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## The 2009 H1N1 Swine Flu Pandemic: Reconciling Goals of Patents and Public Health Initiatives

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### Cover Page Footnote

I would like to thank Professor Jeanne Fromer for her guidance, insight, and review of several drafts of this Note. I would also like to thank the editors and staff of the IPLJ for their careful review of my Note.

# The 2009 H1N1 Swine Flu Pandemic: Reconciling Goals of Patents and Public Health Initiatives

Michelle Kaplan\*

INTRODUCTION .....	992
I. HISTORICAL BACKGROUND.....	997
A. <i>Patent Law</i> .....	997
1. Patent Eligibility and Rights Granted by a Patent.....	998
2. Benefits of and Incentives for Patenting Vaccines.....	1001
3. Morality Debate Surrounding Vaccine Patents..	1003
B. <i>Health Care and Public Health Law</i> .....	1007
1. Public Health Law.....	1008
2. How Vaccines Differ from Other Pharmaceuticals .....	1010
C. <i>2009 H1N1 Swine Flu</i> .....	1012
1. The Current 2009 H1N1 Swine Flu Pandemic ..	1014
2. Previous Swine Flu Outbreaks in the United States—1918 and 1976 .....	1020
3. The 1976 Swine Flu Vaccine.....	1022
4. The 2009 H1N1 Vaccine .....	1026
II. CONFLICTS BETWEEN PATENT LAW AND PUBLIC HEALTH GOALS.....	1027

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992	<i>FORDHAM INTELL. PROP. MEDIA &amp; ENT. L.J.</i>	[Vol. 20:991
	A. <i>Patents' Exclusivity Versus Public Health Disease Prevention</i>	1027
	B. <i>Recommendations to Resolve the Conflict Between Patents and Public Health</i>	1029
	III. CONFLICT BETWEEN PATENT TERMS AND DISEASE DURATION	1038
	A. <i>Conflict Between Influenza Timing and the Patent Term—Is Patent the Right Approach?</i>	1039
	B. <i>Recommendations to Resolve the Conflict Between Disease Duration and the Patent Term</i>	1041
	1. Recommendation: Shortened Patent Term and Expedited Review Process	1041
	2. Recommendation: Patenting the Vaccine Creation Process	1044
	CONCLUSION	1047

## INTRODUCTION

The World Health Organization (“WHO”) declared the 2009 H1N1 swine flu a pandemic on June 11, 2009.<sup>1</sup> This is the first influenza pandemic of the twenty-first century.<sup>2</sup> In response to the rapid spread of the global 2009 H1N1 swine flu, which proved fatal in some cases, pharmaceutical companies developed an effective vaccine against the 2009 H1N1 swine flu (“2009 H1N1 vaccine”).<sup>3</sup> These pharmaceutical companies submitted patent

<sup>1</sup> See Margaret Chan, Dir.-Gen., World Health Org., Statement Recognizing Swine Flu Pandemic 1 (June 11, 2009), available at [http://www.who.int/mediacentre/influenzaAH1N1\\_presstranscript\\_20090611.pdf](http://www.who.int/mediacentre/influenzaAH1N1_presstranscript_20090611.pdf).

<sup>2</sup> See generally Luan-Yin Chang et al., *Novel Swine-Origin Influenza Virus A (H1N1): The First Pandemic of the 21st Century*, 108 J. FORMOS MED. ASSOC. 526 (2009), available at [http://ajws.elsevier.com/ajws\\_archive/200971087A6406.pdf](http://ajws.elsevier.com/ajws_archive/200971087A6406.pdf); Sami Al Hajjar & Kenneth McIntosh, *The First Influenza Pandemic of the 21st Century*, 30 ANN. SAUDI MED. 1 (2010), available at [http://www.saudiannals.net/temp/AnnSaudiMed3011-6952164\\_191841.pdf](http://www.saudiannals.net/temp/AnnSaudiMed3011-6952164_191841.pdf).

<sup>3</sup> See Centers for Disease Control and Prevention, Key Facts About 2009 H1N1 Flu Vaccine, [http://www.cdc.gov/h1n1flu/vaccination/vaccine\\_keyfacts.htm](http://www.cdc.gov/h1n1flu/vaccination/vaccine_keyfacts.htm) (last visited Feb. 21, 2010) [hereinafter CDC, Key Facts About 2009 H1N1 Flu Vaccine]; U.S. Food and Drug Administration, Influenza A (H1N1) 2009 Monovalent Vaccines Composition and Lot Release, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance>

applications for their novel 2009 H1N1 vaccine formulation.<sup>4</sup> Patent law incentivizes inventors to develop new ideas by giving the patentees economic inducements in exchange for the research, development, time, and resources that they invest in producing the invention.<sup>5</sup> Pharmaceutical companies hope to obtain the protections of a patent, which would give them the exclusive right to manufacture and distribute this vaccine.<sup>6</sup>

However, the 2009 H1N1 vaccine poses several unique issues that interfere with the typical structure of patent applications and the associated incentives for patent applicants. For example, while pharmaceutical companies want to patent their inventions, obtain exclusive rights, and generate profits from their vaccines,<sup>7</sup> public health goals are furthered by disseminating the vaccine to as many individuals as possible in order to achieve widespread disease protection by immunizing the public.<sup>8</sup> In addition, whereas patent protection furthers society's goals, patenting pharmaceutical products and biotechnological inventions in general, and the 2009 H1N1 vaccine in particular, raises unique moral questions.<sup>9</sup>

Due to the expected severity of the 2009 H1N1 swine flu pandemic, several public health agencies became actively involved in tracking the 2009 H1N1 influenza virus, educating the public about this illness, suggesting preventative vaccination against this virus, and offering medical treatment options in the event that a patient contracts this disease.<sup>10</sup> The vaccines produced by

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RegulatoryInformation/Post-MarketActivities/LotReleases/ucm181956.htm (last visited Feb. 21, 2010) [hereinafter FDA, Influenza A (H1N1) 2009 Monovalent Vaccines Composition and Lot Release].

<sup>4</sup> See, e.g., U.S. Patent Application No. 20090047353 (filed Nov. 6, 2006).

<sup>5</sup> See ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 127 (rev. 4th ed. 2007).

<sup>6</sup> See Kyle Wamstad, *Priority Review Vouchers—A Piece of the Incentive Puzzle*, 14 VA. J.L. & TECH. 126, 129 (2009).

<sup>7</sup> See *id.* at 131 (“Without the market exclusivity and protections of patented property, researchers would not likely invest significant time and resources to develop modern drug therapies.”).

<sup>8</sup> See Joseph Nicosia III, *Avian Flu: The Consumer Costs of Preparing for Global Pandemic*, 18 LOY. CONSUMER L. REV. 479, 491–92 (2006).

<sup>9</sup> See *infra* Part I.A.3.

<sup>10</sup> See generally Centers for Disease Control and Prevention, 2009 H1N1 Flu, <http://www.cdc.gov/h1n1flu/> (last visited Feb. 21, 2010) [hereinafter CDC, 2009 H1N1 Flu]; World Health Organization, Pandemic (H1N1) 2009, <http://www.who.int/csr/>

pharmaceutical companies will aid public health agencies, such as the WHO and the Centers for Disease Control and Prevention (“CDC”), in implementing their disease management goals. Therefore, these public health agencies, as well as the federal government, collaborated with the pharmaceutical industry to achieve the desired public health goals of reducing 2009 H1N1 swine flu transmission, improving immunity against this disease, and reducing symptoms or severe complications, including death, in instances where the illness cannot be prevented.<sup>11</sup> Yet while public health agencies and government authorities may believe that it is imperative to pool their resources with pharmaceutical companies’ resources for the benefit of the public’s health, the differences between these entities’ immediate goals pose challenges. Specifically, the patentees’ goals of economic rewards and the pharmaceutical companies’ goals of profits could conflict with public health organizations’ goals of safe and effective vaccines and widespread vaccination that will reduce the incidence of disease.

The conflicts existing between patent law and public health objectives are particularly apparent and extremely relevant in the context of the 2009 H1N1 swine flu pandemic. This Note will examine the conflict between the exclusive rights that each pharmaceutical company seeks to achieve via its patents for the 2009 H1N1 vaccine<sup>12</sup> and the requirements of public health agencies and the federal government whose utmost priority is the protection of the public’s health.<sup>13</sup> Specifically, this Note will address two inter-related conflicts that have arisen.<sup>14</sup> The first

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disease/swineflu/en/index.html (last visited Nov. 13, 2009) [hereinafter WHO, Pandemic (H1N1) 2009].

<sup>11</sup> See generally CDC, 2009 H1N1 Flu, *supra* note 10; WHO, Pandemic (H1N1) 2009, *supra* note 10. In addition, the Food and Drug Administration (“FDA”) was actively involved in approving the 2009 H1N1 vaccine in a timely manner. See 21 C.F.R. § 314.2 (2010).

<sup>12</sup> See *supra* note 7 and accompanying text.

<sup>13</sup> See MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, HEALTH CARE LAW AND ETHICS 869 (7th ed. 2007).

<sup>14</sup> A third conflict, which also entails a timing issue, involves the need to create the vaccine and produce it in a timely fashion versus the requirements set forth by the FDA, an agency that must carefully and diligently examine the risks and benefits of the

tension involves the financial gain and the exclusivity right desired by the pharmaceutical companies that have applied for patents as opposed to the goals of public health authorities who seek to immunize as many individuals as possible at no cost to the public. The second related tension involves the notion that an influenza vaccine, in general, is usually effective for only one flu season.<sup>15</sup> This fact partially offsets the inherent financial benefits accrued once a patent is granted to a pharmaceutical company for a patent term of twenty years,<sup>16</sup> a benefit that appears to be unnecessary because the usefulness of the vaccine will have ended after one flu season, a time period of less than one year.<sup>17</sup>

In its evaluation of the first conflict, this Note examines how the United States government intervened in response to the 2009 H1N1 swine flu pandemic in order to resolve this situation in a manner that achieves the desired public health outcome. After purchasing 250 million 2009 H1N1 vaccines from pharmaceutical companies, the federal government made these vaccines available to the public at no charge.<sup>18</sup> This mass purchase of the 2009 H1N1 vaccine by the government satisfied the financial compensation that the pharmaceutical companies sought in return for their research, development, and production efforts while concurrently achieving the public health goal of widespread 2009 H1N1 vaccine distribution. This Note proposes additional solutions that help resolve the aforementioned conflict in the case of the 2009 H1N1 swine flu pandemic; it also presents solutions that can be applied to future pandemics or to public health crises of similar magnitude. For example, in order to combat a shortage not only of the 2009

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proposed vaccine before it is marketed to the public. *See* 21 C.F.R. § 314.2. This conflict will not be addressed in this Note.

<sup>15</sup> *See* ANTHONY E. FIORE, M.D. ET AL., ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES, PREVENTION AND CONTROL OF SEASONAL INFLUENZA WITH VACCINES (2009), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm> (indicating that “[i]nfluenza viruses undergo frequent antigenic change (i.e., antigenic drift); to gain immunity against viruses in circulation, patients must receive an annual vaccination against the influenza viruses that are predicted on the basis of viral surveillance data”).

<sup>16</sup> *See* 35 U.S.C. § 154(a)(2) (2006).

<sup>17</sup> *See supra* note 15 and accompanying text.

<sup>18</sup> *See* Centers for Disease Control and Prevention, H1N1 Flu: What You Should Know and Do This Flu Season If You Are 65 Years and Older (Jan. 19, 2009), <http://www.cdc.gov/h1n1flu/65andolder.htm> [hereinafter CDC, 65 and Older].

H1N1 vaccine, but also shortages of the seasonal flu vaccine, the government could establish additional laboratories specifically for the purpose of vaccine production. These government laboratories could prove beneficial in cases of pandemics, such as the 2009 H1N1 swine flu, when the facilities of the private pharmaceutical companies are overtaxed due to urgent demands for maximal vaccine production. The government laboratories could function in a manner similar to a licensing agreement. Various compensation arrangements could then be created to financially reward the patentee.

The second conflict addressed in this Note analyzes the disparity between the twenty-year length of the patent term<sup>19</sup> and the clinical efficacy of the 2009 H1N1 vaccine or any other influenza vaccines, which are typically limited to only one flu season.<sup>20</sup> It discusses the possibility of employing short-term patents in a manner similar to the rapidly evolving computer software technology industry. This Note also suggests another expedited patent approval process that could be effective in curtailing the deleterious effects associated with public health emergency situations. Under this approach, patents relating to emergency public health crises would be evaluated immediately by the United States Patent and Trademark Office (“PTO”) examiners.<sup>21</sup> On the other hand, this Note posits that vaccines and other biotechnological innovations provide benefits for the public good beyond the initial pandemic or primary disease duration due to the usefulness of the scientific process and methodology introduced by the inventor. Therefore, granting a twenty-year patent would appear logical especially in view of the extensive research that is required prior to releasing the vaccine or other biotechnological innovation. The twenty-year patent would concomitantly promote inventors and pharmaceutical companies to achieve the concurrent goals of combating disease and promoting public health while reaping financial rewards for themselves.

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<sup>19</sup> See 35 U.S.C. § 154(a)(2).

<sup>20</sup> See *supra* note 15 and accompanying text.

<sup>21</sup> The amount of time that a patent examiner typically spends evaluating a patent application during prosecution is eighteen hours. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. REV. 1495, 1500 (2001).



Part I of this Note (1) provides an overview of the rights granted by a patent, a discussion of the incentives for patenting vaccines, and an analysis of the morality of patent law as it relates to vaccines; (2) discusses the goals of public health and health law, and addresses the unique issues that arise with vaccines; and (3) describes the 2009 H1N1 swine flu pandemic and the 2009 H1N1 vaccine, as well as the history of previous flu outbreaks, including the 1976 H1N1 swine flu outbreak and vaccine. Part II of this Note discusses the conflict that arises between patents and public health law within the context of the 2009 H1N1 swine flu pandemic. Recommendations to resolve these conflicts are presented, including an evaluation of the policies that the United States government has already implemented in order to resolve the conflict. Part III of this Note discusses the conflict between the twenty-year patent term and the short duration of public health benefits derived from the clinical use of the 2009 H1N1 vaccine. This section also proposes suggestions to reconcile this conflict, including issuing short-term patents and providing incentives for the long-term value derived from developing biotechnological innovations.

## I. HISTORICAL BACKGROUND

### A. Patent Law

Congress regulates patent law. The United States Constitution grants Congress the “[p]ower . . . to promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries.”<sup>22</sup> Thus, the Constitution authorizes Congress to provide inventors with exclusive rights over their discoveries in order to encourage scientific innovation and progress.<sup>23</sup>

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<sup>22</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>23</sup> Wamstad, *supra* note 6, at 129 (“From its inception Congress has been entrusted to nurture innovation through grants of exclusive market power to patent recipients . . . . [T]he Founders recognized that invention led to utility and authorized Congress to confer an exclusive market right to encourage such invention.”).

This section of the Note evaluates the conferral of patent rights upon scientists and companies who develop biological products,<sup>24</sup> specifically vaccines, in exchange for these companies' assistance in "promot[ing] the [p]rogress of [s]cience."<sup>25</sup> Part I.A.1 delineates the requirements for obtaining a patent and describes the rights that a patentee receives once a patent is issued. Part I.A.2 explains the inherent value and benefit derived by the patentee that would motivate the inventor to seek a patent for the newly invented vaccine. Part I.A.3 discusses the morality debate associated with patenting vaccines and addresses several arguments and counter-arguments.

### 1. Patent Eligibility and Rights Granted by a Patent

The United States codified the Patent Act<sup>26</sup> in order to implement a national standard of patentability.<sup>27</sup> In order to obtain a patent in the United States, an inventor must file an application with the PTO.<sup>28</sup> The PTO engages in a formal evaluation of each application, which must be reviewed by professional examiners.<sup>29</sup> These examiners review each invention that is potentially eligible for a patent to ensure that the device complies with the Patent Act, which sets forth five requirements for patentability: subject matter, utility, novelty, non-obviousness, and disclosure.<sup>30</sup>

The Patent Act specifies that patents will only cover a limited subject matter, which extends to a "process, machine, manufacture, or composition of matter, or any new and useful improvement

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<sup>24</sup> HUGH B. WELLONS ET AL., *BIOTECHNOLOGY AND THE LAW* 605 (2007) ("Biological products include a diverse range of substances, such as vaccines, blood and blood components, allergenics, gene therapy, cellular and tissue-based products, recombinant therapeutic proteins, and xenotransplantation products.").

<sup>25</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>26</sup> See 35 U.S.C. §§ 1-376 (2006).

<sup>27</sup> See MERGES ET AL., *supra* note 5, at 121. Prior to the codification of the first patent statute in 1790, "[s]tate patents were granted in most of the original thirteen colonies, beginning with a Massachusetts patent in 1641." *Id.*

<sup>28</sup> U.S. Patent and Trademark Office, How to Get a Patent, <http://www.uspto.gov/web/patents/howtopat.htm> (last visited Feb. 21, 2010).

<sup>29</sup> See MERGES ET AL., *supra* note 5, at 121.

<sup>30</sup> See *id.* at 124.

thereof.”<sup>31</sup> The second requirement analyzed by the PTO prior to granting a patent is utility.<sup>32</sup> The third requirement, novelty, enumerates a list of conditions wherein a device is not considered to be novel and thus not patentable.<sup>33</sup> The PTO also scrutinizes the invention to ensure that the discovery was not obvious.<sup>34</sup> The Patent Act determines non-obviousness by comparing the current invention with previous developments that have been made in the field.<sup>35</sup> The final factor evaluated by the PTO is disclosure, which

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<sup>31</sup> 35 U.S.C. § 101 (delineating the subject matter eligible for patent). In its 2009 term, the U.S. Supreme Court will decide *Bilski v. Kappos*. *Bilski v. Doll*, 129 S. Ct. 2735 (2009), *argued sub nom.* *Bilski v. Kappos*, No. 08-964, 2009 WL 3750776 (Nov. 9, 2009). The Court may reinterpret § 101 and the statutory scope of patentability at that time. The Patent Act also requires the inventor to include “one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention” in the specification. 35 U.S.C. § 112.

<sup>32</sup> 35 U.S.C. § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . .”). However, the importance of the utility prerequisite to patentability has decreased over time. Currently, the definition of utility is so broad that it even encompasses inventions that have only worked in experimental situations, but have not acquired any actual use. *MERGES ET AL.*, *supra* note 5, at 124 (“Only if an invention has absolutely no ‘practical utility’ will a patent be denied.”). Yet, this broad definition may be slightly circumscribed because it is unclear “whether laboratory promise is enough to establish utility in treating human patients.” *Id.* This quote about the patentability of pharmaceuticals, such as vaccines, during their experimental stages is relevant to the subject matter of this Note, which is concerned with the swine flu. It is also interesting to note that Baxter International Inc., one of the pharmaceutical companies that developed a swine flu vaccine, filed a patent for the vaccine on August 28, 2008, approximately one year before the swine flu outbreak that began in March 2009. U.S. Patent Application No. 20090060950 (filed Aug. 28, 2008). It is likely that in 2008, when Baxter applied for a patent, its vaccine had only been used in experimental settings.

<sup>33</sup> *See* 35 U.S.C. § 102. Therefore, if a device meets any of the criteria set forth in section 102 of the Patent Act, it will not be eligible for a patent. For example, these conditions include objects that were previously known or used, inventions that were previously patented, and creations whose subject matter was not invented by the person seeking the patent. *Id.* § 102(a), (b), (f). Thus, the novelty requirement employs technical rules in order to ensure that the patent applicant was the first to invent the device. *MERGES ET AL.*, *supra* note 5, at 124.

<sup>34</sup> *See* 35 U.S.C. § 103(a) (“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”).

<sup>35</sup> *Id.* This sub-section underscores that “the differences between the subject matter sought to be patented and the prior art” must be scrutinized in order to determine non-obviousness. *Id.* The Patent Act implies that if the differences are not significant enough,

is comprised of the written description requirement, enablement, and setting out the best mode.<sup>36</sup> This prerequisite to obtaining a patent obligates the inventor to disclose the process that was employed when the potentially patentable device was created. This requirement is imposed so that once the patent expires and the patentee no longer maintains the right of exclusivity, others would be able to make the device as well.<sup>37</sup>

A patent is “the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.”<sup>38</sup> A patent holder, or patentee, has

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, and, if the invention is a process, of the right to exclude others from using, offering for sale, or selling through the United States, or importing into the United States, products made by that process . . . .<sup>39</sup>

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the new creation will not be eligible for a patent. Hence, this requirement “attempts to measure . . . the *technical accomplishment* reflected in an invention.” MERGES ET AL., *supra* note 5, at 124 (emphasis in original).

<sup>36</sup> See 35 U.S.C. § 112. This factor requires the patentee to write a description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

*Id.*

<sup>37</sup> See MERGES ET AL., *supra* note 5, at 125 (“The disclosure and ‘enablement’ requirements . . . ensure that those ‘skilled in the art’ of the invention can read and understand the inventor’s contribution, and that after the patent expires they will be able to make and use the invention themselves.”).

<sup>38</sup> U.S. Patent and Trademark Office, General Information Concerning Patents, <http://www.uspto.gov/web/offices/pac/doc/general/index.html> (last visited Sept. 25, 2009). The PTO “examines applications and grants patents on inventions when applications are entitled to them; it publishes and disseminates patent information, records assignment of patents, maintains search files of U.S. and foreign patents, and maintains a search room for public use in examining issued patents and records.” *Id.*

<sup>39</sup> 35 U.S.C. § 154(a)(1). The exclusive right held by the patentee gives “the inventor the right to sue not only those who ‘steal’ his invention, but those who reverse engineer it

These rights are held by the patentee for a term of twenty years, which begins to toll on the date that the patent is filed<sup>40</sup> even though the patentee cannot exercise these exclusivity rights until the date when the patent is granted.<sup>41</sup> Although the patentee possesses these rights under the Patent Act, which include the right to sell the invention,<sup>42</sup> creators of biological products,<sup>43</sup> such as vaccines, are not permitted to sell their inventions in the United States until the United States Food and Drug Administration (“FDA”) grants its approval.<sup>44</sup>

This Note will focus upon vaccines, specifically the 2009 H1N1 swine flu vaccine, which fall within the realm of scientific inventions that are eligible for patents because they comply with the five prerequisites of patentability. Thus, it is presumed that the creators of the 2009 H1N1 vaccine could obtain the right to exclusively create the vaccine for a twenty-year patent term.

## 2. Benefits of and Incentives for Patenting Vaccines

The purpose of patents is to provide the requisite incentive for inventors whose creations will “advance a public good.”<sup>45</sup> However, patent law recognizes that “inventions are public goods that are costly to make and that are difficult to control once they are released into the world.”<sup>46</sup> In order to strike a balance between these ends, patent law relies upon economic principles that provide tangible financial incentives to promote the creation of novel

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and even those who develop the same invention independently.” MERGES ET AL., *supra* note 5, at 127.

<sup>40</sup> See 35 U.S.C. § 154(a)(2). It is also possible for the term of the patent to begin at an earlier date if a previous patent application was filed in accordance with other provisions of the Patent Act. *See id.*; *see also id.* §§ 120, 121, 365(c).

<sup>41</sup> *See id.* § 154(a)(2); *see also* Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 127 (2005).

<sup>42</sup> 35 U.S.C. § 154(a)(1).

<sup>43</sup> *See supra* note 24.

<sup>44</sup> *See* 21 C.F.R. § 601.2 (2010). “The exclusionary right . . . [provided by the Patent Act] does not automatically grant an affirmative right to do anything; patented pharmaceuticals, for instance, must still pass regulatory review at the Food and Drug Administration to be sold legally.” MERGES ET AL., *supra* note 5, at 126.

<sup>45</sup> Wamstad, *supra* note 6, at 130.

<sup>46</sup> MERGES ET AL., *supra* note 5, at 127.

products. For example, patent law provides economic incentives for inventors and scientists to invest time and energy in creating new inventions.<sup>47</sup>

Specifically, “patents provide incentives to individuals by offering them recognition for their creativity and material reward for their marketable inventions. These incentives encourage innovation,”<sup>48</sup> which in turn serves the public good by making these discoveries available to society.<sup>49</sup> It is believed that society would not benefit without patents because inventors would otherwise lack the necessary “incentive to invest in creating, developing, and marketing new products.”<sup>50</sup> This phenomenon is equally relevant to the pharmaceutical industry,<sup>51</sup> which develops vaccines. In order to encourage pharmaceutical companies to innovate, patent law provides the necessary economic motivation for these inventors “by allowing [them] to appropriate the full economic rewards of [their] invention[s].”<sup>52</sup> Thus, the pharmaceutical companies are likely to invest both time and money into scientific research in exchange for the economic rewards that are greatly enhanced by the patent exclusivity rights.<sup>53</sup>

These economic incentives are especially pronounced with regard to patenting influenza vaccines because each vaccine is only effective against a certain strain of a disease.<sup>54</sup> Although a

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<sup>47</sup> See generally 35 U.S.C. § 154(a)(1).

<sup>48</sup> World Intellectual Property Organization, Frequently Asked Questions (FAQs), [http://www.wipo.int/patentscope/en/patents\\_faq.html](http://www.wipo.int/patentscope/en/patents_faq.html) (last visited Feb. 21, 2010) [hereinafter WIPO, Frequently Asked Questions (FAQs)].

<sup>49</sup> Eric D. Zard, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology's Clash with the Public Good*, 6 U. ST. THOMAS L.J. 486, 491 (2009).

<sup>50</sup> MERGES ET AL., *supra* note 5, at 127.

<sup>51</sup> See *supra* note 7 and accompanying text.

<sup>52</sup> MERGES ET AL., *supra* note 5, at 127 (describing the “market-driven incentive to invest in innovation”).

<sup>53</sup> Carol A. Schneider, Felicia Cohn & Cynthia Bonner, *Patenting Life: A View from the Constitution and Beyond*, 24 WHITTIER L. REV. 385, 388 (2002). “This is especially important in the pharmaceutical field, where bringing a new drug to market can cost several hundred million dollars.” *Id.*

<sup>54</sup> See generally Centers for Disease Control and Prevention, Seasonal Influenza, <http://www.cdc.gov/flu/about/qa/disease.htm> (last visited Feb. 21, 2010) [hereinafter CDC, Seasonal Influenza] (“[I]nfluenza viruses are constantly changing so antibod[ies] made against one strain will become less effective against new strains.”). It is also

scientist who is researching a vaccine will devote time to this research just like any other inventor, the time that a scientific researcher devotes to the creation of a flu vaccine will likely only be profitable for one flu season,<sup>55</sup> which generally translates into the winter months of a calendar year.<sup>56</sup> Moreover, the costs of creating the vaccine include not only research and development, but also the costs of production, regulation, and clinical trials.<sup>57</sup> Due to the shortened time frame during which developers of influenza vaccines may recoup their large investments, the creators of vaccines have an even greater “interest in being rewarded for their effort, typically by being able to recoup financial investments in research and development and profit from their inventions.”<sup>58</sup>

### 3. Morality Debate Surrounding Vaccine Patents

Vaccines may be viewed as having components of both pharmaceutical and biotechnological innovations.<sup>59</sup> On the one hand, vaccines act in a manner similar to pharmaceuticals in that they directly combat and lessen the impact of diseases.<sup>60</sup> On the other hand, vaccines are also similar to biotechnological innovations because their development involves the manipulation of viral genetic material.<sup>61</sup>

Both scholars and practitioners have debated the morality of granting patents to the creators of pharmaceuticals. The majority

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necessary to note that more than one flu virus can be present in a given year. *Id.* Furthermore, different variants of the flu exist within each type of influenza virus. *Id.* Thus, it becomes apparent that the word “flu” actually accounts for a lot of variability.

<sup>55</sup> See *supra* note 15 and accompanying text. Although the timing and length of each flu season varies, on average “influenza activity peaks in January or later” in the northern hemisphere. CDC, The Flu Season, <http://www.cdc.gov/flu/about/season/flu-season.htm> (last visited Feb. 21, 2010).

<sup>56</sup> CDC, The Flu Season, *supra* note 55.

<sup>57</sup> See JULIE MILSTEIN & BRENDA CANDRIES, WORLD HEALTH ORG. DEP’T OF VACCINE & BIOLOGICS, ECONOMICS OF VACCINE DEVELOPMENT AND IMPLEMENTATION: CHANGES OVER THE PAST 20 YEARS 3 (1998), [http://www.who.int/immunization\\_supply/introduction/economics\\_vaccineproduction.pdf](http://www.who.int/immunization_supply/introduction/economics_vaccineproduction.pdf).

<sup>58</sup> Zard, *supra* note 49, at 491.

<sup>59</sup> See ANTHONY S. FAUCI ET AL., HARRISON’S PRINCIPLES OF INTERNAL MEDICINE 760–61 (14th ed. 1998).

<sup>60</sup> *Id.* at 761 (“As products to be given to healthy individuals to prevent disease, vaccines not only must be efficacious but also must lack the capacity to cause harm.”).

<sup>61</sup> See *id.* at 760.

of the arguments against patenting pharmaceuticals typically address the exorbitant price associated with a patent and its effects upon developing countries that are unable to afford these treatments.<sup>62</sup> The Doha Declaration, a proclamation issued by the World Trade Organization (“WTO”) Ministerial Conference in November 2001,<sup>63</sup> articulates the argument against patenting pharmaceuticals.<sup>64</sup> The Doha Declaration underscores that patented pharmaceuticals are sold at higher prices thus prohibiting segments of the population from purchasing these patented pharmaceuticals, which they cannot afford.<sup>65</sup> In fact, the Doha Declaration “extend[s] exemptions for pharmaceutical patent protection for poor third world countries until 2016,”<sup>66</sup> thereby allowing citizens of developing countries to more readily access drugs and other treatments to combat HIV and AIDS.<sup>67</sup> In response, those who support granting patents for pharmaceuticals argue that maintaining the patent requirement would actually benefit developing countries because they may be encouraged by the economic incentives to develop their own pharmaceuticals.<sup>68</sup>

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<sup>62</sup> See generally Nicosia, *supra* note 8, at 491–92 (“While wealthier nations would have access to limited supplies of vaccines and antiviral drugs, the poorer countries would endure much higher fatality rates, due to lack of medical treatments.”); Sean McElligott, *Addressing Supply Side Barriers to Introduction of New Vaccines to the Developing World*, 35 AM. J.L. & MED. 415, 415 (2009); Michael A. Santoro, *Human Rights and Human Needs: Diverse Moral Principles Justifying Third World Access to Affordable HIV/AIDS Drugs*, 31 N.C. J. INT’L L. & COM. REG. 923, 939 (2006).

<sup>63</sup> Santoro, *supra* note 62, at 929–30. The Doha Declaration relates specifically to the occurrence and treatment of AIDS in third world countries. See *id.* at 932–33.

<sup>64</sup> See *id.* at 932–33.

<sup>65</sup> See *id.* at 933.

<sup>66</sup> See *id.* at 930.

<sup>67</sup> See *id.* at 932–33 (“The principles enunciated [in the Doha Declaration] helped to ameliorate a formidable obstacle—that is, high prices due to pharmaceutical patents—preventing millions suffering from HIV/AIDS in the third world from obtaining access to life-saving and life-enhancing drugs.”). However, despite the benefits that third world countries gain from the Doha Declaration, they still have difficulties affording the reduced prices of the drugs. *Id.* at 933. Even when these countries manage to obtain these treatments, they encounter additional obstacles relating to the distribution of the pharmaceuticals and a shortage of medical personnel to administer them. *Id.*

<sup>68</sup> Santoro, *supra* note 62, at 928 (“[P]atents are not only good for corporate profits, but also the adoption of strong IP laws would help third world countries to develop their own high technology industries and products in the same manner that such laws spur innovation in developed countries.”).



There are, however, research and development costs associated with creating a vaccine, specifically a vaccine in response to a pandemic.<sup>69</sup> These costs are augmented because countries lack a supply of the needed vaccine at the inception of the pandemic.<sup>70</sup> In fact, commercial vaccine production typically does not occur until approximately three to six months after the start of the pandemic.<sup>71</sup> Moreover, as implied in the Doha Declaration, “manufacturing capacity for influenza vaccines is overwhelmingly concentrated in Europe and North America.”<sup>72</sup> Therefore, it once again becomes unlikely that “developing countries [will] have access to an effective vaccine at an affordable price.”<sup>73</sup> Furthermore, “current production capacity—estimated at around 300 million doses of trivalent seasonal vaccine per year—falls far below the demand that will arise during a pandemic,”<sup>74</sup> which will likely lead to morality problems concerning the distribution of a scarce resource during a public health emergency.<sup>75</sup>

Another argument that has been advanced in support of patenting pharmaceutical inventions is “based on the view that patents were the inventor’s ‘natural right’ or just reward for inventive activity.”<sup>76</sup> This argument is further supported by the Patent Act, which provides the inventor with the right of exclusivity over his creation.<sup>77</sup> As is evidenced by the terms “‘piracy’ and ‘stealing’”<sup>78</sup> to describe copying pharmaceuticals

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<sup>69</sup> World Health Organization, *Vaccine Research and Development: Current Status* (Nov. 2005), [http://www.who.int/csr/disease/avian\\_influenza/vaccineresearch2005\\_11\\_3/en/index.html](http://www.who.int/csr/disease/avian_influenza/vaccineresearch2005_11_3/en/index.html).

<sup>70</sup> *See id.* (“As a pandemic vaccine needs to be a close match to the actual pandemic virus, commercial production cannot begin prior to emergence and characterization of the pandemic virus.”).

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *See* James Tabery & Charles Mackett, *The Ethics of Triage in the Event of an Influenza Pandemic*, 2 *DISASTER MED. & PUB. HEALTH PREPAREDNESS* 2, 114 (2008).

<sup>76</sup> Santoro, *supra* note 62, at 928–29.

<sup>77</sup> *See* 35 U.S.C. § 154(a)(1) (2006); Santoro, *supra* note 62, at 929 (“Others are morally obliged to recognize the rights of inventors by not copying their creative ideas without permission.”).

<sup>78</sup> Santoro, *supra* note 62, at 929 (“Perhaps the most telling indicia of how successful the pharmaceutical companies were in advancing this argument is the highly charged

without permission from the company that initially created and patented the treatment, these arguments proffered by the pharmaceutical companies have been successful.<sup>79</sup>

Similar debates also arise regarding the morality of issuing patents, particularly in relation to biotechnological innovations.<sup>80</sup> These debates consider whether morality should be a component of patent law.<sup>81</sup> One argument notes that “the question of morality in essence concerns the act of creating the technology and as such is problematic within the patent system, since patent law is concerned with protection of technology only.”<sup>82</sup> Thus, this view implies that, although morality and patents are both concerned with the creation process, they are discrete disciplines with differing goals and as such, morality should not be applied to patent law.<sup>83</sup> Those on the other side of the debate, however, contend that “opposing a patent on moral grounds is tantamount to preventing the activity altogether, by a withdrawal of the incentives to perform it, and suggest[] that patent law is a component in regulating, albeit indirectly, the creation of biotechnology.”<sup>84</sup> This argument focuses upon the economic incentives that may serve as motivations for

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moral language that is now commonly used to describe situations when pharmaceutical products are not accorded strong IP protection.”).

<sup>79</sup> *See id.*

<sup>80</sup> *See* Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 687 (2004) (“If patent law is to remain relevant in this era of unprecedented biotechnological advancement, the question arises as to whether patent examiners or courts should be able to deny a patent application or invalidate patents they deem immoral.”). Much of the morality debate surrounding patents relates to the disparities between developed countries that produce the drugs and developing countries that require them. “For example, when pharmaceutical corporations from wealthy industrialized nations charge exorbitant amounts to individuals and public health systems in developing countries for medicine to curb or cure otherwise terminal illnesses, such inflexibility . . . make[s] the development of a universal intellectual property morality all but impossible to achieve.” John Tehranian, *All Rights Reserved? Reassessing Copyright and Patent Enforcement in the Digital Age*, 72 U. CIN. L. REV. 45, 60 (2003). This morality consideration will not be evaluated in this Note, which solely focuses upon the American patent system.

<sup>81</sup> *See* OLIVER MILLS, *BIOTECHNOLOGICAL INVENTIONS: MORAL RESTRAINT AND PATENT LAW* 10 (2005).

<sup>82</sup> *Id.*

<sup>83</sup> *See id.*

<sup>84</sup> *Id.*

scientific researchers to engage in biotechnological innovations that will ultimately benefit society.<sup>85</sup>

Despite the various arguments for and against invoking morality when evaluating patents, the American legal system does not require patent examiners to address the morality of patents.<sup>86</sup> “However, aspects of some recent biotechnology cases could be taken to indicate a limited place in the patent system for moral norms suggesting that such considerations, albeit residual, continue to apply.”<sup>87</sup> Therefore, the evaluation of patents in the United States does not require an analysis of the morality associated with innovation, although morality concerns can be addressed in discrete patent cases.

### *B. Health Care and Public Health Law*

Public health law<sup>88</sup> and the administration of health care to the public must work in concert.<sup>89</sup> This joint effort is especially critical in the event of potentially life-threatening pandemics, such as the 2009 H1N1 swine flu pandemic.<sup>90</sup> In this situation, public health agencies and health care providers should work with the government and with vaccine manufacturers to ensure adequate public education, sufficient availability of the vaccine, and efficient administration of the vaccine to the public.<sup>91</sup> The FDA is a key player in this effort because its approval is required before the pharmaceutical companies can commence production and distribution of the 2009 H1N1 vaccine.<sup>92</sup>

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<sup>85</sup> See *supra* Part I.A.2.

<sup>86</sup> See MILLS, *supra* note 81, at 173; Enerson, *supra* note 80, at 691–92.

<sup>87</sup> MILLS, *supra* note 81, at 50.

<sup>88</sup> Public health law is an expansive field that is composed of eight discrete disciplines: environmental health law; regulation and reporting (surveillance) of disease and injury; laws pertaining to vital statistics; disease and injury control; involuntary testing; contract tracing; immunization and mandatory treatment; and personal restrictions.

<sup>89</sup> See generally Lawrence O. Gostin & Benjamin E. Berkman, *Pandemic Influenza: Ethics, Law and the Public's Health*, 59 ADMIN. L. REV. 121, 140 (2007).

<sup>90</sup> See *id.* (noting that “constructive partnership among government, industry, and the community can vastly improve survival and functioning in an impending crisis”).

<sup>91</sup> See generally CDC, 2009 H1N1 Flu, *supra* note 10; WHO, Pandemic (H1N1) 2009, *supra* note 10.

<sup>92</sup> See 21 C.F.R. § 314.2 (2010).

Part I.B.1 provides an overview of public health law and discusses the initiatives that public health organizations are undertaking in order to ensure the health of the general public during the 2009 H1N1 swine flu pandemic. Part I.B.2 explains the significance of vaccines and describes how vaccines are unique among other biologics.

### 1. Public Health Law

Several public health agencies are working in concert with front-line medical personnel, the government, and pharmaceutical companies in order to combat the 2009 H1N1 swine flu pandemic.<sup>93</sup> For example, public health agencies are actively engaged in the surveillance of the spread of the swine flu pandemic.<sup>94</sup> In addition to tracking the spread of the 2009 H1N1 swine flu virus, public health agencies, such as the CDC and the WHO, educate the public about the virus and encourage the public to become immunized by obtaining the 2009 H1N1 vaccine.<sup>95</sup> Pharmaceutical companies are involved in the public health program by creating not only vaccines, which serve as preventative measures against acquiring the illness,<sup>96</sup> but also antiviral medications to treat the condition.<sup>97</sup> The federal government has also devised a method that allows the 2009 H1N1 vaccine to

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<sup>93</sup> See Gostin & Berkman, *supra* note 89, at 140 (“Planning for an influenza pandemic is vital to success . . . [C]onstructive partnership among government, industry, and the community can vastly improve survival and functioning in an impending crisis.”).

<sup>94</sup> See, e.g., World Health Organization, Pandemic (H1N1) 2009—Update 74, [http://www.who.int/csr/don/2009\\_11\\_13/en/index.html](http://www.who.int/csr/don/2009_11_13/en/index.html) (last visited Feb. 21, 2010); World Health Organization, Timeline: Geographic Spread of Influenza Activity, [http://gamapserver.who.int/h1n1/geographic-spread/h1n1\\_geographic-spread.html](http://gamapserver.who.int/h1n1/geographic-spread/h1n1_geographic-spread.html) (last visited Feb. 21, 2010).

<sup>95</sup> See generally CDC, 2009 H1N1 Flu, *supra* note 10; WHO, Pandemic (H1N1) 2009, *supra* note 10.

<sup>96</sup> See FDA, Influenza A (H1N1) 2009 Monovalent Vaccines Composition and Lot Release, *supra* note 3.

<sup>97</sup> See U.S. Food and Drug Administration, Influenza (Flu) Antiviral Drugs and Related Information, <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm#AntiviralMedications> (last visited Feb. 21, 2010) [hereinafter FDA, Influenza (Flu) Antiviral Drugs and Related Information] (“Antiviral drugs available by prescription can also help to reduce the time it takes for symptoms to improve in uncomplicated illness caused by [the] influenza virus, and are sometimes used in selected situations to reduce the chance of influenza illness if people are exposed to influenza.”).

become widely accessible to members of the general public by financing individuals' purchase of the vaccine.<sup>98</sup> As part of its pandemic preparedness efforts, the government has also been stockpiling antiviral drugs, medications that can be administered to patients following their exposure to the 2009 H1N1 swine flu.<sup>99</sup> Doctors, nurses, and other health care practitioners are involved in the administration of the vaccine and in prescribing the antiviral medication.<sup>100</sup> These practitioners also "play an essential role in influencing the attitudes of patients regarding appropriate immunization."<sup>101</sup>

Public health strategies are "designed to reduce the transmission of disease and to protect individuals from injury."<sup>102</sup> The CDC states that "[t]he single best way to protect against the flu is to get vaccinated each year."<sup>103</sup> Likewise, regarding the 2009 H1N1 swine flu virus, the CDC and other public health agencies are encouraging inoculation as the primary mode of prevention.<sup>104</sup> Since the initial supplies of the 2009 H1N1 vaccine

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<sup>98</sup> See *H1N1 Update on Answers to Physician Questions*, NEWS N.Y. (MSSNY), Nov. 2009, at 12, available at [http://www.mssny.org/mssnycfm/mssnyeditor/File/2009/In\\_the\\_News/NONY/Nov\\_09/NONY-2009-11-web.pdf](http://www.mssny.org/mssnycfm/mssnyeditor/File/2009/In_the_News/NONY/Nov_09/NONY-2009-11-web.pdf) [hereinafter *H1N1 Update on Answers to Physician Questions*]. "The US [sic] government is purchasing all the novel H1N1 vaccine in this country and making it available to physicians and other healthcare providers free of charge." *Id.* In turn, individuals do not have to pay their health care providers for the cost of the 2009 H1N1 vaccine, but they are required to pay the cost involved in administering it. *Id.*

<sup>99</sup> See FDA, *Influenza (Flu) Antiviral Drugs and Related Information*, *supra* note 97. Whereas the 2009 H1N1 vaccine is a preventative measure, antiviral medications are a combative treatment measure designed to ameliorate symptoms of the disease. *Id.*

<sup>100</sup> See generally Centers for Disease Control and Prevention, *Vaccine Information for Clinicians and Health Care Professionals*, <http://www.cdc.gov/h1n1flu/vaccination/professional.htm#6> (last visited Feb. 21, 2010).

<sup>101</sup> FAUCI ET AL., *supra* note 59, at 769.

<sup>102</sup> HALL ET AL., *supra* note 13, at 869.

<sup>103</sup> Centers for Disease Control and Prevention, *Key Facts About Seasonal Flu Vaccine*, <http://www.cdc.gov/flu/protect/keyfacts.htm> (last visited Feb. 21, 2010).

<sup>104</sup> See, e.g., Centers for Disease Control and Prevention, *2009 H1N1 Influenza Vaccine*, [http://www.cdc.gov/h1n1flu/vaccination/public/vaccination\\_qa\\_pub.htm](http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm) (last visited Feb. 21, 2010) [hereinafter CDC, 2009 H1N1 Influenza Vaccine] ("The first and most important step to prevent the flu is to get vaccinated."); World Health Organization, *Vaccines for Pandemic Influenza A(H1N1)*, [http://www.who.int/csr/disease/swineflu/frequently\\_asked\\_questions/vaccine\\_preparedness/en/index.html](http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/en/index.html) (last visited Feb. 21, 2010) [hereinafter WHO, *Vaccines for Pandemic (H1N1)*] ("Influenza vaccines are one of the most effective ways to protect people from contracting illness during influenza

1010 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* [Vol. 20:991

were limited,<sup>105</sup> another public health concern developed regarding the distribution of a scarce resource.<sup>106</sup> In turn, this concern triggered a panoply of social, economic, and political consequences relating to rationing the vaccine.<sup>107</sup>

In addition to providing the 2009 H1N1 vaccine, public health agencies are also educating the public about alternative treatment modalities.<sup>108</sup> The CDC recommends antiviral drugs,<sup>109</sup> such as Tamiflu and Relenza, as a second line of defense to protect against the *symptoms* of the 2009 H1N1 swine flu virus (the vaccine is its recommended *prevention* for the flu).<sup>110</sup> These two antiviral medications can be administered to patients who have already contracted the 2009 H1N1 swine flu virus or have been recently exposed to it.<sup>111</sup> These antiviral treatments shorten the length of time an individual is sick with the flu, lessen the severity of symptoms, and can also prevent serious health complications.<sup>112</sup>

## 2. How Vaccines Differ from Other Pharmaceuticals

Vaccines are biologics composed of either “attenuated live or killed microorganisms or antigenic portions of these agents . . . [that] induce immunity and prevent disease.”<sup>113</sup> Vaccines have

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epidemics and pandemics. . . . The vaccines will boost immunity against the new influenza, and help ensure public health as the pandemic evolves.”)

<sup>105</sup> See CDC, 2009 H1N1 Influenza Vaccine, *supra* note 104 (“When [a] vaccine to protect against 2009 H1N1 first became available, supplies were limited.”).

<sup>106</sup> See generally Nicosia, *supra* note 8, at 491–92.

<sup>107</sup> See Gostin & Berkman, *supra* note 89, at 137–40.

<sup>108</sup> See Centers for Disease Control and Prevention, Antiviral Drugs, 2009–2010 Flu Season, <http://www.cdc.gov/h1n1flu/antiviral.htm> (last visited Feb. 21, 2010) [hereinafter CDC, Antiviral Drugs, 2009–2010 Flu Season].

<sup>109</sup> “Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the flu in your body.” CDC, 2009 H1N1 and Seasonal Flu: What You Should Know About Flu Antiviral Drugs (Oct. 10, 2009), [http://www.cdc.gov/flu/freeresources/2009-10/pdf/Antiviral\\_H1N1\\_factsheet.pdf](http://www.cdc.gov/flu/freeresources/2009-10/pdf/Antiviral_H1N1_factsheet.pdf).

<sup>110</sup> *Id.* Thus, the 2009 H1N1 vaccine is administered in order to prevent individuals from contracting the 2009 H1N1 swine flu virus whereas antiviral medications are prescribed to individuals who were exposed to the 2009 H1N1 swine flu and are combating its symptoms. *Id.*

<sup>111</sup> See *id.*

<sup>112</sup> See *id.*

<sup>113</sup> FAUCI ET AL., *supra* note 59, at 759.

significant public health ramifications.<sup>114</sup> Specifically, regarding contagious diseases that spread from person to person, public health authorities strive to maintain acceptable immunity levels within the population. Achieving herd immunity, “a definable prevalence of immunity in the population above which it becomes difficult for the organism to circulate and reach new susceptibles”<sup>115</sup> lowers the incidence of new disease. Overall, public health agencies have been successful in educating and encouraging the general population to receive vaccines so as to limit the occurrence of contagious diseases that are preventable by vaccination.<sup>116</sup>

Yet, “vaccines must be developed, manufactured, and distributed if they are to be used to protect public health.”<sup>117</sup> This process is composed of four discrete stages, which evaluate both the efficacy and safety of the vaccine being produced.<sup>118</sup> These steps include animal studies to identify the protective antigen, analysis of the antigen’s effect on the immune system, assessment of the vaccine’s safety in human populations of various ages, and an evaluation of the vaccine’s effectiveness in its target population.<sup>119</sup> In the United States, private pharmaceutical companies, rather than governmental organizations, typically create and manufacture vaccines.<sup>120</sup>

However, the production of flu vaccines is particularly complex.<sup>121</sup> Since new strains of the flu emerge each season, a novel flu vaccine must be produced each year to combat the

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<sup>114</sup> *See id.* at 769. For example, “[t]he epidemiologically appropriate use of vaccines has resulted in the global eradication of smallpox; the elimination of poliomyelitis in the Americas; the virtual elimination of congenital rubella syndrome, tetanus, and diphtheria in the United States; and a dramatic reduction in pertussis, rubella, measles, and mumps in the United States.” *Id.* at 758.

<sup>115</sup> *Id.* at 760. Public health agencies must continue to monitor the spread of a contagious illness even after herd immunity is achieved within a population. *See id.* at 769. Furthermore, future generations must also be vaccinated if the illness continues to circulate. *See id.*

<sup>116</sup> *See id.* at 769.

<sup>117</sup> HALL ET AL., *supra* note 13, at 894.

<sup>118</sup> FAUCI ET AL., *supra* note 59, at 760.

<sup>119</sup> *See id.* at 760–61.

<sup>120</sup> HALL ET AL., *supra* note 13, at 894.

<sup>121</sup> *See* FAUCI ET AL., *supra* note 59, at 760.

seasonal flu.<sup>122</sup> Flu vaccine production was unique during 2009 because rather than producing one seasonal flu vaccine, pharmaceutical companies also produced a second vaccine to combat the 2009 H1N1 swine flu virus.<sup>123</sup> In addition to educating the public about the vaccine itself, public health agencies also informed the public that the 2009 flu season may pose a greater public health threat than the one normally encountered in a typical flu season.<sup>124</sup> The modification was necessary because the 2009 H1N1 swine flu was likely to lead to more serious health risks in pregnant women and in individuals who are twenty-five years of age and under when compared to the typical seasonal influenza.<sup>125</sup>

### C. 2009 H1N1 Swine Flu

Swine flu is a type of influenza virus that infects humans, although the virus itself originates in pigs.<sup>126</sup> Swine flu symptoms are similar to those of a typical seasonal flu.<sup>127</sup> The symptoms of the 2009 H1N1 swine flu “include fever, cough, sore throat, runny

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<sup>122</sup> See *id.* (“Influenza virus, characterized biologically by its antigenic drift, periodically emerges in a new antigenic version capable of causing a global pandemic for which a new vaccine must be rapidly devised, produced, and distributed.”).

<sup>123</sup> See CDC, 2009 H1N1 Influenza Vaccine, *supra* note 104. The availability of two vaccines, each providing inoculation against a different strain of flu, resulted in the need for public health agencies to educate the population about the difference between these vaccines. See *id.* Moreover, public health agencies notified the general public that in order to receive immunity to both forms of the flu circulating during the 2009 flu season, they must receive two separate vaccinations. *Id.*

<sup>124</sup> Centers for Disease Control and Prevention, 2009–10 Influenza (Flu) Season, <http://www.cdc.gov/flu/about/season/current-season.htm> (last visited Feb. 21, 2010) [hereinafter CDC, 2009–10 Influenza (Flu) Season]. “There is concern that the 2009 H1N1 virus may cause the season to be worse than a regular flu season—with a lot more people getting sick, being hospitalized and dying than during a regular flu season.” Adraenne Bowe, *How to Avoid the Swine Flu This Season*, *ADVOCATE*, Oct. 21, 2009, <http://www.gcadvocate.com/2009/10/how-to-avoid-the-swine-flu-this-season10/>.

<sup>125</sup> See Centers for Disease Control and Prevention, 2009 H1N1 Flu (“Swine Flu”) and You, <http://www.cdc.gov/h1n1flu/qa.htm> (last visited Feb. 21, 2010) [hereinafter CDC, 2009 H1N1 Flu (“Swine Flu”) and You].

<sup>126</sup> *Id.*

<sup>127</sup> Centers for Disease Control and Prevention, Novel H1N1 Flu: Background on the Situation, <http://www.cdc.gov/h1n1flu/background.htm> (last visited Feb. 21, 2010) [hereinafter CDC, Novel H1N1 Flu: Background on the Situation] (“Novel H1N1 infection has been reported to cause a wide range of flu-like symptoms, including fever, cough, sore throat, body aches, headaches, chills and fatigue. In addition, many people also have reported nausea, vomiting and/or diarrhea.”).



or stuffy nose, body aches, headache, chills and fatigue.”<sup>128</sup> However, the 2009 H1N1 swine flu virus differs from the typical seasonal flu virus.<sup>129</sup> For example, the 2009 “novel H1N1 virus preferentially infects younger people . . . under the age of 25 years.”<sup>130</sup> This particular targeting does not occur with typical flu viruses that infect all ages of the population with an increased frequency among the elderly.<sup>131</sup> Furthermore, it should be noted that between one-third and one-half of the fatal 2009 H1N1 swine flu episodes have occurred in healthy individuals<sup>132</sup> whereas the typical seasonal flu primarily results in death among the frail or elderly populations.<sup>133</sup> The typical flu season in the United States spans from late November through March<sup>134</sup> whereas swine flu can develop on a more erratic time table.<sup>135</sup> For example, in 2009, swine flu was first detected in the United States in April,<sup>136</sup> after the conclusion of the typical flu season.<sup>137</sup> The CDC states that annual vaccination is the best mode of prevention against acquiring the seasonal flu.<sup>138</sup> Similarly, a vaccine has been created in order to prevent the spread of the 2009 H1N1 swine flu virus.<sup>139</sup>

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<sup>128</sup> CDC, 2009 H1N1 Flu (“Swine Flu”) and You, *supra* note 125.

<sup>129</sup> *See generally id.*; CDC, Seasonal Influenza, *supra* note 54; CDC, The Flu Season, *supra* note 55.

<sup>130</sup> Chan, *supra* note 1, at 2.

<sup>131</sup> *See id.*

<sup>132</sup> *See id.* (“Around one third to half of the severe and fatal [swine flu] infections are occurring in previously healthy young and middle-aged people.”).

<sup>133</sup> *See id.*

<sup>134</sup> *See* CDC, The Flu Season, *supra* note 55.

<sup>135</sup> *See* CDC, 2009–10 Influenza (Flu) Season, *supra* note 124.

<sup>136</sup> *See* CDC, 2009 H1N1 Flu (“Swine Flu”) and You, *supra* note 125.

<sup>137</sup> *See* Centers for Disease Control and Prevention, 2008–2009 Influenza Season Week 15 Ending April 18, 2009 (Apr. 24, 2009), [http://www.cdc.gov/flu/weekly/weekly\\_archives2008-2009/weekly15.htm](http://www.cdc.gov/flu/weekly/weekly_archives2008-2009/weekly15.htm). During the week of April 12 to 18, 2009, the seasonal flu decreased to only a 6.2% occurrence in the United States. *Id.* On April 15, 2009, that same week, the CDC confirmed the first case of the 2009 H1N1 swine flu strain in the United States. CDC, Novel H1N1 Flu: Background on the Situation, *supra* note 127. “[I]n the United States, significant novel H1N1 illness has continued into the summer, with localized and in some cases intense outbreaks occurring.” *Id.*

<sup>138</sup> CDC, Seasonal Influenza, *supra* note 54.

<sup>139</sup> CDC, 2009 H1N1 Influenza Vaccine, *supra* note 104. “Vaccines are the most powerful public health tool for control of influenza, and the U.S. government worked closely with manufacturers to take steps in the process to manufacture a 2009 H1N1 vaccine.” HAW. STATE DEP’T OF HEALTH, 2009 H1N1 INFLUENZA VACCINE FREQUENTLY

This section of the Note analyzes the history of the swine flu in the United States as well as the preventative measures that can be taken to combat this strain of influenza. Part I.C.1 summarizes the 2009 H1N1 swine flu pandemic. Part I.C.2 depicts the previous swine flu outbreaks in the United States, which occurred in 1918 and in 1976. Part I.C.3 illustrates the series of events associated with the 1976 swine flu vaccine. Finally, Part I.C.4 describes the current swine flu vaccine that is intended to combat the 2009 H1N1 swine flu.

### 1. The Current 2009 H1N1 Swine Flu Pandemic

On June 11, 2009, the WHO declared a global swine flu pandemic.<sup>140</sup> The WHO's proclamation concomitantly raised the pandemic alert to a Phase 6 level, which reflects the global nature of the disease.<sup>141</sup> Generally, "[a]n influenza pandemic can be defined as a global epidemic of influenza and it occurs when a new influenza virus (i.e. an influenza virus subtype that is not circulating widely in human beings) emerges and starts spreading in a similar way to normal influenza—through coughing and sneezing."<sup>142</sup> Since humans have not been previously exposed to the specific virus, they do not possess the requisite immunity to

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ASKED QUESTIONS (FAQ) 1 (2009), available at [http://hawaii.gov/health/about/reports/H1N1\\_FAQ\\_forWEB.pdf](http://hawaii.gov/health/about/reports/H1N1_FAQ_forWEB.pdf).

<sup>140</sup> Chan, *supra* note 1, at 1. WHO data reveals that on June 11, 2009, there were 28,774 reported cases of the 2009 H1N1 swine flu that occurred in 74 countries. World Health Organization, Influenza A(H1N1)—Update 47 (June 11, 2009), [http://www.who.int/csr/don/2009\\_06\\_11/en](http://www.who.int/csr/don/2009_06_11/en). Of those cases, 144 resulted in death. *Id.*

<sup>141</sup> Chan, *supra* note 1, at 1. "Phases 1–3 [of the WHO phases of pandemic alerts] correlate with preparedness, including capacity development and response planning activities, while Phases 4–6 clearly signal the need for response and mitigation efforts." World Health Organization, Current WHO Phase of Pandemic Alert, [http://www.who.int/csr/disease/avian\\_influenza/phase/en/print.html](http://www.who.int/csr/disease/avian_influenza/phase/en/print.html) (last visited Oct. 12, 2009). Phase 6 is the pandemic phase, which is defined as "human-to-human spread of the virus into at least two countries in one WHO region . . . [and] by community level outbreaks in at least one other country in a different WHO region." *Id.* It should be noted that the WHO elevated the pandemic alert to Phase 6 in response to the spread of the 2009 H1N1 swine flu and not due to the severity of the disease. CDC, Novel H1N1 Flu: Background on the Situation, *supra* note 127.

<sup>142</sup> World Health Organization, Regional Office for Europe, [http://www.euro.who.int/influenza/20080618\\_20](http://www.euro.who.int/influenza/20080618_20) (last visited Feb. 21, 2010) [hereinafter WHO, Regional Office for Europe].

fight the novel flu virus that has emerged and thus are affected by the symptoms of the disease.<sup>143</sup>

This lack of human immunity to pandemic influenzas, like the 2009 H1N1 swine flu virus, causes those who “contract pandemic influenza . . . to experience [a] more serious disease than that caused by normal influenza.”<sup>144</sup> Moreover, the 2009 H1N1 swine flu is not a typical human flu and according to the WHO, the current virulent strain of the swine flu that triggered the pandemic has never infected humans in the past.<sup>145</sup> Furthermore, although this strain is referred to as the swine flu, it is actually a “quadruple reassortant” virus composed of “two genes from flu viruses that normally circulate in pigs in Europe and Asia and bird (avian) genes and human genes.”<sup>146</sup>

This particular swine flu outbreak, which is caused by the 2009 H1N1 swine flu strain, originated in Mexico in March 2009, toward the end of Mexico’s annual flu season.<sup>147</sup> However,

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<sup>143</sup> FAUCI ET AL., *supra* note 59, at 760 (“[A]n individual is susceptible to all serotypes against which he or she lacks [an] antibody.”).

<sup>144</sup> WHO, Regional Office for Europe, *supra* note 142.

<sup>145</sup> See Chan, *supra* note 1, at 1 (“In late April, WHO announced the emergence of a novel influenza A virus . . . . The virus is entirely new, the virus is contagious, spreading easily from one person to another, and from one country to another.”).

<sup>146</sup> CDC, 2009 H1N1 Flu (“Swine Flu”) and You, *supra* note 125 (“This virus was originally referred to as ‘swine flu’ because laboratory testing showed that many of the genes in this new virus were very similar to influenza that normally occur in pigs (swine) in North America. But further study has shown that this new virus is very different from what normally circulates in North American pigs.”).

<sup>147</sup> Donald G. McNeil, Jr., *Flu Outbreak Raises a Set of Questions*, N.Y. TIMES, Apr. 27, 2009, <http://www.nytimes.com/2009/04/27/health/27questions.html> [hereinafter McNeil, *Flu Outbreak Raises a Set of Questions*]. A separate spike in cases of the seasonal flu toward the end of the annual influenza season generally indicates that “B strain flus peak[ed] later in the season.” *Id.* However, B strain flus are mild flus and would not have created the severe illness observed in Mexico. *Id.* Edgar Hernandez, a five year old Mexican boy, was the first to be infected with this novel swine flu. Marc Lacey, *From Edgar, 5, Coughs Heard Round the World*, N.Y. TIMES, Apr. 29, 2009, at A1, available at <http://query.nytimes.com/gst/fullpage.html?res=9501E2DC133CF93AA15757C0A96F9C8B63>. Hernandez has since recovered from the illness. Donald G. McNeil, Jr., *W.H.O. Issues Higher Alert on Swine Flu, with Advice*, N.Y. TIMES, Apr. 28, 2009, at A10, available at <http://www.nytimes.com/2009/04/27/health/27questions.html> [hereinafter McNeil, *W.H.O. Issues Higher Alert on Swine Flu, with Advice*]. It is interesting to note that Edgar Hernandez resides in La Gloria, a Mexican town with a large pig farming industry. *Id.* However, a spokesperson for the pig farming plant claimed that all of its pigs were vaccinated against the flu and none of its workers

Mexican authorities did not detect the peak in respiratory disease and death until early April 2009.<sup>148</sup> At that time, Mexican authorities sent samples of the virus to the United States for assistance in classifying the new disease<sup>149</sup> because only two laboratories possessed the reagents necessary to identify this novel flu strain.<sup>150</sup>

By April 24, 2009, there were seven confirmed cases of 2009 H1N1 swine flu in the United States<sup>151</sup> and nine suspected cases.<sup>152</sup> Three days later, on April 27, 2009, the first swine flu death occurred in the United States.<sup>153</sup> It should be noted, though, that the first death from the 2009 H1N1 swine flu in the United States involved a 23-month old boy who resided in Mexico City.<sup>154</sup> The child was visiting family in Brownsville, Texas, a town located near the Mexican border, when he began to experience symptoms of the virus.<sup>155</sup> Thus, it is possible that this child contracted the 2009 H1N1 swine flu while he was in Mexico rather than in the United States. The toddler spent two weeks at Texas Children's Hospital in Houston before dying from this disease.<sup>156</sup>

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contracted swine flu before Hernandez had gotten sick with the 2009 H1N1 swine flu virus. *Id.*

<sup>148</sup> McNeil, *Flu Outbreak Raises a Set of Questions*, *supra* note 147.

<sup>149</sup> *Id.* (“[The Mexicans] ask[ed] for help genotyping the new virus.”).

<sup>150</sup> *Id.* These laboratories are the CDC laboratory located in Atlanta and the Canadian National Laboratory in Winnipeg, Canada. *Id.* The CDC developed a test kit for identifying the 2009 H1N1 swine flu, which it sent to other states and countries to enable them to diagnose swine flu. McNeil, *W.H.O. Issues Higher Alert on Swine Flu, with Advice*, *supra* note 147. It is possible that this increase in testing for the 2009 H1N1 swine flu in various locations worldwide “could lead to a sharp increase in confirmed cases.” *Id.*

<sup>151</sup> World Health Organization, *Influenza-like Illness in the United States and Mexico* (Apr. 24, 2009), [http://www.who.int/csr/don/2009\\_04\\_24/en](http://www.who.int/csr/don/2009_04_24/en). Of the first seven confirmed cases of 2009 H1N1 swine flu in the United States, five occurred in California and two arose in Texas. *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> See James C. McKinley, Jr., *Mexican Child Visiting U.S. 1st to Die Here of Swine Flu*, N.Y. TIMES, Apr. 30, 2009, at A14, available at <http://query.nytimes.com/gst/fullpage.html?res=9805E4DF1731F933A05757C0A96F9C8B63>.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

Following the emergence of the 2009 H1N1 swine flu in Mexico, the next major outbreak occurred in New York City.<sup>157</sup> The initial cases of the 2009 H1N1 swine flu in New York were all connected to Saint Francis Preparatory School in Fresh Meadows, Queens.<sup>158</sup> Both hospital and city officials in New York noted the overwhelming influx of emergency room visits during the spring of 2009.<sup>159</sup> “On May 25, the worst day of the spring outbreak, 2,500 people visited emergency rooms in the city complaining of influenza-like illness . . . . The number on the same day last year was 150.”<sup>160</sup> New York hospital and city officials also identified a direct correlation between the daily number of hospital visits and the news about 2009 H1N1 swine flu deaths and school closings.<sup>161</sup> Despite the dramatic increase in the numbers of people seeking emergency room care, however, only forty to fifty

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<sup>157</sup> Anemona Hartocollis, *Lesson Learned, City Prepares for a Resurgence of Swine Flu*, N.Y. TIMES, July 21, 2009, at A15, available at <http://www.nytimes.com/2009/07/21/nyregion/21flu.html> [hereinafter Hartocollis, *Lesson Learned, City Prepares for a Resurgence of Swine Flu*].

As of July 7, 909 New Yorkers had been hospitalized with swine flu and 47 had died, a fraction of the 1,000 deaths in New York attributed to influenza each year. City officials estimate that 7 percent to 10 percent of New Yorkers, or 580,000 to 830,000 people, had contracted the H1N1 virus, but most had only mild symptoms. A seasonal flu is usually contracted by 5 percent to 20 percent of the population.

*Id.* According to Dr. Thomas A. Farley, the City Health Commissioner, 930 people were hospitalized with the 2009 H1N1 swine flu and 54 people died of the swine flu in New York. Sewell Chan & Lisa W. Foderaro, *This Time, City Says It's Ready for Swine Flu*, N.Y. TIMES, Sept. 2, 2009, <http://query.nytimes.com/gst/fullpage.html?res=9A04EEDD143DF931A3575AC0A96F9C8B63>. A survey conducted by the city's health department indicates that between 750,000 and 1 million New Yorkers suffered from the swine flu in the spring of 2009. *Id.*

<sup>158</sup> Donald G. McNeil, Jr., *U.S. Declares Public Health Emergency over Swine Flu*, N.Y. TIMES, Apr. 27, 2009, <http://travel.nytimes.com/2009/04/27/world/27flu.html>.

<sup>159</sup> See Hartocollis, *Lesson Learned, City Prepares for a Resurgence of Swine Flu*, *supra* note 157.

<sup>160</sup> *Id.*

<sup>161</sup> See *id.* (“Visits to emergency rooms began to rise sharply on May 16, the day after the first news reports that an assistant principal in Queens had been hospitalized with swine flu. The assistant principal, Mitchell Wiener, died on May 17, and another spike in hospital visits followed.”).

1018 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* [Vol. 20:991

people were actually hospitalized during the worst points of the outbreak in May 2009.<sup>162</sup>

Although the 2009 H1N1 swine flu spread rapidly, the Director-General of the WHO stated that “the overwhelming majority of patients experience mild symptoms and make a rapid and full recovery—often in the absence of any form of medical treatment.”<sup>163</sup> Initially, health officials claimed that the majority of the people who developed severe reactions to the 2009 H1N1 swine flu also suffered from other pre-existing conditions.<sup>164</sup> However, new studies have revealed that among 1,400 hospitalized adults, 46% did not suffer from any pre-existing or chronic conditions.<sup>165</sup>

Moreover, health officials remain concerned because “[p]andemic flus—like the 1918 flu and outbreaks in 1957 and 1968—often strike young, healthy people the hardest.”<sup>166</sup> This phenomenon occurs because the immune response itself in these healthy adults is so intense that rather than solely combating the virus, the violent immune system response also leads to severe pathological ramifications, including death.<sup>167</sup> Experts believe that older people may have acquired some immunity to the 2009 H1N1

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<sup>162</sup> See *id.* (“[I]n an indication of the large number of what doctors call the ‘worried well,’ only 40 to 50 people a day were hospitalized during the worst stretch of that month, records show.”).

<sup>163</sup> Chan, *supra* note 1, at 1–2.

<sup>164</sup> See Mike Stobbe, *Near Half of Swine Flu Patients Otherwise Healthy*, ABC NEWS, Oct. 13, 2009, <http://abcnews.go.com/Health/wireStory?id=8818376>. In a study of 272 patients who were hospitalized with the 2009 H1N1 swine flu for at least a 24 hour period, 83% of the adults and 60% of the children evaluated also suffered from pre-existing conditions. Seema Jain, M.D. et al., *Hospitalized Patients with 2009 H1N1 Influenza in the United States, April-June 2009*, 361 *NEW ENG. J. MED.* 1935, 1935, 1937 (2009), available at <http://content.nejm.org/cgi/content/full/NEJMoa0906695>. Asthma was the most common pre-existing condition observed among these 272 patients. *Id.* at 1937.

<sup>165</sup> See Stobbe, *supra* note 164.

<sup>166</sup> McNeil, *Flu Outbreak Raises a Set of Questions*, *supra* note 147. “Unlike typical flu seasons, when infants and the aged are usually the most vulnerable, none of the initial deaths in Mexico were in people older than 60 or younger than 3 years old, a spokeswoman with the World Health Organization said.” *Id.*

<sup>167</sup> See *id.* (“When a new virus emerges, deaths may occur in healthy adults who mount the strongest immune reactions. Their own defenses—inflammation and leaking fluid in lung cells—can essentially drown them from inside.”).

swine flu due to their exposure to other similar viruses during their lifetime.<sup>168</sup>

President Obama and his administration warned Americans that “[t]he potential for a significant outbreak [of the 2009 H1N1 swine flu] in the fall is looming.”<sup>169</sup> During the spring, summer, and early fall of 2009, biologics and pharmaceuticals were created in order to combat this influenza virus.<sup>170</sup> The 2009 H1N1 vaccine is considered the most effective way to avoid contracting the 2009 H1N1 swine flu.<sup>171</sup> However, antiviral medications, such as Tamiflu or Relenza, are also available to both out-patients and to those hospitalized with either confirmed or suspected cases of swine flu.<sup>172</sup> These antiviral drugs reduce both the severity and the duration of the illness in patients afflicted with swine flu.<sup>173</sup>

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<sup>168</sup> See Stobbe, *supra* note 164.

<sup>169</sup> Donald G. McNeil, Jr., *Obama Warns of Return of Swine Flu in the Fall*, N.Y. TIMES, July 10, 2009, at A18, available at <http://query.nytimes.com/gst/fullpage.html?res=9D07E3DF103CF933A25754C0A96F9C8B63> [hereinafter McNeil, *Obama Warns of Return of Swine Flu in the Fall*] (“The Obama administration warned Americans . . . to be ready for an aggressive return of the swine flu virus in the fall.”). However, an alternative theory, which set forth three arguments, postulated that the 2009 H1N1 swine flu is not likely to be “abnormally lethal” during the fall of 2009. Editorial, *Preparing for the Swine Flu*, N.Y. TIMES, Sept. 1, 2009, [http://www.nytimes.com/2009/09/01/opinion/01tue1.html?\\_r=1](http://www.nytimes.com/2009/09/01/opinion/01tue1.html?_r=1) [hereinafter Editorial, *Preparing for the Swine Flu*]. This theory began by noting the “encouragingly low death rate” in the spring of 2009, wherein only 54 people died of the 2009 H1N1 swine flu among approximately 800,000 New Yorkers who contracted the virus. *Id.* The theory’s second principle stated that “the virus has not become more virulent as it wends its way around the world,” which implied that the fall 2009 outbreak should not be more severe than the outbreak that occurred this past spring. *Id.* Finally, this theory underscored that the “Bush administration and Congress invested heavily in planning and in stockpiling medicines and medical supplies to fight a feared avian flu pandemic that never materialized, and the Obama administration has continued the effort. The same medicines should work against the swine flu virus.” *Id.*

<sup>170</sup> See generally CDC, 2009 H1N1 Flu (“Swine Flu”) and You, *supra* note 125.

<sup>171</sup> See CDC, 2009 H1N1 Influenza Vaccine, *supra* note 104. Part I.C.4 of this Note will discuss the current 2009 H1N1 swine flu vaccine.

<sup>172</sup> See CDC, Antiviral Drugs, 2009–2010 Flu Season, *supra* note 108 (recommending that physicians “prioritize use of these drugs for those patients who are severely ill (such as those who are hospitalized) and those patients who are ill with influenza-like illness and who are higher risk for influenza related complications”).

<sup>173</sup> See *id.* (“[T]hese drugs can reduce the severity of flu symptoms and shorten the time you are sick by 1 or 2 days.”). Three cases of the 2009 H1N1 swine flu were detected where the virus was resistant to Tamiflu. McNeil, *Obama Warns of Return of Swine Flu in the Fall*, *supra* note 169. “Health officials said that they were aware of fears that a

## 2. Previous Swine Flu Outbreaks in the United States—1918 and 1976

A previous swine flu pandemic swept the world in 1918.<sup>174</sup> The 1918 influenza, also known as the Spanish flu,<sup>175</sup> infected approximately one-third of the world's population (estimated to be roughly 500 million people in 1918)<sup>176</sup> and killed between 50 and 100 million people.<sup>177</sup> The morbidity and mortality phenomenon observed during the 2009 H1N1 swine flu virus outbreak reflects that of the Spanish flu, where the “absolute risk of influenza death was higher in those [younger than] 65 years of age than in those [older than] 65.”<sup>178</sup> Therefore, it becomes apparent that the impact of the Spanish flu virus extended beyond 1918 because future swine flu outbreaks exhibited the same morbidity and mortality pattern. It should also be noted that “[a]ll influenza A pandemics since that time . . . have been caused by descendants of the 1918

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Tamiflu-resistant strain of the virus was already spreading silently in the United States, but that they had not seen evidence that it was a threat.” *Id.*

<sup>174</sup> See generally Jeffrey K. Taubenberger & David M. Morens, *1918 Influenza: The Mother of All Pandemics*, 12 EMERGING INFECTIOUS DISEASES 15 (2006), available at <http://www.cdc.gov/ncidod/eid/vol12no01/pdfs/05-0979.pdf> (citing a brief history of the 1918 Spanish flu pandemic in order to illustrate the potential severity of the 2009 H1N1 swine flu virus). There were two additional influenza pandemics in the twentieth century. Robert B. Belshe, M.D., *The Origins of Pandemic Influenza—Lessons from the 1918 Virus*, 353 NEW ENG. J. MED. 2209, 2209 (2005), available at <http://content.nejm.org/cgi/reprint/353/21/2209.pdf>. Asian influenza occurred in 1957 with the H2N2 virus, and the Hong Kong influenza occurred in 1968 with the H3N2 virus. *Id.* These two influenza pandemics were not caused by the H1N1 virus and will not be discussed in this Note.

<sup>175</sup> Nicholas Bakalar, *How (and How Not) to Battle Flu: A Tale of 23 Cities*, N.Y. TIMES, Apr. 17, 2009, at F5, available at <http://www.nytimes.com/2007/04/17/health/17flu.html?scp=2&sq=%22spanish%20flu%22&st=cse>.

<sup>176</sup> Taubenberger & Morens, *supra* note 174, at 15.

<sup>177</sup> *Id.* (“Total deaths were estimated at 50 million and were arguably as high as 100 million.”).

<sup>178</sup> See *id.* at 15, 19. Furthermore, “[n]early half of the [1918] influenza-related deaths . . . were in young adults 20–40 years of age.” *Id.* at 19. Similarly, the WHO noted that “[m]ost cases of severe and fatal infections have been in adults between the ages of 30 and 50 years.” Chan, *supra* note 1, at 2. To this end, the CDC established a priority list of individuals who should receive the 2009 H1N1 vaccine, which prioritizes individuals between the ages of 25 and 64 years old. Centers for Disease Control and Prevention, 2009 H1N1 Vaccination Recommendation, <http://www.cdc.gov/h1n1flu/vaccination/acip.htm> (last visited Feb. 21, 2010).



virus,” except for those caused by avian viruses.<sup>179</sup> The 2009 H1N1 swine flu virus has been found to be a descendent of the Spanish flu virus, and is composed of “key genes from the 1918 virus.”<sup>180</sup> Like the Spanish flu, the 2009 H1N1 swine flu is caused by the H1N1 A strain, which may explain the similar morbidity and mortality patterns observed during both pandemics.<sup>181</sup>

Another swine flu outbreak, which began in January 1976, was detected on an army base in Fort Dix, New Jersey.<sup>182</sup> By the end of January 1976, 155 cases of swine flu were reported at the Fort Dix base.<sup>183</sup> No cases of the 1976 swine flu were reported anywhere else in the United States.<sup>184</sup>

Following the death of an army private, initial concern arose because a young, healthy individual is not typically expected to die from the flu.<sup>185</sup> Subsequently, the CDC tested blood samples from the deceased and determined that he in fact had contracted swine flu.<sup>186</sup> Specifically, the CDC found that the army private’s “immune system had developed antibodies to a strain of flu similar to the Spanish influenza of 1918. That particular strain of swine flu produced the worst human pandemic of the 20<sup>th</sup> century.”<sup>187</sup> This discovery caused CDC scientists and researchers to worry that

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<sup>179</sup> Taubenberger & Morens, *supra* note 174, at 15. The H5N1 and H7N7 viruses are the two main examples of avian viruses that caused human infections. These viruses are not descendants of the 1918 virus. *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* The 2009 H1N1 swine flu is caused by the (A)H1N1 strain. *Id.* Therefore, there is further reason to suspect that the 2009 H1N1 swine flu pandemic could be as virulent as the 1918 flu pandemic.

<sup>182</sup> David J. Sencer & J. Donald Millar, *Reflections on the 1976 Swine Flu Vaccination Program*, 12 EMERGING INFECTIOUS DISEASES 29, 29 (2006), available at <http://www.cdc.gov/ncidod/eid/vol12no01/pdfs/05-0979.pdf>. This Note will analyze the vaccine that was developed in order to combat the 1976 H1N1 swine flu. *See infra* Part I.C.3.

<sup>183</sup> Patrick Di Justo, *The Last Great Swine Flu Epidemic*, SALON, Apr. 28, 2009, [http://www.salon.com/env/feature/2009/04/28/1976\\_swine\\_flu](http://www.salon.com/env/feature/2009/04/28/1976_swine_flu) (“By the end of January, 155 soldiers at Fort Dix reported positive for swine flu antibodies. None of the soldiers’ families or co-workers, however, had been exposed to the virus; all of the reported swine flu cases had been limited to the soldiers in . . . [the] camp.”).

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

another pandemic could result.<sup>188</sup> Government officials shared these concerns: “When studies showed a viral infection similar to the one responsible for the 1918–1919 Swine Flu pandemic, President Ford (and others) urged the appropriation of emergency funds for a nationwide influenza immunization program.”<sup>189</sup>

### 3. The 1976 Swine Flu Vaccine

Fear that the 1976 swine flu would imitate the 1918 Spanish flu by infecting and killing a significant proportion of the world’s population prompted the United States to develop a swine flu vaccine.<sup>190</sup> However, it is necessary to underscore that “even with modern antiviral and antibacterial drugs, vaccines, and prevention knowledge, the return of a pandemic virus equivalent in pathogenicity to the virus of 1918 would likely kill [more than] 100 million people worldwide.”<sup>191</sup>

On March 13, 1976, the director of the CDC, concerned about a swine flu pandemic, “asked Congress for money to develop and test enough swine flu vaccine to immunize at least 80 percent of the population of the United States, believed to be the minimum needed to avoid an epidemic.”<sup>192</sup> Although the director of the CDC set forth four possible proposals regarding actions in response to the swine flu, the CDC recommended that the federal government contract directly with pharmaceutical companies so that an adequate amount of vaccine could be produced to immunize the population.<sup>193</sup> The CDC also suggested that the

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<sup>188</sup> *Id.* (“If [the soldiers at the Fort Dix base] had been exposed to something like the 1918 flu virus, the world could be in for an extensive and lethal outbreak.”).

<sup>189</sup> Nina S. Appel, *Liability in Mass Immunization Programs*, 1980 BYU L. REV. 69, 69.

<sup>190</sup> *Id.* (“When studies showed a viral infection similar to the one responsible for the 1918–1919 Swine Flu pandemic, President Ford (and others) urged the appropriation of emergency funds for a nationwide influenza immunization program.”).

<sup>191</sup> Taubenberger & Morens, *supra* note 174, at 21.

<sup>192</sup> Di Justo, *supra* note 183.

<sup>193</sup> See Sencer & Millar, *supra* note 182, at 30. The first proposal offered by the director of the CDC was to allow the market to operate as usual on the assumption that a swine flu pandemic might not result in 1976. *Id.* The director’s second suggestion, which was ultimately selected, recommended that the federal government “embark on a major program to immunize a highly susceptible population” by contracting with pharmaceutical companies that would develop and produce the requisite amount of swine

“federal government . . . make grants to state health departments to organize and conduct immunization programs . . . [and] provide vaccines to state health departments and private medical practices.”<sup>194</sup> President Ford accepted this proposal that involved both a federal and state government response.<sup>195</sup> Thus, the National Influenza Immunization Program was created.<sup>196</sup>

During production of the 1976 swine flu vaccine, the pharmaceutical companies posed an ultimatum wherein they required that “the federal government indemnify them against claims of adverse reactions as a requirement for release of the vaccine.”<sup>197</sup> The government acquiesced and developed the Swine Flu Act,<sup>198</sup> which assured the manufacturers of the 1976 swine flu

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flu vaccines. *Id.* The third proposal was a “minimal response, in which the federal government would contract for sufficient vaccine to provide to traditional healthcare beneficiaries—military personnel, Native Americans, and Medicare-eligible persons.” *Id.* The final alternative suggested an exclusively federal response without involving the state governments. *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *Id.*

<sup>196</sup> *Id.* The CDC created a new unit to implement the National Influenza Immunization Program. *Id.* This unit:

was responsible for relations with state and local health departments (including administration of the grant program for state operations, technical advice to the procurement staff for vaccine, and warehousing and distribution of the vaccine to state health departments) and established a proactive system of surveillance for possible adverse effects of the influenza vaccine.

*Id.* at 30–31.

<sup>197</sup> *Id.* at 31. It should be noted that:

the legislation completely absolved program participants from any claims of strict liability under Section 402A of the Restatement (Second) of Torts but not as to claims based on common law negligence. This provision tended to alleviate the most serious liability concern of the vaccine manufacturers and required that they obtain insurance covering their liability arising from negligence.

David W. Case, *The EPA’s HPV Challenge Program: A Tort Liability Trap?*, 62 WASH. & LEE L. REV. 147, 200 (2005).

<sup>198</sup> See generally National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113. This statute is

[a]n Act to amend the Public Health Service Act to authorize the establishment and implementation of an emergency national swine flu immunization program and to provide an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the swine flu vaccine under such program.

vaccine that “lawsuits against the government [were] the exclusive remedy for all actions connected with the Swine Flu program.”<sup>199</sup> One commentator notes: “While the manufacturers’ ultimatum reflected the trend of increased litigiousness in American society, its unintended, unmistakable subliminal message blared ‘There’s something wrong with this vaccine.’”<sup>200</sup>

The Swine Flu Act also contained a provision requiring “the development . . . and implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu are fully explained to each individual to whom such a vaccine is to be administered.”<sup>201</sup> Of note, the consent form did not disclose a warning about the possibility of contracting Guillain-Barré syndrome, a severely debilitating neurological disorder.<sup>202</sup>

The swine flu vaccine became available to the public on October 1, 1976.<sup>203</sup> By October 11, 1976, only ten days after the immunization program commenced, approximately forty million people received the swine flu vaccine.<sup>204</sup> That evening, three elderly Americans died shortly after receiving the swine flu vaccine at the same clinic in Pittsburgh, Pennsylvania.<sup>205</sup> Several weeks later, “reports appeared of Guillain-Barré syndrome, a paralyzing neuromuscular disorder, among some people who had

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*Id.*

<sup>199</sup> Appel, *supra* note 189, at 70.

<sup>200</sup> Sencer & Millar, *supra* note 182, at 31. The indemnification caused “public misperception, warranted or not, [which] ensured that every coincidental health event that occurred in the wake of the swine flu shot would be scrutinized and attributed to the vaccine.” *Id.*

<sup>201</sup> National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113. Subsequent lawsuits held that the vaccine manufacturer “had a duty to warn [the vaccine consumer] . . . and that the warning was inadequate to discharge its duty. Administered without an adequate warning, the swine flu vaccine was defective, hence unreasonably dangerous.” *Petty v. United States*, 740 F.2d 1428, 1441 (8th Cir. 1984).

<sup>202</sup> Appel, *supra* note 189, at 71. Guillain-Barré syndrome, “an acute demyelinating polyneuropathy,” is manifested by a motor paralysis that may also be associated with sensory loss. FAUCI ET AL., *supra* note 59, at 2462. In severe cases, patients are unable to breathe on their own. *Id.* The mortality rate associated with Guillain-Barré syndrome is 3–4%. *Id.* More than 85% of patients make a complete recovery. *Id.*

<sup>203</sup> Di Justo, *supra* note 183.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

received swine flu immunizations.”<sup>206</sup> This incidence of Guillain-Barré syndrome required epidemiologists to analyze whether there was a causal connection between the appearance of the neurological condition and the 1976 swine flu vaccine.<sup>207</sup> The overall consensus among epidemiologists was that the number of cases of Guillain-Barré syndrome among swine flu vaccine recipients was in excess of what could be attributed to chance alone.<sup>208</sup> Once a causal connection linked the 1976 swine flu vaccine to Guillain-Barré syndrome, the National Influenza Immunization Program was stopped in December 1976.<sup>209</sup> Ironically, the 1976–1977 “flu season was the most flu-free since records had been kept . . . . The Great Swine Flu Epidemic of 1976 never took place.”<sup>210</sup>

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<sup>206</sup> *Id.* Forty-five deaths are claimed to have occurred as a result of Guillain-Barré syndrome. Appel, *supra* note 189, at 72.

<sup>207</sup> Sencer & Millar, *supra* note 182, at 31.

Because [Guillain-Barré syndrome] cases are always present in the population, the necessary public health questions concerning the cases among vaccine recipients were “Is the number of cases of [Guillain-Barré syndrome] among vaccine recipients higher than would be expected? And if so, are the increased cases the result of increased surveillance or a true increase?”

*Id.*

<sup>208</sup> *See id.*

<sup>209</sup> Appel, *supra* note 189, at 72.

Had H1N1 influenza been transmitted at that time, the small apparent risk of [Guillain-Barré syndrome] from immunization would have been eclipsed by the obvious immediate benefit of vaccine-induced protection against swine flu. However, in December 1976, with [more than] 40 million persons immunized and no evidence of H1N1 transmission, federal health officials decided that the possibility of an association of [Guillain-Barré syndrome] with the vaccine, however small, necessitated stopping immunization . . . .

Sencer & Millar, *supra* note 182, at 31.

<sup>210</sup> Di Justo, *supra* note 183. By December 1979, a total of 912 lawsuits were filed in the United States as a result of the National Influenza Immunization Program. Appel, *supra* note 189, at 72. “Four hundred and ninety-four of the claimants allege Guillain-Barr[é] syndrome, 121 allege other neurological disorders, and 252 claim nonneurological disorders.” *Id.*

#### 4. The 2009 H1N1 Vaccine

The 2009 H1N1 vaccine was created to combat the 2009 H1N1 swine flu virus.<sup>211</sup> This vaccine does not provide immunity against the seasonal flu virus.<sup>212</sup> The FDA granted approval to five separate pharmaceutical companies—Novartis Vaccines and Diagnostics Ltd., MedImmune LLC, CSL Ltd., Sanofi Pasteur, Inc., and ID Biomedical Corporation of Quebec—to market their version of the 2009 H1N1 vaccine in the United States.<sup>213</sup> The vaccine is available in two forms, an injection that consists of the inactive virus and a nasal spray that is composed of the live virus in a weakened state.<sup>214</sup>

The government purchased 250 million doses of the 2009 H1N1 vaccine.<sup>215</sup> The government provided a supply of these vaccines to health care providers for administration to the public.<sup>216</sup> In exchange for receiving the vaccines at no cost, these health care providers were permitted to charge patients only for the cost of administering the vaccine and not for the vaccine itself.<sup>217</sup>

The 2009 H1N1 vaccine was first released on October 5, 2009.<sup>218</sup> Approximately one month after its release, the United States began experiencing a swine flu vaccine shortage.<sup>219</sup> The

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<sup>211</sup> CDC, Key Facts About 2009 H1N1 Flu Vaccine, *supra* note 3. “About two weeks after vaccination, antibodies that provide protection against 2009 H1N1 influenza virus infection will develop in the body.” *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> U.S. Food and Drug Administration, Influenza A (H1N1) 2009 Monovalent, <http://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm181950.htm> (last visited Feb. 28, 2010).

<sup>214</sup> CDC, Key Facts About 2009 H1N1 Flu Vaccine, *supra* note 3.

<sup>215</sup> See CDC, 65 and Older, *supra* note 18.

<sup>216</sup> See *H1N1 Update on Answers to Physician Questions*, *supra* note 98, at 12.

<sup>217</sup> See *id.* at 12–13; Flu.gov, Vaccine Cost, <http://www.flu.gov/individualfamily/vaccination/vcost.html> (last visited Feb. 21, 2010).

<sup>218</sup> Anemona Hartocollis, *Vaccine Here, Swine Flu Fear Creates a Rush*, N.Y. TIMES, Oct. 6, 2009, at A1, available at <http://www.nytimes.com/2009/10/06/nyregion/06vaccine.html?scp=12&sq=swine%20flu%20vaccine&st=cse>.

<sup>219</sup> Donald J. McNeil, Jr., *Nation Is Facing Vaccine Shortage for Seasonal Flu*, N.Y. TIMES, Nov. 5, 2009, at A1, available at <http://www.nytimes.com/2009/11/05/health/05flu.html?scp=2&sq=vaccine&st=cse> [hereinafter McNeil, *Nation Is Facing Vaccine Shortage for Seasonal Flu*]. Anthony S. Fauci, the Director of the National Institute for Allergy and Infectious Diseases, explained this shortage based upon “the inexorable connection between preparedness for pandemic flu and preparedness for seasonal flu.” *Id.*

shortage is expected to increase as the flu season progresses.<sup>220</sup> However, major health complications, including Guillain-Barré syndrome which was a devastating side effect of the 1976 H1N1 vaccine, have not been reported thus far in association with the 2009 H1N1 vaccine.<sup>221</sup>

## II. CONFLICTS BETWEEN PATENT LAW AND PUBLIC HEALTH GOALS

This section discusses the inherent conflict between the incentives included in patent rights and the primary goals of public health. Part A addresses the conflict between the exclusive rights granted by patents and the public health concerns relating to widespread disease prevention. Part B describes the response of the United States government to the 2009 H1N1 swine flu pandemic, critiques this response, and proposes alternative solutions.

### A. *Patents' Exclusivity Versus Public Health Disease Prevention*

The goals and underlying purpose of patent law often conflict with the basic tenets of public health law. The primary purpose of patent law is to provide the patent holder with the right of market exclusivity for the patent term.<sup>222</sup> Thus, if a 2009 H1N1 vaccine manufacturer is granted a patent, this pharmaceutical company would simultaneously gain market exclusivity over the novel

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(internal quotations omitted). Thus, the total flu vaccine production, which included both swine flu and seasonal flu, was predicted to be inadequate because of the “raised demand [which is] beyond what manufacturers can make in a year.” *Id.*

<sup>220</sup> *See id.*

<sup>221</sup> *See* Lauran Neergaard, *New Group Helps US Monitor Swine Flu Shot Safety*, ABC NEWS, Nov. 2, 2009, <http://abcnews.go.com/Health/wireStory?id=8971742> (“Initial reports to a . . . government database—where anyone can report any symptom, and serious ones get intense investigation—showed nothing unusual after the first 10 million vaccinations . . . . Most reports were of sore arms and fever, plus some flu symptoms that suggested people already were infected when they got the shot, too late for it to help.”); *see also* Centers for Disease Control and Prevention, *General Questions and Answers on 2009 H1N1 Influenza Vaccine Safety*, [http://www.cdc.gov/h1n1flu/vaccination/vaccine\\_safety\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm) (last visited Feb. 21, 2010).

<sup>222</sup> *See* Wamstad, *supra* note 6, at 130.

vaccine for the duration of the patent, twenty years from the date the patent application was filed.<sup>223</sup>

One of the primary concerns of public health agencies involves disease prevention.<sup>224</sup> Therefore, “countermeasures to impede transmission”<sup>225</sup> of contagious diseases are a high priority within the realm of public health. Thus, public health interventions include preventative measures, such as vaccination.<sup>226</sup> Indeed, public health agencies, such as the CDC and WHO, recommend that people obtain the 2009 H1N1 vaccine, which serves as inoculation against the 2009 H1N1 swine flu virus.<sup>227</sup> In addition to recommending that people obtain the vaccine, these public health agencies also provide other less invasive recommendations to combat the current swine flu pandemic.<sup>228</sup> These additional recommendations that are offered to the general public in order to minimize exposure to the 2009 H1N1 swine flu include washing one’s hands with soap and water, covering one’s nose and mouth when coughing or sneezing, and avoiding direct contact with one’s eyes, nose, and mouth.<sup>229</sup>

At first glance, it may appear that patent law and public health goals are compatible. In fact, the Supreme Court’s decision in *Eldred v. Ashcroft*,<sup>230</sup> which concerns copyright law, can be extrapolated to “indicate that a patent’s purpose always has been and continues to be to advance a public good through the conferral of a limited private economic privilege.”<sup>231</sup> This promise of

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<sup>223</sup> See 35 U.S.C. § 154(a)(2) (2006).

<sup>224</sup> See Gostin & Berkman, *supra* note 89, at 137.

<sup>225</sup> *Id.*

<sup>226</sup> *Id.*

<sup>227</sup> Centers for Disease Control and Prevention, H1N1 Flu Vaccine—Why the Delay?, <http://www.cdc.gov/Features/H1N1VaccineDelay/> (last visited Feb. 21, 2010) (“A flu vaccine is the single best way to protect against influenza illness. . . . [A] 2009 H1N1 vaccine . . . protect[s] against the 2009 H1N1 influenza virus (sometimes called ‘swine flu’).”); WHO, Vaccines for Pandemic (H1N1), *supra* note 104 (“Influenza vaccines are one of the most effective ways to protect people from contracting illness during influenza epidemics and pandemics. . . . The vaccines will boost immunity against the new influenza, and help ensure public health as the pandemic evolves.”).

<sup>228</sup> See CDC, 2009 H1N1 Flu, *supra* note 10.

<sup>229</sup> See *id.*

<sup>230</sup> 537 U.S. 186 (2003).

<sup>231</sup> Wamstad, *supra* note 6, at 130.



exclusivity inherent in the patent motivates scientists to invent, which in turn results in novel technology that is able to “advance a public good”<sup>232</sup> by allowing society to benefit from this new creation.<sup>233</sup> Likewise, public health agencies attempt to advance the public good by providing health interventions and other preventative measures that will curtail the spread and negative impact of disease.<sup>234</sup> Thus, it seems that both patent law and public health policies seek to advance the public good.

However, an inherent conflict exists between the incentives included in patent rights, such as providing the inventor with financial rewards by guaranteeing an exclusive patent,<sup>235</sup> and the public health goal of making the vaccine widely accessible to the general population.<sup>236</sup> Specifically, segments of the population may be unable to afford the cost of patented vaccines.<sup>237</sup> Thus, a subset of the population may be less likely to receive inoculation and thereby would become more susceptible to the 2009 H1N1 swine flu illness, for example.<sup>238</sup> In light of this public health issue, questions arise regarding whether the 2009 H1N1 vaccine should be patented and furthermore whether it is moral to allow the creators of the 2009 H1N1 vaccine to obtain a patent.<sup>239</sup>

### *B. Recommendations to Resolve the Conflict Between Patents and Public Health*

The PTO’s conferral of a patent for a vaccine has sparked heated discussions between intellectual property scholars, public health agencies, and the government. Much of the contested issues

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<sup>232</sup> *Id.* at 130.

<sup>233</sup> *See* Zard, *supra* note 49, at 491.

<sup>234</sup> *See* Gostin & Berkman, *supra* note 89, at 137.

<sup>235</sup> *See generally* 35 U.S.C. § 154(a)(1)–(2) (2006). *See also* WIPO, Frequently Asked Questions (FAQs), *supra* note 48.

<sup>236</sup> *See* Nicosia, *supra* note 8, at 491–92.

<sup>237</sup> Arnoldo Lacayo, *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 304 (2002) (explaining that “stric[t] enforce[ment] of] pharmaceutical patents enables drug companies in the developed world to charge exorbitant prices that the poor cannot afford”).

<sup>238</sup> *See generally* Nicosia, *supra* note 8, at 491–94.

<sup>239</sup> *See, e.g.*, Anna Bishop, Editorial, *Let’s Get the H1N1 Vaccine to All*, GUELPH MERCURY, Oct. 13, 2009, at A2.

relate to the morality of patenting a vaccine.<sup>240</sup> Whether a vaccine is perceived as a pharmaceutical or as a biotechnological innovation, the crux of the argument is similar. On the one hand, proponents of the patent would like to reward the pharmaceutical company for creating the vaccine.<sup>241</sup> On the other hand, those who oppose the patent are concerned with advancing the public good,<sup>242</sup> which in this case, involves protecting the public health by making the vaccine widely accessible.<sup>243</sup> A patented vaccine is generally more costly.<sup>244</sup> Hence, not all segments of the population would be able to afford a patented vaccine.<sup>245</sup>

Although it is unclear whether the United States government evaluated this issue in these terms, it is apparent that the Obama administration recognized the severity of the viral 2009 H1N1 swine flu pandemic.<sup>246</sup> The Obama administration was also cognizant of the public health requirement that the 2009 H1N1 vaccine be made available to all members of the population.<sup>247</sup> Thus, the federal government devised a solution wherein it purchased 250 million 2009 H1N1 vaccines directly from the pharmaceutical companies that invested time and resources in creating the 2009 H1N1 vaccine.<sup>248</sup> This mass purchase of vaccines served to compensate the pharmaceutical companies for their inventions, while simultaneously permitting the

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<sup>240</sup> Recall that a vaccine can be classified either as a pharmaceutical or as a biotechnological creation. *See supra* text accompanying note 59. Both of these classifications contain inherent morality issues. The two debates were presented in Part I of this Note, which describes the views of proponents and opponents of vaccine patents when vaccines are characterized either as pharmaceuticals or as biotechnological innovations. *See supra* Part I.A.3.

<sup>241</sup> *See* Santoro, *supra* note 62, at 928–29; *see also* MILLS, *supra* note 81, at 10. Similarly, the Patent Act itself recognizes the need to reward the inventor by providing the pharmaceutical company with the right of exclusivity. 35 U.S.C. § 154(a)(1) (2006).

<sup>242</sup> MILLS, *supra* note 81, at 12.

<sup>243</sup> *See* Lacayo, *supra* note 237, at 304; *see also* Nicosia, *supra* note 8, at 491–94.

<sup>244</sup> Lacayo, *supra* note 237, at 304.

<sup>245</sup> *Id.*

<sup>246</sup> *See* McNeil, *Obama Warns of Return of Swine Flu in the Fall*, *supra* note 169.

<sup>247</sup> *See id.* The Obama administration authorized the stockpiling of medicines and treatments designed to combat the 2009 H1N1 swine flu virus. Editorial, *Preparing for the Swine Flu*, *supra* note 169.

<sup>248</sup> David Brown, *Experts Say H1N1 Outrunning Vaccine*, WASH. POST, Nov. 5, 2009, at A4.

pharmaceutical companies to maintain their right of exclusivity.<sup>249</sup> The federal government concurrently addressed the public health concerns by providing the vaccines it purchased to health care providers, and ultimately to the general public, free of charge.<sup>250</sup> This part of the federal government's solution resolves the issue of equal dissemination of an expensive vaccine to various communities regardless of their socioeconomic status and ability to afford the cost of the vaccine. Specifically, public medical clinics were neither permitted to charge patients for the cost of the vaccine nor for its administration.<sup>251</sup> Furthermore, private health care practitioners were only permitted to collect a co-payment for the administration of the 2009 H1N1 vaccine to their insured patients.<sup>252</sup> Private health care providers who were the recipients of federal funding were not permitted to charge the uninsured for the administration of the vaccine.<sup>253</sup> Thus, the government's plan addressed the difficulty of accessing medical care in the absence of insurance coverage,<sup>254</sup> which is another public health concern.

However, it is necessary to evaluate the federal government's plan from a financial perspective. Although the 2009 H1N1 vaccine was made available at no charge to the patient at the time that it was administered, in fact there are hidden costs associated with the vaccine. Rather than actually providing a free vaccine, the federal government redistributed the money in its possession. In order to pay for the 2009 H1N1 vaccine, taxes will likely need to be raised in the future, thereby resulting in indirect payment for the 2009 H1N1 vaccine by taxpaying members of the general

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<sup>249</sup> This decision conforms nicely with the principles of the Patent Act. *See* 35 U.S.C. § 154(a)(1) ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making . . . the invention throughout the United States.").

<sup>250</sup> *See H1N1 Update on Answers to Physician Questions, supra* note 98, at 12–13.

<sup>251</sup> Flu.gov, Vaccine Cost, *supra* note 217.

<sup>252</sup> *See id.* Even private health care providers are unable to charge their insured patients for the cost of the vaccine itself because the practitioners did not purchase the 2009 H1N1 vaccine. *Id.*; *see H1N1 Update on Answers to Physician Questions, supra* note 98, at 12. Rather, the government provided the practitioners with the vaccine at no cost so that it could subsequently be provided to their patients free of charge. *See H1N1 Update on Answers to Physician Questions, supra* note 98, at 12–13.

<sup>253</sup> *See* Flu.gov, Vaccine Cost, *supra* note 217.

<sup>254</sup> *See id.*

1032 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* [Vol. 20:991

public.<sup>255</sup> It is also likely that some of the federal funds that were redistributed in order to fund the 2009 H1N1 vaccine initiative were originally intended to fund other federal government projects that may indirectly be negatively impacted as a result.

The Treasury established a Public Health Emergency Fund that is made available to the Secretary of the Department of Health and Human Services (“HHS”)<sup>256</sup> “without fiscal year limitation . . . only if a public health emergency has been declared by the Secretary.”<sup>257</sup> Following the outbreak of the 2009 H1N1 swine flu pandemic and the April 2009 declaration of a public health emergency by Kathleen Sebelius, Secretary of the HHS,<sup>258</sup> Congress appropriated more money into the Public Health and Social Services Emergency Fund.<sup>259</sup> Congress set aside \$1.85 billion “to prepare for and respond to an influenza pandemic, including the development and purchase of vaccines, antivirals, necessary medical supplies, diagnostics, and other surveillance tools . . . relating to the 2009-H1N1 influenza outbreak.”<sup>260</sup> This Act provides the Secretary of the HHS with three possible alternatives when responding to the 2009 H1N1 swine flu pandemic: (1) depositing the 2009 H1N1 vaccines, antivirals, and other medical supplies purchased in order to combat the 2009 H1N1 swine flu pandemic into the Strategic National Stockpile; (2) constructing privately owned laboratories that could assist in

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<sup>255</sup> Posting of Bonnie Erbe to U.S. News & World Report Opinion, *Obama’s Response to H1N1 Vaccine Crisis Could Be Key to Healthcare Reform*, <http://www.usnews.com/blogs/erbe/2009/10/29/-obamas-response-to-h1n1-vaccine-crisis-could-be-key-to-healthcare-reform.html> (Oct. 29, 2009, 16:32 EST) (discussing how government run healthcare programs historically harm the middle-class taxpayers).

<sup>256</sup> One role of the Secretary of the HHS includes the task of “oversee[ing] advanced research, development, and procurement of qualified countermeasures . . . and qualified pandemic and epidemic products.” 42 U.S.C. § 300hh-10(b)(3) (2006).

<sup>257</sup> *Id.* § 247d.

<sup>258</sup> Jackie Calmes & Donald J. McNeil, Jr., *Obama Declares the Swine Flu an Emergency*, N.Y. TIMES, Oct. 25, 2009, at A1.

<sup>259</sup> See Supplemental Appropriations Act, Pub. L. No. 111-32, 123 Stat. 1859, 1884–86 (2009).

<sup>260</sup> *Id.* at 1884. Of the additional funding worth \$1.85 billion, Congress required that a minimum of \$350 million must be allocated to improving the states’ responses to the 2009 H1N1 swine flu pandemic and that a minimum of \$200 million be provided to the CDC for both laboratory research and surveillance of the 2009 H1N1 swine flu. *Id.* at 1884–85.

the production of an adequate supply of the 2009 H1N1 swine flu vaccine and other necessary biologics; and (3) combining this funding (with the exception of funds that must be allocated to both state preparedness and to the CDC) with other funding that is available to the HHS and other federal agencies.<sup>261</sup>

In addition to the funds made available to the Secretary of the HHS, another \$5.8 billion of funding is controlled directly by the President.<sup>262</sup> These additional funds can be appropriated “as emergency funds required to address critical needs related to emerging influenza viruses.”<sup>263</sup> The President may also allow this additional emergency fund to be used for the purchase of vaccines and other biologics for the Strategic National Stockpile.<sup>264</sup> In addition, after consultation with the Director of the Office of Management and Budget, these funds can be merged with other federal accounts held by either the HHS or other federal agencies for use at their discretion in the event of a public health crisis.<sup>265</sup>

Although the government attempted to ensure equal distribution of the 2009 H1N1 vaccine and initially succeeded in this public health goal, the current scarcity of the vaccine will likely disturb the government’s allocation initiatives.<sup>266</sup> A limited supply of the 2009 H1N1 vaccine will ultimately lead to unequal distribution in some manner because everyone who would like to access the vaccine will be unable to do so. The waning supply could also result in socioeconomic stratification or in other rationing strategies based on the patient’s age, geographic location, exposure to other individuals who are afflicted with the 2009 H1N1 swine flu virus, or based on a first-come-first-served method.<sup>267</sup> In addition, there is a scarcity of the 2009 seasonal flu vaccine.<sup>268</sup> The scarcity of both the 2009 H1N1 vaccine and the

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<sup>261</sup> See *id.* at 1884–86.

<sup>262</sup> *Id.* at 1885.

<sup>263</sup> *Id.*

<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

<sup>266</sup> See Editorial, *Take the Shot*, N.Y. TIMES, Nov. 4, 2009, at A34, available at [http://www.nytimes.com/2009/11/05/opinion/05thu3.html?\\_r=1&scp=2&sq=vaccine%20scarcity&st=cse](http://www.nytimes.com/2009/11/05/opinion/05thu3.html?_r=1&scp=2&sq=vaccine%20scarcity&st=cse).

<sup>267</sup> See generally Gostin & Berkman, *supra* note 89, at 137–40.

<sup>268</sup> McNeil, *Nation Is Facing Vaccine Shortage for Seasonal Flu*, *supra* note 219.

2009 seasonal flu vaccine likely resulted because the resources of the same pharmaceutical companies became overtaxed when the pharmaceutical companies produced both of the influenza vaccines during the 2009 flu season.<sup>269</sup> “Federal officials and independent flu experts have said that the situation was unavoidable, given that the global swine flu pandemic has raised demand for all flu shots far beyond what manufacturers can make in a year.”<sup>270</sup>

This scarcity of the 2009 H1N1 vaccine provides even more importance to the CDC’s Advisory Committee on Immunization Practices (“ACIP”) that establishes a priority list of those individuals who should receive the vaccine.<sup>271</sup> This list includes pregnant women, healthcare providers, all individuals between six months and twenty-four years of age, caregivers of children under six months of age, and people between the ages of twenty-five and sixty-four years old who are suffering from other health complications.<sup>272</sup> ACIP’s prioritization is based upon its evaluation of “current disease patterns, populations most at risk for severe illness based on current trends in illness, hospitalizations and deaths, how much vaccine is expected to be available, and the timing of vaccine availability.”<sup>273</sup> This prioritization list will further ensure that the 2009 H1N1 vaccine is offered widely to all individuals regardless of their socioeconomic class. Thus, individuals who are listed on ACIP’s list will receive vaccination priority and socioeconomic stratification will be avoided. Although this prioritization does benefit some individuals before others, this order of patients requiring priority vaccination was established after analyzing medical needs and thus should not be considered an immoral form of unequal distribution.

Furthermore, in order to avoid socioeconomic stratification, the government must ensure that these 250 million vaccines are available to all segments of the population, to both private

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<sup>269</sup> See generally FDA, Influenza A (H1N1) 2009 Monovalent Vaccines Composition and Lot Release, *supra* note 3.

<sup>270</sup> McNeil, *Nation Is Facing Vaccine Shortage for Seasonal Flu*, *supra* note 219.

<sup>271</sup> See Centers for Disease Control and Prevention, 2009 H1N1 Vaccination Recommendations, <http://www.cdc.gov/h1n1flu/vaccination/acip.htm> (last visited Feb. 21, 2010).

<sup>272</sup> See *id.*

<sup>273</sup> *Id.*

physicians and to public medical clinics. This equality can be established by evaluating which physicians and medical personnel are obtaining the 2009 H1N1 vaccines that the government procured. Similarly, it is also important to consider which projects may be negatively impacted as they will not benefit from the federal funds that were redistributed by the federal government to purchase the 2009 H1N1 vaccine and the sum that was made available in the Public Health Emergency Fund.<sup>274</sup> It is necessary to ensure that the redistributed funding does not negatively impact the funding of other programs for the indigent in order to provide the 2009 H1N1 vaccine at no cost to both the underprivileged population as well as to members of the wealthier population. Monitoring these variables will ensure that these vaccines are being equally distributed to members of all socioeconomic classes.

The resolution that the government adopted is sensible because it adequately recognizes the need to compensate pharmaceutical manufacturers while simultaneously providing the 2009 H1N1 vaccine to the public at no charge. However, it would be preferable that the plan be amended to include a safety net when a vaccine scarcity is encountered during a pandemic. This proposal would encourage the government to set up additional laboratory facilities that would be able to assist the private pharmaceutical companies in producing a sufficient supply of vaccines that may become necessary to counteract the pandemic.<sup>275</sup> In this scenario, private pharmaceutical companies would produce the vaccines to their maximum capacity while simultaneously allowing the government laboratories to produce the balance of the vaccines that are required. The pharmaceutical companies' patents would still be in effect, but government laboratories would assist in the production of the balance of vaccines needed, thus sharing in the exclusivity rights in a manner reminiscent of a licensing

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<sup>274</sup> See *supra* notes 259–60 and accompanying text.

<sup>275</sup> In fact, a similar notion was contemplated by Congress that states, “funds may be used for the construction or renovation of privately owned facilities for the production of pandemic influenza vaccine and other biologics, where the Secretary finds such a contract necessary to secure sufficient supplies of such vaccines or biologics.” Supplemental Appropriations Act, Pub. L. No. 111-32, 123 Stat. 1859, 1885 (2009).

agreement.<sup>276</sup> Therefore, the government would be limited to producing the drug in the short-term only when needed to meet urgent public health needs. In addition, the federal government would provide the pharmaceutical companies with additional compensation for temporarily sharing their right of exclusivity.

If this proposal had been adopted in time for the 2009 H1N1 swine flu pandemic, the government could have assisted the private pharmaceutical companies in manufacturing the 2009 H1N1 vaccine. Thus the public could have benefited as it is much less likely that a scarcity of either the 2009 H1N1 vaccine or the 2009 seasonal flu vaccine would have occurred. Furthermore, the government could have continued to compensate the 2009 H1N1 vaccine's inventors and to provide this vaccine to all segments of the public while concurrently avoiding a vaccine shortage. Preventing a shortage of the 2009 H1N1 vaccine would have likely ensured its equal availability to all members of the population.

Additional methods could be implemented to resolve the conflict that arises between the exclusive rights granted by patents and the urgent need for widespread availability of certain pharmaceutical or biotechnological products to the public in emergency situations. In the past, when governments combated health crises, they did "not avoid the temptation to ignore patent rights when an underlying innovation [was] needed to respond to a crisis such as a health related epidemic."<sup>277</sup> For example, Congress and President George W. Bush's administration were faced with a conflict between a public health emergency and patent law when an anthrax terrorist attack was anticipated in 2001.<sup>278</sup> This conflict resulted because Bayer Pharmaceuticals had been granted a patent

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<sup>276</sup> See 35 U.S.C. § 261 (2006) ("The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

<sup>277</sup> Dennis D. Crouch, *Nil: The Value of Patents in a Major Crisis Such as an Influenza Pandemic*, 39 SETON HALL L. REV. 1125, 1126 (2009), available at <http://law.shu.edu/Students/academics/journals/law-review/Issues/archives/upload/Crouch.pdf>. However, when determining the resulting infringement cases, courts must evaluate the impact of the infringement upon the public before an injunction is imposed. *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

<sup>278</sup> See Crouch, *supra* note 277, at 1128.



for Cipro, an antibiotic drug that cures anthrax.<sup>279</sup> Although the government threatened to break the Cipro patent in order to stockpile the drug, it was able to reach an agreement with Bayer Pharmaceuticals wherein Cipro would be made available at a reduced price, and thus, would be widely accessible to the public in case of a widespread anthrax attack.<sup>280</sup>

In the event that inevitable conflicts arise between patent law and public health needs, the government can decide to break a patent. “A ‘broken’ patent might be defined as a patent whose rights are willfully ignored without recourse.”<sup>281</sup> However, instead of intentionally breaking a patent and purposefully ignoring the rights of patent exclusivity, the government can choose to bend a patent by partially breaking it or merely threatening to break the patent.<sup>282</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.”<sup>283</sup> Yet, if governments were to regularly implement this approach and to disregard patents, a disincentive for pharmaceutical companies to create drugs and vaccines that may be used when responding to public health crises may ensue. Instead, pharmaceutical manufacturers may choose to focus their resources on developing biologics for illnesses that are not infectious diseases or public health threats.<sup>284</sup> Thus, a compromise wherein compensation would be made to the patentees by the government in the event that a patent must be bent or broken would benefit the public health initiative in the long run.

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<sup>279</sup> See *id.* Cipro is a pharmaceutical product; it is not a vaccine. U.S. Patent No. 4,670,444 (filed May 29, 1984) (issued June 2, 1987).

<sup>280</sup> See 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, 127 (2002).

<sup>281</sup> Crouch, *supra* note 277, at 1129.

<sup>282</sup> See *id.* at 1129–30.

<sup>283</sup> *Id.* at 1132.

<sup>284</sup> See *id.* at 1133–34 (“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 reduce the incentive to innovate targeted solutions.”).

Public health goals are also threatened by various other potential costs relating to vaccine production such as the costs associated with the defense of future litigation, for example. Capping such ancillary costs that pharmaceutical producers of drugs or vaccines may potentially incur would bolster public health goals further. Congress can accomplish this goal by extending the safeguards against future litigation in a manner similar to the Swine Flu Act of 1976.<sup>285</sup> The notion of indemnifying the pharmaceutical companies and transferring the risk of litigation to the government exclusively in a manner similar to the Swine Flu Act of 1976<sup>286</sup> would encourage future research and development of novel pharmaceutical or biotechnological innovations. However, this indemnification would entail inherent risks for the government in the instances where drugs and vaccines are determined to be unsafe. In fact, Guillain-Barré syndrome, a potential risk associated with this indemnification materialized in response to the 1976 swine flu vaccine.<sup>287</sup> If needed, the President could allocate some of the government's emergency funds for use in defending or financing settlements for potential lawsuits should they occur. Although this suggestion may include drawbacks for the government, it likely would further incentivize pharmaceutical companies to create drugs and vaccines. Moreover, this policy would contribute to the public good while simultaneously minimizing the financial risks that manufacturers of novel vaccines and other anti-infective products may need to incur.

### III. CONFLICT BETWEEN PATENT TERMS AND DISEASE DURATION

This section analyzes the timing issues that exist between a patent term and the length of time that a flu vaccine is considered effective. Part III.A asks whether patents are the most effective approach to provide incentives for the pharmaceutical companies producing the 2009 H1N1 vaccine while ensuring the public good. The conflict between the relatively short duration of the 2009 H1N1 vaccine's medical utility versus the twenty-year term of

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<sup>285</sup> See *supra* notes 197–99 and accompanying text.

<sup>286</sup> See *supra* note 199 and accompanying text.

<sup>287</sup> See *supra* notes 203–09 and accompanying text.

exclusivity that is conferred when a patent is issued for this vaccine is discussed. Part III.B provides recommendations to resolve this conflict. It proposes that, rather than focusing on the short utility of the flu vaccine itself, patentees recognize that vaccines and other biotechnological innovations benefit the public good beyond the initial disease duration. The usefulness of the scientific process utilized in creating the vaccine that is introduced by the inventor greatly outlasts the relatively short time frame wherein the actual vaccine is used to combat a seasonal disease.

A. *Conflict Between Influenza Timing and the Patent Term—Is Patent the Right Approach?*

Intellectual property law grants patents for a period of twenty years.<sup>288</sup> During the patent term, the patent holder possesses an exclusive right over the patented creation.<sup>289</sup> This exclusivity allows the patentee “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”<sup>290</sup> for the term of the patent.

The Patent Act states that a patent term extends for a period of twenty years.<sup>291</sup> However, in actuality, the patentees do not hold an exclusive right to the invention for the full twenty years described in the statute. In fact, although the twenty-year patent term begins to toll from the date a patent application is filed,<sup>292</sup> the patentees are unable to enforce their exclusivity right until the date

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<sup>288</sup> 35 U.S.C. § 154(a)(2) (2006).

<sup>289</sup> *Id.* § 154(a)(1).

<sup>290</sup> *Id.*

<sup>291</sup> *Id.* § 154(a)(2) (describing a “term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States”).

<sup>292</sup> *Id.*; see Osenga, *supra* note 41, at 127 (discussing problems associated with slow issuance); see also Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. HEALTH CARE L. & POL’Y 111, 123 (2005) (“Since no patent rights exist while the application is pending, the effective term of a patent is twenty years minus the time the PTO takes to examine the application. Although the examination period varies for different types of inventions, the average time is slightly over two years, thus making the average patent term around seventeen to eighteen years, although it may be considerably shorter if the examination time is lengthy.”).

that the patent is granted.<sup>293</sup> “Thus, the period between the date an application is filed and the date the patent ultimately issues is essentially a dead period for the patentee . . . .”<sup>294</sup> Regardless of the length of time it takes the PTO to grant a patent, it will certainly be issued at a later date than when the patent was filed and thus could not possibly provide the patentee with a full twenty years to enjoy the rights of exclusivity.

Vaccine production, including the manufacturing process of the 2009 H1N1 vaccine,<sup>295</sup> is even more complex than the production method for other pharmaceuticals.<sup>296</sup> Unlike other biologics, vaccines “are hard to make”<sup>297</sup> because they must contain the relevant strain of the specific virus that the vaccine aims to prevent, whereas drugs and other pharmaceuticals that combat disease symptoms lack this complexity since they are not specific to certain viral strains.<sup>298</sup> However, typically vaccines are lucrative innovations.<sup>299</sup> Specifically, the Patent Act rewards vaccine creators by allowing them to both reap financial rewards and to exclusively manufacture their invention for the patent term.<sup>300</sup> Yet, the flu vaccine does not share this lucrative characteristic with other vaccines.<sup>301</sup> Flu vaccine “[p]rofits are lower and [an] unused flu vaccine expires after a few months.”<sup>302</sup> Furthermore, in contrast to other vaccines, such as the MMR vaccine which does not change in effectiveness from year to

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<sup>293</sup> 35 U.S.C. § 154(a)(2); Osenga, *supra* note 41, at 127.

<sup>294</sup> Osenga, *supra* note 41, at 127–28.

<sup>295</sup> See, e.g., CDC, Key Facts About 2009 H1N1 Flu Vaccine, *supra* note 3.

<sup>296</sup> See *supra* Part I.B.2 (summarizing the characteristics unique to vaccines); see also McNeil, *Nation Is Facing Vaccine Shortage for Seasonal Flu*, *supra* note 219.

<sup>297</sup> McNeil, *Nation Is Facing Vaccine Shortage for Seasonal Flu*, *supra* note 219.

<sup>298</sup> See generally CDC, Seasonal Influenza, *supra* note 54.

<sup>299</sup> McElligott, *supra* note 62, at 433 n.87.

<sup>300</sup> See WIPO, Frequently Asked Questions (FAQs), *supra* note 48.

<sup>301</sup> See McNeil, *Nation Is Facing Vaccine Shortage for Seasonal Flu*, *supra* note 219.

<sup>302</sup> *Id.*

year,<sup>303</sup> a flu vaccine is generally only profitable for one flu season, which lasts for only several months.<sup>304</sup>

This notion of the limited duration of a flu vaccine's relevance is especially applicable in the case of the 2009 H1N1 vaccine, which is only expected to be clinically effective for the 2009 flu season.<sup>305</sup> Therefore, the swine flu vaccine creator may not need a twenty-year patent. Perhaps another method of acknowledging and rewarding the creator of a flu vaccine would be both more desirable and more efficient.

*B. Recommendations to Resolve the Conflict Between Disease Duration and the Patent Term*

This section provides two recommendations to resolve the conflict between the short duration of a flu season, which is associated with the short-term use of the vaccine, and the twenty-year patent term. Part III.B.1 proposes an eighteen-hour expedited patent application review and a shortened patent term during public health emergencies. The patent application should be evaluated before the rest of the queue. Part III.B.2 resolves the conflict by underscoring the usefulness of the patented vaccine creation process for the twenty-year patent term despite the short-term use of the vaccine itself.

1. Recommendation: Shortened Patent Term and Expedited Review Process

Given the fact that the patent term begins to toll on the date that the patent application is filed and before the patent is issued, creators of pharmaceuticals and other biologics would be unable to benefit from the full twenty-year patent term.<sup>306</sup> This issue is compounded when flu vaccine patents are considered because the

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<sup>303</sup> See generally Centers for Disease Control and Prevention, Measles, Mumps, and Rubella (MMR) Vaccine, <http://www.cdc.gov/vaccinesafety/Vaccines/MMR/MMR.html> (last visited Feb. 21, 2010). The MMR vaccine is a single vaccine that protects against three diseases: measles, mumps, and rubella. *Id.*

<sup>304</sup> See *supra* note 15 and accompanying text; see also CDC, The Flu Season, *supra* note 55.

<sup>305</sup> See generally *H1N1 Update on Answers to Physician Questions*, *supra* note 98, at 10.

<sup>306</sup> 35 U.S.C. § 154(a)(2) (2006).

seasonal flu vaccine is only effective for one flu season.<sup>307</sup> Although the 2009 H1N1 swine flu differs from the seasonal flu<sup>308</sup> and thus it could potentially remain viable for longer than one flu season, the 2009 H1N1 swine flu is a virus that already has begun to mutate.<sup>309</sup> Any change to the 2009 H1N1 swine flu virus could render the 2009 H1N1 vaccine ineffective. In fact, it is ironic that in some cases, the influenza season for which the vaccine was created may conclude before the patent is issued by the PTO.<sup>310</sup> Therefore, it seems that the pharmaceutical companies that created the 2009 H1N1 vaccine would only benefit from an expedited patent application review and would require a shortened exclusivity period.

This quickly changing technology can be analogized to the rapidly evolving computer and software technologies.<sup>311</sup> This is an apt analogy because “an entire generation of programs can cycle within a matter of months, in the continuous process of software development.”<sup>312</sup> Similarly, the effectiveness of the flu vaccine also only lasts for a few months during the flu season.<sup>313</sup> Shortened patent terms have been suggested in response to these quickly evolving software programs.<sup>314</sup> An abbreviated patent term would likely only be chosen when the “subject matter of the

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<sup>307</sup> See *supra* note 15 and accompanying text.

<sup>308</sup> See CDC, 2009 H1N1 Flu, *supra* note 10.

<sup>309</sup> See, e.g., World Health Organization, Public Health Significance of Virus Mutation Detected in Norway (Nov. 20, 2009), [http://www.who.int/csr/disease/swineflu/notes/briefing\\_20091120/en/](http://www.who.int/csr/disease/swineflu/notes/briefing_20091120/en/).

<sup>310</sup> A seasonal flu vaccine is only effective for one flu season, which spans several months. See *supra* note 15 and accompanying text; see also CDC, The Flu Season, *supra* note 55. The patent application for the seasonal flu vaccine will begin to toll when the patent is filed. 35 U.S.C. § 154(a)(2). However, the patent prosecution period is generally two to three years. See generally Ho, *supra* note 292, at 123; Lemley, *supra* note 21, at 1500. Thus, although the flu vaccine will hold a patent for a twenty-year term, the utility of the vaccine will only exist for several months, which will likely coincide with the patent prosecution period.

<sup>311</sup> See generally Osenga, *supra* note 41; Kirk D. Rowe, Note, *Why Pay for What's Free?: Minimizing the Patent Threat to Free and Open Source Software*, 7 J. MARSHALL REV. INTELL. PROP. L. 595 (2008).

<sup>312</sup> Rowe, *supra* note 311, at 617.

<sup>313</sup> See *supra* note 15 and accompanying text.

<sup>314</sup> Osenga, *supra* note 41, at 149 (proposing a six-year patent term); Rowe, *supra* note 311, at 617 (suggesting a seven-year patent term for software).

patent is in a high-tech field with a short life cycle.”<sup>315</sup> In order to ensure the invention’s utility in light of the shortened patent term, proposals for abbreviated patents also contain a guarantee that the patents will be granted within one year of the filing date of the patent application.<sup>316</sup> However, even a one-year patent application evaluation period could render a flu vaccine patent useless because the vaccine would be unlikely to provide an effective medical treatment one year after its creation (a new influenza virus will emerge and a new vaccine will have to be developed). Furthermore, during the evaluation period itself, the creator lacks the right of exclusivity that a patent confers. Yet, it should be noted that “the total average time the [patent] examiner spends on . . . the two- to three- year prosecution of the patent is eighteen hours.”<sup>317</sup> Therefore, the PTO could technically issue a patent, if it intends to grant one at all, within eighteen hours after receiving the patent application. Thus, in public health emergency situations, such as the 2009 H1N1 swine flu pandemic, the PTO should issue a patent within eighteen hours of receiving the patent application. This form of expedited PTO approval would place public health patents that are associated with curtailing emergency public health situations at the beginning of the queue inspected by the patent examiners.

Moreover, rather than applying for patent protection, the creators of the 2009 H1N1 vaccine could be provided with non-patent incentives to produce the vaccine. For example, rather than motivate the pharmaceutical companies to produce the 2009 H1N1 vaccine so that they could obtain a patent and simultaneously obtain the right to exclusivity,<sup>318</sup> the government could have provided the pharmaceutical companies with a payment advance to encourage research and development of flu vaccines. However, the government would be unable to predict which pharmaceutical companies will ultimately succeed in creating the necessary flu vaccine. Thus, in order to provide the pharmaceutical companies

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<sup>315</sup> Osenga, *supra* note 41, at 148.

<sup>316</sup> *See id.*

<sup>317</sup> Lemley, *supra* note 21, at 1500.

<sup>318</sup> *See generally* 35 U.S.C. § 154(a)(2) (2006); WIPO, Frequently Asked Questions (FAQs), *supra* note 48.

with an additional incentive to develop the 2009 H1N1 vaccine in lieu of patents, the federal government could have created a contract with the pharmaceutical companies which could have included bonus clauses to reward the successful and timely production of the flu vaccine. The exact sum of the bonuses to be provided could be adjusted based on the severity and complexity of the disease and the virus strains involved.

## 2. Recommendation: Patenting the Vaccine Creation Process

Upon further analysis, it is possible that pharmaceutical companies could in fact benefit from patenting the 2009 H1N1 vaccine for the full twenty-year term. Although the patented innovation would probably not provide any medical benefit for the duration of the twenty-year patent term for the specific influenza virus it was intended to combat, the scientific process disclosed in the patent could prove beneficial to other scientists for a period of time lasting even longer than the twenty-year patent term.<sup>319</sup> Future scientific creations could be based upon past discoveries by employing the process disclosed in previous patents.<sup>320</sup> In fact, this situation occurred when pharmaceutical companies created the 2009 H1N1 vaccine. This vaccine built on the knowledge and the scientific process utilized by the creators of the 2009 seasonal flu vaccine.<sup>321</sup> The 2009 H1N1 vaccine consists of “a strain change to each manufacturer’s seasonal influenza vaccine.”<sup>322</sup>

Another example involves adjuvants, which can increase an immune cell’s recognition of an antigen and can be used in the production of vaccines.<sup>323</sup> The “development of adjuvants in the 1980s and 1990s are bearing fruit now.”<sup>324</sup> Specifically, adjuvants are used in the 2009 H1N1 vaccine produced by Novartis Vaccines and Diagnostics Ltd. that it submitted for patent.<sup>325</sup> This

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<sup>319</sup> See FDA, Influenza A (H1N1) 2009 Monovalent Vaccines Composition and Lot Release, *supra* note 3.

<sup>320</sup> See *id.*

<sup>321</sup> *Id.*

<sup>322</sup> *Id.*

<sup>323</sup> Nathalie Garcon & Michel Goldman, *Boosting Vaccine Power*, 301 SCI. AM. 72, 78 (2009).

<sup>324</sup> *Id.*

<sup>325</sup> See, e.g., U.S. Patent Application No. 20090047353 (filed Nov. 6, 2006).



application of previously researched scientific technology is extremely beneficial since fewer antigens are required for immunization, which leads to a speedier vaccine production time frame.<sup>326</sup> By adding adjuvants to the vaccine, both the seasonal flu vaccine and the H5N1 avian flu, for example, “elicited protective antibody responses using just a third the amount of antigen in a typical flu season vaccine.”<sup>327</sup>

“Pandemic influenza requires large populations to be vaccinated. Adjuvants can make vaccines effective with less antigen per dose and possibly protective against flu strains that vary slightly from the original.”<sup>328</sup> Thus, it is likely that the 2009 patent application submitted by Novartis Vaccines and Diagnostics Ltd. builds upon scientific processes discovered previously that greatly benefit public health goals. In fact, the National Institutes of Health (“NIH”) is currently sponsoring additional research leading to vaccine adjuvant discovery.<sup>329</sup> “Adjuvants can be used not only to enhance the immune response to a vaccine and thereby offer better protection, but also to extend the vaccine supply if needed, enabling more people to be vaccinated with fewer doses.”<sup>330</sup>

This type of novel vaccine technology is not limited in its application to a seasonal influenza or to a unique pandemic. Rather, its scientific ramifications are long-lasting. The patent holder of adjuvant technology discoveries will most certainly benefit over the twenty-year patent term because the process of adding adjuvants can be patented in addition to patenting the vaccine produced. While the vaccine patent may only provide the patentee with exclusive benefits for a short time period limited to the duration of a flu season, the creation process employed when inventing a flu vaccine will exhibit utility even after the culmination of a particular flu season. Thus, the patentee would

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<sup>326</sup> Garcon & Goldman, *supra* note 323, at 78.

<sup>327</sup> *Id.*

<sup>328</sup> *Id.*

<sup>329</sup> Press Release, Nat’l Insts. of Health, NIAID Announces Vaccine Adjuvant Discovery Contracts (Oct. 8, 2009), <http://www.nih.gov/news/health/oct2009/niaid-08.htm>.

<sup>330</sup> *Id.*

benefit from the twenty-year patent term if the process, as well as the product, is patented.

Additional proof that flu vaccine patents can still provide scientific benefit even when they are no longer medically useful can be gleaned from the patents that were granted in relation to the 1976 H1N1 vaccine.<sup>331</sup> Although the patents granted for the 1976 H1N1 vaccine lost their clinical significance when people who received the vaccination developed Guillain-Barré syndrome, a paralyzing neuromuscular disorder,<sup>332</sup> these patents have maintained their scientific and research benefits and have both been cited in future patent applications as recently as a patent that was filed in 2006 and issued in 2008.<sup>333</sup> The scientific process utilized in the creation of the 1976 H1N1 vaccine has outlasted the usefulness of both the vaccine itself and its twenty-year patent term. This phenomenon illustrates the long term applicability of the creation process. Hence, this analysis underscores the value of a twenty-year patent term that could prove beneficial to the creators of the 2009 H1N1 vaccine if they patent the creation process as well as the vaccine produced.

The debate regarding the utility of a twenty-year patent term for the 2009 H1N1 vaccine must consider whether a vaccine is primarily a pharmaceutical (product) or a biotechnological (process) innovation. If the 2009 H1N1 vaccine is viewed as a pharmaceutical and only the product itself is patented, then its benefits are solely medical and a twenty-year patent term would not provide the patentee with any benefits because the pharmaceutical companies would be unable to capitalize on their

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<sup>331</sup> See U.S. Patent No. 4,009,258 (filed Aug. 5, 1974) (issued Feb. 22, 1977); see also U.S. Patent No. 4,029,763 (filed Jan. 16, 1975) (issued June 14, 1977).

<sup>332</sup> FAUCI ET AL., *supra* note 59, at 2462; Appel, *supra* note 189, at 71.

<sup>333</sup> U.S. Patent No. 7,468,187 (filed Oct. 5, 2006) (issued Dec. 23, 2008). Another eleven patent applications cite to U.S. Patent No. 4,029,763 and a total of sixteen patent applications cite to U.S. Patent No. 4,009,258. U.S. Patent and Trademark Office, Results of Search in U.S. Patent Collection db for REF/4029763, <http://patft.uspto.gov/netacgi/nphParser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnethtml%2Fsearch-adv.htm&r=0&f=S&l=50&d=PALL&Query=ref/4029763> (last visited Nov. 20, 2009); U.S. Patent and Trademark Office, Results of Search in U.S. Patent Collection db for REF/4009258, <http://patft.uspto.gov/netacgi/nphParser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnethtml%2Fsearchadv.htm&r=0&f=S&l=50&d=PALL&Query=ref/4009258> (last visited Nov. 20, 2009).

right of exclusivity for the majority of the patent term.<sup>334</sup> However, if the 2009 H1N1 vaccine is perceived to be a biotechnological innovation and the creation process is patented, then the scientific process involved in creating the vaccine and the information gleaned from the 2009 H1N1 vaccine patent would potentially allow the patentee to reap financial rewards for the full twenty-year patent term.

Patents encourage innovation, thereby leading to pharmaceutical and biotechnological advances that will promote life and benefit the public. Thus, the patent term of twenty years for a flu vaccine is logical if the creation process is patented. The novel technology will be applicable to the creation of other vaccines and will generally promote the public good.

#### CONCLUSION

The 2009 H1N1 swine flu pandemic highlights the tension between the inherent purpose of patent law as set forth in the Patent Act and the goals of public health. Patents seek to reward the pharmaceutical companies that invested time and resources to develop the 2009 H1N1 vaccine<sup>335</sup> whereas public health goals strive to distribute the 2009 H1N1 vaccine widely throughout the population.<sup>336</sup> In an effort to advance public health goals, the federal government purchased 250 million 2009 H1N1 vaccines and engaged in the widespread dissemination of the vaccine at no cost to the public, thereby increasing accessibility of the vaccine

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<sup>334</sup> Each year different strains of the flu virus develop. Therefore, new vaccines will be produced to provide immunity against the new influenza strains. A vaccine will expire after the flu season is over, usually within a year of its production, which signals the end of the profitability of this particular “pharmaceutical product.” See CDC, Shortened Expiration Period for Sanofi Pasteur 2009 H1N1 Vaccine in Pre-filled Syringes Questions & Answers (Feb. 4, 2010), [http://www.cdc.gov/h1n1flu/vaccination/qa\\_expiration.htm](http://www.cdc.gov/h1n1flu/vaccination/qa_expiration.htm); see also N.Y. State Dep’t of Health, Notice of Expiration Date Change of Influenza A (H1N1) 2009 Monovalent Vaccine 1 (Jan. 11, 2010), [http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/health\\_care\\_providers/vaccine/docs/2010-1-11\\_notice\\_of\\_expiration\\_date\\_change.pdf](http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/health_care_providers/vaccine/docs/2010-1-11_notice_of_expiration_date_change.pdf) (listing expiration dates of three different H1N1 2009 Monovalent vaccines as of January 2010).

<sup>335</sup> See *supra* Part I.A.2.

<sup>336</sup> See *supra* Part I.B.1.

despite individuals' socioeconomic statuses.<sup>337</sup> However, the federal government could have assisted private pharmaceutical companies in the production of the vaccine for the length of the pandemic in a manner similar to a licensing agreement in order to avoid the shortages of both the 2009 H1N1 vaccine and the 2009 seasonal flu vaccine.<sup>338</sup>

Another discrepancy exists between the lengthy twenty-year patent term and the reality that an influenza vaccine provides a medical benefit for only several months. However, this conflict only poses problems when considering the 2009 H1N1 vaccine from a purely clinical perspective. Evaluating the 2009 H1N1 vaccine as a biotechnological innovation—as a step forward in the progression of science—rather than as a strictly pharmaceutical advance, permits inventors to reveal valuable scientific creation processes that would remain applicable for a longer length of time than the 2009 H1N1 vaccine's short period of clinical utility.<sup>339</sup> A twenty-year patent term remains valuable to the pharmaceutical companies that created the 2009 H1N1 vaccine because they retain exclusive control over the novel discoveries presented in their research, which could serve as a template for future vaccine production.<sup>340</sup>

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<sup>337</sup> See *supra* Part I.C.4.

<sup>338</sup> See *supra* Part II.B.

<sup>339</sup> See *supra* Part III.B.2.

<sup>340</sup> See *supra* Part III.B.2.