

## **Defending Against Nonperformance Of Life Science Contracts**

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*Law360*, April 21, 2020, 2:45 PM EDT

Many life sciences contracts, including intellectual property licensing agreements, development agreements and supply agreements, contain force majeure clauses. Depending upon the language of these clauses, the COVID-19 pandemic may be an event that triggers these clauses and provides a defense to nonperformance of the contract. Companies that are experiencing difficulties complying with or enforcing compliance with their contracts should carefully examine their contracts to determine if a force majeure clause may excuse performance.

As COVID-19<sup>1</sup> continues to rapidly sweep the globe, government agencies at all levels are being pressed to take difficult measures to curb the spread of the virus. Such measures have included restrictions on travel and congregation that may create business disruption. For example, as of the end of March, 2020, more than 35 states have shelter-in-place rules covering all or part of the state.<sup>2</sup> And, even in states or localities that are not subject to shelter-in-place orders, other factors, such as employee illness, concern about spreading the virus, reduced consumer demand, and supply chain disruptions, are making it difficult for businesses to carry on as usual.

Force majeure provisions seek to allocate the risk between the parties when an unforeseen event makes contract performance impossible or impracticable. Force majeure provisions often are included in life sciences agreements, and may be triggered by the occurrence of an event deemed beyond the control of a party. Typically, the agreement itself will specifically enumerate the events that may trigger the provision. For example, a force majeure provision of a license agreement between pharmaceutical companies may list the following triggering events: “fire, floods, embargoes, terrorism, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or any other Party.” Business disruptions relating to the COVID-19 pandemic may arguably be considered within this language (e.g., labor disturbances, acts of God, or delays in acting by a government authority). Force majeure provisions should be examined closely as the triggering events may vary between agreements.

Because contract interpretation is a matter of state law, a court determining whether a force majeure clause has been triggered by events surrounding the COVID-19

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<sup>1</sup> <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

<sup>2</sup> See e.g., Sarah Mervosh et al., *See Which States and Cities Have Told Residents to Stay at Home*, THE NEW YORK TIMES (Mar. 30, 2020), <https://www.nytimes.com/interactive/2020/us/coronavirus-stay-at-home-order.html>.

pandemic would apply the law of the state under which the contract is governed, whether as a result of a choice of law provision or the circumstances surrounding the contract and the parties.

At present, there have been no cases deciding whether to enforce a force majeure provision due to the COVID-19 pandemic. The following cases, however, may provide guidance as to whether a force majeure provision would be triggered as a result of COVID-19 in the context of life sciences agreements.

***Example of a case in which a court concluded that a force majeure clause WAS triggered:***

In *Acheron Med. Supply LLC v. Cook Inc.*,<sup>3</sup> the Southern District of Indiana, applying Indiana law, held that, when parties to an agreement define the nature of force majeure in their agreement, the scope and effect of the force majeure provision is governed by its specific terms. In that case, Acheron and Cook had entered into an exclusive distribution agreement for various products and devices related to Cook's endoscopy business. The agreement contained the following clause:

Neither Cook nor any Affiliate nor [Acheron] shall be liable for any delay or default caused by force majeure, including, without limitation . . . act of government or . . . agency . . . . The party affected by such a condition shall use every reasonable effort to correct or eliminate the cause which prevents performance and resume performance as soon as possible.

<sup>4</sup>The agreement further provided that Acheron would obtain the necessary Federal Supply Schedule (FSS) contract in order to sell medical supplies to the Veterans Administration ("VA"). However, because Cook was a new company without an established history of providing medical devices for the VA, the government would not award an FSS to Acheron unless Cook underwent an extensive audit by the VA's Office of Inspector General. Cook refused the audit and terminated the agreement. Acheron sued for breach, and Cook counterclaimed, arguing that Acheron failed to secure the FSS award. Acheron raised the defense of force majeure, arguing that the provision expressly enumerated an act of a government agency as a triggering event. The court found that, although Acheron's failure to secure an FSS was a material breach, "[b]y the plain language of the agreement, Acheron is not liable for that breach."<sup>5</sup>

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<sup>3</sup> No. 1:15-cv-1510, 2019 U.S. Dist. LEXIS 105297, at \*6 (S.D. Ind. June 24, 2019) [https://advance.lexis.com/search/?pdmfid=1000516&crd=6010cf27-dea5-4d4c-85be-4266b1f1ffc3&pdsearchterms=Acheron+Med.+Supply+LLC+v.+Cook+Inc.%2c+No.+1%3a15-cv-1510%2c+2019+U.S.+Dist.+LEXIS+105297&pdtypeofsearch=searchboxclick&pdsearchtype=SearchBox&pdstartin=&pdpsf=&pdqtype=and&pdquerytemplateid=&ecomp=973\\_9kk&earg=pdsf&prd=72c20567-d2f3-421c-ad2e-ccb6c440ebbb&srid=6a2b3436-3e97-44ac-ac63-dacae357aefd%20](https://advance.lexis.com/search/?pdmfid=1000516&crd=6010cf27-dea5-4d4c-85be-4266b1f1ffc3&pdsearchterms=Acheron+Med.+Supply+LLC+v.+Cook+Inc.%2c+No.+1%3a15-cv-1510%2c+2019+U.S.+Dist.+LEXIS+105297&pdtypeofsearch=searchboxclick&pdsearchtype=SearchBox&pdstartin=&pdpsf=&pdqtype=and&pdquerytemplateid=&ecomp=973_9kk&earg=pdsf&prd=72c20567-d2f3-421c-ad2e-ccb6c440ebbb&srid=6a2b3436-3e97-44ac-ac63-dacae357aefd%20)

<sup>4</sup> *Id.* at \*6.

<sup>5</sup> *Id.* at \*7.

Applying the reasoning of this case to the COVID-19 pandemic, it is likely the case would be decided the same way if, for example, Acheron failed to obtain an FSS contract due to government imposed restrictions. If, for example, the VA's office was not able to conduct audits due to COVID-19, a court considering whether the force majeure clause had been triggered likely would conclude that it was, and that the force majeure clause excused Acheron's failure to obtain the FSS contract.

***Example of a case in which a court concluded that a force majeure clause WAS NOT triggered:***

In *Watson Labs., Inc. v. Rhone-Poulenc Rorer, Inc.*<sup>6</sup>, the Central District of California, applying California law, held that a party invoking a force majeure defense must establish that it did not have reasonable control over the excusing event. In that case, Watson entered into a supply agreement with Rhone, whereby Rhone agreed to supply all of Watson's requirements of Dilacor XR. At the time of the agreement, Rhone was planning to outsource manufacturing of Dilacor to its subsidiary Centeon. Article 9.1 of the agreement included a force majeure provision, which stated in part:

The obligations of [Rhone] and Watson hereunder shall be subject to any delays or non-performance caused by: acts of God, earthquakes, fires, floods, explosion, sabotage, riot, accidents; regulatory, governmental, or military action or inaction; strikes, lockouts or labor trouble; perils of the sea; or failure or delay in performance by third parties, including suppliers and service providers; or any other cause beyond the reasonable control of either party ("Force Majeure Event").

<sup>7</sup>Shortly after entering into the agreement, Centeon's facility was shut down due to an FDA finding that the plant did not meet current good manufacturing practices ("cGMP"). Watson sued Rhone for breach of contract, and Rhone raised the defense of force majeure, arguing that the FDA's shutdown of its manufacturing facility was an enumerated event in the force majeure clause. In its decision, the court acknowledged that there was little doubt that the shutdown was ordered by the government. However, the court held that, under California law, a party may only invoke the defense of force majeure if the triggering event was "beyond the reasonable control of either party."<sup>8</sup> Because the shutdown was within the control of Rhone, the court would not excuse non-performance due to the force majeure clause.<sup>9</sup>

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<sup>6</sup> 178 F. Supp. 2d 1099, 1110 (C.D. Cal. 2001), <https://advance.lexis.com/search/?pdmfid=1000516&crd=3c61c925-3696-45fc-b627-a41021d1a2ae&pdsearchterms=Watson+Labs.%2C+Inc.+v.+Rhone-Poulenc+Rorer%2C+Inc.%2C+178+F.+Supp.+2d+1099%2C+1110&pdstartin=hlct%3A1%3A1&pdtypeofsearch=searchboxclick&pdsearchtype=SearchBox&pdqtype=and&pdquerytemplateid=&comp=9gr9k&prid=6010cf27-dea5-4d4c-85be-4266b1f1ffc3>

<sup>7</sup> *Id.* at 1109.

<sup>8</sup> *Id.* at 1110.

<sup>9</sup> *Id.*

In contrast to the *Watson* case, if a facility shutdown is caused by COVID-19 related events, such as a coronavirus contamination or large scale employee illnesses, a supplier may try to argue that its inability to meet its supply obligations was due to circumstances beyond its control.

As exemplified by these cases, whether a force majeure provision is enforceable depends not only on the specific language of the provision, but also on the facts at hand and the requirements of the state law governing the contract.

## **Other Potential Defenses To Contract Performance**

Even if a contract does not contain a force majeure clause, there are several other legal doctrines that a party to a life sciences agreement may look towards to relieve contract performance as a result of the COVID-19 pandemic. These remedies include frustration of purpose, impossibility, and illegality.

***Frustration of Purpose:*** The Restatement (Second) of Contracts § 265<sup>10</sup> (1981), defines frustration of purpose as follows:

Where, after a contract is made, a party's principal purpose is substantially frustrated without his fault by the occurrence of an event the non-occurrence of which was a basic assumption on which the contract was made, his remaining duties to render performance are discharged, unless the language or circumstances [of the contract] indicate the contrary.

In the context of COVID-19, a party may attempt to argue, for example, that the purpose of the contract was frustrated due to the disruption of its business caused by the COVID-19 pandemic. See also Uniform Commercial Code § 2-615. Using a supply requirements contract as an example, if a supplier's plant was shut down due to COVID-19 related events, the supplier may argue that its principal purpose – to meet supply requirements, was frustrated by the occurrence of the COVID-19 pandemic, and that the closure due to the pandemic was not the fault of the supplier.

***Impossibility:*** The doctrine of impossibility may excuse contract performance where: (1) performance is objectively impossible and cannot be performed by any means; and (2) the event giving rise to impossibility is unanticipated and unforeseeable. Restatement (Second) of Contracts § 261<sup>11</sup>.

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<sup>10</sup> <https://advance.lexis.com/search/?pdmfid=1000516&crd=07c415d5-91d7-441f-9a11-206ef1c06d0b&pdsearchterms=restatement+second+of+contracts+section+265&pdstartin=hlct%3A1%3A1&pdtypeofsearch=searchboxclick&pdsearchtype=SearchBox&pdqttype=and&pdquerytemplateid=&ecom=9gr9k&prid=3c61c925-3696-45fc-b627-a41021d1a2ae>

<sup>11</sup> <https://advance.lexis.com/search/?pdmfid=1000516&crd=892fb648-fcaf-41f1-8b16-32a0282f3f29&pdsearchterms=restatement+second+of+contracts+section+261&pdstartin=hlct%3A1%3A1&pdtypeofsearch=searchboxclick&pdsearchtype=SearchBox&pdqttype=and&pdquerytemplateid=&ecom=9gr9k&prid=94a4c9d3-d39c-4498-af58-f27b74b1ed72>

Again, you can see how this may play out in the current climate. For example, a party may attempt to argue that its performance under a contract has been made objectively impossible by a work stoppage due to the COVID-19 pandemic, and that these events were not reasonably foreseeable. Again using a supply requirements contract as an example, a supplier could argue that, if its plant was shut down due to COVID-19 related events, its ability to meet its supply obligations was rendered impossible, and that a global pandemic of the scale of COVID-19 was unanticipated and unforeseeable.

**Illegality:** The doctrine of illegality may be invoked if the terms of the contract are unachievable based upon enacted laws. See Restatement (Second) of Contracts § 264<sup>12</sup>.

In the context of COVID-19, a party to a contract may attempt to argue, for example, that contract performance has been rendered illegal due to stay-at-home orders enacted by state or local governments.

## **Practice Tips**

Parties to life sciences contracts containing force majeure provisions that are at risk of nonperformance should consider the following:

- Carefully review the contract terms to determine if the contract has a force majeure clause, and, if it does, which events may trigger the clause.
- Carefully review the contract terms to determine which state's law governs the contract.
- Consult with counsel to determine how courts have interpreted force majeure provisions in the governing state.
- Attempt to mitigate damages. For example, using the Watson/Rhone contract as an example, Rhone might be able to shift production to another plant that was not affected by COVID-19.
- Attempt to negotiate a compromise, such as extending deadlines for performance of certain aspects of the contract.
- Preserve evidence relating to the formation of the contract, past performance of the contract and any nonperformance.
- Continue to monitor state and local rules relating to COVID-19, such as stay-at-home orders and limitations on the number of persons who may gather.
- Parties to agreements that are subject to FDA regulation should continue to monitor FDA-issued guidances for updates on guidelines and procedures relating to COVID-19.
- A party who has licensed intellectual property should take steps to ensure that the licensee is protecting the intellectual property during the force majeure event.

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<sup>12</sup> <https://advance.lexis.com/search/?pdmfid=1000516&crd=94a4c9d3-d39c-4498-af58-f27b74b1ed72&pdsearchterms=restatement+second+of+contracts+section+264&pdstartin=hlct%3A1%3A1&pdtypeofsearch=searchboxclick&pdsearchtype=SearchBox&pdqtype=or&pdquerytemplateid=&ecomp=9gr9k&prid=07c415d5-91d7-441f-9a11-206ef1c06d0b>

- If a licensor has granted an exclusive license, and the licensee breaches due to a force majeure event, the licensor should consider whether its obligations have been cancelled or suspended, so that it can grant a license to another licensee.
- Parties entering into licensing, development or supply agreements during the COVID-19 pandemic should ensure their agreements have force majeure clauses that spell out clearly each party's rights and remedies in the event of a triggering of the force majeure clause.
- Patentees who forebear from enforcing their patent rights during the COVID-19 pandemic should consider whether their actions will result in an implied license to their intellectual property.
- Parties who have their intellectual property taken by the government during the COVID-19 pandemic should consider whether they may have an action against the government pursuant to 28 U.S.C. § 1498.
- Parties to development agreements should consider whether the contract permits an exit strategy in the event that one party cancels or is unable to perform under the agreement due to COVID-19 related events.

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