

# PLAGUES, PANDEMICS, AND PATENTS: LEGALITY AND MORALITY

A. SAMUEL ODDI\*

## ABSTRACT

This article provides a brief historical review of the devastation inflicted by plagues and pandemics and then considers the only recent availability of medicines to prevent, cure, or at least ameliorate the effects of these underlying diseases. It is extremely costly to develop these medicines and to obtain government approval for their distribution. The patent system accordingly plays a key role in providing the incentive to make such investments in developing pharmaceutical inventions. The patent system has become internationalized under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), which requires member states to provide patent protection “in all fields of technology,” including pharmaceutical inventions. The tension is clear between the need for access to life-saving medicines on a world-wide basis and the need to provide a strong incentive via the patent system to insure that such medicines are developed. The tension is particularly acute with respect to the least-developed countries that do not have the ability to pay for such patented medicines and do not even have the technical infrastructure to replicate such medicines. To alleviate this tension somewhat, it has been proposed to amend the compulsory licensing provisions of the TRIPS Agreement to enable these least-developed countries to import patented medications from suppliers in other countries working under compulsory licenses. It is questionable whether this amendment will be a viable solution, particularly if there is a severe pandemic.

The primary purpose of the present article is to address the moral issue of whether a developing country unable to pay for patented medicine may be morally justified in securing that medication from whatever source to prevent the significant loss of life of its nationals. This argument follows the general moral proposition that taking another’s property may be justified to save one’s own or another’s life, but that the property owner is entitled to compensation for

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\* Giles Sutherland Rich Professor in Intellectual Property, University of Akron, School of Law.

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the loss. The legal proposition is the same: requiring compensation of the owner where the taking may be necessary to save life or property and may be quite reasonable under the circumstances. The further proposition is also accepted that a violation of law is a prima facie moral violation. These propositions are conceded in the article and are then extended to the situation where the developing country is incapable of paying for the patented drug and is faced with the significant loss of life of its nationals. The conclusion drawn from the analysis is that even though the law may have been violated, there is no moral violation by the developing country in securing the patented drug while not being able to compensate the patent owner at the TRIPS mandated level of “adequate remuneration.”

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*[W]e tell ourselves that pestilence is a mere bogy of the mind, a bad dream that will pass away. But it doesn't always pass away and, from one bad dream to another, it is men who pass away[.]*

Albert Camus, *The Plague*<sup>1</sup>

### I. INTRODUCTION

Disease, particularly one of epidemic proportions with a high rate of mortality, as defining a plague,<sup>2</sup> would seem to have a symbiotic relationship with invention, with the latter hopefully ameliorating the former. Until very recently, however, patented inventions appear not to have had a significant impact on relieving the scourge of plagues and epidemics, even those of pandemic proportions.<sup>3</sup> Of course, plagues have unfortunately been with us for a lot long-

<sup>1</sup> ALBERT CAMUS, *THE PLAGUE* 37 (Stuart Gilbert trans., Vintage Int'l 1991) (1948). To the “men who pass away” also must be added: women and children and animals and other living things.

<sup>2</sup> “Plague” is defined as “an epidemic disease causing a high rate of mortality.” *Plague Definition*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/pandemic> (last visited Oct.8, 2010); see also John Hollander, *Foreword* to *IN TIME OF PLAGUE: THE HISTORY AND SOCIAL CONSEQUENCES OF LETHAL EPIDEMIC DISEASE* vii, vii-viii (Arien Mack ed., 1991):

We are now in time of plague. But this time it is during a period of our historical consciousness which would seem to have put the very term “plague,” and the realms of ignorance that it signifies for our general knowledge of the etiology of infectious disease, far behind us. The word itself has come to be used in two principle ways. The first designates the epidemic infections by *bacillus pestis* in its various bubonic, pneumonic and septicaemic forms that started to overrun Europe in the fourteenth century, and still manifests for the medical and historical layman an aura of factual rats and lice cloaked by superstitious fiction.

Our other use of “plague” is that of the older and basic term, the biblical and proverbial one, referring to the ten disasters with which the Lord smote the Egyptians in Exodus.

<sup>3</sup> “Pandemic” is defined as “occurring over a wide geographic area and affecting an exceptionally high proportion of the population.” *Pandemic Definition*, MERRIAM-WEBSTER DICTIONARY, <http://www.merriam-webster.com/dictionary/pandemic> (last visited Oct.2, 2010); see also *ENCYCLOPEDIA OF PLAGUE AND PESTILENCE: FROM ANCIENT TIMES TO THE PRESENT* xiii (George Childs Kohn ed., 3d ed. 2008) [hereinafter *ENCYCLOPEDIA*]:

Throughout recorded history, many towns, cities, countries, and regions have been decimated by a particular epidemic—a high prevalence of disease attacking many people in the community at the same time. An epidemic may spread over a wide geographical area, occurring in places throughout

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er than patents. We can trace back more than 3000 years to the ten plagues inflicted on Pharaoh in Exodus,<sup>4</sup> and to the Philistine Plague (Plague of Ashdod) in I Samuel.<sup>5</sup> The first plague epidemic is recorded by Thucydides as occurring in Athens in 430 B.C.E. during the Great Peloponnesian War.<sup>6</sup> Pandemics have occurred throughout history, including the devastating Plague of Justinian of 542 C.E.,<sup>7</sup> the Black Death (Bubonic Plague) of 1347,<sup>8</sup> and the Spanish Influen-

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the world at the same time, thus becoming known as a pandemic. In addition, some diseases seem to have a persistent prevalence in certain places and thus are said to be endemic to the region.

The development of HIV/AIDS treatments is summarized as follows:

The first anti-retroviral drug, zidovudine, or AZT, which inhibits reverse transcriptase (the enzyme that makes copies of the virus's genetic material), was approved by the U.S. Food and Drug Administration (FDA) in 1987; the first protease inhibitor—to stop new viral particles from splitting off from the host CD4 cell—came on the market in 1995. A year later, researchers announced the success of the triple cocktail, a combination of drugs designed to defeat numerous mutations of the virus. Because of such antiretroviral therapy, often administered before an HIV-infected person progresses to AIDS, industrialized countries in the late 1990s saw declines in numbers of new cases of AIDS and of deaths from AIDS.

ENCYCLOPEDIA, *supra* at 162. Antiviral Influenza vaccines date from the late 1990's. Tamiflu was approved Oct. 27, 1999 and Relenza was approved July 26, 1999 by the FDA. *Drugs@FDA*, ACCESSDATA.FDA.GOV, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda> (for Tamiflu, follow “T” and then “TAMIFLU”; for Relenza, follow “R” and then “RELENZA”) (last visited Oct. 9, 2010).

<sup>4</sup> See *Exodus* 7–12 for an account of the ten plagues; see also, FREDERICK F. CARTWRIGHT WITH MICHAEL D. BIDDISS, *DISEASE & HISTORY* 6 (1972) (“This is one example of the effect of disease upon history, for the last terrible visitation upon the Egyptians [the death of all the firstborn] persuaded Pharaoh to allow his Israelite slaves to depart”); Hollander, *supra* note 2, at vii–viii (pointing out that only two of the “plagues” were disease related). It may be interesting to note, as part of the Passover ritual, the application of lamb’s blood to the doorpost and the lintel of each house, which served to “inoculate” the first born of the Israelites because house the Lord passed over by such marked houses. *Exodus* 12.

<sup>5</sup> *I Samuel* 5. The Plague followed the Philistines after they captured the Ark of the Covenant from the Israelites. ENCYCLOPEDIA, *supra* note 3, at 309 (“The disease has been identified by some as bubonic plague, but another suggested diagnosis is hemorrhoids accompanying dysentery.”).

<sup>6</sup> See ENCYCLOPEDIA, *supra* note 3, at 22–23 (identifying the epidemic as the “Great Plague of Athens” or “Plague of Thucydides”); see also CARTWRIGHT, *supra* note 4, at 6–8.

<sup>7</sup> See generally WILLIAM ROSEN, *JUSTINIAN’S FLEA: PLAGUE, EMPIRE, AND THE BIRTH OF EUROPE* (2007) (providing a detailed account of the Plague of Justinian); ENCYCLOPEDIA, *supra* note 3, at 216–18.

<sup>8</sup> See generally ENCYCLOPEDIA, *supra* note 3, at 31–32.

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za Pandemic of 1917.<sup>9</sup> On the other hand, patents have only been around, as a general invention protective system, for somewhat over 500 years.<sup>10</sup> Patents protecting medicines and the processes for making them, however, have not been universally available until relatively recently.<sup>11</sup>

Plagues have been indiscriminate in their killing—without deference to rank or status.<sup>12</sup> Historically, the most viable intervention was to flee from the

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<sup>9</sup> See generally *id.* at 370–72.

<sup>10</sup> See Giulio Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. OFF. SOC'Y 166, 176–77 (1948) (quoting the Venetian patent statute of 1474):

WE HAVE among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our City, more such men come to us every day from divers parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor's honor away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our Commonwealth.

Therefore:

BE IT ENACTED that, by the authority of this Council, every person who shall build any new and ingenious device in this City, not previously made in our Commonwealth, shall give notice of it to the office of our General Welfare Board when it has been reduced to perfection so that it can be used and operated. It being forbidden to every other person in any of our territories and towns to make any further device conforming with and similar to said one, without the consent and license of the author, for the term of 10 years.

<sup>11</sup> See JOSEPH STRAUS, *Implications of the TRIPs Agreement in the Firded of Patent Law*, in 18 FROM GATT TO TRIPs—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 160, 174, ¶ 16 (Friedrich-Karl Beier & Gerhard Schrickler eds., 1996):

The gravest consequence of the lack of minimum standards of patent protection in the Paris Convention was the fact that in 1988 it was established that at that time, *e.g.*, pharmaceutical products were not patentable in 49, animal species in 45, methods for the treatment of the human or animal body in 44, plant varieties in 44, biological processes for the production of plant varieties or animal species in 42, food products in 35, computer programs in 32, chemical products in 22, pharmaceutical processes in 10, processes for the manufacture of food in 9, and micro-organisms in 9 of a total of 92 Paris Union states. In addition, in several Latin-American countries and a number of so-called socialist countries the term of patents and the scope of the patent right were little more than symbolic.

<sup>12</sup> CARTWRIGHT, *supra* note 4, at 18 (“Incurable infectious disease is no respecter of persons; it ravages impartially the highly civilized and the less civilized.”); see also ERWIN H. ACKERKNECHT, *A SHORT HISTORY OF MEDICINE* 211 (The Johns Hopkins Univ. Press rev. ed. 1982) (1955) (“A particularly strong incentive to the development of preventive medicine was given by the four great cholera pandemics which after 1830 swept Europe and the whole world, sparing neither rich nor poor.”) Further, William Rosen writes:

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infected to an uninfected area as best as one could.<sup>13</sup> Limiting travel from contaminated areas<sup>14</sup> and imposing quarantines<sup>15</sup> also proved to be helpful in mitigating the spread of the disease. As the cause of the disease was discovered, its spread could be somewhat controlled, but treatment and cure remained problematic.<sup>16</sup> Thankfully, due to modern medical science, this situation is changing

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The plague produced a literal avalanche of demographic and population shocks, not all of them predictable. As an example, mortality among the very young, who are generally most at risk during epidemics, was actually lower than that among adults, simply because their relatively small body size offers significantly less real estate for the flea. Since only a small percentage of fleas carries the bacterium, the larger number of flea bites found on a larger body increases chances for infection.

ROSEN, *supra* note 7, at 262 (footnotes omitted).

- <sup>13</sup> See Rhys Prichard, *Advice to the Drunkard*, verse 21, in THE MORNING STAR, OR, THE DEVINE POEMS OF MR. REES PRICHARD, FORMERLY VICAR OF LANDOVERY, IN CARMARTHENSHIRE, at 160 (Rev. William Evans trans., 1815), available at <http://books.google.com/books?id=iKoCAAAYAAJ&pg=PA160#v=onepage&q&f=false>:

Flee from a Serpent, lest it sting thy heel—  
 Flee from the plague, lest it strike thee dead—  
 Flee from the fire, lest thou it's [sic] force shou'dst feel—  
 Flee from strong liquor, lest it turn thy head.

- <sup>14</sup> See ENCYCLOPEDIA, *supra* note 3, at 229:

Queen Elizabeth I took strong precautions to protect herself and her court from plague, which posed a constant threat to England throughout her entire reign (1558–1603). When plague broke out in London in 1563 she removed to Windsor Castle and erected a gallows in the town marketplace where anyone coming from London was to be hanged.

- <sup>15</sup> ACKERKNECHT, *supra* note 12, at 91 (discussing growth of “the institution of quarantine as a prophylactic procedure” to prevent the spread of disease); see also CARTWRIGHT, *supra* note 4, at 50 (discussing the detention of visitors by the Republic of Venice in 1377 for thirty and then for forty days (*quaranta giorni*), which was the genesis of word “quarantine”).

- <sup>16</sup> For example, as related in LAURIE GARRETT, *BETRAYAL OF TRUST: THE COLLAPSE OF THE GLOBAL PUBLIC HEALTH* 546 (2000):

In the fourteenth century, as a response to the Black Death, some of the basic tools and laws of public health were created: quarantine, ship inspections, leprosariums, mass burials during epidemics. These were applied crudely, without any understanding of the causes of the scourges sweeping through the fourteenth and fifteenth centuries. All too often such methods of epidemic control were accompanied by ruthless, brutal repressions of the populations thought to be responsible for given diseases, such as the Jews of Europe and Infidels of the Ottoman Empire.

The discovery that Bubonic Plague was caused by bacillus *Pasteurella pestis* transmitted by infected fleas on rodent hosts led to the attempt to eliminate the rodent carriers. See ENCYCLOPEDIA, *supra* note 3, at 101. Malaria is caused by *Plasmodium falciparum* and

and the full impact of at least some pandemics may be medically ameliorated, if not eliminated. Accordingly, today particular patented inventions may provide significant benefits to those suffering from a pandemic disease, provided they have access to them.<sup>17</sup> If the beneficial effects of inventions could be applied to avoid or to end a pandemic, or at least to alleviate its consequences, appropriately rewarding the inventor seems fully justified.

## II. PANDEMICS AND INVENTION: PROBLEMS CONCERNING ACCESS

### A. *Pandemics*

As demonstrated by history, the consequences of pandemics in terms of massive loss of life have been and can be horrendous. The Plague of Justinian in the mid-sixth century has been estimated to have claimed the lives of twenty-five million people.<sup>18</sup> Historians estimate that approximately the same number of people died in Europe as a consequence of the Black Death of the mid-fourteenth century.<sup>19</sup> The Spanish Influenza Pandemic of 1917 can be ranked with the previous two with an estimated loss of life of over twenty million lives and 1200 to 500 million infected.<sup>20</sup> We are all well aware of the devastating consequence of the HIV/AIDS pandemic. This pandemic has been with us for almost three decades. Since the first-documented AIDS case—in June 1981—

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“transmitted by the *Anopheles gambiae* mosquito species.” *Id.* at 4. One of the three main efforts employed to prevent malaria was an effort to eliminate mosquitoes and their breeding grounds. *Id.* at 5. The bacterium *Vibrio comma* or *Vibrio cholera* causes cholera. *Id.* at 242. While slow to be recognized, efforts to prevent cholera were eventually directed toward improving public sanitation and providing clean water supplies. *Id.* at 45.

<sup>17</sup> Pharmaceutical Research and Manufacturers of America (PhRMA) reported in December 2009 that ninety-seven HIV/AIDS products were in development, either in human clinical trials or awaiting approval by the FDA. As of this date, thirty-one drugs have been approved for the treatment of HIV/AIDS. See *97 Medicines and Vaccines Now in Development for HIV/AIDS*, PHRMA.ORG, [http://www.phrma.org/news\\_room/press\\_releases/97\\_medicines\\_and\\_vaccines\\_now\\_in\\_development\\_for\\_hiv%10aids](http://www.phrma.org/news_room/press_releases/97_medicines_and_vaccines_now_in_development_for_hiv%10aids) (last visited Oct. 10, 2010).

<sup>18</sup> ROSEN, *supra* note 7, at 3 (“[T]he Plague of Justinian, to give both pandemic and emperor their names, killed at least twenty-five million people; depopulated entire cities; and depressed birth rates for generations precisely at the time that Justinian’s armies had returned the entire western Mediterranean to imperial control.”).

<sup>19</sup> ENCYCLOPEDIA, *supra* note 3, at 31.

<sup>20</sup> *Id.* at 370; see Laurie Garrett, *The Path of a Pandemic: How One Virus Spread from Pigs and Birds to Humans Around the Globe. and Why Microbes Like the H1N1 Flu Have Become a Growing Threat*, NEWSWEEK, May 18, 2009, at 22, 24 (estimating that the death toll from the 1918 pandemic was in fact up to one-hundred million worldwide).

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through 2008, it is estimated that more than twenty-five million lives have been lost and over thirty-three million persons are presently living while infected with HIV/AIDS.<sup>21</sup> Approximately two million people died from AIDS in 2008.<sup>22</sup> In the United States, it is estimated that through 2007, more than 500,000 individuals have died from AIDS and that approximately a million have been diagnosed with AIDS.<sup>23</sup>

The catastrophic loss of population, of course, has resulted in significant political and societal upheavals. The Plague of Thucydides may have played a significant role in the outcome of the Peloponnesian Wars.<sup>24</sup> In a similar manner, the decline of the Roman Empire may be traced to disease, including malaria and the Plague of Justinian.<sup>25</sup> The significant loss of population as a consequence of the Black Death in the middle of the fourteenth century appears to have played a major role in the decline of the feudal system, increasing the population's access of people to higher social classes and may be seen as marking the end of the Middle Ages.<sup>26</sup> We do not yet know the full social and political

<sup>21</sup> UNAIDS, *AIDS Epidemic Update*, UNAIDS/09.36E/JC1700E at 7 (Nov. 2009), available at [http://data.unaids.org/pub/Report/2009/JC1700\\_Epi\\_Update\\_2009\\_en.pdf](http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf); *Worldwide AIDS & HIV Statistics Including Deaths*, AVERT.ORG, <http://www.avert.org/worldstats.htm> (last visited Oct. 10, 2010).

<sup>22</sup> See AVERT.ORG, *supra* note 21.

<sup>23</sup> See *United States HIV & AIDS Statistics*, AVERT.ORG, <http://www.avert.org/usa-statistics.htm> (last visited Oct. 10, 2010).

<sup>24</sup> CARTWRIGHT, *supra* note 4, at 8 (“The plague of Athens undoubtedly contributed to the downfall of the Athenian empire.”); see also ENCYCLOPEDIA, *supra* note 3, at 23.

<sup>25</sup> While it may be somewhat of an exaggeration, a medical historian and a history professor at Cambridge University claim that “a very severe type of malaria” had a significant impact on the decline of the Roman Empire. They speculate: “Possibly malaria, rather than the decadent luxury imported from the East, accounted for the slackness of spirit which characterized the later years of Rome.” CARTWRIGHT, *supra* note 4, at 11.

<sup>26</sup> ENCYCLOPEDIA, *supra* note 3, at 33.

To many historians, the Black Death marked the end of the Middle Ages and the start of the modern age. Its devastation cleared the way for Europeans to begin to reorganize their societies, to systematize landholding relations between owner/farmer and tenant/laborer on the basis of rent, and to strike a balance between capital and labor.

*Id.* Additionally, Norman Cantor writes:

It can be readily seen that the Black Death accelerated the decline of serfdom and the rise of a prosperous class of peasants, called yeomen, in the fifteenth century. With “grain rotting in the fields” at the summer harvest of 1349, because of labor shortage, the peasants could press for higher wages and further elimination of servile dues and restrictions.



consequences that may result as a consequence of the HIV/AIDS pandemic. The impact is now being felt in many countries in Africa, where there have been significant population losses—resulting in labor losses, debilitation of segments of the population, and many orphaned children.<sup>27</sup>

The most recent pandemic designated by the World Health Organization (“WHO”) was the so-called “Swine” flu, caused by the H1N1 strain of virus, which originated in Mexico and rapidly spread and continues to spread throughout the world.<sup>28</sup> The H1N1 influenza virus is of particular concern because it may be transmitted human-to-human.<sup>29</sup>

### **B. Inventions**

Inventions also often have significant consequences. Indeed, certain inventions have had revolutionary consequences in the sense of changing how we

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NORMAN F. CANTOR, *IN THE WAKE OF THE PLAGUE: THE BLACK DEATH AND THE WORLD IT MADE 202–03* (2001); *see also* CARTWRIGHT, *supra* note 4, at 32–50 (emphasizing the particular impact of the Black Death on English society).

<sup>27</sup> ENCYCLOPEDIA, *supra* note 3, at 380 (discussing the consequences of societal consequences of HIV/AIDS in sub-Saharan Africa); *see also* *The Impact of HIV & AIDS on Africa*, AVERT.ORG, <http://www.avert.org/aids-impact-africa.htm> (last visited Oct. 10, 2010) (discussing the impact of HIV/AIDS in Africa, including the effects on: the health sector (hospitals and health care workers); the household (income, necessities, food production, health care expenses and funeral costs); children (orphans); education (fewer children, teachers); enterprises and workplaces; life expectancy; the economy; and the future).

<sup>28</sup> It is interesting to note the following concerning regarding the H1N1 strain of the virus as reported prior to the April 2009 outbreak:

In 2005, after almost a decade of research, scientists from the Centers for Disease Control and Prevention (CDC), Mount Sinai School of Medicine, and the Armed Forces Institute concluded that the 1917–19 pandemic was caused by an avian (bird) virus, which spread to humans by undergoing some fairly simple mutations. The scientists also focused on a gene in the H1N1 virus (which they had re-created) that allows it to attach itself to cells and then multiply. . . . Virologists always fear that the H1N1 strain may resurface, perhaps in as virulent a form as in 1918.

ENCYCLOPEDIA, *supra* note 3, at 372; *see also* Garrett, *supra* note 20, at 24 (reporting after the April outbreak and stating, “[i]nvestigation of the 1918 influenza pandemic, which is now estimated to have killed up to 100 million people worldwide in 18 months, revealed that the viral culprit was a type H1N1 human flu that had infected pigs, and then circulated back to humans”).

<sup>29</sup> The most severe consequences of the Black Death occurred when the form of the disease converted from rats or fleas-to-humans transmission to the pneumonic type with human-to-human transmission. *See* CARTWRIGHT, *supra* note 4, at 30–31.

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live.<sup>30</sup> Certainly, inventions have played a significant role in the treatment and prevention of diseases, including those diseases of pandemic proportions.<sup>31</sup>

How, then, do patents granting exclusive rights to inventors relate, if at all, to the human suffering and societal disruption inflicted by pandemics? Until the late twentieth century, the answer probably was that the two were not significantly related. Pandemics have come and gone—leaving as stealthily as they came but often returning in the same or altered form.<sup>32</sup> Prevention was generally accomplished by avoidance and luck; treatment was unavailable or mostly ineffective.<sup>33</sup> It was not until recently that medical science provided significant interventions to treat and prevent pandemics.<sup>34</sup> It was not until the awareness of the HIV/AIDS pandemic spread that the public considered patented inventions that might provide a remedy to this dreaded infection.<sup>35</sup> The fact that access to

<sup>30</sup> Revolutionary inventions may be defined as those that produce a “genuine revolution in production or consumption.” FREDERIC M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 448 (2d ed. 1980). Examples of revolutionary inventions include: airplanes, antibiotics, instant and digital photography, lasers, synthetic textiles, tranquilizers, sulfonamides, telegraph, telephone (land and cell), television, transistors, the internet, etc.. See A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 AM. U. L. REV. 1097, 1113 (1989) (discussing the economic importance of revolutionary inventions).

<sup>31</sup> As indicated in GARRETT, *supra* note 16, at 546, prevention was the primary means of dealing with infectious diseases. Later advances in medical science led to developing medicines for the treatment of patients already infected. Inventions played a major role in these developments. For example, modern antidotes for the treatment of Bubonic Plague include tetracyclines, streptomycin, and chloramphenicols. See ENCYCLOPEDIA, *supra* note 3, at 455. Malaria has been treated with chloroquine, which has limited effectiveness. See *id.* A new drug combination (artemether-lumefantrine (“AL”)) that clears the disease from the bloodstream has proved highly effective. *Id.* at 358. Cholera is treated with tetracycline and oral rehydration. *Id.* at 247. Tuberculosis, which kills more than malaria and AIDS combined throughout the world, is treated with isoniazid, rifampin, and pyrazinamide; isoniazid functions as a preventive drug. *Id.* at 297. See also *Drugs@FDA*, ACCESSDATA.FDA.GOV, <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm> (last visited Oct. 11, 2010) (describing safety and availability of antiviral drugs); PHRMA.ORG, *supra* note 17 (stating that thirty-one drugs have been approved for the treatment of HIV/AIDS and ninety-seven products are in the development stage).

<sup>32</sup> A notable example is the so-called “Third Plague Pandemic” which lasted for over a century (from the 1850’s to about 1959). See generally ENCYCLOPEDIA, *supra* note 3, at 310. There were recurrent smallpox epidemics in Great Britain in 1796, 1816, 1837, 1871, and 1901. *Id.* at 50.

<sup>33</sup> See *supra* text accompanying notes 12–16 and notes 12–16.

<sup>34</sup> See *supra* note 3, text accompanying note 17, and note 17.

<sup>35</sup> See Jay Purcell, Note, *Adverse Clinical and Public Health Consequences of Limited Anti-Retroviral Licensing*, 25 BERKELEY TECH. L.J. 103 (2010) (discussing history of patented HIV/AIDS pharmaceuticals).

life-saving or at least life-extending inventions could be restricted by patents has not received universal favor.<sup>36</sup> The tension was enhanced with the realization that the cost of these patented drugs was beyond the reach of many victims of HIV/AIDS in the United States, let alone in the rest of the world.<sup>37</sup> A further matter of public concern is the potential pandemic that may result from the spread of existing and evolving viruses and the perhaps limited availability of a patented vaccine—not only because of cost, but also because of limited production.<sup>38</sup>

<sup>36</sup> See *infra* Part II.B (discussing the negotiations and tensions between developed and developing countries over patent protection for pharmaceuticals).

<sup>37</sup> ENCYCLOPEDIA, *supra* note 3, at 33; see GARRETT, *supra* note 16, at 572:

When AIDS first surfaced in 1981 the global response was a medical, not public health, one: resources were skewed to the search for a cure. Fifteen years later Science offered up HAART, or highly active antiretroviral therapy. But in the long run HAART clearly was not the answer. Its price tag—\$10,000 to \$60,000 a year for the drugs alone—rendered HAART unusable for more than 90 percent of the world's HIV population, estimated in 1999 by the United Nations AIDS Programme to number forty million people.

Garrett reports the following reaction: “Given such a dire backdrop it came as a surprise to no one that the arrival of HAART for wealthy countries sparked rage in poor, HIV-plagued nations. They could not afford the drugs, even when pharmaceutical companies reduced the prices.” *Id.* at 574. The impact of patent protection on pricing is noted by Professor Sykes:

The annual cost of advanced retroviral therapies in South Africa, where one in eight persons is thought to be infected, is said to be about \$12,000, far beyond the means of most South Africans. Only about 5 percent of the 1 million citizens of Thailand believed to be infected are able to afford the AIDS therapies prescribed to them.

Much of the problem is attributed to the prices charged by pharmaceutical companies for their patented medications. A UN study reports, for example, that 150 mg of the HIV drug fluconazole costs \$55 in India, where the drug does not enjoy patent protection, as compared to \$697 in Malaysia, \$703 in Indonesia, and \$817 in the Philippines, where the drug is patented. Similarly, the HIV treatment known as AZT costs \$48 per month in India, as compared to \$239 in the United States, where patent protection exists.

Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT’L L. 47, 47 (2002) (footnotes omitted).

<sup>38</sup> For example, Tamiflu was approved by the FDA as an anti-viral drug for the treatment of influenza in October 1999. ACCESSDATA.FDA.GOV, *supra* note 3. Even though the production of Tamiflu has quadrupled, it was estimated in 2008 that ten additional ten years would pass before there will be enough to “treat twenty percent of the world’s population.” ENCYCLOPEDIA, *supra* note 3, at 27; U.S. DEP’T. OF HEALTH AND HUMAN SERV., *Guidance on Antiviral Drug Use During an Influenza Pandemic* 4 (2008), [http://www.flu.gov/individualfamily/vaccination/antiviral\\_use.pdf](http://www.flu.gov/individualfamily/vaccination/antiviral_use.pdf) (last visited Oct. 11, 2010):

*C. Tension Between Incentive and Access*

Prior to the entry into force of TRIPS,<sup>39</sup> the subject matter that could be protected by patents was left to the social policy of the individual countries. The Paris Convention for the Protection of Industrial Property<sup>40</sup> did not impose a subject-matter requirement on the members of the Union, and numerous members, as well as non-Union members, did not authorize the protection of pharmaceuticals and food products.<sup>41</sup> The TRIPS Agreement changed this, imposing a subject-matter requirement on all members. Article 27, entitled “Patentable Subject Matter,” requires, subject to certain exceptions, that: “patents shall be available for any inventions, whether products or processes, in all fields of technology.”<sup>42</sup> Accordingly, pharmaceuticals must be protected by each member state, including, of course, those pharmaceuticals for the prevention or treatment of pandemic diseases.

By definition, patents grant exclusionary rights to their owners. Under the current international formulation, the owner of the patent has the right to exclude others from “making, using, offering for sale, selling, or importing” the patented invention in the patent-granting country.<sup>43</sup> TRIPS requires members of the World Trade Organization (“WTO”) to implement this exclusivity by domestic legislation, as well as member-state implementation of other provisions of the Agreement.<sup>44</sup> Pharmaceutical enterprises developing drugs for the prevention or treatment of diseases rely heavily on the patent system.<sup>45</sup> The devel-

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The current national target for Federal and State antiviral drug stockpiles is 81 million regimens. This includes 6 million regimens to contain or suppress initial pandemic outbreaks overseas and in the United States, and 75 million regimens targeted for treatment of ill persons. Of the 81 million regimens to be stockpiled, 50 million have been purchased by the Federal Government and 31 million are allocated for State purchase proportional to population, with a 25% Federal cost share.

<sup>39</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1143, 1869 U.N.T.S. 299, (1994) [hereinafter TRIPS].

<sup>40</sup> Paris Convention for the Protection of Industrial Property, 828 U.N.T.S. 305 (Mar. 20, 1883), available at [http://www.wipo.int/treaties/en/ip/paris/summary\\_paris.html](http://www.wipo.int/treaties/en/ip/paris/summary_paris.html).

<sup>41</sup> STRAUS, *supra* note 11, at 174 ¶ 16 (summarizing the number of countries not protecting various subject matter including pharmaceuticals (forty-nine) and food products (thirty-five) prior to the TRIPS Agreement).

<sup>42</sup> TRIPS, *supra* note 39, art. 27(1).

<sup>43</sup> *Id.* art. 28(1).

<sup>44</sup> *Id.* art. 1(1) (“Members shall give effect to the provisions of this Agreement.”).

<sup>45</sup> The basis for this conclusion is summarized by Professor Sykes:

*Plagues, Pandemics, and Patents*

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opment of such drugs is extremely costly, as is the governmental approval process.<sup>46</sup> Without strong patent protection, the incentive to develop new drugs

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Pharmaceuticals are unusual in the extent to which research and development (“R&D”) and regulatory approval costs are a large part of their total production cost. Indeed, the marginal cost of producing pharmaceuticals is often trivial after a drug has been developed and approved by regulators. R&D and regulatory approval costs are incurred in the main by the company that develops a drug initially—subsequent producers of the same drug face much lower costs (although costs of obtaining approval for a generic version of a drug are not trivial). Without some period of restricted competition, the developers of new drugs will be unable to recoup R&D and regulatory approval costs, and the incentive to develop new drugs will diminish greatly.

For this reason, conventional wisdom has it that patent protection is especially important to the rate of technical progress in pharmaceuticals. In one survey by Professor Mansfield, executives in a range of industries were asked to estimate what percentage of inventions commercialized in the early 1980s would not have been developed without patent protection. The average response for all industries was only 14 percent, but for pharmaceuticals the average was 60 percent. Studies that examine the rate of return on pharmaceutical research also underscore the importance of patent protection for recoupment of R&D costs—they show how many R&D expenditures fail to produce valuable new drugs, and how the funding of pharmaceutical research as a whole requires substantial rents on the modest subset of products that prove particularly successful. Patents are essential in this regard.

Sykes, *supra* note 37, at 60–61 (footnotes omitted); *see also Intellectual Property*, PHRMA.ORG, <http://www.phrma.org/taxonomy/term/15> (last visited Oct. 12, 2010):

Pharmaceutical companies rely on government-granted patents to protect their huge investments in researching and developing new drugs. It takes 10–15 years and costs \$800 million on average to bring a new medicine to market.

Without patents to protect all the inventions necessary to develop a drug for a limited time, others could simply copy the drugs immediately, offering their versions at a reduced price since they did not incur the high costs to develop the drug. This would seriously impact the pharmaceutical companies’ ability to recoup their costs and reinvest in other research projects.

<sup>46</sup> *See Innovation*, PHRMA.ORG, <http://www.phrma.org/innovation> (last visited Oct. 12, 2010):

Only one of every 10,000 potential medicines investigated by America’s research-based pharmaceutical companies makes it through the research and development pipeline and is approved for patient use by the United States Food and Drug Administration. Winning approval, on average, takes 15 years of research and development and costs over \$800 million dollars. Potential new medicines pass through several crucial stages on their way from research laboratories to the pharmacy shelf.

Not surprisingly the Senior Vice President and General Counsel of PhRMA rely upon this data to conclude: “Pharmaceutical research and development is a lengthy, risky, and expen-

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is considerably undercut. For these enterprises to recoup the cost of drug development and approval, the exclusive rights granted by patents on a country-by-country basis leads quite expectedly to high prices for the patented drugs. Pandemics like HIV/AIDS, H1N1, and Avian influenza, by definition, are not limited to rich developed countries—where it may be expected that victims of a pandemic would have access to such patented drugs through personal resources, insurance or governmental aid. With respect to developing countries, particularly the least-developed countries (“LDCs”),<sup>47</sup> the ability of the government, let alone the patient, to pay the developed-world price for patented pharmaceuticals is essentially non-existent.<sup>48</sup> The tension between the patent owners and third-

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sive enterprise. The industry depends uniquely on patent and trade secret protections to support its investments in innovative activities.” Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 93 (2004). Compare Mr. Kuhlik’s statement with *Big Pharma Spends More On Advertising Than Research and Development, Study Finds*, SCIENCE DAILY.COM, <http://www.sciencedaily.com/releases/2008/01/080105140107.htm> (last visited Oct. 10, 2010), which discusses a 2004 study by New York University researchers that found the pharmaceutical industry spends almost twice as much on advertising as on research and development (24.4% on promotion versus 13.4% for research and development, based on U.S. sales of \$235.4 billion).

<sup>47</sup> See TRIPS, *supra* note 39, arts. 65, 66 (treating developing countries separately); see also *Least Developed Countries*, UN-OHRLLS.ORG, <http://www.unohrlls.org/en/ldc/related/62/> (last visited Oct. 12, 2010) (giving the United Nations list of forty-nine LDCs); *Standard Country and Area Codes Classifications (M49)*, UNSTATS.UN.ORG, <http://unstats.un.org/unsd/methods/m49/m49regin.htm> (last visited Oct. 12, 2010) (listing countries under various categories, including LDCs, landlocked developing countries, small island developing states, and transitional countries).

<sup>48</sup> Of course, developing and LDCs may receive funding through foreign aid programs enabling them to purchase patented drugs. In addition, various international, governmental, and non-governmental agencies may provide monetary and other assistance. Also, pharmaceutical companies have donated patented drugs to various needy countries. As summarized with respect to “The Global Fund”:

In 2007, the estimated annual funding devoted to AIDS and available for spending on low and middle income countries was ten billion dollars. The Global Fund to Fight AIDS, Tuberculosis and Malaria is one of the largest contributors of funding. By the end of December 2005, the Global Fund had received 4.7 billion dollars in contributions. Pledges will bring the cumulative total to 8.6 billion dollars by the end of 2008. By December 2005, the Global Fund had put 384,000 people on antiretroviral therapy for HIV. These incredible numbers show how much money is being used to help fund AIDS prevention and treatment. This money is given directly to governments of developing countries.

world governments on behalf of their infected nationals becomes palpable. Drugs that may save or extend life are available, but only to those who can afford them.

The relationship between pandemics and patents thus becomes clearer, as does the potential conflict arising from eliminating the former, while still respecting the latter. The relationship is one of tension between the incentive to create inventions that may be capable of preventing or treating a pandemic disease, and at the same time, granting a patent that may deny that access without the patent owner's consent. Like necessity, the availability of patents indeed induces inventions and should become a valuable weapon in the fight against pandemics. On the other hand, if access to needed inventions is denied or restricted by patents, the moral dilemma arises in the vivid form of protecting property at the expense of life and human well-being. This tension raises the moral issue that is the focus of this article, as considered in detail below.

#### *D. TRIPS and Pandemics*

The negotiators of the TRIPS Agreement were, of course, aware of the problem created by requiring member countries to grant patents on pharmaceuticals and the need for these same countries to have access to patented life-saving drugs, especially during times of emergency.<sup>49</sup> Under TRIPS, the exclusive rights that must be granted under patents are not absolute; however, the exceptions as currently in force are not expansive. A "principle" set out in Article 8 provides:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, *provided that such measures are consistent with the provisions of this Agreement*.<sup>50</sup>

The italicized proviso would seem to undercut any broad exception to compliance with TRIPS.<sup>51</sup>

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Jessica L. Greenbaum, Comment, *TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 6 Waiver*, 25 J. CONTEMP. HEALTH L. & POL'Y 142, 164 (2008) (footnotes omitted).

<sup>49</sup> See DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 50–70 (3d ed. 2008) (discussing extensive negotiation history over public health issues relating to patent protection).

<sup>50</sup> TRIPS, *supra* note 39, art. 8(1) (emphasis added).

<sup>51</sup> See GERVAIS, *supra* note 49, at 209.

The major exceptions are found in Article 31, captioned “Other Use Without Authorization of the Rights Holder,” and relate to the grant of compulsory licenses under a patent where the patent owner is compelled without its consent to grant a license to exploit the patent under certain circumstances.<sup>52</sup> The circumstances are many and detailed in Article 31, which includes twelve paragraphs (a)-(l) set out in the margin.<sup>53</sup> Most relevant here are paragraphs (b), (f), and (h):

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<sup>52</sup> TRIPS, *supra* note 39, art. 31.

<sup>53</sup> *Id.*:

Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[\*] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization . . .



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....

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....

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

....

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization . . . .<sup>54</sup>

With respect to these exceptions in Article 31, there are, of course, definitional problems regarding what constitutes a “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”<sup>55</sup> Also, many of the LCDs do not have the technical capability or infrastructure needed to make the patented drug, while paragraph (f) limits the authorization “predominantly for the supply of the domestic market.”<sup>56</sup> Hence, importation from other countries, presumably including those where compulsory licenses have been granted or there is no patent protection, would be prohibited. Finally, there

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[\*] “Other” use refers to use other than that allowed under Article 30.

See GERVAIS, *supra* note 49, at 391 (“Although the drafting of art.31 is abstruse at times, the article is best viewed as a checklist for WTO Members.”) (footnote omitted).

<sup>54</sup> TRIPS, *supra* note 3939, art. 31 (footnote omitted).

<sup>55</sup> *Id.*, art. 31(f).

<sup>56</sup> *Id.*, art. 31(b).

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is the question of “adequate remuneration”—always a problem with respect to compulsory licenses.<sup>57</sup>

In an attempt to redress the problem of access to patented drugs by the LDCs, the WTO, in the Doha Declaration of 2001<sup>58</sup> stated that, in interpreting the TRIPS Agreement:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.<sup>59</sup>

It thus appears that members may self-define what constitutes a “national emergency or other circumstances of extreme urgency.”<sup>60</sup> In addition, the time for LDCs to fully comply with TRIPS was also extended from 2005 to 2013.<sup>61</sup>

In 2002, the WHO in a Resolution entitled “Ensuring Accessibility of Essential Medicines” committed itself “to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicine, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them.”<sup>62</sup> This Resolution provided additional support and pressure for the relaxation of the detailed requirements of Article 31.<sup>63</sup>

Then, in the “2003 Declaration,”<sup>64</sup> the WTO directly addressed paragraph (f) of Article 31, authorizing members to waive their obligations under Article 31(f), and hence permitting members to export patented drugs under

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<sup>57</sup> See *id.*, art. 31(h).

<sup>58</sup> World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, 6, WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2002).

<sup>59</sup> *Id.* ¶ 4.

<sup>60</sup> See TRIPS, *supra* note 39, art. 31(b).

<sup>61</sup> Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (July 1, 2002), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).

<sup>62</sup> World Health Organization [WHO], *Ensuring Accessibility of Essential Medicines*, WHA55.14, at 2, ¶2(6) (May 18, 2002), available at [http://apps.who.int/gb/archive/pdf\\_files/WHA55/ewha5514.pdf](http://apps.who.int/gb/archive/pdf_files/WHA55/ewha5514.pdf).

<sup>63</sup> See *id.* at 1–2.

<sup>64</sup> General Council Decision of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003) [hereinafter 2003 Declaration].

compulsory licenses in that country to other countries needing the drug.<sup>65</sup> In 2005, an amendment to TRIPS was approved by the WTO to add an Article 31bis,<sup>66</sup> which essentially incorporated the “2003 Declaration.”<sup>67</sup> This amendment required ratification by two-thirds of the members by 2007, which has now been extended by two years.<sup>68</sup> The waiver provision of the 2003 Declaration remains in effect pending ratification of Article 31bis.<sup>69</sup> Article 31bis(1) provides:

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.<sup>70</sup>

Under paragraph (2), remuneration must be paid by either the exporting or importing member.<sup>71</sup> Professors Abbott and Reichman have thoroughly analyzed many formal and bureaucratic requirements under Article 31bis.<sup>72</sup>

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<sup>65</sup> See *id.* The preamble to paragraph 2 provides:

The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph[.]

*Id.* ¶ 2.

<sup>66</sup> World Trade Organization, General Council, Amendment of the TRIPS Agreement, Decision of 6 December 2005, WT/L/641 (Dec. 8, 2005) [hereinafter Art. 31bis].

<sup>67</sup> See *id.*

<sup>68</sup> The time was extended until December 31, 2011 “or such later date as may be decided by the Ministerial Conference.” General Council Decision on Amendment of the TRIPS Agreement, *Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/711 (Dec. 18 2007).

<sup>69</sup> See 2003 Declaration, *supra* note 64, ¶ 11 (“This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.”).

<sup>70</sup> Art. 31bis, *supra* note 66, ¶ 1.

<sup>71</sup> *Id.* ¶ 2:

Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those prod-

Canada and Rwanda were the first countries to take advantage of the “2003 Declaration.” Canada granted a compulsory license for the production of a HIV/AIDS drug by a Canadian company and its exportation to Rwanda, which did not have the capability to manufacture the drug.<sup>73</sup> Both before and after the “2003 Declaration” waiver to paragraph (f) of Article 31, a number of developing countries with the capability of producing advanced (and most often patented) pharmaceutical products have taken advantage of the compulsory license provisions of TRIPS to import or export patented pharmaceuticals under compulsory licenses.<sup>74</sup> These grants have been highly controversial and as would be expected, have been challenged by the patent-owning pharmaceutical industry.<sup>75</sup> Nonetheless, in time of threatened emergency, highly developed countries have

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ucts for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

<sup>72</sup> See generally Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921 (2007) (arguing that Article 31bis will provide increased access to pharmaceuticals despite introducing unnecessary administrative burdens).

<sup>73</sup> See GERVAIS, *supra* note 49, at 67–69. It is interesting to note that within the portion of the WTO website dedicated to providing public notification of such licenses, only Canada and Rwanda have given such notice. *Intellectual Property (TRIPS)—TRIPS and Public Health: Dedicated Webpage for Notifications*, WTO.ORG, available at [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/public\\_health\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/public_health_e.htm) (last visited Feb. 17, 2010) (for Rwanda, follow “notifications by importing members” and then follow “view notifications”; for Canada, follow “notifications by exporting members,” and then follow “view notifications”).

<sup>74</sup> Among these countries are Brazil, India, South Africa, and Thailand. Considerable controversy has arisen over Thailand's decision to issue compulsory licenses not only on HIV/AIDS medications, but also on heart and cancer drugs. See generally Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371 (2009) (presenting a comprehensive analysis of the Thailand controversy). India produces approximately twenty percent of the world's generic drugs. See Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AMER. J.L. & MED. 345, 352 (2008). The new Indian patent act authorizes the continued manufacture of now patented drugs upon the payment of reasonable royalties. *Id.* at 350–52. Brazil has granted compulsory licenses for the domestic production of HIV/AIDS drugs. *Id.* at 349–50. In 1997, South Africa enacted a law authorizing the grant of compulsory licenses under patented HIV/AIDS medications. This law was challenged by the South African Pharmaceutical Manufacturers Association; however, under pressure, the Association withdrew the challenge. *Id.* at 354–55.

<sup>75</sup> See, e.g., *Compulsory Licensing Trends Dangerous*, PHARMA.COM, <http://www.phrma.org/node/669> (last visited Feb. 17, 2010); see also Abbott & Reichman, *supra* note 72, at 949–57 (discussing extensively the reaction of governments, including the U.S., the European Commission and the pharmaceutical industry).

and may be expected to grant or threaten to grant compulsory licenses or the equivalent.<sup>76</sup>

It is not the purpose of this article to discuss the merits or demerits of the TRIPS regime as presently constituted with the addition of the Article 31bis amendment, or from a legal, economic, or social welfare standpoint. The literature discussing and analyzing these issues is rich.<sup>77</sup> Nor is it the present purpose

<sup>76</sup> As put by Professors Abbott and Reichman:

In this connection, we note that in 2001 US authorities threatened to issue compulsory licenses with regard to stockpiling Cipro for an anthrax scare. Health and Human Services Secretary Michael Leavitt did much the same thing, regarding access to Tamiflu. We also note that France and Belgium have recently enacted statutes permitting accelerated compulsory licensing of pharmaceuticals when needed. While their official positions hostile to compulsory licensing thus seem intended to inhibit action by foreign governments, they are not actually considered to constrain either the EU or the United States.

Abbott & Reichman, *supra* note 7272, at 939 (footnotes omitted). They also note that all European Union countries “currently regulate[] pharmaceutical prices.” *Id.* at 955; see also Jennifer A. Lazo, Note, *The Life-Saving Medicines Export Act: Why the Proposed U.S. Compulsory Licensing Scheme Will Fail to Export Any Medicines or Save Any Lives*, 33 *BROOK. J. INT’L L.* 237, 249 (2007) (“However, the United States did not need to override the Cipro patent; Bayer agreed to further reduce the price of Cipro, and a deal between Bayer and the U.S. government was reached.”) (footnote omitted).

<sup>77</sup> Professor Gerhart categorizes the state of international intellectual property policy scholarship as follows:

Although the literature is quite diverse, the theoretical, evaluative literature generally revolves around two topics: efficacy and fairness. The efficacy literature seeks to determine the impact of TRIPS on various indicia of national welfare . . . .

. . . .

The fairness literature focuses less on the effects of TRIPS as it pertains to national welfare, and more on the fairness of the bargaining that led to intellectual property harmonization and minimum standards through TRIPS.

Peter M. Gerhart, *Symposium: The International Intellectual Property Regime Complex: The Tragedy of TRIPS*, 2007 *MICH. ST. L. REV.* 143, 145–46 (2007) (footnote omitted). The same may be said with respect to the specific issue of the tension between patent incentives and access to essential medicines. For example, from an economic standpoint, compare Sykes, *supra* note 37, at 48–49:

The ultimate wisdom of measures that relax intellectual property protection for pharmaceuticals in developing countries turns on complex matters, including empirical issues about which one can only hazard an educated guess. It is conceivable that patent rights in the developing world have negligible impact on research incentives. They may simply raise prices on patented drugs, transferring rents to foreign pharmaceutical patent holders, and creating

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deadweight losses by pricing consumers out of the market who are willing to pay the marginal cost of medicines but not the monopoly markup charged by the patent holder.

But there is another possibility, one which in my view better accords with what we know about the importance of patents to pharmaceutical research, and with the extraordinary value to consumers of medicines that successfully treat serious conditions. Developing nations have long had little intellectual property protection for pharmaceuticals, and we have concurrently witnessed an apparent dearth of research into diseases such as malaria and drug-resistant tuberculosis that are of particular importance to these nations. . . . [D]eveloping nations reap the full benefits from lower prices when they do not create pharmaceutical patents, yet the costs in terms of diminished research incentives are largely externalized to the rest of the developing world. The WTO TRIPS agreement held out some promise of overcoming part of this problem. Yet, just as the obligations of developing nations under TRIPS are beginning to take hold, the Doha Declaration casts great doubt on the future credibility of patent rights for pharmaceuticals in developing nations. The result may be quite unfortunate for research incentives, especially those relating to particular diseases,

with Thomas F. Cotter, *Market Fundamentalism and the TRIPS Agreement*, 22 *CARDOZO ARTS & ENT. L.J.* 307, 308–09 (2004):

As someone who often employs law-and-economics analysis in my own scholarship, however, I am intrigued by Professor Sykes' argument that the TRIPS Declaration will decrease, rather than increase, social welfare; Sykes' arguments, and other similar arguments, need to be taken seriously.

Nevertheless, in my view, Sykes and others who argue against the TRIPS Declaration are mostly incorrect. The parade of horrors that they fear is more a spectre of their own imaginations than anything that is reasonably likely to occur. Moreover, by recognizing the need for exceptions to patent protection in emergency situations, the TRIPS Declaration hardly constitutes a radical gloss on the text of the TRIPS Agreement. While it is certainly possible that developing nations may abuse the "Doha solution," as I will explain, this risk appears minimal, particularly in comparison to the risk of doing nothing.

From a legal point of view, based on analyzing the TRIPS Agreement in the light of international law norms, Professor Ho makes a strong argument that Thailand's issuance of compulsory licenses can be justified:

Thailand's aggressive use of compulsory licenses has provided an excellent opportunity to evaluate the scope of compulsory licensing under TRIPS Article 31, as well as problems outside the WTO/TRIPS system. While this article is unlikely to reduce criticism of Thailand's compulsory licensing, it hopefully helps to clarify the appropriate interpretation of TRIPS, as well as identify future issues in need of true clarification. For example, contrary to what is reported in the popular press and by patent owners, no national emergency is required to issue a compulsory license—a country can issue one on grounds of public non-commercial use. However, an important open question

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is what constitutes public non-commercial use since if construed broadly a license could almost always be granted without initially consulting with the patent owner. Similarly, although there is a popular perception that only drugs to treat epidemics such as AIDS are subject to compulsory licensing, an appropriate interpretation of TRIPS readily reveals that there are no restrictions on the type of drug that may be licensed. In addition, despite the desire of patent owners to limit compulsory licenses to very limited circumstances, the actual TRIPS provision only requires that licenses be limited in scope and duration to the stated purpose. Granted, this may seem very broad and perhaps needs further inquiry, but, at a minimum, recognizing the current exaggerations of patent owners is a useful first step.

Ho, *supra* note 74, at 468–69. Professors Abbott and Reichman provided a detailed legal and policy based analysis of the proposed Article 31bis. Among their conclusions:

[G]iven the political rhetoric employed by the multinational pharmaceutical industry and supporting governments, we worry that failure to bring the Amendment into force might provide the basis for a concerted campaign to undermine the Waiver Decision’s vitality. Delay in ratification would be portrayed by some governments, the multinational pharmaceutical industry and prominent financial media outlets as a rejection of the solution. Government and industry pressure may persuade more economically vulnerable governments not to pursue implementation of the solution in national law, or to be reluctant to use it in practice. We believe these risks argue in favor of a more or less timely ratification of the Amendment, though we accept that reasonable minds can differ about the degree of risk associated with delay, or even failure to ratify.

Abbott & Reichman, *supra* note 72, at 985. From a policy perspective Professor Gerhart offers:

The only way in which this system can be changed toward the ideal is to redirect the interests of individual countries from parochial to systemic interests, so that each country recognizes that one of its interests is to take the interest of other countries into account. This would shift the attention of countries from an exclusive focus on efficiency concerns to a focus on distributive values as well. If that shift in focus were to be made, the institutional arrangement for making global policy could easily be transformed into one that is better able to match the real with the ideal.

Gerhart, *supra*, at 184. Professor Yu advocates, in view of the “limited benefits” offered by the amendment of Article 31bis, that the so-called BRICS countries (Brazil, Russia, India, China, and South Africa) should form a coalition that “collectively would possess such immense power to stop the push by the European Communities and the United States to ratchet up global intellectual property standards while threatening to grind the intellectual property harmonization process to a halt.” Yu, *supra* note 74, at 346–47. Professor Dutfield is skeptical of the efficacy of the proposed Article 31bis. See Graham Dutfield, *Delivering Drugs to the Poor: Will the TRIPS Amendment Help?*, 34 AM. J.L. & MED. 107, 114 (2008).

Student notes and comments seem to be based primarily on fairness arguments in favor of developing countries having access to needed medicines, and they offer a variety of proposed amendments to TRIPS. See, e.g., Erin M. Anderson, Note, *Unnecessary Deaths and*

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to consider a generalized human right or entitlement to health care and medicines, in particular whether the medicine is patented or not.<sup>78</sup> Rather, the approach here is to consider the moral position of a member of TRIPS who proceeds to acquire patented pharmaceuticals without the consent of the patent owner and contrary to the Agreement in order to alleviate a pandemic disease in that country. Some legal violation of TRIPS may be assumed, but in particular, the inability of the violating member to pay “adequate remuneration” to the patent owner under a compulsory license or otherwise will be the basic assumption

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*Unnecessary Costs: Getting Patented Drugs to Patients Most in Need*, 29 B.C. THIRD WORLD L.J. 85, 111 (2009) (“Furthermore, the argument that patents are provided to encourage innovation and ensure further research and development is getting in the way of accomplishing the purpose for which these medicines should be created. That is, medicines should be made to treat sickness and disease.”) (footnote omitted); Greenbaum, *supra* note 48, at 163–65 (suggesting a “TRIPS” fund should be created to compensate patent owners funded by all WTO members and humanitarian organizations); Aditi Diya Nag, Note, *The Bird Flu and the Invoking of TRIPS Article 31 “National Emergency” Exception*, 34 SYRACUSE J. INT’L L. & COM. 689, 706–07, 711–12 (2007) (suggesting amending TRIPS to “add[] more precise definitions of what constitutes a “national or extreme urgency”); Riadh Quadir, Note, *Patent Stalemate? The WTO’s Essential Medicines Impasse Between Pharmas and Least Developed Countries*, 61 RUTGERS L. REV. 437, 440–41, 462–66 (2009) (proposing to impose prices for pharmaceuticals on a county-by-county basis and amend TRIPS to eliminate compulsory licenses); Alexandra G. Watson, Note, *International Intellectual Property Rights: Do TRIPS’ Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?*, 32 B.C. INT’L & COMP. L. REV. 143, 158–59 (2009) (“A standardized tiered pricing scheme accompanied by a ban on parallel imports would help secure universally lower prices for developing countries.”); Brittany Whobrey, Note, *International Patent Law and Public Health: Analyzing TRIPS’ Effect on Access to Pharmaceuticals in Developing Countries*, 45 BRANDEIS L.J. 623, 625–26, 639, 641 (2007) (proposing amending TRIPS to impose a pricing structure and eliminate parallel imports). Cf. Stephanie Skees, *Thai-ing Up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand’s AIDS Epidemic?*, 19 PACE INT’L L. REV. 233, 284–85 (2007) (“If the WTO continues to allow the broad interpretation of TRIPS in which compulsory licenses can be abused, everyone will lose out on the life-saving and enhancing benefits that pharmaceutical and biotech companies provide.”).

<sup>78</sup> See generally Alynna C. Smith, *Intellectual Property Rights and the Right to Health: Considering the Case of Medicines* in ETHICS AND LAW OF INTELLECTUAL PROPERTY: CURRENT PROBLEMS IN POLITICS, SCIENCE AND TECHNOLOGY 47–72 (Christian Lenk et al. eds., 2007) (making a compelling case for access to “essential medicines” as a human right); Ellen M. Walker, *The HIV/AIDS Pandemic and Human Rights: A Continuum Approach*, 19 FLA. J. INT’L L. 335, 361 (2007) (“Under TRIPS Article 31(b), the need to protect human rights vis-à-vis HIV/AIDS could constitute a base for a national emergency, circumstances of extreme urgency, or public noncommercial use.”); Melissa McClellan, Note, “Tools for Success”: *The TRIPS Agreement and the Human Right to Essential Medicines*, 12 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 153, 153 (2005) (“Human rights are more than principles to guide the national and global response to AIDS: they are among the most powerful tools to ensure its success.”) (footnote omitted).



and hence a clear violation of Article 31(h).<sup>79</sup> In addition to acquisition directly in the acquiring country, the question of acquisition of the patented drug by importation from another member of TRIPS will be considered.

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<sup>79</sup> What constitutes “adequate remuneration” that would pass muster under the TRIPS Agreement is far from clear. As stated by Professor Ho:

With no clear limits, the interpretation of what constitutes adequate remuneration seems left to the discretion of national authorities, subject only to potential review within the WTO system. Because there is no definition in TRIPS, nations arguably have discretion to choose from a wide variety of options as noted in a thorough report prepared by James Love for the WHO. In addition, WTO panels cannot create new law. As stated by one commentator, “no guidelines have been given under TRIPS and none can be imposed arbitrarily by commentators in interpretation.” It seems that Article 31 may enable countries to impose a price through compulsory licensing that the country could not obtain through voluntary negotiations.

Ho, *supra* note 74, at 409–10 (footnotes omitted). See WHO, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, Health Economics and Drugs 5 (WHO 2005) for the report prepared by James Love. In a comprehensive analysis of the issue, Anthony Taubman, Director (A/G) and Head, Global IP Issues Division, World Intellectual Property Organization (WIPO), summarizes the guidelines:

The WHO has commissioned remuneration guidelines for pharmaceutical [compulsory licenses], which identify a range of relevant factors, including the therapeutic value of a medicine, the public’s ability to pay, input from publicly funded research, public health exigencies, the importance of the patent to the final product, global revenues and profitability, and addressing anti-competitive practices. Yet the experience it surveys suggests an expedient preference for *ex ante* royalty rates—a rule of reason (or rule of thumb), rather than a *per se* rate.

To extract a general trend from diverse experience, the emerging practice seems to be to articulate broad equitable rules for compensation, but within those rules to fix a royalty rate based on the actual economic scale of the authorization, potentially tempered by humanitarian or non-commercial circumstances of the proposed use. Pragmatism has so far led to a greater concentration on setting a fixed royalty rate based on the actual price of the authorized product, although courts on appeal have given greater consideration to the specific circumstances of each case, closer to the expropriation model. Compensation under the Doha Paragraph 6/TRIPS Article 31*bis* arrangement has led to greater emphasis on the economic conditions of the recipient market. There has been no reported experience with other potentially ‘adequate’ forms of compensation—which could include lump sum payments or non-financial compensation, such as extended regulatory exclusivity for other products. Reported royalty rates range from 0.02% to 8%. Courts in several jurisdictions have upheld such rates on appeal.

Anthony Taubman, *Rethinking TRIPS: ‘Adequate Remuneration’ for Non-Voluntary Patent Licensing*, 11 J. INT’L ECON. L. 927, 961–62 (2008) (footnotes omitted).

### III. LAW AND MORALS

The debate over the interrelationship, if any, of law and morals has a long history. There is no intent here to enter into that debate and it will be assumed that one is *prima facie* morally obligated to follow the law.<sup>80</sup> Accordingly, the assumption is made here that it would be *prima facie* immoral for a country bound by the legal regime not to adhere to it. The moral dilemma is a difficult one, particularly when it is assumed that there is at least a *prima facie* moral obligation to obey the law that extends not only to individuals, but also to their country. Some persons, if not all, would agree that it is moral for an individual to take food from the excess of another individual to save oneself from starvation.<sup>81</sup> However, it would seem that most, if not all, would both legally and morally require that the owner be compensated for the food taken. The situation becomes more controversial when the taker of the food is unable to pay the owner. Another complication would result if the person appropriating the food was not the starving person, but the country or state acting as an agent for that person, which is also unable to pay for the food.

The uncompensated appropriation of food could be extended by analogy to patented inventions. One would expect that, if excess food could be taken without compensation by an individual or *a fortiori* by a country or state, less food would be produced.<sup>82</sup> The same consequences would seem to follow for

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<sup>80</sup> See generally William A. Edmundson, *State of the Art: The Duty to Obey the Law*, 10 LEGAL THEORY 215 (2004) (providing a comprehensive review and analysis of the various philosophical views on this issue).

<sup>81</sup> Peter Singer nicely makes the point:

I begin with the assumption that suffering and death from lack of food, shelter, and medical care are bad. I think most people will agree about this, although one may reach the same view by different routes. I shall not argue for this view. People can hold all sorts of eccentric positions, and perhaps from some of them it would not follow that death by starvation is in itself bad. It is difficult, perhaps impossible, to refute such positions, and so for brevity I will henceforth take this assumption as accepted. Those who disagree need read no further.

Peter Singer, *Famine, Affluence, and Morality*, 1 PHILOSOPHY & PUB. AFFAIRS 229, 231 (1972).

<sup>82</sup> As stated by Judge (Professor) Posner as a fundamental aspect of property law:

Imagine a society in which all property rights have been abolished. A farmer plants corn, fertilizes it, and erects scarecrows, but when the corn is ripe, his neighbor reaps it and takes it away for his own use. The farmer has no legal remedy against his neighbor's conduct because he owns neither the land that he sowed nor the crop, where ownership implies the legal right to exclude. Unless defensive measures are feasible (and let us assume for the moment that

the uncompensated taking of patented inventions. There would be a disincentive to invent, including life-saving inventions. How much diminution in the creation of inventions would result is, of course, difficult to quantify and a matter of considerable disagreement.<sup>83</sup> Nonetheless, it is a consideration, both with respect to food and to the production of inventions. To address the issue of the morality of the uncompensated taking of patented inventions in pandemic situations, a number of analogies and hypotheticals will be considered.

### A. *Morality*

Professor Judith Jarvis Thomson<sup>84</sup> is justifiably recognized for her creative use of analogies for analyzing moral issues.<sup>85</sup> Perhaps the most well-known is her analogy of the moral position of a woman who became pregnant as the consequence of being raped and seeks an abortion to a woman who is kidnapped by the Society of Music Lovers and, while unconscious, has her circulatory system connected to that of a famous musician with kidney failure in order to keep him alive for nine months.<sup>86</sup> More apropos in the present context is her “Some Ruminations on Rights,” in which she analyzes the morality of taking the prop-

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they are not), after a few such incidents the cultivation of land will be abandoned and society will shift to methods of subsistence (such as hunting) that involve less preparatory investment.

RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 32 (7th ed. 2007).

<sup>83</sup> In the context of whether net social welfare may be diminished by permitting developing countries to exploit patented inventions under compulsory licenses, as advanced by Professor Sykes, *supra* note 37, Professor Cotter nicely makes the point of the disconnect between economics and morals:

Even if one could demonstrate a net welfare gain—that is, that the developed world’s gains are greater than the developing world’s losses, as measured by willingness to pay—there is nothing in economics that insists one must make such a tradeoff. Whether the tradeoff is desirable or not is a moral issue to which economics does not speak. I suspect that many people—though perhaps not market fundamentalists—would be troubled by a policy that threatens to impose higher prices in the developing world, where they will have an immediate and obvious impact on the lives of real people, in exchange for a possible future benefit to people in the industrialized nations.

Cotter, *supra* note 77, at 337 (footnotes omitted).

<sup>84</sup> Professor Thomson is Professor of Philosophy, Massachusetts Institute of Technology. Judith Jarvis Thomson, *Some Ruminations on Rights*, 19 *ARIZ. L. REV.* 45, 45 n.\* (1977).

<sup>85</sup> See, e.g., *id.*

<sup>86</sup> See Judith Jarvis Thomson, *A Defense of Abortion*, 1 *PHILOSOPHY & PUB. AFFAIRS* 47, 48–49 (1971).

erty of another under various circumstances.<sup>87</sup> It should be noted that Professor Thomson's purpose in undertaking this analysis is to challenge Robert Nozick's assertion in *Anarchy, State, and Utopia*, "that a government which imposes taxes for the purpose of redistribution violates the rights of its citizens."<sup>88</sup> However, her "ruminations" would appear to have general application,<sup>89</sup> and may provide particular insight in the context of a government faced with a pandemic that may be averted or ameliorated by the use of a patented medicine.

Professor Thomson begins with a hypothetical situation:

(A) There is a child who will die if he is not given some drug in the near future. The only bit of that drug which can be obtained for him in the near future is yours. You are out of town, and hence cannot be asked for consent within the available time. You keep your supply of the drug in a locked box on your back porch.<sup>90</sup>

She concludes under the facts of situation (A) that:

So if we break into the box, remove the drug, and feed it to the child, we thereby infringe a number of rights of yours. But I take it that a child's life being at stake, we do not act wrongly if we go ahead; that is, though we *infringe* a number of your rights, we *violate* none of them.<sup>91</sup>

She goes further in the generalization of the moral situation: "It is presumably agreed universally that if we go ahead in (A), we are not to be blamed, punished, scolded, or the like, for doing so."<sup>92</sup> Accordingly, in the moral sense we have not acted wrongfully. She rejects the proposal that while the act might be wrongful, it may be "excusable."<sup>93</sup> Such might be the case if the frantic parents broke into the box and gave the drug to their sick child.<sup>94</sup> However, situation (A) is generalized: "There is a child" and "we" are the actors who are trespassing and appropriating the drug.<sup>95</sup> Again, she concludes "that while we *infringe* some of your rights if we go ahead, we do not *violate* them."<sup>96</sup>

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<sup>87</sup> *See id.*

<sup>88</sup> *Id.* at 45 (citing ROBERT NOZICK, *ANARCHY, STATE, AND UTOPIA* 171–74 (1974)).

<sup>89</sup> Thomson's *Ruminations* article is reprinted in abridged form as Judith Jarvis Thomson, *Some Ruminations of Rights*, in *THE PHILOSOPHY OF LAW: CLASSIC AND CONTEMPORARY READINGS WITH COMMENTARY* 299 (1996).

<sup>90</sup> Thomson, *supra* note 86, at 47.

<sup>91</sup> *Id.* at 48 (emphasis added).

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* at 48.

<sup>95</sup> *Id.*

<sup>96</sup> Thomson, *supra* note 86, at 49 (emphasis added) (footnote omitted).

However, Professor Thomson does require, even though there has been no “violation” of rights of the owner, that “we shall have later to pay [the owner] some, if not all, of the costs we imposed on [the owner] by doing so.”<sup>97</sup> The payment presumably is imposed for the “infringement,” as there is no “violation” of any rights in her analysis. It is also not apparent that the inability on the part of the actors to pay would convert infringement into violation and moral approbation.

She next introduces the construct of stringency of rights.<sup>98</sup> In situation (A), the owner’s rights were “overridden” by the fact that the child will die if we do not go ahead.<sup>99</sup> However, if the owner had to be killed to save the child, Thomson concludes that the “right to not be killed is considerably more stringent than any of your property rights, and would not have been overridden by the child’s need.”<sup>100</sup> Thus, it would appear that the stringency of a right corresponds to its valuation and, in her terms, “[o]nly an absolute right is infinitely stringent” and that “surely it is plain as day that property rights are not infinitely stringent.”<sup>101</sup>

### **B. Legality**

If we return to situation (A), from a legal standpoint it appears that “we” have committed a number of torts and perhaps even criminal violations by entering the real property of the owner, breaking into the box on the porch, and converting the drug by taking possession of it and giving it to the child.<sup>102</sup> If we limit our analysis to the potential torts involved, there is no question that a trespass to land (including breaking into the box) has occurred and that there has been a conversion of personal property, the drug, unless there is some legally recognized justification for the actor’s conduct that may be invoked by the actor to “override” the otherwise tortious conduct.

If the legal terminology of Wesley Hohfeld is used, the owner of the land, the box, and the drug has a “right” not to have his property infringed upon, and the actor has a “duty” not to enter the land or to appropriate the drug.<sup>103</sup> The

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<sup>97</sup> *Id.* at 49–50.

<sup>98</sup> *Id.* at 50.

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> See Thomson, *supra* note 86, at 47–48.

<sup>103</sup> Based upon Professor Hohfeld’s work, Professor Corbin provides the following definitions:

actor's conduct, however, may be privileged, thus transforming its legal relationship to the owner from a "duty-right" to a "privilege no-right."<sup>104</sup> The legal consequence of the "privilege" is to negate (override) the actor's tort (violation of a right) that would otherwise have occurred but for the privilege of the actor under the circumstances.<sup>105</sup>

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(1) RIGHT: A legal relation between two persons. The correlative of *duty*, and the opposite of *no-right*. An enforceable claim to performance [sic] (action or forbearance) by another. It is the legal relation of A to B when society commands action or forbearance by B and will at the instance of A in some manner penalize disobedience. . . .

(2) DUTY: The correlative of the concept *right*, above defined, and the opposite of *privilege*. It is the legal relation of a person, B, who is commanded by society to act or to forbear for the benefit of another person, A, either immediately or in the future, and who will be penalized by society for disobedience.

Arthur L. Corbin, *Legal Analysis and Terminology*, 29 YALE L.J. 163, 167 (1919); see also WESLEY NEWCOMB HOHFELD, FUNDAMENTAL LEGAL CONCEPTS 6–7 (Walter Wheeler. Cook ed., 1920); Wesley Newcomb Hohfeld, *Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 26 YALE L.J. 710, 717, 744 (1917); see generally Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16 (1913) (discussing the meanings of "right" and "duty").

<sup>104</sup> Corbin, *supra* note 103, at 167–68:

(3) PRIVILEGE: The correlative of the legal concept *no-right* and the opposite of *duty*. The legal relation of A to B when A (with respect to B) is *free* or *at liberty* to conduct himself in a certain matter as he pleases; when his conduct is not regulated for the benefit of B by the command of society; and when he is not threatened with any penalty for disobedience, for the reason that society has made no command. . . .

(4) NO-RIGHT: The correlative of *privilege*, and the opposite of *right*. The legal relation of a person (A) in whose behalf society commands nothing of another (B). A has no control over B. A, knowing that he has no-right against B, can answer this question, "What *may* another person (B) do?" (A court will not prevent him or penalize him.)

<sup>105</sup> Corbin gives the example of the privilege of consent converting a right into a no-right:

A statement that a legal relation exists between A and B is a *prediction* as to what society, acting through its courts or executive agents, will do or not do for one and against the other. If A invades B's house, we are able to predict that the police will eject A, that a court will give judgment for damages, and that the sheriff will levy execution. We say that B had a *right* that A should not intrude and that A had a *duty* to stay out. But if B had invited A to enter, we know that those results would not occur. In such case we say that B had *no right* that A should stay out and that A had the *privilege* of entering.

*Id.* at 164–65 (footnotes omitted). The RESTATEMENT (SECOND) OF TORTS adopts this approach:

In situation (A), it is apparent that the owner of the drug has not *expressly* consented to its appropriation.<sup>106</sup> It is not apparent what other privilege could arise except perhaps one of “private necessity” to save the life of the child,<sup>107</sup> or perhaps “public necessity” if the child had a contagious or communicable disease that might infect others in the community.<sup>108</sup> Nonetheless, it does become clear later in Thomson’s analysis of the moral situation that what she has in mind is that, because the owner cannot be contacted or, even if contacted, apparently does not care whether the drug is taken, consent on the part of the own-

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§ 10 Privilege

(1) The word “privilege” is used throughout the Restatement of this Subject to denote the fact that conduct which, under ordinary circumstances, would subject the actor to liability, under particular circumstances does not subject him to such liability.

(2) A privilege may be based upon

- (a) the consent of the other affected by the actor's conduct, or
- (b) the fact that its exercise is necessary for the protection of some interest of the actor or of the public which is of such importance as to justify the harm caused or threatened by its exercise, or
- (c) the fact that the actor is performing a function for the proper performance of which freedom of action is essential.

RESTATEMENT (SECOND) OF TORTS § 10 (1965).

<sup>106</sup> See Thomson, *supra* note 86, at 47.

<sup>107</sup> With respect to land, see RESTATEMENT (SECOND) OF TORTS § 197 (1965):

§ 197 Private Necessity

(1) One is privileged to enter or remain on land in the possession of another if it is or reasonably appears to be necessary to prevent serious harm to

- (a) the actor, or his land or chattels, or
- (b) the other or a third person, or the land or chattels of either, unless the actor knows or has reason to know that the one for whose benefit he enters is unwilling that he shall take such action.

(2) Where the entry is for the benefit of the actor or a third person, he is subject to liability for any harm done in the exercise of the privilege stated in Subsection (1) to any legally protected interest of the possessor in the land or connected with it, except where the threat of harm to avert which the entry is made is caused by the tortious conduct or contributory negligence of the possessor.

<sup>108</sup> See *id.* § 196:

§ 196 Public Necessity

One is privileged to enter land in the possession of another if it is, or if the actor reasonably believes it to be, necessary for the purpose of averting an imminent public disaster

er may be implied or be apparent.<sup>109</sup> In Hohfeldian terms, this would signify that a privilege has arisen by means of the implied consent of the owner.<sup>110</sup> If there is implied consent by the owner, then no tort of trespass to land or conversion of the drug has been committed.<sup>111</sup> The original right of the owner has been converted to the opposite legal relationship of “no right,” with the arising correlative “privilege” of the actors (“we”).<sup>112</sup> Accordingly, if such is the case, no tort has been committed; thus, there has been no legal *infringement* of any rights of the owner, let alone a legal *violation* of those rights in Thomson’s sense.

Nonetheless, there still remains the legal question of whether “we” should be under a duty to pay the owner for any damage suffered. It appears clear that tort law would hold the actor liable and require the actor to compensate the owner for any damages sustained in the trespass to the land, the breaking open of the box, and the conversion of the drug.<sup>113</sup> This evokes the classic

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<sup>109</sup> See *id.* § 892:

§ 892 Meaning of Consent

(1) Consent is willingness in fact for conduct to occur. It may be manifested by action or inaction and need not be communicated to the actor.

(2) If words or conduct are reasonably understood by another to be intended as consent, they constitute apparent consent and are as effective as consent in fact. . . .

[Illustration] c. Apparent consent. Even when the person concerned does not in fact agree to the conduct of the other, his words or acts or even his inaction may manifest a consent that will justify the other in acting in reliance upon them. This is true when the words or acts or silence and inaction, would be understood by a reasonable person as intended to indicate consent and they are in fact so understood by the other. This conduct is not merely evidence that consent in fact exists, to be weighed against a denial. It is a manifestation of apparent consent, which justifies the other in acting on the assumption that consent is given and is as effective to prevent liability in tort as if there were consent in fact. On the other hand, if a reasonable person would not understand from the words or conduct that consent is given, the other is not justified in acting upon the assumption that consent is given even though he honestly so believes; and there is then no apparent consent.

<sup>110</sup> See *supra* text accompanying note 105 (discussing the interpretations of “privilege”).

<sup>111</sup> RESTATEMENT (SECOND) OF TORTS § 10 (1965).

<sup>112</sup> Corbin, *supra* note 103, at 164–65.

<sup>113</sup> RESTATEMENT (SECOND) OF TORTS § 197(2) (1965) (stating that the person having the privilege “is subject to liability for any harm done in the exercise of the privilege”). Thomson prefers not to use the term “compensate.” See Thomson, *supra* note 86, at 50. She explains the reason for this in her conclusion. *Id.* at 60. See *infra* notes 108–09 and accompanying text.



case of *Vincent v. Lake Erie*<sup>114</sup> where a ship owner, after unloading its cargo, had overstayed its time at a particular wharf and thus was a trespasser, but due to a storm the ship owner continued to lash the boat to the dock resulting in damage to the dock. The court concluded that this was a quite reasonable thing to do;<sup>115</sup> nonetheless, the owner to the dock was still entitled to compensation for the damage sustained to it.<sup>116</sup> In essence, the owner of the ship had a privilege to trespass on the owner's dock, but its privilege was limited to not causing any damage. By causing damage (even while acting reasonably), the scope of the privilege was exceeded and the dock owner had a right to recover for this damage, and the ship owner had a duty to pay for the damage.

Situation (A) can be explained in accordance with *Vincent* from a legal standpoint. The actors in situation (A) may have a privilege to trespass and convert the drug in order to save the child's life (which most would consider quite reasonable conduct), but that privilege was exceeded by any damage sustained to the owner's property (the box and the value of the drug).

The moral conclusion reached by Professor Thomson in situation (A) would seem also to be reached in *Vincent*. From a moral standpoint, we would not morally condemn the conduct of the ship owner in *Vincent* for saving the ship any more than we would condemn that of the actors "we" in situation (A) to save the life of a child, even though they both should have to pay for the consequences, at least legally.

### C. *Returning to Morality*

In carrying her moral analysis further, Professor Thomson introduces situation (B), where situation (A) is modified so that the owner of the drug expressly refuses to consent to the taking of the drug from the box on his porch, regardless of the consequence of a child dying.<sup>117</sup> Her analysis of the moral justification for taking the drug draws a distinction between circumstance (X), where the drug is of "little value" to the owner, and circumstance (Y), where it is of "immense value" to the owner.<sup>118</sup> To further illustrate this value dichotomy,

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<sup>114</sup> 124 N.W. 221 (Minn. 1910).

<sup>115</sup> *Id.* at 221–22.

<sup>116</sup> *Id.* (comparing to the almost as famous case of *Ploof v. Putnam*, 71 A. 188 (Vt. 1908), where the court held no trespass had occurred when a vessel in a storm was moored to a private dock without the permission of the dock owner, but no damage had been inflicted on the dock).

<sup>117</sup> Thomson, *supra* note 86, at 52–53.

<sup>118</sup> *Id.* at 54.

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Professor Thomson starts with a toothpick whose breaking in two without the consent of the owner may be justified as moral to save a life, if its owner considered the toothpick to be of “little value.”<sup>119</sup> Beyond the toothpick, however, the slippery slope goes to the destruction of the owner’s only photograph of his dead mother, and then over the cliff to the “destruction of all now existing beautiful works of art.”<sup>120</sup>

She then concludes in situation (*Y*), where the property is of “immense value” to the owner, that we should not proceed to steal the drug to save the child’s life.<sup>121</sup> In justification for this result death of a child, she states:

It is not morally splendid to value bits of property more than human lives; but if there are some which you do—and this is for no morally suspect reason—then it seems to me that there are cases, and that this is one of them, in which we must withdraw.<sup>122</sup>

Professor Thomson justifies the distinction between (*X*), where the property is *little valued*, and (*Y*), where the property is *immensely valued*, by a general proposition, (*T*): “The stringency of *A*’s right that *x* not be broken and *y* not taken away from him varies with the degree to which he values *x*’s not being broken and *y*’s not being taken away from him.”<sup>123</sup>

Whether the property in question is of “immense value” appears to be subjectively determined by its owner and apparently need not be justifiable on any other grounds, except perhaps that the valuation is “for no morally suspect reason.”<sup>124</sup> Thomson also provides an alternative justification that the actors may not be able to reimburse the owner for all of the costs imposed.<sup>125</sup> She prefers proposition (*T*), however, which seems to introduce a “morality scale,” where the degree to which the owner values the property correlates with the “violation” of the property owner’s right, i.e., the higher the property is valued

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<sup>119</sup> *Id.* at 53.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.* at 54.

<sup>122</sup> Thomson, *supra* note 86, at 54.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Thomson states:

But if (*Y*) is true, then it is less likely, perhaps even impossible, that we are going to be able to reimburse you for all of the costs we impose on you by going ahead; and if we take “immense” *very* seriously, it is less likely, perhaps even impossible, that we are even going to be able to pay you a meaningful part of those costs.

*Id.* at 55.

(toward immensity) the more likely that the right will be violated and hence be morally wrong for the actor to proceed.<sup>126</sup>

#### *D. Moral and Legal Analysis*

The difference between Thomsonian moral analysis and Hohfeldian legal analysis can thus be summarized: Thomson conditions the violation of a right that is admittedly infringed on the degree of value that the owner places on the property.<sup>127</sup> If the value is little to the owner, there may be infringement without violation of the right and no moral culpability on the part of the actor.<sup>128</sup> Hohfeld conditions the infringement (i.e., tortious, legally wrongful conduct) of a right on whether that conduct is privileged and the scope of the privilege is not exceeded.<sup>129</sup> If there is a privilege, the owner has no-right that can be infringed; in other words there is no tort—no legally wrongful conduct on the part of the actor. If a privilege is exceeded, a tort is then committed, with the actor breaching a duty owed to the owner not to have its rights legally violated, even though the actor acted reasonably under the circumstances.<sup>130</sup>

#### **IV. PATENT RIGHTS**

Now, if we change situation (A) from a life-saving drug disposed in a box on the owner's porch to an analogous situation involving intangible property protected by a patent:

- (A') There is a child who will die if he is not given some drug in the near future. The only bit of the drug that he can obtain in time is protected by your patent. The drug covered by the patent will cure the particular disease if made in tangible form and administered to the child. From the enabling disclosure in the patent, "we" replicate the drug and give it to the child whose life is thereby saved. It is further assumed that the country in which situation (A') occurs is a member of WTO and accordingly bound by

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

<sup>127</sup> Thomson, *supra* note 86, at 54–55.

<sup>128</sup> *See id.* at 54.

<sup>129</sup> *See supra* notes 104–105 and accompanying text.

<sup>130</sup> *Vincent v. Lake Erie Transp. Co.*, 124 N.W. 221, 222 (Minn. 1910); RESTATEMENT (SECOND) OF TORTS § 197(2) (1965) (stating that the person having the privilege "is subject to liability for any harm done in the exercise of the privilege").

TRIPS. It is further assumed that the patent owner is willing to sell the drug at world-market price.

There seems little question that the patent has been *infringed* unless the patent owner has consented expressly or by implication to the making of the patented drug. In contrast to the situation (A), where the consent of the drug owner may be implied, implication of consent on the part of the patent owner would seem to be more difficult to prove.<sup>131</sup> If the owner throughout situation (A) could not be contacted, consent may possibly be implied from that fact. However, the patent owner presumably could be contacted and the drug presumably would be available for purchase, i.e., the patent owner would consent only if paid its asking price. Hence, according to Thomson's analysis, in addition to the infringement there also has been a *violation* of right granted to the patent owner, unless somehow consent can be implied.

Thus, it would seem that the more appropriate circumstances for comparison would be Thomson's situation (B), where the owner has been telephoned and has expressly refused to consent to the taking of the drug from the box on the porch.<sup>132</sup> In the analogous patent situation (call it situation (B')), no consent (express or implied) is given by the patent owner to infringe the patent on the life-saving drug. Under circumstances including the death of a child, would the patent owner consider the patent of *little value* (X) or of *immense value* (Y)? To repeat Professor Thomson's words, "[i]t is not morally splendid to value bits of property more than human lives" but it would also not be improbable that the patent owner would consider the patent immensely valuable. This is particularly true in the pharmaceutical field, where large amounts of money are often expended in researching, testing, obtaining governmental approval, and acquiring patent protection. Hence, in Thomson's framework of analysis, patent infringement would most likely fall into category (Y), where the owner values the patent immensely.<sup>133</sup> Accordingly, can it follow that there would be any justification for the *infringement* of the patent on a life-saving drug that does not involve the *violation* of the right leading to moral condemnation?

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<sup>131</sup> See Thomson, *supra* note 86, at 47, 52–53 (alluding to a situation where implied consent is given by the inability to reach the right holder).

<sup>132</sup> *Id.* at 52–53.

<sup>133</sup> *Id.*

**A. *Morality Again***

Thus, if none of the normal legal exceptions to violating exclusive patent rights apply as discussed above or if consent on the part of the patent owner cannot be obtained or implied, replicating the patented drug even to save the life of a child would be, according to Professor Thomson's analysis, a *violation* of the patent owner's rights, morally wrongful, and legally impermissible according to the foregoing infringement analysis.

To address further the moral question, consider a not unimaginable situation:

- (C) There is a worldwide pandemic where a large number of people may die unless they are treated by a patented drug. This drug is patented in most countries of the world, including Country *L*. The patents are owned by a multinational pharmaceutical company, Company *P*. Country *L* is one of the least-developed countries in the world. It is in the midst of a pandemic that may result in the death or debilitation of a significant proportion of its population. It does not have adequate resources to expend on patented drugs in the volume required at the demanded by Company *P*, which is its world market price.

In Professor Thomson's system of moral balancing, she compares the value of property to the owner against the loss of a single child's life.<sup>134</sup> As the value of the property to its owner increases (toward immensity), the moral justification for its taking decreases. Another slippery slope argument from the opposite side can be envisioned—from the loss of a single child, to many children, to a substantial proportion of the entire population of Country *L*. Hence, an immense number of people would die unless treated by the patented drug. In other words, does a pandemic change the moral balance from a *violation* of a right to a *non-violation* that is morally justified?

Surely if the balance between violation and non-violation is dependent upon how much the property owner subjectively values the property (immensely for this patent), it should follow that consideration should be given to the immensity of human losses (even objectively and quantitatively evaluated) from

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<sup>134</sup> See *id.* at 54–55.

the failure to have access to a lifesaving drug for whatever reason.<sup>135</sup> Indeed, as Professor Thomson reasoned in the nonconsensual situation *(B)(X)*, where the owner held the property to be of little value, “it would be indecent . . . to refuse consent.”<sup>136</sup> Thus, it should follow a fortiori that it would be indecent to refuse consent in situation *(C)(Y)*, where the immensity of value is overridden by the immensity of loss of human life.

### ***B. Payment for the Infringement***

If the immensity of the loss of life can result in the moral non-violation of the patent right, how then should the question of damages for the *infringed* but not *violated* patent right be resolved under circumstances where country L cannot pay for the infringement, at least, at market prices demanded by Company P? From a patent law standpoint, it would appear at minimum that the infringer should be required to pay for this infringement, which would make the result consistent with the legal results discussed above.<sup>137</sup> In the language of Article 31, when a compulsory license would be justified under “national emergency or other circumstances of extreme urgency . . . the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”<sup>138</sup>

On the other hand, from a moral point of view, how has the patent owner been harmed when its rights have not been *violated* but only *infringed* under most compelling circumstances? Thomson, in situation *(A)*, would require payment for the infringement but not for the violation,<sup>139</sup> and certainly this is the legal result in *Vincent*.<sup>140</sup> However, Professor Thomson does not, in any of her hypotheticals, condition the violation of a right on the ability of the actors to pay for any damage sustained by the owner of the property. It is not apparent from Professor Thomson’s analysis, at least to me, that she would consider it to be morally wrong for an actor not to have the ability to pay for a life-saving drug. Indeed, with respect to obtaining consent to break the toothpick, she states: “We ask if we can, but you are feeling refractory and say ‘No.’ Can we not go ahead

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<sup>135</sup> To the number of deaths occurring in Country *L* due to the lack of access to the lifesaving patented drug should also be added the loss of life or debilitation resulting from the spread of the disease to other countries from the infected populace of *L*.

<sup>136</sup> Thomson, *supra* note 86, at 54.

<sup>137</sup> See *supra* text accompanying note 113.

<sup>138</sup> TRIPS, *supra* note 39, art. 31(b), (h).

<sup>139</sup> Thomson, *supra* note 86, at 49–50.

<sup>140</sup> See *Vincent v. Lake Erie Transp. Co.*, 124 N.W. 221, 222 (Minn. 1910).

and snap it in two . . . ?”<sup>141</sup> It seems quite clear that the toothpick is not for sale and that consent will not be given whether you can pay for the toothpick or not.<sup>142</sup> The law, of course, would impose a legal duty for the converting tortfeasor to pay for the drug. However, any privilege that an actor might have would not be conditioned on the ability of the actor to pay for any damage caused in exceeding the privilege. Again, the presumption is that the actor is acting reasonably in converting the drug to save a life and not to sell the drug for personal gain.

Also, there is the consideration of the non-rivalist nature of patent rights compared to the tangible drug. The owner of the patent did not suffer the loss of any tangible drugs, but only the infringement of its exclusive right to exclude others. In fact, Country *L* would have to expend resources in order to replicate Company *P*'s patented drug or to secure the drug from other sources, presumably by paying the source. In reality, the remuneration that Company *P* could expect is that which Country *L* can pay, if any at all. The risk of non-compensation, as always, must fall on the party who sustained the harm. If the injuring party is without resources, the injured bears the loss. But, again, this inability to pay on the part of Country *L* does not override its non-violating conduct in infringing the patent and does not transform such conduct into a wrongful violation of the patent owner's rights. Saving the lives of its nationals is a more stringent right overriding the failure to pay for the infringement and one that is morally justified.

Situation (*C*) can be extended to another not-unrealistic one:

- (*D*) Country *L* does not have the technical wherewithal to produce the patented drug. In addition, assume that while the patent owner has obtained patent protection in substantially every country in the world, including Country *L*, it failed to obtain a patent on the drug in Country *Z*. Company *Z*, domiciled in Country *Z*, is already producing the drug for domestic use and is willing to supply the drug to Country *L* at substantially lower prices than Company *P* charges.

As there is no patent on the drug in Country *Z*, there no infringement of the patent right or any violation of that right from a legal or moral sense in Country *Z*. Anyone may freely make, use, sell, offer for sale or import the drug, provided those infringing acts are limited to the territorial limits of Country *Z*.

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<sup>141</sup> Thomson, *supra* note 86, at 53.

<sup>142</sup> *Id.*

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Legally, of course, the drug may not be exported from Country Z into other countries where there is patent protection, including Country L.<sup>143</sup>

Situation (D) can be modified to situation (D'), where Company P has been granted a patent in Country Z, but Company Z has been granted a compulsory license in Country Z under Company P's patent to supply the domestic market of Country Z. As discussed above, according to the waiver provision of the 2003 Declaration, Company Z could be authorized to import the drug into Country L.<sup>144</sup> However, the problem remains that any such importation would be subject to adequate remuneration being paid to Company P by either Company Z or Country L.<sup>145</sup>

The question then becomes in situations (D) and (D') whether we can extend the moral justification for exploiting the patent in Country L to importation from Country Z. First, with respect to Country L: if it is morally justified by the immense loss of life anticipated in Country L by not providing the patented drug to its people, even if this entails infringement of the patent, the manner of infringement would not be seen to be of primary concern, i.e., whether the drug is made in Country L illegally or in Country Z legally. Second, does this justification, however, extend to the sale of the drug by Company Z in Country L, thereby infringing Company P's patent? It would seem to extend if Country Z is the only source of low-cost, life-saving drugs that Country L can afford. The immense loss of life in Country L would override the value Company P places on its patent. Country L can only afford to buy the low cost drugs from Country Z, and Company P is unwilling to sell at that price.

Another way of looking at situation (D) or (D') is by referring back to Thomson's situation (A) and adding the following to that situation:

(A'') Suppose the actors who open the box borrow a crowbar from another person who knows that it is going to be used to break open the box and obtain the needed drug.

Perhaps more analogous to the making of the drug in Country Z and its importation into Country L would be situation (A'''), where the actors hire and pay a locksmith to open the box.<sup>146</sup> It is not apparent that this would change

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<sup>143</sup> See TRIPS, *supra* note 39, art. 28(1) (obligating members to convert the exclusive right of importing into the patent-granting country to the patent owner in that country).

<sup>144</sup> See *supra* notes 62–72 and accompanying text.

<sup>145</sup> See Article 31bis, *supra* note 66, ¶ 2.

<sup>146</sup> Having a locksmith open the box presumably would not entail any damage to the box or at least less damage than using a crowbar.



the morality of breaking into the box and taking the drug. After all, the actors are “we” and hence should include aiders and abettors, such as the lender of the crowbar, and the locksmith who is being paid, as well as Company Z, who is being paid at least something for supplying the drug to Country L.

### C. *Returning to Remuneration*

Should the fact that the infringement in Country L is achieved by the importation of the drug by Company Z affect the analysis with respect to remuneration? According to situation (D), Country L can afford to pay for the imported drug only at the price charged by Company Z. If any additional cost (e.g., a reasonable royalty) is imposed on Company W in order to import the drug into Country L, this will increase the price of the drug beyond the ability of Country L to pay, and it will be denied access to the drug. In situation (D'), if Company W must pay the royalty awarded under the compulsory license, it will not be able to sell the drug to Country L at an affordable price. Again, the risk of non-compensation would fall on the patent owner. Company P could, of course, match Company Z's price and recoup at least some value for its patent.<sup>147</sup> Nonetheless, according to this analysis, there may be infringement of the

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<sup>147</sup> This strategy may not be a good one on a global basis, as it is likely other countries would demand most-favored nation treatment. Professor Dutfield offers the following rationale:

There is another possible reason why patent-holding companies are reluctant to drop drug prices in developing countries to marginal cost or just above it. Trebilcock and Howse suggest that drug companies have a "strategic desire . . . not to reveal, by such pricing, just how low their marginal costs actually were; this information could be used by large purchasers of medicines—governments or private health insurers—to bargain down the price of medicines in rich, developed countries. Hence, drug companies have been prepared in some instances to give away medicines to poor countries, rather than price them at marginal cost—and have presented this behaviour as 'charitable.'" Of course, giving away drugs to the poor is to be welcomed whether or not the motivations are altruistic!

Dutfield, *supra* note 77, at 114 (quoting MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 470 (3d ed. 2005)). Pharmaceutical companies have preferred a “low-volume, high [price]” strategy rather than a “high-volume, low [price]” one for a variety of reasons as indicated by Professors Abbott and Reichman:

There are different theories to account for this resistance. One is that because a patent monopoly gives control over prices, the lack of competition simply dulls any incentive to price-differentiate. A second theory is that the pharmaceutical companies fear a “reference pricing backlash,” which would occur if low prices in developing countries were used as benchmarks by price regulators in developed countries. A third theory is that selling needed medi-

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patent but no violation of the patent owner's rights, and Country *L* would be morally justified in proceeding in situations (*D*) and (*D'*).

### *D. Who Are "We?" and the Right Owner's Share*

Professor Thomson's primary concern in her article is to rebut Robert Nozick's assertion that a government's imposition of taxes for purposes of redistribution is a violation of the rights of its citizens.<sup>148</sup> Her conclusion in reference to the payment for breaking into the box and taking the drug in situation (*A*) is that the owner, while being entitled to be paid for the damage to his box and the loss of the drug, must also share in the loss resulting in the redistribution:

If I am right, it follows that we need not reimburse you for the entire cost of repairing or replacing the box and replacing the drug, but only such part of that cost as leaves you to pay the same amount as each of the rest of us. It is for this reason that I preferred not to speak of that payment as *compensation*: its point is not so much to compensate for a loss as to reduce that loss to the point at which it is no greater than ours.<sup>149</sup>

Hence, transforming this analysis to the *infringement* but not the *violation* of a patent on a drug that will save the lives of an *immense* number of people would require that the patent owner share in the loss for this infringement. The amount that the infringer has the ability to pay will reduce the patent owner's share somewhat. Nonetheless, in this view, the "we" includes the right holder who shares with the rest of us the moral responsibility for alleviating immense human suffering and death. Whether permitting the infringer to pay what it can meets the standard "to reduce that loss [of the patent owner] to the point at which it is no greater than ours"<sup>150</sup> is conjectural at best, but we are dealing with the immensity of a pandemic.<sup>151</sup>

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cines to the affluent at very high prices in developing countries is objectively more profitable than mass-marketing at low prices. A fourth theory is that pharmaceutical companies are concerned that parallel imported, favorably priced medicines would compete with higher priced offerings. A fifth theory is that all the above four theories play some part in resistance to price discrimination.

Abbott & Reichman, *supra* note 72, at 970–71 (footnotes omitted).

<sup>148</sup> Thomson, *supra* note 86, at 45.

<sup>149</sup> *Id.* at 60.

<sup>150</sup> *Id.*

<sup>151</sup> The CDC's published statistics provide perspective regarding this immensity:

## V. CONCLUSION

Intellectual property owners, as other property owners, expect that their property rights will not be infringed. The law provides redress for any infringement of property rights. In Hohfeldian terms, property owners have a *right* not to have their property infringed (e.g., trespassed or converted) and that the rest of us are under a correlative *duty* not to so infringe.<sup>152</sup> The legal consequences of infringement may be severe, including criminal sanctions and civil remedies. Private property may, of course, be appropriated by the state against the will of its owner in the public interest by eminent domain or similar powers. The governmental grant of compulsory licenses is the mechanism in patent law for achieving this end. The patent owners subject to such licenses often threaten private sanctions, including refusing to market certain products in the granting country, refusing to invest in the infrastructure of that country, and seeking international and domestic sanctions for such conduct.<sup>153</sup> Partisan industry groups

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Using the same methodology, CDC updated the estimates to include the time period from April 2009 through January 16, 2010 on February 12, 2010.

- CDC estimates that between 41 million and 84 million cases of 2009 H1N1 occurred between April 2009 and January 16, 2010. The mid-level in this range is about 57 million people infected with 2009 H1N1.
- CDC estimates that between about 183,000 and 378,000 H1N1-related hospitalizations occurred between April 2009 and January 16, 2010. The mid-level in this range is about 257,000 2009 H1N1-related hospitalizations.
- CDC estimates that between about 8,330 and 17,160 2009 H1N1-related deaths occurred between April 2009 and January 16, 2010. The mid-level in this range is about 11,690 2009 H1N1-related deaths.

*Updated CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009–April 10, 2010*, CENTERS FOR DISEASE CONTROL AND PREVENTION (May 14, 2010, 10:30 AM), [http://www.cdc.gov/h1n1flu/estimates\\_2009\\_h1n1.htm](http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm) (last visited Oct. 11, 2010); see also *Situation Updates – Pandemic (H1N1) 2009*, WORLD HEALTH ORGANIZATION, <http://www.who.int/csr/disease/swineflu/updates/en/> (last visited Oct. 11, 2010) (providing weekly updates on the pandemic on an international basis from April 2009 to date).

<sup>152</sup> See *supra* text accompanying note 103103.

<sup>153</sup> See Donald G. McNeil, Jr., *Medicine Merchants: Patent and Patients; As Devastating Epidemics Increase, Nations Take On Drug Companies*, N.Y. TIMES, July 9, 2000, § 1:

In 1997, when South Africa tried to pass a law allowing the health minister to ignore the Patents Act in health crises, the United States lobbied hard against it. President Clinton raised the issue with President Nelson Mandela, the Commerce Department put South Africa on a watch list that is the first

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have been known to use harsh epithets, including “theft,” against developing countries that would deign to grant or threaten to grant compulsory licenses.<sup>154</sup>

While the law may require sanctions or remedies, at least in the form of compensation for the infringement or for a public taking under a compulsory license, it does not automatically follow that all infringements are immoral. Most of us would not morally condemn those who would take the medicine out of the owner’s excess, even without the owner’s consent, to save a child’s life (and even more if many could be saved). Nonetheless, most of us would expect that the law would require that the owner be compensated for what most people would consider reasonable, and to many, necessary, conduct of taking the medicine. The same legal and moral analyses and conclusions should apply *a fortiori* to the infringement of patents covering essential medicines when the infringement constitutes reasonable conduct to permit the treatment of individuals who otherwise may die or suffer serious consequences. However, the morality of the infringement should not be determined by the ability to compensate patent owners. The inability of the infringer to pay adequate remuneration should not convert moral conduct into immoral conduct.

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step toward trade sanctions, and a bill went through Congress making all American aid to South Africa contingent on dropping the law.

The South African pharmaceutical industry, which included subsidiaries of American and European companies, took the pressure much further. It closed factories, canceled investments and took out scare ads suggesting that babies could be hurt by counterfeit generic drugs. Its chief lobbyist, Mirryena Deeb, threatened to cut off all new drug discoveries to South Africa if the law passed, including AIDS drugs, cancer drugs and antibiotics. Asked in a March 1998 interview if she was literally threatening to let thousands of South Africans die, she reluctantly conceded: “In so many words, yes.”

See also Jonathan Head, *Thailand Takes on Drug Giants*, BBC NEWS, <http://news.bbc.co.uk/2/hi/asia-pacific/6587379.stm> (last updated Apr. 26, 2007):

The drug companies have always assumed that the Trips exception would only be used for a dire emergency, like HIV/Aids or avian flu.

Issuing a compulsory licence for a heart drug, they say, breaks the spirit of the agreement.

Abbott has now withdrawn all its future products from the Thai market—including a new heat-resistant form of Kaletra which is desperately needed by HIV patients.

<sup>154</sup> With respect to Brazil’s plan to grant compulsory licenses, see Katherine Griffiths, *Abbott Set to Strike Deal with Brazil to Cut Cost of Aids Drug*, INDEPENDENT (U.K.), July 9, 2005, (Business), at 61 (“The process was condemned this week by the international trade body which represents drugs companies. The Geneva-based International Federation of Pharmaceutical Manufacturers described Brazil’s campaign as ‘theft.’”).

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Thus, those countries that grant compulsory licenses in order to supply essential medicines to their own nationals or to the nationals of other countries without the ability to produce the needed medicines should not be condemned morally, according to the rationale presented above, even if adequate remuneration is not provided to the patent owner as required by TRIPS. Certainly, with the ambiguity of what constitutes adequate remuneration in most circumstances, it would seem that awarding remuneration on a reasoned basis by applying guidelines based on the ability to pay would satisfy the legal requirements of TRIPS. Under these circumstances, the grant of the compulsory license is not only moral, but legal. However, even if the remuneration was found by a WTO panel not to be adequate, this inadequacy should not be condemned as immoral if the underlying purpose of the grant of the compulsory license was justified.