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# DIGITAL INNOVATION AND DISRUPTION

2021-2022 WEBINAR SERIES

**COVID-19 AND BEYOND: Life Sciences Supply Chain and  
Manufacturing Transactions**

A Discussion of Key Contracting Considerations

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# Presenters



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# Supply Chain Disruption (and Resilience)

[100-day-supply-chain-review-report.pdf \(whitehouse.gov\)](#):

“The COVID-19 pandemic and resulting economic dislocation revealed long-standing vulnerabilities in our supply chains.”

The Lasting Impact Of COVID-19 On Emerging Life Sciences Supply Chain – MassBio:

“...this pandemic merely exposed supply chain weaknesses already there...”

Continuing COVID hot spots and variants...

And now...Ukraine (and inflation)...

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# Key Contracting Considerations:

**Force Majeure**  
**Supply and Service Adjustments**  
**Change Control**  
**Business Continuity**  
**Termination and Transition**  
**Other**

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# Force Majeure

The image is a composite graphic. The background is a deep blue and black space filled with numerous stars. In the center, a glowing horizon line of a globe or planet is visible, with a bright sun or star behind it. Below the horizon, a cityscape is shown at night, with lights from buildings and streets. Overlaid on the city and globe is a network of glowing lines and nodes, resembling a global communication or data network. The nodes are small, bright circles in various colors (orange, blue, white), and the lines are thin, connecting them in a complex web.

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# Force Majeure Clauses

The impact of COVID-19 has garnered greater attention on force majeure clauses.

Force majeure clause

“a contractual provision allocating the risk of loss if performance becomes impossible or impracticable, especially as a result of an event or effect that the parties could not have anticipated or controlled”

Excuses a party's performance under certain unforeseen circumstances.

There is no “one size fits all” force majeure clause and the precise language of the clause can significantly impact its application.

Therefore, it is incumbent during the contract drafting process to identify which circumstances will and will not excuse performance and tailor the language to fit the parties' intent.

# COVID Impact

- Prior to the pandemic, parties may have felt comfortable using generalized, catch-all provisions such as “events beyond a party’s reasonable control,” or “acts of God.”
- The pandemic has shown that certain catch-all provisions may be insufficient to enable a party’s nonperformance.
- Also consider listing some specific supply chain disruptions (e.g., availability of materials)

- States vary in their interpretation of both force majeure clauses and the legal doctrines of impossibility and frustration of purpose.
- E.g., New York “will generally only excuse a party’s nonperformance if the event that caused the party’s nonperformance is specifically identified”.

- Given that this pandemic is ongoing, it may make sense to specifically document the impact of the pandemic.
- E.g., a supplier may want to add a provision that says: “Buyer expressly acknowledges and agrees that it was not and will not be possible for Seller to foresee, plan for, or mitigate all the consequences that the existence and spread of the SARS-CoV-2 virus may have or cause, including without limitation, the actions or recommendations by authorities.”
- Note that some force majeure provisions use words like “unforeseeable”.



# Potential Ukraine Compounding Impact

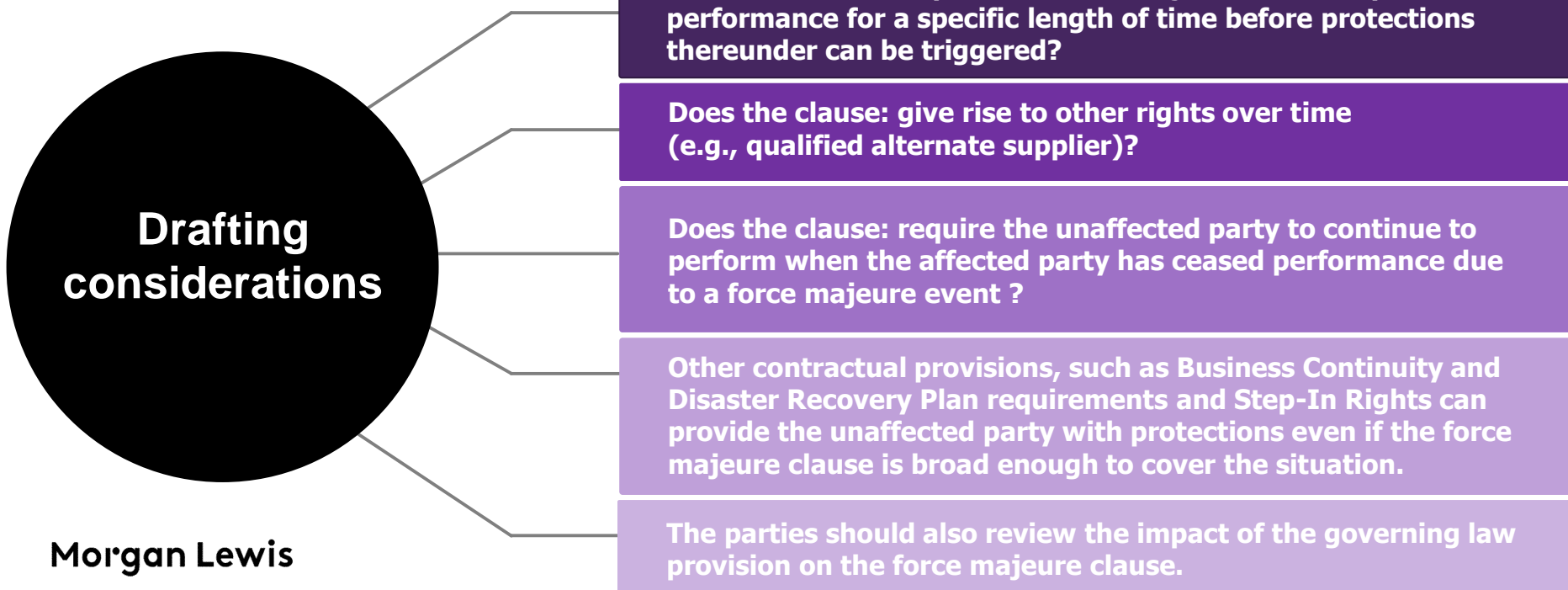
- In addition to COVID, the war in Ukraine could cause, or exacerbate, supply chain disruptions.
- Consider other potentially relevant force majeure circumstances (e.g., government sanctions, blockades, or embargoes).
- Note that “war” might be listed but could depend on how direct/insurmountable the effects are.

- Some other potential disruptions: labor disputes/shortages (the Great Resignation).
- Note that significant inflation is typically **not** an excuse. But look at the specific language (e.g., commercially impractical).

- For better preparation/adaptability, consider requiring prompt notification of any reasonably likely inability or delay (before performance is fully affected). Similarly, consider transparency/data/reporting.
- Consider providing for a qualified alternate supplier, including cooperation and procedures/duration.

# Other Factors

In addition to documenting whether a force majeure clause covers a pandemic or government-imposed shutdown (or embargo), there are other common provisions in a force majeure provision that should be carefully reviewed.



**Does the clause: require the force majeure event to prevent performance for a specific length of time before protections thereunder can be triggered?**

**Does the clause: give rise to other rights over time (e.g., qualified alternate supplier)?**

**Does the clause: require the unaffected party to continue to perform when the affected party has ceased performance due to a force majeure event ?**

**Other contractual provisions, such as Business Continuity and Disaster Recovery Plan requirements and Step-In Rights can provide the unaffected party with protections even if the force majeure clause is broad enough to cover the situation.**

**The parties should also review the impact of the governing law provision on the force majeure clause.**

**Drafting  
considerations**



# Current Example

- Life Sciences issues related to recent Russian sanctions.
- A lot of press attention focused on the designation on the Unverified List (UVL) of WuXi, which is a well-known contract manufacturer in the life sciences space:
- [BIS Unverified List: What Designations Mean for Your Business – Publications | Morgan Lewis](#)
- Would FM or termination provisions apply here?

# Supply and Service Adjustments

The image is a composite background. At the top, a bright sun or star is on the horizon, casting a glow over a dark, starry space. Below this, a cityscape is visible at night, with lights from buildings and streets. Overlaid on the city is a network of glowing lines and nodes, resembling a global communication or data network. The lines are primarily blue and orange, connecting various points across the city and extending towards the horizon.

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# Supply Adjustment

The image is a composite graphic. The background is a deep blue space filled with stars and a bright, glowing sun or star on the horizon, creating a lens flare effect. In the foreground, a cityscape is visible at night, with lights from buildings and streets. Overlaid on the city and extending into the space is a network of glowing lines and nodes, resembling a global communication or supply network. The lines are primarily blue and orange, connecting various points across the city and into the sky.

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# New Supply Strategies

## Sole Source vs. Dual Source

- Companies used to negotiate sole source deals in connection with locking in price.
- Companies are going to be more open to having a second source to shift volume to in times of crisis, even though that source may not be the lowest bidder.
- Technology has become so good/efficient, that smaller lead times and on-time deliveries were somewhat taken for granted. The issue is if the process breaks, it's harder to fix when you don't have any backup.



# New Supply Strategies

## Warehousing and Supply

- Companies are considering keeping inventory/warehousing components where they weren't doing so before. (e.g. adding contract language similar to requirements to stock X% over forecast or stock a certain volume of product) . This might not apply with certain ingredients due to shelf life, but it's something to consider.
- Previously, you'd see sweeping statements in contracts (e.g. "meet our requirements, have sufficient supply"), but if the suppliers couldn't perform, that language doesn't provide an immediate solution. In that instance the suppliers often claimed FM and left the customer with remedies like termination or sue for breach (in a time where everyone is strapped). In this instance, what would've been more helpful was pre-planned for self-help.
- So now, we're seeing companies restructuring supply chains to build in/account for fault-tolerance.

# New Supply Strategies

## Carefully crated pricing mechanisms

- Suppliers are sending letters just saying “we’re going to institute an x% across the board price hike”.
- Price mechanisms tied to a commodity index might not tell the whole story.
- Review what really effects price and be more thoughtful about ways to price so there’s redundancy.

# Rethinking Service Provisions

## Requirements regarding location

- Many agreements include strict requirements on the location of personnel (and sometimes materials).
- These restrictions are often coupled with requirements on the type of technology that can be used when connecting to or accessing the customer's systems or interacting with end users, security requirements and detailed connectivity and bandwidth requirements.
- Rules and provisions regarding reopening and shifting back to the on-premise working models is a major issue that is being discussed within both customer and supplier organizations.


## Waivers/Amendments

- The Agreement, including Service Locations, Descriptions and SLAs should be reviewed to determine whether waivers or amendments are necessary and consider whether the terms are appropriate and have short-term and long-term applicability. Consider the scope/duration of flexibility.
- A waiver may have been necessary to enable continued work, but future changed working methods may in turn trigger reexamination of business deal.

## Long-term models

- Based on emerging hybrid models, remote working will be in place for the long term and therefore a temporary waiver may be insufficient.
- Consider impact on all terms of the Agreement and potential re-negotiation.

# Travel Restrictions



Pandemic travel restrictions, together with new company policies and guidelines, have led to a significant decrease in travel.

In addition, accelerated adoption of remote work service delivery may make travel and “on-site” assumptions in ongoing agreements inapplicable (including out-of-country personnel working in-country through work visas).

While short-term travel restrictions generally may be tolerated, the long-term consequences on service solutions should be reviewed, including service descriptions and SLAs, and there may need to be changes to resource and skill demand, costs, and flexibility added to the Agreements.

Immigration issues, particularly in the United States, may result in the decrease in the number of available visa and work permits, and the ability to leverage offshore resources physically onshore will continue to evolve.



# Renegotiation / New Agreements

What we're seeing here is a trend toward self-sufficiency (or at least redundancy) (e.g. multiple sources, warehousing and storage agreements) and self-help (i.e. offset language)

We are also seeing an uptick in the number of new services and supply deals. The combination of remote working and pandemic impact have accelerated the adoption of digital technologies and business transformations to take a more pro-active view of the realities of remote workplaces.

Suppliers and customers that implement self-sufficiency and self-help, as well as recognize and incorporate changes in the work environment can offer a value add to their counterparts and act as market leaders.

# Change Control



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# The Challenge

## Sudden changes in demand and business models

### Ability to scale infrastructure

- Increased network capabilities
- Increased demand for cloud services and collaboration tools
- Shift to online transactions
- Increased automation and AI

### Ability to quickly scale to meet demand

- Need to build flexibility in to react to market changes and changes in internal roadmap

# Contract Considerations

1

Establish ability to increase and decrease volumes on demand with known pricing impact and no / limited impact on service levels. Communication, procedures, and relationship management are important.

Supplier shall increase or decrease the volume of the Services as necessary to meet demand in accordance with **Exhibit XX**. Supplier shall increase or decrease the quantity of Services provided pursuant to **Exhibit XX** with no change in the applicable service levels, and Supplier shall promptly implement such required changes in accordance with **Exhibit XX**.



# Contract Considerations

2

Demand management

- ✓ Demand management
- ✓ Forecasting
- ✓ Require notice periods for additional/ decreased resources

Indicative View	Pre-Commitment View	Commitment View
<p><b>Establish forecasting model.</b></p>	<p>Overall limits on Customer's right to make changes to the forecast.</p>	<p>Set time period when forecast is locked, provided that Customer can:</p> <ul style="list-style-type: none"> <li>• Increase demand by XX% and decrease demand by XX%, each above or below the "Commitment View" forecast.</li> <li>• Increase demand due to regulatory-related requests.</li> <li>• Agreed Changes to Services.</li> </ul>

# Business Continuity



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# Business Continuity and Key Considerations

- Force Majeure is an excuse for failure to perform based on certain defined (usually dramatic or unforeseen) events, but you still have a business to run.
- Business Continuity (DR/BC) is a collection of policies, rights and procedures designed to keep your business running regardless of a Force Majeure event.
- Note: A good BCP will allow business to proceed regardless of whether or not a FME has been claimed. Ideal to require suppliers/vendors to have a BCP/do more. Plans ideally to be coordinated.
- Many businesses were able to get some relief from FM, but vendors had to look closely at their business to be able to continue to operate their business (again, requirements for vendors in the supply chain to have more responsibility in the event of a FME).

Three threshold issues to resolve:

Issue #1: Using (and getting/giving permission for) remote workforce.

Issue #2: Security technology support required to allow efficient work/continuity of services.

Issue #3: This begets the question, how will we handle security/is this new environment secure?



# Additional Contract Provisions

- Step-In Rights
  - If and for so long as any Force Majeure Event prevents, hinders or delays performance or receipt of any Services or availability of the Systems for the periods set forth in **XXX** or the DR/BC Plan, Company may implement the **Step-In Rights** under Section XXX.
- Termination Rights for DR/BCP Plan Failures
  - If the Force Majeure Event prevents or is likely to prevent Supplier from implementing the DR/BC Plan, Company may terminate the Agreement in whole or in part.
  - If Supplier does not restore the Services within any of the time frames set forth in the DR/BC Plan or **Section XXX**, then Company may terminate the Agreement for cause.
- New World for BCP

Think about revamping plan/adding contractual language to match modern-day circumstances (remote work, etc.).

# Additional Contract Provisions

- Excused Events
  - Supplier's nonperformance excused if and to the extent (a) resulting from Customer's failure to perform its responsibilities expressly set forth in the Agreement and (b) Supplier provides Company with reasonable notice of such nonperformance and (c) Supplier uses commercially reasonable efforts to perform notwithstanding Company's failure to perform.
  - Does clause provide for Customer to pay additional costs of Supplier?
- Assumptions supporting Supplier's Fees and Service Delivery Obligations
- Change Control or Amendment to Implement New Methods of Delivering Service

# Reviewing the Provisions

- Example: In the event of a disaster or business interruption, Supplier shall at a minimum restore the Services and Systems in accordance with **Attachment XXX** by implementing the BCDR Plan. If any of the Services are not reinstated within the applicable time period so that Company receives all of the Services in accordance with the Agreement, then Company may procure such Services from an alternate source and Supplier shall reimburse Company for the costs and expenses incurred by Company in procuring such Services.
- Example: In the event of implementation of the BCDR Plan, Supplier shall not increase the Fees.



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# Termination and Transition

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# Termination for Convenience: What are customers and suppliers thinking?

In typical agreements, the customer will push for a termination right relating to the supplier's breach.

However, as COVID demonstrates (i.e. customer asking for things they didn't previously ask for and suppliers being less flexible and/or doing the same with respect to pricing and timelines), the parties may consider adding to contracts the right to terminate for their convenience (without cause), which could cover any of the following situations:

1

- Customer may no longer want the contract as a result of, among other things, having been acquired since the contract signing or seeing changes in the technology/market that are not covered in the agreement, reduction in workforce, etc.
- Supplier may no longer want the contract as a result of, among other things, the inability to staff the work, the inability to meet timelines, or the inability to provide the services at previously agreed upon pricing.

2

- Adding the customer's right to termination for convenience can avoid the potential dispute over whether the customer has the right to terminate for breach. Example scenario: The customer is not satisfied with the service provider's performance under the contract even though the provider is meeting its minimum service level and other performance requirements under the contract.
- Suppliers may want flexibility to change the way they provide services based on the economic impact of certain events.

# Termination Fee

If the customer requests the right to terminate the contract for its convenience, the supplier may request a **termination fee**.

The supplier invested money to enter into the deal and is expecting to have those costs "**amortized**" over the expected term of the contract.

If the term is cut short due to termination for convenience, the amortization period is cut short and the supplier is **not** getting the expected benefits of the deal.

For this reason, termination fees are often defined in a **downward-sliding scale** over the term of the contract, with the highest termination fees seen early in the term.

Other termination fee components to be included are the costs of breaking any **third-party contracts** the supplier entered into in order to perform the contract, costs associated with the supplier's **re-deployment of personnel and assets**, and **anticipated profits** from the unfulfilled portion of the contract term.



# Other Termination Considerations

- Other points to consider:
  - The amount of time between the customer's notice of termination and the effective date of the termination.
  - Whether there is a period of time following the signing of the contract where the customer is not allowed to exercise its right to terminate for convenience.
  - Termination for insolvency.
  - Customers may be thinking there are reasons for termination that are not a breach but for which termination for convenience fees should not be paid (regulatory change, force majeure event, etc.). Depending on leverage, supplier might push back on this (per prior conversation on investment in relationship and support).



# Transition Points to Consider

- If a relationship ends, what are the provisions that govern the transition of the relationship?
  - Termination provisions provide the customer the ability to transition to a new vendor or in-house services.
  - Ongoing patient care in connection with medical devices or services.
- Transition considerations:
  - Time period (including time before expiration)
  - Cost coverage (Service fees and additional costs)
  - New vendor or in-house (speed at which transition could be accomplished)
  - Return of materials/data
  - Confidentiality and IP
- Contract provisions should be reasonably clear and detailed – relationship may be problematic at that point. Supplier might not accept vague, open-ended obligations.

# Other Provisions

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# Additional Potential Issues

- Exclusivity
  - Consider resilience (similar to termination)
- Inflation
  - Price adjustments (e.g., fully burdened manufacturing cost)
  - Relation to exclusivity/termination
- Territory
  - Careful with, e.g., “worldwide”
  - Consider potential for changing borders
- Sublicensing
- CFIUS (e.g., “critical technology”; “emerging and foundational technologies”; “sensitive personal data”)



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# Biography



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Emily Lowe represents clients in commercial transactions, with a focus on the acquisition, use, protection, development, and commercialization of technology and biotechnology. Emily helps domestic and international companies commercialize their products through various commercial vehicles, including manufacturing and supply agreements and distribution strategies, and development and licensing agreements.

Additionally, Emily assists clients in marketing their products and services online and through joint marketing agreements, sales representative agreements, and distribution agreements. She focuses on the software, specialized manufacturing, consumer products and retail industries. Emily also has experience in licensing software and providing services to sports teams and sports leagues.

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Ben is a member of the Emerging Leadership Board of the Pittsburgh Venture Capital Association.

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