IP Licensing in the Age of Coronavirus


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While there have been no changes to U.S. intellectual property law as a direct result of the coronavirus crisis, the pandemic has changed the world in which intellectual property licenses operate. This article examines licensing issues that intellectual property counsel will need to consider now and in the future.

Supervening Events May Impact IP Licenses

The best way to protect a party to a contract against the risk of supervening events that may delay the performance of the contract or make performance impossible is to address the events expressly in the contract. The coronavirus pandemic highlights some supervening events relevant to IP licensing agreements.

The following risks should be considered during licensing negotiations and, if necessary, covered in the licensing agreement:

• That the licensee will be unable to meet royalty minimums due to manufacturing and supply chain disruptions caused by an epidemic or pandemic

• That the licensor will bow to pressure to license to other parties, a technology that is vital in a public health emergency at a lower royalty rate or even for free

• That the licensor will be reluctant to enforce a licensed patent on technology that is vital in a public health emergency

• That the licensor’s technology will be subject to compulsory patent licensing during a public health emergency in a country that has such provisions

• That a licensor who has licensed a trademark will fail to enforce its trademark against a surge of counterfeit products in short supply during a pandemic

During the urgent medical research and experimental use of drugs that may occur during a pandemic, counsel for life sciences companies also need to be aware of strategic patenting tactics that may be used to obtain leverage in licensing negotiations, as explained below.

Minimum Royalty Provisions and Force Majeure

Licensing agreements often include minimum royalty provisions to address the risk to the licensor that the license will not generate adequate running royalty income. See Patent Licenses: Key Provisions — Patent License Payment & Royalty Provisions. The current pandemic highlights the risk that a licensee may fail to make or sell sufficient product to meet its minimum royalty obligations due to events beyond its control. A licensee may be forced to cease manufacturing the licensed product during an epidemic or a government-ordered shutdown or when a foreign manufacturer on which it relies for parts is forced to cease operations for similar reasons.

A force majeure clause may help mitigate this risk to the licensee. This type of clause typically provides that neither party shall be liable to the other for delay in any performance or for the failure to perform under the agreement when such delay or failure is occasioned by enumerated events beyond its control. In trying to streamline and simplify
license agreements, it is often tempting to omit provisions that address seemingly far-fetched scenarios. Clients may demand a short form license agreement or resist the inclusion of what they regard as excessive legalese or boilerplate. It is not uncommon for intellectual property licenses to omit a force majeure clause entirely or to include one that does not list epidemics or pandemics. (See Trademark License Agreement (Pro-Licensee) for an example of a force majeure clause that includes epidemics).

Force majeure is a concept borrowed from French law. While force majeure is codified as a defense against breach of contract in many civil law systems, in common law countries, the availability of the defense generally depends on the wording of the contract. Even in an international licensing agreement in which one or more parties is domiciled in a civil law country, if the agreement is subject to the laws of a common-law country, you should consider including a force majeure clause.

The interpretation of a force majeure clause in the U.S. is dictated by the state law that governs the contract. Generally, force majeure clauses are narrowly construed. For example, under New York law, a force majeure clause must include the specific unforeseeable event that is claimed to have prevented performance. See Kel Kim Corp. v. Central Markets, Inc., 70 N.Y.2d 900, 902-03, 519 N.E.2d 295, 524 N.Y.S.2d 384 (1987).

As illustrated by recent events, in drafting a force majeure clause, you should list epidemics, pandemics, states of emergency, business shutdowns, and stay-at-home directives issued by local or national governments. Be aware of the potential differences between an epidemic and a pandemic. The coronavirus was an epidemic in some parts of the world months before it was declared a pandemic by the World Health Organization.

It is also a good idea to include a catchall category (e.g., “other events or circumstances not within the reasonable control of the party affected”). However, the effectiveness of a catchall category depends on the contract law of the state. Also, using the phrase “including but not limited to” before the list of specific force majeure events, rather than merely “including,” may decrease the risk that a court will limit the clause to the specifically enumerated events. See Corbin on Contracts § 74.19.

A party seeking to enforce a force majeure clause will need to give the required notice under the clause and establish causation (i.e., that an event listed in the force majeure clause caused the nonperformance of the contract obligation). Counsel will also need to gather evidence that the relevant event listed in the force majeure clause existed during the relevant time. Establishing that an epidemic or other emergency in another country prevented necessary product manufacturing or supply of parts may be challenging. Be aware that in civil law countries, local or national governments may declare that the event in question constitutes force majeure under national law. The declaration may take the form of a certificate or other official document. While not, of course, binding on U.S. courts, such evidence may be persuasive.

**Most Favored Licensee and IP Enforcement Provisions**

In non-exclusive licenses, the licensee may negotiate a most favored licensee provision. This type of clause protects against the risk that the intellectual property owner may license a subsequent licensee to practice the licensed subject matter at a significantly lower royalty rate or on other more favorable terms.

A most favored licensee clause typically provides that if a future license to a different licensee contains terms that are more favorable to the licensee, then the first licensee has the option to adopt those terms in its license. The clause may be limited to the royalty rate or may include other license terms. For more on most favored licensee clauses, see Patent Licenses: Key Provisions — Patent License Payment & Royalty Provisions.

The risk that others will receive more favorable license terms is a substantial threat to any licensee who relies on licensed rights in a competitive environment. See JP Morgan Chase Bank, N.A. v. Data Treasury Corp., 823 F.3d 1006, 1012 (5th Cir. 2016) (enforcing a most favored licensee clause). A competitor with lower royalty costs may damage the licensee’s business by eroding its sales volume or prices for the licensed products.
The same risk underlies another common provision in intellectual property licenses, namely, a provision obliging the licensor to enforce the licensed intellectual property against infringers. Infringement of the licensed intellectual property, unless stopped, allows the infringer to make use of the licensed intellectual property at no cost and, thus, potentially eat into the licensee’s sales or force it to lower its prices. In the case of trademark or trade dress infringement, infringers may also dilute the value of the brand that the licensee has paid to use.

The coronavirus pandemic serves to highlight the importance of including a most favored licensee clause and a robust enforcement provision in a non-exclusive IP license for products that may be vital in a public health emergency. In the current crisis, owners of intellectual property on medical equipment, personal protective equipment (PPE), drugs, vaccine technology, and diagnostic tests may face pressure to license their patents at low or no cost or refrain from enforcing their patents.

For example, see How COVID-19 Could Shake Up Patent Strategies, noting that a patent owner who filed an infringement suit against a company that was developing coronavirus tests ended up having to offer a royalty-free license for pandemic-related uses. Also noted is the fact that Gilead, maker of the experimental antiviral drug Remdesivir (originally targeted at Ebola but found to have potential in treating the coronavirus), abandoned its bid for orphan drug exclusivity after critics accused it of trying to profit from the pandemic. Also, the pandemic has prompted temporary open-source licensing of patent portfolios held by some large technology companies and research institutions. See Open Covid Pledge.

Patent licenses that extend to countries that have provisions for compulsory licensing of patents raise similar concerns. For example, in response to the coronavirus pandemic, Canada introduced a new amendment to its patent law that provides for compulsory licensing of a patented invention to the extent necessary to respond to a public health emergency.

Whether as a result of altruism, public pressure, or fear of reputational damage, many patent owners will be reluctant to enforce patents on vital equipment, drugs or diagnostic tests amid a pandemic. A possible solution is to include in the IP enforcement clause, a provision that:

- Permits nonenforcement or royalty-free licensing to third parties during a public health emergency
- Suspends or reduces the licensee’s royalty payments for the duration of the period of nonenforcement or royalty-free or compulsory licensing
- Provides other compensation to the licensee (e.g., providing public credit to the licensee for permitting the nonenforcement or royalty-free licensing during the emergency)

While patents may be seen as a hindrance in addressing a public health emergency, the opposite is true of trademarks. Trademarks are a designation of source. Being able to trust the source of PPE and medical equipment is vital.

In the coronavirus pandemic, substandard and counterfeit PPE and disinfectants have proliferated to meet increased demand. This underscores the importance of including a robust enforcement provision in a trademark license agreement for these kinds of products, requiring the licensor to pursue counterfeiters in a timely fashion. In these circumstances, courts are likely to be receptive to granting temporary restraining orders and preliminary injunctions based on the need to protect the public from the dangers of using a counterfeit product.

**Strategic Patenting and Licensing Tactics in an Epidemic**

Counsel for life sciences companies need to be alert to strategic patenting and licensing tactics that may be employed as a result of the accelerated research and experimental use of drugs that occur during an epidemic.

Normally, research on a potential new use of an investigational drug by an entity other than the company that has sought FDA approval for the drug would take place under the protection of a joint venture or collaboration agreement. Such agreements typically contain provisions that govern the filing and ownership of patents resulting from the research. See Drafting a Contractual Joint Venture Agreement, Intellectual Property Assets and Joint
Ventures and Sponsored Research Agreement (Collaborative Research - Jointly Owned Intellectual Property). However, the urgency of treating patients in an epidemic may not allow for the prior negotiation of an elaborate agreement of this type.

Gilead’s experience with its investigational antiviral drug Remdesivir illustrates some important considerations. Gilead provided its drug to treat coronavirus patients in China. Then a Chinese research institute announced that it had applied for a patent on the drug as a coronavirus treatment. It is too soon to say whether the institute’s application will ever be granted. Gilead, no doubt, has earlier patents and patent applications on the drug compound and methods of use that likely qualify as prior art that may prevent the institute from obtaining a patent.

There has been speculation as to the institute’s motive for seemingly rushing to file a patent application on the use of Gilead’s drug to treat the coronavirus. The most obvious explanation that is it is simply standard operating procedure. Researchers generally file a patent application before publishing the research that led to the invention. If they publish their research before filing a patent application, the publication will usually constitute anticipating prior art that prevents the grant of a patent. (While the U.S. has a limited one-year grace period during which inventors may publish their work without sacrificing a patent filing, this grace period does not exist for patent applications filed in other countries. See Prior Art Fundamentals — Exceptions to Section 102(a)(1) Prior Art under Section 102(b)(1)).

In the coronavirus pandemic, researchers are publishing their results on the use of drugs to treat the illness as soon as possible to share potentially life-saving information with the worldwide medical community. Early publication inevitably accelerates any patent application filing resulting from the research.

However, another possible reason for the institute’s patent filing may be to obtain leverage in negotiating a patent license with Gilead. If the institute obtains its own patent, it may then have something valuable to offer Gilead in a cross-license.

Drug companies that provide investigational drugs for compassionate use in response to an urgent medical need to treat a new disease should consider how to protect against preemptive patenting of a new use for the drug. At a minimum, they should consider providing the drug only on the condition that neither the entity to which the drug is provided nor its related entities will seek to patent or help third parties to patent the use of the drug to treat the new disease.

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