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I. INTRODUCTION

The COVID-19 pandemic has laid bare inherent tensions between the protection of intellectual property (IP) and the health of individuals touched by life-threatening medical conditions. A few examples have even made front page news. Hospitals are searching desperately for ventilator parts while 3-D printing instructions for such parts remain unshared for fear of liability. And potentially lifesaving medicines remain out of reach because their manufacture and distribution on sufficient scale is limited by the threat of patent infringement.[1] The threat of liability for IP infringement also dampens the ability to innovate under emergency conditions, intensifying the tension between the protection of IP and the protection of human lives. A number of policy responses have been proposed to address this tension, including the exercise of government rights under the Defense Production Act to IP

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[1] *See, e.g.*, Glyn Moody, *Volunteers 3D-Print Unobtainable $11,000 Valve for $1 to Keep COVID-19 Patients Alive; Original Manufacturer Threatens to Sue*, TECHDIRT (Mar. 17, 2020), https://www.techdirt.com/articles/20200317/04381644114/volunteers-3d-print-unobtainable-11000-valve-1-to-keep-covid-19-patients-alive-original-manufacturer-threatens-to-sue.shtml [https://perma.cc/DZX2-JX4G].

contexts;[2] government use of patented technologies;[3] compulsory licensing;[4] legislation that would allow for emergency overrides to IP protections;[5] and efforts to encourage companies to make their IP freely available on a voluntary basis, most notably through the Open COVID Pledge.[6] But fears of disrupting IP protections have curtailed the use of these measures, leaving the tensions between IP protection and lifesaving access largely untouched.

Instead of looking for solutions that would entail legislative action, a stretch of emergency powers, or vague private commitments, we suggest that the law already provides a mechanism for addressing this tension in the form of the age-old common tort law doctrine of necessity (aka lesser-harm or lesser-evil defense). Our proposed use of the necessity defense is specifically designed to address the lack of adequate mechanisms within IP law to balance the social value of preventing harm through unauthorized use of IP against the social value of providing strong property rights in lifesaving technologies.[7] Even where the public interest is explicitly taken into account—such as in the case of judicial decisions to grant an injunction against a patent infringer or under the copyright fair use doctrine—the nature of this public interest remains amorphous, the weight it carries limited, and it is usually untethered from concerns about access to lifesaving technologies.[8] We sug-

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[2] Defense Production Act of 1950, 50 U.S.C. §§ 4501–4568.

[3] Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1 (2020).

[4] *See, e.g.*, Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, CONN. L. REV. (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3636456 [https://perma.cc/YF9N-C3YM]; *see also* Frederick M. Abbot & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535 (2020).

[5] *See, e.g.*, Facilitating Innovation to Fight Coronavirus Act, S. 3630, 116th Cong. (2020).

[6] *See* OPEN COVID PLEDGE, https://opencovidpledge.org/ [https://perma.cc/CXB5-PHUD] (last visited June 27, 2021); *see also* Jorge L. Contreras, *Expanding Access to Patents for COVID-19*, *in* ASSESSING LEGAL RESPONSES TO COVID-19 158, 160 (Scott Burris et al. eds., 2020).

[7] While the market impact of our proposal is likely to be limited, given the parameters of the defense as we describe it in the paper, it should also be acknowledged that there is an ongoing unsettled debate about the relationship between the "strength" of patent rights and innovation which makes judging the market impact of changes in IP law both difficult to ascertain and contested. *See, e.g.*, Heidi Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome* (Nat'l Bureau of Econ. Rsch., Working Paper No. 16213, 2010); Petra Moser, *Patents and Innovation: Evidence from Economic History*, 27 J. ECON. PERSP. 23 (2013).

[8] *See, e.g.*, eBay Inc. v. MercExchange, LLC, 547 US 388, 393–94 (2006) (holding that the traditional four-factor test, which includes the public interest, should be used in making decisions about whether to award an injunction for patent infringement). Despite the directive to consider the public interest, there seems to have been little change to decision-making about injunctive relief due to public interest concerns post-*eBay*. *See, e.g.*, Christopher B. Seaman, *Permanent Injunctions in Patent Litigation after* eBay*: An Empirical Study*, 101 IOWA L. REV. 1949, 1982–83 (2016). While the ITC provides a more robust role for the public interest in determining whether to issue an exclusion order for infringing goods entering the United States, judges have rarely

gest that the defense of necessity can help inject responsiveness to urgent public health needs into the IP ecosystem in a way that avoids significant changes or impediments to its functioning. While drawing from examples that are specific to a highly disruptive public health crisis, our proposal also responds to broader, systemic shortcomings in the way IP law impacts access to lifesaving technologies.[9]

II. CHILLING EFFECTS OF PROPRIETARY FRAMEWORKS ON EMERGENCY ACCESS TO WELFARE-ENHANCING GOODS

Many of the goods needed to respond to emerging and acute public health problems are covered by a web of IP rights. This web consists primarily of patents, but it may also include other forms of IP, such as copyrights and trade secrets.[10] The presence of an inflexible web of IP rights may yield particularly troubling results for social welfare during sudden or large-scale crises. The exclusionary ability of an IP rightsholder, uncertainty about the scope of IP rights, or simply the lack of time to obtain permission to use or replicate IP-protected goods may lead to situations in which an otherwise overriding interest (either public or individual) in accessing these goods is set aside due to concern of liability. As a result, society loses the potentially immense social value of unauthorized use of IP to meet emergency health needs.[11] This has likely been the case during the COVID-19 pandemic.

To illustrate, consider an example drawn from the first wave of the COVID-19 pandemic. At the height of the first wave of the pandemic, a hospital in Northern Italy came close to running out of valves for ventilators, critical for keeping severely ill COVID-19 patients alive.[12] When

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invoked the public interest to deny an exclusionary order. *See, e.g.*, Kristen J. Osenga, *What Happened to the Public's Interest in Patent Law?*, 19 FEDERALIST SOC'Y REV. 198, 200 (2018) (discussing the limited role of public interest as a factor limiting patent rights).

[9] The arguments made in response to measures such as the one we propose often focus on the need for strong incentives to produce lifesaving technologies. In other work, we take on the question of whether the current incentive structure(s) created by the patent and other market-based systems actually produce the optimal level and type of innovation needed to respond to public health emergencies. *See, e.g.*, Yaniv Heled et al., *The Problem with Relying on Profit-Driven Models to Produce Pandemic Drugs,* J.L. & BIOSCI. Jan.–Dec. 2020.

[10] The full extent of the intersection of these different IP regimes and rights as they pertain to biomedical products have yet to be fully fleshed out in doctrine and caselaw. *See generally*, *e.g.*, DINUSHA MENDIS ET AL., 3D PRINTING AND BEYOND: INTELLECTUAL PROPERTY AND REGULATION (2019).

[11] Under U.S. law, except in specific instances, infringement of patents, trademarks, and copyrights and misappropriation of trade secrets are strict liability torts, requiring the IP owner to establish only that (1) the IP right is valid, and (2) there was violation of the right by the alleged infringer. Establishing a scienter is not required. For a discussion of strict liability in the context of patent law, see Roger D. Blair & Thomas F. Cotter, *Strict Liability and Its Alternatives in Patent Law*, 17 BERKELEY TECH. L.J. 799 (2002).

[12] *See* Anas Essop, *Hospital in Italy Turns to 3D Printing to Save Lives of Coronavirus Patients*, 3D PRINTING INDUS. (Mar. 18, 2020), https://3dprintingindustry.com/news/hospital-in-italy-

the manufacturer of the valves, which are patented and normally sold for slightly above $10,000 each,[13] was unable to provide replacement valves, the hospital obtained and used locally 3-D printed copies made by local engineers.[14] The Italian engineers 3-D–printed one hundred copies within a day at a cost that barely exceeded $1 per valve.[15] Despite the apparent social value of making their work more broadly available, the engineers were unwilling to share the 3-D printing instructions for the valves with others for fear of liability arising from IP infringement.[16]

While this early pandemic story of IP access barriers to ventilator valves made headline news, many other examples are inevitably occurring without publicity, for obvious reasons. Even in times of crisis, there is little incentive for parties partaking in unauthorized use of IP to draw attention to their actions. In other cases, the untold story may be one of missed opportunity, where unauthorized use of lifesaving technologies does not occur due to overdeterrence. Ideally, for example, one could envision chemists and compounding pharmacists engaging in unauthorized manufacturing of patented lifesaving pharmaceuticals that are in short supply or priced beyond the reach of certain patients and entities. Other lifesaving work might require the misappropriation of proprietary clinical information and manufacturing know-how necessary to develop and manufacture the lifesaving treatments. IP rights could deter unauthorized use of protected technologies in such situations despite such use being both socially desirable and ethically justifiable. This reality may be especially prevalent in countries like the United States, where IP laws do not make exceptions for lifesaving conduct, even during a public health emergency.

Access to technologies protected by IP can be obtained through private licensing, compulsory licensing, patent pledges, and pooling arrangements. Underuse of technologies covered by IP in situations of extreme public need is attributable, in large part, to the inadequacy of these mechanisms for balancing IP rights and the public interest in speed and flexibility in cases of crisis or emergency.

Contemporary IP regimes make the use and transfer of protected technologies largely dependent on complex and time-consuming private

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turns-to-3d-printing-to-save-lives-of-coronavirus-patients-169136/ [https://perma.cc/8H6D-TT8Z].

[13] *See* Moody, *supra* note 1.

[14] *See* Essop, *supra* note 12.

[15] *See id.*

[16] *See* Moody, *supra* note 1. Although not acknowledged at the time, the actions of this team of engineers had almost certainly already infringed at least some IP laws, including, potentially, in the creation and use of the digital file containing instructions on how to print the valves, the 3-D printing of the valves, the creation of the printed valves themselves, the installation of the valves into ventilators, and the use of the valves.

negotiations between parties, with highly uncertain outcomes. IP laws presume that parties in need of such technologies have the time, resources and expertise necessary to conduct such negotiations and do not make allowances for the flexibility and speed required in situations of urgent need.[17]

Public mechanisms for securing access to IP to meet emergency needs, such as compulsory licensing and march-in rights, are time-consuming, politically fraught, and often require centralized, coordinated action.[18]

Pledges of non-assertion of IP rights depend on the varying goodwill of a plethora of players, are typically restricted to a relatively small set of embodiments of the requisite technology, and may present enforceability problems. The limitations of IP pledges were made apparent during the recent pledge of non-assertion of rights by the pharmaceutical companies AstraZeneca and Moderna concerning their COVID-19 vaccines. These pledges were in practice substantially more limited than initially understood by the public at large.[19]

Pooling mechanisms, which provide some ex-ante certainty, are similarly limited in scope, types of technology, number of participants, and public awareness. The Open COVID Pledge, for example, was rapidly formed to enable "holders of intellectual property to share [ ] their intellectual property for the purposes of ending and mitigating the COVID-19 Pandemic,"[20] but it did not attract many participants and technologies in crucial fields such as those related to vaccines. This pooling attempt ran parallel to efforts by governments and international organizations to coordinate the development of technologies for the response to the pandemic, each competing for public awareness,

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[17] *See, e.g.*, Joshua D. Sarnoff, *TRIPS, COVID-19, and the Right to Repair and Produce Needed Medical Products in Emergencies (Part 1 of 2)*, TRADERX REP. (June 11, 2020), https://www.traderxreport.com/covid-19/trips-covid-19-and-the-right-to-repair-and-produce-needed-medical-products-in-emergencies-part-1-of-2/ [https://perma.cc/W8ZE-U257] (suggesting the need for a legislative repair exemption from IP liability to address public health emergencies); Jorge L. Contreras, *Research and Repair: Expanding Exceptions to Patent Infringement in Response to a Pandemic*, J.L. & BIOSCI., Jan.–June 2020, at 2–7 (reviewing the limitations of existing research and repair exemptions from IP liability during a pandemic); Ellen 't Hoen, *Protect Against Market Exclusivity in the Fight Against COVID-19*, 26 NATURE MED. 813, 813 (2020) (discussing the obstacles posed by IP to the development of treatments for COVID-19 and the limitations of existing mechanisms of limiting IP).

[18] *See, e.g.*, EDUARDO MOISÉS PEÑALVER & SONIA K. KATYAL, PROPERTY OUTLAWS 93–108 (2010) (describing the fraught nature of attempting to issue compulsory licenses during public health emergencies).

[19] *See, e.g.*, Donato Paolo Mancini, *AstraZeneca Vaccine Document Shows Limit of No-Profit Pledge*, FIN. TIMES (Oct. 7, 2020), https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686 [https://perma.cc/XK9K-WVW4].

[20] *Frequently Asked Questions*, OPEN COVID-19 PLEDGE, https://opencovidpledge.org/faqs/ [https://perma.cc/LNV6-G4LU] (last visited June 27, 2021).

participation, and technological reach, and each ultimately limited in impact.

Overall, the inability to meet extraordinary needs for biomedical goods through existing IP mechanisms such as those discussed above may lead to detrimental personal and public health outcomes, including the worsening of disease and loss of human life.

We argue that contemporary IP needs a flexible solution to address access to technologies under conditions of dire need—in particular, access to biomedical technologies during a public health crisis. Although such a solution may vary in form, the basic approach of excepting certain types of conduct from IP liability to achieve public health goals is applicable across different fields of IP, as demonstrated in recent work by Michael Carrier, Eduardo Moisés Peñalver and Sonia Katyal, and others.[21] Any solution should balance observing legally established IP rights, on the one hand, with access to protected technologies without rightsholder permission in situations of dire need. Our argument is that we have one such solution that lies in plain (legal) sight, in the common-law tort doctrine of necessity. We conclude that IP law should incorporate this age-old doctrine in much the same way as it has done for other doctrines originating in torts and other bodies of law.

III. A SOLUTION HIDING IN PLAIN (LEGAL) SIGHT: APPLYING THE DOCTRINE OF NECESSITY TO IP

The exact origins of the doctrine of necessity in English common law are uncertain, but cases in which necessity established a defense to tort liability go back at least as far as the 1500s.[22] From English law,

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[21] *See* Karen E. Sandrik, *Reframing Patent Remedies*, 67 U. MIAMI L. REV. 95, 142–45 (2012) (proposing an incomplete privilege to infringe patents similar to the necessity defense); PEÑALVER & KATYAL, *supra* note 18, at 190–97 (discussing necessity as a possible mechanism for overcoming patent protections during public health emergencies); *see generally* Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 DUKE L.J. 1 (2004) (describing the role of the necessity doctrine and necessity defense across different areas of intellectual property); Deepa Varadarajan, *Trade Secret Fair Use*, 83 FORDHAM L. REV. 1401 (2014) (highlighting the need for additional exceptions to trade secrecy protections, including to promote and safeguard public health).

[22] *See, e.g.*, Brian Angelo Lee, *Emergency Takings*, 114 MICH. L. REV. 391, 403 n.56 (2015) (citing Maleverer v. Spinke, 73 Eng. Rep. 79 (K.B.) 81 (1537) ("Yet we will well agree that in some cases a man may justify the commission of a tort, and that is in cases where it sounds for the public good . . . a man may justify pulling down an [sic] house on fire for the safety of the neighbouring houses . . . .")); John P. Finan & John Ritson, *Tortious Necessity; The Privileged Defense*, 26 AKRON L. REV. 1, 1–2 (1992) (describing additional old English cases in which the necessity defense served to shield from tort liability); Mouse's Case, 12 Co. Rep. 63 (1608) (justifying the tossing of personal luggage from a ferry to save its passengers' lives during a storm).

the necessity doctrine has seamlessly "migrated" to the law of the colonies and then to American tort law, where it has continuously served as an affirmative defense against tort claims.[23]

Necessity, also known as the "lesser of two evils" defense, is typically raised as a defense against liability for tortious acts resulting in property damage, primarily by way of trespass or conversion.[24] Tort law distinguishes between two kinds of necessity: private necessity and public necessity. Under both private and public necessity, tortfeasors are privileged to trespass on land or chattel in possession of another if the tortfeasors reasonably believe such acts are necessary for protecting the person or property of themselves, another person, or the public.[25] Two significant differences mark the line between private and public necessity. First, whereas private necessity applies to tortious acts aimed at averting injuries to the tortfeasor or an identifiable, specific third person, public necessity encompasses acts that the tortfeasor undertakes to avert an imminent public disaster.[26] Second, whereas public necessity, like self-defense, provides a complete or near complete defense that shields the tortfeasor from any liability for any harm, private necessity results in an incomplete privilege only and requires compensation of the property owner for damages caused as a result of the tortfeasor's acts.[27]

Importantly, the privilege arising from both private necessity and public necessity is contingent upon proportionality. The tortfeasor's actions taken to protect the interests of herself, others, and the public must not be disproportionate to the harm caused by the tortfeasor in her efforts to avert the perceived imminent harm.[28]

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[23] For early American decisions, see Putnam v. Payne, 13 Johns. 312 (N.Y. Sup. Ct. 1816) (sanctioning the killing of a "ferocious and dangerous dog" permitted to run freely by its owner); Seavey v. Preble, 64 Me. 120, 123 (1874) (justifying the removal of wallpaper from the walls of rooms in which smallpox patients were confined).

[24] *See Necessity*, BLACK'S LAW DICTIONARY (11th ed. 2019); RESTATEMENT (SECOND) OF TORTS §§ 196, 197, 261–63 (AM. L. INST. 1965).

[25] *See* RESTATEMENT (SECOND) OF TORTS §§ 196–97 (AM. L. INST. 1965).

[26] *See id.*

[27] DAN B. DOBBS ET AL., THE LAW OF TORTS § 117 (2d ed. 2020); Vincent v. Lake Erie Transp. Co., 109 Minn. 456, 460 (1910) (holding that a tortfeasor who damages the property of another must compensate the property owner for the damage despite acting out of necessity to avoid imminent harm to his ship). *But compare* Wegner v. Milwaukee Mutual Ins. Co., 479 N.W.2d 38, 42 (Wis. 1991) (holding that the doctrine of public necessity still requires a public municipality to pay just compensation to the injured party), *with* Surocco v. Geary, 3 Cal. 69, 74 (1853) (holding the plaintiff cannot recover for value of goods in a house where tearing down or destroying the house was necessary in good faith for the purpose of saving adjacent buildings).

[28] *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 278 (AM. L. INST. 1965; DOBBS, ET AL., *supra* note 27, at § 117.

The attractiveness of the necessity defense as a ready-made way of balancing competing private and public interests in contexts of emergencies has also led scholars to explore its application in a variety of areas beyond tort law. Examples include the use of necessity in customary international law to alleviate pressures on sovereign debtors[29] and in pandemic-fueled contract disputes.[30] As we argue below, the necessity defense fits particularly well into IP law.

A. Bringing Tort Law Doctrines into IP

The contours and landscape of IP law evolve constantly. Although IP law has been increasingly expressed in statutes, it is not a strictly code-based body of law, and many aspects of IP rely heavily on common law reasoning from within and outside of IP law.[31] As such, judges deciding IP matters have allowed litigants to make arguments rooted in other areas of law, and courts have frequently "imported" doctrines from other bodies of law into IP law, with many such doctrines later becoming incorporated into IP statutes.[32]

Our current perception of IP rights—as a form of property—and of the nature of lawsuits to enforce such rights—as grounded in tort

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[29] *See, e.g.*, W. Mark C. Weidemaier & Mitu Gulati, *Necessity and the COVID-19 Pandemic*, CAP. MKTS. L.J., June 12, 2020, at 1–3.

[30] *See, e.g.*, Dwight Kealy, *Can You Cancel a Contract Due to Coronavirus (COVID-19)?*, CONCORD CONNECTOR (Mar. 31, 2020), https://www.concordlawschool.edu/blog/news/cancel-contract-coronavirus-covid-19/ [https://perma.cc/Q5CE-XXQS].

[31] *See, e.g.*, Edmund W. Kitch, *Intellectual Property and the Common Law*, 78 VA. L. REV. 293 (1992).

[32] The most famous example for an "importation" of a tort common law doctrine that did not exist the relevant statute and its implementation to an IP case is Sony Corp. v. Universal City Studios, 464 U.S. 417 (1984). The Supreme Court said: "The absence of . . . express language in the copyright statute does not preclude the imposition of liability for copyright infringement on certain parties who have not themselves engaged in the infringing activity." *Id.* at 435. And later, "[t]here is no precedent in the law of copyright for the imposition of vicarious liability on such a theory." *Id.* at 439. For cases in which courts deciding IP matters created new doctrines that have later become part of the common law of IP, see, for example, Hotchkiss v. Greenwood, 52 U.S. 248, 269–70 (1850) (creating what would later become the obviousness doctrine in patent law, which was also, ultimately, incorporated into the patent statute 102 years later); Whittemore v. Cutter, 29 F. Cas. 1120, 1121, (C.C.D. Mass. 1813) (No. 17,600) (effectively creating an experimental use defense in patent law, which has since been recognized and applied by courts deciding patent cases); Morton Salt Co. v. G. S. Suppiger Co., 314 U.S. 488, 493 (1942) (creating the equity-based doctrine of patent misuse), *abrogated by* Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006); Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390, 401–02 (1926) (establishing a new type of anticipation doctrine in patent law for inventions disclosed in earlier patent applications that are only published or issued after the anticipated invention; this doctrine would later be made part of the Patent Act of 1952); *see also*, *generally*, Jay Dratler, Jr., Palsgraf*, Principles of Tort Law, and the Persistent Need for Common-Law Judgment in IP Infringement Cases,* 3 AKRON INTELL. PROP. J. 23, 26 (2009) (explaining how courts "are [building a] rational jurisprudence of secondary liability for IP infringement upon the foundation of . . . two great common-law principles of tort law: proximate cause and culpability.").

law[33]—suggest that there are no major theoretical or doctrinal impediments to applying the necessity doctrine in IP matters.[34] Indeed, as argued by Professor Michael Carrier in his 2004 article, "Cabining Intellectual Property Through a Property Paradigm," necessity, along with other equitable and common-law defenses, already either plays or could play a significant role in limiting intellectual property rights under existing property law in the context of public health emergencies.[35] IP law's close connection to a property law framework creates an opportunity to draw from the necessity doctrine to address deficits in the existing IP ecosystem.

To be sure, IP law already includes a variety of well-established mechanisms for limiting the enforceability of IP rights.[36] However, the COVID-19 pandemic has provided us with at least one particularly stark example of how these existing mechanisms offer inadequate protections from liability in situations involving public health emergencies. We propose incorporating the necessity defense into IP law as an additional mechanism in the legal toolkit of protections from liability. The necessity defense would coexist with other mechanisms already embedded into national and international IP frameworks, such as march-in rights,[37] compulsory licensing,[38] and government patent use.[39] It would operate much like a safety valve, becoming available to multiple players during large-scale crises. The need for such a safety valve has become ever more salient in light of ongoing difficulties in deploying existing mechanisms designed to balance the exclusionary effects of IP rights during the current public health crisis.[40] Although we confine our

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[33] *See, e.g.*, Dratler, *supra* note 32, at 25 ("Infringement of intellectual property (IP) is just a kind of tort.").

[34] That the necessity defense has not had occasion to make its IP debut is, perhaps, unsurprising. As a relative "newcomer," IP law may not have had proper opportunity to encounter situations that could give rise to circumstances of necessity, which would have prompted the implementation of this old tort law doctrine in IP claims. For the readers less familiar with the relative newness of intellectual property laws when compared to other branches of the law (e.g., real property), see, for example, William W. Fisher III, *The Growth of Intellectual Property: A History of the Ownership of Ideas in the United States* (1999), https://cyber.harvard.edu/property99/history.html [https://perma.cc/27WV-QK7U].

[35] *See* Carrier, *supra* note 21, at 123–27; s*ee also* PEÑALVER & KATYAL, *supra* note 18, at 190–97 (advancing necessity as a possible mechanism for overcoming IP protections during public health emergencies); Sandrik, *supra* note 21, at 143 (proposing an incomplete privilege to infringe IP similar to the necessity defense).

[36] *See generally* Carrier, *supra* note 21.

[37] 35 U.S.C. § 203 (2019).

[38] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299; *see also* Kumar, *supra* note 4.

[39] 28 U.S.C. § 1498(a) (2019).

[40] *See, e.g.*, Ryan Whalen, *The Bayh–Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching in?*, 109 NW. U. L. REV. 1083, 1083 (2015) (noting that the U.S. government has never exercised march-in rights over federally funded inventions).

analysis here to a carefully tailored version of the necessity defense, focusing primarily on patent law, the necessity doctrine could also be easily applied in other areas of IP.

B. Applying Private Necessity and Public Necessity to IP Law

When thinking about the necessity defense in the context of the COVID-19 pandemic, one can envision several scenarios in which the doctrine may be helpful to further the goals of protecting individual and public health. Take the 3-D printing of respirator valves as an example. The engineers who 3-D scanned the valves, created the 3-D printing instructions file, and then used the file to print the replacement valves could potentially be subject to a whole range of patent infringement claims. Claims against the engineers could include infringement of any patent claims covering the valves themselves and the process of making them, inducement of infringement of any patent claims involving the use of the valves or respirators containing them, and contributory infringement by making the valve 3-D printing instructions widely available. The engineers might also be liable for copyright infringement involving the file containing the software instructions for printing the valves. In light of this smorgasbord of potential liabilities, it is unsurprising that the engineers were highly reluctant to share the printing instructions for the respirator valves with others who may have been facing the same problem as the local hospital. The uncertainty regarding the nature and scope of liability exacerbates the problem. Indeed, most people, let alone "Good Samaritans" like the Italian engineers, do not have the time or resources to seek a freedom-to-operate opinion that could clarify the legal landscape or to defend themselves against a potentially multifaceted IP infringement lawsuit.

Had the engineers known that they could rely on the necessity defense to protect themselves from liability, this would have reduced the perceived and actual risk of sharing the 3-D printing instructions with others. Since the engineers' actions were meant to address a public health emergency and help save the lives of non-specifically identified, critically ill patients in need of ventilators, the engineers would have been able to defend themselves by raising the public necessity defense. The necessity defense would have privileged their actions and shielded them from liability for any IP infringement damages that may have resulted from their actions. This is an example of what we view as a case of "public necessity." The necessity defense would serve to protect the infringers from liability for their infringement as it relates to activities done without expectation of payment to save nonspecific individuals from a life-threatening condition during a public health crisis.

However, the application of the defense becomes more complicated if the engineers were to assist specific, identified individuals or entities such as the local hospital in Northern Italy. In such a case, the necessity may be viewed as "private" because the infringement takes place to satisfy a specific private need and, moreover, may sometimes involve payment to the infringer. In the case of private necessity, although the infringer will be liable for damages, the infringing actions are privileged in the sense that they cannot be enjoined, and the necessity context will inform the determination of damage awards. By making the private necessity defense available, courts could send a strong signal that certain infringing actions are privileged under the law and that infringement of IP rights, even when intentional, does not always constitute wrongful conduct. It would also, presumably, have ramifications for the damages awarded in such cases, which may be relatively low on account of the privilege.[41]

In another example, chemists and compounding pharmacists may be able to fabricate a patented pharmaceutical which is in short supply but is necessary to treat patients suffering from COVID-19, such as the drug remdesivir. Such chemists and compounding pharmacists may be highly reluctant to help alleviate the dire need for such medicine if they know they may be liable for patent infringement. Knowing that they would have a defense against infringement claims would allow them to address the public health emergency of COVID-19 by reducing the drug shortage. In this example, the cost of compounding the drug may be significant, in contrast to the nominal cost of creating the 3-D printing instructions and the actual printing of the respirator valves from the previous example. In that case it may serve the public interest to allow the compounding pharmacists to receive reimbursement for their efforts by individuals and entities procuring the drug. While compensation for costs seems important, however, it is unclear what price, beyond the cost of manufacturing the drug, the compounding pharmacists should be able to charge if they wish to raise a necessity defense.

The answer to the dilemma of whether to allow for compensation for infringement may lie not in the question of whether the necessity defense should be made available (we think it should), but rather the type of necessity that the compounding pharmacists should be able to

[41] Consider, for example, the damages that might accrue if the actions of the engineers using 3-D printing to make valves were challenged. At $10,000 per valve, an award of actual damages to the valves' IP rightsholder could potentially deter the engineers from assisting the local hospital. However, should the IP rightsholder bring suit against the engineers, which it may be reluctant to do for various reasons not the least of which being public relations concerns, it is possible that a court deciding the matter of damages would only award the rightsholders reasonable damages under the circumstances. See below for further discussion of such a scenario.

assert—private or public. We believe that if the pharmacists merely recoup their manufacturing costs, then the public-service nature of their actions mandates that they should be able to raise a public necessity defense. Allowing the pharmacists to do so would render them not liable for any damages their actions may have caused.[42] On the other hand, if the pharmacists sold the compounded drug for more than its cost of production, the compounding pharmacists should still be allowed to raise a private necessity defense and benefit from the privilege itself. They would then need to pay some or all of their profits to the IP rightsholder as reasonable royalties under the circumstances.[43]

C. Balancing "Necessity" with Incentives for Innovation

The analysis of whether the necessity defense should be available to IP infringers, and in what form, becomes more complicated when it is not clear whether the public or private need is sufficiently dire to constitute an "emergency." It also becomes more complicated in situations in which it is unclear whether the possibility of harm to the individual or the public due to inaction is sufficiently imminent and whether the acts that might constitute infringement are indeed a "lesser evil." The need to preserve adequate incentives for innovation compounds the challenge of delineating the proper boundaries of the necessity defense.

The balancing that the necessity doctrine must embody a balancing of the need to respond to emergency needs and the need to protect long-term incentives to invest in the very technologies that become important in times of crisis. Maintaining the doctrine's focus on "necessity," carefully construed, offers the best way to preserve long-term incentives to innovate by limiting the protection it affords to infringers to situations of emergency. Yet determining what constitutes actual necessity—a task which will likely fall mainly to the courts—is likely to be the most challenging aspect of this defense. If "necessity" is defined too broadly, it will discourage the use of existing mechanisms for securing IP rights in situations where such transactions may be feasible and impact the value of IP rights for goods with potential lifesaving uses. If defined too narrowly, it will not provide adequate reassurance to those

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[42] *See infra* Part III.D.

[43] *See generally* Kenneth W. Simmons, *Self-Defense, Necessity, and the Duty to Compensate in Law and Morality*, 55 SAN DIEGO L. REV. 357 (2018) (discussing the compensation requirements in situations of self-defense); Lee, *supra* note 22, at 401 (arguing that in cases in which necessity is asserted and in which compensation is warranted, "the just amount of compensation may be partial compensation.").

who might otherwise engage in potentially infringing lifesaving activity.[44] And if defined in a way that leads to uncertainty, it will fail to protect incentives both for emergency use and for innovation.

The challenges of defining "necessity" in a way that gets the balance right may be clearly illustrated in the context of HIV/AIDS, for which treatments are available but inaccessible to many despite its recognition as an epidemic.[45] Suppose the compounding pharmacists discussed in an earlier example would now like to fabricate their own version of the treatment known as pre-exposure prophylaxis, or PrEP, for HIV/AIDS,[46] which they intend to hand out for free or at a minimal cost to individuals who are at high risk of contracting HIV but cannot otherwise afford PrEP. Would the AIDS epidemic qualify as sufficiently dire to be considered a public health emergency? Will the risk of contracting HIV and developing AIDS sans-PrEP be viewed by courts as sufficiently imminent to necessitate the infringement of PrEP patents?

One possible solution would be to condition the applicability of the necessity defense on a formal declaration of a public health crisis (or similar assessment) by agencies within the Department of Health and Human Services, such as the National Centers for Disease Control and Prevention (CDC) or the National Institutes of Health (NIH), or perhaps a global health-oriented institution like the World Health Organization.[47] Under such a scenario, the HIV/AIDS crisis in the United States, which as of late 2020 is regarded as an epidemic by the CDC and other public health-oriented agencies, would potentially qualify as one of the limited cases in which the necessity defense should become available in IP matters.[48]

However, even limiting the application of the necessity defense to recognized health emergencies leaves open questions about the application of the defense. Would the infringement of IP rights in PrEP be viewed by the courts as the "lesser evil," for example, when balancing the policy goal of maintaining incentives for innovation in the area of

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[44] *See* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972); Ian Ayres & J. M. Balkin, *Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond*, 106 YALE L.J. 703, 704 (1996); Louis Kaplow & Steven Shavell, *Property Rules Versus Liability Rules: An Economic Analysis*, 109 HARV. L. REV. 713 (1997).

[45] *See Fact Sheet: Today's HIV/AIDS Epidemic*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 2016), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf [https://perma.cc/KC9S-L7MC].

[46] *See PrEP*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/basics/prep.html [https://perma.cc/62G6-CFA9] (last visited June 27, 2021).

[47] Another similar solution proposed by Professor Michael Carrier is to use the standard of the Model State Emergency Health Powers Act as a threshold for determining what constitutes a public health emergency of sufficient severity to justify the use of necessity as a defense to IP infringement claims. *See* Carrier, *supra* note 21, at 125–27.

[48] *See Fact Sheet: Today's HIV/AIDS Epidemic*, *supra* note 45.

AIDS treatments with making such treatments available to individuals who cannot afford them? Difficult questions like these will pervade the IP cases in which the necessity defense is likely to be argued. The fact that applying the doctrine will require complex line drawing with competing interests in mind should not, however, discourage courts from allowing necessity arguments to be made in IP cases in the first place. Nor should it be taken as an indication that the necessity doctrine is unsuitable for IP law. It only means that the necessity doctrine warrants thoughtful application in this new legal territory, requiring careful consideration by judges on a case-by-case basis.

D. Who Pays for the Infringement?

A remaining critical issue that needs addressing for our proposed approach to work is how to allocate the cost of the privileged infringement. If the answer is not the IP rightsholder, then who should bear the cost of the infringement? This issue becomes particularly salient in cases of public necessity, in which IP rightsholders would remain without any remedy for damages they may have suffered due to the necessary infringement.

Here, we take a cue from Professor Stephen Sugarman, who has powerfully argued that in an ideal society rightsholders should not be troubled by their losses but rather "pleased that their property was able to be used to facilitate . . . a socially desirable outcome."[49] He thus advocates for a regime in which necessity gives rise to weakened, "commonly owned" property rights, especially where the infringer cannot afford to pay.[50] This is not, admittedly, how most IP rightsholders—especially biomedical product manufacturers—are likely to view situations of necessity.[51] Supply limitations are considered integral to the "IP bargain." It is at best doubtful that the IP rightsholders will embrace the view that they ought to be pleased that their property rights were set aside without their approval or authorization to facilitate a socially desirable outcome.[52]

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[49] *See* Stephen D. Sugarman, *The Necessity Defense and the Failure of Tort Theory: The Case Against Strict Liability for Damages Caused While Exercising Self-Help in an Emergency*, 5 ISSUES IN LEGAL SCHOLARSHIP, no. 2, 2005, at 2.

[50] *Id.* at 4. Notably, Professor Sugarman's argument was made mostly in the context of private necessity and in critique of the legal duty to compensate the rightsholder. Some of Professor Sugarman's arguments, however, are applicable to the context of public necessity, where the duty to compensate does not exist in most cases.

[51] *See, e.g.*, JULES COLEMAN, RISKS AND WRONGS 292–96 (1992) (describing a particularly relevant example where one diabetic—Hal—is, in his opinion, under a duty to compensate another insulin user—Carla—for some insulin that Hal took from Carla in order to save his life).

[52] Indeed, pharmaceutical companies have expressed significant reluctance to make their IP available more widely even during the height of the COVID-19 pandemic. *See, e.g.*, Brenda Sandburg, *Should Pharma Release IP for COVID-19 Research? Novartis Exec Weighs In*, PINK SHEET

The IP system rewards invention with private property rights. Thus, many will feel that it would be unfair for rightsholders whose IP was effectively appropriated by infringers and courts—under the judicial finding of necessity—to be the sole bearers of the cost of such appropriation. In situations of public necessity, where the infringement confers a broad public benefit, it may feel particularly unfair to impose the costs on the rightsholder. Furthermore, as discussed earlier, leaving IP rightsholders without remedy might be at odds with IP law's underlying premise—indeed, raison d'être—of incentivizing innovation and creative activities.[53]

We further recognize that our proposal has implications from an innovation policy perspective, as any mechanism that weakens the IP status quo may have chilling effects for research and development in the affected fields. But these effects are likely to be limited given that the application of the necessity defense we proposed is highly limited in breadth and scope. Our proposal seeks to respond to situations of extreme public health need in which the goals of one branch of the law (intellectual property) temporarily retreat to help achieve the goals of another area of law and policy (public health) under circumstances of abnormally heightened challenges. In considering such a tradeoff, it is essential to remember that IP is merely a means to an end—an instrument created by society to achieve desirable goals. As such, IP protections ought to recede where a specific, immediate, and undeniable public benefit requires it. Arguably, the balance we are articulating and accentuating through the necessity defense is inherent in the original design of the IP system and serves its original objectives.

Moreover, the unfairness to rightsholders will be less troubling where the damages from an infringement are likely to be low. In most cases where the necessity defense is likely to succeed, damages to IP rightsholders are unlikely to be substantial. In the case of the 3-D printed ventilator parts or compounding pharmacists making a drug in severe shortage, for example, the defense serves to meet urgent needs in situations of market failure in which no clear profit opportunities are lost. The defense, thus, solves a capacity problem and facilitates satisfying urgent public needs at a price that makes them unattractive to IP

(May 18, 2020), https://pink.pharmaintelligence.informa.com/PS142186/Should-Pharma-Release-IP-For-COVID-19-Research-Novartis-Exec-Weighs-In [https://perma.cc/WTZ3-27LC].

[53] It would be difficult if not impossible to weigh the respective long-term benefits of IP law and the short-term benefits of setting aside of IP rights to meet a public necessity. Where one prevails, the other might suffer. *But see* Carrier, *supra* note 21, at 126 (arguing that the potential adverse effects of application of the necessity defense to IP during public health emergencies might be less severe than expected); PEÑALVER & KATYAL, *supra* note 18, at 194–96 (arguing that "it is far from obvious what the magnitude of the impact of any given increase or decrease in intellectual property protection will be" subsequent to application of the necessity defense, especially given the unpredictable nature of public health emergencies).

holders or their licensees. Specifically, under U.S. patent law, if the defense sidesteps a capacity problem, and solving the problem does not impact sales, then there are no lost profits to recover and arguably little by way of reasonable royalties.[54] Thus, if the defense is used to facilitate treatments for people who could otherwise not afford such treatments, IP rightsholders may not be able to establish that they have lost revenue due to the excused infringement.[55]

In some cases, however, the damages to IP rightsholders due to the necessity-privileged infringements may be significant. In the extreme case in which the privileged infringement severely undermines the economic sphere of the IP right, we propose that the IP rightsholder be able to seek compensation under the Tucker Act.[56] In such cases, IP rightsholders should be able to sue the government by filing a lawsuit against the U.S. government in the Court of Federal Claims for what effectively amounts to a government taking of the rightsholder's IP right—by judicial action—under the Fifth Amendment to the U.S. Constitution.

In those more likely cases where IP rightsholders suffer provable, non-minimal damages due to the exercise of the defense and in which the infringement does not result in a destruction of the IP in its entirety, we agree with Sugarman that insurance may provide adequate relief. As Sugarman notes, "[s]omeone who owns property of value knows (or surely should know) about insurance, and . . . the prudent thing is to buy insurance to protect losses beyond what . . . is a modest and readily absorbable loss."[57] Reliance on insurance in such cases is likely to increase insurance rates for rightsholders as a group. The financial impact of such increase, which would presumably be extremely small,[58] may then be further mitigated by passing its cost along to and spreading it among consumers, thereby rolling it on to the public, which benefitted from the privileged infringement in the first place.

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[54] *See* Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978) ("To obtain as damages the profits on sales he would have made absent the infringement, i.e., the sales made by the infringer, a patent owner must prove," among other factors, "his manufacturing and marketing capability to exploit the demand.").

[55] *See id.* ("To obtain as damages the profits on sales he would have made absent the infringement, i.e., the sales made by the infringer, a patent owner must prove . . . demand for the patented product.").

[56] 28 U.S.C. §§ 1346, 1491 (2019). The Tucker Act waives the United States' sovereign immunity to certain kinds of claims, including in cases of takings claims under the Fifth Amendment.

[57] Sugarman, *supra* note 49, at 110 (arguing that an innocent self-help reasonable rescuer should be placed in the same category as a natural peril, like a storm (or a pandemic)). The insurance solution may also prove useful in private-necessity situations, where the infringer is a business entity. Under such circumstances, the infringer's insurance coverage may serve to alleviate the financial burden of its duty to compensate the rightsholder for the privileged infringement.

[58] *See* Sugarman, *supra* note 49, at 111.

IV. CONCLUSION

In this Article, we have made a case for incorporating the necessity doctrine into IP law. The case is particularly compelling in the area of patent law, where certain types of health-related goods are often covered by multiple layers of IP rights. We have explained how necessity claims may allow defendants to avoid liability in circumstances where infringement of IP rights is necessary to prevent adverse public health outcomes. Our proposal honors a tradition of cross-pollination among legal fields in the pursuit of improved mechanisms for balancing IP rights and access to lifesaving goods.

Adopting the necessity doctrine in IP law can play an essential role in increasing preparedness ahead of future outbreaks of infectious diseases and in other public health emergencies. We conclude that the time is ripe for the necessity defense to take its place as an old-new tool for resolving IP disputes. Doing so would be ethically sound and would help resolve some of the many public health critiques that have been leveled at IP law by attenuating ingrained misalignments between IP frameworks and the furtherance of public health goals.