

## Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic

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### I. INTRODUCTION

Classic patent theory relies on an incentive model to justify the grant of exclusionary patent rights.<sup>1</sup> Under the model, potential patent rights provide an incentive to those who would set about the task of innovating. In constitutional language, this incentive operates to “promote the progress” in the “useful arts.”<sup>2</sup> Patents are only one tool of innovation policy, and we regularly find innovation even in the absence of any direct governmental sponsorship or activity.<sup>3</sup> In this essay, I focus on the role of patents in relation to a potential global crisis such as an influenza pandemic or other public health crisis.

Part II considers the reality that patent rights will be largely ignored during an epidemic and that any post-crisis compensation would likely be low when compared to traditional patent rewards or settlements entered under threat of injunctive relief. In some situations, such as use of a patented invention by a state or local government, a patentee may have no recourse.<sup>4</sup> Part III raises a separate issue that stems from the relatively long time frame for obtaining

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<sup>1</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 11–12 (2003); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–30 (1989); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977) (incentive to invent).

<sup>2</sup> U.S. CONST. art. III, § 8, cl. 8.

<sup>3</sup> See, e.g., Kal Raustiala & Christopher Sprigman, *The Piracy Paradox: Innovation and Intellectual Property in Fashion Design*, 92 VA. L. REV. 1687 (2006).

<sup>4</sup> See *infra* notes 28–32.

patent rights as compared with the time frame of an epidemic. Patent rights are only obtained through the typically slow process of patent prosecution. Consequently, innovation triggered by the onset of an epidemic might not be protected by patent rights until well after the crisis has abated. This realization suggests that the role of patents rests with longer-term preparation and follow-up, rather than with protecting innovations triggered by the specific crisis itself. Part IV considers how these diminished patent rights alter the incentive to innovate. As foreshadowed, I conclude that patent rights offer little innovation incentive in the face of an impending crisis. Optimistically, under this same formulation, patents may provide an incentive to ensure that the crisis is never realized. Part V recognizes that innovation still takes place in the absence of enforceable patent rights. A wide variety of incentives play a role in producing innovation, and reduced patent value does not mean that innovation will end or necessarily be reduced. I suggest that the absence of strong patent rights may well be good for crisis policy.

For brevity, this essay primarily focuses on treatment of practical and legal issues within the borders of the United States. The title of the essay, “Nil,” is a bald overstatement, although some nuance is required before discovering the value of patents in a global crisis such as an influenza pandemic. With hope, the value comes in helping to generate innovations that aid in preparing for these crises and prevent such crises from ever being realized.

## II. PATENTS AS NON-ENFORCEABLE RIGHTS DURING AN EPIDEMIC

The political reality is easy to understand. Governments have taken significant steps to combat health crises in the past, and will not avoid the temptation to ignore patent rights when an underlying innovation is needed to respond to a crisis such as a health related epidemic.<sup>5</sup> I postulate a formula—that during a public health crisis the government will ignore any patent rights if (1) the patented technol-

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<sup>5</sup> See generally *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (upholding as constitutional a Massachusetts law authorizing a city or town to make smallpox vaccinations mandatory for all residents); Ernest B. Abbott, *Law, Federalism, the Constitution, and Control of Pandemic Flu*, 9 ASIAN-PAC. L. & POL'Y J. 185, 186–204 (2008) (evaluating the scope of government authority to protect from a public health emergency); Christopher T. Nidel, *Public Health, Hypocrisy, and Brown-Skinned People*, 59 FOOD & DRUG L.J. 355 (2004) (discussing the ability of sovereign governments to use their police powers to remove private rights to combat a public health crisis); J. Kelly Strader, *Criminalization as a Policy Response to a Public Health Crisis*, 27 J. MARSHALL L. REV. 435 (1994) (discussing government actions to criminalize activities which increase the threat of HIV exposure).

ogy will aid in resolving the crisis and (2) a favorable license is not readily available. In the United States, the Supreme Court arguably endorsed such a doctrine in its 2006 decision in *eBay Inc. v. MercExchange, LLC*.<sup>6</sup> *eBay* formalized the notion that a court must consider the public impact before issuing an injunction to block infringing activities.<sup>7</sup> Before *eBay*, injunctive relief was regularly awarded as a matter of course once the patentee proved infringement of a valid patent. Yet, in those heady days of strong exclusionary rights, public health concerns could still be sufficient to lead a court away from issuing injunctive relief.<sup>8</sup> For example, in *City of Milwaukee v. Activated Sludge, Inc.*, the Seventh Circuit denied the patentee's request for injunctive relief, even though the patent had been deemed valid and infringed.<sup>9</sup> According to the court, the proposed relief of shutting down the infringing sewage treatment process would have wreaked too much havoc on the public interest:

If . . . the injunction ordered by the trial court is made permanent in this case, it would close the sewage plant, leaving the entire community without any means for the disposal of raw sewage other than running it into Lake Michigan, thereby polluting its water and endangering the health and lives of that and other adjoining communities. . . . [W]here, as here, the health and the lives of more than a half a million people are involved, we think no risk should be taken, and we feel impelled to deny appellee's contention.<sup>10</sup>

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<sup>6</sup> See 547 U.S. 388 (2006).

<sup>7</sup> See *id.* at 391; see also Julie A. Burger & Justin Brunner, *A Court's Dilemma: When Patents Conflict with Public Health*, 12 VA. J.L. & TECH. 7, ¶¶ 71–127 (2007), [http://www.vjolt.net/vol12/issue4/v12i4\\_a1-Burger.pdf](http://www.vjolt.net/vol12/issue4/v12i4_a1-Burger.pdf) (suggesting mechanisms for extending the public interest factor); Henry E. Smith, *Institutions and Indirectness in Intellectual Property*, 157 U. PA. L. REV. 2083, 2131 (2009) (suggesting that the public interest factor is treated as a narrowly applied “safety valve”).

<sup>8</sup> See *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* Ethicists and theologians have argued that a patent holder is ethically obligated to open access to needed inventions during special emergencies. See Gabriel J. Michael, *Catholic Thought and Intellectual Property: Learning from the Ethics of Obligation*, 25 J.L. & RELIGION (forthcoming Spring 2010), available at <http://ssrn.com/abstract=1349769>. Beyond ethics, in a true major public health crisis, it is unlikely that a company with an ongoing business interest—especially a pharmaceutical company with close governmental-regulatory ties—would seek injunctive relief unless the patentee was convinced that it could supply the entire market without complaints of access. In line with this rule of marketing, some patentee litigants have elected to request only continuing damages for ongoing infringement rather than seeking permanent injunctive relief. For instance, in a suit charging Eli Lilly with infringement for the sale of its osteoporosis drug Evista, the plaintiffs only

*City of Milwaukee* is an older case. A more recent example directly related to health epidemics involved Bayer's patent on Ciprofloxacin ("Cipro").<sup>11</sup> In 2001, Congress and President George W. Bush's administration were reported to have seriously considered "breaking" Bayer's patent on Cipro in order to stockpile the drug against a potential anthrax attack.<sup>12</sup> Instead, the federal government reportedly used the threat of breaking the patent to negotiate a long-term contract with Bayer at an unusually low price.<sup>13</sup> This approach might be termed "bending" the patent, as discussed below.

The Cipro case is important because it may help define the ambiguous terms "crisis" and "epidemic" within political realities. The "crisis" in the Cipro case was not an immediate need for medication to treat affected persons, but was instead a desire to stockpile medication in preparation for a potential threat. In the end, the threat did not materialize and no stockpile was necessary. In hindsight it appears that the crisis, like many health crises of the past, was primarily a political crisis.<sup>14</sup> The Cipro case also helps reflect on the notion that, in order to avoid a "broken" patent, the offered license must be favorable for the government.<sup>15</sup>

None of the reported post-*eBay* injunctive relief decisions involve either governmental infringement or a potential crisis-like need. Yet, even without those indicators, courts have denied injunctive relief in

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sought "monetary damages, including but not limited to a reasonable royalty for Defendant Lilly's current and future infringement." Complaint at 2, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 529 F. Supp. 2d 106 (D. Mass. 2005) (No. 02-cv-11280), 2002 WL 33027597.

<sup>11</sup> *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (discussing the patent in relation to allegedly anticompetitive settlement agreements), *cert. denied*, 129 S. Ct. 2828 (2009).

<sup>12</sup> Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 126-27 (2002).

<sup>13</sup> *Id.* at 127.

<sup>14</sup> *Cf.* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 393-95 (2d ed. 2008) (discussing the political background of the 1976 swine flu immunization program); RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE EPIDEMIC THAT NEVER WAS: POLICY-MAKING AND THE SWINE FLU SCARE 27-28 (rev. ed., Vintage Books 1983) (1982) (same); N. Pieter M. O'Leary, *Bioterrorism or Avian Influenza: California, The Model State Emergency Health Powers Act, and Protecting Civil Liberties During a Public Health Emergency*, 42 CAL. W. L. REV. 249, 280-85 (2006) (discussing specific limits in a proposed California Emergency Health Powers Act that may limit political overreaching).

<sup>15</sup> Admittedly, external factors such as regulatory capture or governmental leadership ineffectiveness may alter this outcome and provide an avenue for a patentee to negotiate more favorable agreements.

a substantial number of recent cases.<sup>16</sup> In *z4 Techs, Inc. v. Microsoft Corp.*, for instance, the Court refused to grant the patentee an injunction to stop Microsoft from continuing to infringe its software patent.<sup>17</sup> In *Paice, LLC v. Toyota Motor Corp.*, the patentee was refused an injunction to stop Toyota from continuing to infringe.<sup>18</sup> In both cases, relief was denied primarily because (1) the patentees failed to prove that continued infringement caused any irreparable harm and (2) injunctive relief would have been burdensome because the patented invention implicated only small portions of much larger products.<sup>19</sup> The courts here are not completely devaluing the patent right, but their denial of permanent relief shifts the situation from one in which strong property rules are applied to a regime of liability rules.<sup>20</sup>

I should take a moment here to define my terms of “breaking” and “bending” patents. A patent’s underlying value is in its legal and apparent exclusionary power. A “broken” patent might be defined as a patent whose rights are willfully ignored without recourse. A patent that is merely “bent” may have only suffered under the threat of be-

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<sup>16</sup> See cases cited *infra* note 18.

<sup>17</sup> 434 F. Supp. 2d 437, 440–41, 444 (E.D. Tex. 2006).

<sup>18</sup> No. 2:04-CV-211-DF, 2006 WL 2385139, at \*4 (E.D. Tex. Aug. 16, 2006), *aff’d in part, vacated on other grounds*, 504 F.3d 1293, 1316 (Fed. Cir. 2007); see also, Dennis Crouch, *Injunction Granted to TiVo; Injunction Denied in Favor of Toyota*, PATENTLY-O, Aug. 18, 2006, [http://www.patentlyo.com/patent/2006/08/injunction\\_gran.html](http://www.patentlyo.com/patent/2006/08/injunction_gran.html). For other recent cases where permanent injunctive relief has been denied, see *Armando v. Microsoft Corp.*, 517 F.3d 1353 (Fed. Cir. 2008); *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363 (Fed. Cir. 2008); *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, 592 F. Supp. 2d 727 (D. Del. 2009); *Voile Mfg. Corp. v. Dandurand*, 551 F. Supp. 2d 1301 (D. Utah 2008) (preliminary injunction denied); *MercExchange, L.L.C. v. eBay, Inc.*, 500 F. Supp. 2d 556 (E.D. Va. 2007); *IMX, Inc. v. Lendingtree, LLC*, 469 F. Supp. 2d 203 (D. Del. 2007) (denied without prejudice); *Sundance, Inc. v. DeMonte Fabricating, Ltd.*, No. 02-73543, 2007 WL 37742 (E.D. Mich. Jan. 4, 2007); *Finisar Corp. v. DirecTV Group, Inc.*, No. 1:05-CV-264, 2006 U.S. Dist. LEXIS 76380 (E.D. Tex. July 7, 2006); *Voda v. Cordis Corp.*, No. CIV-03-1512-L, 2006 U.S. Dist. LEXIS 37961 (W.D. Okla. June 8, 2006).

<sup>19</sup> *z4Techs, Inc.*, 434 F. Supp. 2d at 444; *Paice, LLC*, 2006 WL 2385139, at \*4–5.

<sup>20</sup> Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1119–20 (1972). Injunctive relief is generally considered a higher value reward than ongoing monetary damages. See Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1993 (2007). In essence, injunctive relief puts full control of the intellectual property in the hands of the patentee who is then in a strong position to name a settlement price or even to refuse to settle. There is no settled theory for calculating ongoing damages for patent infringement. See *Paice, LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1313–15 (Fed. Cir. 2007) (suggesting one method for calculating such damages). Thus, it is possible that a proper ongoing damage calculation would actually be greater than the potential settlement price.

ing broken or perhaps is only partially broken. In the context of this paper, the breaking and bending of patents is assumed to occur by, or on behalf of, governmental entities.<sup>21</sup> Because the United States government has largely waived its rights of sovereign immunity and allows private patent holders to sue the government for infringement,<sup>22</sup> the government is unlikely to break patents entirely.

Allegations of patent infringement against the federal government must be brought in the Court of Federal Claims (CFC), which imposes procedural requirements that limit some of the potential patent rights available.<sup>23</sup> The CFC does not offer a right to jury trial, disallows injunctive relief, disallows enhanced or punitive damages for willful infringement of patent rights, disallows relief for some would-be infringing activities, and eliminates the potential for actions against private contractors authorized to infringe by the federal government.<sup>24</sup> Section 1498 provides the only practical mechanism for pursuing actions against the federal government; other legal mechanisms, such as takings claims, have been largely unsuccessful.<sup>25</sup> Courts do not ordinarily consider patent infringement by the government to be an uncompensated taking under the Fifth Amendment.<sup>26</sup> Although the term 'compulsory license' is not used in the statute, these limitations on rights allow the federal government to bend patent rights by declaring a compulsory license to use patented inventions without first obtaining any rights.

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<sup>21</sup> The assumption that breaking patents is restricted to governmental activities is not necessary for the arguments, but it merely simplifies the issues treated in the paper. Although not directly parallel, Mark Lemley rightly suggests that private entities ignore many patent rights. Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 21 (2008).

<sup>22</sup> 28 U.S.C. § 1498(a) (2006).

<sup>23</sup> *Id.* § 1498(a), (b), (e).

<sup>24</sup> *Id.*; see also *Zoltek Corp. v. United States*, 442 F.3d 1345, 1349, 1351 (Fed. Cir. 2006).

<sup>25</sup> See *Zoltek*, 442 F.3d at 1353; Cahoy, *supra* note 12, at 175. Furthermore, during a crisis, ordinary takings principles do not apply as the government applies police power to achieve its public purposes. See *Miller v. United States*, 78 U.S. 268 (1870); *Teresi v. California*, 225 Cal. Rptr. 517, 518–19 (Cal. Ct. App. 1986) (holding that damages resulting from a police-power response to an extreme emergency are excepted from the constitutional requirement that compensation be paid for property taken for public use); *In re N.J.A.C. 11:1-20*, 505 A.2d 177, 182, 185 (N.J. Super. Ct. App. Div. 1986) (emergency measures enacted to protect public health did not constitute a taking); Royal C. Gardner, *Invoking Private Property Rights for Environmental Purposes: The Takings Implications of Government-Authorized Aerial Pesticide Spraying*, 18 STAN. ENVTL. L.J. 65, 88–93 (1999).

<sup>26</sup> *Zoltek*, 442 F.3d at 1353.

Individual states may also apply pressure and threaten unauthorized use.<sup>27</sup> In fact, for several reasons, the threat of patent breaking by individual states is heightened. First, states generally have not waived their sovereign immunity against patent infringement actions.<sup>28</sup> State immunity from suit derives from the Eleventh Amendment of the U.S. Constitution, which protects states from “[t]he Judicial power of the United States.”<sup>29</sup> The Supreme Court has held that state immunity goes beyond the text of the Eleventh Amendment and is also rooted in “the structure of the original Constitution itself.”<sup>30</sup> In *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, the Supreme Court held that states may assert sovereign immunity as a defense against charges of patent infringement.<sup>31</sup> In addition to sovereign immunity, practical considerations may also push state and local governments away from providing compensation for use of a patented invention. Less money is available. State and local budgets are dramatically lower than those of the federal government. Additionally, unlike the federal government, state and local governments often abide by strict budgeting principles.<sup>32</sup>

The governing international agreement—the Trade-Related Aspects of Intellectual Property Rights (TRIPS)—includes additional provisions that legitimize patent breaking in limited circumstances such as a national emergency. When this occurs, TRIPS indicates

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<sup>27</sup> See *infra* notes 28–32.

<sup>28</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 635 (1999); Marci A. Hamilton & David Schoenbrod, *The Reaffirmation of Proportionality Analysis Under Section 5 of the Fourteenth Amendment*, 21 CARDOZO L. REV. 469, 472 (1999); Daniel J. Meltzer, *State Sovereign Immunity: Five Authors in Search of a Theory*, 75 NOTRE DAME L. REV. 1011 (2000); Peter S. Menell, *Economic Implications of State Sovereign Immunity from Infringement of Federal Intellectual Property Rights*, 33 LOY. L.A. L. REV. 1339, 1401 (2000); Eugene Volokh, *Sovereign Immunity and Intellectual Property*, 73 S. CAL. L. REV. 1161, 1161 (2000); Ernest A Young, *State Sovereign Immunity and the Future of Federalism*, 1999 SUP. CT. REV. 1, 13–16 (1999).

<sup>29</sup> U.S. CONST. amend. XI; *State Sovereign Immunity under the Eleventh Amendment and its Effects on Intellectual Property Enforcement, Hearing Before the Subcomm. on Courts and Intellectual Property of the S. Comm. on the Judiciary*, 106th Cong. (2000) (statement of Q. Todd Dickinson, Director, United States Patent and Trademark Office), available at <http://www.ogc.doc.gov/ogc/legreg/testimon/106s/dickinson0727.htm>.

<sup>30</sup> *Alden v. Maine*, 527 U.S. 706, 728 (1999).

<sup>31</sup> See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 647–48 (1999). Although *Ex parte Young*, 209 U.S. 123, 154 (1908), provides a limited exception to the state immunity doctrine by allowing plaintiffs to sue state officials for injunctive relief rather than suing the state itself, that doctrine has seen little success in modern patent cases.

<sup>32</sup> Michael Abramowicz, *Speeding the Crawl to the Top*, 20 YALE J. ON REG. 139, 158 (2003). As a practical matter, innovations that could be easily replicated in a decentralized fashion would be locally without recourse.

that the patentee should eventually receive some compensation based on “the economic value of the authorization.”<sup>33</sup> In all likelihood, however, that ex-post payment will be a small fraction of the potential monopoly profits that could have been earned.<sup>34</sup>

The bottom line here is that—in an emergent crisis—government entities will likely have both the legal right and political mandate to bend if not break patent rights over innovations deemed important in resolving the crisis.

### III. THE NON-CRISIS TIME FRAME OF PATENTS

Time Frame of the innovation and patenting processes also matter. In many likely scenarios, the crisis may pass before patent rights become available. Patent protection is not automatic. Rather, it involves a substantive examination process that often takes years.<sup>35</sup> This delay in perfecting rights is relevant when considering the role of patent rights during a crisis such as a health epidemic. In cases where innovation is spurred by the crisis itself, the innovator may have only fleeting hope of quickly obtaining patent protection.<sup>36</sup> This situation is quite likely to arise in a health crisis where anti-viral or anti-microbial treatments are engineered only after isolating the offensive biologic agent.<sup>37</sup>

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<sup>33</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31, Apr. 15, 1994, 33 I.L.M. 81 [hereinafter TRIPS Agreement]. Article 31 includes several specific limits on when a country can issue compulsory licenses of privately held patents. For instance, each use must be considered on its individual merit, efforts must be made to obtain authorization from the rights holder, the use should be predominantly for the domestic market of the authorizing member nation, and the compulsory use must be revoked when it is no longer needed.

<sup>34</sup> Dennis Crouch, *Intellectual Property in a Public Health Crisis*, PATENTLY-O, Oct. 22, 2008, <http://www.patentlyo.com/patent/2008/10/intellectual-pr.html>.

<sup>35</sup> In a 2009 study of 20,000+ prosecution history files, I found that more than fifty percent of patent applications are still pending three-years after filing. See Dennis Crouch, *Patent Application Pendency: Percent of Applications Still Pending*, PATENTLY-O, July 17, 2009, <http://www.patentlyo.com/patent/2009/07/patent-application-pendency-percent-of-applications-still-pending.html>. In addition, most patents actually claim priority to one or more priority documents such as prior patent applications, foreign patent applications, or provisional patent applications. See Dennis Crouch, *Priority Claims in Issued Patents*, PATENTLY-O, July 26, 2009, <http://www.patentlyo.com/patent/2009/07/priority-claims-in-issued-patents.html>. These successive filings further add to the pendency period. Time is also required to prepare patent application materials before filing, thus further pushing back the eventual effective date of the issued patent.

<sup>36</sup> See *supra* note 35.

<sup>37</sup> This is the procedure used annually to create the influenza vaccine. See Audio recording: Matthew Reynolds, Centers for Disease Control, 2007–2008 Influenza



During pendency of the application, the applicant has no right to stop would-be infringement. A limited statutory provision does provide “provisional rights” and back damages after issuance,<sup>38</sup> but that provision is so narrowly drafted that ten years after its 1999 passage, a comprehensive online search failed to reveal a single reported decision indicating that an infringer had been held liable for provisional damages.<sup>39</sup>

The timing of a crisis could be weeks, months, or potentially years. That timing makes a difference in patent law. In the same way that light waves act differently around objects whose size is on the same order as the light wavelength,<sup>40</sup> patent law only becomes applicable if a patent may issue before the crisis is complete. Before the patent issues, the invention may be used without recourse under the patent laws. Even after issuance, however, infringers do not simply pay their share of compensation. Patent litigation typically consumes years and, as discussed above, high value awards of injunctive relief would be unlikely in the midst of a crisis.

#### IV. THE INCENTIVE TO INNOVATE OFFERED BY PATENT LAW IN A CRISIS SITUATION

Parts II and III developed the notion that innovators will have diminished or even nonexistent patent rights during a public health crisis situation. This part briefly considers how these diminished patent rights alter the incentive to innovate. Patent law operates under the assumption that the promise of strong patent rights provides an incentive to innovate.<sup>41</sup> If the law offers weaker rights, a potential innovator will presumably feel marginally less inclined to pursue the innovation. Following that premise, we expect that the reduced strength of patent rights during a public health crisis would likely re-

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Vaccine Production and Distribution, *available at* <http://www2a.cdc.gov/podcasts/download.asp?f=6678&af=t>.

<sup>38</sup> 35 U.S.C. § 154(d) (2006).

<sup>39</sup> To conduct this study, I broadly searched for mention of the provisional rights statute in the federal case law databases of LexisNexis and Westlaw. I also performed a parallel search using the Lexmachina docket search database. In one case, a district court denied a pretrial motion to preclude a plaintiff from seeking provisional rights. *First Years, Inc. v. Munchkin, Inc.*, No. 07-cv-558-bbc, 2008 U.S. Dist. LEXIS 70482, at \*6 (W.D. Wisc., Sept. 17, 2008). However, that case settled before the court made any further substantive ruling.

<sup>40</sup> DAVID BREWSTER, A TREATISE ON OPTICS 95 (London, Longman, Rees, Orme, Brown & Green 1831), *available at* <http://books.google.com/books?id=opYAAAAAMAAJ>.

<sup>41</sup> Dennis Crouch, *The Patent Lottery: Exploiting Behavioral Economics for the Common Good*, 16 GEO. MASON L. REV. 141, 141 (2008).

duce the incentive to innovate targeted solutions. As I discuss in a recently published paper on the patent lottery effect, the exact relationship between potential rights and incentive to innovate is difficult to define.<sup>42</sup> Thus, although it is well established that patent rights create an incentive to invent, no one knows the exact incentive impact of shifts in the strength of patent rights. However, despite challenges to the assumption of incentives, the general theory has largely sat well with its commentators for hundreds of years.

Although patent rights may fail to provide full incentives to develop responses to an epidemic, I am cautiously optimistic that patents do have some role in *preparing for* a crisis. The loss of rights described in Parts II and III results from either the critical public need for access to the invention during a major crisis or the short timeline of the crisis. Patents can still provide a strong incentive to create innovations that help prepare for and prevent potential crises, since governments are less likely to upset patent rights outside of the crisis situation.<sup>43</sup> Thus, the remaining incentive pushes innovators toward mechanisms that prevent the crisis from forming in the first place.

#### V. INNOVATION WILL HAPPEN: ALTERNATIVE APPROACHES TO CRISIS INNOVATION

This section briefly considers alternative approaches to crisis innovation. A simple model of the decision to innovate considers the additional value of the various incentives and disincentives. A tremendous amount of innovation occurs without any external stimulus or incentive.<sup>44</sup> As discussed above, in some situations, patents can provide additional incentives. Ordinarily, patent rights help prevent free riding by follow-on copycats, thus allowing the patentee to generate revenue based on the innovation. At times, patentees can use contract rights to achieve the same result. Notably, rights can be controlled through contracts such as confidentiality agreements and ma-

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<sup>42</sup> *Id.*

<sup>43</sup> Some patents that would be potentially useful in a crisis may have non-crisis uses that are substantial enough to provide innovators incentive to invest in research and development. Cipro and oseltamivir phosphate (Tamiflu) are two such examples. In those cases, the innovation may still be developed despite an understanding that the patent rights may be ignored in a crisis situation. The crisis value could be seen as a spillover benefit.

<sup>44</sup> This natural innovation might be seen as simply human nature, since many humans are naturally innovative and enjoy the process.

terial transfer agreements (MTAs).<sup>45</sup> In some areas of technology, these contractual rights can be quite strong especially where the innovation is difficult and expensive to reproduce.<sup>46</sup> For instance, Professor O'Connor identifies MTAs as particularly strong in stem cell research because the value is in the stem cell line itself, rather than in the idea of how to create a stem cell:

The recent focus on patents as a hindrance to stem cell research may turn out to be a red herring. The real culprits are material transfer agreements (MTAs), which govern the transfer of cell lines and other biological materials. The MTA's primary purpose in life sciences research is to set contractual rights and obligations between parties where one party transfers biological materials to the other. For example, MTAs often focus on the physical handling, use, and distribution of the materials by the recipient, ensuring that the recipient complies with regulations for research involving humans or animals. Although these interests are legitimate, evidence indicates that owners of important biological research materials use their nonpatent property rights to require recipient consent to arguably onerous MTAs, which include provisions governing intellectual property rights (IPR). When an intended recipient's institution refuses to sign the MTA, the researcher cannot access the biological materials, and in some cases cannot pursue her research.<sup>47</sup>

A surprising study recently confirmed the power of the MTAs when it determined that MTAs and confidentiality agreements create more of a hindrance to agricultural research than opposing patent rights.<sup>48</sup>

In crisis preparation, the greatest incentive may come from direct government support through public funding of research and emergency preparations. This managed innovation makes sense in the absence of patent rights, but even if patents were largely enforceable, we might not expect that innovators would necessarily choose to invest in crisis preparation. In this context, the problem with the patent regime is that it broadly offers a promise of rights without directing innovators toward any particular area of innovation. Thus, al-

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<sup>45</sup> See generally Sean O'Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics*, 21 BERKELEY TECH. L.J. 1017 (2006) (discussing the use of MTAs as a source of property protection).

<sup>46</sup> See *id.* at 1017–18.

<sup>47</sup> *Id.*

<sup>48</sup> Zhen Lei, Rakhi Juneja & Brian D. Wright, *Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research*, 27 NATURE BIOTECHNOLOGY 36 (2009), available at <http://www.nature.com/nbt/journal/v27/n1/pdf/nbt0109-36.pdf>; see also Posting of Kevin Noonan to Patent Docs, <http://www.patentdocs.org> (Feb. 3, 2009, 11:38 p.m.) (critiquing the study conclusions).

though patents may serve as useful tools for generally fueling innovation, the broad range of potentially protectable subject matter means that any one particular innovation remains unlikely. Even if monopoly-level returns could be expected for a patentee whose innovation aided in solving a major crisis, there is no guarantee that a potential innovator would take the risk, especially after taking into account the low probability that the planned-for crisis would occur.

In addition to providing up-front funding, the government may also provide prior contracts and guarantees that rights will not be violated even in a crisis. Where forethought is possible, a cooperative agreement could guarantee public access to innovative products and guarantee that developers are repaid. If this solution is done through a statutory or regulatory framework, it may be necessary to do so through federal action because of the preemptive nature of the patent laws.<sup>49</sup>

## VI. CONCLUSION

Potential patent rights fail to provide a strong incentive to innovate solutions to a potential major crisis such as a health epidemic. In some cases, patent rights may spur innovation that prevents a crisis altogether. In other cases, however, more directed management will be necessary.

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<sup>49</sup> See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 168 (1989) (holding that Florida statute providing “patent-like protection for ideas deemed unprotected under the present federal scheme” was preempted by the Supremacy Clause).