt industries globally. Companies have had to make tough decisions to adapt their operations to a dramatically changed global economy. Transfer pricing typically focuses on ensuring that profits align with value creation and satisfying competing tax authorities that intercompany prices are arm’s length and not opportunistic (or worse). Now, however, many companies are faced with decreased revenues, increased costs, supply chain challenges, remote workforces, and immobile customers.

Essential operations face new protocols and restrictions to ensure employee safety. Rather than determining an arm’s-length allocation of global system profits, companies may now face system losses. Prior recessions (for example, the 2008 financial crisis) provide companies a playbook for managing through economic downturns. However, the economic impact of the COVID-19 pandemic appears to be hitting differently and distinctly by industry.

The life sciences industry (defined for our purposes as companies operating in the fields of biotechnology, pharmaceuticals, and medical devices, contract research organizations (CROs), and pharmaceutical or medical device distributors) arguably plays the leading role in the top priority of the pandemic — diagnosing and treating patients affected by the coronavirus as well as identifying possible cures and vaccines to prevent the spread of the disease and recurrence of the pandemic. The COVID-19 pandemic is accelerating trends in the industry that had begun to take hold before the pandemic (for example, digitalization, collaborations, and commercialization efficiencies), while also establishing a new operating environment. The traditional value chains within the life sciences industry are rapidly evolving and are unlikely to revert to the pre-COVID-19 models. Thus, transfer pricing policies and methods will need to be adapted as well.

Here we focus on key trends affecting the life sciences industry in the COVID-19 pandemic and the associated transfer pricing considerations: reshaping research and development; the digitalization effect; collaboration in a new environment; and supply chain constraints.

II. Reshaping R&D

Risky and expensive R&D has been a hallmark of the life sciences industry for decades. Drug discovery and preclinical testing helps researchers develop models for pharmacological profiles that then must be proven out through years of progressive clinical trials in which investigational drugs are tested on humans. The resulting clinical trial data is submitted for regulatory approval, which is conferred on only a handful of initial targets. The typical drug development and approval time for the U.S. market is between nine and 12 years, although a reduced time frame is sometimes granted through the accelerated approval process instituted by the Food and Drug Administration. With a patent life of 20 years, this time frame leaves roughly 10 years of patent-protected sales to recoup the R&D investment not
only for the successful products but also for failed R&D projects.

The COVID-19 pandemic has forced a change in the way life sciences companies manage their R&D activities and has often redirected the focus from current portfolios to developing treatments and tools to combat the disease.

Social distancing campaigns implemented by countries globally have resulted in companies being forced to delay or even shut down clinical trials. It can be difficult, if not impossible, to enroll patients for new clinical trials if people cannot travel to administration sites for screening and for administering the investigational drugs under the trial protocols as well as for monitoring endpoints to evaluate safety and efficacy. Virtual visits may allow some trials to move forward, but others that require in-person infusions or treatments may not adapt as easily.

Because of the delays in clinical trials, companies may need to push out launch date expectations, which shortens the patent-protected sales period. Companies that adapt to more virtual approaches are also incurring investment costs in developing new infrastructure and retraining professionals to conduct trials in a fundamentally altered manner. Also, there may be some concern as to whether a new approach may compromise the data — for example, if patients self-report information, it may not be as reliable as if a medical professional were conducting the assessment. This may result in additional costs to validate the collected data.

The CRO sector in particular is at the forefront of assessing opportunities to keep clinical trials progressing, whether it is through remote operations support, developing technological solutions into the clinical trial process, or in-home clinical trial setups. CROs are also operating as the first line of support for pharmaceutical companies as vaccine trials are being conducted and are partnering with companies to help efficiently conduct trials and output results for review by the FDA and other government agencies.¹

Conversely, life sciences companies that are directly involved in developing vaccines, antiviral drugs, and other possible cures or treatments to combat the coronavirus are seeing accelerated plans to push clinical trials and regulatory approvals in record time. The FDA, along with other regulatory agencies globally, has established emergency use authorization procedures to help accelerate the process, which is leading to authorizations within less than three months as opposed to the nine-to-12-year time frame previously cited. In this case, a company’s R&D costs are significantly reduced and in some cases may be subsidized by government funding or foundation grants.

A significant change in the key regulatory approval process raises some concern as to whether product liability may increase, absent the more extensive trials and more traditional review. For pipeline products that are not COVID-19 related, however, R&D costs may be increased and the likelihood of approval may be lowered as the clinical trial timeline is extended, with the attendant inefficiencies of stopping and restarting programs and de-prioritization of review by the FDA or other authorities. In summary, the effect will depend on a company’s particular facts and circumstances.

Medical device companies have also had to reassess their R&D pipelines because of the pandemic, even more so because of the cutback in elective procedures being performed globally. With companies in the medical device space showing declines in revenues attributable to the pandemic, the industry has shifted toward developing new ventilators, masks, testing kits, respirators, and other medical devices. Although production capacity is a general issue that medical device companies are facing as they assist with the pandemic, the development of testing kits has become the primary focus because the ability to properly present diagnostic readings and detection of COVID-19 is crucial in managing the pandemic.

Over the past few months, medical device companies have received FDA authorization² for

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distribution of testing kits; however, some of the authorized tests still do not have 100 percent efficacy on their antibody test for the coronavirus. Even within the medical device sector, the landscape of R&D has drastically changed and will lead to revisiting the processes by which products are developed for commercialization.

A. Transfer Pricing Considerations

In the life sciences industry, R&D activities are typically viewed as central to establishing the legal and economic ownership of intellectual property, resulting in what is often referred to as product IP. Where the R&D activities are performed, the type of R&D conducted, which entities are funding the at-risk R&D, the IP governance structure around clinical trial progression and other key decisions, the key individuals in the organization capable of driving the R&D decision-making — these elements all play a role in assessing the value creation attributable to affiliates within a multinational enterprise operating in the life sciences industry.

The disruptions to existing operations, such as pivoting to developing treatments or devices relevant to the COVID-19 pandemic, can cause unintended consequences for an existing transfer pricing policy. Awareness and careful monitoring of R&D costs, new investments and decision-making responsibilities (for example, accounting for the development, enhancement, maintenance, protection, and exploitation characteristics) is needed to ensure alignment with the intended product IP ownership. Further, to the extent affiliates enter into agreements with government agencies (for example, authorizations and government contracts and approvals), it will be important to assess whether that party has the right to commit the resources of other affiliates that may be affected. Also, impacts to product IP may take nontraditional forms. For example, if a company chooses to waive patent rights to its compounds so that other organizations may also conduct research programs to accelerate the drive for a cure, there is value in the forgone profits associated with that product IP that should be considered.

The R&D activities performed because of the pandemic may also present opportunities for companies to assess the tax implications of the new functions performed, assets used and developed, and risks incurred, in line with the current tax structures of jurisdictions globally — whether it is patent box or foreign-derived intangible income regime impacts, tax planning opportunities around losses, or any other R&D or IP tax consideration in the relevant jurisdictions. As costs are incurred because of the delay or shutdown of clinical trials, or from donations given to governments and organizations, companies will need to monitor the total costs incurred, assess whether any are shareholder costs, and identify which entities in their structure would bear these costs for the period affecting operations.

And, as is a best practice across all industries, companies should also assess their intercompany and third-party agreements to identify any terms and conditions that may affect how costs are incurred because of a failure to conduct clinical trials or other such liabilities. This point is especially relevant in the life sciences industry, in which third-party license agreements and collaboration agreements are readily available, providing evidence of arm’s-length behavior regarding these issues.

Finally, tax professionals should be aware of changes in the magnitude and trading parties for some types of intercompany transactions and associated tax implications (for example, base erosion and antiabuse tax).

B. Takeaway

The COVID-19 pandemic has had a major effect on the R&D processes typically performed within the industry. Companies in the life sciences industry have shifted focus to assisting with development plans for antiviral drugs and medical devices to support hospitals globally through the pandemic, but they have also had to take major hits to their pipelines. These trends suggest a reassessment of current transfer pricing structures to manage these changes to their core

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2. This concept was initially introduced through the initiatives developed by the OECD against base erosion and profit shifting, specifically BEPS action 8.
functions and possibly a revaluation of the company’s pre-commercial IP.

III. The Digitalization Effect

The COVID-19 pandemic has transformed people’s daily lives as more and more activities that were previously conducted in person are being conducted virtually. It has had a similar effect on the life sciences industry. Digitalization of activities in the life sciences industry isn’t new, but through the COVID-19 pandemic, companies in the industry have accelerated their integration of digitalization across functions, creating efficiencies and even reducing costs. This shift to a more digital approach may require investing in infrastructure, hiring new employees, or retraining an existing workforce in other functional areas as well. Below, we further discuss the impact of digitalization on three key functional areas within the life sciences industry.

A. R&D

As mentioned, life sciences companies have seen a shift in their timelines and processes through this pandemic, motivating them to migrate toward siteless virtual trials, digital communication through trial monitoring with patients, and various digital interface solutions. The digitalization of the R&D process also leads to capturing and mining an abundance of new data. New perspectives gained through the data analytics and algorithms can drive efficiencies and insights, and ultimately may reduce costs and increase efficiency of one of the largest areas of spending for many life sciences companies. Companies are considering specialized IT systems to help characterize drug candidates earlier in the discovery and development phase. As companies accelerate the push to more digitalized and data driven in their R&D processes, expectations on timelines for discovery and development are likely to compress as well.

The digitalization of product development for medical devices, especially testing kits, has taken on particular urgency in light of the pandemic. The ability to digitally monitor the spread of the coronavirus, to confidentially access electronic health records for patients, and to measure a patient’s current status and provide real-time feedback is all part of the digitalization of products and is all accessible through the development of proprietary software algorithms, dashboards, and tools.

B. Manufacturing Efficiencies

Manufacturing, like nearly all aspects of the life sciences industry, is highly regulated and thus requires significant costs to set up, maintain, and execute. Also, some segments of manufacturing in the life sciences industry involve significant know-how and may be highly capital intensive.

Over the past several years, and even more so recently because of the COVID-19 pandemic, companies have looked to use software platforms and algorithms to help automate the manufacturing process, increase efficiencies, and sustain quality without significant future costs. Companies choosing to digitalize their functions consider the upfront costs and time needed, but the goal is to establish a more streamlined process for future benefit. For example, predictive analytics have been used by companies to effectively manage production plans and control raw material and inventory levels. Robotics and automation help companies standardize manufacturing processes, which reduces quality issues and improves regulatory compliance timelines.

As companies progress through the COVID-19 pandemic, there may be more drive toward developing digital assets to help streamline manufacturing. Companies may try to avoid the disruption witnessed in this pandemic by automating processes that can be controlled offsite as needed to ensure the safety of the labor force and avoid contamination of the products.

C. Marketing During the Pandemic

Through the use of sales representatives, medical-science liaisons (MSLs), and marketing campaigns (conferences and events), the life sciences industry has always stayed in close contact with patients, doctors, and hospitals to facilitate the communication of the highly technical, scientific information around their

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5 Nate Beyor et al., “A Digital Redesign for Clinical Trials,” Boston Consulting Group (June 11, 2019).
products. This communication is also highly regulated in most markets. With the COVID-19 pandemic, many of the traditional formats for communication are unavailable, leading the industry to shift toward digital marketing solutions.

Patients had over the past several years begun to monitor their own health and assess the treatments that may work for them through various online and digital tools and resources. Digital engagement technologies such as social media, mobile apps, and other forms of communication open up outlets for marketing, exchange of information, and recruitment for trials. Pharmaceutical sales reps, MSLs, and patient service teams can reach patients, physicians, and caregivers through social media and apps, and patients can use patient portals to access their medical records and communicate with physicians.

Doctors can also liaise directly with pharmaceutical sales reps and MSLs through videoconferencing to address questions on the products and any other items typically discussed. Further, in training the pharmaceutical sales reps, MSLs, and patient service teams, companies are building “virtual launch platforms” to help with training on products to be marketed to patients, physicians, and caregivers.

Although companies value the face-to-face interactions developed by their marketing teams, the COVID-19 pandemic again has accelerated the industry’s interest in new methods and approaches to marketing that will affect how marketing is conducted in the future. Like R&D expenditures, sales and marketing activities can be a very large expense category for life sciences companies. To the extent that digital approaches can drive efficiencies, we may expect to see a corresponding change in the value chain and value drivers.

D. Transfer Pricing Considerations

As shown through the OECD’s recent work, taxation of the digital economy has emerged as a key area of transfer pricing enforcement. It is clear from the proposals that have been debated so far that the OECD sees digitalization as extending to traditional industries, such as life sciences. With the digitalization of the life sciences industry, the key focus areas remain regarding (1) where development is occurring for the proprietary software, algorithms, and solutions; (2) how revenue is generated from the digital assets developed by the company; and (3) what defines the routine and non-routine activities occurring in the digitalization efforts for a company’s value chain.

During this pandemic, as digital solutions are being rapidly developed and used, companies will need to monitor where costs are incurred for digital development activities, as well as identify how and where key activities are occurring in the event they are transformed because of the pandemic. Finally, companies should assess whether transfer prices established in their current transfer pricing structure require any changes to remuneration strategies resulting from the digitalization activities being performed. There may be planning opportunities around centers of excellence as companies invest in their digital transformation.

The potential for a permanent establishment is inherent in a remote environment with a change in how employees are performing their activities (for example, lack of travel), where digitalization only furthers the potential PE risk for companies globally. The OECD secretariat has issued its recommendations on the implications of the COVID-19 crisis on cross-border workers and other related cross-border matters, based on an analysis of the international tax treaty rules. Several countries appear to be formally or tacitly overlooking or forgiving sudden changes in assignment length and residency status, sympathetic to the exceptional nature of the changes resulting from the COVID-19 crisis. However, in some cases, the period for forgiveness is limited. Once that period ends, the assignee’s situation vis-à-vis the host country’s authorities must be regularized. Therefore, for those individuals in positions that may trigger potential PE risk (for example, signing contracts remotely and executives performing functions in their home jurisdiction rather than traveling to the
company’s location), companies should monitor these functions and consider whether the country to which the risk lies has enacted any rulings accounting for PE risk or whether the risk is material enough to warrant further tax and transfer pricing considerations.9

E. Takeaway

As the life sciences industry accelerates its adoption of digitalization, it is important to stay in tune with the impact on the company’s value chain and to monitor whether changes in the transfer pricing structure should be contemplated as new activities are being performed.

IV. Collaboration in a New Environment

In a competitive industry such as the life sciences industry, R&D and innovation takes center stage. Historically, companies had been conducting their R&D activities mostly in-house because of regulatory limitations (for example, antitrust laws), IP protection concerns, differences in company culture, and other considerations. However, in their efforts to improve the drug discovery and development process, many companies began to adopt an “open science” model, which had been reshaping the industry.10

A 2016 Forbes study showed that many of the major pharmaceutical companies were struggling with their “freshness index,” measured by sales from recently approved drugs, and that leading companies in the industry were those that had found a way to steadily deliver innovations, mostly through external collaboration and public engagement.11 As this pandemic has led to emergency situations for companies to come to the forefront and rapidly identify treatments, collaborations have increased, with companies sharing resources and clinical trial data even more with governments and one another to help increase testing capacity and to develop treatments for COVID-19.

The industry has seen a wide array of collaborations in the past couple of months, in both the pharmaceutical and the medical device sectors. The Department of Justice Antitrust Division and the Federal Trade Commission, along with similar departments in other jurisdictions, have recently issued statements concerning COVID-19 to help define processes and establish steps to expedite collaboration.12 Companies are assessing all collaborative measures to ensure financial stability and overall success, which can lead to complex arrangements. Considerations on structures such as joint ventures, partnerships, and other endeavors are contemplated through this process, which also requires a key focus on what IP elements are shared by which entities.

The reduced restrictions on IP sharing are a newer phenomenon in recent collaborations, primarily because of the efforts between collaborators to provide quicker access to information and technology for use in developing antiviral drugs and medical devices. Examples of this include the sharing of manufacturing process design for ventilators, respirators, and masks. Further, to the extent IP is shared for products previously developed and launched by companies, additional concerns arise as the sharing of IP may lead to increased generic competition.

Although companies have begun to overcome these hurdles and solidify solutions to ensure that their IP is protected through these processes, the collaboration agreements do present challenges to the current structures for companies globally.

A. Transfer Pricing Considerations

Given that the collaboration agreements discussed are purely third-party arrangements, companies will at times not consider the transfer pricing implications of entering into them. However, there are many issues to be addressed in entering into collaboration agreements. Typical questions from a transfer pricing perspective include:

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• Which entity is signing the collaboration agreements? Does it have the legal or economic ownership to the IP contributed through the collaboration agreements? If not, how will the signing entity receive these rights?
• Which entities within the group will perform R&D services? How will they be compensated?
• Who is on the joint steering committee from each collaborator’s organization? Are they located in the same jurisdiction as the IP ownership? If not, how has decision-making for the product been managed within the structure?
• Who will be responsible for manufacturing and commercialization? How will the commercialization strategy be established?
• How will losses through this collaboration agreement be recognized by the relevant parties? Where will costs be primarily incurred in the structure?

Those questions are not exhaustive, but they show a line of thinking toward ensuring that development, enhancement, maintenance, protection, and exploitation considerations are met and proper remuneration is given to the relevant entities involved in the collaboration agreements. Further, entering into collaboration agreements will present companies with opportunities to align the tax structure appropriately and ensure transfer prices are at arm’s length once development, production, and distribution begin for the relevant products. Collaboration agreements can also present opportunities for comparable uncontrolled prices to be available to companies for future years, under specific circumstances, which can help enhance transfer pricing positions established.

B. Takeaway

As companies look to collaborate with one another in the life sciences industry, the tax considerations associated with the collaboration agreement need to be assessed, including the entities involved, the roles and responsibilities expected through the arrangement, and how IP is shared among the relevant parties.

V. Supply Chain Constraints

The impact of the COVID-19 pandemic on the supply chain of products in the life sciences industry, notably the production and distribution of products to patients and consumers, is well documented and continues to create issues for the supply of products globally. As of August 2019, only 28 percent of facilities manufacturing active pharmaceutical ingredients (APIs) and 47 percent of facilities producing finished dosage forms of drugs for the U.S. market were located in the United States. The two primary locations of manufacturing for APIs and finished products are China and India, which had historically benefited pharmaceutical companies because of their low costs and production efficiencies. However, the spread of COVID-19, and China being the initial epicenter of the pandemic, has caused a drastic slowdown in production and strained the supply of drugs.

Countries are beginning to consider alternative strategies to address this issue, primarily through increased localized manufacturing or alternative manufacturing in jurisdictions. For example, India announced investments of about $1.3 billion to reduce dependence on Chinese API production. China has also begun to produce again as it emerges from quarantine; however, given trade restrictions with China and other key factors, China is likely to reemerge slowly as a manufacturer of APIs.

The FDA has also been monitoring the supply of drugs into the U.S. market and has identified those at risk of supply shortages. To counteract the risk, the FDA has defined measures to ensure that the drugs identified do not actually meet “short supply” status through this pandemic. As the monitoring of drug supply continues, supply shortage remains a major issue and will require companies to change course and assess new production strategies.

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For more personalized therapies, such as specific gene therapies that rely on a patient’s blood and plasms, the disruption in the supply chain has an even bigger effect because it is difficult not only to extract the blood without human interaction but also to transport the supply to a production site (at times across countries) for further processing before transporting back to the patient for infusion. The travel bans in place have made this even more challenging, but companies have found methods so that therapies are produced and supplied to patients in an appropriate time frame. As the pandemic progresses, companies operating in unique fields within the pharmaceutical subindustry will need to develop innovative supply chain alterations to ensure that proper supply and distribution is provided to their patients.

The pandemic has also exposed the global market to shortages in key medical devices needed to battle COVID-19, with a short supply of respirators, masks, and face shields, and limited stockpiles by countries to deal with the speed at which COVID-19 has spread. Further, the quality of products being produced in such short order has led to concerns of the effect they may cause in use, such as medical professionals exposed to the disease quicker than others because of lack of quality medical supplies.

Companies in many industries have taken part in the manufacture and production of medical devices (such as masks and ventilators), moving from their regular supply chain plans to help produce items for use in the United States and around the world. As described previously, production collaborations have shared technology to help increase output of medical devices for immediate use, with companies in the automotive, retail, and other industries helping out. An interesting facet in these collaborations is that competitors are now sharing technology details and plans with the public to increase medical device output. However, the sharing of technology comes with challenges and there may be long-term effects depending on output required in the future.

The commercialization of products may also be affected by the nature of products and the demand risk for some products. Life-sustaining drugs are likely less to be affected by the pandemic, and in some cases companies may even witness a short-term spike in sales as doctors provide prescriptions for a longer period. However, discretionary drugs or devices may experience a decline in sales or even a complete halt as some governments have ordered a suspension of most nonessential procedures, which can affect a company’s transfer pricing results.

The industry is repositioning its focus on commercialization toward the COVID-19 pandemic support, but it continues to establish innovative methods to account for the current supply chain issues affecting normal operations, whether through realigning its manufacturing footprint or identifying new opportunities for collaboration with third parties in jurisdictions with favorable circumstances on production capacity.

A. Transfer Pricing Considerations

As noted, the potential change in demand for drugs and medical devices through the COVID-19 pandemic will also have transfer pricing effects for companies when the production of nonessential drugs has declined. For example, a company may be experiencing low sales for a product in a specific jurisdiction, which may be attributable to the drug being nonessential or a less successful product launch caused by fewer visits by the sales reps. If the company has been targeting an operating margin for the local distributor, it will need to adjust its intercompany pricing to conform to the arm’s-length standard. Alternatively, the company may have to resort to other measures such as a service fee or a credit/debit note, which leads to other tax implications (for example, value added taxes and custom duties).

With the realignment of supply chains to account for commercialization constraints, companies need to also monitor the potential impact of IP transfers and value attributable to

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16 Honeywell, “N95 Masks and the Coronavirus: More Production Underway.”
warehousing and logistics functions and production capacity, in accordance with the relevant local tax rulings and regulations in place. For most countries globally, the relevant guidelines fall under chapter IX of the OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations as it pertains to business restructurings, as well as the exit taxation rules from a local tax perspective for the relevant jurisdictions.

A potential transfer pricing consideration in altering the supply chain and production of products is the transfer of production know-how and whether the jurisdiction from which functions are being transferred deserves remuneration of any kind. The same situations occur for warehousing and logistics functions within an organization, to the extent their functions are altered because of realignment of supply chain structures.

More than just the manufacture of products, the change in actual supply of products into a market will require companies to redefine intercompany arrangements for the purchase and distribution of products, which may have implications not only for transfer pricing but also for trade and customs (depending on the jurisdiction products are manufactured and sold from).

Companies will need to ensure that they have answered questions like these: Will the changes in my supply chain be short term or long term? If long term, will the appropriate compensation be needed for transferring functions, assets, and risks depending on the activity within the supply chain? If short term, do my intercompany arrangements allow for flexibility in changes to the supply chain?

B. Takeaway

Companies that are moving quickly to make changes to account for these supply chain disruptions will need to think about the ramifications from a tax perspective in order to ensure that both short-term and long-term impacts are addressed appropriately.

VI. Conclusion

The life sciences industry is faced with myriad opportunities and challenges from the COVID-19 pandemic. As companies progress through these important issues and address the effects on their respective value chains (from development to distribution), companies should also manage their potential transfer pricing implications to any changes to the business and ensure that their intercompany structures remain fit to purpose and that planning opportunities aren’t overlooked.19

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