

3-19-2018

## IP Neutrality and Benefit Sharing for Seasonal Flu: An Argument In Favor of WHO PIP Framework Expansion

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### Recommended Citation

Arielle Sloan, *IP Neutrality and Benefit Sharing for Seasonal Flu: An Argument In Favor of WHO PIP Framework Expansion*, 17 Chi. -Kent J. Intell. Prop. 296 (2018).

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IP NEUTRALITY AND BENEFIT SHARING FOR SEASONAL  
FLU: AN ARGUMENT IN FAVOR OF WHO PIP FRAMEWORK  
EXPANSION

ARIELLE SLOAN\*

*Abstract*

*Currently, countries that share samples of influenza viruses with a global WHO network called GISRS can participate in IP and benefit-sharing agreements over their samples only if those samples are considered potential pandemic triggers. Some key players in public health want to change that by extending those protections to seasonal flu viruses. Others argue that doing so will be problematic, by, for example, creating too much red tape for vaccine research and development or by destroying the progress that has already been made in creating GISRS. In this battle between WHO stakeholders, expanding the scope of IP and benefits agreements to seasonal flu virus-donating countries will satisfy both parties in the long term and save lives.*

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\* April 2018, J.D. Candidate, Brigham Young University. The author would like to thank Professor Clark Asay and her family for continually encouraging her to write and for supporting her in that endeavor. She would also like to thank the wonderful editing team at the Chicago-Kent Journal of Intellectual Property for their diligence in editing this paper. The opinions the author shares here are solely her own and subject to change as global discussion continues on this very important issue. She is also grateful to the international community for their respectful and thoughtful dialogue in this area.

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## INTRODUCTION

“I was on duty,” recalled James H. Wallace, “on Friday, September 13, 1918, when I was assigned to a ward of ‘flu’ patients. [The flu] had struck the training station like a bomb and the 100,000 men there suddenly filled up the hospital’s 3,000-beds . . . . The death rate was unbelievable, over 100 a day.”<sup>1</sup> David Burke explained that his father “remembered that sometimes the railroad station at Fort Devens would be stacked with the coffins of recruits who had died from the flu.”<sup>2</sup>

The deaths that these men describe all sprang from the largest flu pandemic of the modern age, which is marked in the annals of history as the

1. Jay McAuliffe, *Dr. James H. Wallace*, CTNS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/publications/panflu/stories/warstories\\_wallace.html](https://www.cdc.gov/publications/panflu/stories/warstories_wallace.html) (last visited Oct. 27, 2016).

2. David P. Burke, *Paul J. Burke*, CTNS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/publications/panflu/stories/warstories\\_burke.html](https://www.cdc.gov/publications/panflu/stories/warstories_burke.html) (last updated June 3, 2014) (quoting his father, Paul J. Burke).

Spanish flu.<sup>3</sup> Although it is unknown where the pandemic started,<sup>4</sup> it spread wildly through the ranks of soldiers fighting in the First World War.<sup>5</sup> It is believed that “about one-third of the planet’s population” was infected with the flu during that time and that “more U.S. soldiers died from the 1918 flu than were killed in battle during the war.”<sup>6</sup>

Since that horrific pandemic, several other potent flu virus strains have swept across the globe and have taken their tolls on human life. In the 1950s, for example, one flu pandemic killed about two million people, while another in the 1960s claimed another million.<sup>7</sup> Recently, from 2009 to 2010, another, commonly known as “swine flu,” killed 14,000.<sup>8</sup> Experts predict that another flu pandemic is imminent.<sup>9</sup>

In preparing for the next flu pandemic, policymakers and researchers around the world need to focus on an underestimated and strongly-related threat: seasonal flu.<sup>10</sup> International seasonal flu surveillance keeps the flu vaccine industry alive between pandemic cycles, promotes the kind of technological innovation and network-building that prepares the world for pandemics, and helps mitigate the significant toll that seasonal flu takes on public health and the economy.<sup>11</sup>

3. *1918 Flu Pandemic*, HISTORY, <http://www.history.com/topics/1918-flu-pandemic> (last visited Nov. 14, 2016) [hereinafter *1918 Flu Pandemic*].

4. Jennifer Latson, *What Made the Spanish Flu so Deadly?*, TIME (March 11, 2015), <http://time.com/3731745/spanish-flu-history/> (“Some researchers believe the story began on the morning of . . . Mar. 11, 1918, when a soldier in Fort Riley, Kans., went to the camp infirmary with a fever.”).

5. *Id.*; *1918 Flu Pandemic*, *supra* note 3.

6. *1918 Flu Pandemic*, *supra* note 3.

7. *Id.*

8. *Id.*; Katherine Harmon, *What Will the Next Influenza Pandemic Look Like?*, SCIENTIFIC AMERICAN (Sep. 19, 2011), <https://www.scientificamerican.com/article/next-influenza-pandemic/>.

9. *See, e.g.*, Harmon, *supra* note 8.

10. In many ways, seasonal flu is the overlooked step-sibling of pandemic influenza. It is common and rarely lethal.

11. For example, it is estimated that seasonal flu has killed just as many individuals over the last century as all of the major flu pandemics during the same time. Ab Osterhaus, Ron Fouchier & Guus Rimmelzwaan, *Towards Universal Influenza Vaccines?*, 366 PHIL. TRANS. R. SOC. B. 2766, 2766 (2011). Amazingly, by one estimate, there have been more deaths from seasonal flu even in specific years than from individual flu pandemics. Peter Doshi, *Trends in Recorded Influenza Mortality: United States, 1900–2004*, 98 AM. J. PUB. HEALTH, 939, 941 (2008) (“For example, the 1941–1942, 1942–1943, 1943–1944, 1944–1945, 1945–1946, 1946–1947, and 1952–1953 nonpandemic seasons were all deadlier than the 1957–1958 pandemic season.”). While there is some controversy surrounding the statistical modeling of seasonal flu deaths, the debate over how best to model those deaths is beyond the scope of this paper. *Id.* at 943. Even in its mildest form, seasonal flu often leads to medical visits, missed days of work and lower work productivity among a large segment of the population, costing consumers and businesses billions of dollars every year. *See* Noelle-Angelique M. Molinari et al., *The Annual Impact of Seasonal Influenza in the US: Measuring Disease Burden and Costs*, 25 VACCINE 5086, 5093 tbl.5 (2007).

Unfortunately, despite its potential benefits, seasonal flu research is arguably partially dis-incentivized in international legal agreements. More specifically, under a global research program run by the World Health Organization (WHO), certain intellectual property safeguards only extend to pandemic influenza viruses that are donated to its research network—not to donated seasonal viruses.<sup>12</sup> In May 2017, the World Health Assembly adopted a decision that requires the Director General to study whether or not to extend that framework, but it is unclear how long that will take.<sup>13</sup> And while there has at least been active debate in the area, with some participants in support of the initiative<sup>14</sup> and some against,<sup>15</sup> one of the most important perspectives to hear in this discussion about intellectual property—that is, an intellectual property perspective—does not seem to have voiced a strong opinion in the matter.

Some evidence suggests that attorneys have been influencing WHO discussions on this topic from the inside, a possibility that has worried some scientists who fear that attorneys have anti-public health biases.<sup>16</sup> These fears have some basis in reality: public health and intellectual property are sometimes viewed as enemies or, at best, awkward allies in global development work.<sup>17</sup>

However, not all intellectual property law perspectives run against public health.<sup>18</sup> The IP perspective offered in this article is based on the

Moreover, if seasonal flu mutates into a form that the human immune system cannot fight, it may spread in pandemic-like fashion. See *How the Flu Virus Can Change: "Drift" and "Shift,"* CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/about/viruses/change.htm> (last visited Feb. 25, 2018).

12. See Catherine Saez, *WHO Debates Expansion of Role In Virus-Sharing*, INT. PROP. WATCH (Aug. 31, 2016), <http://www.ip-watch.org/2016/08/31/who-debates-expansion-of-role-in-virus-sharing/>.

13. IMPLEMENTATION OF DECISION WHA70(10) 8(B): QUESTIONS & ANSWERS, WHO 3, 9 (2017). The Director-General will issue a report on this study in May of 2018. *Id.* At 9. See generally REPORT OF THE 2016 PIP FRAMEWORK REVIEW GROUP, REVIEW OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK, WORLD HEALTH ORG., (Dec. 29, 2016), [http://apps.who.int/gb/ebwha/pdf\\_files/EB140/B140\\_16-en.pdf?ua=1](http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1).

14. Saez, *supra* note 12.

15. *Id.*; see generally discussion *infra*.

16. Catherine Saez, *WHO Flu Pandemic Framework Working, Group Says; Some Concerned*, INT. PROP. WATCH (Aug. 30, 2016), <https://www.ip-watch.org/2016/08/30/who-flu-pandemic-framework-working-group-says-others-concerned/>.

17. See, e.g., Susan K. Sell, *The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions*, 77 TEMP. L. REV. 363, 363 (2004).

18. Generally, intellectual property perspectives need to take both business and scientific interests into account, but in the virus and vaccine context, for example, some scholars may be split over what kind of "science" is valuable in intellectual property policy considerations. Some may support the advancement of the science behind improved vaccine-related technologies but not find as much value in the science behind public health, which is also critical in vaccine discussions.

simple premise that when people are healthy, they can devote less time to sickness and more time to education, family, and work: a phenomenon which, on a large scale, could translate into gains in economy, trade, and innovation. The purpose of this paper is to provide an analysis of the seasonal flu network debate through this pro-public health intellectual property lens and explain how extending WHO contractual protection to seasonal flu viruses can protect scientific innovation, public health, and business interests in the long run.

In order to make this argument that WHO's viral exchange legal protections should extend to seasonal flu viruses, I will provide an introduction to seasonal flu and describe its effect on global health and economy in Part II. I will then discuss the structure of WHO's virus network and the legal protections that the program provides to pandemic flu virus donor countries in Part III. In Part IV, I will analyze the policy debate on extending that protection to seasonal virus donor countries and explain why the extension arguments are stronger. In Part V, I will discuss considerations that the WHO should take into account if it does eventually decide to extend legal protection to seasonal flu. In Part VI, I will conclude.

## I. AN INTRODUCTION TO SEASONAL FLU

In a 2015 flu shot commercial, an office birthday party is depicted in which a middle-aged male employee is told to make a wish before blowing out birthday candles.<sup>19</sup> He does so and then proceeds to involuntarily cough and sneeze all over the top of the cake.<sup>20</sup> His act leaves his cake-loving co-worker in a quandary over whether or not she should eat a slice.<sup>21</sup>

This comical portrayal of seasonal flu illustrates a hyperbolic, but perhaps, partially accurate, American perception of this illness: no one wants to get the flu, but a germ-infested cake might be worth the risk. This sentiment toward the flu makes sense, of course: for the majority of Americans, the seasonal flu that comes around every winter may necessitate a few weeks of bed rest, but the experience is rarely life-threatening.

19. See *Rite Aid TV Commercial, 'Janet Loves Cake'*, ISpot.TV (Dec. 12, 2015), <https://www.ispot.tv/ad/AkDL/rite-aid-janet-loves-cake> (last visited Feb. 19, 2018).

20. *Id.*

21. *Id.*

Considering the low death rate<sup>22</sup> attributable to seasonal flu and the attitude that the general American population has toward it, then, it is important to understand what seasonal influenza is and how it impacts health.

### A. An Epidemiological Snapshot of Seasonal Influenza

Seasonal influenza is an extremely common illness. According to one estimate, seasonal influenza spreads to about a quarter of all children and five to ten percent of adults every year.<sup>23</sup> The spread of this illness, which is caused by a contagious virus, peaks in winter in colder climates and experiences more sporadic cycles in warmer climates.<sup>24</sup> Seasonal influenza has a stronger effect on vulnerable populations, including pregnant women, the elderly, children, and individuals with serious health conditions.<sup>25</sup>

### B. The Influenza Virus

Seasonal influenza is caused by invasive packaged genetic material, also known as a virus.<sup>26</sup> When flu viruses enter the human body, they use host cells to replicate themselves<sup>27</sup> and can contribute to host cell self-destruction.<sup>28</sup> Between losing cells and experiencing the activation of their own immune systems,<sup>29</sup> flu sufferers start to feel the effects of a flu virus invasion in short order: fever, sore throat, headaches and muscle aches, for example.<sup>30</sup>

22. CTRS. FOR DISEASE CONTROL & PREVENTION, *Seasonal Influenza, More Information*, <http://www.cdc.gov/flu/about/qa/disease.htm#people> (last updated Oct. 12, 2017) (“[I]n the United States [generally,] millions of people become ill, hundreds of thousands are hospitalized and thousands or tens of thousands of people die from flu every year.”).

23. World Health Org., *H5N1 Avian Influenza: First Steps Towards Development of a Human Vaccine*, 33 WKLY. EPIDEMIOLOGICAL REC. 277, 281 (Aug. 19, 2005), <http://www.who.int/wer/2005/wer8033.pdf>.

24. *Influenza (Seasonal)*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs211/en/> (last updated Jan. 2018).

25. *Id.*

26. Peter M. Crosta, *Viruses: An Introduction*, MED. NEWS TODAY (July 11, 2016), <http://www.medicalnewstoday.com/articles/158179.php>.

27. Craig Freudenrich, *How Viruses Work*, HOWSTUFFWORKS SCI. (Oct. 19, 2000), <http://science.howstuffworks.com/life/cellular-microscopic/virus-human3.htm>.

28. See generally S. Tripathi et al., *Influenza A Virus Nucleoprotein Induces Apoptosis in Human Airway Epithelial Cells: Implications of a Novel Interaction Between Nucleoprotein and Host Protein Clustering*, 4 CELL DEATH & DISEASE 562 (2013).

29. See Freudenrich, *supra* note 27.

30. *Key Facts About Influenza (Flu)*, CTRS. FOR DISEASE CONTROL & PREV., <http://www.cdc.gov/flu/keyfacts.htm> (last accessed Oct. 13, 2016).

In expelling the flu virus from one's system, an individual may, naturally, cough or sneeze,<sup>31</sup> sending virus particles hurtling toward other individuals who, then, will similarly have to fight off viral invasion.<sup>32</sup> The severity of that invasion will depend on the virus' interplay with the human immune system: when a virus is weak or the immune system is strong, viral spreading will do little damage. However, for some individuals with weak immune systems, the flu virus can cause deadly complications, like pneumonia.<sup>33</sup> For the same reason, people in many lower- and middle-income countries, where nutrition and healthcare are less-readily accessible, are susceptible to seasonal flu.<sup>34</sup>

When a virus mutates in a way that the human immune system cannot defeat, that virus has more lethal potential.<sup>35</sup> Viruses that shift from animal species to human species, for example, are said to have this potential because human immune systems are not used to their mode of operation.<sup>36</sup> In cases like these, especially strong flu viruses can cause international disease outbreaks, also known as pandemics.<sup>37</sup>

The primary difference then, between seasonal and pandemic influenza is, in some ways, just a matter of degree. It is true that some flu virus strains may be considered less prone to mutation than others.<sup>38</sup> However, in theory, any virus can mutate radically into a form that humans cannot fight off, and this mutation can result in another Spanish flu.<sup>39</sup> Consequently, it is of vital importance to monitor and research as many viral strains as possible.

31. Freudenrich, *supra* note 27.

32. *Key Facts About Influenza (Flu)*, *supra* note 30.

33. *Id.*

34. *See Influenza (Seasonal)*, *supra* note 24.

35. *See How the Flu Virus Can Change: "Drift" and "Shift"*, *supra* note 11.

36. *See Transmission of Influenza Viruses from Animals to People*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/flu/about/viruses/transmission.htm> (last updated Aug. 19, 2014) ("Antigenic shift results when a new influenza A subtype to which most people have little or no immune protection infects humans. If this new virus causes illness in people and can spread easily from person to person, an influenza pandemic can occur.").

37. *What is a Pandemic?*, WORLD HEALTH ORG. (Feb. 24, 2010), [http://www.who.int/csr/disease/swineflu/frequently\\_asked\\_questions/pandemic/en/](http://www.who.int/csr/disease/swineflu/frequently_asked_questions/pandemic/en/).

38. *See generally* Eri Nobusawa & Katsuhiko Sato, *Comparison of the Mutation Rates of Human Influenza A and B Viruses*, 80 J. VIROLOGY 3675 (2006).

39. *See supra* Part I.



### C. *The Influenza Vaccine*

Seasonal flu viruses can be used to produce flu vaccines, which are a primary prevention tool used to combat the flu. If a viral infection could be considered a test of an immune system's strength, a vaccine could be considered a practice exam. Vaccines often consist of toxins or weakened, partial, or dead viruses that the body can learn to fight against without the threat of being taken over.<sup>40</sup> Once the immune system learns to fend off a certain viral strain, that knowledge sticks with the immune system: a knowledge that enables it to quickly conquer the actual virus upon invasion.<sup>41</sup>

Vaccination has been called "the most cost-effective way to reduce [the seasonal flu] disease burden,"<sup>42</sup> and due to the impact that vaccination has on population health, vaccine use boosts the economy as well. After all, the flu vaccine prevents deaths and hospitalizations, but it also reduces lost work days.<sup>43</sup> According to one estimate, if 75% of individuals recommended to receive the seasonal flu vaccine in twenty-seven European countries actually did so, 1.6 to 1.7 million more individuals would avoid the flu, about 10,000 deaths would be avoided, and about a million lost days of work would be recouped.<sup>44</sup> Such public health gains would translate to an estimated €200 million in combined *annual* savings.<sup>45</sup>

### D. *Seasonal influenza antiviral drugs*

Seasonal influenza viral material can also be used to develop antiviral drugs. The Centers for Disease Control and Prevention (CDC) views antiviral drugs as "a second line of defense to treat [seasonal] flu."<sup>46</sup> While a flu shot prevents an individual from developing the flu, antiviral drugs can

40. CTRS. FOR DISEASE CONTROL & PREVENTION, UNDERSTANDING HOW VACCINES WORK 1–2 (2013), <https://web.archive.org/web/20150213181503/http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-understand-color-office.pdf>.

41. *See id.*

42. Osterhaus, Fouchier & Rimmelzwaan, *supra* note 11, at 2766.

43. PREAUD ET AL., ANNUAL PUBLIC HEALTH AND ECONOMIC BENEFITS OF SEASONAL INFLUENZA VACCINATION: A EUROPEAN ESTIMATE 1, 8 (2014), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4141103/pdf/12889\\_2013\\_Article\\_6962.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4141103/pdf/12889_2013_Article_6962.pdf).

44. *Id.*

45. *Id.*

46. *What You Should Know About Flu Antiviral Drugs*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Aug. 11, 2016), <http://www.cdc.gov/flu/antivirals/whatyoushould.htm>.

shorten the duration of sickness and make symptoms more bearable.<sup>47</sup> In doing so, antiviral drugs, like vaccines, can contribute to public health gains and cost savings by decreasing sick days, hospitalizations, and deaths.<sup>48</sup>

*E. The impact of seasonal flu research on pandemic flu research*

By researching and developing seasonal flu vaccines and antivirals, of course, scientists do not simply protect populations from seasonal flu: they also prepare the world for pandemic flu by keeping vaccine manufacturers financially afloat and by advancing flu research generally. Kenneth McLean and colleagues explain that “[i]f influenza immunization rates stagnate or drop[,] this could result in manufacturers reducing or stopping their seasonal vaccine production [and] impact the global capacity for pandemic influenza vaccines.”<sup>49</sup> In other words, decreasing seasonal flu vaccine sales could hurt pandemic flu preparedness both by reducing annual vaccine manufacturer profits and by slowing down flu research.

Moreover, because seasonal influenza strains are similar to and could theoretically *become* pandemic strains through mutation,<sup>50</sup> technologies that scientists develop around seasonal influenza often have direct application to pandemic flu. For example, WHO once listed a seasonal flu vaccine technology as one of the “most promising avenues for short and medium term development of pandemic influenza vaccines.”<sup>51</sup> Without seasonal influenza research and technology, our level of pandemic flu preparedness could weaken significantly.

## II. WHO’S RESEARCH DATABASE

It is in this context—knowing how similar seasonal and pandemic influenza truly are and how seasonal flu research can prepare the world for pandemic flu—that we approach the question of how WHO’s flu research system currently handles seasonal flu viruses.

47. *Id.*

48. *See id.*

49. Kenneth A. McLean et al., *The 2015 Global Production Capacity of Seasonal and Pandemic Influenza Vaccine*, 34 *VACCINE* 5410, 5412 (2016).

50. REVIEW OF THE PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS, PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK REVIEW GROUP, § 3.2.1 (2016) [hereinafter PIP FRAMEWORK REVIEW].

51. *Questions and Answers on Pandemic Influenza Vaccine*, WORLD HEALTH ORG. (May 9, 2007), [http://www.who.int/immunization/newsroom/PI\\_QAs/en/](http://www.who.int/immunization/newsroom/PI_QAs/en/).

Currently, the structure of WHO's research network, also known as the Global Influenza Surveillance and Response System (GISRS), only provides certain legal protections to countries that donate flu virus strains with "pandemic potential."<sup>52</sup> Before delving into the debate on whether or not seasonal flu should also receive these protections, I will discuss the origins of this system and how it currently operates.

#### A. *GISN and the Indonesian Avian Flu Revolt of 2007*

The international flu monitoring system we know today as the GISRS has been in existence since 1952, although it was originally called the Global Influenza Surveillance Network, or GISN.<sup>53</sup> The purpose of this system is to monitor virus mutations and alert global leaders when pandemics are likely to occur.<sup>54</sup> The system operates in part by bringing seasonal and pandemic flu virus strains from around the world to WHO-affiliated labs and manufacturers, who conduct research on these strains and then develop vaccines and antivirals to combat them.<sup>55</sup>

Although the network operated successfully for over half a century, an incident related to Avian flu in 2007 created a need for GISN overhaul. During that year, the nation of Indonesia withheld one of its Avian flu strains from WHO's flu database, choosing instead to work with a pharmaceutical company to produce a vaccine for it.<sup>56</sup>

The nation explained that it was doing so in part because it was angry with WHO.<sup>57</sup> According to one report, "Indonesia blamed the World Health Organization . . . for the government's decision to stop sharing samples of the H5N1 bird flu virus, claiming that the United Nations agency passed

52. *Global Influenza Surveillance and Response System (GISRS)*, WORLD HEALTH ORG., [http://www.who.int/influenza/gisrs\\_laboratory/en/](http://www.who.int/influenza/gisrs_laboratory/en/) (last visited Feb. 15, 2018).

53. *Id.*; TERMS OF REFERENCE FOR NATIONAL INFLUENZA CENTERS OF THE GLOBAL INFLUENZA SURVEILLANCE AND RESPONSE SYSTEM, WORLD HEALTH ORG. 1 (2017), [http://www.who.int/influenza/gisrs\\_laboratory/national\\_influenza\\_centres/tor\\_nic.pdf](http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/tor_nic.pdf).

54. *Global Influenza Surveillance and Response System (GISRS)*, *supra* note 52.

55. *WHO Global Influenza Surveillance and Response System (GISRS) Surveillance and Vaccine Development*, WHO COLLABORATING CNTR. FOR REFERENCE & RES. ON INFLUENZA, [http://www.influenzacentre.org/centre\\_GISRS.htm](http://www.influenzacentre.org/centre_GISRS.htm) (last visited Feb. 15, 2018).

56. David P. Fidler, *Indonesia's Decision to Withhold Influenza Virus Samples from the World Health Organization: Implications for International Law*, ASIL INSIGHTS (Feb. 28, 2007), <https://www.asil.org/insights/volume/11/issue/4/indonesias-decision-withhold-influenza-virus-samples-world-health>.

57. *Id.*

them on to pharmaceutical companies to make vaccines that Jakarta had to buy at high prices.”<sup>58</sup>

Two reactions emerged out of Indonesia’s radical move: one was fear that other countries might follow Indonesia’s lead and keep their viruses to themselves as “sovereign property.”<sup>59</sup> Another was anger at WHO for turning the GISN network into a “virus vacuum:” taking viruses from poor countries and allowing wealthy industries to patent and/or profit from the results for free without giving back.<sup>60</sup> After all, Indonesia’s experience was not an isolated incident. When Avian flu struck Mexico in 2009, wealthy countries took the virus strain that Mexico donated into vaccines and took care of their own populations before turning back to Mexico.<sup>61</sup> In fact, although ninety-five WHO-partnering countries did not have a way to get vaccines on their own during that pandemic, only two received WHO aid within ten months of the first reported cases.<sup>62</sup>

So, really, the Indonesian Avian flu experience highlighted two major problems with the GISN: first, there was no intellectual property framework that regulated how viral material could be used by WHO laboratories or manufacturers, and second, there was little incentive for wealthy manufacturers to “give back” to donors in any way.

### B. *The GISRS and the PIP Framework*

These kinds of experiences prompted negotiations between WHO and partner countries to overhaul the virus sharing network, with a dual focus on intellectual property ownership of viral resources and equitable sharing of benefits. As a result of these negotiations, WHO created a new legal model

58. *Id.* (quoting John Aglionby & Andrew Jack, *Indonesia Accuses WHO of Misusing Flu Sample*, FIN. TIMES (Feb. 8, 2007, 2:00 AM), [http://www.ft.com/cms/s/0/e565960c-b719-11db-8bc2-0000779e2340.html?ft\\_site=falcon&desktop=true#axzz4SrQvQzuW](http://www.ft.com/cms/s/0/e565960c-b719-11db-8bc2-0000779e2340.html?ft_site=falcon&desktop=true#axzz4SrQvQzuW)).

59. Richard Holbrooke & Laurie Garrett, ‘Sovereignty’ *That Risks Global Health*, WASH. POST (Aug. 10, 2008), <http://www.washingtonpost.com/wp-dyn/content/article/2008/08/08/AR2008080802919.html>.

60. See Edward Hammond, *Indonesia Fights to Change WHO Rules on Flu Vaccines*, GRAIN (Apr. 18, 2009), <https://www.grain.org/article/entries/761-indonesia-fights-to-change-who-rules-on-flu-vaccines>.

61. Charles Lawson, *Who Shall Live When Not All Can Live? Intellectual Property in Accessing and Benefit-Sharing Influenza Viruses Through the World Health Organisation*, 18 J.L.M. 554, 574 (2011).

62. *Id.* (citing Chan Chee Khoo, *Equitable Access to Pandemic Flu Vaccines*, THIRD WORLD NETWORK INFO SERV. ON INT. PROP. ISSUES (Mar. 2010), [http://www.twn.my/title2/intellectual\\_property/info.service/2010/ipr.info.100311.htm](http://www.twn.my/title2/intellectual_property/info.service/2010/ipr.info.100311.htm)).

for virus sharing in WHO's flu database, also known as the Pandemic Influenza Preparedness (PIP) Framework,<sup>63</sup> and changed its network name from GISN to the "Global Influenza Surveillance and Response System" (GISRS).<sup>64</sup>

The main goal of this new PIP Framework was to improve GISRS<sup>65</sup> by giving countries an assurance that they would be able to benefit in some way for sharing their viral information with WHO.<sup>66</sup> As noted by WHO, "[t]he PIP Framework aims to improve . . . the [GISRS] so it is more fair, transparent, equitable, efficient, and effective in facilitating the sharing of influenza viruses with pandemic potential and [in] increasing . . . access to pandemic influenza vaccines and other benefits."<sup>67</sup> In order to build a more open-access virus community and support vaccine technology benefits sharing, the PIP Framework utilizes a contract system<sup>68</sup> that prevents viral material from being patented and provides partner countries (or WHO generally) with certain benefits.<sup>69</sup> This contract system operates through two separate agreements, also known as Standard Material Transfer Agreements 1 and 2 (SMTAs 1 and 2).<sup>70</sup>

SMTA 1 is an agreement made among WHO laboratories to facilitate open-access virus sharing.<sup>71</sup> Under this agreement, laboratories that donate viruses to the network promise to handle those viruses according to established WHO and safety guidelines.<sup>72</sup> In exchange, the laboratories that receive those viruses promise to involve donor laboratories in their research

63. David P. Fidler & Lawrence O. Gostin, *WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health*, 306 JAMA 200, 200 (2011).

64. *Global Influenza Surveillance and Response System (GISRS)*, *supra* note 52.

65. Fidler & Gostin, *supra* note 63, at 201 (describing the PIP Framework as improving the "legitimacy" of the system).

66. *Id.* at 200.

67. PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS ("PIP FRAMEWORK"): QUESTIONS AND ANSWERS, WORLD HEALTH ORG. 3 (Sep. 2011), [http://www.who.int/influenza/pip/PIP\\_FQA\\_Nov\\_2011.pdf](http://www.who.int/influenza/pip/PIP_FQA_Nov_2011.pdf). [hereinafter WHO, PIP FRAMEWORK Q&A].

68. Fidler & Gostin, *supra* note 63, at 201.

69. PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK Q&AS, WORLD HEALTH ORG. 3, [http://www.who.int/influenza/pip/QA\\_Flyer.pdf](http://www.who.int/influenza/pip/QA_Flyer.pdf) (2016).

70. PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS, WORLD HEALTH ORG. 29–32 (2011) [hereinafter WHO, PIP Framework].

71. *Id.* at 29–36.

72. *Id.* at 30.

and acknowledge donor laboratories if that research leads to publishable or presentation-worthy scientific findings.<sup>73</sup> Finally, both donors and recipients promise, very simply, that they will not “seek to obtain any intellectual property rights” on donated viral material.<sup>74</sup> This agreement does not extend to IP rights obtained on material before the PIP Framework was adopted—rather, those prior rights are left intact, and so are any IP-backed technologies involved in preparing donor material.<sup>75</sup>

SMTA 2 is a benefit sharing agreement that WHO can make with non-WHO entities, such as vaccine and antiviral manufacturers.<sup>76</sup> Under the agreement, WHO gives a flu virus to a manufacturer in exchange for certain benefits.<sup>77</sup> Manufacturers can choose which benefits they’d like to provide to WHO: some of the options include “donat[ing] at least 10% of real time pandemic vaccine production to WHO,” selling the same amount to WHO at low cost, or “[g]rant[ing] to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable.”<sup>78</sup> Manufacturers are also required to “consider” other good-will offers, like donating vaccines, transferring technology, and providing WHO with sublicenses for its intellectual property.<sup>79</sup>

If a vaccine manufacturer wants to license its vaccine-related intellectual property to low- or middle-income countries (“LMICs”) under this agreement, it can do so in several ways. By one method, the manufacturer can contract directly with a developing country and receive royalties under mutual terms, as long as those terms are “fair and reasonable.”<sup>80</sup> In determining what is fair and reasonable, the contracting parties are supposed to consider factors like the developing country’s technological advancement and already-held intellectual property rights in the vaccine field.<sup>81</sup> Under the second option, the manufacturer can opt to grant licenses to LMICs or to WHO directly, who can then sublicense certain

73. *Id.* at 30–31, art. 5.2–5.3.

74. *Id.* at 31, art. 6.1.

75. *Id.* at 31, art. 6.2–6.3.

76. *Id.* at 33–36.

77. *Id.* at 33–35.

78. *Id.* at 34, art. 4.1.1(A).

79. *Id.* at 35, art. 4.1.1(C).

80. *Id.* at 34, art. 4.1.1(A5).

81. *Id.*

vaccine-related technology to LMICs.<sup>82</sup> In either case, manufacturers who choose to license their IP must report to WHO on how their license agreements are coming along.<sup>83</sup>

In summary, the PIP Framework is important because it provides industries with an assurance that pandemic flu viruses will remain open access, and it gives donating countries the knowledge that when pandemics strike, WHO will be able to provide them with vaccines or relevant technology to fight back.

### III. TO EXTEND OR NOT TO EXTEND: THAT IS THE DEBATE

The PIP Framework is currently undergoing a review, and in these review meetings, stakeholders have raised several issues with the GISRS system.<sup>84</sup> One of these issues is that the PIP Framework only covers pandemic influenza<sup>85</sup> even though seasonal influenza viruses are also donated to GISRS.<sup>86</sup> Directly expanding the framework to cover seasonal influenza<sup>87</sup> is one of three alternatives on the table; stakeholders have also

82. *Id.* at 34, art. 4.1.1(A6).

83. *Id.* at 34, art. 4.1.1 (“Where Option 5 or 6 is selected, the Recipient shall regularly provide to WHO information on granted licenses and the status of implementation of the licensing agreement. WHO shall provide such information to the Advisory Group.”).

84. Catherine Saez, *Review of WHO Pandemic Flu Preparedness: Data Sequencing And Other Issues*, INT. PROP. WATCH (Mar. 31, 2016), <http://www.ip-watch.org/2016/03/31/review-of-who-pandemic-flu-preparedness-data-sequencing-and-other-issues/> [hereinafter Saez, *Review of Pandemic Flu*].

85. *Id.*

86. WHO *Global Influenza Surveillance and Response System (GISRS) Surveillance and Vaccine Development*, *supra* note 55. It should be noted that seasonal influenza vaccine work is indirectly involved in GISRS and the PIP Framework. For example, GISRS spending covers both pandemic and seasonal influenza laboratory research, and companies are required to donate money to GISRS that is proportionate to both pandemic and seasonal influenza “product sales.” IMPLEMENTATION OF DECISION WHA70(10)8(B) SCOPING PAPER ON APPROACHES TO SEASONAL INFLUENZA AND GENETIC SEQUENCE DATA UNDER THE PIP FRAMEWORK (“SCOPING PAPER”), WORLD HEALTH ORG. ¶ 24 (Oct. 2017), <http://www.who.int/influenza/pip/scopingpaper.pdf> [hereinafter SCOPING PAPER].

87. In theory, direct incorporation might be as simple as making three changes: first, the line “[t]his Framework does not apply to seasonal influenza” would need to be struck from the agreement; second, the definition of “[i]nfluenza virus with human pandemic potential” would need to include seasonal influenza viruses; and third, SMTA 2—the benefits sharing contract—would need to include a section where vaccine manufacturers chose to provide WHO with one of a list of seasonal flu vaccine benefits. See WHO, PIP FRAMEWORK Q&A, *supra* note 67, at 7, 9, 33–35. However, that section could theoretically be copied from the pandemic influenza benefits sharing section, by, for example, allowing companies to donate a fraction of their seasonal flu vaccines to LMICs. *Id.* at 33–35. The language of every other provision in the agreement could likely remain the same. In doing so, the entire PIP Framework would cover seasonal and pandemic influenza. However, if extension were chosen,

discussed the creation of a parallel agreement that covers seasonal influenza only and the allowance of seasonal influenza coverage under a separate international agreement called the Nagoya Protocol.<sup>88</sup> In this paper, the term “framework expansion” will be used primarily to indicate direct expansion of the framework, but I do not oppose a parallel agreement or an interpretation of the Nagoya Protocol that would preserve benefit sharing and IP considerations inherent in the PIP Framework.

The question of whether or not to expand benefit sharing and IP protection generally is being heavily debated: drafting language in an agreement is one thing, but implementing it is another, and there are many arguments for and against extension at WHO. On one side of the debate, WHO reviewers<sup>89</sup> and the Gates Foundation have voiced support for research into Framework extension.<sup>90</sup> On the other side, a variety of groups, including the pharmaceutical industry,<sup>91</sup> the Third World Network,<sup>92</sup> and GISAID,<sup>93</sup> have opposed extension. Still others, including a representative of WHO Collaborating Centre, once urged to look into the possibility with caution.<sup>94</sup> In this Part, I will discuss several arguments for and against extension and explain why the arguments in favor of extension are superior as a matter of innovation, economy, and public health.

#### A. *Industry Argument 1: Too Much Red Tape*

At the August 29, 2016 PIP Framework review meeting, a representative of pharmaceutical giant Sanofi Pasteur asked that the PIP

stakeholders could, naturally, carve out a section in the new framework with exceptions and new requirements for seasonal influenza sharing specifically.

88. SCOPING PAPER, *supra* note 86, at ¶ 26.

89. PRELIMINARY FINDINGS, PIP FRAMEWORK REVIEW GROUP 2016, 3 (Aug. 19, 2016), [http://www.who.int/influenza/pip/2016-review/pip\\_review\\_group\\_prelim\\_findings.pdf?ua=1](http://www.who.int/influenza/pip/2016-review/pip_review_group_prelim_findings.pdf?ua=1) (discussing framework expansion).

90. Saez, *Review of Pandemic Flu*, *supra* note 84.

91. Catherine Saez, *WHO Debates Expansion of Role In Virus-Sharing*, INT. PROP. WATCH (Aug. 31, 2016), <http://www.ip-watch.org/2016/08/31/who-debates-expansion-of-role-in-virus-sharing/> [hereinafter Saez, *WHO Debates Role*].

92. Saez, *Review of Pandemic Flu*, *supra* note 84.

93. GISAID, GISAID'S COMMENTS ON THE PRELIMINARY FINDINGS OF THE PIP FRAMEWORK REVIEW GROUP 2016, 1 (2016).

94. Saez, *WHO Debates Role*, *supra* note 91. *But see The Inclusion of Seasonal Influenza Viruses and Genetic Sequence Data (GSD) in the Context of the Pandemic Influenza Preparedness (PIP) Framework*, [http://www.who.int/influenza/pip/CC\\_ERL\\_DirectorsPositionPaper\\_8b.pdf](http://www.who.int/influenza/pip/CC_ERL_DirectorsPositionPaper_8b.pdf) (last visited Feb. 21, 2018) (in which the directors of that group, but not the group itself, took a position against expansion).



Framework not be extended to seasonal flu because extension could “[require] obligation[s] that ha[d] already been committed by the third parties . . . for example industry, . . . to be revised . . . [and] add another layer of . . . complexity.”<sup>95</sup> Another industry representative agreed with those assertions without providing much added detail.<sup>96</sup> However, at one point during her comments, she did state her group’s belief that “the contribution[s] provided the industry . . . ha[d] been sufficient.”<sup>97</sup> Others have noted that companies already provide funding to GISRS based in part on seasonal flu vaccine sales.<sup>98</sup>

These comments seem to suggest that manufacturers view the PIP Framework generally as a burden and an extension of that burden as unreasonable. This suggestion is made stronger by the fact that, even under the current PIP Framework, very few manufacturers have even signed onto the SMTA 2 provisions.<sup>99</sup> The reasons for this sentiment, of course, are understandable: being asked to donate ten percent of a vaccine supply to WHO during a pandemic, transfer technology to a developing nation, or produce low-cost intellectual property licensing agreements, for example, are not small financial or logistical matters.

Although the red tape concerns of industry are certainly understandable, expanding the PIP Framework to include seasonal influenza could lower some very thick red tape in the long run. Generally speaking, seasonal influenza patenting is already something of a free-for-all:<sup>100</sup> a situation that can lead to patent thickets,<sup>101</sup> tight control over virus-related material (and, consequently, the vaccines that are made of viral material) by certain corporations, and expensive licensing agreements that hinder competition.

95. Saez, *WHO Debates Role*, *supra* note 91; *2016 Review of the PIP Framework Webcast*, WORLD HEALTH ORG. (Aug. 29, 2016), <http://who.int/influenza/pip/2016-review/webcasts/en/> [hereinafter WHO, *2016 Review Webcast*] (starting at minute 46:52).

96. WHO, *2016 Review Webcast*, *supra* note 95, at 53:20.

97. *Id.* at 49:32.

98. See SCOPING PAPER, *supra* note 86, at 5.

99. WHO, *2016 Review Webcast*, *supra* note 95, at 1:17:28.

100. This kind of situation has happened before. Antonio Regalado, *Scientists’ Hunt for SARS Cure Turns to Race for Patent Rights*, WALL ST. J., <http://www.wsj.com/articles/SB105209016979730900> (last updated May 5, 2003, 3:41 PM).

101. See generally Dana Beldiman, *Patent Choke Points in the Influenza-Related Medicines Industry: Can Patent Pools Provide Balanced Access?*, 15 TUL. J. TECH. & INT. PROP. 31 (2012). This article is particularly interesting because it criticizes the current framework for not protecting IP rights enough. See *id.* generally. However, in this article, I suggest that minimum protections for seasonal flu are better than nothing, which is the current standard.

According to Martin Friede, who leads WHO's Technology Transfer Initiative,<sup>102</sup> about 10,000 patent applications have been filed for vaccines in the past two decades, and many patent-holding entities want royalties from manufacturers.<sup>103</sup> And, as Dana Beldiman explains, “[d]epending on the density of the thicket (number of patents to be licensed, economic and political dynamics among the players, etc.) it is possible that *none* of the players [in influenza medicine manufacturing] will be able to assemble all the requisite rights to a product.”<sup>104</sup>

The PIP Framework's prohibition on patenting donated material may appear to cover only a small piece of the potential thicket pie. However, this kind of prohibition is an important check on the unleashing of epidemics.<sup>105</sup> All it takes is for one country, like Indonesia in 2007, to give one of its own manufacturers exclusive rights to develop a vaccine on a virus. Or for a country, like China in 2002, to keep a virus a complete secret from the world until the virus spreads to neighboring countries.<sup>106</sup> Or for researchers, like several in Canada in 2003, to try to patent a virus and consider charging royalties downstream.<sup>107</sup>

Although none of these historical events led to public health catastrophes, and seasonal flu strains can mutate quickly, it would be unwise for us to push our luck in the future by allowing patent ownership of material closely linked to donated seasonal viruses by WHO-affiliated laboratories. If the PIP Framework is not extended to seasonal flu, the seasonal flu vaccine world could be primed for further patent thickening, vaccine monopolization, and industry stifling and put a chokehold on seasonal vaccine development.

102. Catherine Saez, *Access to Vaccines, Patents Growing Concerns, Panelists Say*, INT. PROP. WATCH (Oct. 6, 2014), <http://www.ip-watch.org/2014/06/10/access-to-vaccines-patents-growing-concerns-panellists-say/> [hereinafter Saez, *Access to Vaccines*].

103. *Id.*

104. See Beldiman, *supra* note 102, at 47 (emphasis added).

105. A technical paper from the Life Sciences Program at the World Intellectual Property Organization voiced a similar concern about pandemic flu before PIP Framework extensions were extended to it. See WORKING PAPER: PATENT ISSUES RELATED TO INFLUENZA VIRUSES AND THEIR GENES, LIFE SCIENCES PROGRAM, WORLD INTELLECTUAL PROPERTY ORG. 1, 4 (2007), [http://www.wipo.int/export/sites/www/policy/en/global\\_health/pdf/influenza.pdf](http://www.wipo.int/export/sites/www/policy/en/global_health/pdf/influenza.pdf) (“Relatively few patents or patent applications claim bare H5N1 genetic material as such, although some cases exist and may require closer examination, since they could constrain wider downstream usage of the genetic material claimed, such as in the development of new vaccines or production of vaccines.”).

106. Holbrooke & Garrett, *supra* note 59 (referring to the SARS virus).

107. Regalado, *supra* note 100.

Extending the PIP Framework as a whole to seasonal influenza might create red tape for industry, building a network of non-patentable seasonal flu viruses through PIP Framework extension might be worth the extra hassle.

*B. Industry Argument 2: Extension Incentivizes ‘Handout’  
Culture for Seasonal Flu Preparedness*

Among some companies, there may be a sentiment that LMICs simply need to develop their own vaccines<sup>108</sup> rather than rely on free seasonal flu vaccines or technology transfer from SMTA 2 agreements. As of 2002, fourteen companies on a WHO task force were producing 90% of the world’s flu vaccines,<sup>109</sup> and many large pharmaceutical companies are located in higher-income nations.<sup>110</sup> Disparities in research and development mirror geographic disparities in wealth: “companies [in high-income countries] devote between 15 and 20 percent of their profit to R&D, [while those in lower-income countries devote] 2 or 3 percent.”<sup>111</sup>

The sentiment that manufacturers in developed countries dislike sharing seasonal flu resources with LMICs is suggested by the fact that companies that have signed SMTA agreements have already been reluctant to participate in developing country tech transfer for *pandemic* flu.<sup>112</sup> Although this reluctance may stem from a number of factors, such as feasibility concerns, companies likely also fear the loss of their patented inventions or trade secrets<sup>113</sup> to groups that have not put in the work to develop them on their own.

It is unknown how many vaccine manufacturers are opposed to PIP Framework expansion on the ground that they already feel they are doing

108. *Id.*

109. VACCINES FOR PANDEMIC INFLUENZA, WORLD HEALTH ORG. 9 (Nov. 12, 2004), [http://www.who.int/influenza/resources/documents/WHO\\_CDS\\_CSR\\_GIP\\_2004\\_3.pdf](http://www.who.int/influenza/resources/documents/WHO_CDS_CSR_GIP_2004_3.pdf).

110. *Id.* at 14–16.

111. Saez, *Access to Vaccines*, *supra* note 102.

112. PIP FRAMEWORK REVIEW GROUP 2016, WORLD HEALTH ORG. 7 (Aug. 19, 2016), <http://www.ip-watch.org/weblog/wp-content/uploads/2016/08/PIP-Review-Group-Preliminary-Findings-August-2016.pdf>.

113. *Id.*; *Methodological and Technological Issues in Technology Transfer*, INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, <http://www.ipcc.ch/ipccreports/sres/tectran/index.php?idp=202> (last visited Feb. 16, 2018) (“A major requirement for successful agreement in technology transfer is the guarantee of intellectual property rights (IPR). Without an IPR law that is effectively enforced, there is little incentive for private companies to share their technology.”).

more than their fair share. However, this argument, however justified, appears to suggest that those in LMICs are simply lazy. Although nations have difficulty developing their own vaccine networks for many reasons, none of those are reasons why they should be ignored. To a much greater extent than wealthier countries, for example, LMICs are constantly trying to combat ubiquitous poverty, severe illness, poor educational systems, sustainable resource issues, and unstable or unsafe social and political climates.<sup>114</sup> If anything, the fact that developing nations have bigger fish to fry than seasonal influenza should morally compel companies in wealthier nations to share seasonal influenza vaccine benefits.

However, if that rationale isn't enough to persuade a company to expand benefits sharing to seasonal influenza, the business potential of investing in developing companies should. Stanley Plotkin explains that the vaccine industry is in danger, presumably due to high costs of production and patent thicketing, and notes that "fewer companies are developing vaccines."<sup>115</sup> One thing that smaller members of the vaccine industry could hypothetically do to survive is develop global partnerships through mutual, low-cost licensing and sharing of technology, and the SMTA 2 agreement facilitates these kinds of deals for pandemic flu. Extending that framework to seasonal flu could help the industry become more collaborative and profitable overall by creating stronger international benefits-sharing networks.

### C. Industry Argument 3: We Want Our Patents

A related problem that industry might have with extending the Framework is that extension would limit industry's ability to patent seasonal viruses.<sup>116</sup> This would be less of an argument for manufacturers than for

114. Many of these issues are directly discussed in the 2030 Agenda for Sustainable Development. *Resolution Adopted by the General Assembly on 25 September 2015*, UNITED NATIONS, A/RES/70/1, 14 (Oct. 21, 2015), [http://www.un.org/en/ga/search/view\\_doc.asp?symbol=A/RES/70/1&Lang=E](http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E).

115. Saez, *Access to Vaccines*, *supra* note 102 (quoting Saez in her discussion of Plotkin's commentary).

116. The literature has not focused much on this specific issue, perhaps because WHO-participating labs have not done much patenting in this arena in the past, there is little research on current patenting behavior, or it has been hard to trace such activity. *See generally* Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539, 1618–20 (2017). However, outside laws or agreements notwithstanding, if seasonal influenza were under the PIP Agreement, SMTA 1's non-patenting standards would apply to it. This issue has been discussed in relation to genetic sequence data, however, which could be used to develop vaccines generally. *See, e.g.*, IMPLEMENTATION OF DECISION WHA70(10) 8(B) EVIDENCE FOR "SCOPING PAPER ON APPROACHES TO

WHO-participating research laboratories, because only laboratories sign the intellectual property agreement that restricts viral patenting.<sup>117</sup>

The notion that a virus can be patented may seem odd for some readers, but it is, in fact, an option in many countries.<sup>118</sup> The patentability of viruses in the United States has recently come under debate, but in certain ways, virus-related material has been patentable for years in our country<sup>119</sup> and in others.<sup>120</sup> Dana Beldiman explains that some courts “have viewed isolated genes as [distinct] from what exists in nature and considered them patent eligible. Other jurisdictions view isolated genes as patentable even if they are similar to what exists in nature, albeit only if a specific useful function can be articulated.”<sup>121</sup>

Patenting viral material helps industries to safeguard their own research and increase their profits by, for example, licensing out their products for a fee.<sup>122</sup> And in the case of seasonal influenza, where manufacturers may work with only slightly different virus strains each year, holding broad patents on virus-related material could protect research even as viruses change.<sup>123</sup> The

*SEASONAL INFLUENZA AND GENETIC SEQUENCE DATA UNDER THE PIP FRAMEWORK* (“SCOPING PAPER”) A17 (2017), <http://www.who.int/influenza/pip/seasonalcompilation.pdf?ua=1> [hereinafter EVIDENCE FOR SCOPING PAPER].

117. See *supra* Section III.B.

118. See Andre Mayer, *Can You Patent a Disease?*, CBC NEWS, <http://www.cbc.ca/news/health/can-you-patent-a-disease-1.1355379> (last updated June 12, 2013).

119. The United States, for example, holds a patent on the Ebola Virus. See Human Ebola Virus Species and Compositions and Methods Thereof, U.S. Patent No. 2012/0251502 A1 (issued Oct. 4, 2012).

120. Claudio Chiarolla, *Intellectual Property Rights and Benefit Sharing from Marine Genetic Resources in Areas Beyond National Jurisdiction: Current Discussions and Regulatory Options*, 4 QUEEN MARY J. INTELL. PROP. 171, 176–77 (2014). (“In the United States, three categories of inventions are non-patentable: laws of nature, natural phenomena, and abstract ideas [based on the ‘Product of nature doctrine’]. The boundaries of such doctrine are routinely tested in disputes that concern the patentability of DNA and its alleged positive or stifling effects on biological innovation. In addition to the United States, Australia, Canada, Indonesia, Japan, Singapore and the 18 Member States of the African Regional Intellectual Property Organization generally allow full patentability of animals, plants and biological processes without particular restrictions.”)

121. Beldiman, *supra* note 101, at 41.

122. *Scientists Race to Patent SARS Virus*, NBC NEWS (last updated Nov. 4, 2003), [http://www.nbcnews.com/id/3076748/ns/health-infectious\\_diseases/t/scientists-race-patent-sars-virus/#.WC0OjfkK8](http://www.nbcnews.com/id/3076748/ns/health-infectious_diseases/t/scientists-race-patent-sars-virus/#.WC0OjfkK8).

123. See EDWARD HAMMOND, SOME INTELLECTUAL PROPERTY ISSUES RELATED TO H5N1 INFLUENZA VIRUSES, RESEARCH, AND VACCINES, THIRD WORLD NETWORK 1, 8 (2009), <https://www.twm.my/title2/IPR/pdf/ipr12.pdf> (“The changeable nature of influenza has led some research groups, including at least one major company (Merck), to seek new influenza vaccines that do not rely on particular HA or NA sequences. Others have laid claim to sequences and any other sequence that is similar, for example, 90% or more of the same. At least one other has responded by attempting to patent large numbers of varying HA and NA genes.”).

only problem with this, of course, is that the bonuses of virus patenting do not go to industry collectively but to the companies with the power to patent their inventions the quickest. As flu viruses, vaccines, and other technologies become patented more frequently, patent thickets can emerge,<sup>124</sup> making it harder for small vaccine manufacturers to acquire all of the licenses necessary to produce their own vaccines.<sup>125</sup> Extending the PIP Framework to seasonal flu, on the other hand, will create an open network of unpatented seasonal flu viruses that will facilitate global flu research among *all* manufacturers: not just the biggest corporations.

#### *D. Public Health Argument 1: Unraveling Progress*

One concern raised by a nonprofit organization called the Third World Network was that expanding the PIP Framework to include seasonal influenza would potentially undo WHO's progress by requiring an overhaul of the Framework itself.<sup>126</sup> This concern was partially echoed by GISAID in a 2016 PIP Framework commentary:

It should be remembered that agreement to the PIP [Framework] was only possible by the exclusion of seasonal influenza viruses, given the likely complications and potential disadvantages [it would have created for] the well-established operational GISRS sharing and benefit system, and [the confusion it would have caused] between epidemic seasonal influenza and the special health emergency of an influenza pandemic.<sup>127</sup>

These comments suggest that there is general concern about expanding the Framework, whether because there is a fear that parties will not agree to

124. Beldiman, *supra* note 101, at 35 (“[Patent thickets] result in a suboptimal functioning of the patent system and exacerbate the natural process of narrowing of the number of players who place product on the market. The end effect may be a single-player or even a no-player scenario at the commercialization stage, a result that cannot support the Framework’s availability and affordability objectives.”).

125. *See id.* at 48.

126. WHO, *2016 Review Webcast*, *supra* note 95, at 1:03:45.

127. GISAID’S COMMENTS ON THE PRELIMINARY FINDINGS OF THE PIP FRAMEWORK REVIEW GROUP 2016 (2016) [http://platform.gisaid.org/epi3/app\\_entities/entities/downloads/gisaid\\_comments\\_pip\\_rg\\_prelim\\_findings.pdf](http://platform.gisaid.org/epi3/app_entities/entities/downloads/gisaid_comments_pip_rg_prelim_findings.pdf).

it or because changing the Framework could be difficult. These concerns, however, seem to be speculative. The United States and Australia, for example, have expressed openness to framework expansion discussion.<sup>128</sup> Notably, there is a concern that laboratories would deal with significant additional paperwork and tracking issues under an expanded Framework,<sup>129</sup> but WHO partners can certainly look into building local GISRS tracking infrastructure or crafting the extension in a way that makes tracking easier or less cumbersome for seasonal flu strains than for pandemic flu.<sup>130</sup>

*E. Public Health Argument 2: Not Strong Enough for the Nagoya Protocol*

The Nagoya Protocol is an international agreement adopted in 2010 that commits countries to share genetic resources in a manner that promotes access equity.<sup>131</sup> It is unclear whether the PIP Framework might exempt pandemic flu genetic material from the requirements of the Nagoya Protocol.<sup>132</sup> An industry representative at the August 2016 PIP Framework meeting brought forth an argument against Framework expansion that was connected to the Nagoya Protocol. She explained,

we do not think that including seasonal influenza into the PIP Framework will solve the issue of [the] Nagoya Protocol. First of all, it's . . . [a] voluntary framework, so it probably will not provide the legal certainty that might be needed. Second of all, WHO GISRS could be elevated itself to provide some level of certainty.<sup>133</sup>

This sentiment has been echoed elsewhere, and to some groups, the question of the Nagoya Protocol is the main issue to consider in deciding

128. See EVIDENCE FOR SCOPING PAPER, *supra* note 116, at 8. Note that Norway, and potentially other countries, appear to oppose PIP Framework expansion, although it is unclear whether this opinion might change if the Framework were expanded in a way that would not overload GISRS. See *id.* at 8.

129. SCOPING PAPER, *supra* note 86, at 7.

130. See WHO, 2016 Review Webcast, *supra* note 95, at 1:04:22 (presenting a similar idea).

131. *About the Nagoya Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, <https://www.cbd.int/abs/about/#objective> (last visited Nov. 16, 2016).

132. SCOPING PAPER, *supra* note 86, at ¶¶ 18–19.

133. WHO, 2016 Review Webcast, *supra* note 95, at 53:19.

whether or not to extend the PIP Framework to cover seasonal influenza.<sup>134</sup> The idea that the PIP Framework could do more to approach the standards of the Nagoya Protocol and generally explain the roles of participating entities more clearly is certainly true. For example, the intellectual property protections that the PIP Framework provides have been considered ambiguous in recent scholarship,<sup>135</sup> and those protections could be clarified and strengthened.

However, strengthening the Framework to match the demands of the Nagoya Protocol is a different (albeit related) issue than that of expanding the Framework to include seasonal influenza. Perhaps the PIP Framework can be simultaneously strengthened and extended to seasonal influenza. In so doing, countries would not feel confused about which standards—the Nagoya Protocol’s or the PIP Framework’s—would need to be followed in donating different kinds of viral flu material to GISRS.<sup>136</sup>

#### F. *The Marketing Argument: LMICs Don’t Care.*

One of the other arguments brought up at the August 2016 meeting against expanding the seasonal influenza framework was that “[i]n some regions, there is really no demand” for seasonal flu vaccines.<sup>137</sup> This argument was echoed by Adam Kamradt-Scott and Kelley Lee, who explained that major pharmaceutical companies are often located in wealthy countries because LMICs are focused on more pressing illnesses than seasonal flu and lack the money to purchase vaccines.<sup>138</sup>

In all practicality, though, as long as seasonal influenza kills vulnerable populations around the globe, there will be a *potential* market for seasonal influenza vaccines. And in countries like Madagascar, where a 2002 seasonal flu epidemic “had a case-fatality rate of 3% as compared to <0.1% in other influenza pandemics,” and the Congo, where an influenza outbreak had an

134. See, e.g., SEASONAL INFLUENZA COMMENTS, *supra* note 94, at 1, 3.

135. See Beldiman, *supra* note 101, at 40 (“The meaning of the term ‘materials’ in [SMTA 1] is ambiguous: Does the prohibition against obtaining IP rights merely cover the sample’s physical layer or does it extend to its informational layer, including its DNA structure?”).

136. See EVIDENCE FOR SCOPING PAPER, *supra* note 116, at S15.

137. WHO, *2016 Review Webcast*, *supra* note 95, at 47:53 (stated by an industry representative).

138. Adam Kamradt-Scott & Kelley Lee, *The 2011 Pandemic Influenza Preparedness Framework: Global Health Secured or a Missed Opportunity?*, 59 *POLIT. STUD.* 831, 836–37 (2011).



even higher case-fatality rate among children under five years old, that market condition is clearly being met.<sup>139</sup>

Therefore, if the market demand appears to be low, it is not due to a lack of need but likely due to other problems, like a lack of awareness about the benefits of the flu shot or insufficient funds to pay for one. The first can be corrected through public health education, and the second by marketing the vaccine at affordable rates. If WHO partners make an effort to educate the public in developing nations about seasonal flu vaccines and find a way to bring seasonal vaccines to them at prices they can afford, the public will likely respond. In fact, as WHO notes, “an increasing number of low and middle income countries situated in the tropics and subtropics have considered introducing or expanding seasonal influenza vaccination in their national immunization program.”<sup>140</sup> And because the PIP Framework essentially eliminates licensing fees tied to basic viral applications<sup>141</sup> and allows industry to contribute benefits to LMICs in a variety of ways, it should be possible for industry to help find creative ways to provide vaccines in these areas that are more reasonably priced.

In short, it is true that the PIP Framework is primarily a public health tool for promoting fair and sustainable trading among nations. However, as previously noted, a program that promotes global health also promotes global economy, trade, and stability by extension. By expanding the PIP Framework to include seasonal influenza, adjustments will definitely be required. However, if negotiated appropriately, this effort could go a long way toward improving the global vaccine industry, global health, and the economy overall. Based on the arguments that have been discussed here, WHO should consider extending the PIP Framework to include seasonal influenza.

#### IV. FURTHER CONSIDERATIONS

The question of whether or not to extend the PIP Framework to include seasonal influenza is a simple one, in the sense that it will eventually be resolved through a “yes/no” answer. However, in answering that question, WHO will find itself asking others, such as: “How do we extend the

139. *Africa Flu Alliance*, WORLD HEALTH ORG., [http://www.who.int/influenza/preparedness/africa\\_flu/en/](http://www.who.int/influenza/preparedness/africa_flu/en/) (last visited Feb. 28, 2018).

140. *Influenza Vaccine in Tropics and Subtropics*, WORLD HEALTH ORG., <http://www.who.int/influenza/vaccines/tropics/en/> (last visited Feb. 23, 2018).

141. See generally Beldiman, *supra* note 101, at 34.

Framework?” “Should the Framework’s intellectual property protections be improved generally?” And, “What is our philosophy moving forward on the role of public health in international vaccine policy?” In this section, I will briefly address each of these questions.

First, in extending the Framework, WHO would have some flexibility in implementation: it could extend the PIP Framework itself or develop a linked Framework just for seasonal influenza, it could add many seasonal flu benefits sharing options to SMTA 2 or just a few, and it could choose whether to implement the Framework’s changes all at once, in stages, or through a pilot program.<sup>142</sup>

Second, while considering Framework extension, WHO will likely consider strengthening and clarifying its IP protections as a whole. Dana Beldiman has, for example, suggested creating patent pool systems within the WHO network that cover vaccine-related technologies to prevent further patent thickets from forming.<sup>143</sup> Alternatively, an industry representative has suggested building “certainty” into the Framework,<sup>144</sup> and this could be done in part by making the IP neutrality provision of the PIP Framework more concrete.<sup>145</sup> For example, the agreement could specify whether or to what extent variations or derivatives of viral material can be patented by WHO laboratories under SMTA 1. The discussion of how WHO should specifically build upon its current IP framework is beyond the scope of this paper. However, in general, if WHO does decide to move forward with PIP Framework extension, it should consider extension an opportunity to make the current flu virus sharing network more open and collaborative as a whole.

Third, in moving forward, WHO will need to reconsider its view on the role that public health plays in vaccine agreements. The stakeholders that WHO has worked with during this process have represented the needs of business, research, and public health. However, the interests of these stakeholders have frequently clashed in discussions. Obviously, WHO cannot afford to ignore or discount any of these perspectives. However, WHO, as an institution dedicated to public health, might do well to frame future efforts in the IP arena as a promotion of long-term international economic growth by promoting international health and well-being.

142. See WHO, *2016 Review Webcast*, *supra* note 95, at 1:04:22 (a few of these ideas are expressed).

143. See *id.*; Beldiman, *supra* note 101, at 54–61.

144. WHO, *2016 Review Webcast*, *supra* note 95, at 53:37.

145. See Beldiman, *supra* note 101, at 40.

## CONCLUSION

Intellectual property can be used as a tool to further important public health and business goals simultaneously, especially in the global virus-sharing context. Seasonal influenza is a pervasive public health problem that can have far-reaching effects on human life and on the economy. However, laboratories within WHO can currently patent seasonal flu viruses, which can create dangerous monopolies and roadblocks in vaccine research and development. Protecting the open access nature of seasonal flu virus sharing and providing seasonal flu donor countries with seasonal flu products, licenses, and technologies can boost industry and protect global health. WHO should consider not only extending the PIP Framework to seasonal flu but also making its provisions stronger.