

7 Ways COVID-19 Product Makers Can Mitigate IP Infringement

By **Mark Supko, Kathryn Clune, Brian Gearing, John McCarthy and Nicole Owren-Wiest**

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Established manufacturing companies are typically well informed about the patent infringement risks they face as a result of making and selling their core products, but what happens when such a manufacturer seeks to serve the public interest by quickly retooling its facilities to produce different products desperately needed to help combat the COVID-19 pandemic?

Although one would like to think that patent owners would approach the situation altruistically, the risk of infringement liability — including the possibility of sanctions due to willful infringement — should not be overlooked.

Indeed, as recently as March 9, a nonpracticing entity accused a molecular diagnostics company of willful patent infringement and sought to enjoin the company from making and selling U.S. Food and Drug Administration-approved COVID-19 test kits.

Here, we present several practical strategies that a manufacturer can use to help mitigate these very real risks.

Seek Protection Under the Federal Acquisition Regulation

Perhaps the most effective way for a manufacturer to mitigate the risk of patent infringement liability is to ensure that its new products are manufactured and sold pursuant to a contract with an agency of the federal government.

Under Title 28 of U.S. Code Section 1498, a manufacturer cannot be held liable for patent infringement when it makes products for the U.S. Instead, the patent owner is restricted to bringing a lawsuit against the government in the U.S. Court of Federal Claims, where the only available remedy is reasonable compensation for any infringement.

In order to secure this protection, a manufacturer should ensure that any contract to supply new products to the federal government includes the Federal Acquisition Regulation authorization and consent clause.[1] Alternatively, depending on the specificity of the contract's requirements, authorization and consent may be implied.



Mark Supko



Kathryn Clune



Brian Gearing



John McCarthy



Nicole Owren-Wiest

Either way, if the contract directs the company to use a patented invention, the government can be deemed to have authorized and consented to the infringement.

Interestingly, the Defense Production Act of 1950, which President Donald Trump recently invoked to require a U.S. automaker to manufacture ventilators, does not expressly immunize manufacturers against patent infringement suits. The statute allows the government to prioritize orders and control the allocation of scarce supplies, but does not invoke the protections of Section 1498.

Even if a contract includes the authorization and consent clause, the manufacturer should ensure that the contract does not also include the FAR's standard indemnification clause,[2] or any comparable provision, that would require the manufacturer to reimburse the government for damages or settlement payments to patent owners. Given the current public health crisis, manufacturers should be in a strong bargaining position to negotiate such protections.

Explore Whether the Federal Government Can Grant a License

For patented inventions that were conceived or first built in the performance of a U.S. government contract, the federal government has broad licensing rights. For instance, the government has the right to license such inventions on a nonexclusive basis for government purposes, which clearly would include responding to the COVID-19 crisis.

In addition, to the extent granting of an exclusive license or actual transfer of title to the invention is deemed necessary to alleviate health or safety needs, the federal agency that funded the contract can invoke so-called march-in rights to do so. Accordingly, a manufacturer faced with a potentially problematic patent should investigate the circumstances under which the patented invention arose to determine whether a license may be available from the federal government.

Secure Indemnification From the Purchaser

As the name implies, the Federal Acquisition Regulation only applies to products made for the federal government; therefore, a manufacturer producing products for a state governmental agency or a private entity (e.g., a hospital) must seek other forms of protection from patent suits. In such a case, the manufacturer should try to include the broadest possible indemnification provision in its supply contract.

These provisions typically require the purchaser to "defend, indemnify and hold harmless" the manufacturer from any infringement claim arising from the manufacture, use or sale of the products to be supplied, including claims for so-called indirect infringement arising from a customer's use of a supplied product in a manner allegedly covered by a patent.

And while such an indemnification provision will not prevent a patent owner from filing suit against the manufacturer, both the cost of defending that suit and responsibility for any damages or royalty payments ultimately would be borne by the purchasing state agency or private entity, not the manufacturer.

Conversely, manufacturers should be mindful that some states, such as New York, have implemented procurement guidelines that call for the inclusion of indemnification rights in the state's favor, similar to the FAR provision discussed above. Accordingly, a manufacturer contracting with a state agency should

ensure that the agreement does not require the manufacturer to indemnify the state in connection with patent infringement claims.

Again, manufacturers who retool operations to produce COVID-19 related goods should be in a strong bargaining position to negotiate favorable indemnification terms from states or private entities that need those goods.

Negotiate a License With a Known Patent Holder

Sometimes a manufacturer may be aware that a proposed new product is covered by one or more existing patents, such as when a commercially available product to be emulated is marked with a patent number. In such a case, a manufacturer who produces such a product without the patent owner's permission runs the risk of being found a willful infringer, potentially subjecting the manufacturer to an award of enhanced damages (up to three times the amount of compensatory damages awarded) and attorney fees.

While one would expect that a court would be disinclined to impose such sanctions on a manufacturer who was acting for the public good rather than seeking commercial gain from someone else's invention, prudence suggests at least trying to negotiate a license with the patent owner on commercially reasonable terms.

Such a license would ideally provide the patent owner with reasonable compensation for use of the patented invention under the circumstances, although not so much that the manufacturer would be supplying the licensed products at a loss.

Manufacturers should also be mindful of whether any proposed new product practices a standard promulgated by a standards setting organization. In such cases, the owner of a patent necessary to practice a standard (i.e., a standard-essential patent) may already be obligated to license the patent on fair, reasonable and nondiscriminatory terms, or even for free.

Indeed, an altruistic patent owner otherwise entitled to collect royalties may be willing to grant a royalty-free license in view of the dire circumstances the country now faces, particularly in view of the typically low royalty rates necessary to satisfy the FRAND requirement.

Commission a Clearance Opinion

In some circumstances, a manufacturer may not know if there are patents covering the new product to be produced. In that case, a relatively risk-averse company may want to assess the patent landscape by engaging a patent attorney to search for existing patents that potentially could be infringed by the proposed product.

If relevant patents are found, the patent attorney can then provide a legal opinion regarding the risk that the manufacturer could be found to infringe the patent in future litigation.

On the other hand, a less risk-averse company may not want to know what patents are out there. Although patent infringement is a strict liability offense, meaning a company can be found liable for infringement even if it didn't know about the patent in question, there is little risk of a willful infringement finding with respect to patents of which an accused infringer was unaware.

Indeed, for that reason, many companies have a policy of not undertaking patent clearances before launching a new product, treating the risk of future patent infringement suits as part of the cost of doing business.

Alternatively, a manufacturer may be unable (or even unwilling, such as where time is of the essence) to negotiate a license from a known patent holder on reasonable terms. In such a circumstance, the risk of a willful infringement finding can be mitigated by obtaining an opinion from competent patent counsel advising that the patent of concern is invalid (for example, in view of earlier patents, publications or products), or that it will not be infringed by the product the manufacturer intends to produce.

To this end, a patent attorney also may be able to assist the manufacturer in designing around the patent by modifying the proposed product to exclude a feature required by the patent.

Lobby Congress to Legislate Immunity From Suit

For a relatively large manufacturer whose production plans are of a scale that the company could be exposed to a substantial risk of liability, the situation may justify the time and expense of lobbying Congress for relief.

For example, the COVID-19 Emergency Response Act currently working its way through the legislative process in Canada would impose a compulsory license on patent owners to shield companies manufacturing and selling much-needed drugs and medical devices from infringement suits.

Such measures apparently are being considered in the U.S. and would seem to be a logical and reasonable extension of the DPA for Congress to enact.

Run the Risk

Finally, a company planning to retool in order to produce products to help combat the coronavirus pandemic may simply elect to run the risk of future infringement suits, as the potential for adverse consequences may be deemed acceptably low. Patent owners risk public backlash for filing infringement suits against manufacturers of products intended to help combat COVID-19.

In fact, the backlash was so severe for one such patent owner that it offered the defendants a royalty-free license less than two weeks after filing an infringement complaint. Thus, a manufacturer faced with an infringement claim should consider a public relations strategy in addition to the more typical defensive strategies.

In the same vein, there would seem to be little or no risk that a manufacturer would be enjoined by a court from making COVID-19 products, as one factor that courts are required to consider is whether an injunction would serve the public interest. Here, the answer most certainly is that it would not, and indeed there are numerous cases of injunctions being denied where an infringing product was needed for public health or safety purposes.

Similarly, it seems very unlikely that a judge or jury would impose a burdensome damages award on a manufacturer who sought to serve the public interest by producing desperately needed medical supplies. Of course, this assumes the manufacturer comported itself accordingly and did not try to take advantage of the crisis by selling its products at a price that a judge or jury might view as excessive.

Conclusion

The risk of patent infringement suits is a fact of life for companies today, including those who seek to answer the call for products needed to combat the current public health crisis. As can be seen above, manufacturers planning to produce new products to meet this virtually unprecedented demand have a variety of options for dealing with that risk, ranging from taking one's chances to contractual protections to seeking help from Congress.

And while there is no one-size fits-all solution, it is advisable that any company venturing into a new, COVID-19-inspired product line at least evaluate the risks so that it can make an informed decision about how to deal with them.

Mark Supko, Kathryn Clune, Brian Gearing, John McCarthy and Nicole Owren-Wiest are partners at Crowell & Moring LLP.

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[1] 48 CFR § 52.227-1.

[2] 48 CFR § 52.227-3.