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Which Protectors Need More Protection? Analyzing Legal Possibilities of Reducing Patent Protection to Protect National Defense Companies

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WHICH PROTECTORS NEED MORE PROTECTION? ANALYZING LEGAL POSSIBILITIES OF REDUCING PATENT PROTECTION TO PROTECT NATIONAL DEFENSE COMPANIES

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ABSTRACT

Following the initial urgency of the COVID-19 pandemic, patent owners did not hesitate in filing infringement lawsuits around the country to enforce their claims to parts of the novel mRNA technology used in many of the successful COVID-19 vaccinations. Accused infringers in these suits include companies like Moderna and Pfizer, once heralded in the eyes of the public as the heroes of the pandemic and protectors of America's national security. Despite several federal statutes claiming to grant such accused companies some immunity from patent infringement, these suits were often not dismissed in their earliest stages, leaving questions about the scope of protection granted to national security companies, even in the face of a national emergency. Given the high cost of defending patent infringement suits as well as the urgent need to protect Americans during national security threats, lawmakers should not only consider the benefits of implementing policies that are strongly protective of patent owners. Instead, they must also contemplate the need to protect companies providing national security protections from excessive patent litigation lawsuits. Striking a balance between protecting both patent owners and accused patent infringers who contribute to key national security defense technologies will be critical as new types of threats begin to appear from bad actors around the world.

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INTRODUCTION

The United States is moving into a new age with unprecedented threats to its national security from several key enemies.¹ From the outside, autocratic governments, such as Russia, are consistently working to undermine democracies around the world.² Additionally, state-sponsored international terrorist organizations are still active in several parts of the globe, despite several decades of conflict in the Middle East designed to curb radicalism.³ From the inside, an uptick in domestic terrorism tragedies, like mass shootings in places of worship and grocery stores, showcase the wide range of threats posed from some of our own citizens.⁴ In fact, the House Committee on Homeland Security recently identified domestic security threats as the “greatest terrorism threat” to America.⁵ Consequently, lawmakers must not only consider threats to national security from hostile nations, but also from private citizens living within United States borders.

The types of threats posed by these hostile parties are also rapidly changing as technology continues to advance. Threats from enemies seeking to build weapons of mass destruction are not new; shortly after 9/11, President Bush was unequivocally determined to counter these threats by building defenses against ballistic missiles.⁶ Fears of nuclear warfare have increased since the invasion of Ukraine by Russia, which has unfortunately inspired Kim Jong Un of North Korea to become more aggressive in its war planning tactics.⁷

¹ See Biden-Harris Administration National Security Strategy 2022, at 2 (Oct. 12, 2022) (“From the earliest days of my Presidency, I have argued that our world is at an inflection point.”).

² *Id.* at 3.

³ *Counterterrorism Guide: Terrorist Groups*, OFFICE OF DIRECTOR OF NATIONAL INTELLIGENCE, <https://www.dni.gov/nctc/groups.html> (last visited Nov. 8, 2022).

⁴ National Strategy for Countering Domestic Terrorism, at 2-3 (Jun. 2021).

⁵ BENNIE THOMPSON OF H. COMM. ON HOMELAND SEC., 117TH CONG., DOMESTIC TERRORISM IS A THREAT WE CAN’T IGNORE (2022), <https://homeland.house.gov/news/in-the-news/domestic-terrorism-is-a-threat-we-cant-ignore>.

⁶ George W. Bush, *Overview of America’s International Strategy*, WHITE HOUSE ARCHIVES (Sept. 17, 2002), <https://georgewbush-whitehouse.archives.gov/nsc/nssall.html>.

⁷ Foster Klug, *North Korea takes inspiration from Putin’s nuke threats*, AP NEWS (Oct. 13, 2022), <https://apnews.com/article/russia-ukraine-putin-seoul-united-nations-nuclear-weapons-ab71f575cf671bb4661368d8633b1234>. North Korea has launched more missiles this year than in any previous year and has recently embarked on a two-week barrage to simulate “hit[ting] and wip[ing] out” potential United States targets, according to North Korean media.

However, until COVID-19, less attention was drawn to the potential use of biological weapons.⁸ Although enemies seeking to use biological weapons may be limited to groups with apocalyptic ideologies or those with sufficient knowledge and resources to build such a weapon,⁹ bioterrorism threats should not be discounted as a threat requiring less attention. Contrarily, policymakers should actively work to learn from the mistakes made during COVID-19 and use these lessons to prepare *ex ante* for future pandemics, which could include one engineered by a bad actor. COVID-19 was a stark reminder of the hazards posed to our national security by infectious diseases and it highlighted weak spots in our defense strategies when dealing with this type of threat.¹⁰ Such improvements to these strategies are especially critical given advances in biotechnology like CRISPR-Cas9, which continues to make genetic tailoring of organisms, including viruses, more efficient, and could ultimately be used to create a gene-edited pathogen with a high lethality and contagiousness.¹¹

As technology continues to develop, intellectual property in the form of patents will continue to reign as a key mechanism to protect an entity's inventions, providing a patent holder with a competitive edge and thus further incentive to innovate.¹² Particularly in the realm of inventions

⁸ Gary A. Ackerman, Zachary Kallenborn, & Philipp C. Bleek, *Going Viral: Implications of COVID-19 for Bioterrorism*, 15 CTC SENTINEL 1 (2022), <https://ctc.westpoint.edu/going-viral-implications-of-covid-19-for-bioterrorism/>.

⁹ *Id.*

¹⁰ The United States released its first biodefense strategy in 2018. U.S. DEP'T OF HEALTH & HUMAN SERVICES: ADMINISTRATION FOR STRATEGIC PREPAREDNESS & RESPONSE, NATIONAL BIODEFENSE STRATEGY, <https://aspr.hhs.gov/biodefense/Pages/default.aspx> (last visited Nov. 8, 2022). It was updated in October 2022 after COVID-19 highlighted the vulnerabilities in America's preparedness for biological threats. Specifically, it recognized that, "few other national security threats are capable of producing catastrophic and potentially existential global consequences at the scale and speed of biological threats" and that, moving forward, a fundamental transformation of our capabilities was required to ensure our readiness for pandemics in the future. Memorandum from Joseph R. Biden on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (Oct. 18, 2022) (on file with author).

¹¹ See Pin Lean Lau, *How gene editing could be used as a weapon, and what to do about it*, PHYS (Nov. 15, 2021), <https://phys.org/news/2021-11-gene-weapon.html>; Charlie Dunlap & Meredith Primrose Jones, *The Security Concerns of Dual-Use CRISPR*, LAWFIRE (Oct. 5, 2022), <https://sites.duke.edu/lawfire/2022/10/05/guest-post-meredith-primrose-jones-on-the-security-concerns-of-a-dual-use-crispr/> (describing the potential for CRISPR to be weaponized). For a more scientific perspective, see Margaret E. Kosal, *Emerging Life Sciences and Possible Threats to International Security*, 64 ORBIS 599 (2020).

¹² See *What is Intellectual Property?* WORLD INTELL. PROP. ORG., <https://www.wipo.int/about-ip/en/> (last visited Dec. 8, 2022). Intellectual

created for national security purposes, the United States must continue to ensure inventors are given these incentives to catapult our technological capabilities into an uncertain future with unknown threats from a barrage of enemies. In sum, intellectual property is undoubtedly critical to national security, if for no reason other than to keep up with increasing intellectual property protections in autocratic states for new forms of vital technologies.¹³

Nevertheless, in strengthening patent protections, policymakers must still consider the costs to accused infringers who are ultimately found liable for encroaching on a patentee's rights. Of critical concern is the possibility that an accused infringer is a company contributing to the country's national security.¹⁴ Currently, patent law provides patent holders with a valid patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States, or importing the invention into the United States.¹⁵ This wide range of condemned

property refers to the protections given to “creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce” that allow inventors and creators to earn benefits from their works. It is comprised of patents, copyrights, and trademarks. Patents are often the type of intellectual property used to protect technological inventions and, in the United States, are given in accordance with a specific body of law.

¹³ See Andrew Iancu and David J. Kappos, *U.S. Intellectual Property Is Critical to National Security*, CENTER FOR STRATEGIC AND INTERNATIONAL STUDIES (Jul. 12, 2021) (arguing in favor of strong intellectual property protections to further protect new technologies like artificial intelligence and quantum computers from potentially hostile parties, like China, seeking to alter the global order with their own intellectual property protections). See also Final Report Part II: Winning the Technology Competition, Chapter 12: Intellectual Property, at 206-07 NATIONAL SECURITY COMMISSION ON ARTIFICIAL INTELLIGENCE (2021) (advocating reforms to the existing patent system to better protect artificial intelligence and other emerging technologies and arguing in favor of the President issuing an executive order “to recognize IP as a national priority and require the development of a comprehensive plan to reform and create IP policies and regimes that further national security”).

¹⁴ See 35 U.S.C. § 271 (a); *Patent infringement*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/patent_infringement (last visited Dec. 8, 2022). By definition, patent infringement arises when one “makes, uses, offers to sell, or sells any patented invention.” However, in practice when writing a patent, a “patented invention” is often broken up into several claims that, together, describe each of the elements of the invention and limitations of the scope of the patent owner's rights. Thus, in the real world, patent infringement can arise when one develops a product that contains each element comprising a single patent claim. One need not copy the precise structure of an entire patented invention to be liable for patent infringement; they need only copy all of the elements of a single claim in the patent protecting the invention.

¹⁵ 35 U.S.C. § 271.

activities by non-patent holders leads to litigators filing, on average, 4,000 infringement suits a year against accused infringers.¹⁶ For the unfortunate accused infringer who becomes a defendant, a patent suit can be costly. The average cost of defending a patent infringement suit can range from \$2.3 million to \$4 million.¹⁷ Awards in successful patent infringement suits can range from a few million dollars to more than \$2 billion.¹⁸ In a world where small businesses play a vital role in contributing to the country's national security, allowing one of these companies to become financially crippled by becoming a liable defendant in a patent infringement suit is not a mere inconvenience to its legal department, but a serious danger to the entire United States.¹⁹ Even worse, successful patent suits can lead to defendants being enjoined from manufacturing or selling their accused products, potentially causing a deficit in technology available to the military.²⁰

Accordingly, it is difficult, yet of the utmost importance, to strike a balance between granting national security companies limited immunity

¹⁶ Gloria Huang, *Lex Machina Releases its 2022 Patent Litigation Report*, LEX MACHINA BLOG (May 19, 2022), <https://lexmachina.com/blog/lex-machina-releases-its-2022-patent-litigation-report/>

¹⁷ Russ Krajec, Press Release, *Current Patent Litigation Costs Are Between \$2.3 to \$4M—from the BlueIron blog*, AP NEWS (Jul. 10, 2020), <https://apnews.com/press-release/news-direct-corporation/technology-business-intellectual-property-patents-a5dd5a7d415e7bae6878c87656e90112>.

¹⁸ Barry Herman, *Lessons From The Largest Patent Damages Award In History*, LAW 360 (Jan. 20, 2017), <https://www.law360.com/articles/882857/lessons-from-the-largest-patent-damages-award-in-history>. To be considered a small business contractor with any agency of the federal government, the entity must qualify based on regulations promulgated by the U.S. Small Business Administration, which take into consideration an entity's total annual income. <https://www.sba.gov/federal-contracting/contracting-guide/size-standards> For reference, a small business providing basic engineering services must bring in less than \$22.5 million a year in revenue. If providing military equipment or if awarded a contract under the National Energy Policy Act of 1992, the entity may bring in up to \$41.5 million a year in revenue. See <https://www.sba.gov/size-standards/index.html>

¹⁹ See DEPARTMENT OF DEFENSE, *WHY SMALL BUSINESSES ARE ESSENTIAL TO U.S. NATIONAL SECURITY* (2021). (“Small businesses do more with more, and their innovations, agility, and diversity are pivotal, not only to DOD but to national security.”). The Department of Defense awards more than \$80 billion in contracts to small businesses. *Id.*

²⁰ *But see i4i Ltd. Ptrp. v. Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010) (citing *eBay v. MercExchange LLC*, 547 U.S. 388, 391 (2006)) (stating the four-factor test used by courts to determine whether to issue injunctive relief). Because a court must consider whether the public service would be “disserved” by a permanent injunction, a non-practicing entity would probably be unlikely to get an injunction to estop an infringer from practicing an invention that is key to protecting national security. Nevertheless, given the discretion left to courts in deciding to grant an injunction, such a possibility still exists.

from patent infringement suits while still enforcing patents that protect some of the nation's most vital inventions. Although existing statutes like the Public Readiness and Emergency Preparedness ("PREP") Act²¹ and the Bayh-Dole Act²² perhaps implicitly acknowledge the need to protect our national security when intellectual property protections are involved, they fail to strike this balance; they do not guarantee companies contributing to the national security any blanket immunity from patent infringement suits under any circumstances, even in the event of a national emergency.²³

Consequently, although national security companies may directly benefit the government and its people by contributing to greater protections from threats emanating from both within and abroad, the onus is currently still placed on these entities, if accused of patent infringement, to piece together defenses. Assuming a patent is found to be valid, the patent holder is not required to affirmatively explain to a court the benefits, or lack thereof, to *others* of patent enforcement, even in the midst of a national security threat, like COVID-19.²⁴ This conclusion seems obvious: from its origins, America has often not required a property owner to affirmatively show why they wish to enforce their property rights, but rather has maintained the sanctity of property by deferring to the sole desires of the property owner.²⁵ However, with intangible property, like patent rights, that do not only benefit the property owner but may also be used by non-patent holders to benefit the government and American public during a national

²¹ See 42 U.S.C. §247d-6d (a)(1), (i)(1) (granting covered persons immunity "from suit and liability under Federal and State law with respect to *all* claims for loss . . . resulting from . . . the use by an individual of a covered countermeasure," which arguably could include monetary damages resulting from infringement on a patent, and defining a "covered countermeasure" as including "a qualified pandemic or epidemic product" or "a security countermeasure" (emphasis added)).

²² See 35 U.S.C. § 203(a) (affording the government the right to "march-in" and require that certain patent holders who have received federal research funding grant a license to an applicant if the patent holder has not taken action to practice the patent as "necessary to alleviate health or safety needs").

²³ See, e.g., Joseph Evall, Richard Mark and Amanda First, *Don't Count On PREP Act To Defend Pandemic IP Infringement*, LAW 360, Jul. 2, 2020, at 3 (arguing that the PREP Act likely will not provide COVID vaccine manufacturers immunity from patent infringement suits).

²⁴ Pamela Faber, *Why Pandemics Are National Security Threats*, IN DEPTH BLOG (May 4, 2021), <https://www.cna.org/our-media/indepth/2021/05/why-pandemics-are-national-security-threats/>.

²⁵ See 2 WILLIAM BLACKSTONE, COMMENTARIES *2 (describing property as "that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe").

crisis, such a conclusion should not be so readily presumed as consistent with our traditional patriotic values of freedom and liberty.

Thus, in a world where defenses to modern threats are becoming increasingly reliant on improvements in technology and non-practicing entities sometimes referred to as “patent trolls” prowl about the nation’s most popular patent litigation venues,²⁶ Congress should design and pass a statute to protect national security companies from needless and unworthy patent litigation suits, while simultaneously providing inventors of national security technology with adequate incentives to continue innovating and preparing for the next generation of threats. Striking this balance should be a key focus of lawmakers seeking to reform parts of the patent system that touch technology primarily used to protect the country’s national security.

This Note will first propose a hypothetical situation whereby the existence of a small company that is the sole provider of a key national security defense product used by private citizens during a bioterrorism threat is endangered by a non-practicing entity seeking to enforce a patent it cheaply purchased from a third-party that was down on its luck. It will then evaluate potential immunity for accused infringers under the existing takings provision governing the use of patented inventions by the government,²⁷ the Defense Production Act,²⁸ and the PREP Act,²⁹ and point out current shortcomings of each to support the conclusion that reform is needed to prevent our own patent system from interfering with our national security. Last, it will apply existing law to the proposed hypothetical to concretely illustrate these shortcomings and evaluate potential policy solutions that lawmakers should consider to effectively strike a balance between patent legislation and national security protection

I. BACKGROUND

A. Current COVID-19 Patent Infringement Lawsuits

In mid-2020, as the COVID-19 pandemic wreaked havoc in the country and stole the lives of thousands of Americans while researchers worked tirelessly for solutions, one of the nation’s key vaccine manufacturers proposed an informal and unlikely truce: Moderna’s President Dr. Stephen Hoge publicly committed to not pursuing patent infringement suits against alleged infringers as long as the pandemic

²⁶ For more on the role of non-practicing entities in patent litigation suits, see John R. Allison, Mark A. Lemley & David L. Schwartz, *How Often Do Non-Practicing Entities Win Patent Suits?*, 32 BERKLEY TECH. L. J. 235 (2017).

²⁷ 28 U.S.C. §1498(a).

²⁸ 50 U.S.C. §§ 4501-4568.

²⁹ 42 U.S.C. §247d-6d.

continued.³⁰ In reaching this decision, Dr. Hoge reported that, although Moderna believed other entities were infringing its patent rights by manufacturing COVID-19 vaccines with a particular type of gene-based technology, Moderna did not wish to use its intellectual property to make vaccines less available.³¹

Such a proposal was not uncommon in 2020. Around the same time, the Program on the Information Justice and Intellectual Property at American University Washington College of Law brought together scientists, lawyers and entrepreneurs who worked together to create the “Open Covid Pledge.” This project allowed organizations to agree to make their patents freely available in an effort to stop the COVID-19 pandemic.³² Some of its pledgors included large technology companies, like Microsoft and Amazon; engineering firms providing for national defense solutions, like Sandia National Laboratories; and Unified Patents, an organization designed to prevent non-practicing entities (NPEs) known as “patent trolls” from asserting invalid or unsubstantiated patent assertions against hardworking companies seeking to provide useful innovations to the public.³³

i. Arbutus v. Moderna

Although voluntary efforts to combat aggressive intellectual property enforcement during the height of COVID-19 may have staved off some lawsuits, such altruistic efforts have since ceased as the pandemic has cooled down.³⁴ On February 28, 2022, Arbutus Biopharma Corporation

³⁰ Peter Loftus, *Moderna Vows to Not Enforce COVID-19 Vaccine Patents During Pandemic*, THE WALL STREET JOURNAL (Oct. 8, 2020), <https://www.wsj.com/articles/moderna-vows-to-not-enforce-covid-19-vaccine-patents-during-pandemic-11602154805>.

³¹ *Id.*

³² OPEN COVID PLEDGE: ABOUT US, <https://opencovidpledge.org/about/> (last visited Nov. 8, 2022).

³³ OPEN COVID PLEDGE: PARTNERS, <https://opencovidpledge.org/partners/> (last visited Nov. 8, 2022). The colloquial term “patent troll” refers to entities that “use patents as legal weapons, instead of actually creating any new products or coming up with new ideas.” They often acquire cheap patents with broad claims from companies approaching insolvency, and aggressively enforce it in the sole pursuit of fast and large monetary gains, without any desire to use the patent to create any new invention. *Patents: Patent Trolls*, ELEC. FRONTIER FOUND., <https://www EFF.ORG/issues/resources-patent-troll-victims> (last visited Dec. 8, 2022). For more information on how Unified Patents operates to deter NPEs, see UNIFIED PATNERS: FAQ, <https://www.unifiedpatents.com/faq> (last visited Nov. 8, 2022).

³⁴ One could argue that these pledges were enough to prevent companies from suing each other in the most trying times, and thus that it should be of little concern that there are not legal protections in place to prevent NPEs from asserting unsubstantiated infringement claims against the nation’s heroes during a national

(“Arbutus”) and Genevant Sciences GmbH (“Genevant”) filed suit against Moderna.³⁵ Together, the plaintiffs allege that Arbutus scientists spent several years researching lipid particles and ultimately obtained several patents on the mechanism used by Moderna’s “revolutionary” vaccine to deliver the mRNA particles into target cells.³⁶ Genevant owns or holds licenses to some of these patents.³⁷

Since the pandemic’s inception, several entities developing mRNA vaccines have allegedly sought to license Arbutus’s technology from Genevant.³⁸ Although Moderna spent several years before the pandemic seeking to gain rights to use the Acutus-Genevant patents, it ultimately failed to acquire a license.³⁹ Despite this failure, Acutus and Genevant allege that Moderna used the patented technology anyway to develop its famous mRNA vaccine only a few weeks into the pandemic and quickly started clinical trials.⁴⁰ Thus, although this quick turnaround may have saved the lives of many by jumpstarting the process of producing vaccines, Moderna now faces a patent infringement suit, the consequence of its failure to negotiate a license prior to jumping into action.

In response to the Acutus-Genevant complaint, Moderna filed a 12(b)(6) motion, arguing the action should be dismissed for failure to state a claim.⁴¹ From Moderna’s viewpoint, in the middle of a deadly global pandemic, it took critical steps to save innumerable lives by applying its years of work and resources in mRNA research to rapidly develop a COVID-19 vaccine.⁴² Specifically, Moderna emphasized that it had entered into a contract with the United States Government to supply it with the COVID-19 vaccines.⁴³ Because of this agreement to purchase vaccines, largely to be used by the American public and administered by non-governmental entities, Moderna alleges it is immune to suit under 28 U.S.C. § 1498 (a) for any doses that were purchased by the federal government

emergency. However, given the gravity of threats to America’s national security and their potential lethality, such voluntary efforts should not be relied upon for future emergencies. We can (and arguably should) hope for the best in humanity, but must prepare for the worst in this scenario.

³⁵ Complaint for Patent Infringement & Demand for Jury Trial at 1, Arbutus Biopharma Corp. v. Moderna, Inc., No. 22-252 (filed Feb. 28, 2022).

³⁶ *Id.* at 10-11.

³⁷ *Id.* at 5-6.

³⁸ *Id.* at 11.

³⁹ *Id.* at 12-13.

⁴⁰ *Id.* at 14-15.

⁴¹ Defendants’ Opening Brief in Support of Their Partial Motion to Dismiss Pursuant to Federal Rule of Civil Procedure 12(b)(6) at 1, Arbutus Biopharma Corp. v. Moderna, Inc., No. 22-252 (filed May 6, 2022).

⁴² *Id.* at 4.

⁴³ *Id.* at 5.

under that contract and that any claims for these doses should instead be brought against the government in the Court of Federal Claims.⁴⁴

ii. Alnylam v. Moderna

A similar suit was filed against Moderna by Alnylam Pharmaceuticals (“Alnylam”) less than a month later in March of 2022.⁴⁵ Like Arbutus and Genevant, Alnylam alleges to have invented and patented a lipid nanoparticle that can be paired with an mRNA particle to deliver the mRNA into a target cell.⁴⁶ Alnylam also alleges to have attempted licensing the patent at issue to Moderna several years prior to the pandemic and gave Moderna confidential information during these licensing negotiations.⁴⁷ Ultimately, Moderna again did not agree to a license.⁴⁸ However, slightly different from the fact pattern alleged by Arbutus and Genevant, Moderna allegedly incorporated Alnylam’s patented invention into a vaccine made for non-COVID purposes nearly five years prior to the start of the pandemic, and then continued to use the accused product in its COVID-19 vaccines.⁴⁹ Thus, although Moderna’s fast turnaround time jumpstarted the COVID-19 vaccine process, the accused product may have been in use by other Moderna vaccines several years prior to the start of the pandemic emergency.

Moderna raised a similar argument in the suit brought by Alnylam, filing essential the same opening brief and arguing that it is immune to suit under 28 U.S.C. § 1498 (a) because of the contract it had with the federal government to supply the COVID-19 vaccines, which largely went to members of the public to increase widespread immunity and were administered by non-governmental entities.⁵⁰

iii. Moderna v. Pfizer

Most recently, in late August of 2022, Moderna filed a suit against the Pfizer, Inc. (“Pfizer”) and BioNTech US, Inc. (“BioNTech”) partnership.⁵¹ Moderna claims to have spearheaded the movement of

⁴⁴ *Id.* at 9-10.

⁴⁵ Complaint for Patent Infringement & Demand for Jury Trial at 1, Alnylam Pharmaceuticals, Inc. v. Moderna, Inc., No. 22-cv-335 (filed Mar. 16, 2022).

⁴⁶ *Id.* at 5.

⁴⁷ *Id.* at 7-8.

⁴⁸ *Id.* at 8.

⁴⁹ *Id.* at 8-9.

⁵⁰ Defendants’ Opening Brief In Support Of Their Partial Motion To Dismiss Pursuant To Federal Rule Of Civil Procedure 12(b)(6) at 13-14, Alnylam Pharmaceuticals, Inc. v. Moderna, Inc., No. 22-cv-335 (filed May 23, 2022).

⁵¹ Complaint for Patent Infringement & Demand for Jury Trial at 1, Moderna US, Inc. v. Pfizer, Inc. and BioNTech US Inc., No. 1:22-cv-11378 (filed Aug. 26, 2022). Since the COVID-19 vaccines came out, Moderna and Pfizer-BioNTech

making mRNA vaccines a reality since its founding.⁵² Interestingly, it also alleges to have started studying how lipid nanoparticles can carry mRNA to its target cell and incorporated this technology after completing several experiments itself.⁵³ From its work over several years, Moderna claims to have been uniquely situated to respond to the COVID-19 crisis.⁵⁴ However, Moderna alleges that the Pfizer-BioNTech partnership followed its lead and took advantage of work it had done previously by incorporating critical features from Moderna's mRNA technology patents into the Pfizer-BioNTech mRNA vaccines.⁵⁵

To rebut *ex ante* any defense Pfizer could have raised under 28 U.S.C. § 1498 (a) as a federal contractor, Moderna narrowly and explicitly tailored the scope of its lawsuit to only seek damages from sales *not* subject to § 1498.⁵⁶ Interestingly, it also only sought damages for activities occurring *after* March 8, 2022, the date that Moderna's patent pledge from the height of the pandemic ceased.⁵⁷

B. Proposed Hypothetical

The preceding three cases arising out of the COVID-19 pandemic give rise to a general abstraction of facts that could arise in any emergency threatening the national security of the United States. Specifically, such a situation can be considered in the context of a bioterrorism emergency, which could be created if one of the nation's enemies were to use advanced genetic engineering techniques, such as the CRISPR-Cas9 complex, to create an organism with an artificially high lethality and contagiousness that was then released into the public. If a threat like this were to arise, the United States would need to act quickly and efficiently to find a solution, such as a vaccine or drug, and would need to rely on *cooperation* between private biotechnology corporations, *not* intellectual property litigation inspired by animosity, just as it did to find an effective vaccine during the COVID-19 pandemic.

Imagine there exists a biotechnology start-up firm, Entity A, specializing in a new technology, Widget X, that has the potential to create a single vaccine for all infectious diseases, including those that have been

have been the sole two distributors in the United States for the mRNA version. Each has since become somewhat of a household name. *See* <https://www.the-scientist.com/news-opinion/moderna-vs-pfizer-is-there-a-best-mrna-vaccine-69229>

⁵² *Id.* at 1-2.

⁵³ *Id.* at 3.

⁵⁴ *Id.* at 4.

⁵⁵ *Id.* at 6-7.

⁵⁶ *Id.* at 9.

⁵⁷ *Id.* at 9.

artificially modified for higher degrees of lethality and contagiousness.⁵⁸ Although Entity A has spent several years working on Widget X and has acquired a large patent portfolio, it has failed to make its inventions profitable. Despite efforts by venture capitalists to provide it with sufficient funds, Entity A is approaching insolvency. In a last-ditch effort to save some of its assets, Entity A decides to sell its patent portfolio on Widget X for a price much lower than its fair market value. Entity A finds a prospective seller, Non-Practicing Entity B (“NPE B”) and pitches the patent portfolio.

After several hours of negotiations with Entity A, NPE B agrees to purchase the patent portfolio in its entirety, and thus acquires any rights to enforce or license the patents. Although NPE B does not plan on practicing the inventions itself, it does plan on using the patent portfolio to threaten suit against other biotechnology firms working in the same arena. After all, NPE B’s entire business plan involves convincing small start-ups working on cutting edge technology to agree to expensive licenses to avoid the higher costs of patent litigation. Through the purchase of the patent portfolio, NPE B effectively gains control over a significant portion of the entire scientific landscape related to Widget X.

Shortly after NPE B purchases the patents, the federal government gets word of a threat posed by an international terrorist group. The group has successfully used CRISPR to create a genetically modified virus capable of killing half of all people it infects and, if released into the public, will spread rapidly. The federal government identifies this virus as a bioterrorism emergency with a significant threat to the country’s national security.⁵⁹ It rapidly begins looking for private biotechnology companies

⁵⁸ Although slightly hyperbolized, there are reports that researchers are attempting to create a single vaccine for any variant of any coronavirus. *See, e.g., Zach Sweger, New engineered proteins could be used to develop adaption-proof COVID vaccine*, PENN STATE RESEARCH BLOG (Oct. 18, 2022), <https://www.psu.edu/news/research/story/new-engineered-proteins-could-be-used-develop-adaptation-proof-covid-vaccine/>.

⁵⁹ *See generally Emergency Preparedness and Response: Bioterrorism*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://emergency.cdc.gov/bioterrorism/> (last visited Dec. 8, 2022). The government has prepared several documents to instruct first responders and lab technicians on steps to take in the event of a bioterrorism emergency. It has also prepared information for the general public on steps to take specifically in the event of an anthrax attack, smallpox attack, glanders attack, and melioidiosis attack. To give an idea of the level of severity of the virus described in the Proposed Hypothetical, this Note assumes the fictitious virus has been positively identified by lab technicians working at the Centers for Disease Control and Prevention as one which causes severe illness and death frequently and for which there is no known cure.

within the United States that have capabilities to create a powerful vaccine against the virus. It must work quickly, as it hopes to have a significant portion of the population vaccinated before the virus is unleashed on the public.

In its rapid search for a solution, the government finds Entity C, a small start-up that has been working for several years to create a revolutionary vaccine that, similar to Widget X, can prepare the body to target and kill nearly every infectious particle with which it comes in contact. Interestingly, Entity C arrived at this idea by itself – it has not heard of Entity A or its patent portfolio but read about Widget X several years prior in a journal article. Entity C has not yet started preparing the vaccine but, upon conversations with the government, believes it can incorporate the technology it has been studying for several years and have a safe vaccine ready for clinical trials within a couple of weeks. The federal government enters into a contract to purchase several million doses upon the completion of the clinical trials, which it will have distributed mostly to non-governmental healthcare facilities who will give the vaccine mostly to private citizens. Entity C immediately springs into action, using the technology it has personally studied for years. It does not give a second thought to Widget X or question whether its technology will infringe on any potential patents held by other biotechnology companies.

A few months later, Entity C has successfully completed the clinical trials and received Emergency Use Authorization from the Food and Drug Administration for the vaccine. The federal government celebrates the vaccine, telling reporters there is now a solution to the bioterrorism threat that has forced everyone to stay indoors for the last several months. The Secretary of the Department of Health and Human Services issues a declaration under the Public Readiness and Emergency Preparedness Act (“PREP Act”) declaring the vaccine a “covered countermeasure” immune to suit.⁶⁰ Entity C hires a private distribution company to send the vaccines that were purchased by the government to healthcare facilities around the country. Each healthcare facility has been approved by the government, which has ensured they are equitably distributed in rural areas, cities and suburbs alike. Hospital D, a private hospital in Missouri, does not have a contract with the government, but is on the approved list of healthcare providers and receives several hundred doses of the vaccine. Its nurses immediately begin to inoculate local patients.

Unfortunately, the supply chain lags and, despite several contract development and manufacturing organizations hard at work, the government contract ceases before all American citizens are vaccinated. Entity C decides it can improve its own facilities to up the supply of

⁶⁰ See discussion *infra* Part III.C.

vaccines and begins to enter into contracts with private healthcare facilities independently. One of these healthcare facilities is Hospital E, a small private hospital in rural Alaska, which immediately begins inoculating local residents.

Amid the chaos and before all Americans are vaccinated, NPE B sues Entity C, Hospital D, and Hospital E, alleging patent infringement for using Widget X in the vaccine and giving it to patients. Although Entity C's vaccine does not clearly infringe the Widget X patent portfolio, it arguably may fall under the scope of several claims of some of the patents.

II. EXISTING LAW

Several existing statutes may provide the defendants in each of the described suits valid defenses in the event of a national bioterrorism threat. These statutes are: (1) 28 U.S.C. § 1498, which provides for takings of patented inventions by the government; (2) the Defense Production Act (“DPA”);⁶¹ (3) the Public Readiness and Emergency Preparedness Act (“PREP Act”);⁶² and (4) the Bayh-Dole Act.⁶³ However, there is no existing legislation to clearly prevent suits of this type, there is little guidance from courts on whether such defenses would apply in these unprecedented circumstances, and the success of the defense would largely depend on several factors, including whether the accused infringer had a government contract at the time of the alleged infringement and the scope of such a contract.

⁶¹ 50 U.S.C. §§ 4501-4568

⁶² 42 U.S.C. §§ 247d-6d

⁶³ 35 U.S.C. §§ 200-212. In instances where a small business or nonprofit has accepted research funding from the federal government that gives rise to a patented invention, the Bayh-Dole Act includes a provision under § 203 that allows the government to “march in” under specific circumstances and require the patent holder to grant another applicant or the government itself a license to use the patented invention. Section 203(a)(2) contemplates such compulsory licensing specifically if “necessary to alleviate health or safety needs which are not reasonably satisfied by the [patent holder].” Although such a scenario may arise in the case of a non-practicing entity holding a patent critical to protecting national security but not using it, any march-in activity by the government would result in another entity getting a valid *license* to practice the invention. Because this Note focuses on a hypothetical situation where a license to practice a critical invention was *not* involved, it will not elaborate further on march-in rights under the Bayh-Dole Act in cases of bioterrorism and national health emergencies threatening national security.

A. 28 U.S.C. § 1498

28 U.S.C. § 1498 (a) requires the United States to pay reasonable and entire compensation when it uses and manufactures a patented invention without a license from the patent owner. It also requires any patent owner pursuing a patent infringement claim against the United States to bring the action in the Court of Federal Claims.⁶⁴ If the patent owner pursuing a patent infringement claim against the United States is an independent inventor, nonprofit organization, or entity with no more than 500 employees during the five year period prior to the accused infringing event, the United States may also be required to pay reasonable legal costs acquired from pursuing litigation, including attorneys fees.⁶⁵

Section 1498 (a) also describes who is covered when a patented invention is used to benefit the United States. Specifically, it states that, “[w]henever a [patented] invention . . . is used or manufactured *by or for the United States*,” the patent owner must pursue an action against the United States itself in the Court of Federal Claims.⁶⁶ A patented invention is used or manufactured “for the United States” when the use or manufacture of the patented invention is “by a contractor, a subcontractor, or any person, firm, or corporation [(1)] *for the Government* and [(2)] with the authorization or consent of the Government.”⁶⁷ Thus, although federal contractors and subcontractors using or manufacturing patented inventions to fulfill their obligations under their federal contracts have some immunity from suit from patent holders, Section 1498 (a) explicitly requires a federal contractor seeking immunity to show two elements: (1) that their use or manufacture of the patented invention was “for” the federal government; and (2) that the federal government authorized or consented to the infringing conduct.⁶⁸

i. *The use of the patented invention by the federal contractor must have been “for the Government.”*

Several courts have interpreted when the use or manufacture of a patented invention is “for” the federal government. Historically, Section 1498(a) has often been viewed as protecting patentees as well as the manufacturers of war materials who may have infringed on a patent while providing such materials to the government.⁶⁹ The legislative history from

⁶⁴ 28 U.S.C. § 1498 (a)

⁶⁵ *Id.* However, the court may not require the payment of such fees if it finds the United States was substantially justified in the infringement or that special circumstances exist that would make the payment of such fees unjust. *Id.*

⁶⁶ *Id.* (emphasis added)

⁶⁷ *Id.* (emphasis added)

⁶⁸ *See id.*

⁶⁹ *See, e.g.,* Richmond Screw Anchor Co. v. U.S., 275 U.S. 331, 345 (1928) (“The intention and purpose of Congress in the act of 1918 was to stimulate contractors to

the time of Section 1498(a)'s enactment generally supports the argument that the protections should be afforded to government contractors in exceptional times, specifically during wars, to ensure patent rights and takings concerns did not get in the way of the federal government trying to protect the national security.⁷⁰

However, some courts have defined “for the Government” as having broader applicability outside of times of war in situations where a federal contractor acted to benefit the government by providing a technology that enhanced the country’s national security. For instance, the Federal Circuit has found Section 1498(a) applied when three regional Federal Reserve Banks acting in conjunction with a bureau in the Department of the Treasury contracted with a private software engineering firm to create a fraud detector system for checks.⁷¹ In finding that this system was designed “for the Government,” the Federal Circuit decided that the Treasury was not a mere tangential beneficiary of the fraud detector system that happened to benefit only incidentally from the primary benefits paid to the private banks and engineering firm.⁷² Instead, it found that the Treasury directly benefitted from the more efficient technology because, in order for the fraud detector system to work, the Treasury itself needed to encode each check that was to be deposited at one of the private reserve banks.⁷³ Thus, the Treasury was not merely paying for the detector system, but also was using it by encoding the checks and benefitted from its

furnish what was needed for the war, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents. The letter of the Assistant Secretary of the Navy, upon which the act of 1918 was passed, leaves no doubt that this was the occasion for it.”)

⁷⁰ See 56 Cong. Rec. 7961 (1918) (statement of Rep. William H. Padgett) (describing the 1918 amendment to Section 1498 allowing the patentee to pursue actions by a private federal contractor against the United States instead of against the contractor itself as “necessary and urgent” to “expedite the manufacture of war material”).

⁷¹ *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, 583 F.3d 1371, 1379 (Fed. Cir. 2009); see also *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362-63 (finding the technology at issue was used “for the government” when its use by a private airline corporation improved the detection of fraudulent passports and thus enhanced border security and improved the government’s capabilities to monitor people flowing in and out of its borders). When a private entity is required to perform a quasi-governmental function that the government would otherwise have to perform itself, such an action is said to be “for the government.” *Japan Airlines*, 769 F.3d at 1362-63.

⁷² *Id.*

⁷³ *Id.* at 1373.

efficiency, so the system could be said to have been designed “for the Government.”⁷⁴

In cases where national security is not involved, courts tend to be more skeptical of finding that alleged infringing activity was “for the Government” when the beneficiaries are private individuals who use the patented invention without any intervention or decision-making by a governmental agency, who merely foots the bill. For instance, in *Larson v. U.S.*, the court found that the use of a patented splint by healthcare providers on their Medicare and Medicaid patients was not a use of a patented invention “by or for the Government,” since the only parties benefitting from the splint were the patients and their healthcare providers.⁷⁵ Although the government may have had a general interest in the care of the patients and were paying for such care, the court considered any benefit to the government to be too attenuated for Section 1498 to apply.⁷⁶ Importantly, it explicitly stated that “[m]edical care is provided for the benefit of the patient, not the government.”⁷⁷

Most recently, in the *Arbutus-Genevant* case, despite the presence of a national health emergency during the COVID-19 pandemic, the court denied Moderna’s motion to dismiss the infringement claims for failure to state a claim on Section 1498 grounds.⁷⁸ The court found that, although Moderna had an agreement with the government to supply its COVID-19 vaccine and that such supplies were intended to help support its nationwide vaccination effort, the government was only an incidental beneficiary.⁷⁹ Citing *Larson*, the court reasoned that the government only had an interest in protecting its citizens, and thus that the development of the vaccine was for America’s people rather than for the government.⁸⁰ It also pointed out that generic language in the preamble of a redacted government contract with a private entity cannot be the sole indicator of whether the use of an invention by the private entity is for the government, since allowing such would be to find that *any* project with a government contract used to

⁷⁴ *Id.* at 1379.

⁷⁵ 26 Cl. Ct. 365, 369 (Ct. Cl. 1992); *see also* *Carrier Corp. v. United States*, 534 F.2d 244, 247 (Ct. Cl. 1976) (finding that a federal contractor that used a patented device to make only *its* job easier was not a use “by or for the Government” for Section 1498 purposes, since it was not at all useful to or used by the government in carrying out its duties).

⁷⁶ *Id.*

⁷⁷ *Id.* (citing *Home Health Services, Inc. v. Currie*, 531 F.Supp. 476, 479-80 (D.S.C.1982), *aff’d*, 706 F.2d 497 (4th Cir.1983)).

⁷⁸ *Arbutus Biopharma Corp. v. Moderna, Inc.*, 2022 WL 16635341 at 7 (D. Del. Nov. 2, 2022).

⁷⁹ *Id.*

⁸⁰ *Id.*

forward a well-intentioned policy goal would be subject to a Section 1498 defense.⁸¹

ii. The government must have consented to or authorized the infringing conduct.

In determining the second element of Section 1498, courts can find that the government either explicitly or implicitly consented to or authorized the infringing conduct of a federal contractor.⁸² In a federal contract, the government can add express provisions to broadly consent to any patented invention or infringing use by the contractor, or it can expressly limit the scope of the consent, such as only consenting to infringing conduct if doing so is necessary for the contractor to meet the obligations of the contract or specifications of the government's proposed design.⁸³ In determining whether the government impliedly consented to the infringing conduct, courts generally only find such consent when the government set forth particular specifications that required the infringement of a specific patent.⁸⁴ Thus, the federal contractor generally must show that their infringing contract was necessary to meet their obligations under the contract due to the government's specific specifications and that the government had some knowledge of the infringement.⁸⁵

In the *Arbutus-Genevant* case, the court also found that Moderna had not satisfied the authorization element of the Section 1498 defense in moving to dismiss under 12(b)(6). The contract between Moderna and the government contained a broad consent provision stating that the government authorized Moderna's use of *any* patented invention in performing its obligations, including those used by Moderna in the

⁸¹ *Id. But see* Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 *Yale J. of L. & Tech.* 1, 33-39 (advocating in favor of using Section 1498 during the Covid-19 crisis and explaining its potential benefits if it were to be used during such a national health emergency).

⁸² *See, e.g., TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986) (finding government consent despite the lack of an explicit authorization or consent letter when the guidelines of the government's bidding procedure required a prospective federal contractor to display the allegedly infringing product that was at issue in the bid at a demonstration, even though the government's specifications did not absolutely require the federal contractor to infringe any patented product).

⁸³ *Madey v. Duke Univ.*, 413 F.Supp.2d 601, 608 (M.D.N.C. 2006).

⁸⁴ *Windsurfing Int'l, Inc. v. Ostermann*, 534 F.Supp. 581, 588 (S.D.N.Y. 1982).

⁸⁵ *Larson v. U.S.*, 26 Cl. Ct. 365, 370 (Ct. Cl. 1992); *see also Carrier Corp. v. United States*, 534 F.2d 244, 247-48 (Ct. Cl. 1976) (finding no government consent to infringing conduct when the contractor themselves chose to use a patented device without anything in the government contract requiring use of such a device).

“structure or composition” of the vaccine itself.⁸⁶ However, despite this seemingly broad consent, the court found that it could not rule out the possibility that other redacted provisions of the contract limited the scope of this provision.⁸⁷ Importantly, the court decided that, given the nature of the emergency which required the government to act quickly to find a vaccine, it should not decide whether the government truly consented to be liable for *any* infringing acts without a statement of interest from the government expressly stating that they intended such.⁸⁸

B. Defense Production Act

The Defense Production Act (“DPA”) was passed to ensure the government could protect the national security during “military conflicts, natural or man-caused disasters, or acts of terrorism” by having sufficient supplies necessary for national defense provided by domestic industries.⁸⁹ Title I of the DPA gives the President the authority to require federal contractors to prioritize performance of any contract deemed necessary to promote the national defense, and allows the President to require any party deemed capable of performance to accept a priority contract.⁹⁰ A contract that has been deemed necessary of prioritization includes the language “rated order.”⁹¹ When a party inevitably accepts and performs a contract

⁸⁶ *Arbutus Biopharma Corp. v. Moderna, Inc.*, 2022 WL 16635341 at 8 (D. Del. Nov. 2, 2022). The consent provision used in the government’s contract with Moderna comes from 48 C.F.R. § 52.227-1, which lays out the standard provision to be included by the government in its contracts with federal contractors.

⁸⁷ *Id.*

⁸⁸ *Compare id.* (having the effect of *requiring* a statement of interest to find authorization and consent from the government) *with Arlton v. Aerovironment, Inc.*, 2021 WL 1589302 at 9 (C.D. Cal. Apr. 22, 2021) (finding authorization and consent *first* based on the presence in the contract of the standard provision laid out in § 52.227-1 and only using the government’s statement of interest *second* as a confirmatory mechanism).

⁸⁹ 50 U.S.C. § 4502(b). “National defense” is defined in § 4552(14) to cover activities conducted for “emergency preparedness,” which is broadly defined by the Stafford Act in 42 U.S.C. § 5195(a)(3) as including “all those activities and measures designed or undertaken to prepare for or minimize the effects of a hazard upon the civilian population, [and] to deal with the immediate emergency conditions which would be created by the hazard . . .”

⁹⁰ 50 U.S.C. § 4511(a). Although not explicitly allowed in the DPA, the President has delegated the authority to require prioritization of a federal contract to heads of certain departments and agencies, including to the Secretary of Defense. *See* Exec. Order 13603.

⁹¹ U.S. DEP’T OF HOMELAND SEC.: FEDERAL EMERGENCY MANAGEMENT AGENCY, INFORMATION FOR CONTRACTORS ABOUT PRIORITY RATED ORDERS, https://www.fema.gov/disaster/defense-production-act/information-contractors-about-priority-rated-orders#Rated_Order (last visited Nov. 8, 2022). During Operation Warp Speed, President Trump used the DPA 18 times to facilitate the

requiring prioritization by the President or an agency with delegated authority, the party is given a limited scope of immunity in Section 4557 of the DPA for actions taken to comply with the prioritization requirements, including for conduct complying with orders later deemed to be invalid.⁹²

C. Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act (“PREP Act”) allows the Secretary of the Department of Health and Human Services (HHS) to issue a declaration for specific countermeasures able to fight against a public health threat and grant immunity “with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.”⁹³ The PREP Act broadly defines “loss” to cover “any type of loss,” but explicitly includes death; physical, mental, or emotional injury; fear of physical, mental, or emotional injury; and loss of or damage to property.⁹⁴ However, the “loss” must have “a causal relationship with the administration to or use by an individual of a covered countermeasure,” such as by having a causal relationship with the design, development, manufacture, formulation, sale, administration, or use of the countermeasure.⁹⁵ Additionally, the countermeasure causing the loss must have been: (1) “administered or used” during the effective period of the

production of a Covid-19 vaccine. Press Release, Donald J. Trump, President, Statement from the Press Secretary on Operation Warp Speed (Dec. 29, 2020), <https://trumpwhitehouse.archives.gov/briefings-statements/statement-press-secretary-123020/>. Given the redacted nature of the vaccine contracts available to the public, it is unclear exactly how the DPA was used in the process. Sydney Lupkin, *Defense Production Act Speeds Up Vaccine Production*, NPR (Mar. 13, 2021, 7:00 AM), <https://www.npr.org/sections/health-shots/2021/03/13/976531488/defense-production-act-speeds-up-vaccine-production>. However, a former spokesperson for the Office of the Secretary of Defense has released a statement that all six Covid-19 vaccine contractors, include Moderna and Pfizer, received government contracts with a priority rating. Lisa Simunaci, *Defense Production Act is shot in the arm for Warp Speed’s mission*, DVIDSHUB (Dec. 31, 2020), <https://www.dvidshub.net/news/386211/defense-production-act-shot-arm-warp-speeds-mission>.

⁹² 50 U.S.C. § 4557. Courts have largely decided how such immunity would apply in cases involving alleged torts committed by federal contractors when carrying out prioritization contracts. *See, e.g., In re Agent Orange Product Liability Litigation*, 597 F.Supp. 740, 845 (E.D.N.Y. 1984) (finding immunity did not apply to chemical companies who manufactured Agent Orange during the Vietnam War and caused injuries to war veterans). As of this writing, they have yet to decide how immunity under § 4557 would apply to federal contractors accused of patent infringement.

⁹³ 42 U.S.C. § 247d-6d(a)(1)

⁹⁴ 42 U.S.C. § 247d-6d(a)(2)(A) (emphasis added)

⁹⁵ 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis added)

declaration for that specific countermeasure, and (2) “administered or used” for the disease specified in the declaration.⁹⁶

Courts have started to interpret the PREP Act in the context of the COVID-19 public health emergency.⁹⁷ In the only patent infringement case invoking the PREP Act as a defense and moving for dismissal for failure to state a claim at the pre-answer filing stage, the court did *not* determine that the PREP Act unequivocally does *not* apply to patent infringement cases.⁹⁸ However, the court ultimately denied the defendant’s motion to dismiss on the grounds that, before any discovery, the record was not yet clear whether the accused product itself, a special type of nasal swab, was a “covered countermeasure.”⁹⁹ Specifically, the court looked to a letter from the Food and Drug Administration (FDA) approving emergency use authorization of a COVID-19 test that included the accused nasal swab, which would have been used in conjunction with the test.¹⁰⁰ Although the defendants argued that emergency use authorization by the FDA made the COVID-19 test a “covered countermeasure” for purposes of PREP Act immunity, the court refused to find that the emergency use authorization extended to the accused nasal swab itself, and thus could not find that the nasal swab was a “covered countermeasure.”¹⁰¹

The court also considered a government contract between the defendant and the Air Force, which explicitly included a clause stating that the defendant’s test kit was a “covered countermeasure” and thus the defendants were immune to suit under the PREP Act.¹⁰² Again, although the accused nasal swab was a necessary part of the test kit, the court refused to find that it was the “covered countermeasure” immune to suit under the PREP Act.¹⁰³ Additionally, although the Air Force added the provision to

⁹⁶ 42 U.S.C. § 247d-6d(a)(2)(3)(A)-(B). The PREP Act creates a rebuttable presumption that any administration or use of a countermeasure covered by a declaration is for the disease specified by the declaration. § 247d-6d(a)(6).

⁹⁷ Several cases have considered whether the PREP Act preempts state law tort claims in cases against adult residential facilities arising out of Covid-related deaths. *See, e.g., Feliciano v. Wayne Ctr.*, 2022 WL 16636607 at 1 (S.D.N.Y. Nov. 2, 2022).

⁹⁸ *See generally Copan Italia S.p.A. v. Puritan Medical Products Company, LLC*, 2022 WL 1773450 (D. Me. Jun. 1, 2022) (denying defendant’s motion to dismiss on other grounds). As of the time of this writing, however, courts have not yet affirmatively determined, either in Covid-related litigation or otherwise, that the PREP Act *does* provide an accused infringer immunity in a patent litigation suit, even if all prerequisite conditions are met.

⁹⁹ *Id.* at 5.

¹⁰⁰ *Id.* at 3-4.

¹⁰¹ *Id.* at 4.

¹⁰² *Id.*

¹⁰³ *Id.*

the contract, the court did not grant any deference to them, since the Air Force is not the branch responsible for administering the PREP Act.¹⁰⁴

III. ARGUMENTS AND RECOMMENDATIONS

In patent litigation, a successful pre-answer motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure is particularly helpful in preventing future unnecessary and expensive litigation.¹⁰⁵ If expectations and obligations of federal contractors and those acting to further the government’s national security interests were clear to patent holders who were aware that any suits filed against such entities would be unsuccessful during a public health emergency or bioterrorism scenario, there would likely be fewer patent infringement suits during these critical time periods.¹⁰⁶ In the unlikely event that an infringement suit *were* filed, clear guidance from policymakers would allow courts to dismiss cases with obvious defenses under a Rule 12(b)(6) motion for failure to state a claim.

Dismissing cases in the early stages is not only beneficial for the accused infringers who would otherwise have to defend themselves. Instead, when the country’s national security is threatened, the government and its people are perhaps the parties *most* benefitted by giving key protectors grace and allowing them to continue to work to defend the public’s health.¹⁰⁷ However, the cases coming out of the COVID-19 pandemic make clear that courts are allowing patent infringement cases to continue beyond the Rule 12(b)(6) phase,¹⁰⁸ despite the dangers to national

¹⁰⁴ *Id.*

¹⁰⁵ See Eric Levi, *Five Years after Form 18: Post-Iqbal–Twombly Rule 12(b)(6) and 12(c) Motions to Dismiss Patent Infringement Claims*, IPWATCHDOG (Jun. 3, 2021, 12:15 PM), <https://ipwatchdog.com/2021/06/03/five-years-form-18-post-iqbal-twombly-rule-12b6-12c-motions-dismiss-patent-infringement-claims/id=134198/> (“Fed. R. Civ. P. 12(b)(6) and 12(c) motions have developed into a targeted, widely-used tactic. Both motions provide defendants with a low-risk, high-reward opportunity.”)

¹⁰⁶ AUSTRALIAN GOV’T ATT’Y GEN. DEP’T, CLEARER COMMONWEALTH LAWS: CAUSES OF COMPLEX LEGISLATION AND STRATEGIES TO ADDRESS THESE 1 (2014), <https://www.ag.gov.au/legal-system/publications/causes-complex-legislation-and-strategies-address-these> (“Complex legislation makes it difficult, expensive and time-consuming for people to understand their legal rights and obligations. This creates burdens for business and restricts access to justice.”).

¹⁰⁷ See, e.g., Oliver J. Watson et al., *Global impact of the first year of COVID-19 vaccination: a mathematical modelling study*, 22 LANCET 1293, 1296 (2022) (estimating that, during the COVID-19 pandemic, 18.1 million deaths were averted because of successful vaccines).

¹⁰⁸ See, e.g., *Arbutus Biopharma Corp. v. Moderna, Inc.*, 2022 WL 16635341 at 7 (D. Del. Nov. 2, 2022) (“At this early stage of the litigation, I find this case more akin to *Larson* . . . Based on the allegations of the Complaint, which I must

security inherent in a public health emergency. Thus, given the existing legal framework, it is not at all clear that a public hero working to defend the country from an artificially modified virus posing a bioterrorism threat would be granted any kind of immunity from patent infringement allegations brought by a non-practicing entity seeking to capitalize on the vulnerabilities of a nation under attack.

A. Entities With Federal Contracts

The existence of contracts with the federal government to provide private individuals tools to combat a viral threat creates additional possibilities of defenses in patent infringement suits brought against Entity C in the proposed hypothetical, and Moderna and Pfizer in the COVID-19 cases. However, despite seemingly clear language in the government contract with Moderna, the District of Delaware has *still* refused to dismiss the case under a Section 1498(a) analysis, finding that both elements of the Section 1498(a) defense had not been met for purposes of a 12(b)(6) motion.¹⁰⁹ Accordingly, in an effort to prepare for enhanced protections of the national security during a future bioterrorism event, lawmakers should see COVID-19 litigation as reason to clarify both the scope of Section 1498(a) and Section 4557 of the Defense Production Act (DPA) to ensure each provides immunity to accused patent infringers during a national public health emergency.

i. Section 1498(a) Analysis Under Existing Law

The *Genevant-Arbutus* case makes clear that, as is, Section 1498(a) will not provide a surefire defense to accused infringers just because they have a contract with the federal government to provide private individuals with biodefense mechanisms during a national emergency.¹¹⁰ Consequently, Entity C in the proposed hypothetical should not assume that merely attaching a redacted government contract to a Rule 12(b)(6) motion will make a patent infringement case dissipate, even if clear and unredacted provisions in the attached contract grant Entity C immunity.

First, under the *Arbutus* reasoning, even if a government contract with Entity C stated that Entity C was acting to further a national security policy by producing vaccines to lead a nationwide vaccine effort, a court would likely struggle to find that this language demonstrated the benefit

accept as true, the development and sale of the vaccines was for the benefit of the vaccine's recipients.”)

¹⁰⁹ *Id.*

¹¹⁰ *See id.* (“Absent clear language, either in the Complaint or the Contract, establishing that the development of the vaccine was “for the Government,” I find that this dispute is not appropriate for resolution in a Rule 12(b)(6) motion. As noted above, section 1498(a) is an affirmative defense rather than a jurisdictional bar.”).

was “for the government” as required by the first element of Section 1498(a).¹¹¹ Moreover, because Entity C is providing a vaccine for the American people, the *Arbutus* reasoning would prohibit this benefit as being “for the government.”¹¹² Instead, a court would find that the direct beneficiaries are private individuals. Although a government policy protecting the national security is incidentally forwarded by private individuals receiving the vaccine, the *Arbutus* reasoning would mandate finding such a benefit to be merely incidental, resulting from the direct benefits provided to individual vaccine recipients.

The *Arbutus* court and future courts dealing with patent infringement cases in national health emergencies should rethink its analogy to *Larson*, and instead consider analogizing these fact patterns to *Advanced Software*. Although *Larson* also dealt with private individuals receiving health benefits from private healthcare facilities, the similarities to the factual situation in a bioterrorism threat end there.¹¹³ Unlike the accused product in *Larson*, the accused product being produced by Entity C in the proposed hypothetical is a vaccine to prohibit a deadly virus from spreading throughout the country and wiping out entire towns and cities. Unlike an elderly person on Medicare who receives a sling for a fractured arm, a lethal virus unleashed by an international terrorist group does not only threaten the wellbeing of a single person who fell down the stairs; it threatens the entire country, hence the designation of a bioterrorism threat as a danger to the country’s national security.

Moreover, as a democracy, the American government is entirely composed of its people.¹¹⁴ If there were a deadly virus spreading through cities and towns, it would infect the households of government employees and private individuals alike. Without its people, there would be no American government. Accordingly, to analogize a national biodefense tool

¹¹¹ See *id.* at 6 (noting the language of Moderna’s contract that explicitly states that “[t]he Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population”). Nevertheless, the court refused to find that this clear language supported a finding that the benefit of the vaccines was “for the government.” *Id.* at 7.

¹¹² See *Id.* at 6-7.

¹¹³ See generally *Larson v. U.S.*, 26 Cl. Ct. 365 (Cl. Ct. 1992) (finding beneficiaries of Medicare and Medicaid programs receiving patented slings were not directly benefitting the government).

¹¹⁴ See *Human Rights Themes: Democracy*, COUNCIL OF EUROPE, <https://www.coe.int/en/web/compass/democracy> (last visited Dec. 8, 2022). The term “democracy” translated to Greek literally means “people power” or “power of the people” and thus derives its power directly from the will of its constituents.

to a sling for a single elderly person with a non-communicable illness is akin to comparing apples to oranges – they are both medical devices, but the similarities in terms of their purposes end there. Thus, a court should easily find that vaccines stopping the annihilation of the American people are much more similar to the fraud detector system in *Advanced Software*.¹¹⁵

Second, under the *Arbutus* reasoning, even if the government were to include its standard language under FAR 52.227-1 “authorizing and consenting” to Entity C using *any* patented invention when performing the contract and this unredacted language were included in the contract attached to a Rule 12(b)(6) motion, Entity C could *still* not rely on a court finding the government “authorized and consented” to the use of Widget X in developing the vaccine.¹¹⁶ Particularly, under *Arbutus*, a court may find that the very existence of a bioterrorism emergency put the government in such a position as to be unable to consent to using Widget X in the development of Entity C’s vaccine.¹¹⁷

However, it is exactly during a bioterrorism emergency that such “authorization and consent” should be found. With Section 1498’s entire purpose being to incentivize the development of national defense technologies during national emergencies,¹¹⁸ finding that the government was in a forced situation during such an emergency and unable to consent to suit would run completely contrary to this purpose. A government contract with the standard authorization and consent provisions would give a biotechnology company, like Entity C, while operating in the midst of a crisis, some reassurance that it could do what it needed to provide a biodefense to the American people and thus protect the national security. Following the *Arbutus* reasoning and finding that Entity C did not, in fact, have immunity when working under emergency conditions would not only upset the expectations of Entity C. It would discourage future government contractors from using cutting-edge, critical technology out of fear of not

¹¹⁵ See *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, 583 F.3d 1371, 1379 (Fed. Cir. 2009) (finding the Treasury benefitted from the fraud detector system because it was able to do its job more efficiently).

¹¹⁶ See *Arbutus Biopharma Corp.*, 2022 WL 16635341 at 8 (emphasis added) (internal citations omitted) (“Although the incorporation of FAR 52.227-1 in contracts has been deemed to constitute “authorization and consent,” even express authorization and consent may be limited by other clauses in a contract. The contract before me here is incomplete and heavily redacted. While Moderna posits that all of the relevant portions of the contract are available, *any ruling as to authorization and consent would be premature given that it remains unsettled whether the Government, in seeking to hasten the development of a vaccine, actually consented to the use of a patented invention and agreed to accept any liability for such use.*”).

¹¹⁷ See *id.*

¹¹⁸ See *Richmond Screw Anchor Co. v. U.S.*, 275 U.S. 331, 345 (1928).

being protected from a patent infringement suit, even if the patented technology could save thousands of lives.

ii. Section 4557 Analysis Under Existing Language of Defense Production Act

If the government’s contract with Entity C were issued under an Executive Order by the President and marked as a “rated order,” Entity C may be able to raise a defense under Section 4557 of the DPA when accused by NPE B of infringing Widget X’s patent portfolio.¹¹⁹ However, because courts have not yet decided how Section 4557 would apply in a patent infringement suit, and such a defense would depend on a federal government contract being a rated order, Entity C could not rely *ex ante* on this defense.

iii. Policy Proposals

Lawmakers should consider the potential power of both a Section 1498(a) defense and a Section 4557 defense at the motion-to-dismiss stage of a patent litigation lawsuit and consider clarifying the scope of each as they relate to patent infringement during an active national security threat. For instance, lawmakers should consider acting to both Section 1498 and Section 4557 a process for an *in-camera* review of the non-redacted contract at the motion-to-dismiss stage. If, based on the redacted nature of a government contract, courts struggle to determine whether the FAR 52.227-1 provision in a contract truly “authorizes and consents” to a federal contractor’s use of any patented invention in carrying out its obligations, the court should have access to a non-redacted version. Although federal contracts may themselves contain pertinent national security information, courts have used *in-camera* review processes to preview classified documents in other arenas of national security litigation.¹²⁰

Lawmakers should also consider revising whether Section 1498(a) requires, at the motion-to-dismiss stage, the government to file a statement of interest indicating its express consent of the infringing activities. In *Arbutus*, the court appeared to make this statement of interest a *requirement*.¹²¹ However, nothing in Section 1498(a) explicitly or implicitly requires the government to file a statement of interest a condition of finding consent or authorization. Absent express wording in the contract or the FAR 52.227-1 provision, the legislature should also consider adding a list of factors that courts can use to determine whether the government “consented

¹¹⁹ See *supra* Part III.B.

¹²⁰ See, e.g., 50 U.S.C. § 1803(e)(2); FISA Ct. R. 30 (in camera review) (describing how the Foreign Intelligence Surveillance Court conducts review of FISA petitions in camera).

¹²¹ *Arbutus*, 2022 WL 16635341 at 8 (emphasis added).

or authorized” the infringing conduct. This list may, and should, consider the exigencies of the situation, whether the government participated in the planning of the invention’s design, whether representatives from the government supervised the project or visited the manufacturer’s facilities, and whether the government had any *ex ante* knowledge that completing the contract would require infringing on an issued patent.¹²² Such factors would continue to allow courts discretion in deciding whether to find authorization or consent by the government, based on available evidence at the time the defense is raised, but would give them some guidance on what constitutes a high enough level of authorization or consent to warrant invoking Section 1498(a) as a defense dismissing a claim against the accused infringer.

B. Entities Without Federal Contracts or With Ceased Federal Contracts

i. Analysis Under the PREP Act

For accused infringers who are (1) healthcare providers without government contracts, like Hospitals D and E in the above hypothetical, or (2) biotechnology companies working outside of the scope of their federal contracts, such as when Entity C sells vaccines not covered by any existing federal contract directly to private healthcare facilities who will administer the vaccine, the best early defense in a patent infringement suit would likely arise under the PREP Act, since Section 1498(a) and the DPA each require the existence of a valid federal contract.¹²³ However, such a defense at the motion-to-dismiss stage likely would not be successful, given the interpretation of a “covered countermeasure” by the only court applying the PREP Act as a defense in a patent infringement suit.¹²⁴

As currently interpreted, the “covered countermeasure” described in the declaration by the Secretary of the Department of Health and Human Services, and thus immune to suit, must be the accused product itself.¹²⁵ It is not enough for the accused product to be a *component* of the covered

¹²² See Morten & Duan, *supra* note 81, at 50 (describing the four factors that will determine whether §1498 will be advantageous as being “(1) speed, (2) flexibility, (3) ex post determination of the appropriate compensation . . . , and (4) determination of that compensation by an impartial adjudicator”). The proposed factors take into consideration the Morten & Duan factors predicting whether §1498 will be more advantageous over other potential mechanisms.

¹²³ See *supra* Part III.

¹²⁴ For reference, in this scenario, Hospitals D and E would likely be accused of direct infringement for using a patented invention under 35 U.S.C. § 271(a). Entity C would likely be accused of indirect infringement under 35 U.S.C. § 271(b) or (c) for actively inducing direct infringement by the hospitals or contributing to their direct infringement by selling them the accused product.

¹²⁵ See *supra* Part III.C.

countermeasure. In *Copan Italia S.p.A. v. Puritan Medical Products Company*, the court denied a motion to dismiss for failure to state a claim, finding that the “covered countermeasure” described in the declaration by the Secretary of the Department of Health and Human Services was the COVID-19 test itself, but *not* the swab necessary to carry out the test.¹²⁶ Similarly, in the proposed hypothetical, the part of the vaccine accused of the infringement was a specific piece of technology used in the vaccine. Although that technology may be necessary for the vaccine to function, the Secretary in the proposed hypothetical declared the “covered countermeasure” to be the vaccine itself, not the patented technology used in it. Accordingly, accused infringers merely attempting to protect the public from a deadly threat from one of the nation’s many enemies would be highly dependent on the definition in the declaration by the Secretary of the Department of Health and Human Services of a “covered countermeasure.”

Under the reasoning of the court in *Copan Italia*, a similar result would likely arise if Moderna were to raise the PREP Act as a defense at the motion-to-dismiss stage. There, the lipid particle technology accused of infringement was merely used in the vaccine to carry the mRNA particles to the target cells.¹²⁷ Thus, although that allegedly patented technology was necessary for the vaccine to work correctly, it is the vaccine itself that received Emergency Use Authorization by the FDA and therefore is the “covered countermeasure” under the reasoning of *Copan Italia*.¹²⁸ It is not immediately clear that a court would consider the lipid particle technology to also be a “covered countermeasure” itself.

Interestingly, the court in *Copan Italia* did not consider the language of the PREP Act at all in interpreting the “covered countermeasure” to only include the test kit but not the accused product necessary for the test kit to function.¹²⁹ If it had, perhaps it would have reached a different result. Several word choices in the PREP Act point toward the “covered countermeasure” broadly encompassing the technologies necessary for it to properly function. For instance, although

¹²⁶ *Copan Italia S.p.A. v. Puritan Medical Products Company, LLC*, 2022 WL 1773450 at 3-4 (D. Me. Jun. 1, 2022).

¹²⁷ Complaint for Patent Infringement & Demand for Jury Trial at 10-11, *Arbutus Biopharma Corp. v. Moderna, Inc.*, No. 22-252 (filed Feb. 28, 2022).

¹²⁸ *See, e.g.*, Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022) (referring to the “covered countermeasures” generally as the COVID-19 vaccines but not referring to any of the technology necessary for their administration).

¹²⁹ *See generally id.* at 3-4 (considering only the language of government contract but not directly looking to the language of the PREP Act).

there must be a “causal relationship” between the claim for loss and administration or use of a covered countermeasure, the PREP Act explicitly states that the loss can arise out of the design and formulation of that countermeasure.¹³⁰ Presumably, a loss arising from use of a patented invention that is part of the “design” or “formulation” of a covered countermeasure would be immune to suit under this section, even if the declaration did not explicitly define the use of the patented invention itself as part of the countermeasure.

Moreover, the court’s reasoning in *Copan Italia* did not consider the entire policy behind the PREP Act: to grant entities protecting the public from a health threat protection from crippling lawsuits and thus incentivizing their participation in forwarding a governmental policy protective of the country’s national security.¹³¹ If it had, it would have recognized that only providing immunity from suit for the precise “covered countermeasure,” but *not* for any patented technologies used by the countermeasure to fulfill its purpose, would not give entities engaged in the fight against a biohazard much immunity *at all*. In fact, entities fighting against a bioterrorism threat may be prone to use more traditional, less cutting-edge technology if they knew that only the stated countermeasure itself were immune to suit, but not any of the patented technologies used to make the countermeasure successful. For instance, Entity C may use an old existing technology no longer covered by a patent to create the vaccine, instead of implementing its modern technology that arguably infringed on the Widget X patent portfolio, since patented technology that is not explicitly the stated countermeasure itself is not covered by a PREP Act defense under *Copan Italia*. Such a philosophy would lead to an incredible risk to the national security if threatened by a bioterrorism event.

ii. Policy Proposals

Although the PREP Act lays solid groundwork for patent infringement immunity during a national health threat, it leaves several questions for courts attempting to interpret its scope. Accordingly, lawmakers should take steps to clarify how it applies to entities developing and using novel inventions by making two key changes.

First, although not at issue in the *Copan Italia* case, lawmakers should add a provision defining loss to include *intellectual* property loss.

¹³⁰ 42 U.S.C. §247d-6d(a)(2)(B).

¹³¹ Statement from the Press Secretary, 2020 WL 1164298 at 1 (Mar. 11, 2020) (“The Secretary of Health and Human Services has already taken bold steps to incentivize the development of vaccines, therapeutics and other products and expand the availability of other needed products to address COVID-19 by issuing a declaration under the Public Readiness and Emergency Preparedness (PREP) Act.”)

Currently, the PREP Act extends immunity to “loss[es] of or damage to property, including business interruption loss.”¹³² However, in practical guidance pieces, some patent litigators still question whether this “property” loss includes losses of intellectual property, such as monetary losses from patent infringement.¹³³ Accordingly, an entity, like a healthcare provider, may be immune to a *tort* suit for negligently injecting a patient as an incentive to further the government’s national security objective of inoculating patients against a deadly virus. Nevertheless, it does not necessarily follow that the same entity would be immune to a *patent infringement* suit for forwarding the same government objective, since losses from patent infringement are generally purely monetary.

Second, since it is not unequivocally clear that courts will interpret “covered countermeasures” to include the patented technology needed to execute them,¹³⁴ lawmakers should consider clarifying what must be included in the Secretary’s declaration that will provide manufacturers and healthcare providers sufficient immunity. For instance, in the definition of a “covered countermeasure” in § 247d-6d(i)(1), it should explicitly state that any countermeasure approved by the Secretary includes “any patented device or technology used by the countermeasure to achieve its purpose.” Lawmakers should also consider amending the definition of a “qualified pandemic product” in § 247d-6d(i)(7) to add a similar disclaimer.¹³⁵

In making these reforms, lawmakers need to consider constitutional concerns of taking intellectual property.¹³⁶ As the agency responsible for

¹³² 42 U.S.C. §247d-6d(a)(2)(A)(iv).

¹³³ See, e.g., Joseph Evall, Richard Mark and Amanda First, *Don’t Count On PREP Act To Defend Pandemic IP Infringement*, LAW360 (Jul. 2, 2020) (finding that, although lost profits from patent infringement could be considered “damage” to property, one would typically not consider purely monetary damages as property damage) (citing *Berry Plastics Corp. v. Illinois Nat’l Ins. Co.*, 903 F.3d 630, 636 (7th Cir. 2018) (finding economic losses differ from “property damage”)).

¹³⁴ See *Copan Italia S.p.A. v. Puritan Medical Products Company, LLC*, 2022 WL 1773450 at 3-4 (D. Me. Jun. 1, 2022).

¹³⁵ Under § 247d-6d(i)(1), “covered countermeasures” may include “a qualified pandemic or epidemic product.” Under § 247d-6d(i)(7), a “qualified pandemic or epidemic product” includes “a product or technology intended to *enhance* the use or effect of a drug, biological product, or device” that would be used to prevent a pandemic (emphasis added). However, what it means for a product or technology to “enhance” a device used to prevent a pandemic is unclear.

¹³⁶ See *Horne v. Department of Agriculture*, 576 U.S. 350, 359-60 (2015) (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)) (“[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation,

issuing a declaration of immunity under the PREP Act, perhaps the Department of Health and Human Services could coordinate with the Patent and Trademark Office to add a small annual fee onto issued patent applications to be collected for the term of a valid patent. These fees could be pooled together into an account that could pay patent holders in the event that a party infringes their patent during a national health emergency or bioterrorism threat while forwarding a national security interest. With this type of fee arrangement plan, although some patent holders would still include NPEs not utilizing their patent protections to forward any national security interest, at least these NPEs would be contributing annually to a pool of money that ultimately allows entities to work to end a health threat without fear of a patent infringement suit.

CONCLUSION

Since the country's birth, property ownership has historically been viewed as a distinct example of American liberty and freedom.¹³⁷ Intellectual property is generally portrayed with similar patriotic values, as it gives American companies a competitive edge by incentivizing them to create some of the most advanced technology in the world.¹³⁸ However, America's national security should not yield to intellectual property protections. Accordingly, lawmakers should consider *ex ante* how patent protections on national defense inventions will yield during national emergencies to give grace to entities working to preserve the national security. As we come out of a nationwide pandemic and begin to consider the consequences of ambiguous statutes in current patent litigation suits, there is no better time than the present to pursue reform in striking a balance between national security interests and intellectual property protections.

any more than it can appropriate or use without compensation land which has been patented to a private purchaser.”)

¹³⁷ See generally Charles A. Reich, *The New Property*, 73 *YALE L.J.* 733 (1964) (defending property rights in America under the rationale that they promote individual freedoms).

¹³⁸ See Iancu and Kappos, *supra* note 13.