

COVID19 IP Update: Can 3D Printing Be the Solution to the Medical Supply Shortage?

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As the pandemic worsens, more and more hospitals and medical providers are experiencing shortfalls of critical supplies, including ventilators, face shields, and masks. Those with 3D printers and idle manufacturing centers are stepping up to the call and quickly ramping up to design, print, and distribute these critical supplies. But we keep seeing the same question: Do we need to worry about patent infringement even though there is a worldwide pandemic? Could federal government intervention change the playing field? The answer to both questions is a qualified yes.

Ultimately, we think patent risk is only moderate. (We think there is little or no copyright risk given the [availability of designs with free licenses](#).) Although neither the Patent Act nor the common law provides a full defense against patent infringement based on emergency or medical necessity, there both legal and practical factors mitigating the risk of suit or significant damages. The value of assisting in the ongoing crisis and any associated goodwill is likely higher than exposure to risk. In addition, the federal government has two avenues by which it could eliminate risk entirely. Or a state governor could attempt to deputize a manufacturer as an “arm of the state” for purposes of meeting the needs of the pandemic, potentially insulating those manufacturers from risk.

Below we try to calm any fears of those wishing to come to the aid of medical providers, both with legal and practical implications should a patent holder attempt to block or capitalize on the delivery of critical medical supplies via 3D printing.

Legal and Practical Factors Limit Patent Risk

As noted, there is no free-standing patent defense that would fully immunize an infringer from liability based on a defense of medical necessity or emergency aid. Nevertheless, these extraordinary circumstances likely limit the remedies available to a patent holder. The immense risk of public relations backlash against a litigious plaintiff could also serve as a natural limitation on true risk.

- ***Injunctive Relief.*** It is extremely unlikely that a court would grant injunctive relief against ongoing attempts to address a health crisis. In considering whether to grant a preliminary injunction, courts are required to account for “the public interest.” *Winter v. Natural Resources Defense*

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Council, Inc., 555 U.S. 7, 20 (2008). A court would be hard pressed to grant injunctive relief when the public interest so strongly favors an unauthorized use.

- **Damages.** Damages would still be available, but there are strong arguments both for limiting any damages to a reasonable royalty and limiting that reasonable royalty to minimal or nominal damages.

Likely the largest potential damages measure in this instance would be lost profits claimed by a patent holder, who might assert that the value of protective medical equipment was extraordinarily high during the pandemic. In order to recover lost profits, a patentee must show that it had the capacity to make the sales made by the infringer. *See Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551–52 (Fed. Cir. 1994) (to recover lost profits a patent owner must prove “manufacturing and marketing capability to exploit the demand ...”). A patentee must also prove that the infringement caused it to lose the asserted profits. This is usually shown through “but for” causation. A saturated market with several low-cost alternatives weighs against lost profits. *See, e.g., BIC Leisure Products, Inc. v. Windsurfing Intern., Inc.*, 1 F.3d 1214, 1671 (Fed. Cir. 1993).

There are strong arguments that a patent-holder could not satisfy any of these standards. Most notably, the entire reason manufacturers must rise to the occasion to produce and donate these medical supplies is because pre-existing suppliers cannot meet the current demand. In addition, there are several manufacturers of face masks and multiple different 3D-printed design files being freely distributed, which almost certainly means there are available non-infringing alternatives. Because of this, the patentee is unlikely to be able to show “but for” causation. Lost profit damages are therefore likely unavailable.

With damages for lost profits excluded, the patent holder would be left only with the possibility of a reasonable royalty based on donations, and thus a revenue base of \$0. Although an accused infringer’s profits—or the absence of profits—are not necessarily the only factor driving the reasonable royalty analysis, we think in this instance the fact that companies would not be commercializing the products would weigh heavily for judges or juries sympathetic to those who tried to help. And there is precedent for an award of nominal damages where infringement is not commercialized, including in a case where an infringing drug was donated to a compassionate use. *E.g., Trustees of Columbia Univ. in City of New York v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90, 120 (D. Mass. 2002) (court awarded only nominal damages for infringing donated drugs); *see Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1350 (Fed. Cir. 2000) (vacating award where infringement was limited to non-commercialized testing).

- **Willfulness.** Exposure to a willfulness finding under 35 U.S.C. § 284 is minimal. Whether enhanced damages are appropriate is a question reserved to the court's discretion. See *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1931-32 (2016). And it is very unlikely that any judge would find a 3D printer's conduct "willful, wanton, malicious bad-faith, deliberate, consciously wrongful, flagrant, or ... characteristic of a pirate." *Id.* at 1933. So while the threat of an infringement suit would still exist, it would be mitigated somewhat by headwinds against a substantial recovery for the patent holder.

Perhaps most important here, however, are practical and public relations considerations. For manufacturers, the risk mitigators described above may mean that the good deed and goodwill occasioned by pitching in in times of crisis outweighs patent risk.

As for the patent holder, it would face a violent public relations backlash if it attempted to sue. Two recent examples suggest public opinion is likely to overwhelm any attempt to enforce patents against manufacturers trying to provide aid. First, a patent assertion entity called Labrador Diagnostics brought a patent infringement suit against one of the few companies making a COVID-19 diagnostic test. Days later, extraordinary negative publicity [caused Labrador to grant a royalty-free license](#). Similarly, in Italy, a patent holder refused to provide blueprints to a 3D printer for a valve necessary to keep breathing equipment functional, [resulting in significant negative backlash](#).

The Federal Government Could Act to Immunize Manufacturers

Patent risk could be eliminated entirely through federal action.

- **Countermeasure Immunity through HHS.** The most powerful means for eliminating any legal risk—that is, not only the risk of patent liability—is potential immunity under a recent declaration issued by the Department of Health and Human Services.

On March 10, the Department of Health and Human Services [issued a declaration](#) that enables the Secretary of HHS to grant immunity with respect to certain treatments, devices, or equipment that the Secretary designates as countermeasures for the pandemic. Where the Secretary makes such a designation, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." PHSA Sec. 319F-3(a)(1). This immunity "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging,

marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.” PHSA Sec. 319F–3(a)(2)(B).

It is unclear whether and in what manner the HHS intends to consider and approve requests for designation as a qualified countermeasure. The FDA’s website does, however, include contact information for the submission of requests for approval of certain “personal respiratory protective devices.” See <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>. It may be worth seeking approval through that mechanism.

The Defense Production Act and 28 U.S.C. § 1498. Another powerful avenue for mobilizing 3D printing capabilities without exposure to patent liability is the Defense Production Act (DPA). The DPA provides the President with broad authority in times of national emergency to direct private industry to accept and prioritize performance of government contracts or to purchase essential materials or supplies. President Trump invoked the DPA on March 18, and the most recent reports are that the federal government is beginning to use it for mass orders of respirators. The President can now at any time issue “rated orders” to anyone with a suitable 3D printer, immediately turning those with 3D printers into government contractors, and requiring prompt production of the required supplies.

If the President employed the DPA in this way, it would immunize a 3D printer performing a DPA contract from patent liability. This immunity flows from 28 U.S.C. § 1498, which provides that the sole remedy for patent infringement resulting from performance of a government contract is a suit against the federal government in the U.S. Court of Claims. In a § 1498 action, the patentee may seek only “reasonable and entire compensation”—ordinarily a reasonable royalty—and may not obtain injunctive relief. The federal government could therefore use the DPA to immediately and effectively mobilize 3D printers, taking upon itself the cost of compensating the owner of any infringed patent.

- ***Compulsory license.*** A final, perhaps more cumbersome, option would be the federal government’s attempt to employ compulsory licenses for any patent blocking the production of critical medical supplies. Other countries have taken similar steps. For example, [China permits drug makers to make generic versions](#) of patented medicines. [Chile also recently passed legislation](#) authorizing the issuance of compulsory licenses to fight the COVID-19 outbreak.

The United States does not have a general statute permitting the government to issue compulsory licenses. Rather, it has a few specific

statutes that allow for the issuance of compulsory licenses in specific circumstances, none of which apply expressly to national health emergencies. But if intellectual property obstacles to treatment or prevention become significant enough to get the attention of Congress, the United States could take steps to enact temporary measures like Chile's to permit compulsory licenses.

Of course, the challenges with the above options is that they would require federal action by a department with delegated DPA authority, likely the Department of Health and Human Service. Although the federal government has triggered and appears to be using the above mechanisms, it may be focused on larger-scale contracting.

State Governors Could Grant Limited Immunity

Finally, failing federal action, state executive branches could attempt to cloak manufacturers in sovereign immunity for purposes of meeting supply shortfalls caused by COVID-19. For example, in California, the Government possesses the power to “commandeer” private operations to meet an ongoing emergency—much like the President’s power under the DPA. Cal. Gov’t Code § 8572. There are solid (if perhaps novel) arguments that the exercise of this power would turn a manufacturer subject to such an order into an “arm of the state,” cloaking it in sovereign immunity and immunity under the Eleventh Amendment of the constitution. *See Miller v. Filter*, 150 Cal. App. 4th 652, 669-70, 58 Cal. Rptr. 3d 671, 684 (2007) (“For purposes of the immunity statute, a ‘public employee’...includes an...employee, or servant, whether or not compensated, but does not include an independent contractor”); *Alden v. Maine*, 527 U.S. 706, 756-57, 119 S. Ct. 2240, 2267 (1999).

For state action to help, it would need to come quickly, and so would almost certainly require an executive order by the executive branch. And state-based attempts to immunize private manufacturers are a somewhat novel concept that may contain geographic or substantive limits. But if a state were amenable in light of the ongoing emergency, it could potentially fashion an emergency order that would provide comfort to manufacturers.

3D printers wishing to assist with the ongoing crisis should consider the above options on a case-by-case basis in determining their overall exposure to risk. Although risk cannot be fully eliminated, the COVID-19 pandemic calls for extraordinary action, and the public good would be well-served by companies bringing the full force of innovation to bear.