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Some Protection from Patent Infringement Suits Is Available to Those Who Make and Provide Personal Protective Equipment and Ventilators in Response to the COVID-19 Crisis

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Many companies have retooled (or are considering retooling) their businesses to meet the rising demand for personal protective equipment ("PPE"), ventilators, and other products or services to address the COVID-19 pandemic. Moreover, on April 2, 2020, the President ordered the Department of Health and Human Services to use its authority under the Defense Production Act ("DPA") of 1950, as amended, 50 U.S.C. §§ 4501 *et seq.*, to facilitate the supply of materials for the production of ventilators by several companies operating in the United States.[1] This alert reviews the limited protection against potential patent infringement lawsuits and damages that the law provides for infringement that occurs during the production, use, or sale of products or services in response to these emergency declarations.

Under the Patent Act, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). The Act further provides for an award of damages "adequate to compensate for the infringement," which may be trebled in certain instances, 35 U.S.C. § 284; injunctive relief is also available. 35 U.S.C. § 283.

The Patent Act creates no exceptions for patent infringement damages during public health crises or pandemics such as COVID-19, but several other statutes and doctrines may provide some protections for businesses responding to urgent demands for products or services. As discussed below, some protections may be available for manufacturers and providers of emergency equipment under a Declaration pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d; the DPA; and a statute relating to government use of patents, 28 U.S.C. § 1498(a). This alert also considers arguments that might be advanced to minimize damages for the infringement of patent claims that might cover certain emergency equipment. Although the principles discussed here are relevant to many emergency activities taken during the COVID-19 pandemic, the development and marketing of new pharmaceutical treatments for COVID-19 raises additional patent issues that this alert does not address.

I. Potential Protection from Patent Infringement Liability

A. The PREP Act and PREP Declaration

As described in a previous client alert, on March 17, 2020, Alex Azar, Secretary of the

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Department of Health and Human Services (HHS), issued a Declaration activating the PREP Act, 42 U.S.C. § 247d-6d. The Declaration extends immunity "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" administration or use of qualifying products used to combat or reduce the spread of COVID-19 (the "PREP Declaration").[2] Along with other recent FDA guidance relaxing regulatory oversight for certain COVID-19-fighting products, the PREP Declaration protects manufacturers, suppliers, distributors, and others helping to mitigate supply shortages during the current crisis.

There are several pertinent limitations on the applicability of the PREP Declaration to the circumstances described here. First, no court has yet determined that immunity under the PREP Act extends to immunity from liability for patent infringement. Although the PREP Act confers "immun[ity] from suit and liability under Federal and State law," nothing in the Act or legislative history shows specific consideration of intellectual property laws. There is also no express exclusion of patent suits, however, and potential defendants would be expected to argue that in view of the broad language of the statute, combined with courts' frequent treatment of patent law as a species of statutory tort law, PREP Act immunity from suit "under Federal . . . law" includes claims of patent infringement.[3]

Second, even if the PREP Act applies to patent infringement, not every product used in response to COVID-19 is a qualified product under the PREP Declaration. For example, a qualified product must be FDA approved, licensed for use under the Public Health Service Act, or cleared for use under a FDA emergency use authorization (EUA).[4]

Thus, activities directed towards masks and ventilators that are not approved by FDA or NIOSH (or otherwise authorized by FDA based on compliance with foreign agency standards), and that are not created pursuant to a federal contract or governmental response, are not likely to be afforded PREP Act immunity. In short, protections under the PREP Act are limited, and businesses should consider these limitations when evaluating whether the PREP Declaration protects their activities.[5]

B. The Defense Production Act and 28 U.S.C. § 1498(a)

Individuals or businesses that facilitate the production of COVID-19 response products through contracts with the federal government, including those arising from the President's recent invocation of the DPA, are granted certain protections from patent infringement liability under 28 U.S.C. § 1498(a).

1. The DPA

The DPA authorizes the President to require businesses to prioritize any of their government contracts deemed "necessary or appropriate to promote the national defense" "over performance under any other contract," and "to require" private businesses to "accept[] and perform[]" such government contracts where the President finds those businesses capable of performance. 50 U.S.C. § 4511(a)(1). The DPA also confers on the President the authority "to allocate materials, services, and facilities, to such extent as he shall deem necessary or appropriate." 50 U.S.C. § 4511(a)(2). These powers can be used to control the distribution of materials in the United States market, but only where the President first finds that those materials are "a scarce and critical material essential to the national defense," and that "the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material . . . ." 50 U.S.C. § 4511(b).

This is the case with personal protective equipment and ventilators used to combat the COVID-19 virus: the President's March 18, 2020 Executive Order specifically found that "personal protective equipment and ventilators" met "the criteria specified in [§ 4511(b)]," and further delegated the Secretary of Health and Human Services to "identify additional specific health and medical resources" that met § 4511(b)'s criteria. The President then

invoked the DPA on March 27, 2020, ordering "General Motors Company to accept, perform and prioritize contracts or orders for the number of ventilators that the Secretary determines to be appropriate." And on April 2, 2020, as previously noted, the President again invoked the DPA, ordering the Secretary of Health and Human Services to use its DPA authority to facilitate the supply of materials for the production of ventilators by a handful of companies in addition to General Motors.

2. Section 28 U.S.C. 1498(a) Protects Certain Federal Contractors from Liability

Although the DPA does not itself create immunity from claims of patent infringement against those ordered to perform contracts under the DPA,[6] another federal statute effectively supplies an affirmative defense for federal government contractors who face patent infringement claims. That protection, codified at 28 U.S.C. § 1498(a), limits a patent owner's remedy for infringement of inventions "used or manufactured by or for the United States"—i.e., inventions used or manufactured "with the authorization and consent of the Government"—to an "action against the United States in the United States Court of Federal Claims for the recovery of . . . reasonable and entire compensation for such use and manufacture." 28 U.S.C. § 1498(a).[7] That section requires the United States government to defend such actions, waiving its sovereign immunity in the process. The U.S. government's "consent and authorization" for a contractor to use and manufacture a patented invention can be expressly made in the applicable contract, pursuant to Federal Acquisition Regulation ("FAR") 52.227-1.[8] Accordingly, federal contractors cannot be held *directly* liable for patent infringement claims arising from conduct undertaken for the benefit of the federal government, with that government's authorization and consent.[9]

But the protections of § 1498(a) only go so far. A federal contractor nevertheless may be required to indemnify the government for any damages assessed in a suit that proceeds by virtue of § 1498(a). Indeed, FAR 27.201-1(d) authorizes the Government to require certain contractors to reimburse it for patent infringement "liability" and "costs" incurred in performing the contract by inserting an indemnity clause into the contract.[10] It would thus behoove federal contractors to try to exclude that clause from government contracts—if possible. Moreover, parties to federal contracts arising from the DPA might argue that such an indemnity clause is unenforceable under FAR-52.227-3(b)(1), which provides that the indemnity clause does not apply to infringement claims where, among other things, the infringement results from "the Contracting Officer . . . directing a manner of performance of the contract not normally used by the Contractor." Although the scope of that exception does not appear to have been tested in the context of the DPA, it is expected that contractors ordered to facilitate the manufacture of products they do not normally produce would argue for its application in these circumstances.

In short, a federal contract for the manufacture, supply, and distribution of PPE and ventilators may help insulate manufacturers and others from direct claims of patent infringement for certain activities, but that protection may be of limited value if they are thereafter required to indemnify the government against such claims.

II. Businesses Meeting the Urgent Needs of the COVID-19 Pandemic May Be Expected to Argue That Any Patent Damages for Their Activities Should Be Minimal

The expected arguments for minimizing patent damages and other remedies for the production, sale, or use of infringing PPE and ventilators during the pandemic—even in the absence of a federal contract—find some support in existing Federal Circuit case law.

A. Injunctive Relief Would Be Unlikely

As an initial matter, it is unlikely that patent owners could obtain injunctive relief against

infringers of patents on PPE and ventilators in the context of the COVID-19 crisis. To obtain a permanent injunction against an infringer, a patentee must satisfy the well-established four-factor test, by showing that: "(1) it has suffered an irreparable injury; (2) remedies available at law are inadequate to compensate for that injury; (3) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) the public interest would not be "disserved" by a permanent injunction."[11] Patentees would have tremendous difficulty meeting their burden for the seemingly obvious reason that enjoining the production of supplies that prevent the spread of COVID-19 and treat infected individuals would disserve the public interest. Indeed, the Federal Circuit has held that the public interest would be disserved by a reduction in availability of cancer and hepatitis test kits, and pacemakers—at times where no comparable global health pandemics were declared.[12] A patentee's expected failure to meet the public interest prong would almost certainly be fatal to any claim for injunctive relief.[13]

B. Defendants' Arguments for Reduced Damages Might Find Purchase with a Court

A patent owner who prevails in patent litigation is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer," 35 U.S.C. § 284. Moreover, "the court may increase the damages up to three times the amount found or assessed," an enhancement that typically involves a finding of willful infringement. *Id.* The circumstances of the COVID-19 pandemic would render unlikely any award of lost profits damages or enhanced damages for willful infringement. Lost profits damages require the patentee to show (among other things) that it had the manufacturing and marketing capability to meet public demand for the product.[14] The extraordinary present need for PPE and ventilators, as two examples, would militate against such a showing.

An award of enhanced damages for willful infringement rests within the district court's discretion for "egregious cases of misconduct beyond typical infringement."[15] Even during a pandemic, the question of whether infringement directed toward preventing the spread of COVID-19 meets the "egregious" standard may depend on a variety of factors, among them whether the government directed production of the product or service—in which case a court may very well find the infringing conduct does not constitute the "malicious, bad-faith" conduct the egregious standard is intended to capture.[16] Likewise, the Patent Act provides that the "court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. We do not expect courts to find that cases arising out of the COVID-19 pandemic are "exceptional" such that prevailing plaintiffs are entitled to fees—but in circumstances where defendants prevail, courts might use a finding that the case was "exceptional" to deter meritless suits against companies attempting to address the COVID-19 pandemic.

The minimum damages to which prevailing patent-holders are entitled are a "reasonable royalty." Manufacturers, distributors, and users of COVID-19 response products who are found liable for patent infringement would be expected to argue that any such reasonable royalty would be minimal under the circumstances.[17]

C. Commentators Have Suggested Other Ways to Permit Businesses to Respond to the Current Emergency Without the Risk of Infringement Suits and Liability

The urgency of the COVID-19 crisis has given rise to other suggestions for ways to permit businesses to provide urgently-needed supplies without the risk of defending against expensive patent infringement litigation and being assessed damages. One suggestion calls for the donation of intellectual property rights to the fight against COVID-19. For example, on March 31, 2020, a group of prominent scientists, lawyers, and entrepreneurs

introduced the “Open COVID Pledge,” in an effort to promote the removal of obstacles involving intellectual property in the fight against COVID-19. The pledge, available on the group’s website, is intended for signature by “patent, copyright and other intellectual and industrial property rights (other than trademarks and trade secrets)” and would grant a non-exclusive, royalty-free, worldwide license to such intellectual property “for the sole purpose of ending” the COVID-19 pandemic. The license would be limited in time to the period of December 1, 2019 until one year after the World Health Organization declares the pandemic to have ended.

Companies such as Intel and Mozilla have reportedly joined the Open COVID-19 pledge. While it remains to be seen how many patent holders ultimately do so, the pledge itself reflects a sentiment that companies contribute to the fight against the pandemic by forgoing the enforcement of their intellectual property rights—in essence, by donating them. But that sentiment—which may dissuade intellectual property owners from bringing suit *now*—may ultimately be significantly less valuable than an enforceable pledge or right. Because even if a non-binding spirit of public contribution (and public pressure) prevents patent owners from asserting infringement claims during the current climate, businesses should bear in mind that the current emergency will (hopefully) abate, and that patent-holders may typically seek damages for six years of pre-suit damages—meaning that activities now may not be the subject of suits until 2026, when the climate may be different.

In sum, businesses or individuals facilitating the manufacture, supply, distribution, and use of COVID-19 response products should be mindful that many of these products are subject to patents. While the PREP Act and PREP Declaration may afford immunity from patent infringement claims in limited instances, and while federal contractors may rely on 28 U.S.C. § 1498 as an affirmative defense to such claims, other persons and entities that infringe patent claims on PPE and ventilator components could conceivably face reasonable royalty damages. Those considering aiding in the production or distribution of PPE and ventilators should consider doing so through federal government contracts, and by negotiating license agreements with patent holders upfront. Likewise, legislative and regulatory solutions (such as, for example, clear tax benefits for the donation of intellectual property for use by businesses trying to meet emergency needs), and business philanthropy, may help address the emergency, and businesses are advised to monitor any such developments. We will report on any advances of note. Government actions impacting intellectual property rights owners may also raise constitutional issues concerning property rights more broadly, as addressed in a prior client alert available here.

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[1] These companies include General Electric Company; Hill-Rom Holdings, Inc.; Medtronic Public Limited Company; ResMed Inc.; Royal Philips N.V.; and Vyaire Medical, Inc. The President previously invoked his powers under the DPA, on March 27, 2020, by requiring that General Motors Company “accept, perform and prioritize contracts or orders for the number of ventilators that the Secretary [of Health and Human Services] determines to be appropriate.”

[2] 85 Fed. Reg. 15198 (March 17, 2020).

[3] *See Carbice Corp. of Am. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 33 (1931); *Akamai v. Limelight Networks Inc.*, 786 F.3d 899, 905 (Fed. Cir. 2015), *rev’d on other grounds*, 797 F.3d 1020 (Fed. Cir. 2015) (*en banc*) (*per curiam*); *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365 (Fed. Cir. 2008); *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 806 F.2d 1565, 1579 (Fed. Cir. 1986).

[4] 85 Fed. Reg. 15198 § VI (“Covered Countermeasures”) (“To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act, or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.”)

[5] 85 Fed. Reg. 15198 (March 17, 2020).

[6] The DPA states that "[n]o person shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order issued pursuant to this chapter[.]" 50 U.S.C. § 4557. But that provision has been interpreted to apply only to third-party breach of contract claims against parties whose performances of their contracts were frustrated under a DPA order. *See Hercules, Inc. v. United States*, 24 F.3d 188, 203-04 (Fed. Cir. 1994), *aff'd*, 516 U.S. 417 (1996).

[7] The full text of 28 U.S.C. § 1498(a) provides: "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."; *see also Liberty Ammunition, Inc. v. United States*, 835 F.3d 1388, 1394 n.3 (Fed. Cir. 2016) (noting that § 1498 effects a waiver of the government's sovereign immunity).

[8] FAR 52.227-1 more specifically sets forth an express grant of "authorization and consent" for contractors and subcontractors for the use and manufacture of any patented invention (1) embodied in the structure or composition of any article delivered to and accepted by the government related to a government contract; or (2) used in machinery, tools, or methods necessary for a contractor to comply with the specifications of a contract, or if such use is directed by a contracting officer's specific written instructions.

[9] *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359 (Fed. Cir. 2014); *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322-23 (Fed. Cir. 2012) (*en banc*); *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, 583 F.3d 1371, 1376-77 (Fed. Cir. 2009).

[10] The indemnity clause is set forth in FAR 52.227-3 (titled "Patent Indemnity") and provides that "[t]he contractor shall indemnify the Government and its officers, agents, and employees against liability, including costs, for any infringement of any United States patent . . . arising out of the manufacture or delivery of supplies, the performance of services, or the construction, alteration, modification, or repair of real property . . . or out of the use or disposal by or for the account of the Government of such supplies or construction work."

[11] *i4i Ltd. Ptrp. v. Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010) (citing *eBay v. MercExchange L.L.C*, 547 U.S. 388, 391 (2006)).

[12] *Hybritech Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1458 (Fed. Cir. 1988); *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 864 (Fed. Cir. 1986).

[13] *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (finding district court erred in granting permanent injunction where it found that the public interest would be disserved by one). The same is true with respect to obtaining preliminary injunctive relief, which similarly requires that the patentee establish that the balance of equities weighs in its favor, that the injunction serves the public interest, that it is likely to succeed on the merits, and that it will suffer irreparable harm in the absence of an injunction. *Trebro Mfg., Inc. v. Firefly Equipment, LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014).

[14] *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1285 (Fed. Cir. 2017) (citing *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978)). The patentee must also show demand for the patented product, an absence of acceptable

non-infringing alternatives, and the amount of profit it would have made. *See id.*

[15] *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1929 (2016).

[16] *Id.* at 1932.

[17] *See* 35 U.S.C. § 284 (providing that a court "shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer"). The reasonable royalty is commonly calculated by attempting "to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began." *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). In cases where only components of a product infringe a patent, the patentee must "apportion or separate the damages" between the patented and unpatented parts of the multicomponent product. *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp.*, 879 F.3d 1332, 1349 (Fed. Cir. 2018).

Gibson Dunn lawyers regularly counsel clients on the issues raised by this pandemic, and we are working with many of our clients on their response to COVID-19. For additional information, please contact any member of the firm's Coronavirus (COVID-19) Response Team. Please also feel free to contact the Gibson Dunn lawyer with whom you usually work, or the authors:

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