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Copying Copyright: Adopting a Fair Use Defense in Patent Law in Times of Public Health Crisis

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Copying Copyright

ADOPTING A FAIR USE DEFENSE IN PATENT LAW IN TIMES OF PUBLIC HEALTH CRISIS

INTRODUCTION

Epidemics have devastated humankind for centuries, far before the Declaration of Independence was even signed.[1] In fact, when the Declaration of Independence was signed in 1776, Boston was in the midst of the final years of a century-long string of smallpox epidemics.[2] By 1800, a vaccine surfaced in England when Dr. Edward Jenner successfully used the cowpox virus to ameliorate the spread of smallpox.[3] Dr. Jenner's findings arguably "laid the foundation for modern vaccinology."[4] It took nearly another century, however, for vaccines to take hold as accepted public health mechanisms,[5] and smallpox was not declared eradicated for almost two hundred years after the vaccine's introduction.[6]

This switch from individualized inoculations to widespread vaccinations had, and continues to have, a profound effect on public health.[7] This is not only because vaccines prevent deadly diseases in an individual, but because vaccines also

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[1] *See generally* J.N. HAYS, EPIDEMICS AND PANDEMICS: THEIR IMPACTS ON HUMAN HISTORY (2005) (describing historical epidemics, both domestic and international).

[2] Jonathan E. Henry, *Experience in Massachusetts and a Few Other Places with Small-Pox and Vaccination*, 185 BOS. MED. & SURGICAL J. 221, 221 (1921).

[3] Alexandra Minna Stern & Howard Markel, *The History of Vaccines and Immunization: Familiar Patterns, New Challenges*, 24 HEALTH AFF. 611, 612 (2005).

[4] *Id.*

[5] *Id.* at 613.

[6] *See* U.S. Ctrs. for Disease Control and Prevention, *Smallpox*, CDC: NAT'L CTR. FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES, DIVISION OF HIGH-CONSEQUENCE PATHOGENS AND PATHOLOGY (July 12, 2017), https://www.cdc.gov/smallpox/index.html#:~:text=In%201980%2C%20the%20World%20Health,occurring%20smallpox%20have%20happened%20since [https://perma.cc/U2RJ-HUWJ].

[7] *See generally* Brian Greenwood, *The Contribution of Vaccination to Global Health: Past, Present and Future*, 369 PHIL. TRANSACTIONS OF THE ROYAL SOC'Y B 1 (2014) (discussing the impact of vaccinations on global health, including the eradication of multiple infectious diseases).

establish herd immunity,[8] protecting the public as a whole.[9] Vaccines have become a cornerstone of modern medicine, preventing countless cases of disease.[10]

Given the simultaneous rise of advanced disease prevention and treatment[11] and the great potential for mass public uptake, it is unsurprising that the U.S. pharmaceutical industry has grown to an estimated $775 billion in annual sales revenue.[12] It is clear that the commercialization of the manufacturing and distribution of important public health measures, including vaccines and disease treatments, is not without controversy. Of particular debate, despite the vital importance of disease prevention and treatment, is that vaccine and other drug manufacturers monopolize their products and control them through intellectual property and patent laws.[13]

This temporary monopoly has its justifications. For patent holders, "[p]atent rights protect inventions that are costly to create and equally expensive to protect once they are released to the world."[14] As such, patent rights are seen as "broad categorical prohibitions that outlaw any use or replication of the patented invention."[15] The value of patents[16]—specifically, in the protection of innovation—is clear in the eye of an inventor.[17] This value stems from the overarching objectives of patent law, as the law

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[8] Herd immunity, or "community immunity," is defined as the reduction in the spread of disease within a population due to the immunity of a large number of people. U.S. Ctrs. for Disease Control and Prevention, *Glossary: Community Immunity*, CDC: VACCINES & IMMUNIZATIONS (July 30, 2020), https://www.cdc.gov/vaccines/terms/glossary.html#community immunity [https://perma.cc/TZ2E-2A3K].

[9] *See* Stern & Markel, *supra* note 3, at 617.

[10] *See* Fangjun Zhou et al., *Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009*, 133 PEDIATRICS 577, 581 (2014) (finding that vaccines prevented millions of disease cases in just one birth cohort among thirteen diseases).

[11] Outside of vaccines, which are preventative, some examples of pharmaceutical disease treatments include antibiotics, antivirals, and other prescription medications that aim to target a specific disease.

[12] This estimate reflects 2015 data. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS (2017), at 1, https://www.gao.gov/assets/690/688472.pdf [https://perma.cc/77SJ-2S95].

[13] COMMITTEE ON THE CHILDREN'S VACCINE INITIATIVE, PLANNING ALTERNATIVE STRATEGIES, INST. OF MED., ACHIEVING THE VISION 103 (Violaine S. Mitchell et al. eds., 1993), https://www.ncbi.nlm.nih.gov/books/NBK236421/ [https://perma.cc/7ZNT-2JAZ] [hereinafter COMMITTEE ON THE CHILDREN'S VACCINE INITIATIVE].

[14] Gideon Parchomovsky & Alex Stein, *Intellectual Property Defenses*, 113 COLUM. L. REV. 1483, 1498 (2013).

[15] *Id.*

[16] Throughout this note, "patent" refers to utility patents, which comprise "[a]pproximately 90 percent of issued patents." CRAIG ALLEN NARD, THE LAW OF PATENTS 40 (4th ed. 2017) (describing the three different categories of patents, including utility, design, and plant patents).

[17] *See* Stephanie Plamondon Bair, *The Psychology of Patent Protection*, 48 CONN. L. REV. 297, 299 (2015) (explaining the various reasons that inventors seek patent protection, such as "financial encouragement . . . to invent" or as a "reward for . . . contribut[ing] to society").

> seeks to foster and reward invention . . . it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires . . . [it] seek[s] to assure that ideas in the public domain remain there for the free use of the public.[18]

These objectives are rooted in the basic right to exclude that is afforded by patent law. In the United States, patent law grants inventors the right to exclude others from particular uses of the invention[19] for a term of twenty years.[20] In other words, for twenty years, an inventor generally has exclusive authority to dictate who can replicate and manufacture the patented invention.[21] This lengthy term becomes problematic in connection with epidemics,[22] which are by their nature time-sensitive to address.[23] This is not to say that patents do not have a place in the realm of public health,[24] but patents have the potential to bar necessary access to life-saving innovations, such as access to affordable disease treatments.[25]

To illustrate the problem, consider hepatitis C as an example. A single twelve-week regimen of Sofosbuvir,[26] a drug that has an over 90 percent cure rate for hepatitis C, costs insurance companies $84,000.[27] In response, insurance

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[18] Lorelei Ritchie de Larena, *What Copyright Teaches Patent Law About "Fair Use" and Why Universities Are Ignoring the Lesson*, 84 OR. L. REV. 779, 781 (2006) (quoting Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979)).

[19] 35 U.S.C. § 154(a)(1) (patentees have "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States").

[20] 35 U.S.C. § 154(a)(2) (this section of the statute applies only to utility and plant patents; the term for design patents is governed by a different section). It is also worth noting that patents for drugs and "medical device[s], food additive[s], or color additive[s] subject to regulation under the Federal Food, Drug, and Cosmetic Act" may be extended beyond the twenty-year exclusionary term to account for precommercialization regulatory review (such as U.S. Food and Drug Administration (FDA) review). *See* 35 U.S.C § 156.

[21] Neel U. Sukhatme, *Regulatory Monopoly and Differential Pricing in the Market for Patents*, 71 WASH. & LEE L. REV. 1855, 1857 (2014).

[22] An epidemic is "an increase, often sudden, in the number of cases of a disease above what is normally expected in that population area." *Lesson 1: Introduction to Epidemiology*, U.S. CTRS. FOR DISEASE CONTROL AND PREVENTION (May 18, 2012), https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html#:~:text=Epidemic%20refers%20to%20an%20increase,a%20more%20limited%20geographic%20area [https://perma.cc/2L8F-YG2V].

[23] *See* Tasha Stehling-Ariza et al., *Establishment of CDC Global Rapid Response Team to Ensure Global Health Security*, 23 EMERGING INFECTIOUS DISEASES S203, S203 (2017).

[24] After all, "[p]atents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals." Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFF. 302, 302 (2015). This essentially means that without patents, there would be no innovation, and without innovation there is no progress. *See id.* (describing the "essential role[] [of patents] in encouraging innovation in biopharmaceuticals").

[25] Lauren S. Luna, *Patently Limited: The Conflict Between Public Health and Patent Rights*, 53 U.S.F. L. REV. 343, 345–50 (2019).

[26] Sofosbuvir, while not the only treatment for hepatitis C, is the most effective treatment that is also easier for patients to tolerate. Brandy Henry, *Drug Pricing & Challenges to Hepatitis C Treatment Access*, 14 J. HEALTH BIOMED. L. 265, 266 (2018).

[27] Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFF. 791, 792 (2016).

companies may choose not cover the drug at all, or severely limit approvals of coverage until a patient has marked indicators of advanced disease.[28] Unsurprisingly, only a small portion—2.4 percent—of Medicaid patients diagnosed with hepatitis C were found to be receiving treatment.[29] And the $84,000 price tag has nothing to do with the typical recoupment costs associated with researching or manufacturing the drug. The astronomical costs are purely a result of the pharmaceutical company's patenting of the drug, which gives them the power to set unrestrained prices for the patented product.[30]

These issues within patent law and public health are both common and apparent, and are aggravated when a new public health crisis emerges. Manufacturers' ability to legally monopolize, without a clear solution to the access problems that patents create during public health crises, will continue to wreak havoc on individuals who fall victim to epidemics. Imagine living in the middle of a novel epidemic and a life-saving treatment exists, but is priced at $84,000 per regimen.[31] If the epidemic is widespread, insurance companies would likely avoid covering the treatment altogether.[32] On principal alone, this is not only unconscionable, but completely unethical when so many lives are at stake. So, what is to be done when patent owners possess these justified—but seemingly all-powerful—rights to exclude, yet the public has a serious need for their patented invention?

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[28] *See* Henry, *supra* note 26, at 266–67 (describing the various restrictions placed on coverage of hepatitis C treatment, including the requirement from some insurance companies that a patient have "documented fibrotic changes in the liver").

[29] *See* Kapczynski & Kesselheim, *supra* note 27, at 792.

[30] *Id.* Patent law's right to exclude essentially gives that patentee the sole power in determining who can manufacture and distribute the drug and at what price, regardless of the obvious societal need. *See* Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 284 (2016) (recognizing the "drug-pricing trap" that affords patentees exclusionary powers in the market).

[31] While obviously grossly exaggerated, it is worth noting that even a much lower price of healthcare is painstakingly unaffordable for some populations. Timothy Jost, *Affordability: The Most Urgent Health Reform Issue for Ordinary Americans*, HEALTH AFF. BLOG (Feb. 29, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160229.053330/full/ [https://perma.cc/7E6U-QG6E] (describing the access issue of low-income populations and the fact that "[m]any do not have enough [net income] to even pay for the deductible of their [insurance] coverage, much less the out-of-pocket limit").

[32] Unfortunately, this was the reality during the COVID-19 pandemic when, over a year in, a large portion of insurers stopped "waiving out-of-pocket costs for COVID-19 treatment." Jared Ortaliza et al., *Most Private Insurers are No Longer Waiving Cost-Sharing for COVID-19 Treatment*, HEALTH SYS. TRACKER (Aug. 19, 2021), https://www.healthsystemtracker.org/brief/most-private-insurers-are-no-longer-waiving-cost-sharing-for-covid-19-treatment/ [https://perma.cc/PSQ4-T3G7]. And in the case of the hepatitis C example, if the total population of those living with hepatitis C (3.7 million people) were to be treated, the cost would result in healthcare spending of $310 billion in just one year. *See* Henry, *supra* note 26, at 266–67.

It should be noted that, although exclusivity seems to be an unassailable characteristic of patent law, this monopoly is not without existing defenses.[33] Yet, the application of these defenses is problematic in the public health sphere. For example, courts will sometimes deny a patent holder's request for an injunction based on public health necessity,[34] however, this practice is based on equitable considerations and, therefore, the standard is quite variable.[35] Moreover, scholars have highlighted the issue with patents and public access, noting that "[o]ne of the biggest challenges currently facing the U.S. patent system as it relates to the biotechnology and pharmaceutical industries is that of balancing the diverse interests of research tool patentees, drug discovery researchers, and the general public."[36] While some scholars propose working within current patent law to solve the problem of adequate public access, such as by allowing the government to exercise control over certain patents,[37] these solutions do not mold well to public health crises. Thus, it is necessary to look outside of patent law for assistance in crafting a proper solution.

Meanwhile, copyright law offers a unique solution to the problems faced in patent defenses. In contrast to patent law, copyright law contains both statutory and common law infringement defenses that permit infringements for the public benefit.[38] More specifically, copyright law's fair use doctrine is a statutorily grounded affirmative defense that permits the use of copyrighted material even if the use constitutes an infringement in certain instances.[39] The application of the fair use doctrine is largely subjective, commonly "based on social values and societal perspectives."[40] This subjective nature requires a case-by-case inquiry, which renders the use of the defense largely fact-specific.[41] Copyright fair use is an attractive starting point for public health applications of patent law, and while its precise factors are not

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[33] *See* Maureen A. O'Rourke, *Toward A Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1196–99 (2000).

[34] *See* COMMITTEE ON THE CHILDREN'S VACCINE INITIATIVE, *supra* note 13, at 105.

[35] *Id.*

[36] Brendan M. O'Malley, Merck v. Integra *and Its Aftermath: A Safe Harbor for the Commercial Use of Biotechnology Research Tools?*, 23 CARDOZO ARTS & ENT. L.J. 739, 739 (2006).

[37] *See* Kapczynski & Kesselheim, *supra* note 27, at 793. (arguing that the federal government has the power under 28 U.S.C. Section 1498 to infringe on patents "as long as it provides 'reasonable and entire compensation' to the patent holder"); *see infra* Sections I.B.1–2.

[38] *See* O'Rourke, *supra* note 33, at 1192.

[39] *See* Parchomovsky & Stein, *supra* note 14, at 1495; O'Rourke, *supra* note 33, at 1180.

[40] Ned Snow, *Who Decides Fair Use-Judge or Jury?*, 94 WASH. L. REV. 275, 316 (2019).

[41] *Id.* at 279.

particularly relevant to patent law and public health, its objectives can lend a helping hand in crafting an appropriate solution. Patent fair use, as applied in this note, would effectively act as a compulsory licensing scheme that is justified by patent law's own version of copyright's public benefit objective.[42] This scheme would allow a case-by-case, judicially-controlled defense that is available only during public health crises, with reasonable compensation reserved for the patent owner.

The rationale behind adopting a fair use defense for patent law is robust. First, one major justification for adopting fair use in patent law draws on the similarity in objectives between copyright and patent law.[43] While both categories of intellectual property law afford the right to exclude, there are numerous examples of infringing uses that may be considered necessary to achieve the objectives of copyright law.[44] This is a principle that patent law can benefit from, especially in light of the argument that the public has a competing interest in obtaining access to innovations and that the patentee, in commercializing such innovations, may not take into account the public interest.[45] Second, applying fair use-like objectives to patent law may prevent patentees from engaging in harmful commercialization practices.[46] However, to preserve the patentee's aforementioned interests to the fullest extent practicable, fair use within patent law should be limited.

This note argues for the imposition of a statutory fair use defense for patented public health measures during times of public health crisis. In the age of pandemics and other major public health issues, the public interest has become a more important factor for judges to consider in the context of patent infringement.[47] Congress should adopt a statute, incorporating lessons from copyright fair use, that would allow—albeit in a

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[42] A compulsory license is defined as a license "that allows certain people to pay a royalty and use an invention without the patentee's permission." *Compulsory License*, BLACK'S LAW DICTIONARY (10th ed. 2014).

[43] Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA: THE J. OF L. & TECH. 243, 261 (1990) (arguing that "de minimis infringement is in fact *necessary* to maintain part of our constitutional directive to protect intellectual property" (emphasis added)).

[44] *See id.* at 259–61 (1990); *see also More Information on Fair Use*, U.S. COPYRIGHT OFF., https://www.copyright.gov/fair-use/more-info.html#:~:text=Section%20107%20of%20the%20Copyright,may%20qualify%20as%20fair%20use. [https://perma.cc/V5PJ-HK47] (noting "criticism, comment, news reporting, teaching, scholarship, and research" as potential fair uses of copyrighted work).

[45] *See* Ritchie de Larena, *supra* note 18, at 786 ("We cannot assume that a patentee will act in the public interest by commercializing a patented invention if it is not in the patentee's direct, short-term economic interest to do so.").

[46] *See id.*

[47] *See infra* Sections I.B.3, III.B.

more limited application—the fair use defense under patent law. Specifically, to preserve the patent system, the statute should include a burden of production on the infringer to show a public health crisis, such as epidemic levels of disease, and an attempt to license. Although this note argues primarily for objective components of fair use to be instated in patent law, it also argues for the consideration of relevant policy concerns, notably, the justification and public health value of an infringement. A statutory fair use defense would have lasting impacts on public health, paving a pathway for necessary and timely distribution of patented public health measures.[48]

Part I of this note explores existing patent remedies, defenses for alleged infringers, and why those defenses fail in the context of a public health crisis. Specifically, this section will describe the current defenses of march-in rights, 28 U.S.C. § 1498(a), and the injunctive relief public interest factor. Part II illustrates past public health crises, including the HIV/AIDS pandemic and the COVID-19 pandemic as case studies to highlight the problems within patent law and public health and the need to move toward fair use. Part III details the parallelism between copyright and patent law and lays the groundwork for using lessons learned in copyright fair use as a model for patent law. This Part also explains the necessary background of copyright fair use and analyzes how courts that consider injunctive relief in patent infringement cases already implement a fair use-like analysis. Part IV proposes the application of a fair use doctrine, coupled with reasonable compensation, to patent law under the circumstances of a public health crisis. This Part argues for legislative action to establish a fair use defense in patent law under specific circumstances relating to public health crises and proposes statutory factors to limit the doctrine's scope. It analyzes the broader implications on inventors and the incentive to invent. This note concludes with a discussion of the potential impact of the proposed solution on public health and future public health crises, while preserving the value and integrity of the patent system.

I. BACKGROUND

To fully capture the problem with patent law in public health contexts, it is important to begin with a discussion of the existing remedies for patent holders and the available defenses to patent infringers. While the right to exclude and protect one's work

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[48] *See* Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265, 302–04 (2011).

is immensely important, no law is without its defenses, and alleged infringers do have a limited number of defenses in their arsenal to invoke in response to a patent infringement suit.[49] Nevertheless, this Part shows why those defenses fail for public health crises.

A. Patent Law Remedies

Some infringement defenses in patent law stem from the remedies a patent holder can seek during litigation. Federal law grants patentees civil remedies for patent infringement via damages or equitable relief.[50] The patentee may seek monetary damages by proving either "lost profits, or if lost profits cannot be proved, by using a *reasonable royalty* method."[51] Separately, and of particular relevance to this note, patentees may also seek equitable relief[52] in the form of preliminary or permanent injunctions.[53] To succeed in obtaining a preliminary injunction,[54] courts consider: "(1) a likelihood of success on the merits, (2) an irreparable injury, (3) that the balance of hardships falls in [the patentee's] favor, and (4) that the public interest counsels in favor of a preliminary injunction."[55] Similarly, for a patentee to succeed in obtaining permanent injunctive relief for patent infringement,[56] the Supreme Court in *eBay v. MercExchange*[57] set forth a four-factor test for courts to consider:

> (1) that [the patentee] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of

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[49] *See generally* Parchomovsky & Stein, *supra* note 14 (describing the various defenses available in intellectual property law).

[50] 35 U.S.C. §§ 283–284.

[51] *See* NARD, *supra* note 16, at 889 (emphasis in original).

[52] 35 U.S.C. § 284.

[53] *See* NARD, *supra* note 16, at 943.

[54] A preliminary injunction is sought "before a final ruling on the defendant's infringement liability." *Id.*

[55] Jacob S. Sherkow, *Preliminary Injunctions Post*-Mayo *and* Myriad, 67 STAN. L. REV. ONLINE 1, 3 (2014) (citing Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)).

[56] A permanent injunction "is sought after a final ruling on the defendant's infringement liability." *See* NARD, *supra* note 16, at 943.

[57] For background, in *eBay*, the respondent held several patents relating to business methods "designed to facilitate the sale of goods between private individuals." eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 390 (2006). Respondent sued eBay for patent infringement based on eBay's website that enables sales among private individuals and sought both damages and a permanent injunction. *Id.* at 390–91. The court of appeals reversed the district court's denial of a permanent injunction, based on the "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." *Id.* at 391. The Supreme Court vacated the court of appeals ruling, finding "[j]ust as the District Court erred in its categorical denial of injunctive relief, the Court of Appeals erred in its categorical grant of such relief." *Id.* at 394. The Supreme Court instead held that an injunctive relief requires an equitable analysis of the four factors that the analysis is within the district court's discretion. *Id.*

> hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[58]

The Supreme Court has held that the burden of proof for an infringement lies with the patentee, even when the alleged patent infringer was the party that filed an action.[59] Because courts have moved away from the default of automatically granting a patentee's request for injunction, the increased burden of proof on the patent holder gives infringers an attractive avenue of defense.[60]

B. Existing Patent Infringement Defenses

As opposed to remedies, which are available to the patentee, the alleged patent infringer also has existing tools of defense against a claim of patent infringement.[61] There are various ways to defend an infringement, such as by challenging the validity of the patent or claiming experimental use.[62] However, in the context of a public health crisis, there are only a limited number of relevant defenses available, specifically "march-in rights" and the public interest factor of injunctive relief, as explained below.[63]

1. March-In Rights

One of the more relevant defenses for patent infringement in the public health context, known as march-in rights, comes from the Bayh-Dole Act.[64] Granted by federal law, march-in rights allow federal agencies that provide funding for inventions to assume control over the invention in certain

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[58] *Id.* at 391.

[59] Medtronic, Inc. v. Mirowski Family Ventures, L.L.C., 571 U.S. 191, 193–94 (2014).

[60] Camille Sizemore Halterman, *Patent Rights v. Public Access: Interpreting the Public Interest Factor in Pharmaceutical Patent Infringement Cases*, 42 S. ILL. U.L.J. 499, 505 (2018) ("Based on *eBay*, a court's decision about injunctions is no longer based on a 'categorical rule,' but rather 'an act of equitable discretion' based on the four factor-test.").

[61] *See* NARD, *supra* note 16, at 671.

[62] *Id.* An alleged patent infringer can potentially file an offensive declaratory judgement lawsuit to challenge the validity of the patent, which can be an advantageous litigation maneuver, particularly when it comes to choice of venue. *Id.* at 766.

[63] Another patent infringement defense exists in the health context where, by statute, a "medical practitioner" that uses a patented "medical activity" is protected from patent infringement liability. 35 U.S.C. § 287(c)(1). However, this note does not explore this defense, as it relates to individual provider practice, rather than public health as a whole.

[64] 35 U.S.C. § 203; Carolyn L. Treasure et al., *Do March-In Rights Ensure Access to Medical Products Arising from Federally Funded Research? A Qualitative Study*, 93 MILBANK Q. 761, 763 (2015).

circumstances.[65] March-in rights also allow "private enterprises" to petition federal agencies to exercise their march-in rights.[66] The invocation of these rights essentially nullifies an exclusive license and grants the government "authority to relicense" the invention.[67] For example, imagine a university develops and patents a treatment for HIV, partially funded by the National Institutes of Health (NIH), and subsequently grants an exclusive license for that treatment to pharmaceutical company A, who does not take steps towards commercialization.[68] If pharmaceutical company B petitions the NIH to invoke march-in rights, and the NIH subsequently approves, then the NIH would assume a license for the treatment, pharmaceutical company A's exclusive license would end, and the NIH could relicense the treatment to other companies, such as pharmaceutical company B.[69]

However, as clearly stated, march-in rights only apply to the government's right to march-in on publicly funded inventions, leaving out purely privately-funded inventions.[70] And, the government has never actually exercised its authority to march-in.[71] Even if it were to do so, one study found that among a sample of new drugs approved by the Food and Drug Administration, only 9 percent were eligible for the government to exercise its march-in rights, based on receipt of federal funding or government

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[65] 35 U.S.C § 203(a). Under 35 U.S.C. § 203, a federal agency can require a patent assignee or exclusive licensee to grant the federal agency a license. *Id.* When a patent assignee or exclusive licensee refuses the federal agency's initial request for a license under Section 203, the federal agency can then grant the license to itself if it is found that:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

Id.

[66] JOHN R. THOMAS, CONG. RES. SERV., MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (2016).

[67] *See* Treasure et al., *supra* note 64, at 763; *see also* § 203(a) (enumerating the circumstances under which a federal agency can invoke march-in rights).

[68] This hypothetical scenario is adapted from a real-world example of march-in rights. *See* Treasure et al., *supra* note 64, at 771–73.

[69] *See id.* at 768–69.

[70] *See id.* at 768.

[71] Jordan Paradise, *COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision*, J. OF L. & THE BIOSCI. 1, 6 (2020).

assignment of the patent.[72] While the sample used was significantly smaller than the totality of the pharmaceutical industry,[73] it begins to paint the picture of why march-in rights are not enough to address necessary infringements.

The legislative history of the Bayh-Dole Act indicates why Congress limited march-in rights to only the government, intentionally leaving out the private sector.[74] Because federal funds were used for the research and development of the invention, members of Congress believed that the invention should "remain available to the public and should not create an exclusive right or interest in any person."[75] To require taxpayers to fund research and development and then subsequently "be forced to subsidize a private monopoly and have to pay twice" is inherently unfair.[76] Yet, at the same time, the legislative history reveals that Congress intended to allow private companies to retain exclusivity rights because they should be able to reap what they sow.[77]

Despite Congress's intent to leave untouched the exclusivity rights for purely private inventors, this leaves an opportunity for a glaring monopoly within the private sector, since march-in rights only apply to innovations developed with government funding.[78] Especially in the context of a public health crisis, the monopoly within the private sector essentially leaves the lives of the general population in the hands of a very small number of private companies.

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[72] Bhaven N. Sampat & Frank R. Lichtenberg, *What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?*, 30 HEALTH AFF. 332, 333–35 (2011) ("[*P*]*ublic-sector patents* [are defined as] all of those that were assigned to a government agency (which generally resulted from research conducted inside that agency) and all of those with government interest statements (most of which came from academic laboratories that had received government funding, generally through extramural research grants.)").

[73] *See id.* at 334 (noting the limitations of the sample to new drugs and those with patent data in the Food and Drug Administration's Orange Book).

[74] *See Patent and Trademark Law Amendments of 1980: Hearing on H.R. 6933 Before a Subcomm. Of the H. Comm. on Gov't Operations*, 96th Cong. (1980) [hereinafter *Patent and Trademark Hearing*].

[75] *Id.* at 136–37 (letter from Morris K. Udall, Chairman, House Committee on Interior and Insular Affairs, to Jack Brooks, Chairman, House Committee on Government Operations).

[76] *Id.* at 134–35 (letter from Ralph Nader, to Jack Brooks, Chairman, House Committee on Government Operations).

[77] *Id.*; *see also id.* at 143 (letter from Philip M. Klutznick, Secretary of Commerce, to Jack Brooks, Chairman, House Committee on Government Operations) ("[A] private company will not make the necessary investment without some assurance that, if successful, it will be able to earn a fair return.").

[78] *See generally Patent and Trademark Hearing*, *supra* note 74 (presenting testimony that speaks to why the private sector was left out of the Bayh-Dole Act, indicating a trend of "you reap what you sow" arguments).

2. 28 U.S.C. § 1498(a)

Notwithstanding the private sector's absence in march-in-rights, 28 U.S.C. § 1498(a) has distinct features that at first glance seem to fill that gap. Specifically, 28 U.S.C. § 1498(a) "gives the government the right to use patented inventions without permission, while paying the patent holder 'reasonable and entire compensation.'"[79] This provision can be distinguished from march-in-rights in that 28 U.S.C. § 1498(a): (1) applies regardless of the patent's funding source; (2) only applies to federal government use;[80] and (3) provides the patentee with reasonable compensation for the government use, rather than granting the government a license.[81] In effect, 28 U.S.C. § 1498(a) gives the federal government "a form of governmental immunity" from patent infringement litigation.[82]

While it seems as if we could stop here, the fact that 28 U.S.C. § 1498(a) only applies to the government or its contractors is a major downfall. The government can use this statute to permit private companies to infringe on a patent, but it still requires that the government be a middle person. To demonstrate why this is a problem, 28 U.S.C. § 1498(a) has only been invoked once for patents involving pharmaceutical products.[83] Despite the major public health issues that have plagued the United States in the last forty years, including HIV/AIDS, hepatitis C, and COVID-19, the government has not stepped in to use 28 U.S.C. § 1498(a).[84]

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[79] *See* Kapczynski & Kesselheim, *supra* note 27, at 792.

[80] More specifically, federal government use includes "use of a patented invention by the U.S. government, or one of its contractors with the authorization or consent of the U.S. government." *See* THOMAS, *supra* note 66, at 8.

[81] *Id.*

[82] *See* Kapczynski & Kesselheim, *supra* note 27, at 792 ("Under [the government use provision], patent holders can demand royalties but cannot stop the government from producing the medicine or allowing others (in this case, generic manufacturers) to produce or import the medicine.").

[83] *Id.* at 794 (explaining the government's use of 28 U.S.C. § 1498(a) in the 2001 anthrax scare to "stockpile" ciproflaxin, an antibiotic used as treatment for anthrax poisoning).

[84] Instead, both the Biden and Trump Administrations invoked the Defense Production Act in the wake of COVID-19 to increase supply of vaccines. Sydney Lupkin, *Defense Production Act Speeds Up Vaccine Production*, NPR (Mar. 13, 2021), https://www.npr.org/sections/health-shots/2021/03/13/976531488/defense-production-act-speeds-up-vaccine-production [https://perma.cc/47Y8-HEZB]; *see* 50 U.S.C. §§ 4501–4568. The Defense Production Act gives the President the authority to, among other things: (1) "require persons (including businesses and corporations) to prioritize and accept contracts for materials and services as necessary to promote the national defense"; and (2) "incentivize the domestic industrial base to expand the production and supply of critical materials and goods." CONG. RES. SERV., THE DEFENSE PRODUCTION ACT OF 1950: HISTORY, AUTHORITIES, AND CONSIDERATIONS FOR CONGRESS Summary (2020). Despite its part in helping drive the mass manufacture and distribution of COVID-19 vaccines, the Defense Production Act, alone, is not connected to intellectual property rights. In addition, the Defense Production Act requires substantial government spending. *See* Isaac Arnsdorf, *The Defense Production Act Gives the President Power—but Not Much Funding*, PROPUBLICA (Mar. 25, 2020, 2:46 PM), https://www.propublica.org/article/the-defense-production-act-gives-the-president-power-

Accordingly, relying on the government to decide when there is a public health crisis and when to act is not realistic.[85]

3. Injunctive Relief: The Public Interest Factor

Another available defense lies directly within the court. In common-law patent infringement cases where patentees seek injunctive relief, courts consider several factors differing only slightly by the type of equitable relief sought,[86] and both of the aforementioned preliminary and permanent injunction tests share the public interest factor.[87] Accordingly, in a balancing test of sorts, a court can weigh the public interest factor to deny injunctive relief in certain situations, in favor of the alleged infringer.[88] This factor is most predominantly relevant in the context of public health and the pharmaceutical industry,[89] which leads to the assumption that this existing defensive avenue is sufficient to permit patent infringements during public health crises.

However, the public interest factor is touted as being one of the "most controversial and difficult [injunctive relief factors] to apply."[90] In the land of permanent injunctions, the aftermath of the Supreme Court decision in *eBay* resulted in courts nonhomogeneously weighing the four factors.[91] Thus, "although the equitable factors provide courts with flexibility in their analysis, that same flexibility renders futile any attempt to compare the analysis of the various courts based on the four factors."[92] More specific to the public interest factor, "[c]ourts are split on how the public interest is served in granting permanent injunctions in pharmaceutical cases."[93] This inconsistency in the

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but-not-much-funding [https://perma.cc/M2F6-59BQ]. As such, this note does not delve into the Defense Production Act as a solution for patents and future public health crises.

[85] This is especially true in light of the Trump Administration's frequent dismissal of COVID-19 as a real public health threat, despite the insurmountable scientific evidence to the contrary. *See* Shannon Pettypiece, *'This Was Avoidable': Trump has been downplaying the virus from the start*, NBC NEWS (Oct. 2, 2020, 8:54 AM), https://www.nbcnews.com/politics/white-house/was-avoidable-trump-falls-victim-his-own-false-messaging-coronavirus-n1241775 [https://perma.cc/DCM9-SYHD].

[86] *See supra* Section I.A.

[87] Richard L. Stroup, Susan Tull & Mindy Ehrenfried, *Patent Holder's Equitable Remedies in Patent Infringement Actions Before Federal Courts and the International Trade Commission*, 99 J. PATENT & TRADEMARK OFF. SOC'Y 530, 558, 571 (2017).

[88] *See* Lance Wyatt, *Rebuttable Presumption of Public Interest in Protecting the Public Health—The Necessity for Denying Injunctive Relief in Medically-Related Patent Infringement Cases After* Ebay *v.* Mercexchange, 13 CHI.-KENT J. INTELL. PROP. 298, 309 (2013).

[89] *See* NARD, *supra* note 16, at 960.

[90] *Id.*

[91] *See* Wyatt, *supra* note 88, at 309.

[92] Benjamin Petersen, *Injunctive Relief in the Post-Ebay World*, 23 BERKELEY TECH. L.J. 193, 197 (2008).

[93] *See* Sizemore Halterman, *supra* note 60, at 502. "[S]ome courts have viewed the public interest factor as including only the interests of the general public." *See* Petersen, *supra*

application of the injunctive relief factors essentially leaves the public interest defense to chance,[94] much like the copyright fair use defense.[95] And further, courts rule on injunctive relief in the remedies phase of infringement litigation, which may even be a separate proceeding in the patent context.[96] Procedurally, a ruling on a permanent injunction could take years,[97] at which point a public health crisis would have come and gone.

II. PAST PUBLIC HEALTH CRISES AS CASE STUDIES FOR REFORM

Discussing the remedies and corresponding problematic defenses in patent law is ineffective without examining the contextual relevance of public health. Traditionally, "[p]atents have long been the crown jewels of the pharma industry" due to the magnitude of costs associated with the research and development of pharmaceutical products.[98] However, there is a major ethical argument when it comes to public health crises and patents: that pharmaceutical companies have such omnipotent control over drug prices and subsequently profit exclusively from mass morbidity and mortality in the wake of public health emergencies.[99] An analysis of two major epidemics, namely the HIV/AIDS[100] pandemic and the COVID-19 pandemic, will help demonstrate more clearly the issues with existing patent laws and public health crises.

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note 92, at 197 (citing Paice L.L.C. v. Toyota Motor Corp., No. 2:04-CV-211-DF, 2006 WL 2385139, at *2 (E.D. Tex. Aug. 16, 2006)). Alternatively, "others have considered the possible plight of the infringer's employees if an injunction were to be issued a matter of public interest." *Id.* (citing Sundance v. DeMonte Fabricating, Ltd., No. 02-73543, 2007 WL 37742, at *2 (E.D. Mich. Jan. 4, 2007)).

[94] *See* Sizemore Halterman, *supra* note 60, at 520 ("The Supreme Court's decision in *eBay v. MercExchange* gave courts more flexibility in granting and denying injunctions as courts must now make this decision by balancing four equitable factors.").

[95] *See infra* Section III.A.

[96] Lauren Cohen et al., *"Troll" Check?: A Proposal for Administrative Review of Patent Litigation*, 97 B.U. L. REV. 1775, 1792 (2017).

[97] *Id.* at 1793.

[98] *See* Sizemore Halterman, *supra* note 60, at 499.

[99] *See generally* Martin L. Hirsch, *Side Effects of Corporate Greed: Pharmaceutical Companies Need A Dose of Corporate Social Responsibility*, 9 MINN. J.L. SCI. & TECH. 607, 607 (2008) (explaining that "[c]orporate governance in pharmaceutical companies that focuses on the shareholder's bottom line is completely inconsistent with health care, medicine and access to pharmaceuticals, where the patient should come first"). This note does not intend to demonize the pharmaceutical industry. The saying that "there are two sides to every story" applies strongly here, and this note attempts to fairly present the duality of interests in the topic of patents and public health.

[100] HIV stands for "human immunodeficiency virus" and AIDS stands for "acquired immunodeficiency syndrome," which is caused by untreated HIV. Ctrs for Disease Control and Prevention, *What is HIV?*, CDC: ABOUT HIV (Sept. 2020), https://www.cdc.gov/hiv/basics/whatishiv.html [https://perma.cc/P2JZ-XVQ9].

A. HIV/AIDS Pandemic

AIDS first emerged "as a new clinical syndrome [in] 1981,"[101] and HIV was discovered as the cause of AIDS shortly thereafter.[102] AIDS quickly rose to nationwide epidemic levels, reaching its highest levels of incidence in 1995.[103] That same year, there were nine treatments in existence that "transform[ed] HIV into a chronic condition," a disease previously understood as certain death.[104] However, to this day, HIV remains prevalent across the globe—in the United States alone, nearly 1.2 million people were living with HIV in 2018.[105] And worldwide, 38 million people were living with HIV in 2019.[106] With the epidemic lasting nearly forty years and counting,[107] it is astonishing how advanced prevention capabilities and treatments have not put a halt to this ongoing public health crisis.[108]

There is no doubt that the pharmaceutical industry transformed the survival rates of HIV/AIDS through new drug and treatment discoveries.[109] However, drug prices for HIV treatments and prophylactics in the United States remain exorbitant.[110] In just one example, Truvada, a brand of PrEP[111] medication that helps to reduce HIV transmission, was manufactured and patented by Gilead Sciences, a biopharmaceutical company in the United

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[101] U.C.S. F., *History of the AIDS Epidemic in the United States*, HIV INSITE: EPIDEMIOLOGY OF HIV/AIDS IN THE UNITED STATES (Mar. 2003), http://hivinsite.ucsf.edu/insite?page=kb-01-03 [https://perma.cc/65LF-R64R].

[102] *HIV and AIDS Timeline: 1985*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Oct. 21, 2020), https://npin.cdc.gov/pages/hiv-and-aids-timeline#1980 [https://perma.cc/TX42-RCV2].

[103] *See History of the AIDS Epidemic in the United States*, *supra* note 101.

[104] Jay Purcell, *Adverse Clinical and Public Health Consequences of Limited Anti-Retroviral Licensing*, 25 BERKELEY TECH. L.J. 103, 103 (2010); *see also Why the HIV Epidemic Is Not Over*, WORLD HEALTH ORG. https://www.who.int/news-room/spotlight/why-the-hiv-epidemic-is-not-over [https://perma.cc/9LGC-UNNB].

[105] *Basic Statistics*, CTRS FOR DISEASE CONTROL AND PREVENTION: HIV BASICS (July 1, 2020), https://www.cdc.gov/hiv/basics/statistics.html [https://perma.cc/NA5C-ENAP].

[106] *HIV/AIDS Factsheet*, WORLD HEALTH ORG. (July 6, 2020), https://www.who.int/news-room/fact-sheets/detail/hiv-aids [https://perma.cc/J822-DXDR].

[107] *See Why the HIV Epidemic Is Not Over*, *supra* note 104.

[108] *See* Robert Walter Eisinger & Anthony S. Fauci, *Ending the HIV/AIDS Pandemic as an Epidemiological and Global Public Health Phenomenon*, 24 EMERGING INFECTIOUS DISEASES 413, 415 (2018) (describing the challenges of ending the HIV and AIDS pandemic, including a lack of ongoing resources required for adequate treatment and prevention).

[109] *Today's HIV/AIDS Epidemic*, CTRS, FOR DISEASE CONTROL AND PREVENTION: FACTSHEET (Aug. 2016), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf [https://perma.cc/8R46-VKQL].

[110] *See* Donald G. McNeil Jr. & Apoorva Mandavilli, *Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says*, N.Y. TIMES: GLOBAL HEALTH (Nov. 8, 2019), https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html [https://perma.cc/AE2E-XLNJ] (discussing the barrier created by a $20,000 price tag on H.I.V. medication).

[111] "PrEP" stands for "pre-exposure prophylaxis," which prevents those who are at "very high risk of getting HIV to prevent HIV infection by taking a pill every day." *Pre-Exposure Prophylaxis (PrEP)*, CTRS. FOR DISEASE CONTROL AND PREVENTION: HIV/AIDS (May 13, 2020), https://www.cdc.gov/hiv/risk/prep/index.html [https://perma.cc/RK2J-ZKVP].

States.[112] During its time under Gilead's patent, Truvada's price increased to $20,000 per year for each patient,[113] although equivalents in other countries cost only $75.[114] Despite the fact that insurance covers Truvada and Gilead has its own low-income pricing program, patients still face out-of-pocket costs, some as high as $1,600 a month.[115] Truvada was the only FDA-approved PrEP drug for the majority of the decade between 2010 and 2020 and reduced the risk of contracting HIV by 99 percent.[116] Given the risk-reduction capabilities, coupled with the exorbitant price, there was likely a considerable loss of opportunity for mass prevention.[117] While this example is only the microscopic tip of the iceberg in terms of patent-related issues in HIV treatments,[118] it is telling with respect to the effects that patents can have on public health crises.[119] Given the forty-year global battle with HIV, like with many other public health problems, prevention becomes a priority just as important, if not more, than treatment.[120] With a monopoly over a nearly 100 percent effective means for preventing a deadly virus and a cost that exceeds its lower-cost counterparts in other countries,[121] this demonstrates the vast reach of pharmaceutical companies during times of public health crisis.[122]

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[112] *See* McNeil Jr. & Mandavilli, *supra* note 110.

[113] *Id.* This number reflects health care spending, not individual patient costs.

[114] Tina Rosenberg, *H.I.V. Drugs Cost $75 in Africa, $39,000 in the U.S. Does It Matter?*, N.Y. TIMES (Sept. 18, 2018), https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html [https://perma.cc/S47G-X5S3].

[115] Shefali Luthra & Anna Gorman, *Out-of-Pocket Costs Put HIV Prevention Drug Out of Reach for Many At Risk*, KAISER HEALTH NEWS (July 3, 2018), https://khn.org/news/out-of-pocket-costs-put-hiv-prevention-drug-out-of-reach-for-many-at-risk/ [https://perma.cc/N25G-M8HM].

[116] E.J. Mundell, *Don't Use Pricey New HIV PrEP Drug When Generics Available: Study*, HEALTHDAY NEWS (Mar. 9, 2020), https://consumer.healthday.com/aids-information-1/aids-and-hiv-sexually-transmitted-diseases-news-607/don-t-use-pricey-new-hiv-prep-drug-when-generics-available-study-755506.html [https://perma.cc/3HSQ-VZ7N].

[117] *See id.*

[118] *See e.g.*, Ellen 't Hoen, Jonathan Berger, Alexandra Calmy & Suerie Moon, *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All*, 14 J. INT. AIDS SOC. 15 (2011) (describing the global issues faced by the HIV/AIDS crisis in light of international patenting).

[119] *See* Michelle Kaplan, *The 2009 H1N1 Swine Flu Pandemic: Reconciling Goals of Patents and Public Health Initiatives*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 991, 1027 (2010) ("The goals and underlying purpose of patent law often conflict with the basic tenets of public health law.").

[120] *See* Lawrence O. Gostin & Benjamin E. Berkman, *Pandemic Influenza: Ethics, Law, and the Public's Health*, 59 ADMIN. L. REV. 121, 137 (2007) ("As the historic mission of public health is prevention, countermeasures to impede transmission should be a high priority.").

[121] Insurance unfortunately does not offer consistent results for coverage of PrEP, so both those with insurance and without insurance face cost barriers to prevention. *See generally* Emma Sophia Kay & Rogerio M. Pinto, *Is Insurance a Barrier to HIV Preexposure Prophylaxis? Clarifying the Issue*, 110 AJPH 61 (2020) (examining the coverage of PrEP by different insurance plans).

[122] *See generally* David Blumenthal, *It's the Monopolies, Stupid!*, COMMONWEALTH FUND: BLOG (May 24, 2018), https://www.commonwealthfund.org/blog/2018/its-monopolies-

B. COVID-19 Pandemic

At first glance, the emergence of the COVID-19 pandemic implicated the same tension between pharmaceutical companies and public health that existed during the HIV/AIDS epidemic.[123] The government in Wuhan, China began reporting cases of an unidentified pneumonia-like illness on December 31, 2019, and by January 30, 2020, the World Health Organization (WHO) "declared a global health emergency."[124] The illness was given the name "COVID-19" on February 11, 2020,[125] and thereafter, cases rose rapidly to epidemic levels in countries across the globe, leading the WHO to characterize COVID-19 as a pandemic on March 11, 2020.[126]

Very early on in the COVID-19 pandemic, there was a global race to a vaccine and naturally, a race to patent.[127] In May of 2020, the WHO "formed a patent pool—essentially asking researchers to share proprietary information" with the goal of generating vaccines and treatments more quickly, while also gearing up to streamline access around the globe.[128] While the United States did not opt into the WHO pool, a similar U.S.-

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stupid [https://perma.cc/AEN8-XXUN] (explaining the impact of patent monopolies over drugs and that "[a]s long as drug companies . . . hold monopoly . . . power over potent new therapies, there is no free market solution to lowering drug prices").

[123] While this note only explores the domestic implications of patents and public health measures, it is also crucial to note that there are major issues that surfaced on the global scale regarding patents, intellectual property, and access. A year into the COVID-19 pandemic, while the United States saw progress due to vaccine availability, India and South America were experiencing devastating losses. *See* Thomas Kaplan & Sheryl Gay Stolberg, *The Biden Administration Says It Will Support Lifting Patent Protections to Help Produce More Vaccines Globally*, N.Y. TIMES, https://www.nytimes.com/live/2021/05/05/world/covid-vaccine-coronavirus-cases#covid-vaccine-patent-biden [https://perma.cc/BUP8-KZBA] (describing the global COVID-19 crisis and the importance of international support for hard-hit countries); *see also* Dalindyebo Shabalala, *How to Get COVID-19 Vaccines to Poor Countries – and Still Keep Patent Benefits for Drugmakers*, THE CONVERSATION (Apr. 14, 2021, 3:20 PM), https://theconversation.com/how-to-get-covid-19-vaccines-to-poor-countries-and-still-keep-patent-benefits-for-drugmakers-158384 [https://perma.cc/9MJL-J22C] (explaining the international issues between patents and global COVID-19 vaccine access, including limitations on international compulsory licensing schemes and the complexity of intellectual property protections).

[124] Derrick Bryson Taylor, *A Timeline of the Coronavirus Pandemic*, N.Y. TIMES (Mar. 17, 2021), https://www.nytimes.com/article/coronavirus-timeline.html [https://perma.cc/C6KX-TAA7].

[125] *Id.*

[126] *Listings of WHO's Response to COVID-19*, WORLD HEALTH ORG. (June 29, 2020), https://www.who.int/news/item/29-06-2020-covidtimeline [https://perma.cc/VZ7H-TR27].

[127] Cynthia Koons, *The Vaccine Scramble is Also a Scramble for Patents*, BLOOMBERG BUSINESSWK. (Aug. 12, 2020), https://www.bloomberg.com/features/2020-covid-vaccine-patent-price/ [https://perma.cc/3932-P6MM].

[128] *Id.*

based patent pool called the Open COVID Pledge was created.[129] Pharmaceutical companies opted out.[130]

Interestingly, however, Moderna, a pharmaceutical company that was the first to conduct clinical trials for a COVID-19 vaccine,[131] vowed not to "enforce patents related to its experimental Covid-19 vaccine while the pandemic continue[d]."[132] In light of the trend of pharmaceutical companies opting out of patent pools, Moderna's move was surprising, yet welcome.[133] One of the largest problems with fighting public health crises is orchestrating fast, efficient mass manufacture and distribution of necessary vaccinations or treatments.[134] However, taking Moderna's vow as an example, the pharmaceutical company acknowledged that not enforcing patent rights during the pandemic would increase necessary access to life-saving vaccines.[135]

With that being said, vaccines present vastly different patent issues than prophylactics for HIV.[136] In fact, critics of the recent surge in patent skepticism argue that patents are not the problem to access in the vaccine context.[137] Their main arguments include: (1) COVID-19 vaccine patent owners are incentivized to expand access

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[129] *Id.*

[130] While entirely speculative, it is possible that pharmaceutical companies opted out because COVID-19 "could be a big market." *See* Koons, *supra* note 127; *see also Pledgors*, OPEN COVID PLEDGE, https://opencovidpledge.org/partners/ [https://perma.cc/9N6W-R8LS].

[131] Jonathan Corum et al., *Coronavirus Vaccine Tracker*, N.Y. TIMES (Oct. 29, 2020), https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html [https://perma.cc/ECG6-QJHW].

[132] Peter Loftus, *Moderna Vows to Not Enforce Covid-19 Vaccine Patents During Pandemic*, WALL STREET J. (Oct. 8, 2020, 7:00 AM), https://www.wsj.com/articles/moderna-vows-to-not-enforce-covid-19-vaccine-patents-during-pandemic-11602154805 [https://perma.cc/C8FG-XZ65]. Although Moderna's COVID-19 efforts were funded by the National Institutes of Health and thus could be subject to march-in rights, it was nonetheless a promising step forward in ensuring the balance between patents and public health necessity. *See* Corum et al., *supra* note 131.

[133] *See generally* Molly Callahan, *Should Pharmaceutical Companies Give Up their Patent Protections to Find a Vaccine for COVID-19?*, MED. PRESS (Apr. 15, 2020), https://medicalxpress.com/news/2020-04-pharmaceutical-companies-patent-vaccine-covid-.html [https://perma.cc/XFS7-9B9R] (explaining that, in the beginning of the COVID-19 pandemic, some questioned whether pharmaceutical companies should give up patent rights for a COVID-19 vaccine).

[134] National Vaccine Advisory Committee, *Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program – A Report of the National Vaccine Advisory Committee*, 128 PUBLIC HEALTH REPORTS 78, 89 (2013).

[135] *See* Loftus, *supra* note 132 ("[Moderna is] not interested in using that IP to decrease the number of vaccines available in a pandemic.").

[136] Vaccines, in contrast to other pharmaceuticals, are products of several layers of IP rights, and thus "[t]rue generic vaccines" are nonexistent. Martin Friede, Intellectual Property and License Management with Respect to Vaccines, Presentation at the World Health Organization Technology Transfer Workshop (2010).

[137] *See generally* Jacob S. Sherkow et al., *Are Patents the Cause of—Or Solution To—COVID-19 Vaccine Innovation Problems? (No!)*, *in* INNOVATION INSTITUTIONS AND COVID-19 (describing why patents are not to blame in the vaccine-access context).

rather than restrict access due to the demand; (2) there are no biosimilar regulatory pathways to facilitate market entry; (3) patents are not the only form of intellectual property implicated by vaccine production, and thus lessening patent exclusivity is ineffective as a solution; (4) other manufacturers are not simply on standby, rather the companies would need time to establish production capacity; and (5) dropping the patent veil would disincentivize the owner-companies from expanding the vaccine supply themselves.[138] In addition, pharmaceutical companies themselves maintain that the problem with vaccine shortages and lack of access are not due to patent exclusivity, but instead the scarcity of raw materials.[139] They further argue, "[e]vidence that patents . . . hinder[] development of COVID-19-related technologies or that patentees were restricting access to increase profits would help make the case for compulsory licensing during this pandemic," but that such evidence is nonexistent.[140] These arguments are not unfounded—patents are only one of many barriers when it comes to the production of, and ultimately access to, vaccines. Specifically, vaccines "are complex biologics that are . . . difficult to replicate."[141] And compounding the problem, "there have been no biosimilar vaccines (in the U.S. or elsewhere), and the FDA and its counterparts abroad haven't even issued guidelines on the regulatory steps that would be needed for biosimilar vaccine approval."[142] But, the lack of regulatory oversight of biosimilar vaccines cannot be an excuse. Recognizing the immense importance of the role pharmaceutical companies play in the prevention and treatment of disease, the HIV/AIDS and COVID-19 pandemics demonstrate both the complexity of patent rights in the public health context and the need to strike a balance between the competing interests of inventor protections and public health necessity.[143]

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[138] *Id.*

[139] Damien Garde et al., *Waiver of Patent Rights on Covid-19 Vaccines, In Near Term, May be More Symbolic Than Substantive*, STAT NEWS (May 6, 2021), https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/ [https://perma.cc/2EN6-BTDJ].

[140] Nicholson Price et al., *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism, An Effective Spur to Innovation, or Something in Between?*, *in* INNOVATION INSTITUTIONS AND COVID-19 89 (2020).

[141] *See* Sherkow et al., *supra* note 137, at 146 ("[E]ven without patents, new firms can't enter the market because there is currently no regulatory pathway for generic vaccines.").

[142] *Id.*

[143] *See* Kaplan, *supra* note 119, at 1027 ("The goals and underlying purpose of patent law often conflict with the basic tenets of public health law.").

III. LEARNING FROM A SISTER LAW: COPYRIGHT AND THE PARALLELISM WITH PATENTS

One place to look for a solution to the balance problem between patents and public health crises is other areas of intellectual property law; there is no need to reinvent the wheel if there are solutions that can be found in similar laws. Under the umbrella of intellectual property, patent law and copyright law are markedly different.[144] While patent law provides protections for inventions and discoveries, copyright law provides protections for "original works of authorship."[145] Yet, patent and copyright law are also remarkably similar and both are derived from the same clause of the U.S. Constitution.[146] Article I, section 8, clause 8 provides Congress with the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[147] This denotes a common overarching goal between copyright law and patent law to protect and incentivize creation.[148] Given their parallel nature, it is only natural to find a solution for our problems with patent law in copyright law.

A. Copyright Fair Use Defense

Originating in common law in 1841,[149] copyright law's fair use doctrine was codified into statute by Congress in 1976.[150] Section 107 of the Copyright Act provides:

> In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include—
>
> (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
>
> (2) the nature of the copyrighted work;

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[144] *Copyright in General*, U.S. COPYRIGHT OFF.: FREQUENTLY ASKED QUESTIONS, https://www.copyright.gov/help/faq/faq-general.html#:~:text=Copyright%2C%20a%20form%20of%20intellectual,%2C%20computer%20software%2C%20and%20architecture [https://perma.cc/26S6-5WEU].

[145] *Id.*

[146] *See* Ritchie de Larena, *supra* note 18, at 802.

[147] U.S. CONST. art. I, § 8, cl. 8.

[148] Dennis S. Karjala, *Distinguishing Patent and Copyright Subject Matter*, 35 CONN. L. REV. 439, 441–42 (2003).

[149] Lauren Gorab, *A Fair Use to Remember: Restoring Application of the Fair Use Doctrine to Strengthen Copyright Law and Disarm Abusive Copyright Litigation*, 87 FORDHAM L. REV. 703, 709 (2018).

[150] *See* Snow, *supra* note 40, at 281.

> (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
>
> (4) the effect of the use upon the potential market for or value of the copyrighted work.[151]

While a plaintiff maintains the pleading standard for an infringement claim to establish a prima facia case, the burden of sufficiently pleading a fair use defense based on the above four factors is placed on the defendant.[152]

Under copyright law, the fair use doctrine is a defense to copyright infringement that excuses certain uses of copyrighted works.[153] Essentially, fair use reins in the traditional exclusivity afforded to copyright owners.[154] Furthermore, "fair use has [historically] been an all-or-nothing defense."[155] Either the infringer is successful in invoking the defense and can continue the use, or the infringer is unsuccessful and will be subject to damages and an injunction.[156] Placing limits on exclusivity is important in certain circumstances to ensure public access and enrichment from the information in the copyrighted work.[157] Traditionally, the fair use doctrine is invoked when the secondary use pertains to "criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research," though these examples are not an exhaustive inventory of fair use's application.[158]

Because the circumstances for the invocation of fair use in copyright are vastly different than those in the public health context, this note seeks to analogize to copyright's established objectives and insights rather than to replicate its' exact factors. A notable feature of the fair use doctrine is the discretionary application of factors, which allows for the balancing of interests between copyright owners and the public.[159] In fact, this balancing nature of the fair use doctrine was exactly the intent of Congress.[160] The legislative history provides that fair use was meant to "be judged on the totality of the facts in the particular case by balancing all the factors."[161] As such, Congress

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[151] 17 U.S.C. § 107.

[152] *See* Gorab, *supra* note 149, at 713–14.

[153] *Id.* at 705.

[154] *Id.* at 705.

[155] *See* O'Rourke, *supra* note 33, at 1190.

[156] *Id.*

[157] *See* Gorab, *supra* note 149, at 708.

[158] ROBERT A. GORMAN, JANE C. GINSBURG & R. ANTHONY REESE, COPYRIGHT: CASES AND MATERIALS 949 (9th ed. 2017).

[159] Pamela Samuelson, *Unbundling Fair Uses*, 77 FORDHAM L. REV. 2537, 2540 (2009).

[160] *See* H.R. REP. NO. 102-836, at 3–4 (1992).

[161] *Id.*

anticipated that "fair use litigation will always be piecemeal" and as a result, "no legislative solution can answer in advance the outcome of a given dispute."[162]

However, the inherently discretionary nature of the fair use inquiry in copyright is also seen as a major downfall to the defense.[163] As mentioned previously, Congress intentionally enacted a "case-by-case" standard, rather than a rule.[164] The imposition of a statutory standard allows for a great deal of judicial discretion, meaning "[n]o single factor is dispositive, and the factors need not be weighted equally."[165] The underlying flexible, permissive nature creates major uncertainty in the doctrine's application.[166] The issue then becomes that "[r]isk-averse users may avoid socially desirable uses that might qualify as fair use, simply because they are unwilling to take the risk."[167] In turn, this "chilling effect" of a case-by-case inquiry clearly dampens fair use's maximum potential.[168]

Despite its limitations, copyright fair use provides important lessons for patent law. The underpinnings of fair use address the major problem faced in patent law during public health crises, which is that patents are exceptionally exclusionary by nature.[169] However, the flexibility and deference afforded to the court in copyright fair use is strikingly similar to how we see in the way courts apply the public interest factor for injunctive relief in patent litigation.[170] Yet, this is a lesson we can learn from in patents, particularly, that a more rule-like approach is necessary to provide more certainty among both patent holders and potential infringers.[171] In addition, copyright fair use allows for zero liability

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[162] *Id.*

[163] *See* Samuelson, *supra* note 159, at 2540 ("Fair use is, however, often decried for the unpredictability said to attend the fact-intensive, case-by-case nature of fair use analysis and/or to result from the lack of judicial consensus on the fundamental principles that underlie fair use."); *see also* Rich Stim, *Measuring Fair Use: The Four Factors*, STAN. U. LIBR.: COPYRIGHT AND FAIR USE, https://fairuse.stanford.edu/overview/fair-use/four-factors/ [https://perma.cc/LUC9-G543] ("It's important to understand that [the fair use] factors are only guidelines that courts are free to adapt to particular situations on a case-by-case basis. In other words, a judge has a great deal of freedom when making a fair use determination, so the outcome in any given case can be hard to predict.").

[164] Niva Elkin-Koren & Orit Fischman-Afori, *Rulifying Fair Use*, 59 ARIZ. L. REV. 161, 176 (2017).

[165] *See* Gorab, *supra* note 149, at 710.

[166] *See* Michael W. Carroll, *Fixing Fair Use*, 85 N.C. L. REV. 1087, 1100 (2007).

[167] *See* Elkin-Koren & Fischman-Afori, *supra* note 164, at 189.

[168] *See id.* ("The clear solution to this legal deficiency is to elaborate the open standard using guiding rules, while maintaining the flexible framework of the standard.").

[169] *See* O'Rourke, *supra* note 33, at 1186 (explaining how patent rights are more extensive than copyright rights, despite a patent's shorter time period of exclusivity).

[170] *See supra* Section I.B.3.

[171] *See generally* Elkin-Koren & Fischman-Afori, *supra* note 164 (arguing that, while the judiciary should keep their discretion, a rule-like guidepost in fair use will provide more predictability and in turn advance copyright law's objectives).

use, which is not feasible for patent law.[172] We will return to these lessons later,[173] however, before we do, it is necessary to grapple with whether patent law is ready for a fair use doctrine, especially in regard to public health circumstances.

B. Fair Use-Like Characteristics of Patent Injunctive Relief Decisions

As the fair use doctrine under copyright law was conceived in common law and later codified into statute,[174] it is possible that patent law is already following the same path. In the *eBay* opinion that solidified the four-factor test for permanent injunctive relief in patent infringement cases, Justice Thomas invoked lessons from copyright law to support the creation of the factors and the discretion afforded to the district courts in deciding whether an injunction was appropriate.[175] It follows that this case not only serves as a landmark for transforming how courts rule on permanent injunctions in patent infringement cases,[176] but it also serves as a stepping stone for invoking lessons from copyright law into patent law.[177] With this in mind, a closer look at how district courts have analyzed patent infringement cases for injunctive relief offers a first glimpse into the existing fair use-like characteristics in patent common law, as described in the relevant cases below.

In *Waters Corp. v. Agilent Techs. Inc.*, Waters held the exclusive license for the GlycoWorks Kit which "assist[s] in the detection and labeling of compounds," an important product for drug development purposes, and sued Agilent, seeking a preliminary injunction based on Agilent's alleged infringement for a similar product.[178] Agilent's allegedly infringing product made up nearly a quarter of the market share and was a "critical pathway for biologic drug development and FDA submission."[179]

First, the court found that Waters had demonstrated a likelihood of success on the merits of infringement.[180] However, the

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[172] *See infra* Section IV.A.

[173] *See infra* Section IV.A.

[174] *See supra* Section III.A.

[175] eBay Inc. v. MercExchange L.L.C. 547 U.S. 388, 392–93 (2005); *see* NARD, *supra* note 16, at 980.

[176] *See generally* Petersen, *supra* note 92, at 194 (describing the trends in post-*eBay* cases, moving from a traditionally automatic grant of injunctions for infringement to a more heterogenous mix of injunctive relief).

[177] *See eBay Inc.*, 547 U.S. at 392–93 (to determine whether the court's use of the typical discretionary four-factor injunctive relief test was applicable in patent settings, the court analyzed the use in copyright law as a similar comparator to patent law).

[178] Waters Corp. v. Agilent Tech. Inc., 410 F. Supp. 3d 702, 706 (D. Del. 2019).

[179] *Id.* at 717.

[180] *Id.* at 707–13.

court held that Waters would not suffer irreparable harm because Waters delayed bringing an action, thus demonstrating any harm was not imminent; it also held that diminution in market share and lost profits "standing alone [were] insufficient to prove irreparable harm."[181] This same reasoning applied to the balance of hardships factor, which ultimately led the court to hold that the balance tipped in favor of Agilent.[182] Finally, the court analyzed the public interest factor, finding it to, again, favor Agilent.[183] Taking into account the allegedly infringing product's critical use among researchers and drug manufacturers for "drug development and regulatory approval," and particularly the detrimental effect an injunction would have on these stakeholders in terms of new drug development, the court found that the public interest would be disserved by an injunction.[184] Ultimately, despite finding a likelihood of success on the merits, the court denied the preliminary injunction.[185]

Comparably, in *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, the district court denied Abbott's motion for a preliminary injunction for Edwards' allegedly infringing mitral valve clip.[186] Though the court found that the irreparable harm prong was not satisfied because the alleged infringement occurred outside of the United States, it nevertheless analyzed the other three injunction factors.[187] In analyzing the public interest factor in particular, the court noted that, "[i]n litigation such as this involving a medical product, the public has 'two primary interests'—*i.e.,* the 'protection of intellectual-property rights and access to necessary and effective medical care.'"[188] The court ultimately found that the public interest factor favored Edwards because "at least some physicians—and more importantly patients—are likely to suffer negative consequences if [Edwards' product] is no longer available."[189] Similar to the *Abbott* court's public interest finding, the court in *Vascular Sols. L.L.C. v. Medtronic, Inc.*[190] found that, in addition to the other factors and "[i]n the absence of a

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[181] *Id.* at 713–16.

[182] *Id.* at 713–17.

[183] *Id.* at 717–18.

[184] *Id.*

[185] *Id.* at 707–18.

[186] Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp., No. 19-CV-149(MN), 2019 WL 2521305, at *1 (D. Del. June 6, 2019).

[187] *Id.* at *18–27.

[188] *Id.* at *25.

[189] *Id.* at *27.

[190] In *Vascular Solutions*, the plaintiffs held patents for cardiac guide catheters and brought an infringement claim against Medtronic. Vascular Sols. L.L.C. v. Medtronic, Inc., No. 19-CV-1760(PJS/TNL), 2020 WL 1809195, at *1 (D. Minn. Apr. 9, 2020).

likelihood of success on the merits, the public interest weighs against limiting competition and in favor of permitting the sale of potentially lifesaving medical devices."[191]

Yet, the public interest factor can only push a court's decision to decline injunctive relief so far. For example, the court in *BlephEx, L.L.C. v. Myco Industries, Inc.*[192] distinguished the public interest factor, holding that Myco's allegedly infringing treatment, while cost effective and important for public health purposes, did not serve the public interest.[193] The court found that Myco, arguing that its treatment was more cost effective than the patented treatment, did not in fact pass the savings on to the patient, but rather to the physician to help providers maximize profits.[194]

While the above cases are not copyright's fair use factors reincarnated into patent law, they demonstrate a trend of courts making decisions based on objectives similar to those that undergird copyright's fair use defense.[195] Recall the aim of fair use detailed in Section III.A: "to ensure public access to and 'public enrichment' from the information in the copyrighted work."[196] Comparing this aim to the cases above is telling. The findings in *Waters*, *Abbott*, *Vascular*, and *BlephEx* show the courts' sympathy towards both public access to the infringing product and public enrichment.[197] For instance, in *Waters*, the court was concerned with taking away a crucial tool from the public even though the plaintiff showed a likelihood of success on the merits in regard to infringement.[198] The same trend exists in both *Abbott* and *Vascular*, where the public's access to medical care, in those instances, outweighed the patentee's right to exclude.[199]

Although the *BlephEx* court granted the patentee's motion for injunctive relief, the findings in the case nonetheless support the proposition that the court was concerned with both public

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[191] *Id.* at *7.

[192] In *BlephEx*, the plaintiff held a patent for an ocular debris-removing instrument and method used in the treatment of ocular disorders. BlephEx, L.L.C. v. Myco Indus., Inc., No. 19-13089, 2020 WL 5951504, at *1 (E.D. Mich. Oct. 8, 2020). The defendant sold their competing product, which was advertised as having bonus debris-cleaning features, for "less than one third" of the plaintiff's cost, which forced the plaintiff to lower their prices. *Id.* at *2–3.

[193] *Id.* at *1, 2, 8.

[194] *Id.*

[195] *See* Strandburg, *supra* note 48, at 278 ("The lower courts' responses to the *eBay* ruling demonstrate that district court judges, at least, find it useful to have some mechanism for ex post tailoring at their disposal.").

[196] *See supra* Section III.A.

[197] While the courts' sympathy towards fair use objectives follows from the cited case law, courts in general lack consistency in the application of the public interest factor of injunctive relief, especially in the medical context. *See* Wyatt, *supra* note 88, at 321–22.

[198] *Waters Corp.*, 410 F. Supp. 3d at 707–18.

[199] *Abbott Cardiovascular Sys., Inc.*, 2019 WL 2521305, at *27; *Vascular Sols. L.L.C.*, 2020 WL 1809195, at *7.

access and public enrichment. In *BlephEx*, the court partially based its holding on finding that the public was not enriched, but instead it was the providers that were reaping the benefits of the infringing product.[200] All four of these cases show the courts' willingness to weigh the balance between important patent rights and fair uses of infringing inventions. Taking this logic one step further, there is an overlapping trend among courts to order continued royalties to be paid to a patentee in conjunction with an injunction denial, effectively creating a compulsory license.[201]

Just as copyright's fair use was grounded in common law before eventually becoming solidified in statute,[202] it appears as though patent law is following suit. Now more than ever, patent law is ready for a statutory fair use defense.[203]

IV. ADOPTING A "FAIR USE" DEFENSE IN PATENT LAW FOR PUBLIC HEALTH CRISES

The lack of a stable patent infringement defense for public health crises,[204] coupled with a trend in the courts to apply a fair use-like analysis in considering injunctive relief,[205] calls for the statutory adoption of fair use factors in patent law. This note is not the first to propose fair use factors in patent law,[206] but it is the first to suggest a narrow, rule-like approach.

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[200] *BlephEx, L.L.C.*, 2020 WL 5951504, at *1, 2, 8.

[201] *See* Strandburg, *supra* note 48, at 278.

[202] *See supra* Section III.A.

[203] *See* Strandburg, *supra* note 48, at 281 (explaining the need for fair use in patent law given the evolving nature of both law and technology).

[204] *See supra* Sections I.A–B.

[205] *See supra* Part II.

[206] Professor O'Rourke suggested the implementation of

> five factors relevant to a fair use finding: (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented work.

See O'Rourke, *supra* note 33, at 1205. And Professor Strandburg proposed the following patent fair use factors:

> 1. Is there a justifiable failure to purchase or license due to: a. The social value of making the invention available to a market that the patentee will not be able to serve, such as those who are unable to pay or those for whom the transaction costs of licensing are prohibitive (taking into account the potential damage to the patentee's interests by arbitrage); b. An 'anti-patent' license failure due to the patentee's attempt to squelch further innovation or to exert control over markets beyond the scope of the claims; or c. A failure to license due to anticommons-type holdup? 2. Did the infringer make a substantial improvement over the patentee's invention and was there some reason for blocking patent failure? 3. Does the availability of alternative innovation paradigms in the technological arena provide evidence of reduced importance of patent incentives? 4. Was the infringer a knowing copyist, independent

A. Copyright Lessons Revisited

While patent fair use factors should be narrowly tailored for use of the defense during a patent dispute in nationwide public health crises, the lessons learned from copyright fair use provide a helpful guide in terms of the formulation of factors to apply to patent law.[207] First and foremost, the overall justification for a copyright fair use defense, as discussed throughout this note, is the most important takeaway to consider for patent law. That is, to ensure necessary public access and public enrichment.[208]

And while the aim of copyright fair use is compelling, copyright fair use also tells us what not to do. First, as mentioned previously, copyright fair use lacks a rule-like application.[209] Given the downside of copyright fair use as a defense unpredictably applied on a case-by-case basis, fair use's application in patent law must be more rule-like to mitigate unpredictability and provide greater judicial uniformity.[210] The way courts have analyzed the injunctive relief factors shows an exigency for greater uniformity that should be applied in patent fair use.[211] Second, copyright fair use allows for a complete infringement, without royalties or damages for the copyright owner—essentially, the provision of a free compulsory license.[212] But, reasonable compensation in the patent context is necessary to protect patent owners.[213] After all,

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> inventor, or something in between? If the infringer was not a knowing copyist, was her failure to locate the patent through search reasonable in light of patent search costs in the particular technology, custom in the industry, the foreseeability of infringement, and the infringer's commercial, noncommercial, or small entity status?

See Strandburg, *supra* note 48, at 299–300.

[207] *See supra* Section III.A; *see also* Strandburg, *supra* note 48, at 278 ("[T]here are situations in which the social costs of exclusivity in a particular context simply outweigh the social benefits of the additional patent incentive provided by infringement liability in that context, such that use in that context should be permitted without conditions.").

[208] *See* Gorab, *supra* note 149, at 708.

[209] More specifically,

> [w]ithin the literature on rules and standards, fair use is a quintessential standard. It is well established that standards trade off greater ex ante certainty for greater ex post context sensitivity unless cultural or other contextual factors function to cabin a decisionmaker's discretion. One strategy for improving the ex ante certainty of a legal standard's application is to subject its application to evidentiary presumptions, which limit the range of relevant evidence.

See Carroll, *supra* note 166, at 1100.

[210] *See supra* Section III.A.

[211] *See supra* Section III.B.

[212] *See* O'Rourke, *supra* note 33, at 1190.

[213] *See infra* Section IV.C; *see also* O'Rourke, *supra* note 33, at 1208; Strandburg, *supra* note 48, 280 ("Importantly, O'Rourke suggests that a fee should sometimes be charged for patent 'fair use.' In this respect her proposal foreshadows the

despite their monopolization of life-saving treatments, it must be acknowledged that pharmaceutical companies possess the substantial ability to promote health and save lives—without the pharmaceutical industry, vaccines and treatments simply would not exist to the extent they do today.[214]

B. Proposed Patent Fair Use Factors

Applying the lessons learned from existing patent defenses, copyright law, and other scholars who have proposed a more generalized patent fair use defense, Congress should mandate that courts consider the factors listed below when determining if there has been a fair use of a drug covered by a patent. In particular, these factors will be of limited application, and while the court has discretion in its application of each copyright fair use factor,[215] the proposed patent fair use factors constitute more of an "on-off switch" to provide for greater judicial clarity and to limit judicial discretion.

In addition to the three factors described below, Congress should ensure that a defense of fair use is coupled with reasonable compensation for the use.[216] In essence, an alleged infringer that successfully invokes the patent fair use defense would be granted a compulsory license and the ensuing responsibility to pay reasonable royalties as decided by the court.[217] And, much like copyright law, the burden should remain on the patentee to plead a prima facie infringement case, with the burden of proof for using a fair use defense then placed on the alleged infringer.

1. Factor One: Evidence of a Public Health Crisis

Factor One inquires whether the federal government declared a public health emergency pursuant to the laws of that

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practices of those district courts that have ordered ongoing royalties while denying injunctions in the wake of *eBay*.").

[214] Pepe Lee Chang, *Who's in the Business of Saving Lives?*, 31 J. MED. & PHIL. 465, 465 (2006).

[215] *See* Stim, *supra* note 163.

[216] *See* O'Rourke, *supra* note 33, at 1234 ("[A]warding a royalty may both help to enable competition and safeguard patentees' incentives.").

[217] While this solution arguably fits more precisely with nonvaccine pharmaceuticals (due to the implications detailed in Section II.B), the application to vaccines is not totally lost. One side effect of adopting a compulsory licensing scheme is that "the mere threat of a compulsory license often results in consensual purchase agreements covering all aspects of pricing and production, which may be conducted either by the patentee or under his licensee." Orit Fischman Afori et al., A Global Pandemic Remedy to Vaccine Nationalism (Apr. 19, 2021) (unpublished manuscript) (on file with publisher). In other words, rather than risk being subject to compulsory licenses, patent owners would make a greater effort in their distribution efforts.

jurisdiction, or, in the event that the federal government has not declared a public health emergency, whether there is reasonable evidence of nationwide epidemic levels of disease, infection, or other public health issues.[218] Required evidence should include epidemiological reports from local, state, or national health authorities or data reports of relevant variables, including incidence, prevalence, infection rate, or mortality rate,[219] and testimony from an expert in the field to further validate the reports (e.g., an epidemiologist or infectious disease doctor.) This factor represents the narrow threshold that limits the doctrine's application in patent infringement cases.

2. Factor Two: Attempt to License

Factor Two looks to whether the parties attempted to license prior to litigation.[220] Borrowed from Professor Strandburg, this factor has particular importance in public health crises, but for a different reason than those set forth by Professor Strandburg.[221] Particularly in the context of a public health crisis, the only inquiry that should matter is whether the alleged infringer attempted to obtain a license so as to encourage good faith dealings among the patent holder and potential licensees. Requiring an attempt to license helps to protect the patent owner by allowing the owner to try negotiating any licenses on their terms as a first step. Only when this licensing fails would the fair use defense kick in.[222]

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[218] *Public Health Emergency Declaration* ,U.S. DEPT. OF HEALTH & HUMAN SERVS., (Nov. 26, 2019), https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx [https://perma.cc/5UPN-RKUX] (as an existing example of what this inquiry would look like, consider the following: "The Secretary of the Department of Health and Human Services (HHS) may, under Section 319 of the Public Health Service (PHS) Act, determine that: a) a disease or disorder presents a public health emergency (PHE); or b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists."). A similar trigger has been proposed on the global scale. *See* Fischman Afori et al., *supra* note 217 (proposing a global compulsory licensing scheme that relies on a World Health Organization pandemic declaration as a trigger).

[219] *See* LEON GORDIS, EPIDEMIOLOGY, 34 tbl. 2-4 (James Merritt et al. eds., 4th ed. 2009) (explaining the steps in the investigation of an outbreak, including "defin[ing] the outbreak and validat[ing] the existence of an outbreak" through common epidemiological methods).

[220] *See* Strandburg, *supra* note 48, at 300.

[221] Professor Strandburg describes several reasons a license might fail, including "[a]nti-patent refusals" and "anticommons issues." *Id.* at 295–97 (internal quotations omitted).

[222] Here, it is necessary to consider what would constitute a sufficient licensing attempt for purposes of this factor. Another area of patent law can be of assistance. In the technology sphere, patent holders who hold "standard essential patents (SEPs)," must agree to license their patents on "fair, reasonable, and non-discriminatory (FRAND) terms." Jay P. Kesan & Carol M. Hayes, *Frand's Forever: Standards, Patent Transfers, and Licensing Commitments*, 89 IND. L.J. 231, 233 (2014). To ensure good faith efforts to license for the purposes of fair use, the statute should import the requirement of a FRAND attempt to voluntary licensing.

3. Factor Three: Justification for Use

Finally, Factor Three, the justification for the use, including whether "the [use] is necessary to alleviate health or safety needs which are not [or cannot be] reasonably satisfied" by the patentee, is repurposed from existing march-in rights.[223] This factor ensures that there is a connection between the use and the public health emergency. Further, this factor allows the alleged infringer to show that, in the context of the public health emergency, the use was necessary in furtherance of public health, for example, to aid public access to life-saving vaccines or treatments. Out of all three factors, this factor presents the only opportunity for some semblance of judicial discretion in weighing policy considerations to ensure alleged infringers do not take advantage of the defense.

C. Application and Implications

Applying fair use in this narrow, rule-like manner is advantageous because it still seeks to protect the patent owner.[224] Patent rights remain an important fixture in our society—this is especially true in the pharmaceutical industry, where companies front extraordinary costs to innovate.[225] The inclusion of reasonable compensation, should an infringer successfully assert the defense, ensures that this investment is protected and the limitation of its use during public health emergencies protects owners from an overbroad application of fair use.[226]

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[223] 35 U.S.C. § 203(a).

[224] It is worth noting that this limited application of a patent fair use defense that, in effect, creates a compulsory license, is also compatible with requirements under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which is an international agreement among World Trade Organization (WTO) members, including the United States, that sets minimum standards for patents (among other intellectual property). *See Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm [https://perma.cc/2L8H-6RSA]; *see also Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/5VSX-B8EH] (describing how the TRIPS Agreement allows voluntary licensing attempts to be bypassed if there is a national emergency); *Members and Observers*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm [https://perma.cc/YA72-4KTZ]. Under the TRIPS Agreement, a member is able to implement compulsory licensing schemes only if certain conditions have been met, including a requirement to attempt to voluntarily license, and that the patent owner receive reasonable compensation for the compulsory license. *Pharmaceutical Patents and the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm [https://perma.cc/7WZL-WCZQ]. The solution prescribed in this note contains both of those conditions, and requires a licensing attempt even under emergency situations.

[225] *See* Strandburg, *supra* note 48, at 303.

[226] *See* O'Rourke, *supra* note 33, at 1242 ("Fair use might be criticized as an overbroad solution to a limited problem.").

Though the proposed factors do not foist a general fair use defense upon a patentee, there may still be pushback against this narrow defense. Professor Strandburg argued that these types of defenses may induce skepticism on two fronts: "First, one might argue that incorporating infringement exemptions and defenses into patent law will undermine the certainty of rights that is the aim of the emphasis on defined patent scope. Second, one might argue that exemptions and defenses will undermine incentives to invent, disclose, and disseminate."[227] Additionally, pharmaceutical companies largely oppose compulsory licensing mechanisms, even when the compulsory license is coupled with royalties.[228] The potential consequence that may surface with the availability of a patent fair use defense is that companies may no longer want to front the major investment that the research and development of pharmaceuticals requires.[229] In 2017 alone, the pharmaceutical industry spent $71.4 billion on research and development of pharmaceuticals.[230] The promise of patent exclusivity is how these companies can be sure to achieve a return on that investment.[231]

However, these arguments are more relevant to a generalized fair use defense than they are here.[232] The narrow fair use defense proposed in this note would only apply under limited circumstances, namely when there is evidence of a public health emergency and an attempt to license with the patentee. And where copyright use is discretionary, this note argues for a more rule-like approach that affords greater clarity to patent owners regarding allowable infringements.[233] On top of the limited nature, the allowance of reasonable compensation for the infringement,[234] despite the opposition, only further supports the

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[227] *See* Strandburg, *supra* note 48, at 276.

[228] Natalie J. Tanner, *Understanding the Disparity in Availability of Prescription Drugs in the United States: Compromise May Be the Answer*, 2 IND. HEALTH L. REV. 267, 288 (2005).

[229] *Id.*

[230] Andrew Dunn, *Drugmakers say R&D Spending Hit Record in 2017*, BIOPHARMA Dive (Aug. 13, 2018), https://www.biopharmadive.com/news/phrma-research-development-spending-industry-report/529943/ [https://perma.cc/MV2B-YMDE].

[231] *See* Strandburg, *supra* note 48, at 294–95.

[232] *Id.* at 276 ("[B]oth inventors and users of patented technology will naturally incorporate the potential for such exemptions into their planning (including licensing negotiations.)").

[233] *See* James Gibson, *Risk Aversion and Rights Accretion in Intellectual Property Law*, 116 YALE L.J. 882, 889 (2007).

[234] The courts have discretion in determining what constitutes reasonable compensation and some courts will examine what are called the *Georgia-Pacific* factors to guide their determination. *See* NARD, *supra* note 16, at 941. One notable factor that courts may consider is what royalties the patentee has established with other licensees. *Id.* Reasonableness should be determined by looking to "the amount invested in the relevant drug, adjusted for the risk of failure and to permit companies to earn reasonable or average profits." *See* Kapczynski & Kesselheim, *supra* note 27, at 793.

contention that this proposal simultaneously protects the rights of patent owners while enhancing public health efforts.

The impact of these factors will be slight for patent owners, yet significant for public health. For example, given the nature of epidemics, mass vaccination (without any natural herd immunity) is typically the only way to slow the spread of disease.[235] With millions of vaccines needed to combat an epidemic in the United States, the time it takes for a pharmaceutical company to manufacture and distribute a vaccine varies greatly.[236] Returning to COVID-19 as a case study, several pharmaceutical companies pledged early on in the pandemic to offer their "excess manufacturing capacity" to help quickly bring a vaccine to the public.[237] Along with Moderna's pledge to not enforce its patents during the pandemic,[238] this group effort on behalf of pharmaceutical companies not only showed the dire public need for access, but also demonstrated the willingness of pharmaceutical companies to engage in cooperative efforts in public health crises. In a way, this is the fair use doctrine at work outside of the courts.[239]

CONCLUSION

There is no doubt that patent law is a valuable staple in our society, helping to facilitate innovation and technological advancement through a temporary monopoly.[240] However, during public health crises, the monopoly that patent law affords companies becomes a major barrier for efficient public access to vaccines and treatments.[241] Unfortunately, the remedies currently available in patent law are insufficient to address this problem.[242]

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[235] *See Vaccines Protect Your Community*, U.S. DEPT. OF HEALTH & HUMAN SERVS., (Feb. 2020). https://www.vaccines.gov/basics/work/protection [https://perma.cc/F9D6-9MTV].

[236] One pharmaceutical company estimated the time to "produce, package, and deliver" vaccines can take anywhere from six to thirty-six months to achieve. *Manufacturing vaccines is a Complex Journey*, SANOFI (Sept. 2019), https://www.sanofi.com/en/your-health/vaccines/production [https://perma.cc/26JD-TJAN]. Miraculously, in the United States, 165 million doses of COVID-19 vaccines were administered by April 4, 2021. *More Than 658 Million Shots Given: Covid-19 Tracker*, BLOOMBERG (Apr. 4, 2021), https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/ [https://perma.cc/2YG8-NTDK]. That is only four months after the first COVID-19 vaccine received emergency FDA approval. *See* Corum et al., *supra* note 131.

[237] Drew Armstrong, *The World's Most Loathed Industry Gave Us a Vaccine in Record Time*, BLOOMBERG BUSINESSWEEK (Dec. 23, 2020), https://www.bloomberg.com/news/features/2020-12-23/covid-vaccine-how-big-pharma-saved-the-world-in-2020 [https://perma.cc/YAT2-RQJW].

[238] *See supra* Section II.B.

[239] However, this is not to say that fair use should be left to private entities to voluntarily cooperate during public health crises.

[240] *See* Grossman, *supra* note 43, at 246.

[241] Philip A. Perry, *Patent (and Public Health) Pending*, 8 ETHICS J. OF THE AM. MED. ASS'N 387, 387 (2006).

[242] *See supra* Section I.A.

Looking to copyright law for answers, the objectives of the fair use doctrine provide a notable model for a defense in patent law. A narrow, more rule-like version of fair use offers a unique solution for issues that arise with access to patented inventions during times of public health crisis. Specifically, Congress should adopt the following factors for courts to consider as a fair use defense to patent infringement: (1) whether the federal government declared a public health emergency pursuant to the laws of that jurisdiction, or, in the event that the federal government has not declared a public health emergency, whether there is reasonable evidence of nationwide epidemic levels of disease, infection, or other public health issue; (2) whether there was a failure to purchase or license the patented invention; and (3) the justification for the use.

The proposed limited fair use defense preserves both the value of patents and the incentives to patent, while at the same time ensuring public health needs are met. Adopting the fair use defense in patent law in times of intense public need would have lasting effects. This defense would translate to greater, more efficient access to lifesaving measures during public health crises. In light of the competing interests between patent owners and the public health, a fair use defense in patent law is just what the doctor ordered.

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