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INSIGHT: Covid-19 Disruption in Life Sciences Industry—Tax, Trade, Value Chain Considerations



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The life sciences industry (which, for purposes of this article, we define as including pharmaceutical, biotechnology, and medical device companies) sits at the epicenter of the Covid-19 pandemic, and has experienced varied impacts across business sectors. Some life sciences companies have felt minimal disruption to their supply chains and, ultimately, lesser adverse effects to revenue, while others are seeing more significant disruption. While some of the challenges faced by life sciences companies are unique to this industry, many others, and the lessons learned in addressing them, are common across all industries.

The immediate issues and the responses alike are complex, and often require a comprehensive and holistic view of multiple disciplines to develop effective solutions. Consequently, we will structure our discussion based on three of the most significant challenges posed by Covid-19 disruption, and identify some of the key issues for life sciences companies from a tax, trade, and valuation perspective (while acknowledging that many of the issues discussed below are not exclusive to the specific challenges in relation to which they are discussed).

In Section I, we will discuss the new (and not so new) supply chain issues that life sciences companies are currently facing. Section II will address financing and cash flow. In Section III, we will talk about material issues in the research and development context. Finally,

in Section IV, we will take a moment to look ahead in terms of trends, opportunities, and issues for life sciences companies, beyond the immediate disruption of Covid-19.

I. SUPPLY CHAIN CONSIDERATIONS

Covid-19 has caused disruption to the supply chains of life sciences companies on a number of fronts. On the consumer front, there has been a range of factors that have influenced the demand for products. Currently, there is an intense focus on Covid-19 ameliorative medications and products, tests, and protective equipment. In contrast, consumption of other drug products or medical devices obtained by patients in a medical facility may be reduced as a result of, for example, elective surgeries and procedures being deferred, or sporting events and other injury-prone activities being cancelled. These factors create “lumpiness” of supply and demand (and differing ripple effects on revenue) within the life sciences industry and possibly even between business units of a single company.

Even where demand remains robust, some life sciences companies have experienced or signaled potential difficulty getting products to market due to supply chain disruption. In the life sciences industry, production is often located outside of the U.S., with China being a critical manufacturing jurisdiction. At the time of this writing, while manufacturing in China has at least partially resumed, a company may continue to sustain impacts to its supply chain at different times and in different jurisdictions as the virus peaks, ebbs, and potentially resurges. Quick “lifting and shifting” of produc-

tion is largely not possible given regulatory constraints, and in many cases would take years to accomplish—far beyond a useful timeframe in pandemic conditions.

With these waves in productivity, life sciences companies are weighing the question of whether and to what extent they should restructure supply chains in response to immediate demands against the longer-term effects of any such restructuring. Some of the larger life sciences companies are reporting that they have an adequate supply of inventory and/or materials for the near term, but not all companies, particularly smaller ones, have the same level of resources. Even assuming sufficient inventory and supplies on hand, transportation has proven to be a challenge, particularly as some jurisdictions have constrained exports or the availability of Covid-19-related products, such as personal protective equipment (PPE) or active pharmaceutical ingredients.

As life sciences companies struggle with their supply chain issues, they should consider direct and indirect tax issues and related solutions that may help manage or mitigate associated costs.

Crisis Management Teams

One response to the Covid-19 crises is that companies are establishing crisis management teams—that is, dedicated teams focused on managing, among other critical issues, global supply chain disruption. As these working groups convene (virtually) to anticipate and address emerging issues and work to prepare the company for an uncertain future, it is important for the tax team to be connected to the process. Actions taken by these crisis management teams may drive significant value for an organization, and the early inclusion of the tax team could help identify possible tax planning opportunities as well as tax risks mitigated. For example, temporary operational changes made with respect to sourcing of raw materials, production modification, or accelerated R&D on therapies or vaccines may be implemented through one-off intercompany transactions that will need to be appropriately transfer priced. Restrictions on employee or executive travel may introduce unanticipated taxable nexus issues.

In addition, the crisis management teams themselves come with tax considerations. Do the teams present their own permanent establishment risks? Should costs incurred by a crisis management team be charged out to affiliated companies in different geographies? If so, is it appropriate to charge it out at cost, with a small mark up, based on some form of contingency, or under some other methodology? How should the charges be allocated among “principal” companies and limited risk distributors or contract manufacturers? Are the costs deductible in the affiliates’ jurisdictions, versus included in cost of goods sold or treated as stewardship costs? Tax by no means will drive the discussions, but it would make sense for the tax considerations to be included in the crisis management team’s analysis.

Trade and Customs Considerations

Tariffs represent a potentially significant indirect tax cost that should also be considered when moving goods across borders. Even before Covid-19, companies were experiencing trade disruption on a number of fronts in the form of retaliatory tariffs, increased protectionism, and economic nationalism. In addition to the normal

rates of customs duty, there are currently retaliatory tariffs on Chinese and EU origin products of up to 25%, as well as select other products such as steel (25%) and aluminum (10%) from many countries. The China tariffs affect a significant portion of all goods imported from China, which is also a major production location for the life sciences industry. And while finished drugs have generally enjoyed duty-free status, the same has not necessarily been true of medical devices and PPE.

Covid-19 significantly amplified the pressure of managing trade costs for life science companies. As the demand for products within the life sciences industry ebbs and flows among the various jurisdictions, life sciences companies need to be flexible with respect to their inventory management, and send drugs, treatments, and PPE where needed—which is not necessarily predictable from day to day. There are several tried and trusted techniques, as well as a few born of necessity, to mitigate the trade costs associated with the product movement.

■ **Take advantage of available tariff exclusions.** Tariff exclusions may be granted by the U.S. Trade Representative (USTR), with respect to certain products manufactured in China and subject to the retaliatory Section 301 tariff under the Trade Act of 1974. Products with the same Harmonized Tariff Schedule (HTS) classification of excluded products are also eligible for the exclusion, i.e., a granted exclusion relates to specified products and not to the applicant importer. Although the USTR is not accepting new exclusion applications, exclusion determinations are still being issued for previously submitted applications. Furthermore, an exclusion is retroactive to the date the tariffs were implemented and valid for one year. As a result, companies that monitor exclusions, aggressively seek refunds, and claim the exclusion on imports may see significant tariff savings. In addition to the general exclusion process available for China Tariffs, the government recently announced a process by which companies can request exclusions for products imported from China that are essential for the fight against Covid-19. The administrative burden for applying for a Covid-19 exclusion is much lower than in previous exclusion processes. In this instance, an importer must only explain how the product contributes to the fight against Covid-19 and include a description of the product. It also appears that the USTR will be adjudicating these requests much more quickly than it has with non-medical products.

■ **Utilize duty draw back for re-exported products.** Duty drawback enables importers to reclaim 99% of the duties paid on imported products that are eventually exported (regardless of whether they are further manufactured in the U.S.). Furthermore, duty drawback is highly flexible: duty drawback is available for exported goods that match HTS classification of imported goods, and is not limited just to the specific goods that were originally imported. Additionally, the importer and exporter of the goods do not have to be the same (so, for example, could be different entities within the same U.S. group). This is a highly successful program for many importers, especially those impacted by Section 301 tariffs, and through regulatory changes arising from the Trade Enforcement and Trade Facilitation Act, duty drawback has become a fairly streamlined process, facilitating cash flow for importers.

■ **Maintain inventory in foreign trade zones.** A foreign trade zone (FTZ) is a designated area within the

U.S. that is considered outside of the U.S. customs territory. An importer may “admit” goods into an FTZ but only pay duty on them when they are withdrawn from the FTZ and entered into the U.S., giving the effect of short term financing. Not only does an FTZ enhance cash flow savings and reduce broker costs, but it can also provide flexible warehousing solutions. Goods that are ultimately exported from an FTZ avoid U.S. customs duties altogether.

■ **Confirm country of origin.** Although shifting location of production is not necessarily easy or even, in cases, possible for life sciences companies, it is worth confirming country of origin for imported products, particularly if any production activities (including, e.g., finishing or packaging) have been successfully relocated to address disruption issues. Country of origin—in particular, with respect to retaliatory tariffs or tariff relief under trade agreements—can be a significant driver of the tariff rate imposed on an imported product. Country of origin is determined by the location where the last “substantial transformation” of the product occurred. This is a very fact-specific determination, but for importers who successfully demonstrate a “favorable” country of origin, the tariff savings can more than justify the effort.

■ **Confirm accurate product valuation.** With the price of pharmaceuticals, treatments, and medical devices reacting to increased (or reduced) short term demand, and with the possible need for companies to respond to supply chain disruption, product value may be volatile. Importers should consider whether and how they could demonstrate that any price spike is both current and temporary, i.e., no retrospective adjustment is warranted, that could lead to an additional duty adjustment. Further, note that importers must declare imported goods at an accurate customs value, or face penalties of up to twice the U.S. government’s revenue loss (up to four times the revenue loss, in cases of gross negligence). Even duty-free goods must be declared accurately, as compliance failures may be penalized up to 40% of the value of the goods. Finally, tax code [Section 1059A](#) prevents importers from whipsawing the government, by capping cost of goods sold for tax purposes, at the declared customs value—something to keep in mind as companies work through the inventory cost issues discussed below.

Each of these opportunities for duty savings can also help life sciences companies increase cash flow during this economic down-turn when there may be cash shortfalls. Additionally, even when the economy picks back up, many of these programs will still be applicable and will provide on-going savings.

Inventory Considerations

Also worth mentioning for consideration are the U.S. tax rules related to inventory. In particular, recently revised regulations concerning the capitalization of costs to inventory for tax purposes have added a layer of complexity. Specific portions of the new regulations address various scenarios that could be significant in the current environment, including idled assets, royalties, and research expenditures. Inventory costing for tax purposes tends to be quite complicated, and thus it is prudent to model out the interplay between evolving facts and evolving regulatory rules.

Finally, companies that are exporting inventory should remember the various direct tax incentives that could apply. In particular, the foreign derived intangible income (FDII) regime provides a preferential U.S. effective tax rate—potentially as a low as 13.125%—by allowing U.S. corporations a deduction under tax code [Section 250](#) against certain export sales and licenses. However, the Section 250 deduction may be reduced or eliminated under a taxable income limitation when the U.S. corporation’s FDII-eligible income and global intangible low-taxed income (GILTI) (also eligible for a deduction under Section 250, but in this case up to 50%) exceed its taxable income. Companies experiencing losses, and that are consequently unable to access FDII benefits, may be able to direct export activities through deconsolidated U.S. subsidiaries. Alternatively, companies may consider the application of other export rules, e.g., under the interest charge domestic sales corporation (IC-DISC) regime.

Donations

Many life science companies have made substantial contributions in response to the Covid-19 health crisis—from donations of potential Covid-19 therapies and PPE to the contribution of scientific expertise and technologies. Given the magnitude of these donations as well as some recently enacted favorable tax provisions, consideration of the tax impacts is prudent.

Contributions to charitable organizations generally give rise to charitable contribution deductions. However, with respect to other, foreign or non-exempt donees, the analysis can get much more complicated. Depending on the specific facts and circumstances, it is possible that a deduction is available as ordinary and necessary business expenses, or that a company may be able to take a deduction under the loss provisions. The specific treatment for tax purposes depends on a variety of factors, including the nature of the contributed inventory and the nature of the donee. A word of warning—even in cases where a tax code [Section 162](#) business expense is a viable alternative to a tax code [Section 170](#) charitable deduction, there may be different base erosion anti-abuse tax (BEAT) implications. That is, the cost of products sold by a foreign manufacturer to a related U.S. distributor, and that are ultimately contributed, loses its treatment as cost of goods sold—and, consequently, protection from the BEAT. Section 170 deductions arising from subsequent donations are, we believe, not as vulnerable to the BEAT as Section 162 deductions. Life sciences companies with BEAT exposure should keep this in mind when evaluating the tax consequences of their charitable activities.

Also note, transfer pricing policies generally related to charitable donations must align the assumption of costs and risks of the donation with the expectation of benefits from the donations. These benefits are likely to take the form of positive reputational effects; query, in an intercompany supply chain structure, whether the beneficiary is an offshore principal, a limited risk distributor, etc. While charitable donations are not a new phenomenon, the current conditions have put pressure on transfer prices more generally and historical pricing may need to be adjusted for current extraordinary economic conditions. These could include unusually high levels of donations, and in forms or in locations that are different from the norm for the company. For example,

the cost of a donation that takes the form of waived intellectual property (IP) rights and the benefits of any corporate reputational effects of that donation may not automatically be aligned, and should be evaluated for transfer pricing purposes.

II. CASH FLOW AND FINANCING

Another area of focus is cash flow, including cash tax savings opportunities.

CARES Act

Congress passed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. No. 116-136, the third piece of a series of legislative packages promulgated to provide emergency relief in response to Covid-19. Among other things, the CARES Act includes several provisions intended to provide needed cash flow for taxpayers.

One notable feature of the CARES Act is the temporary easing of the tax code [Section 163\(j\)](#) interest expense limitation. The legislation commonly referred to as the Tax Cuts and Jobs Act (TCJA), Pub. L. No. 115-97, had capped a taxpayer's interest deductions under Section 163(j) to 30% of "adjusted taxable income" (net interest expense in excess of the limitation can be carried forward indefinitely). The CARES Act increases the Section 163(j) limitation to 50% of adjusted taxable income, for taxable years beginning in 2019 and 2020, and allows taxpayers to elect to use taxable income for the last taxable year beginning in 2019, for purposes of determining its adjusted taxable income for its taxable year beginning in 2020. Along with the Federal Reserve's reduction of the central bank rate to nearly zero (0%-0.25%) on March 15, 2020, the ability to take an increased interest deduction can provide a significant boost to cash flow.

For those taxpayers that are facing net operating losses (NOLs), the CARES Act relieves the 80% NOL limitation imposed by the TCJA and allows a five-year carryback, for NOLs incurred in taxable years beginning after Dec. 31, 2017, and beginning before Jan. 1, 2021. This allows taxpayers to take NOLs that, as a result of the TCJA, would have been absorbed in a 21% rate environment, and carry them back into a 35% rate environment. As an added bonus, the carryback of a post-TCJA NOL to pre-TCJA years potentially allows taxpayers to reduce their prospective liability under the BEAT, FDII, and GILTI deduction limitations under Section 250, and Section 163(j) limitation issues that could result from carrying the NOL forward.

The CARES Act also made a technical amendment related to qualified improvement property. While the intent under the TCJA had been to provide a 15-year life and bonus depreciation with respect to such property in the U.S., the legislative text mistakenly resulted in a 39-year life with no bonus depreciation. The CARES Act has remedied this result retroactively, and the IRS has issued related procedures, which dependent upon the facts at issue could involve tax accounting method changes or amended returns.

Asset Valuation

On a related point, companies may also want to consider how cash flow issues are affecting asset valua-

tions. During the first quarter of 2020, many companies found themselves facing impairment concerns under Accounting Standards Codification (ASC) 350 and 360 for the first time since the financial crisis of 2008. These provisions set forth financial reporting guidance covering indefinite and long lived asset impairment, including examples of triggering events such as "a deterioration in general economic conditions, or a deterioration in the environment in which the entity operates." A triggering event can become an impairment charge when the cash flow related to an asset or a reporting unit becomes compromised.

If an impairment charge is being considered for financial reporting purposes, it could be a signal that the legal entities associated with that reporting unit have diminished in value and could result in built-in gains or ordinary loss deductions for tax purposes. Importantly, the tax rules for claiming such deductions as well as for losses on assets are complicated and do not necessarily synchronize with the timing of impairments. Nonetheless, the existence of impairment charges should trigger consideration of the potential viability of worthless stock deductions, separation of underperforming assets, or legal entity rationalization.

Transfer Pricing Considerations

An additional consideration relates to transfer pricing in response to cash flow issues and losses in transactions between affiliates. A question arising with particularly high frequency in light of the unusual profit outcomes many companies are experiencing is whether the transfer prices of routine entities, which could be distributors, manufacturers or service providers, are still appropriate or should be revised. Such entities often earn profit margins or markups within target ranges.

The most appropriate approach to the transfer prices will depend on the specific facts, but some options to consider are (i) whether to continue to get to target margin established prior to the downturn based on the comparable benchmarks; (ii) whether to reduce target margin but still stay within the established pre-downturn benchmark range; or (iii) whether the routine entity should earn profit below the target range established prior to the downturn. For example, consider whether certain extraordinary costs should not be subject to a mark-up. These extraordinary costs could relate to items such as idle sales force expense or the charitable donations discussed earlier. It is important to carefully consider the facts. For example, is the sales force truly idle or is it being trained for improved or modified job performance in the future, for instance to pursue marketing efforts remotely?

In any pricing determination, it will be important to consider the interests of both parties in light of the realistic alternatives available to them. In that context, companies should consider third party evidence, including from their own contracts with third parties, on pricing or repricing of agreements in face of disruption.

There are various other contexts in which questions are arising on transfer pricing, including the treatment of crisis management costs (as noted above), intangible property valuations, royalty payments, exit charges, and interest rates on loans—all of which could have implications for cash flows within the group.

III. RESEARCH AND DEVELOPMENT

Aside from the race to develop Covid-19 vaccines, treatments, and modified PPE, which creates its own “lumpiness” in terms of R&D, many life sciences companies are facing challenges within their non-Covid-19 pipeline portfolio. Important studies have been disrupted as research laboratories may be staffed by fewer scientists and supporting personnel in light of social distancing requirements. Clinical trials are being slowed or halted as a result of difficulty enrolling patients and/or administering the requisite testing. Life sciences companies are responding to these challenges in interesting and creative ways including, for example, experimenting with virtual clinical trials or supplementing “live” R&D efforts with software solutions.

Among other things, for U.S. and/or foreign tax purposes, life sciences companies might consider whether a move to virtual activities could change the characterization of intercompany R&D services fees for U.S. and/or foreign tax purposes. Does this introduce a license fee or royalty component into the mix? Does the source of income shift from the place where individual researchers are performing trials, to a location where servers or software developers sit? Companies should check relevant rules, including treaties, to determine the exact effect, if any, of this paradigm change. Furthermore, the more a company relies on technology in its supply chains—particularly technology that gives it a competitive advantage—the greater value its technology assets have within the broader organization. Profits allocations and other determinations based at least in part on asset value should be revisited to take this increased value into account. Companies should also consider which legal entities should fund, own and/or manage new technology assets.

Many life sciences companies are seeing a significant uptick in R&D activity (and, correlatively, expenses), because they are racing to create new Covid-19 therapies, vaccines, and equipment. To accommodate this, some are collaborating with partners, and others are modifying production equipment in the race to provide innovative solutions. The U.S. tax rules governing deduction and credit eligibility of R&D expenses (which require, in part, that they be for resolution of uncertainty as to the capability, method, or design with respect to a product or process) provide favorable tax treatment for such endeavors. Further, other jurisdictions, including many states within the U.S. and many countries around the world, also provide similar relief for R&D investments.

Those companies that have struggled with the BEAT (i.e., with respect to deductions for payments made to foreign related persons) may be facing a bigger potential tax liability as a result of increased R&D activities. In that case, remember that R&D expense cannot be capitalized into cost of goods sold, and R&D is a “black-listed” activity so that the cost component of R&D service fees are not eligible for the services cost method exception to the BEAT. Nonetheless, there are a number of ways to mitigate the BEAT exposure of increased R&D spend. Companies could consider strategies like elective amortization of R&D expenses under tax code [Section 59\(e\)](#), or changes in tax method of accounting under tax code [Section 174](#) (weighed against any potential benefits of the new CARES Act provisions, discussed above). Again, modeling is key for determining

which, if any, expenses could be most beneficially accelerated or deferred, and should include a broad range of interactive issues, such as expense allocation for foreign tax credit purposes, FDI, etc.

In addition to the tax treatment of R&D expenses, there are a number of transfer pricing issues to consider with respect to IP development in the Covid-19 context. It is possible that the differential impact of the current economic downturn could lead to swings—short term or otherwise—in reasonably anticipated benefits and how companies allocate R&D costs in a cost-sharing arrangement. In addition, with the urgency around R&D efforts, contributions and developments may be coming from affiliates that are not otherwise involved in such efforts. As noted above, these instances may result in unanticipated ownership of high value IP. Life sciences companies should be evaluating whether high-value IP has been created in tax inefficient locations, and the alternatives for transferring the IP to another geography (i.e., within the framework of the group’s centralized IP holding and management structure). The transfer of high-value IP could be a costly endeavor for a company, from both the U.S. and foreign tax perspectives, as such IP would typically need to be transferred at fair market value (not at the cost of development).

While frenzied R&D is going on in some parts of the life sciences industry, others are seeing the opposite as a result of Covid-19. Continued R&D or monetization of R&D investment of non-Covid-19 drugs may be suffering setbacks, as the FDA prioritizes new Covid-19 drug applications or more of the available resources are funneled towards Covid-19 drug development. Time is an important component in the valuation equation. Lost time in the “in-process” R&D pipeline can result in a devaluation of an asset simply because costs continue to be incurred and commercial sales are delayed. While there may be no degradation in the science behind a study, the mechanics of an income based valuation model alone can result in a decline in the value of the asset, when delays occur. While loss of asset value is never a desired result, life sciences companies may consider devaluation as providing an opportunity to move IP. (Consider the transition costs noted above, and in particular the differences between gain recognition rules that look to a snapshot value of the transferred IP, and those that scale the tax consequences to continued success or failure of the IP over time.)

IV. LOOKING AHEAD

Let’s conclude with a few thoughts on what trends we might see for life sciences companies as we emerge from the Covid-19 pandemic. Companies will need to rethink the long-term viability of their current supply chain, and may move toward increased decentralization of production and warehousing while still balancing shelf life and other product considerations. Increased automation and remote workforce will almost certainly be factors as well, to reduce vulnerability to significant personnel-related disruption. Digitalization and distancing can also be expected to become bigger features in R&D activities. Increased experience with accelerated FDA drug approval processes—already seen for priority review voucher holders—could lead to greater process efficiencies going forward.

All of these factors will have correlative effects on companies’ expectations related to enterprise risk and

return on investment and, consequently, could also affect overall enterprise value. Robust business modeling will be critical in the second half of 2020, particularly for life sciences companies contemplating strategic options for product portfolio optimization, capital planning, potential business combinations, or simply reacting to the constant changes in the tax and regulatory environment. While there are still questions as to exactly what “Life after Covid-19” will be like, consideration of the direct and indirect tax implications of getting through and moving past disruption could ease transition to the industry’s “new normal.”

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