

# TRIPS ARTICLE 31BIS AND H1N1 SWINE FLU: ANY EMERGENCY OR URGENCY EXCEPTION TO PATENT PROTECTION?

Dawn Dziuba

## SUMMARY

This Article examines the application of the emergency exception to patent protection as embodied in TRIPS Article 31, along with the recent Article 31bis amendment. This Article also explores economic and policy concerns surrounding the application of the emergency exception using HIV/AIDS and bird flu as examples. Finally, this Article examines the potential application of the emergency exemption in the case of the swine flu/H1N1 virus.

## I. BACKGROUND OF TRIPS AND OF THE ARTICLE 31BIS AMENDMENT

This section discusses the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) Article 31, along with the World Trade Organization (“WTO”) decision that led up to the amendment 31bis. The WTO is an international organization that deals with rules of commerce and trade between nations.<sup>1</sup> The WTO administers the TRIPS agreement, which regulates intellectual property rights among its members.<sup>2</sup> This Agreement is important because the interpretation of relevant law governing patents may impact the manufacture, distribution and spread of medication in times of crisis. This section focuses on the section of TRIPS that would apply in times of national emergency.

### A. ARTICLE 31

Article 31(b) provides an exception to the general prohibition against the use of patentable subject matter without authorization of the rights holder. This “other use” exception applies only in certain circumstances.<sup>3</sup> Specifically,

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1. See World Trade Organization homepage, [http://www.wto.org/english/thewto\\_e/whatis\\_e/whatis\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm) (last visited Dec. 22, 2010).  
2. See Agreement on Trade Related Aspects of Intellectual Property Rights, available at <http://www.worldtradelaw.net/uragreements/tripsagreement.pdf> (last visited Dec. 22, 2010).  
3. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(b),

Article 31(b) provides that:

[S]uch 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 . . . .<sup>4</sup>

Thus, the “other use” exception can only be applied in circumstances of “national emergency or “extreme emergency.” The language of TRIPS is ambiguous in that it does not provide a definition of “national emergency” or “extreme urgency”<sup>5</sup> and gives no other guidance for what circumstances would qualify as such. But this language was intentionally left vague, and has produced substantial discussion regarding the scope of these terms.<sup>6</sup> It is arguable whether these terms include HIV or AIDS, the bird flu, chronic conditions, or others medical scenarios.

Even after the Doha Declaration,<sup>7</sup> scholars are undecided as to whether the TRIPS ambiguities have been resolved.<sup>8</sup> Specifically, the argument is that the Declaration fell short of defining the language with any certainty and granted power to individual WTO members to define for themselves what constitutes a national emergency.<sup>9</sup> According to Jennifer Bjornberg:

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Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf) [hereinafter TRIPS Agreement].

4. *Id.* (emphasis added).

5. *Id.*

6. Angela G. Thornton-Millard, *Intellectual Property Rights and the AIDS Epidemic in Sub-Saharan Africa*, 11 *TRANSNAT'L L. & CONTEMP. PROBS.* 517, 532 (2001).

7. The Doha Declaration provides for circumstances where governments may issue compulsory licenses on otherwise patented medications when deemed necessary to protect the public health. See <http://www.worldtradelaw.net/doha/tripshealth.pdf> (last visited Dec. 22, 2010).

8. Jennifer Bjornberg, *Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?*, 27 *Nw. J. INT'L L. & BUS.* 199, 214 (2006).

9. *Id.*

It is not clear, for example, that the WTO requires that Brazil be steeped in disease before declaring the compulsory licensing a necessity. The licensing of a medication against the will of the patent holder may be a necessary means of averting such disaster. It is unclear, however, how well an argument such as this would hold without some clear declaration from the WTO. As the Doha Declaration shows, the WTO has been hesitant to provide a concrete definition of “national emergency” on which an outcome could be easily predicted.<sup>10</sup>

However, the lack of a definition may be necessary to give individual nation states the ability to respond rapidly to conditions that constitute a “national emergency” or “extreme urgency” relative to the circumstances that formulate the “norm” for that particular country.

#### B. WAIVER

In the event of national emergency or a circumstance of extreme urgency, Article 31(b) waives the need to obtain authorization from the right holder of a patented product to use that product.<sup>11</sup> The waiver concept is important because it means that patent rights will go unprotected if such conditions exist. In the case of a national emergency or circumstances of extreme urgency, companies may not be required to negotiate for use prior to the grant of a compulsory license.

#### C. DOMESTIC USE REQUIREMENT, WTO DECISIONS, AND THE AMENDMENT

Section (f) of Article 31 imposes a domestic use requirement on any country that invokes the compulsory use exception. It reads: “[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use . . . .”<sup>12</sup> Professor George Tsai suggests that this means the compulsory use of the patented product has to be “predominantly for the supply of the domestic market of the Member authorizing such use . . . .”<sup>13</sup> He argues that the “domestic use” requirement creates a barrier for poor and less developed countries, and the “barrier comes from the fact that these nations simply do not have, and often are not capable of obtaining, the technological means to engineer and produce generic drugs.”<sup>14</sup> Tsai lists the obstacles to local production as “a lack of skilled labor, a weak financial sector, the

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10. *Id.* at 218 (emphasis added).

11. *See* TRIPS Agreement, *supra* note 3, art. 31(b).

12. *Id.* at 31(f).

13. *See* George Tsai, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes Under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063, 1072 (2009).

14. *Id.*

diminished flow of foreign investment, the questionable quality of product, the lack of an efficient system for storing and transporting drugs, and the lack of an enforceable regime of drug legislation.”<sup>15</sup>

As a result of these challenges, the WTO modified Article 31(f)'s domestic use requirement and recognized that “exceptional circumstances exist justifying waivers” of the domestic use requirement for pharmaceutical products.<sup>16</sup> On December 6, 2005, the WTO council set forth the considerations underlying its decision.<sup>17</sup> In particular, the Council noted the need “to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement . . . .”<sup>18</sup> The Council placed particular consideration on “the importance of a rapid response to those needs . . . .”<sup>19</sup> After the WTO's decision, the TRIPS council permanently amended “the TRIPS agreement to incorporate the system of compulsory licensing proposed” in the August 30, 2003 decision.<sup>20</sup> These decisions reflected the need to implement paragraph 6 of the Doha Declaration, which states, “[W]e recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”<sup>21</sup>

The decision to approve the amendment to the TRIPS agreement containing Article 31bis was made on December 6, 2005.<sup>22</sup> Members of the council were initially given until December 1, 2007 to ratify the amendment, but this deadline has been extended until December 31, 2011.<sup>23</sup>

#### D. ARTICLE 31BIS

Article 31bis provides an exception to certain requirements under Article

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15. *Id.* at 1073.

16. *See* TRIPS Agreement, *supra* note 3, art. 31(b).

17. *See* Decision by General Council for TRIPS, Amendment of the TRIPS Agreement, WT/L/641 (Dec. 6, 2005), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm) (last visited Dec 22, 2010) [hereinafter Amendment].

18. *Id.*

19. *Id.*

20. *See* Tsai, *supra* note 13, at 1073.

21. *Id.*

22. *See* Press Release, World Trade Organization, Members OK Amendment to make Health Flexibility Permanent WTO Doc. PRESS/426 (Dec. 6, 2005), available at [http://www.wto.org/english/news\\_e/pres05\\_e/pr426\\_e.htm](http://www.wto.org/english/news_e/pres05_e/pr426_e.htm).

23. World Trade Organization, Members Accepting Amendments of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last visited Apr. 27, 2010). Countries that have accepted the amendment include: the United States, Switzerland, El Salvador, Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, European Communities, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, Albania, Macau, China, Canada, Columbia, Zambia, Nicaragua, Pakistan, and the Former Yugoslav Republic of Macedonia. *Id.*

31(f) with respect to the grant of a compulsory license, along with the exportation of a pharmaceutical product to an eligible importing member.

Article 31(f) provides “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use[.]”<sup>24</sup> The first paragraph of Article 31bis creates an exception to this requirement, and the second paragraph of Article 31bis sets forth the details of the exception as follows:

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory [license] 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.

2. Where a compulsory [license] 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 [license] 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 products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.<sup>25</sup>

## II. INTERPRETING AND APPLYING TRIPS

### A. INTENTION OF DRAFTERS

Scholars differ over the intention and purpose of the TRIPs agreement. For example, Professor Aditi Diya Nag writes, “TRIPS attempts to achieve a fair balance between protection of IP rights and social and economic welfare. Therefore, the national emergency exception is not a mere loophole, but an opportunity for the right holder to act with concern for his global surroundings.”<sup>26</sup> According to George Tsai, although the language of the TRIPS agreement “is undoubtedly open ended, the humanitarian motivation of

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24. See TRIPS Agreement, *supra* note 3, art. 31(b).

25. See Amendment, *supra* note 17.

26. See Aditi Diya Nag, *The Bird Flu and the Invoking of TRIPS Article 31 “National Emergency” Exception*, 34 SYRACUSE J. INT’L L. & COM. 689, 712-13 (2007).

the drafters is clear: the benefits from technological innovation cannot accrue only to the makers of that technology, and consequently, the agreement must protect both manufacturer rights and user rights in a manner conducive to social welfare.”<sup>27</sup>

However, Professor Robert Shapiro has pointed out that “TRIPS was drafted after extensive lobbying by international pharmaceutical manufacturers and reflects many values [favorable] to large multi-national corporations.”<sup>28</sup> Shapiro further describes the ying and yang embodied in the TRIPS agreement:

TRIPS is based on a private property model that exhibits two rationales in tension with each other. The first rationale focuses on the property owner, as it is an individual’s prerogative to do with one’s property as one pleases. The underlying rationale of property rights is that property holders should have the freedom to engage in maximally free contracts. In addition, property rights ensure a return on investment. This approach provides an incentive to produce property and as a result, inventors will continue to produce. Thus, there is very little room for government interference.

The second rationale examines the public policy perspective in which property rights can be legitimately encumbered with public regulation to strike a balance between the interests of producers and consumers of intellectual property rights. The public policy alternative is embedded in the provision of TRIPS. There is much discretion afforded in the exceptions that TRIPS allows; for example, it is unclear whether a country must declare a national health emergency to invoke compulsory licensing.<sup>29</sup>

The debate over the different underlying intentions is important in the interpretation of TRIPS provisions, particularly when key terms are left undefined. As discussed, the lack of clearly defined terms gives wide latitude, and arguably, autonomy, to individual countries determining whether Article 31 applies to them.

#### *B. EMERGENCY USE EXCEPTION QUESTIONS*

The emergency use exception might have a negative impact on incentives

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27. See Tsai, *supra* note 13, at 1071.

28. See Robert Shapiro, *Patent Infringement During a Time of National Emergency: Are Canadian, American and Mexican Governments Permitted to do so Under Their Domestic Law, NAFTA and TRIPS; If so at what Cost?*, 18 WINDSOR REV. LEGAL & SOC. ISSUES 37, 50 (2004).

29. *Id.* at 50-51.

for patent development and creation. For example, the public health exception “may ultimately serve as a chilling disincentive for research and development of new drugs in the developed countries, which in the long term has the potential of indiscriminately disadvantaging all the peoples of the world.”<sup>30</sup> Professor Nag argues that, “[T]here is often a misconception that protection under TRIPS is a burden on the developing world and hence undesirable, if not unfair.” He then points out that “The contrary can often be true.”<sup>31</sup>

However, there are reasons why developing countries would find TRIPS desirable for the public health interest. Nadine Farid writes:

Combating public health crises is a critical component of improving a state’s stability and enabling its growth. These characteristics will better permit a state to operate a functional intellectual property system that properly rewards incentives and allows for legitimate trade, as mandated and structured by TRIPS. Obtaining access to patented pharmaceuticals is necessary to effectively combat public health crises. In turn, managing public health crises with the use of patented pharmaceuticals will only be possible if those pharmaceuticals are made affordable. Thus, in order for TRIPS to be implemented effectively and its goals achieved, there must be a system in place by which developing countries can access affordable pharmaceuticals and stem the public health issues that impede economic development.<sup>32</sup>

Similarly, Arnaldo Locavo argues that just like their responses to threats of terrorism, “Governments will act to respond to actual and potential national emergencies even to the point of ignoring the much valued rights of intellectual property holders.”<sup>33</sup> This is consistent with Shapiro’s perspective that “A nation’s survival should trump intellectual property rights . . . [and that t]he international community should come to the aid of developing nations who are struggling with an epidemic in an effort to help supply those citizens with the required drugs.”<sup>34</sup>

In contrast, Noah Lars, professor of law at University of Florida, cautions against the negative effect of compulsory licenses:

Imagine that the government prohibited drug manufacturers

30. See Arnaldo Lacayo, *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 297 (2002).

31. See Nag, *supra* note 26, at 696.

32. See Nadine Farid, *Reconsidering the TRIPS-Based Non-Violation Complaint 2* (2009) (unpublished article, on file with author), available at <http://works.bepress.com/nadinefarid/3/>.

33. See Lacayo, *supra* note 30, at 318.

34. Shapiro, *supra* note 28, at 57.

from generating any profit on sales of vaccines and other critical pharmaceuticals, allowing them to recoup only their expenses for raw materials and counting on their corporate public-spiritedness to continue supplying the market. Although members of the pharmaceutical industry participate in a variety of charitable activities, altruism alone will not maintain product lines that generate little or no profit.<sup>35</sup>

Thus, the tension between public health and the rights of patent holders affects the discussion of the national emergency exception to TRIPS protection. The case examples below further illustrate this point.

### III. CASE EXAMPLES

This section explores the cases of HIV/AIDS and bird flu in relation to the emergency exception of TRIPS.

#### A. HIV/AIDS

##### 1. SCOPE OF THE EPIDEMIC

Johanna Kiehl has argued that Article 31(b)'s waiver provision could be interpreted in a manner as to not encompass a public health emergency like the HIV/AIDS epidemic.<sup>36</sup> In her 2002 analysis, Kiehl projected that the number of HIV infections in Asia and the Pacific region could exceed those in Africa by 2010.<sup>37</sup> In comparison, the Joint United Nations Program on HIV/AIDS reported that in 2006 there were an estimated 700,000 people living with HIV in China<sup>38</sup> while there were 5.5 million people living with HIV in South Africa.<sup>39</sup>

Additionally, HIV/AIDs can have economic consequences. According to

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35. Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 753 (2003).

36. See Johanna Kiehl, *TRIPS Article 31(B) and the HIV/AIDS Epidemic*, 10 J. INTELL. PROP. L. 143, 144 (2002).

37. *Id.*

38. Joint United Nations Programme on HIV/AIDS [UNAIDS] & World Health Organization [WHO], *Asia: AIDS Epidemic Update Regional Summary*, UNAIDS/08.09E/JC1527E (Mar. 2008), available at [http://data.unaids.org/pub/Report/2008/jc1527\\_epibriefs\\_asia\\_en.pdf](http://data.unaids.org/pub/Report/2008/jc1527_epibriefs_asia_en.pdf).

39. Joint United Nations Programme on HIV/AIDS [UNAIDS] & World Health Organization [WHO], *Sub-Saharan Africa: AIDS Epidemic Update Regional Summary*, UNAIDS/08.08E/JC1526E (Mar. 2008), available at [http://data.unaids.org/pub/Report/2008/JC1526\\_epibriefs\\_subsaharanafrika\\_en.pdf](http://data.unaids.org/pub/Report/2008/JC1526_epibriefs_subsaharanafrika_en.pdf). See generally Joint United Nations Programme on HIV/AIDS [UNAIDS], *2007 AIDS Epidemic Update*, <http://www.unaids.org/en/KnowledgeCentre/HIVData/EpiUpdate/EpiUpdArchive/2007/default.asp>.



Keihl, “AIDS-related costs to African firms may include absenteeism, productivity declines, health and insurance payments, and recruitment and training.”<sup>40</sup> Shapiro argues that “The reason for the large gap between those infected and those being treated is due to the high cost of drugs.”<sup>41</sup> Companies are concerned that they might not be able to capture value on research and development costs if their exclusive ownership is threatened.<sup>42</sup> The “cocktails of drugs” usually given to HIV patients can run thousands of dollars.<sup>43</sup> In her assessment, Keihl also looked at the potential for political instability as a consequence of the conditions created by the AIDS epidemic.<sup>44</sup>

## 2. APPLICATION OF ARTICLE 31 TO HIV/AIDS

According to Keihl, the potential of an unfavorable ruling by the WTO is a factor in deciding whether to bring a compulsory licensing action.<sup>45</sup> Keihl argues that “[e]ven if a WTO panel believes [that] a human right to health exists and should be considered in the balance, many people believe strong intellectual property protection accomplishes public health objectives.”<sup>46</sup>

When interpreting TRIPS, especially the application/construction of Article 31(b), countries have a questionable amount of room to balance intellectual property protection with other potential policy objectives.<sup>47</sup> In analyzing the application, Keihl writes:

According to the plain terms of Article 8.1, public health measures adopted by Members must be “consistent with the provisions of this Agreement” (such as TRIPS Article 27.1 . . . ) and “necessary” to protect public health. A panel will find that TRIPS Article 31(b) public health emergency legislation is not consistent with TRIPS Article 27.1, that it is not “necessary” under Article 8.1, and that when the other terms of Article 31 are applied in the HIV/AIDS context, it upsets the basic balance of the Agreement.<sup>48</sup>

Keihl points out that a challenge might be a discrimination problem under Article 27.1, and she questions whether the scope of the legislation is limited to certain pharmaceuticals.<sup>49</sup> This could depend on the legal scope of the

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40. Keihl, *supra* note 36, at 145.

41. Shapiro, *supra* note 28, at 56.

42. See Keihl, *supra* note 36, at 170.

43. Shapiro, *supra* note 28, at 56.

44. See Keihl, *supra* note 36, at 146.

45. *Id.* at 154.

46. *Id.* at 159.

47. *Id.* at 163.

48. *Id.* at 165.

49. *Id.* at 166.

legislation that attempts to utilize the exception.<sup>50</sup>

### B. BIRD FLU POTENTIAL

Some scholars argue that the bird flu crisis could trigger the emergency exception to Article 31 and 31bis, and they discuss the potential application of Article 31bis in situations of national emergency or extreme urgency.<sup>51</sup> The bird flu crisis case is particularly relevant because of its similarity to the swine flu crisis.<sup>52</sup>

Bird flu (a.k.a. avian influenza H5N1 flu virus) is typically transmitted amongst wild birds, but the virus can also be transmitted from birds to humans.<sup>53</sup> According to the Centers for Disease Control and Prevention (CDC), more than a dozen countries have reported approximately 400 cases of human infection with highly pathogenic avian influenza A (H5N1) viruses globally.<sup>54</sup> However, the CDC reports that any human-to-human transmission of H5N1 bird flu "has been limited, inefficient and unsustainable."<sup>55</sup>

Roche Laboratories, Inc., the manufacturer of the bird flu vaccine Tamiflu,<sup>56</sup> came under international pressure and ended up donating three million doses of the vaccine to the World Health Organization (WHO) free of charge.<sup>57</sup> However, some countries, like India, have questioned whether this supply would be adequate to meet worldwide needs.<sup>58</sup> The Indian government encouraged one of its domestic pharmaceutical companies, Cipla, to manufacture a generic version of the Tamiflu vaccine.<sup>59</sup> Cipla anticipated that it could manufacture the generic version of the vaccine at a much lower price

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50. See Kiehl, *supra* note 36, at 166.

51. See Nag, *supra* note 26, at 691.

52. There are some important similarities and differences between the swine flu and the bird flu. The signs and symptoms of the swine flu are somewhat similar to the bird flu and seasonal flu strains; however, swine flu is more likely to result in death of humans infected with the virus. The similarities between the swine flu virus and the avian flu virus occur because of how the swine flu virus developed from mutations of previous viruses including strains of human influenza, avian flu, and pig flu. See University of Maryland (2009, April 30). Swine Flu Outbreak Illuminated By Avian Flu Research, <http://www.sciencedaily.com/releases/2009/04/090429132238.htm> (last visited Dec. 29, 2010).

53. See Center for Disease Control and Prevention, Key Facts About Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus, <http://www.cdc.gov/flu/avian/gen-info/facts.htm> (last visited Mar. 28, 2010) [hereinafter Key Facts].

54. See Center for Disease Control and Prevention, Avian Influenza A Virus Infections of Humans (2008), <http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm> (last visited Mar. 28, 2010).

55. See Key Facts, *supra* note 53.

56. See Jean-François Tremblay, *Roche may Grant Tamiflu Licenses: Cipla Intends Mass Production of Antiviral to Supply India and Other Countries*, 83 CHEMICAL & ENGINEERING NEWS 43, at 17 (2005), available at <http://pubs.acs.org/cen/news/83/i43/8343notw8.html>.

57. See Nag, *supra* note 26, at 699.

58. *Id.*

59. See Tremblay, *supra* note 56.

than what Roche was selling Tamiflu for at retail.<sup>60</sup> Additionally, Cipla wanted to sell its generic product at a much cheaper price than Roche's Tamiflu, particularly in countries that did not recognize Roche's patent on the brand product.<sup>61</sup> In a likely attempt to maintain control over the market, Roche was later accused of licensing additional doses of the vaccine to a small group of manufacturers, the entire list of which is kept a secret.<sup>62</sup>

However, Cipla's manufacture of a generic Tamiflu can be justified through the use of the Article 31bis's national emergency exception if the bird flu was considered a matter of national emergency or extreme urgency.<sup>63</sup> As discussed, the bird flu did not reach the point of being transmitted from human-to-human and was not classified as a full pandemic. Cost of the treatment itself may not "have a place in the legal consideration of arguing for patent rights violations."<sup>64</sup> However, the expectations and standards set by the international community are influential. Nag also addresses criticisms that compulsory licensing harms the patent holder:

Compulsory licenses . . . are not a weapon against a patent holder (such as Roche) just because it refused to grant a voluntary patent license to a third party (Cipla). This would in fact destroy the quintessential nature of the patent – the patent holder's right to say no to forced sharing. The international community recognizes, however, that TRIPS gives countries a process by which to address their concerns and disputes, especially in cases of extreme circumstances or urgency, where it can be argued that certain other considerations (of greater public well-being) would prevail over those of patent protection.<sup>65</sup>

### C. ANTHRAX & BIOTERRORIST THREATS

An Anthrax threat is a useful case scenario in which to analyze Article 31's effect on combating bioterrorism. In 2001, several prominent U.S. citizens were sent a form of anthrax (*Bacillus anthracis*) through the mail.<sup>66</sup> Bayer makes Ciproflaxin (also known generically as Cipro), which can treat the inhalation anthrax.<sup>67</sup> Allegedly, the U.S. government initially bought enough Cipro to treat important government officials, but not enough for the mass U.S.

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60. *Id.*

61. *Id.*

62. *See* Nag, *supra* note 26, at 699.

63. *Id.* at 703.

64. *Id.* at 704.

65. *Id.* at 706.

66. *See* Shapiro, *supra* note 28, at 39.

67. *Id.*

populace.<sup>68</sup> Bayer initially saw this as an opportunity to make a profit by getting companies to agree not to manufacture the drug and allowing the lack of competition to drive up the price of Cipro.<sup>69</sup> Shapiro estimates that if these manufacturers could have sold a generic version, the cost of Cipro would have been cut in half.<sup>70</sup> The possibility of patent infringement became an issue as the U.S. government contemplated infringing Bayer's patent. Ultimately, the U.S. government was able to negotiate with Bayer to purchase Cipro at a reduced cost in order to moot the potential infringement.<sup>71</sup>

#### IV. SWINE FLU?

##### A. HYPOTHETICAL: SWINE FLU CRISIS

Imagine the following scenario. The outbreak of the swine flu suddenly skyrockets and researchers and experts are unable to determine why. Amidst the confusion, company XYZ stumbles upon a vaccine that may fight off the virus. Does this scenario trigger the exception of Article 31 and 31bis? It is important to remember that Article 31 is a defense to patent infringement. Simply put, the question is whether the prerequisite conditions exist for the exception's application.

##### B. SCOPE OF PANDEMIC

Although TRIPS Article 31 could potentially apply to the swine flu crisis, it is unclear whether such a crisis would satisfy the extreme urgency or national emergency requirements. However, comparing the disease's scope and magnitude to the previously discussed HIV/AIDS, bird flu, and Anthrax examples gives some indication as to Article 31's application to swine flu.

In March 2009, swine flu was detected among humans for the first time.<sup>72</sup> In human infections, swine flu typically takes the form of a respiratory infection.<sup>73</sup> This infection exploits the immune system and leads to possibility of secondary infections, major organ dysfunction, and even death.<sup>74</sup>

However, even with the severity of these symptoms, it is unclear whether swine flu could qualify as a pandemic. The World Health Organization's (WHO) definition of pandemic contains three elements: (1) "a new influenza virus subtype emerges;" (2) "it infects humans, causing serious illness;" and (3)

68. *Id.*

69. *Id.* at 40.

70. *Id.*

71. *Id.* at 41.

72. *Swine Flu: FAQ*, CBC News, July 21, 2009, <http://www.cbc.ca/health/story/2009/04/24/f-swineflu-faq.html> [hereinafter *Swine Flu: FAQ*].

73. *Id.*

74. *Id.*

“it spreads easily and sustainably among humans.”<sup>75</sup> Using these elements, the WHO classified swine flu, or the H1N1 influenza, as a pandemic, which was the first time that WHO has issued a global flu “epidemic” in more than forty years.<sup>76</sup> The last pandemic was the Hong Kong flu which killed more than one million people in 1968.<sup>77</sup>

This classification places swine flu at Level 6, the WHO’s highest alert level, and means that the H1N1 swine flu virus can spread from person to person in a sustained manner of transmission in two or more regions on the globe.<sup>78</sup> CBC News reported that, “The pandemic declaration sends a signal to governments to spend more on containing the virus and to drugmakers to speed up the development of a swine flu vaccine. However, it does not mean the virus is causing more severe illnesses or deaths.”<sup>79</sup>

Initial estimates may have been too conservative. One such estimate indicated that as of June 2009 there had been more than 27,737 cases of swine flu, including 141 deaths.<sup>80</sup> However, as of July 31, 2009, the WHO had documented an estimated 162,000 cases of the swine flu throughout the world, including more than 1,154 deaths.<sup>81</sup> Additionally, it has become clear that generally younger, otherwise healthy people are more susceptible to the swine flu virus.<sup>82</sup>

Difficulties in estimating exact numbers stem from the fact that instances of the swine flu may be underreported. Specifically, not everyone who is infected seeks medical attention and those that do may not even be tested for the swine flu.<sup>83</sup> In 2009, the Centers for Disease Control and Prevention (CDC) acknowledged that it may be impossible to verify the exact numbers of H1N1 swine flu cases.<sup>84</sup> As of November 12, 2009, the CDC estimated that:

[B]etween 43 million and 89 million cases of 2009 H1N1 occurred between April 2009 and April 10, 2010. The mid-level in this range is about 61 million people infected with

75. See Nag, *supra* note 26, at 698.

76. See *WHO Declares Swine Flu Pandemic, no Change in Canada’s Approach*, CBC NEWS, June 11, 2009, <http://www.cbc.ca/world/story/2009/06/11/swine-flu-virus-who-pandemic.html>.

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. *Swine Flu Cases Climb Among U.S. Soldiers in Iraq*, ASSOCIATED PRESS, Aug. 12, 2009, available at [http://www.msnbc.msn.com/id/32386260/ns/health-cold\\_and\\_flu/ns/health-swine\\_flu/](http://www.msnbc.msn.com/id/32386260/ns/health-cold_and_flu/ns/health-swine_flu/).

82. *Tracking Swine Flu may Become Easier*, CBC NEWS, July 31, 2009, <http://www.cbc.ca/health/story/2009/07/31/swine-flu-who.html>.

83. Centers for Disease Control and Prevention, *CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April 2009 – March 13, 2010*, [http://www.cdc.gov/h1n1flu/estimates\\_2009\\_h1n1.htm](http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm) (last visited Dec. 22, 2010).

84. *Id.*

2009 H1N1. CDC estimates that between about 195,000 and 403,000 H1N1-related hospitalizations occurred between April 2009 and April 10, 2010. The mid-level in this range is about 274,000 2009 H1N1-related hospitalizations. CDC estimates that there were between about 8,870 and 18,300 2009 H1N1-related deaths that occurred between April 2009 and April 10, 2010. The mid-level in this range is about 12,470 2009 H1N1-related deaths.<sup>85</sup>

It is clear that swine flu can have a significant economic impact. In April and May of 2009, many major airlines waived fees or refunded tickets for passengers who had initially been destined for Mexico.<sup>86</sup> Additionally, some hotels reported taking extra precautions in the disinfection and cleaning of rooms, while others allowed cancellations altogether.<sup>87</sup> Furthermore, costs associated with purchasing pandemic-related insurance policies have a direct effect on other areas of the economy.<sup>88</sup>

Swine flu's impact on the function of local businesses can also have a direct impact on the economy. For example, businesses could experience losses if forced to close or if the access to the physical location of the business is limited.<sup>89</sup> Several employment law newsletters across the states have addressed the concern about how businesses can protect employees from swine flu while simultaneously maintaining normal operating levels and limiting detriments to productivity.<sup>90</sup> Further, swine producers reported that they suffered financial losses due to misconceptions about how the swine flu disease is spread.<sup>91</sup>

### C. TREATMENT AND LIMITATIONS

Several possible vaccines for H1N1 swine flu are going through the testing and development process, including two prescription anti-viral drugs, oseltamivir (Tamiflu) and zanamivir (Relenza).<sup>92</sup> However, these drugs have limited application, and they can only be used to treat relatively severe cases.<sup>93</sup>

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85. *Id.* See generally *id.* for a discussion on influenza-associated hospitalizations collected through the CDC.

86. Deirdre Van Dyk, *Has Swine Flu Infected Your Travel Plans?*, TIME, May 4, 2009, <http://www.time.com/time/travel/article/0,31542,1895467,00.html>.

87. *Id.*

88. *Id.*

89. See generally James Davis, Richard Lewis & Noel Paul, *The Limits of Insurance Coverage to Compensate Victims of a Swine Flu Pandemic*, LexisNexis Communities 2009 Emerging Issues 3572 (Apr. 30, 2009).

90. *Id.*

91. Brian Brus, *Pigs Getting Bum Rap due to Name of Flu Virus Strain*, THE J. REC. (May 4, 2009), available at <http://journalrecord.com/2009/05/04/pigs-getting-bum-rap-due-to-name-of-virus/>.

92. See *Swine Flu: FAQ*, *supra* note 72.

93. *Id.*

The question of who would receive any vaccines available for the swine flu virus is complicated. In the United States, the Advisory Committee on Immunization Practices, a body that counsels the federal government on vaccine matters, recommends that 160 million people in so-called “high risk” groups should be vaccinated as a preventive measure.<sup>94</sup> High risk groups include people who come into contact with young infants, health care and emergency medical service workers, pregnant women, youth under age twenty-four, and those age twenty-four through sixty-five with specific underlying medical conditions.<sup>95</sup>

In addition to these priorities, distribution of available vaccines would be limited by special considerations. For example, some researchers have advised pregnant women not to be vaccinated because of concerns of thimerosal, a preservative in the vaccine that contains mercury, a substance with links to autism.<sup>96</sup> Additionally, with respect to the antiviral drugs Tamiflu and Relenza, manufactured by Roche Holdings AG and GlaxoSmithKline PLC, the British Medical Journal reported that researchers have advised that children under twelve should not take these drugs because the drugs may do them more harm than good.<sup>97</sup> Finally, there is a narrower list for receiving the vaccine should supplies be tight, which could be narrowed down to around 60 million people.<sup>98</sup>

#### D. IMPLICATIONS

As discussed previously, the WHO has declared swine flu to be a pandemic. The WHO’s position strongly supports an argument for invoking the national emergency exception. The impact of swine flu has exceeded that of the bird flu or avian influenza. The fact that swine flu can be readily and reliably transmitted from human to human increases the sense of urgency for some type of measure to become available. It is clear that this is an “extreme urgency.”

Because there are also limitations on the availability of a swine flu vaccination, limited supply and a potentially high demand may mean that there is an increased likelihood that the Article 31 exemption could be invoked by a country extreme urgency or national emergency. For example, U.S. President Barack Obama declared that the 2009 H1N1 swine flu was a national emergency on October 24, 2009.<sup>99</sup> Because the members of the WTO are

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94. *Id.*

95. Betsy McKay, *Pregnant Women, Kids to get Vaccine First*, WALL ST. J. (July 30, 2009), at A3, available at <http://online.wsj.com/article/SB124887563173290207.html>.

96. *Id.*

97. *Flu Drug use Discouraged*, WALL ST. J. (Aug. 10, 2009), available at <http://online.wsj.com/article/SB10001424052970203612504574342680430728144.html>.

98. See McKay, *supra* note 95.

99. Sharona Hoffman, *Measure for Measure: The Government’s Response to H1N1 and Remaining Liability Issues*, 2009 Emerging Issues 4567 (Nov. 13, 2009), available at <http://law.lexisnexis.com/webcenters/lexisone/Emerging-Issues-Analysis/Sharona-Hoffman-on->

permitted latitude to evaluate whether their country is in a state of “national emergency,” President Obama’s declaration of the 2009 H1N1 virus as a national emergency could support a manufacturer’s argument for exercising an exception to Article 31 of the TRIPS agreement. President Obama’s declaration could be important evidence if litigation results over the issue of a patent and whether the prerequisite conditions for national emergency exception existed. Further, if the exception is exercised, there is still a question of how the provision that allows production predominantly for the supply of the domestic market will be applied.

## V. SPECIAL CONCERNS

This section addresses special concerns regarding interpretation and application of the national emergency exception.

### A. TIME

Under the TRIPS agreement, patents are provided protection for twenty years.<sup>100</sup> According to Kiehl, “The idea behind compulsory licenses is that they offer some protection against abuses of power . . . .”<sup>101</sup> The time limitation on Article 31(c) as to when the circumstances of urgency or national emergency no longer exist and are unlikely to occur is also questionable.<sup>102</sup> This limitation is of an uncertain length because it is unclear what will satisfy Article 31’s language: “if and when the circumstances which led to it cease to exist and are unlikely to recur.”<sup>103</sup> Although this provision may be one attempted method of protecting against abuse of the TRIPS agreement, it is still susceptible to an overly broad interpretation.<sup>104</sup>

Thus, if Article 31 were invoked because of the severity of the swine flu for the production of one of the vaccinations mentioned previously, it is still unclear how long this compulsory license would extend or what would have to happen for there to be an adequate cessation of the conditions of the pandemic that invoked the exception. How long would the emergency exception to TRIPS be valid if there is uncertainty in the prospect of the severity of the pandemic? The United States could argue, at a minimum, that as long as President Obama considers the 2009 H1N1 swine flu to be a national emergency, this exception will persist.

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Measure-for-Measure-The-Governments-Response-to-H1N1-and-Remaining-Liability-Issues.

100. See TRIPS Agreement, *supra* note 3, art. 33.

101. See Kiehl, *supra* note 36, at 162.

102. *Id.*

103. See TRIPS Agreement, *supra* note 3, art. 31(g).

104. See, e.g., Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement?*, 21 N.Y.L. SCH. J. INT'L & COMP. L. 109, 116 (2001).



### B. POSSIBLE LOOPHOLE

Another concern is that the national emergency clause is a “loophole” that could “be used against pharmaceutical companies in a time of disease or global despair.” For example, according to Nag:

In a time when a possibly pandemic disease affects the world . . . it is no surprise that the possibility of using a loophole in the agreement is very tempting. Nevertheless, if TRIPS were revised by adding more precise definitions of what constitutes a “national [emergency] or extreme urgency,” then it would intensify the enforcement powers of the agreement by closing up such loopholes.<sup>105</sup>

The case examples discussed above reveal that the lack of precise definitions within Article 31 presents significant challenges. An unanswered question is whether chronic conditions should potentially be considered for the national emergency exception.<sup>106</sup> It would be useful to have further clarification regarding the extent of the conditions and effects of the underlying basis for the exception so that we could better discern just what types of situations will invoke this exception.

### C. MONEY

If a compulsory license were granted, further complications would exist concerning what compensation should be given for any such license. Article 31bis attempts to address this, but the language in paragraphs one and two, which addresses importing and exporting countries, is cumbersome. A standard compensation was proposed in a bill, but Congress never passed it. In the Public Health Emergency Medicines Act, “[T]he 9 factors to use in determining what reasonable compensation is for a patent infringement under the Public Health Emergency Medicines Act include:

- (1) evidence of the risks and costs associated with the invention claimed in the patent and the commercial

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105. See Nag, *supra* note 26, at 712.

106. Some situations that meet the criteria for the national emergency exception may waver in the severity of the emergency, thus raising the question of whether a chronic condition meets the national emergency exception. For example, an influenza virus may reach the state of pandemic, then subside to non-pandemic state, but then re-emerge at a later date at an increasing rate of infection. This may be the case with the swine flu, as some physicians in the United Kingdom became concerned about a swine flu resurgence because of deaths from the H1N1 flu in December 2010. See Bosely, Sarah (Health Editor, “Flu Surge Alarms Doctors as Virus Hits Children,” <http://www.guardian.co.uk/society/2010/dec/23/flu-surge-doctors-virus-children> (last visited Dec 27, 2010).

development of products that use the invention; (2) evidence of the efficacy and innovative nature and importance to the public health of the invention or products using the invention; (3) the degree to which the invention benefited from publicly funded research; (4) the need for adequate incentives for the creation and commercialization of new inventions; (5) the interests of the public as patients and payers for health care services; (6) the public health benefits of expanded access to the invention; (7) the benefits of making the invention available to working families and retired persons; (8) the need to correct anti-competitive practices; or (9) other public interest considerations.<sup>107</sup>

Likely, this bill never received congressional approval because the bill heavily favors social interests at the expense of intellectual property rights. However, the bill is useful in enumerating specific factors to be considered in determining compensation, especially those factors that are consistent with goals of the TRIPS Agreement. For example, factors (1) and (4) of the proposed Public Health Emergency Medicines Act recognize the importance of maintaining strong incentives for the development of intellectual property rights. Factor (9) is very general, and the "other public interest considerations" language leaves countries room for social welfare considerations. These considerations include, among other things, governmental interest in public health and safety and the cost of disseminating access on a broad scale.

### CONCLUSION

A strong case could be made that the swine flu would fall under the Article 31 emergency exemption, especially given that it reached pandemic status, its potential of human-to-human transmission, and the scope of the condition. However, as we have seen, there is still ambiguity regarding just how the emergency exemption to Article 31 would be applied, how long it would continue, and how compensation would be decided. The swine flu has moved through a post-pandemic state, but may resurge with a second wind of outbreaks, yielding the potential for increased infections from its initial pandemic numbers -- this possibility makes addressing the questions raised by Article 31 ever more urgent.<sup>108</sup> The resurgence of swine flu could cause an increased demand on the medications affected by the national emergency exception.<sup>109</sup>

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107. See Shapiro, *supra* note 28, at 60 n.102.

108. See Kelland, Kate, "Flu Kills 27 in Britain," Reuters, December 26, 2010, available at <http://www.reuters.com/article/idUKTRE6BM2UI20101224?type=companyNews>.

109. See Campbell, Denis, "Doctors Warn of Flu Crisis," The Gaurdian, December 17, 2010, available at <http://www.guardian.co.uk/society/2010/dec/17/doctors-warn-flu-crisis>.