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Order without Intellectual Property Law : Open Science in Influenza

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ORDER WITHOUT INTELLECTUAL PROPERTY LAW: OPEN SCIENCE IN INFLUENZA

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Today, intellectual property (IP) scholars accept that IP as an approach to information production has serious limits. But what lies beyond IP? A new literature on "intellectual production without IP" (or "IP without IP") has emerged to explore this question, but its examples and explanations have yet to convince skeptics. This Article reorients this new literature via a study of a hard case: a global influenza virus-sharing network that has for decades produced critically important information goods, at significant expense, and in a loose-knit group—all without recourse to IP. I analyze the Network as an example of "open science," a mode of information production that differs strikingly from conventional IP, and yet that successfully produces important scientific goods in response to social need. The theory and example developed here refute the most powerful criticisms of the emerging "IP without IP" literature, and provide a stronger foundation for this important new field. Even where capital costs are high, creation without IP can be reasonably effective in social terms, if it can link sources of funding to reputational and evaluative feedback loops like those that characterize open science. It can also be sustained over time, even by loose-knit groups and where the stakes are high, because organizations and other forms of law can help to stabilize cooperation. I also show that contract law is well suited to modes of information production that rely upon a "supply side" rather than "demand side" model. In its most important instances, "order without IP" is not order without governance, nor order without law. Recognizing this can help

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us better ground this new field, and better study and support forms of knowledge production that deserve our attention, and that sometimes sustain our very lives.

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INTRODUCTION

In August 1997, a three-year-old boy was admitted to a hospital in Hong Kong, critically ill. Tests showed that he had influenza, a virus that has circulated in humans for thousands of years.[1] Far more striking was the *type* of flu that he had contracted—an avian type, H5N1, that had never before been seen in humans.[2]

While Ebola and Zika have more recently captured the headlines, there is no existing virus more dangerous than influenza.[3] In 1918-1920, a flu pandemic killed an estimated 50 to 100 million people around the world, most of them young adults.[4] A similar pandemic today could take the lives of hun-

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1 Christopher W. Potter, *Chronicle of Influenza Pandemics*, *in* TEXTBOOK OF INFLUENZA 3, 3 (Karl G. Nicholson et al. eds., 1998).

2 J.C. de Jong et al., *A Pandemic Warning?*, 389 NATURE 554, 554 (1997).

3 Michael T. Osterholm, *Preparing for the Next Pandemic*, 84 FOREIGN AFF. 24, 26 (2005) ("[O]f the more than 1,500 microbes known to cause disease in humans, influenza continues to be the king in terms of overall mortality."). *See also* Sonia Shah, *Is Bird Flu Back?*, N.Y. TIMES, Feb. 7, 2016, at 6 (noting that the H5N1 pandemic of 2009 killed an estimated 200,000 people).

4 *See, e.g.*, K. David Patterson & Gerald F. Pyle, *The Geography and Mortality of the 1918 Influenza Pandemic*, 65 BULL. HIST. MED. 4, 19 (1991).

dreds of thousands and perhaps millions of people in the United States alone.[5]

Influenza pandemics occur when radically new strains that evade our immunities emerge and become transmissible between humans.[6] The new avian strain, therefore, was of major concern to influenza scientists.[7] The one institution most critical to our ability to respond to it is a little-known network called the World Health Organization's "Global Influenza Surveillance and Response Network," or "GISRS"[8] (here, simply "the Flu Network" or the "Network").

The flurry of activity that followed the emergence of H5N1 shows the work of the Network at its most dramatic. Immediately after the boy was hospitalized, scientists from two Network Collaborating Centers were sent as a rapid response team to Hong Kong.[9] Working with local authorities and a WHO Task Force, the team traced the virus to poultry in northern Hong Kong, and traced the boy's contacts to determine whether he had recently had contact with sick chickens.[10] More cases soon emerged, and new evidence suggested that the virus provoked a catastrophic immune response in humans, frequently causing organ failure and death.[11] Investigators worked exhaustively, putting in eighteen-hour days, knocking on doors, tracing contacts, and gathering blood, sputum, and chicken

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5 U.S. DEP'T OF HEALTH & HUMAN SERVS, HHS PANDEMIC INFLUENZA PLAN 18 (Nov. 2005).

6 *See infra* Part I.

7 Michael Rosenwald, *The Flu Hunter*, SMITHSONIAN, Jan. 2006, at 183, 184–85.

8 Typically pronounced "gis–ris."

9 *See* Gretchen Reynolds, *The Flu Hunters*, N.Y. TIMES, Nov. 7, 2004, at 41–42. *See also* René Snacken et al., *The Next Influenza Pandemic: Lessons from Hong Kong, 1997*, 5 EMERGING INFECTIOUS DISEASES 195, 197 (1999) ("Investigation of the circumstances surrounding each case was undertaken by the local authorities with assistance from the World Health Organization Collaborating Centers in the United States and Japan."); *id.* (noting that a WHO Task Force initiated a "technical investigation and evaluation of the Hong Kong situation," and that a small staff from Japan and the US "join[ed] local authorities in collecting information needed for risk assessment"); *see also infra* p. 126 (describing the role of Collaborating Centers in the Network).

10 *See* Reynolds, *supra* note 9, at 42 (describing the investigation); Snacken et al., *supra* note 9, at 197 (describing the Task Force). Contact tracing helps determine whether the virus has become transmissible between people, which can inaugurate a new pandemic. *See* Reynolds, *supra* note 9, at 39.

11 K. Y. Yuen et al., *Clinical Features and Rapid Viral Diagnosis of Human Disease Associated with Avian Influenza A H5N1 Virus*, 351 LANCET 467, 469–70 (1998).

droppings.[12] They shipped virus samples on dry ice to the Network's labs in Atlanta, Melbourne, London, and Tokyo for analysis. The scientists at those labs too worked late into the night, analyzing the thousands of samples shipped to them and beginning the work needed to develop a vaccine.[13]

The virus was not yet transmissible between humans, but given how deadly it was, it was critical to slow the process by which it could reproduce and mutate. The scientific team recommended that every chicken in Hong Kong be slaughtered, and the government agreed.[14] In four days, 1.5 million chickens were killed, effectively ending the epidemic in poultry, and H5N1 in humans, in the city.[15] The moment was a dramatic success for the Flu Network.[16]

Though it is almost unknown, the WHO's Flu Network is critically important to global health. It provides our global architecture for predicting and responding to pandemic flu, and it also plays a central role in our response to seasonal flu, which is a major public health concern in its own right.[17] The Flu Network collects and examines millions of virus samples a year, chooses the virus strains that go into flu vaccines, and helps to refine seed viruses that are used to manufacture the seasonal flu vaccine every year. If you have been vaccinated against the flu, the Network, in a sense, is a part of you. Your immune system carries its traces around.

A study of the Flu Network is valuable not only because of its critical importance to global health. The Network also provides a pivotal example for current intellectual property (IP) scholarship. IP scholarship has for decades been centered on a simple account: IP is necessary to achieve the information pro-

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12 Patricia Guthrie, *CDC Virus Fighters Go Where the Action Is*, ATLANTA J. CONST., http://www.cdc.gov/excite/careers/fighters.htm [https://perma.cc/UX7J-R9DD] (last visited Aug. 2, 2014); Reynolds, *supra* note 9, at 42.

13 Guthrie, *supra* note 12.

14 Reynolds, *supra* note 9, at 38; Rosenwald, *supra* note 7, at 184; Miriam Shuchman, *Improving Global Health—Margaret Chan at the WHO*, 356 NEW ENG. J. MED. 653, 655 (2007).

15 Kelvin K.W. To et al., *The Emergence of Influenza A H7N9 in Human Beings 16 Years After Influenza A H5N1: A Tale of Two Cities*, 13 LANCET INFECTIOUS DISEASES 809, 818 (2013).

16 Aleksandr S. Lipatov et al., *Influenza: Emergence and Control*, 78 J. VIROLOGY 8951, 8955 (2004); Shuchman, *supra* note 14, at 654–55.

17 In the United States, for example, seasonal influenza causes, on average, tens of thousands of deaths each year. *See* William W. Thompson et al., *Mortality Associated with Influenza and Respiratory Syncytial Virus in the United States*, 289 JAMA 179, 185 (2003); William W. Thompson et al., *Influenza-Associated Hospitalizations in the United States*, 292 JAMA 1333, 1333–34 (2004).

duction that we as a society desire.[18] But over the last few years, the field has come to recognize that IP as an approach has both significant costs and substantial limits.[19] In response, an important new scholarly literature on "intellectual production without intellectual property," or "IP without IP" has emerged.[20]

This new literature has two primary strands. The "norms-based" strand argues that norms sometimes provide a viable alternative to formal intellectual property law.[21] Case studies

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18 *See, e.g.*, ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 11–17 (6th ed. 2012) (summarizing the standard efficiency-based justification for IP); *see also id.* at 11 (describing this as "the dominant paradigm for analyzing and justifying the various forms of intellectual property protection); *infra* Part I. I use the term "information" here in the sense in which it is used in the IP and economics literature, to refer to a broad range of immaterial resources, from scientific formulas and data, to cultural products in their intangible form (for example, musical compositions or the text of a novel).

19 For example, IP can be costly because exclusive rights in information can be extraordinarily hard to define, trace, and value, making transaction problems a still more serious issue here than they are in the realm of tangible property. It is limited because it covers only some intellectual goods and indeed cannot be extended symmetrically across different kinds of information goods. *See infra* Part I.

20 Mario Biagioli coined the term "IP Without IP," but it was made salient by Rochelle Dreyfuss. *See* Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 CARDOZO L. REV. 1437, 1437 n.*, 1439 (2010).

21 *See, e.g.*, Emmanuelle Fauchart & Eric von Hippel, *Norms-Based Intellectual Property Systems: The Case of French Chefs*, 19 ORG. SCI. 187, 187 (2008) (arguing that norms-based IP is used by French chefs to protect new recipes); Dotan Oliar & Christopher Sprigman, *There's No Free Laugh (Anymore): The Emergence of Intellectual Property Norms and the Transformation of Stand-Up Comedy*, 94 VA. L. REV. 1787, 1809–12 (2008) (arguing that comedians' social norms offer significant protection for creators' incentives to produce new content); *see also* David Fagundes, *Talk Derby to Me: Intellectual Property Norms Governing Roller Derby Pseudonyms*, 90 TEX. L. REV. 1094, 1146 (2012) (discussing extralegal regulation in roller derbies); Jacob Loshin, *Secrets Revealed: Protecting Magicians' Intellectual Property Without Law*, *in* LAW AND MAGIC: A COLLECTION OF ESSAYS 123 *passim* (Christine A. Corcos ed., 2010) (describing the role of norms in sustaining creation among magicians); Aaron Perzanowski, *Tattoos & IP Norms*, 98 MINN. L. REV. 511, 577–84 (2013) (explaining why tattooers "have opted consistently for informal social norms rather than the formal property-like rules of copyright law"). This strand has been strongly influenced by the work of law and norms scholars. *See, e.g.*, Lisa Bernstein, *Opting Out of the Legal System: Extralegal Contractual Relations in the Diamond Industry*, 21 J. LEGAL STUD. 115, 124–30 (1992) (discussing the diamond industry's reliance on internal norms and procedures to handle disputes); ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES 176–78 (1991) (discussing how neighbors often settle disputes outside of courts). The norms-based IP without IP literature should be distinguished from a contiguous literature that questions the need for IP in various industries, such as fashion, but that does not invoke norms as an alternative means to support creative work. *See* Christopher J. Buccafusco, *On the Legal Consequences of Sauces: Should Thomas Keller's Recipes Be Per Se Copyrightable?*, 24 CARDOZO ARTS & ENT. L. J. 1121, 1155 (2007); Kal Raustiala & Christo-

in this vein have shown that groups such as magicians, stand-up comedians, and French chefs successfully create immaterial goods, relying on informal norms that typically resemble IP rights and that are backed up by reputational sanctions.[22] A second "commons-based" strand of this literature has emerged from Yochai Benkler's work.[23] Drawing on examples such as open source software and Wikipedia, Benkler argues that the advent of networked digital computers has unleashed the potential for more open and collaborative forms of information production.[24] He describes commons-based production as driven primarily by social motivation and/or strategies of indirect appropriation.[25] It operates, he argues, via emergent cooperation and involves "rare use of formal processes; never of law or managerial fiat."[26]

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pher Sprigman, *The Piracy Paradox: Innovation and Intellectual Property in Fashion Design*, 92 VA. L. REV. 1687, 1718–32 (2006). These studies focus not on norms, but on special qualities of particular creative goods or markets that make low-IP environments a stable equilibrium.

22 For example, one such account focuses on magicians, who invent new magic tricks with regularity, although IP law provides little effective protection for such tricks. The secret, the author argues, is in the informal norms that stand in for—and seem to closely track—formal IP law. These norms, for example, forbid the copying of tricks created by others, unless the tricks have been widely shared, published, or sold. There is also a strong norm against revealing the secrets of magicians to non-magicians. Violations of these norms can result in serious reputational harm, and forms of retaliation, such as "not be[ing] invited to give lectures, . . . perform in magic competitions, or [feature] in trade publications." Loshin, *supra* note 21, at 138.

23 *See* YOCHAI BENKLER, WEALTH OF NETWORKS (2006); Yochai Benkler, *Coase's Penguin, or, Linux and* The Nature of the Firm, 112 YALE L.J. 369 (2002). The banner of the commons has been taken up by many, and most prominently by Madison, Frischmann, Strandburg. *See* Michael Madison, Brett M. Frischmann & Katherine J. Strandburg, *Constructing Commons in the Cultural Environment*, 95 CORNELL L. REV. 657 (2010).

24 BENKLER, *supra* note 23, at 99–102. Benkler also refers to this mode as "peer production," which is characterized by "peers who interact and collaborate without being organized on either a market-based or a managerial/hierarchical model." Benkler, *Coase's Penguin*, *supra* note 23, at 381.

25 *See id.* at 424–25; BENKLER, *supra* note 23, at 99. Indirect appropriation facilitates the more open forms of production that Benkler describes in market settings, such as when lawyers or open-source software firms sell services without asserting exclusive rights over the information produced in the process. Benkler, *Coase's Penguin*, *supra* note 23, at 424–25.

26 Yochai Benkler, *Commons and Growth: The Essential Role of Open Commons in Market Economies*, 80 U. CHI. L. REV. 1499, 1554 (2013). Elsewhere he recognizes that open source software licenses may play an important role in stabilizing cooperation. *See* Benkler, *Coase's Penguin*, *supra* note 23, at 445 ("This commitment would require specific licenses that secure access to work over time to everyone, including contributors."). Implicitly, he suggests that this is not reliance on law in some sense, because it seeks only to secure the commons from incursions from IP, so that in a world without IP, open source software might not require even this form of recourse to law. *See id.*

Skeptics, however, have remained unpersuaded that this emerging literature reveals a robust or important alternative to IP. They argue that the norms-based strand focuses on "niche" settings, where the value of information is low and where groups are close-knit.[27] If groups are large or loose-knit, and/or where asset values or capital costs are high, in turn, they argue that "IP without IP" will "tend to be replaced by property-based arrangements."[28] They contend, drawing on the existing law and norms literature, that a system that relies on norms backed up by reputational sanctions will work well only if people are closely enough connected to one another to observe rule-breaking and to care about their reputation in the group. If the information goods being produced have more value, then participants may also have stronger incentives to defect. If capital costs are high, self-funding will be difficult. But without property, groups may have difficulty accessing external funding. If, however, "IP without IP" can only operate in these settings, then it truly may be a "niche" phenomenon that does not deserve substantial attention.

The "commons-based" strand identifies more valuable forms of creation that often emerge from large and dispersed groups. But here too, capital costs tend to be low. With its focus on intrinsic motivation and technology, the commons-based literature also arguably offers a too-rosy conception of unmediated social cooperation.[29] Critics point out that such

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27 *See* Robert P. Merges, *Economics of Intellectual Property Law*, *in* OXFORD HANDBOOK OF LAW AND ECONOMICS, at *7 (Francesco Parisi ed., forthcoming), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2412251 [https://perma.cc/EAE4-UFWW]; *see also* Jonathan M. Barnett, *The Illusion of the Commons*, 25 BERKELEY TECH. L.J. 1751, 1755 (2010) (arguing that "the sharing model works in settings that are small in scale, size, value, and diversity"). The term "close-knit" is important to the law and norms literature, because it describes the conditions under which individuals, acting informally, are thought to be able to enforce norms successfully. While it sometimes is taken to describe the small size of a group, more accurately understood, a group is close-knit "when informal power is broadly distributed among group members and the information pertinent to informal control circulates easily among them." ELLICKSON, *supra* note 21, at 177–78; *see also* Lior Jacob Strahilevitz, *Social Norms from Close-Knit Groups to Loose-Knit Groups*, 70 U. CHI. L. REV. 359, 359–360 (2003) (citing Ellickson's definition and contrasting close-knit groups with loose-knit groups).

28 Barnett, *supra* note 27, at 1755; *see also* Merges, *supra* note 27, at *7 ("[O]nce groups grow beyond a certain size, and the economic value of their activities passes some threshold, informal norms cease to work.").

29 *See, e.g.*, David A. Hoffman & Salil K. Mehra, *Wikitruth through Wikiorder*, 59 EMORY L.J. 151, 155 (2009) (arguing that work on commons-based peer production "generally ha[s] not articulated a mechanism that would coordinate such altruistic production"); Lior Jacob Strahilevitz, *Review: Wealth Without Markets?*, 116 YALE L.J. 1472, 1493–95 (2007) (arguing that Benkler does not "adequately confront" the problem that commons-based communities are vulnerable to mali-

systems do not address the power of bad actors—or "trolls"—to sabotage cooperation.[30] They argue that market-proprietary production is better able to discipline such actors and so is more durable.[31] Contemporary empirical accounts of several of the leading examples from the commons literature also show them as more complex and fraught than first supposed. Wikipedia today, for example, is governed by an extraordinary array of rules and sanctions, and has an active and formal internal dispute settlement system.[32]

Finally, both strands of the "IP without IP" literature have not clearly confronted the most analytically powerful aspect of the market-based account: the claim that markets not only produce information but also direct investments *appropriately* toward collective social aims. The canonical defense of IP is that it directs investment "efficiently," because it permits dispersed market signals of preference to drive investments in new information.[33] The strong version of this argument is clearly problematic, given both the long-standing critiques of efficiency as a value[34] and the pervasive problem of market failures in information production.[35] But the canonical defense of IP *does* at least respond to the normative sensibility that underpins the field: innovative activities should both be reasonably effective and serve socially defined priorities.[36]

Magicians and comedians produce creative works, to be sure, but do they produce enough of them, or the right kind, from a social perspective? The norms literature has largely

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cious users). This is perhaps particularly so given what we know about the preconditions of cooperation in the tangible commons. *See* the Ostrom discussion *infra* Part IV.

30 Strahilevitz, *supra* note 29, at 1495; Hoffman & Mehra, *supra* note 29, at 160.

31 Strahilevitz, *supra* note 29, at 1495.

32 *See* DARIUSZ JEMIELNIAK, COMMON KNOWLEDGE? AN ETHNOGRAPHY OF WIKIPEDIA 17–22, 29–84 (2014).

33 *See infra* notes 74–75; 81–82.

34 *See, e.g.*, Ronald M. Dworkin, *Is Wealth a Value?*, 9 J. LEGAL STUD. 191, 200–01 (1980) (providing a normative critique of wealth maximization).

35 *See* Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 981–93 (2012).

36 These values are typically understood as welfarist in nature. *See* William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168, 177 (Stephen R. Munzer ed., 2001). In the United States in particular, the field is structured by collective priorities rather than, say, conceptions of authors' rights. *See, e.g.*, MERGES ET AL., *supra* note 18, at 11–12 (making this point and suggesting that this value inheres in the U.S. Constitution).

ignored the question.[37] If commons-based peer production is driven in significant part by individual motives, may it sometimes produce the wrong kinds of goods from a social perspective? The commons literature tends to assume this question away by describing commons-based creation as "intrinsically" or "socially" motivated.[38]

To counter critics, the field needs examples of "IP without IP" that are capital intensive and produce valuable social goods. The most informative examples will involve loose-knit groups that are able to sustain cooperation over time, despite threats from within and without. The most normatively attractive instances of "IP without IP" will also have mechanisms to link investment to social aims.

This Article describes just such a case.[39] The Flu Network is capital intensive, produces goods of enormous social value, and has operated successfully for decades without any significant recourse to intellectual property rights. It has succeeded despite its global reach and loose-knit nature,[40] and despite significant internal conflict, including a recent crisis so significant that the Network nearly collapsed. That crisis triggered

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37 Many of the central contributions in the literature do not address allocation at all. *See* Fagundes, *supra* note 21; Fauchart & von Hippel, *supra* note 21; Loshin, *supra* note 21. *But see* Oliar & Sprigman, *supra* note 21, at 1856–57 (noting that the informal IP regime encourages jokes that are "point-of-view" driven and so harder to steal). The leading examples in the literature focus on information goods produced in market settings, such as comedy clubs and restaurants, and presumably would draw upon the same normative defense that the market-exclusionary account draws on, that links market signals to social value. But at times they also invoke intrinsic motivations, and could be read to suggest that there are other values at stake in the system (the transcendence of art, for example) that also shape its productive output. They also tend to say little about the potential problem that without property, the goods in question may be produced but in inadequate supply. *But see, e.g.*, Oliar & Sprigman, *supra* note 21, at 1858–59 (implying that a greater role for formal IP in comedy might have little net effect on the amount of comedy produced, because it would increase returns but also transaction costs).

38 This tends to obscure the reality of social conflict and hierarchy, as well as a tendency for individuals and groups to have particular—and sometimes exclusive—interests. Many more of Wikipedia's editors are men than women, and from the global North rather than the South, likely contributing to significant gendered and geographic disparities in coverage. *See, e.g.*, Tom Simonite, *The Decline of Wikipedia*, 116 MIT Tech. Rev. 51, 52 (2013) ("Among the significant problems that aren't getting resolved is the site's skewed coverage: its entries on Pok[é]mon and female porn stars are comprehensive, but its pages on female novelists or places in sub-Saharan Africa are sketchy."); Wikipedia, *Gender Bias*, https://en.wikipedia.org/wiki/Gender_bias_on_Wikipedia [https://perma.cc/CYH7-GHLS] (last visited Sept. 8, 2016).

39 For more on the value of the case study approach and the methods that I use here see Appendix A.

40 *See infra* subpart III.B.

years of high-level diplomatic negotiations and led to legal agreements that provide an exceptionally good window into the norms and rules that are central to the Network's success.[41]

The Flu Network, as I will describe, works via a distinct model of information production that we can call "open science." Although a schematic description of open science has existed for several decades, the model has received almost no attention in the legal literature.[42] In open science, those making new discoveries freely share them rather than excluding others. In exchange, they earn reputational credit, which in turn can lead to increased funding and salary. Information sharing allows scientists to judge the quality of one another's

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41 This conflict also provides methodological advantages, because it facilitates "process tracing." *See* Appendix A.

42 The foundations of the open science system were first described by the sociologist Robert Merton, who famously emphasized the importance of priority and sharing to scientific work. *See generally* Robert K. Merton, *Priorities in Scientific Discovery: A Chapter in the Sociology of Science*, 22 AM. SOC. REV. 635, 645–46 (1957) (making these points). Drawing directly on Merton's work, Partha Dasgupta and Paul David proposed a schematic model of open science two decades ago. *See* Partha Dasgupta & Paul A. David, *Toward a New Economics of Science*, 23 RES. POL'Y 487, 499 (1994). Their model has been invoked sporadically in the legal literature, but has never received sustained attention. *See, e.g.*, Bernardita Escobar Andrae, *Scientific Productivity and Gender Performance Under Open and Proprietary Science Systems: The Case of Chile in Recent Years*, 19 AM. U. J. GENDER SOC. POL'Y & L. 799, 799–800 (2011) (briefly describing Dasgupta and David's account of open science); Jorge L. Contreras, *Data Sharing, Latency Variables, and Science Commons*, 25 BERKELEY TECH. L.J. 1601, 1622 (2010) (citing David's concept of open science in passing); Dan M. Kahan, *The Logic of Reciprocity: Trust, Collective Action, and Law*, 102 MICH. L. REV. 71, 91 (2003) (invoking Dasgupta and David in a broader discussion of theories of collective action). The importance of public funding to science has been recognized by some in the IP literature, but as will become clear, understanding open science—what makes it work well, or fail—requires far more than simple recognition of the role of public funding in science. While the existing literature has taken note of Merton's account of scientific norms, it also has focused dominantly on the obligation to share, and not engaged with the more elaborate open science model—and with potential failures within open science—the way I do here. *See, e.g.*, Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE. L.J. 177, 180–81 (1987) (relying on Merton to argue that there is a tension between norms in biotechnology and the recent expansion of patents in that domain); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 90 (1999) (invoking Mertonian "communism" in science, and arguing that scientific sharing is plausibly efficient and should be reinforced by law). Robert Merges and Kathy Strandburg have sought to develop an understanding of science as distinct from the market-exclusionary system, in ways compatible with the account I develop here. *See* Katherine Strandburg, *Norms and the Sharing of Research Materials and Tacit Knowledge*, *in* WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY 85, 92 (Rochelle C. Dreyfuss et al. eds., Oxford Univ. Press. 2010); Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 SOC. PHIL. & POL'Y 145, 146 (2009). Neither, however, engages with the processes, cycles, and tensions of open science as I do here.

work. Financial support typically comes from governments, which rely significantly upon scientific reputation and priorities to inform their decisions. Open science works very differently than the market-exclusionary model of information production but, like that same system, has plausibly effective mechanisms to mobilize decentralized information and to dynamically link investment to social aims.

The case study developed here helps validate the open science model, but it also offers some important correctives to it. For example, rules in open science—such as those mandating credit or forbidding exclusive appropriation through patents—are often more difficult to enforce than the basic model suggests. There is also more potential for misalignment between states' interests and scientists' interests than the basic model predicts. The basic model also can give us no reason to think open science will respond adequately to *global* aims or needs, given the potential for conflict between funders and the simple fact that many states lack the resources and/or the structures of political accountability that are presupposed in the basic model. Open science, as I describe, will in fact have difficulty generating investment in accordance with global need, and will tend to respond more to polities with more resources and with more accountable governments.

A closer look at the example offered by the Network, however, also allows us to better understand how conflicts such as these are managed in open science. Addressing these tensions in the Network has required not merely norms, intrinsic motivations, and technology—the resources stressed in the existing "IP without IP" literature. It has also required recourse to organizations and to law. By linking an empirical analysis of the Network to the most sophisticated body of literature that analyzes the informal cooperation of groups—the literature spawned by Elinor Ostrom's work on the commons—I show that the Network has used organizations and law to serve many of the same functions that are important to cooperation in groups managing common-pool resources. Organizations and law help clearly define group and resource boundaries, facilitate the monitoring and enforcement of rules, manage the interpretation and revision of norms, and mediate the group's relationship to the "outside." They can also be critical to the cultivation of a shared ethos and of trust, which are also crucial for cooperation, especially in loose-knit groups where enforcement is inevitably imperfect. Finally, organizations and law in the Network have also helped those within it cultivate a

sense of *purpose*. A close study of the Network, in fact, requires us to move beyond a simplified rational actor model of open science and "IP without IP," as we begin to recognize the role that law and organizations play in sustaining both.

The account developed here decisively refutes the most important criticisms of the "IP without IP" literature. First, it shows that capital-intensive production without IP can be sustained over time to produce information goods of extraordinarily high value. Generalizing from the Network's experience, I suggest that even where capital costs are high, creation without IP can be effective and responsive to social aims, if reputational and evaluative circuits can be linked to a source of capital, as in open science. Second, the account here shows that loose-knit groups can cooperate, even under extraordinary strain. But criticisms of the "IP without IP" literature have some merit: that cooperation is not likely to be sustained under strain by norms alone. Rather, where stakes are high and groups are loose-knit, cooperation without IP likely requires recourse to organizations and law. In its most importance instances, order without IP will not be order without law, nor will it be order without constraint or coordination.

This is emphatically not to say, as some critics have, that "IP without IP" inevitably relies upon forms of exclusion that "operate with an approximately equivalent effect" to IP itself.[43] In the Network, organizations and law are being used instead to produce the kinds of governance and interpersonal goods described by scholars like Ostrom and Elizabeth Anderson, in the support of a production system that is more oriented toward sharing rather than exclusion. The law deployed here is, in addition, not conventional IP law but rather contract law. Although contract law lacks some of the power of IP, it may be perfectly adequate to sustain "IP without IP," especially when it supports not a demand-side model but a supply-side model that is contingent upon cooperation among an identifiable (even if not close-knit) group.

In the pages that follow, Part I provides background on influenza, and describes the key information production tasks required to respond to the threat of seasonal and pandemic flu. Part II develops a detailed empirical account of the Flu Network, based upon three-dozen interviews, as well as patent analysis, citation analysis, analysis of sample and sequence sharing, and archival research. Part III describes the system of

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43 Barnett, *supra* note 27, at 1754.

production that sustains the Network, drawing on the existing model of open science. It then returns to the example of the Network to clarify some of the allocative mechanisms (and potential problems) of the basic model, and to describe how the Network has succeeded, particularly in periods of enormous strain. Part IV derives lessons from the case study, arguing that the next wave of this literature should focus on a new set of examples and also return to old examples, to see them anew in the wake of the lessons that the Flu Network has to teach us.

I
INFLUENZA, IP, AND OPEN SCIENCE

A. Influenza: A Primer

Colloquially, we often call any sudden and severe respiratory illness "the flu." True influenza, however, is caused by a distinct family of RNA viruses.[44] It usually has mild effects in its seasonal form—fever, aches, and respiratory symptoms that last up to a week—but it can be extraordinarily lethal when a new pandemic strain emerges.[45] A pandemic like the one in 1918-1920 could take the lives of nearly two million people in the United States alone.[46]

Influenza pandemics have emerged with some regularity over the last century,[47] and new influenza pandemics today are considered inevitable, given the nature of the virus and conditions of contemporary agriculture and travel.[48] The core problem is the volatile nature of the influenza virus itself. Influenza mutates constantly. Small mutations in the virus cause pre-

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44 GEORGE DEHNER, INFLUENZA: A CENTURY OF SCIENCE AND PUBLIC HEALTH RESPONSE 23 (2012).

45 *See supra* notes 4–5.

46 *See* U.S. DEP'T OF HEALTH & HUMAN SERVS, *supra* note 5.

47 de Jong et al., *supra* note 2, at 554.

48 *See* W. Bruine De Bruin et al, *Expert Judgments of Pandemic Influenza Risks*, 1 GLOBAL PUBLIC HEALTH 178, 189–90 (2006) (discussing the likelihood of an influenza outbreak); Richard J. Webby & Robert G. Webster, *Are We Ready for Pandemic Influenza?*, 203 SCIENCE 1519, 1520–21 (2003) ("Influenza experts agree that another influenza pandemic is inevitable and may be imminent."); *see also* PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., EXEC. OFFICE OF THE PRESIDENT, REPORT TO THE PRESIDENT ON REENGINEERING THE INFLUENZA VACCINE PRODUCTION ENTERPRISE TO MEET THE CHALLENGES OF PANDEMIC INFLUENZA, at v–vi (2010) [hereinafter PCAST REPORT], http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST-Influenza-Vaccinology-Report.pdf [https://perma.cc/7SWF-VACE] (framing the importance of effective vaccine supply as a matter of when, not if, the next influenza pandemic occurs); Patrick Adams, *The Influenza Enigma*, 90 BULL. WORLD HEALTH ORG. 250, 251 (2012) (describing risk factors thought to increase the risk of pandemic outbreaks, such as intensification of agriculture).

dictable waves of sickness almost every year.[49] Seasonal flu is less serious than pandemic flu, but still can be deadly to the vulnerable, and particularly the elderly.[50] The virus can also change in more radical ways, reshuffling its genome, typically in an animal host, resulting in strains that are radically different from any that have circulated before.[51] Pandemics occur when radically new strains that evade immunities emerge, and become transmissible between humans.

Two kinds of measures are critical to the public health response to both pandemic and seasonal flu: "social countermeasures" that aim to contain its spread, and "medical countermeasures" such as vaccines and treatments that can prevent infection and improve survival rates.

Social countermeasures range in intensity from, for example, hand-washing to school closings and travel restrictions. Their efficacy depends on characteristics of the pandemic strain, as well as on how early the measures can be enacted.[52] The Network's rapid reaction to H5N1 via the poultry cull in Hong Kong was critical to stopping human cases there, for example, and significantly slowed the advance of new human cases to other regions.[53] Once a new strain emerges that is transmissible between humans, models suggest it might still be contained to a particular region, if it is only moderately infectious.[54] A highly infectious strain, however, will inevitably spread quickly around the world, even in the face of highly intrusive restrictions such as bans on air travel.[55]

Medicines that directly combat the influenza virus exist, but recent studies suggest that they may alleviate some symp-

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49 Alan J. Hay, *The Virus Genome and Its Replication*, *in* TEXTBOOK OF INFLUENZA 43, 43 (Karl G. Nicholson et al. eds., 1998).

50 *See* Thompson et al., *Mortality Associated with Influenza*, *supra* note 17, at 185; Thompson et al., *Influenza-Associated Hospitalizations*, *supra* note 17, at 1333.

51 JAN WILSCHUT & JANET E. MCELHANEY, INFLUENZA 45–46 (2005). Pandemic strains like the one that struck in 1919 have been traced to flu viruses that circulated in birds, so scientists are particularly concerned when they see a new avian flu that is capable of infecting a human. de Jong et al., *supra* note 2, at 554. They are still more concerned when that flu can also infect other animal hosts, and shows signs of being very lethal. *See* Rosenwald, *supra* note 7, at 183.

52 Arin Dutta, *The Effectiveness of Policies to Control a Human Pandemic: A Literature Review* 40–44 (World Bank Dev. Research Grp., Working Paper No. 4524, 2008).

53 *See infra* text accompanying notes 192–93.

54 Dutta, *supra* note 52, at 40. Social control measures such as school closings may also slow the rate of spread of influenza. *See, e.g.*, Gerargo Chowell et al., *Characterizing the Epidemiology of the 2009 Influenza A/H1N1 Pandemic in Mexico*, PLOS MED., May 24, 2011, at 6–7.

55 Dutta, *supra* note 52, at 42.

toms yet have no significant effect on flu-related complications.[56] Flu vaccines, therefore, are the most important medical countermeasure against influenza. Indeed, they are often described as the single most important tool in this context,[57] because they are the only one that can provide prolonged individual protection against infection.[58]

Influenza vaccines have been around since the 1940s, and are still largely made in the same way that they were then—by growing live influenza viruses in eggs, purifying and killing them, and administering them by injection.[59] Such vaccines appear to be reasonably or even highly effective, but only if they are well matched to circulating strains.[60]

The traditional mode of vaccine production, however, may be inadequate in a pandemic. Egg-based production of vaccines is difficult to scale up quickly.[61] It is also slow, taking at least five months, and at times up to a year.[62] With seasonal flu, early strain selection leaves eight to nine months to pro-

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56 Tom Jefferson et al, *Neuraminidase inhibitors for preventing and treating influenza in adults and children*, Cochrane Database of Systematic Reviews 2014, Issue 4. Art. No.: CD008965. DOI: 10.1002/14651858.CD008965.pub4.

57 *See, e.g.*, *Key Facts About Seasonal Flu Vaccine*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/protect/keyfacts.htm [https://perma.cc/KL3Z-TXPD] ("An annual seasonal flu vaccine is the best way to reduce your risk of getting sick with seasonal flu and spreading it to others.").

58 *Questions and Answers on Pandemic Influenza Vaccine*, WORLD HEALTH ORG. (May 9, 2007), https://www.cdc.gov/flu/protect/keyfacts.htm [https://perma.cc/ VP57-S2ZA].

59 PCAST REPORT, *supra* note 48 at 11; Interview with John McCauley, Director, WHO Collaborating Ctr. for Reference & Research on Influenza, U.K. (Nov. 18, 2011).

60 *See, e.g.*, Kristin L. Nichol, *Efficacy/Clinical Effectiveness of Inactivated Influenza Virus Vaccines in Adults*, *in* TEXTBOOK OF INFLUENZA 358, 361 (Karl G. Nicholson et al. eds., 1998) (collecting studies that report between 70 and 90 percent efficacy for years when the vaccine is well matched); Tom Jefferson et al., *Vaccines for Preventing Influenza in Healthy Adults*, 2010 Cochrane Database of Sys. Rev. 1, 7 (2010) (estimating 73% efficacy in healthy adults); Michael T. Osterholm et al., *Efficacy and Effectiveness of Influenza Vaccines: A Systematic Review and Meta-Analysis*, 12 LANCET INFECTIOUS DISEASES 36, 39 (2012) (estimating 59% efficacy in healthy adults); *Vaccine Effectiveness - How Well Does the Flu Vaccine Work?*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/flu/about/qa/vaccineeffect.htm [https://perma.cc/CZ4R-XHW8] ("[R]ecent studies show vaccine reduces the risk of flu illness by about 50% to 60% among the overall population during seasons when most circulating flu viruses are like the vaccine viruses.").

61 Egg-based production, for example, relies upon the availability of millions of fertilized chicken eggs of a precise age, raised in special, sterile environments. The number of eggs required is also enormous. The third-largest consumer of eggs in the UK is a flu vaccine manufacturing plant. *See* PCAST REPORT, *supra* note 48, at 34.

62 *A Description of the Process of Seasonal and H5N1 Influenza Vaccine Virus Selection and Development*, WORLD HEALTH ORG. 10 (Nov. 19, 2007), http://www

duce the vaccine.[63] In a serious pandemic, however, this delay significantly undermines the ameliorative potential of vaccines.[64] Egg-based production may also not work for a pandemic avian strain, because avian strains can kill the eggs in which they are grown.[65]

In the wake of H5N1, governments have therefore poured enormous sums into improving vaccine manufacture, much of this going to the private sector.[66] The new technologies under experiment are numerous and complex,[67] but nearly all of them would still depend upon the use of circulating virus strains as the basis for the vaccine, and have received substantial public sector support.[68]

.who.int/influenza/resources/documents/influenza_vaccine-virus_selection/en [http://perma.cc/8R27-G8UD] [hereinafter *WHO Selection Description*].

63 PCAST REPORT, *supra* note 48, at 2.

64 For example, it was nearly six months after the identification of the H1N1 outbreak that the first doses of the pandemic vaccine became available, which was too late to provide protection for most of the population in the United States. *Id.* at 2. It would have taken nearly a year to produce enough vaccine to protect the whole U.S. population against H1N1. *Id.* at vi.

65 *See* Anatole Krattiger et al., *Intellectual Property Management Strategies to Accelerate the Development and Access of Vaccines and Diagnostics: Case Studies on Pandemic Influenza, Malaria and SARS*, 2 INNOVATION STRATEGY TODAY 67, 76–77 (2006).

66 The U.S. Congress, for example, appropriated nearly $6 billion to improving pandemic preparedness in 2007. CHARLES E. JOHNSON, ASSISTANT SEC'Y FOR RES. & TECH., DEP'T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS ON PANDEMIC INFLUENZA PREPAREDNESS FUNDING 1–2 (2007), https://www.medicalcountermeasures.gov/barda/documents/hhspanfluspending-0706.pdf [https://perma.cc/8ZQP-JE7X]. Some of this money went to improve global systems such as the Flu Network. *Id.* at 2. About $1.5 billion went directly to private sector companies, to help these companies improve manufacturing facilities and techniques, and to meet regulatory demands, particularly in order to speed along non-egg based technologies for pandemic vaccines. *Id.*; *see also* Kevin Freking, *5 Drug Companies Get Flu Vaccine Funding*, WASH. POST (May 4, 2006, 8:40 PM), http://www.washingtonpost.com/wp-dyn/content/article/2006/05/04/AR2006050400893.html [https://perma.cc/C7G4-4QM8] (reporting that several drug manufacturers received more than $1 billion in Federal funding in 2006 to fund development for speedier mass production of virus vaccines).

67 For an accessible overview of recent influenza vaccine technology developments, see generally PCAST REPORT, *supra* note 48. The most important of these include cell-based manufacture (which is increasingly viable and could eliminate the need for eggs), live attenuated vaccines (which are old but only recently used more widely), and dose-sparing adjuvants. *See id.*, at 34–35, 46.

68 There is some hope that a universal vaccine may be possible, which would be based upon parts of the virus that do not change, and so provide broad and perhaps long-term protection, and not rely on access to this year's strains for the vaccine. PCAST REPORT, *supra* note 48, at 51–52. Recent research suggests that this pathway may have promise, but it is still highly uncertain whether it will succeed. *Id.* at 53–55; Antionetta Impagliazzo et al., *A Stable Trimeric Influenza Hemagglutinin Stem as a Broadly Protective Immunogen*, 349 SCIENCE 1301, 1301 (2015). Notably, public sector funding has also been key here: researchers at the U.S. National Institute of Allergy and Infectious Disease are leading one of the

Synthesizing this, we can identify two key types of informational needs where influenza is concerned. The first is *surveillance*. New strains of influenza emerge constantly, and circulate around the world quickly.[69] To have effective vaccines, as well as to prepare hospitals and other health agencies for particularly severe seasons or new pandemics, scientists must constantly monitor the virus as it evolves around the world. New viruses must be typed, so scientists can isolate which strains are circulating and quickly identify any radical new strains that might result in a pandemic outbreak. Scientists also must track the health effects of different circulating strains (identifying how many cases are showing up in hospitals, how severe they are, and the like), to develop an accurate picture of the dangers of different strains. As I will describe, these are among the key tasks of the Flu Network.

A second set of informational needs relate to *medical countermeasures*. Vaccines, in particular, are considered the most urgent and promising domain of development. To generate an effective vaccine for seasonal and pandemic flu, scientists must select the appropriate strains to be included in vaccines, isolate corresponding viral strains, and modify them to grow well in industrial settings.[70] Scientists also need reagents that allow evaluation of the potency of new vaccines—a critical regulatory step, particularly because vaccines are produced in slightly different form each year.[71] Last, there is a need for forward-looking research that can help speed vaccine production, move us away from egg-based production, and—though there is a

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major new initiatives, and another involves key collaborators from the public sector. *See* Hadi M. Yassine et al., *Hemagglutinin-Stem Nanoparticles Generate Heterosubtypic Influenza Protection*, 21 NATURE MED. 1065, 1065 n.1 (2015) (NIAID team); Impagliazzo et al., *supra* note 68, at 1301 (involving researchers from public sector).

69 Colin A. Russell et al., *The Global Circulation of Seasonal Influenza A (H3N2) Viruses*, 320 SCI. 340, 341 (2008). New strains have long been thought to typically emerge in East and South-East Asia (where influenza circulates continuously), and spread westward across the world, making surveillance in this region a high priority. *Id*; *but see* Patrick Adams, *The Influenza Enigma*, 90 BULL. WORLD HEALTH ORG. 250, 251 (2012) (providing evidence that viral patterns of circulation may not be this predictable).

70 *WHO Selection Description*, *supra* note 62, at 7. To make seed strains for avian strains (which kill eggs), scientists must use synthetic methods, via a process known as "reverse genetics." *WHO Selection Description*, *supra* note 62, at 9; PCAST REPORT, *supra* note 48 at 24–25.

71 *See Conversations with the Director: Michael Shaw*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 30, 2012), http://www.cdc.gov/about/cdcdirector/conversations/shaw.html [https://perma.cc/T5MT-YCY2] (last visited Aug. 2, 2014).

great deal of uncertainty about the viability of this approach—ideally develop vaccines with more universal potential.[72]

B. The Economics of Information Production in Influenza

The economics of information goods begin with the insight that information has the qualities of a public good: it is non-rivalous and also difficult to exclude in the absence of strong legal entitlements (or, IP rights).[73] As a result, if we want "efficient" levels of production of information goods in markets, we may need exclusive rights regimes.[74]

This forms the basis of the canonical justification for IP.[75] If information is expensive to produce but cheap to reproduce, actors in competitive markets will not produce as much of it as we wish from a social perspective. IP rights help create dynamic incentives for the production of information, because they allow investors to exclude competitors for a period of time and so recoup their investment.

It is also widely recognized, however, that IP generates inefficiencies from both static and dynamic perspectives.[76] The non-rivalrous nature of information means that its marginal cost—the cost needed to produce an additional unit for consumption—is zero.[77] In static perspective, only at a price of zero, then, will information be consumed at socially optimal amounts. IP also creates dynamic inefficiencies because information is an input and output of its own production.[78] Supra-marginal cost pricing suppresses uptake by producers.[79] This is why leading information economists, harkening back to the foundational work of Kenneth Arrow, actively debate the com-

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72 *See supra* note 68.

73 *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 623–24 (Nat'l Bureau Comm. for Econ. Res., Comm. on Econ. Growth of the Soc. Sci. Res. Council ed., 1962).

74 Efficiency in this context is usually defined via either the Kaldor-Hicks or wealth-maximizing criterion. Fisher, *supra* note 36, at 177.

75 *See* MERGES, MENELL & LEMLEY, *supra* note 18, at 12–13; Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1033, 1037–40 (2005).

76 *See, e.g.*, BENKLER, *supra* note 23, at 36–40 (outlining such inefficiencies); SUZANNE SCOTCHMER, INNOVATIONS AND INCENTIVES 140 (2006) (same).

77 *See* Arrow, *supra* note 73, at 614–15.

78 For more on this problem, and additional drawbacks such as the potential for racing, see Kapczynski, *supra* note 35, at 982.

79 *See* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPS. 29, 30–31 (1991).

parative efficiency of IP and various alternatives, such as government grants and prizes.[80]

The most powerful defense of the superiority of IP over these other approaches is based on a simple challenge: How will governments know which information resources we want, and how much we should spend?[81] The main virtue of IP over other alternatives is said to be its allocative advantage: because it relies on prices and markets, it is thought to be a good tool for mobilizing decentralized information about demand.[82] Allocation, it turns out, is the key to economic arguments about information production. Because information is non-rivalrous, concerns about conservation or depletion that are important in the tangible property context are here irrelevant. You cannot deplete information, but you can waste the resources you invest in developing information, or make poor decisions about which information goods to invest in.

The allocative argument for the market-exclusionary approach is powerful. But recent scholarship on IP has sharpened our understanding of its limits. For example, property regimes require frictionless transactions if efficient allocation is to occur. But transaction costs are particularly acute where information is concerned, because of intense uncertainties related to the bounds of IP rights, as well as their value.[83] There

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80 *See* Arrow, *supra* note 73, at 623; Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691, 691, 697–98, 701 (1983).

81 *See* Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1, 19–20 (1969).

82 *See id.* at 12–13; WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 24 (2003).

83 For example, entitlements in information are often unclear, because the metes and bounds of information are far more difficult to map than the metes and bounds of tangible resources. *See* Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 274–75 (2007). The bounds of associated legal entitlements are also often unclear. *See, e.g.*, *id.* at 275 (noting that "[i]t is difficult—and in many cases impossible—to know whether one is 'trespassing' upon another's IP right," and describing the uncertainties generated by the idea/expression distinction and fair use in copyright, as well as the lack of an independent invention defense in patent law). To this can be added major problems in identification of owners, especially in copyright. *See, e.g.*, David R. Hansen et al., *Solving the Orphan Works Problem for the United States*, 37 COLUM. J.L. & ARTS 1, 4–14 (2013) (discussing the pervasive problem of being unable to locate, through a reasonably diligent search, the owners of old copyrights). Information production is also characterized by high levels of uncertainty, making informational imperfections and asymmetries in bargaining particularly likely. *See, e.g.*, Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 83–84 (1994) (noting that strategic bargaining problems may be especially common in the context of patent law because advances in technology are particularly hard to value).

are many settings, additionally, where even if market actors have strong IP rights, they will underinvest in information goods. Externalities are one issue here: IP rights will undervalue solutions to pollution problems, for example, because of pervasive externalities in the "market" for pollution.[84] Discounting and the unpredictable nature of innovation are another: IP works poorly to incentivize basic R&D, for example, because of the high degree of uncertainty and long periods of time before it yields commercial application.[85]

Already implicit in this account are several important reasons that market exclusion will not be adequate to produce most of the information goods we need to address influenza. The facts, data, and virus samples that are essential to high quality flu surveillance are classic "basic" information goods. They must be able to be accessed by many parties and recombined readily to be useful, and it is hard to assign a value in advance to any particular fact, datum, or sample. IP law also provides very little protection for these kinds of information goods.[86] This may not be a coincidence because an IP law that did extend to these goods would function poorly to produce the goods that we need. This is not only because of discounting

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84 *See* Ian Ayres & Amy Kapczynski, *Innovation Sticks: The Limited Case for Penalizing Failures to Innovate*, 82 CHI. L. REV. 1781, 1812–22 (2015). On the externality problem in IP more generally, see Frischmann & Lemley, *supra* note 83.

85 Economists have long concluded that markets are likely to underproduce "basic" science. *See* Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297, 304 (1959); *see also* Dasgupta & David, *supra* note 42, at 490 (discussing the economics of basic research and the divergence between private and social returns to basic research outlays). The more upstream a set of research inputs are, for example, the more significant transaction costs problems are likely to be. Early stage research is likely to be unusually uncertain in value, making licensing negotiations particularly difficult. *See* LANDES & POSNER, *supra* note 82, at 307; *see also* SCOTCHMER, *supra* note 76, at 141 (emphasizing the problems of information asymmetry in licensing).

86 Patent law only covers new inventions and processes, and excludes from its scope products of nature, such as wild-type viruses. *See* 35 U.S.C. § 101 (2016) (making eligible for patents "any new and useful process, machine, manufacture, or composition of matter"). Also unpatentable are abstract ideas, natural correlations, and discovered facts. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70–71 (2012). Finally, genetic sequences identical to those found in nature are increasingly considered unpatentable. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116–19 (2013); *D'Arcy v Myriad Genetics* [2015] HCA 35 (Austl.). Copyright law does not cover facts, and provides no protection for databases absent some level of creativity in their creation. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 348 (1999). European law protects databases under a *sui generis* regime in certain circumstances, but this is unusual and not a very robust form of protection. *See* Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases, 1996 O.J. (L 77) 20, 25–26.

and transaction cost dynamics, but also because much of this information is highly non-excludable even in the presence of property rights.[87]

The second set of information goods, related to medical countermeasures and vaccines in particular, are also difficult to produce in sufficient amount in markets, but for different reasons. Here, there is much more scope within existing IP law for exclusive rights. For example, patent claims may cover modified genetic material,[88] diagnostic reagents,[89] processes of making vaccines or therapeutics,[90] and therapeutic agents such as small molecule drugs or the viral particles that could be important to universal vaccines.[91] For seasonal flu, patents are a poor incentive, nonetheless, because the existing technologies work fairly well (given access to the surveillance goods described above).[92]

Pandemic flu is a far graver concern, but its unpredictability creates significant barriers to market-led investment. A serious new flu pandemic is considered inevitable, but rather like a major earthquake, its timing is highly uncertain.[93] One study surveying experts revealed that they predicted a 100% chance that a new flu pandemic will occur in the next thirty years.[94] But patents last only twenty years, and the dis-

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87 *See, e.g.*, Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1902–05 (2013) (providing a theory and examples of non-excludability and analyzing its implications for patent scholarship). One of the Network's most important roles is to announce a new pandemic. Such information is extraordinarily valuable, but is not in any practical way excludable, even if law permitted it to be treated as property.

88 *See, e.g.*, *Ass'n for Molecular Pathology*, 133 S. Ct. at 2115 (concluding that modified DNA is patentable subject matter); *see also* Directive 98/44, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, 13 (stating in Article 3(2) that "biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature").

89 *See* U.S. Patent No. 5,156,949 (filed Dec. 24, 1987) (claiming reagent for detecting HIV); U.S. Patent No. 6,074,816 (filed Sept. 16, 1994) (claiming reagent for detecting hepatitis C virus).

90 35 U.S.C. § 101 (2012) (making eligible for patents "any new and useful process, machine, manufacture, or composition of matter").

91 Two recent major papers on advances toward universal vaccines, for example, disclose patent applications related to the research in question. *See* Impagliazzo et al., supra note 68; Yassineet al., *supra* note 68.

92 Externalities play a role in undermining incentives for improvements as well: vaccination confers benefits on others, and individuals may not take these benefits fully into account when deciding whether to be vaccinated.

93 *See supra* note 48.

94 Bruine De Bruin et al., *supra* note 48, at 183–84.

counted present value for firms of profits many years away quickly diminishes.

Moreover, in a true pandemic setting, with millions critically ill, patent holders would be under unthinkable political pressure to voluntarily permit use of the patent. And in the alternative, consistent with international law, countries could simply override patents.[95] For example, at the highpoint of the concern about a new avian flu pandemic, it became clear that one suite of patents could be an impediment to public scientists working to create reference strains for H5N1 vaccines.[96] The company holding the patents immediately publicly announced that it would license them to government organizations and developing countries at no cost, to develop vaccines for public health purposes.[97]

In fact, IP will plausibly be least efficacious for some of the most important kinds of information goods. We might call this an example of the "bell curve" of property law. Where property is of low value, or very high value, private property systems may be difficult to establish or administer. At low value, the costs of the formal system will often be higher than the rewards.[98] But where the value of property is exceptionally high—as would be a patent on a key vaccine component in a global pandemic—states are unlikely to tolerate property-as-sovereignty and will act on their own sovereign authority to override it.[99]

Therefore, it is of little surprise that, as implied above and described in more detail below, the vast majority of the scientific goods we need for influenza have long been produced not

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95 *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (providing processes for compulsory licensing of patents).

96 INITIATIVE FOR VACCINE RESEARCH, WORLD HEALTH ORG., MAPPING OF INTELLECTUAL PROPERTY RELATED TO THE PRODUCTION OF PANDEMIC INFLUENZA VACCINES 18 (2007) (hereinafter IVR REPORT 2007).

97 *Id.*

98 *See* Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 356 (1967).

99 *See, e.g.*, *Dealing with Anthrax: Patent Problems Pending*, THE ECONOMIST Oct. 27, 2001, at 14 (describing how, after the anthrax attack in the United States in 2001, the Canadian government sought to buy a stockpile of generic anthrax treatments, only relenting when the patent-holding company dramatically reduced the price and increased supply); Jill Carroll & Ron Winslow, *Bayer Agrees to Slash Price for Cipro Drug*, WALL ST. J., Oct. 25, 2001, at A3 (describing Bayer's dramatic reduction of the price for its anthrax drug to the U.S. government after the HHS secretary threatened to procure generics despite Bayer's patent after the 2001 anthrax attack).

via markets but via government funding.[100] That funding might be considered the answer to how information is produced without IP, but funding alone does not answer any of the most acute questions posed by the IP literature: How can such funding work *well*? What is its logic, when and how might it succeed or fail, and how, in particular, can it address the critical allocative question at the center of contemporary information economics, and the field of IP law?

The Flu Network provides an excellent case for the exploration of these questions. It is a critical element of our global scientific and public health infrastructure. It has proven remarkably stable and successful over time.[101] It has operated for decades without any significant recourse to intellectual property. How then, has the Network motivated and organized its work? It is to our case study of the Network's long history, crisis, and recent reconstruction that we now turn.

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100 *See supra* note 66 (describing government funding of new vaccine technologies); *see also infra* subpart II.B (describing the activities and government funding of the Flu Network). There is some private financing, and a great deal of private sector patenting (see Appendix B) in influenza research, focused almost uniformly on medical counter-measures. But much of this receives public funding, for the reasons described above.

101 WORLD HEALTH ORG., STRENGTHENING RESPONSE TO PANDEMICS AND OTHER PUBLIC-HEALTH EMERGENCIES: REPORT OF THE REVIEW COMMITTEE ON THE FUNCTIONING OF THE INTERNATIONAL HEALTH REGULATIONS (2005) AND ON PANDEMIC INFLUENZA (H1N1) 2009 at 75–76 (2011) (in a report by an independent review committee, describing the Network's rapid response to the H1N1 swine flu outbreak, concluding that the Network "had worked well and facilitated the timely detection, identification, initial characterization and monitoring of the pandemic (H1N1) 2009 virus," and noting that this was "the first time that a worldwide laboratory initiative was well-coordinated for an extended period of time"). *See* Nancy J. Cox et al., *Influenza: Global Surveillance for Epidemic and Pandemic Variants*, 10 EUR. J. EPIDEMIOLOGY 467, 469 (1994) (describing the Network as "quite successful"); Interview with Alan Hay, Former Director, WHO Collaborating Ctr. for Reference & Research on Influenza, U.K. (Nov. 18, 2011) (commenting that the Network "is still held up as . . . a prime example[ ] of an international network that works"); *see also* J.M. Wood, *Selection of Influenza Vaccine Strains and Developing Pandemic Vaccines*, 20 VACCINE B40, B40 (2002) (noting the Flu Network as "one of the most successful of the WHO programmes"). For evidence that its strain selection has worked relatively well, see L. Steinbrück, T.R. Klingen & A.C. McHardy, *Computational Prediction of Vaccine Strains for Human Influenza A (H3N2) Viruses*, 88 J. VIROLOGY 12123, 12128 (2014) (66% accuracy); *see also* Colin A. Russell et al, *Influenza Vaccine Strain Selection and Recent Studies on the Global Migration of Seasonal Influenza Viruses*, 26 VACCINE D31, D32 (2008) (noting that "substantial mismatch" between WHO strain selections and circulating strains is "infrequent" but that strain selection could be further improved through better understanding of global flu migration patterns).

II
FLU TRACKERS

A. History and Structure

When the World Health Organization was launched in 1947, one of its first initiatives was the creation of the Flu Network.[102] With 1919 still very much in living memory, the impetus was clear—by tracing and collecting new flu strains, if a dangerous new strain emerged, "it might perhaps be possible to prevent world-wide spread of the disease by means of prophylactic immunization."[103]

The Network began, as it would operate for decades, in largely informal fashion.[104] Several early participants were luminaries in the scientific world, such as Jonas Salk, who invented the polio vaccine.[105] Through personal contacts, a small network of elite scientists was developed to share viruses, techniques, and reagents across borders.[106]

Since then, the Network has grown substantially and become much more formal in nature. But its basic structure has remained the same for decades. "National Influenza Centers" (which I will call "national labs") are responsible for the ground-level work needed to create the "surveillance-related" information goods described above. Today, there are more than 140 of these labs, in more than 110 countries[107]—a number that has been significantly and very deliberately increased over time.[108]

These national labs work with local doctors and hospitals, or with sentinel surveillance sites, to collect nose and throat swabs of sick patients, and to test them for the influenza virus.

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102 M.M. Kaplan, *The Role of the World Health Organization in the Study of Influenza*, 288 PHIL. TRANSACTIONS ROYAL SOC'Y LONDON SERIES B BIOLOGICAL SCI. 417, 417 (1980).

103 World Health Org., Priority Comm., Proposal for the Setting Up of a Committee on Influenza Made by the Representative of the Netherlands, U.N. Doc. No. WHO.IC/P/1 (Apr. 3, 1947) (on file with author).

104 The Network's institutional home was just "a couple of laboratory rooms and some animal quarters" in London. Kaplan, *supra* note 102, at 418.

105 In the 1940s, Salk helped create the first successful influenza vaccine, and was an early collaborator with the Network. CHARLES HERBERT STUART-HARRIS & GEOFFREY C. SCHILD, INFLUENZA: THE VIRUSES AND THE DISEASE 165 (1976). Other famous scientists involved with the Network included Sir Christopher Andrewes, whose team had first isolated the influenza virus, and who led the London lab. *See* Kaplan, *supra* note 102, at 129; MRC NAT'L INST. FOR MED. RESEARCH, A CENTURY OF SCIENCE FOR HEALTH 233, 238–39 (2015).

106 Kaplan, *supra* note 102, at 417–19.

107 *See National Influenza Centres*, WORLD HEALTH ORG. (Jan. 12, 2017), http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/list/en [https://perma.cc/T753-P7BR] [hereinafter Network NICs].

108 Kaplan, *supra* note 102, at 419.

Where the virus is present, they perform preliminary genetic or antigenic analysis to identify the particular sub-strains circulating.[109] They also collect relevant epidemiological data (for example, about flu hospitalization rates) and provide weekly updates on the influenza situation in their country during their flu season.[110]

After their preliminary analysis, national labs forward both representative strains and novel strains on to a WHO "Collaborating Center"—labs that also play a critical role in surveillance, but that in addition generate information goods critical to medical countermeasures to the flu. For decades, there were only two CCs—one in London and the other in the US (now, at the CDC)—which constituted the main scientific leadership of the Network.[111] Today, the group is more diversified, with CCs in Melbourne, Tokyo, Memphis, and most recently Beijing. The CCs can analyze influenza viruses in much more depth, and each is a very substantial research institution in its own right.[112] Their terms of reference are also much more demanding than for the national centers. They are required to do more in-depth analysis of the viruses and data sent on by national labs, and to share this information with the WHO and other Network labs.[113] When outbreaks such as H5N1 occur, CCs are required to help WHO member states by investigating and responding.[114] They also create standard reagents and antisera for labs around the world, which helps standardize diagnostic and laboratory practices and facilitates the regulation of vaccines.[115]

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109 *See WHO Global Influenza Program, Terms of Reference for National Influenza Centers*, WORLD HEALTH ORG., http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/terms_of_reference_for_national_influenza_centres.pdf [https://perma.cc/M8WD-N5CK].

110 *WHO Selection Description*, *supra* note 62, at 4.

111 Interview with Alan Hay, *supra* note 101; Kaplan, *supra* note 102, at 420.

112 For example, all CCs must have Biosafety Level 3 laboratories. *See Core Terms of Reference for WHO Collaborating Centres for Reference and Research on Influenza*, WORLD HEALTH ORG. (Oct. 12, 2006), http://www.who.int/entity/influenza/gisrs_laboratory/collaborating_centres/whocccoretor2006.pdf?ua=1 [https://perma.cc/9RQS-46PF] [hereinafter *WHO CC Terms*].

113 *See WHO CC Terms*, *supra* note 112.

114 These duties are formalized in terms of reference, and labs can be de-designated if they fail in their assigned tasks. For more on enforcement of these rules, see *infra* pp. 168–70.

115 *See WHO Selection Description*, *supra* note 62, at 8; *WHO CC Terms*, *supra* note 112. The CCs provide antisera and reagents for free to WHO labs, but may ask for cost-reimbursement if for-profit clinics want to use them. *See Conversations with the Director: Michael Shaw*, *supra* note 71. Standardization of diagnostic kits and other reagents can dramatically increase efficiency, much as interchangeable parts on an assembly line do.

Perhaps most remarkable is the extensive involvement that the CCs have in the creation of flu vaccines. Twice a year, the CCs meet with other Network experts, with no manufacturers in the room, and decide which strains should be included in seasonal flu vaccines.[116] Their recommendations are made public,[117] and while countries are not required to follow them, in practice they almost always do.[118] When potential pandemic strains emerge, a similar but much accelerated process is followed, in an attempt to protect people and regions that are later affected with a vaccine matched to the pandemic strain.

CCs and the Network's "essential regulatory labs" (ERLs) also play a critical role in the creation of information needed to facilitate influenza vaccines. They help to make the modified, "high-growth" virus strains that grow well in industrial settings.[119] These seed strains are then transferred, free of charge, to vaccine manufacturers (typically in the private sector).[120]

B. Motivation in the Network

For the Network to function well, governments must support it financially. And, its scientists must collect high-quality samples, rapidly and accurately analyze them, and quickly forward the relevant strains to the WHO Network. Also critical,

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116 In a normal year, they meet in February to discuss the Northern hemisphere, and in September to discuss the Southern hemisphere. *See WHO Selection Description*, *supra* note 62, at 6; Reynolds, *supra* note 9, at 39. Manufacturers are excluded because there are possible conflicts of interest, for example because companies may favor strains that are easier to produce or that they have existing experience with. *See* Interview with Masato Tashiro, Director, WHO Collaborating Ctr. for Reference & Research on Influenza, Japan, in Geneva, Switz. (Nov. 16, 2011).

117 *WHO Selection Description*, *supra* note 62, at 6.

118 Interview with Terry Besselaar, WHO Global Influenza Surveillance and Response Sys. (Nov. 8, 2011); Interview with Alan Hay, *supra* note 101; Interview with John McCauley, *supra* note 59; *see also WHO Selection Description*, *supra* note 62, at 9 (noting that sometimes a national regulatory agency will instead require an antigenically similar strain).

119 *WHO Selection Description*, *supra* note 62, at 7 (describing three labs, one of which is a WHO lab, and another that is closely linked to the Australian CC, that undertake this work). When pandemic strains are involved, the process may require synthetic production of seed strains, as happened with H7N9. *Summary of Status of Development and Availability of Avian Influenza A(H7N9) Candidate Vaccine Viruses*, WORLD HEALTH ORG. (May 25, 2013), http://www.who.int/entity/influenza/vaccines/virus/candidates_reagents/summary_a_h7n9_cvv_20130525.pdf [https://perma.cc/J8UM-AERP].

120 Interview with Terry Besselaar, *supra* note 118; Interview with Masato Tashiro, *supra* note 116. Today, vaccine manufacturers benefitting from such materials are expected to make a financial contribution to facilitate pandemic preparedness. *See infra* note 153.

and demanding, is the work done in the CCs to select the best strains for vaccines, optimize seed strains, design reagents for diagnosis, and evaluate vaccine quality. When a new pandemic strain emerges, work in the Network requires enormous effort.[121] Why do countries support the Network? And why do scientists in the Network, who are not compensated directly for participating in the Network, nonetheless participate?[122] How do they coordinate their work and mobilize effort with very little centralized hierarchy? What generates the intensity of effort in pandemic periods, what facilitates the broad collaboration that the Network requires for its success, and what stimulates the path-breaking scientific work that occurs in the most sophisticated labs in the Network?

Here, and when discussing scientific motivation in the Network, I rely significantly on interviews with Network participants.[123] Humans, of course, are complicated, and do not always understand or accurately report their own motives.[124] Where possible, I therefore supplement interviews with data from other sources, to determine if other evidence is consistent with what is described by Network scientists.[125] Notably, where other-regarding motives and norms are consistently reported, we can also discern a social logic at work that demands concern for others. Values in the Network, as I will later describe, are important, even though they do not invariably coincide with behavior.

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121 *See, e.g.*, Interview with Michael Shaw, Senior Advisor for Lab. Sci., WHO Collaborating Ctr. for Reference & Research on Influenza (Feb. 5, 2014) (describing long hours for CDC scientists when new pandemic strains emerge).

122 Network scientists typically are salaried employees whose compensation is not keyed in a granular way toward their performance, or even to the hours that they work. *See* Interview with Michael Shaw, *supra* note 121 (indicating that scientists are not paid overtime at the CDC, though certain technicians are eligible for overtime). Scientists working for firms that operate in the market-exclusionary mode may be compensated in similar ways, raising interesting questions about whether R&D firms, on the inside, follow something more like a market exclusionary model or something more like open science.

123 See Appendix A for details of the interview methodology.

124 People may, for example, have poor access to their true motivations, or if they are aware of their motives, may be inclined to misreport them. They might emphasize other-regarding concerns, for example, and minimize the degree to which they act out of self-interest. For more on this, see Appendix A.

125 For example, if facts show (as they do) that scientists in the Network are not directly compensated from the publication of a paper or sharing of a sample, this fact is important to show that another form of motivation likely supports these activities. Similarly, if scientists report open sharing of their data, it matters that such reports are validated in the norms recently codified by the Network, and in the databases that host such data.

1. *Government Funding and Motivation*

The Network's activity does not correlate to a market-exclusionary mode of information production. Formal intellectual property rights have played no role in supporting the Network's activities, from its inception through to the present day. Network labs have only rarely sought patents related to influenza, and this only recently.[126] There is no evidence that any of these patents have been licensed, and some Network members have perceived the few Network-relevant patents that they hold as "defensive" in nature.[127] As will soon become clear, these patents *did* nonetheless have implications for the Network. In the crucible of the 2005 return of H5N1, they became a focal point for accusations that some labs were betraying the ethos and rules of the Network.[128]

Instead of relying on IP, funding for Flu Network labs has historically come almost exclusively from public sources—overwhelmingly government, with modest additional support from other non-profit sources such as foundations.[129] Indeed, government support is a precondition for designation as a Network lab.[130] Because the vast majority of funding flows from national governments directly to their laboratories, there is no centralized accounting of the annual running costs of the Network. It has been estimated, however, at about $56 million.[131] The WHO's budget for Network activities is much smaller, around $2 million in 2011.[132] As this reflects, the WHO has

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126 *See* Appendix B at 5–6.

127 *Id.* at 7.

128 *See infra* subpart II.C.

129 WORLD HEALTH ORG., STRENGTHENING THE WHO GLOBAL INFLUENZA SURVEILLANCE NETWORK (GISN), REPORT OF THE 3RD MEETING WITH NATIONAL INFLUENZA CENTRES (NICS) HELD IN HAMMAMET, TUNISIA 13 (2011) [hereinafter STRENGTHENING GISN REPORT], http://www.who.int/influenza/gisrs_laboratory/GISN_Meeting_Report_apr2011.pdf [https://perma.cc/Y2CA-DBBP]; *see also* Interview with Alan Hay, *supra* note 101 ("[M]ost of the national labs are being funded nationally."); Interview with Wenqing Zhang, Team Lead, Virus Monitoring, Assessment & Vaccine Support (VMV), WHO (Oct. 1, 2013) (explaining that those that are not supported directly by governments get funding through their status as academic institutions, or through foundations).

130 Interview with Wenqing Zhang, Team Lead, Virus Monitoring, Assessment and Vaccine Support (VMV), WHO (Nov. 15, 2011).

131 *Id.*; Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, World Health Assembly Res. WHA 64.5, at 21 n.1 (May 24, 2011) [hereinafter PIP Framework], http://apps.who.int/gb/pip [https://perma.cc/SV9V-YCMK] (last visited Aug. 2, 2014).

132 Interview with Wenqing Zhang, *supra* note 130. Before H5N1 the WHO provided no direct funding to national labs, but after H5N1 more resources were provided, allowing the WHO limited funds for capacity building and targeted training courses in certain developing countries. *Id.* Recent contributions from

historically been responsible for coordinating the Network, while national governments directly support the labs.[133]

Why do governments pay these costs, and why do they participate in the Network? Critically, many governments, particularly in developed and wealthier developing countries, are concerned about flu surveillance nationally and want high quality vaccines.[134] They want national capacity, and deploying this capacity for the purposes of the Network is a low cost way to improve vaccines.[135] Being part of a global scientific network is understood to increase the skills and information-base of local scientists, and to give states a voice in the transnational activities of the Network.[136]

Developing countries that do not use the seasonal flu vaccine, but where pandemic strains have been active recently, may see local influenza surveillance as an important investment as well.[137] This is less true, however, in countries with

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industry have given the WHO additional resources that are now primarily directed to capacity building in local labs. *See infra* note 153.

133 *See* W. Chas. Cockburn, *The Programme of the World Health Organization in Medical Virology*, *in* 6 PROGRESS IN MED. VIROLOGY 175, 177–78 (J.L. Melnick ed., 1964) (describing the Network in the 1960s as comprised of "national centres [that] freely give their voluntary collaboration" and identifying WHO's role as coordination, standardization, and collection of information); Interview with Alan Hay, *supra* note 101 ("WHO may have had some little startup money or things, but in general, they don't [fund the labs;] all the time that I've known, WHO didn't give anything really.").

134 *See, e.g.*, Interview with Anne Kelso, Director, WHO Collaborating Ctr. for Reference & Research on Influenza, Austl. (Oct. 29, 2013) (describing Australia's motivation as including interest in the southern strain selection process and pandemic preparedness).

135 *See, e.g.*, Interview with Ian Gust, Former Member, WHO Expert Comm. on Virus Diseases, Former Head, Austl. CC (Oct. 16, 2013) ("[E]ach of the laboratories which is involved in the WHO Network is already involved in diagnostic or public health work in their own countries for which they are being funded by their national or state government. And it's simply a matter of provision of information that they're already collecting or strains of viruses that they're already collecting and passing those onto a third party . . . [Participating in the GISRS is] not without cost. But it's usually built into the cost of running those centers.").

136 *See, e.g.*, Interview with Anne Kelso, *supra* note 134 ("[I]t's to the country's advantage to be part of this Network, to get the inside information, to get the extra assistance that might flow"); *id.* (citing the benefits of "having a seat at the table"); Interview with John McCauley, *supra* note 59 ("I would suspect the benefits of joining in [for countries] is actually *just* being part of the community and the network and to actually know what's going on and therefore be able to advise when something happens."). This is consistent with what others have observed: governments tend to be willing to support transnational scientific collaborations where they see the local benefits as sufficiently large to justify the local expenditure. *See* CAROLINE S. WAGNER, THE NEW INVISIBLE COLLEGE: SCIENCE FOR DEVELOPMENT 107 (2008).

137 Interview with Keiji Fukuda, Assistant Director-General for Health, Sec.& Environ., World Health Org., in Geneva, Switz. (Nov. 7, 2011) ("[T]his system has

very limited human and financial resources, and where there is no emergent pandemic strain or clear impact of seasonal flu.[138] For these reasons, national labs in some developing countries, and particularly in sub-Saharan Africa, tend to be less well-funded for influenza-related activities and concomitantly less able to participate in some of the Network's activities.[139] Historically, the WHO office provided little direct financial support to national labs and instead provided support via the provision of some reagents as well as training.[140] This has frustrated some in the national labs, especially where they feel they have insufficient capacity, for example in terms of the necessary laboratory equipment, to provide what the WHO requests.[141]

In the aftermath of the H5N1 crisis, the WHO began to receive funds from donor governments for capacity building, and so has begun to provide modest support to national labs, primarily through a virus shipment fund where labs can send influenza viruses to the WHO CCs for free as well as training courses.[142] Donor governments also have at times funded national labs directly, or provided the WHO with earmarked funds to meet particular needs of national labs.[143] The US CDC, for example, has funded training and shipping fees for national labs in the Network for a number of years.[144] Countries thus are differently situated with respect to their own perceived na-

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some role to play in detecting and preparing for a pandemic, so that affects everybody, and that brings in developing countries as well as developed countries"); *see also* Interview with Yuelong Shu, Director, WHO Collaborating Ctr. for Reference & Research on Influenza, China (Nov. 26, 2013) (explaining that China is more concerned with pandemics than the seasonal flu).

138 For example, in tropical countries there is no seasonality to influenza, making its burdens less obvious. *See* Interview with Masato Tashiro, *supra* note 116; Cécile Viboud et al., *Influenza in Tropical Regions*, 3 PLOS MED. 468, 468 (2006).

139 *See* Interview with Terry Besselaar, *supra* note 118 (describing the capacity of the Network in Africa as a significant issue, ameliorated to some degree with new funds made available after H5N1); *see also* Interview with Ian Gust, *supra* note 116 (describing some national labs historically as having provided very few samples); Interview with JM Heraud, Head, Virology Unit & Nat'l Influenza Ctr., Madag. (Feb. 6, 2014) (describing the funding for his lab in Madagascar, which comes almost entirely from donors, with very little from the government itself).

140 *See* Interview with Terry Besselaar, *supra* note 118.

141 *Id.*

142 *Id.* Post H5N1, resources from donor governments have increased, and have been used by the WHO to address such gaps, for example by funding modest capacity-building in labs particularly in Africa, and covering the shipping costs for national labs that are sending viruses to CCs (paid for by a fund created by the CDC). *See* Interview with Terry Besselaar, *supra* note 118; Interview with Wenqing Zhang, *supra* note 130.

143 Interview with Terry Besselaar, *supra* note 118.

144 *Id.*

tional interest in influenza itself, and that has historically generated a certain divide within the Network, with countries that perceive little for themselves at stake providing less support for their own scientists to participate in Network activities.[145]

Network scientists also report that funding for Network activities has been inconsistent. In the early years, WHO operated on "a shoestring," with insufficient funds to keep staff on long-term contracts and to consistently fund Network meetings.[146] Funds for Network activities sharply increased after the H5N1 outbreak, but decreased thereafter, in the shadow of the global financial crisis.[147] The Network has also been affected by the general funding situation of the WHO, which has been extremely precarious in recent years.[148] Since the 1980s, member states have withdrawn much of the WHO's institutional funding, leaving the agency—the Network's WHO office included—reliant on so-called "extra-budgetary" contributions.[149] These voluntary contributions by states and donors, earmarked for particular projects, now make up nearly 80% of the agency's budget.[150]

To address needs for funding for activities in periods where state support is insufficient, Network scientists have sometimes proposed contributions from private companies.[151] For most of the history of the Network, these were rejected, because of concerns about conflicts of interest.[152] The Network's new legal Framework—the agreement brokered in 2011 to resolve

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145 Interview with Keiji Fukuda, *supra* note 137 (describing not all countries as sharing the same "level of interest" in influenza); Interview with Ian Gust, *supra* note 135 (describing some national labs as historically having provided few samples to the Network).

146 Interview with Alan Hay, *supra* note 101.

147 Interview with Terry Besselaar, *supra* note 118.

148 *See* Kate Kelland, *The World Health Organization's Critical Challenge: Healing Itself*, REUTERS (Feb. 8, 2016, 11:55 AM), http://www.reuters.com/investigates/special-report/health-who-future/ [https://perma.cc/P5CU-9P4S] (describing the "budget pressures" facing WHO since the global financial crisis).

149 World Health Org., Sixty-Fourth World Health Assembly, Proposed Programme Budget 2014–2015, U.N. Doc. No. A66/7, at 12 (April 19, 2013).

150 *Id.* The WHO also now relies heavily on non-state actors for support. The Gates Foundation, for example, provides 10% of the WHO's voluntary contributions, making it the third largest contributor after the US (16%) and the UK (11%). World Health Org., Voluntary Contributions by Fund and by Contributor, 2015, U.N. Doc. No. A69/INF./3, at 2, 8–9 (May 13, 2016).

151 For example, in the early 2000s, a proposal to obtain Network funding from industry was rejected. Interview with Ian Gust, *supra* note 135.

152 *Id.*; *see also* Interview with Masato Tashiro, *supra* note 116 (describing complex negotiations to ensure that the Australian CC was fully publicly funded, after a vaccine manufacturing company with which it had ties was privatized). There were some very minor exceptions. For example, the CC in London in recent years had received a small amount of funding from industry to help support work

the conflict—broke new ground by for the first time demanding a significant financial contribution from industry. But it also deliberately fenced this funding off to tasks involving pandemic preparedness, with the intent that industry funds not displace government funding of the Network.[153]

Scientists in the Network have, over the years, found ways to deliberately cultivate support from states for their work, for example, by "showing [countries] that the lab capacity developed for flu is applicable for other diseases as well," and "getting across the message that developing capacity for influenza helps you in other ways."[154] The WHO has also supported and facilitated burden-of-disease studies, so that scientists could then "go into a country and show that this many people are dying [and] you're also having this dollar amount of impact in your economy due to people missing work, having to stay home and take care of sick children—you know, things that they probably hadn't even thought about."[155]

At a macro level, then, the priorities of the Network are established by governments, when they make decisions about how and whether to fund the labs. These decisions are deeply informed by scientists, however, and scientists also make the more granular decisions about Network priorities and practices. Particularly in its early years, the day-to-day governance of the Network was delegated to scientists themselves. Still today, scientists, who run the national labs and who occupy positions in the WHO office, make key decisions.[156] The Net-

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to make viruses adapted to their vaccine-making process. McCauley interview, supra note 59.

153 *See* PIP Framework, *supra* note 131, art. 6.14.3, at 21; *see also* Interview with Wenqing Zhang, *supra* note 130 (noting that the reasoning was that Network labs "should be supported by the government"). Contributions began in 2011; the total contributed by the end of 2015 was nearly $31 million. WHO, PARTNERSHIP CONTRIBUTION ANNUAL REPORT 2015 63 WHO/OHE/PED/2016.01. The funds are administered by the WHO, and have been spent primarily to enhance laboratory and surveillance capacity, with the remainder for activities such as risk-communication. *Id.* at 65. The partnership contribution has the potential, over time, to both substantially increase the resources available to the Network, and to invite more industry influence over the Network. The structure of disbursement, however, appears to be designed to minimize industry influence, with WHO deciding on allocations and priorities, guided by an advisory board that includes no representation from industry. *Id.* at 51.

154 Interview with Michael Shaw, *supra* note 121.

155 *Id.*

156 For example, significant decisions, such as the one to undertake a separate annual recommendation for vaccines for the Southern Hemisphere, have historically always been made "by the WHO or through consultation with representatives from the network and from the CCs, ERLs and National Influenza Centers." Interview with Wenqing Zhang, *supra* note 132. The Network also has an "expert

work itself is also uniformly described as a "voluntary" one.[157] As Hay described it, until the emergence of H5N1 and the recent watershed negotiations, there were also very few formal rules inside of the Network.[158] Decisions were not made hierarchically, from the governmental level down, but organically and horizontally, from scientist to scientist.[159] For example, in the 1990s, the Network decided to begin making formal recommendations for the composition of the flu vaccine twice a year rather than once a year, to better serve the needs of Southern countries (whose seasonal flu occurs during their winter, which is our summer).[160] The decision was made by Network scientists, led by emerging scientific practice and consensus rather than a top-down directive from states.

2. *Scientific Motivation in the Network*

In interviews, Network scientists cited a variety of factors when asked to describe why scientists contribute to the Network, and why they exert such effort to advance influenza sci-

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group" from the CCs that facilitates technical decision-making. *Id.* The most significant outputs of the Network, such as the annual vaccine strain recommendations, are made entirely by scientists, who meet annually at meetings convened by the WHO. *See WHO Selection Description*, *supra* note 65, at 6.

157 *See, e.g.*, Interview with Wenqing Zhang, *supra* note 132; *see also* Interview with Alan Hay, *supra* note 101 (describing the Network as an informal arrangement involving "anyone who wished to participate"). As experts in influenza, scientists in the GISRS labs may also have influence on a state's decision to participate in the GISRS Network. *See, e.g.*, Interview with Marilda Siqueira, Head, WHO Nat'l Influenza Ctr., Braz. (Oct. 8, 2013). Historically, the Network's reach has extended across geopolitical lines. Both China and Iran, for example, are longtime members, and even North Korea today has a national lab. *See* Network NICs, *supra* note 107.

158 *See* Interview with Alan Hay, *supra* note 101; *see also* Interview with Masato Tashiro, *supra* note 116 (describing the informal process of norm-making or rule-making in the Network, as "traditional—not [a] rule but an agreement").

159 For example, as Alan Hay, one of the longest-serving and most widely respected influenza scientists in the Network, put it: "there [were] one or two cases where their Ministry [of Health] might say [to a National lab], 'Well, why do we continue to support you to do this?' And I have written one or two, three, I can't remember, letters of support to those labs as to why what they were doing was important for the Network . . . . [B]ut . . . in many cases what these labs did were determined by the people running the labs." As Hay described it, "you take responsibility for doing something, so you have to decide what is necessary for you to do it . . . within the constraints of the budget. . . . And that's just the nature of the science that you're trying to do on a day-to-day basis." Interview with Alan Hay, *supra* note 101. Hay has worked on influenza for decades, and ran the WHO CC in London from 1993 to 2009. *See Alan Hay, Director of the WHO Collaborating Centre for Reference and Research on Influenza at the Francis Crick Institute, UK*, INT'L SOC'Y FOR INFLUENZA & OTHER RESPIRATORY VIRUS DISEASES, https://isirv.org/site/index.php/board-members/10-board/55-alan-hay [https://perma.cc/E3S4-7HJY].

160 Interview with Alan Hay, *supra* note 101.

ence, if not in the pursuit of financial gain. Three forms of motivation or allegiance in particular were cited regularly. A commitment to public health and an affinity for scientific inquiry were often described first, and a desire for credit and scientific reputation added later. Scientists often described several of these motivations together, one merging into the next. They also often characterized these values as a historical achievement, and as shared by some scientists more than others.

Consider, for example, these statements from scientists that are or were important in the CCs and in the Network's Geneva office:

> It's worked because you have a sufficient number of individuals that are keen to make it work. It doesn't work because WHO is telling people what to do, okay? It works because people understand this is important and they want to be part of it. . . . I think it partly is linked to the mentality of that time [when the Network was created], which is different from the mentality of today. . . . [W]hen we graduated, we didn't think about money. . . . [I]t was more[,] what were you going to *do*.[161]
>
> [T]here was quite clear understanding in the past that what we were doing was a public health role, a scientific role. You know, part of it was fed by the scientific interest. If it didn't have interest, I wouldn't have done it. You know, you weren't getting anything [i.e., compensation] out of it. And monitoring what's going on, there's always some twists of scientific interest that come out of it. And very often just at the technical level, in the assays you're using that stop functioning and things like that. So your continuing it feeds into your research interests.[162]
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> If you're involved in public health your ultimate ambition is to preserve or improve the health of the public. And this is just one of those ways in which you can do it.[163]

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161 Interview with Alan Hay, *supra* note 101. For similar statements, see Interview with Julian Druce, Head, Nat'l Influence Ctr., Austl. (Oct. 16, 2013) ("[I]t is all for the greater good at the end of the day. And I think that everyone that participates in it does sense that and feel that."); Interview with John McCauley, *supra* note 59 (invoking the "global good" when describing why scientists share and publicize their findings even before publications are accepted); Interview with Masato Tashiro, *supra* note 116 ("Our motivation was only the contribution internationally for . . . vaccine development and selection. . . ."); *id.* (describing the key motivation to contribute to the GISRS being "global public health safety").

162 Interview with Alan Hay, *supra* note 101.

163 Interview with Ian Gust, *supra* note 135. Gust is also a long-time flu scientist, who ran the CC in Australia. *See Professor Ian Gust*, LONDON SCH. OF HYGIENE & TROPICAL MED., http://www.lshtm.ac.uk/alumni/survey/professor_ian_gust.html [https://perma.cc/47HW-YM85] (last visited Feb. 11, 2017).

> [The Network started from the spirit of] public health needs, because their memory of the Spanish Flu in 1918 still was vivid at that time in 1950, or 1940. . . . [P]ublic health good, collaboration, this type of spirit start[ed] this Network. . . . [P]eople really were working together out of good willingness and collaboration. So a lot of our work actually was conducted automatically. . . . There was no legal document, binding document . . . or people talking about "I'll give you this, what I could get in return?" . . . . So we were lucky it started that way.[164]
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> I think in a lot of cases you see it[—]especially in the developing countries[—]you see very dedicated people are actually trying to do something good[.] [T]hey're trying to make a contribution to society. They're trying to improve the health of their fellow citizens. . . . [I]t's an internal drive that's hard to define. It's the excitement of facing a challenge and succeeding.[165]
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> [T]he genesis of it was pure public health. There's no reason . . . the UN would have gotten together to single out influenza if it was simply a scientific or technical issue. It was really the public health concerns about influenza, which started the discussions. Nonetheless, the maintenance of the system, particularly through much of the early decades, I think, relied a lot upon scientific interest, interpersonal relations, institution to institution relations, and so on.[166]

Scientists in the national centers likewise described motivations that merged the advancement of public health and the language of scientific interest. As one Australian scientist described it, sharing viruses in the Network provides a means both to protect "the greater good of the population," as well as to allow scientists to "analyz[e] what's around" and what might go into the next vaccine.[167] A scientist in Brazil described similarly both a sense of public importance of their virus sharing work, but also a pleasure in the science, noting:

> [I]n terms of benefits, . . . it's a very interesting Network because we can have in more or less real time what happens in different parts of the world. . . . [T]hat's a very dynamic way to work. [You asked me] what are your benefits as a scientist [to participating in the Network]. I think that sharing information is, for me, is absolutely an amazing way to work.[168]

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164 Interview with Wenqing Zhang, *supra* note 130.

165 Interview with Michael Shaw, *supra* note 121.

166 Interview with Keiji Fukuda, *supra* note 137. For a brief bio, see Reynolds, *supra* note 9, at 38.

167 Interview with Julian Druce, *supra* note 161.

168 Interview with Marilda Siqueira, *supra* note 157.

Notably, very similar accounts of the importance of both a sense of public mission and of scientific inquiry to the Network were offered by Network members decades ago.[169]

When asked about why individuals participated in the Network, scientists would refer to credit and self-interest, but also to a sense of community, as well as the importance of values of respect and fairness, particularly for those in the national labs. As one long-time CC head put it,

> [I]f you want people to cooperate in doing something which is purely altruistic and not necessarily in their own day to day interest and [that] causes them extra work, you need to make sure that they realize that there's value in what they're doing, that the information that they're creating is an effort globally and that you think they are wonderful and you hope that they'll continue doing it. . . . [I]t's like any endeavor in life. If you want people to do things for you, you have to be nice to them, and make them feel wanted and trusted and valued.[170]

Many others also noted that a sense of community among the various labs was critical to the Network's success.[171] The CCs also described personal connections with national labs especially in their region, as well as trainings and technical support, as an important part of their role.[172] Through this process, as one scientist described, CCs and national labs become "intimately connected."[173] It was clear from interviews that many of the scientists in the Network, and particularly in the CCs, knew each other well. One described the Network as feeling "a bit like a family."[174]

Scientists also connected participation in the WHO system with their ability to do their own scientific work, because WHO accreditation, or credit from the scientific system of publication

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169 Cockburn, *supra* note 133, at 184. The then-head of the Network at WHO said this when describing its operation: "Virologists will always want as precise an identification as possible of the viruses they isolate, not only because of the epidemiological importance of such identification, but also because of the fact that this is essential for the satisfaction of the natural curiosity of the scientist." *Id.*

170 Interview with Ian Gust, *supra* note 135.

171 *See* Interview with Terry Besselaar, *supra* note 118 ("[W]e try and keep in touch with [Network scientists and] thank[ ] them for their contributions, it doesn't matter how small they are, . . . to make them feel part of the Network[.] [A]nd we do try and invite them to training workshops etc., so at least they're getting something out of the system."); Interview with Alan Hay, *supra* note 101 (describing the importance of "good personal relationship[s]" and "personal interaction," as well as the mutual sharing of information).

172 *See* Interview with Masato Tashiro, *supra* note 116.

173 *Id.*

174 Interview with Terry Besselaar, *supra* note 118.

more generally, helped support their efforts to fund their labs. The Australian head of a national lab, for example, said: "You do get kudos, you are able to say you're a WHO National Influenza Center. . . . [That has value for the individual, and] when we apply to the government for this or that or the other, it always helps . . . ."[175] Scientists in labs in Madagascar and Brazil both noted that there were important connections between scientific credit, for example as marked by authorship or acknowledgement in scientific papers, and government support for their work.[176]

Both also cited examples of cases where data from their labs had been used in publications without acknowledgement of their efforts to gather the data. When asked why this was problematic, one replied:

> I think that sometimes they don't realize the work that has been [done] by the people in the country that collect data. . . . I was really involved in setting up of the Network in Madagascar. Now I know how [much] work [and] negotiation with people [it is]. . . . [S]ince it is a lot of work . . . all the people who are working in the Network [should be able to say], "Look, it's my name, I am acknowledged." . . . [P]eople are proud of that. . . . And also we have to justify to the Ministry of Health what we are doing. So imagine [that] all the papers regarding Madagascar were published by other people without acknowledgment. Look, when I'm going to the Minister of Health and telling him we are doing this, we are doing that—these [acknowledgements] are showing the value.[177]

Quickly in conversations about motivation, then, issues of credit emerge, in a language that reflects its importance both as a reward in itself, and as a signal to funders, who use such acknowledgement as evidence of the importance or success of the lab they are funding.[178] A lead CDC scientist, when asked why credit was important for scientists in the Network, said: "Well, there are two drivers; one is just the personal satisfaction of being recognized for what you've done. The other is of course professional advancement; being able to put something on your CV when you're asking for promotion or applying for a different position."[179] While labs in the Network are supposed

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175 Interview with Julian Druce, *supra* note 161.

176 Interview with JM Heraud, *supra* note 139; Interview with Marilda Siqueira, *supra* note 157.

177 Interview with JM Heraud, *supra* note 139.

178 *See* Interview with Yuelong Shu, *supra* note 137 (describing credit as a "fundamental or a basic principle" of the Network, because credit provides a form of compensation to national labs for their hard work).

179 Interview with Michael Shaw, *supra* note 121.

to have committed financial support from their governments, and thus are often less dependent upon grants than other scientists, publication records and peer recognition can impact promotions or the level of support a lab receives.[180] Beyond that, as one scientist put it, "I think everybody likes to have a nice fleshy CV. I mean, you being at Yale, I'm sure you understand that."[181]

In the archive, one can find traces of scientists engaged in close reading of the reports of the Network, and issuing corrections when they believe that their contributions are insufficiently recognized.[182] Other documents also reflect the deep importance of reputation, for example, with references to scientists getting "very hot under the collar" if possible mistakes in their work are aired publicly.[183] Finally, as discussed below, one key complaint that brought the Indonesian crisis to a head in 2007 was that the work of scientists in the national labs was not being adequately recognized.[184] Some of the strongest evidence of the importance of credit to Network scientists comes from complaints that the basic scientific obligation to give credit and to include those who provide materials in your collaborations and papers was not always scrupulously respected.[185]

As these sources reflect, there are a range of ways that credit and recognition are granted in the Network. Some are informal, as in the archival example noted above, where un-

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180 *Id.*

181 *Id.*

182 *See, e.g.*, World Health Org., Second World Health Assembly, World Influenza Centre, Provisional Agenda Item 8.16.4.2, at 5, U.N. Doc. No. A2/62 (June 15, 1949), http://apps.who.int/iris/bitstream/10665/98934/1/WHA2_62_eng.pdf [http://perma.cc/WR77-T9XY] (issuing a correction that acknowledges that certain virus samples had been "isolated at the Institut Pasteur, Paris"),

183 Letter from C.H. Andrewes to Dr. C. Klimt (Nov. 6, 1950) (on file with author) (describing the sensitivities of publicly suggesting that a scientists' results were the result of contamination).

184 *See infra* note 204 and accompanying text.

185 *See* Interview with Ian Gust, *supra* note 135 (describing appropriate credit as something that sometimes people in the Network "overlooked or forgot" and noting that "occasionally that caused resentment"); Interview with Anne Kelso, *supra* note 134 (describing "cases where laboratories and the individual scientists felt that they'd been, if you like, done over by other center people, Collaborating Centers who might have then published data based on their viruses without acknowledgement or without including them in the research. And this is particularly awkward at the interface between surveillance and research. If a National Influenza Center has sent viruses to a Collaborating Center for surveillance purposes, and then the Collaborating Center does work that the National Influenza Center sees as research and publishes a paper without them on it, then that's understandably disturbing."); *see also infra* notes 203–12 and accompanying text.

published reports of the Network were in dispute.[186] Speakers at Network events are also chosen in part to acknowledge and reward excellence in the national labs.[187] Interviewees also described a formal system of credit and accreditation that was of great importance. Several noted that the WHO system of designating official national labs and CCs was valuable as a signal to other scientists, as well as governments, of the scientific capacity of the lab.[188] Most frequently, however, references to credit and reputation were linked to the system of scientific publication. The current head of the London CC, John McCauley, for example, described scientists in general as wanting "recognition for observations and discoveries," which he described as "done through publication."[189] The most intense disputes about credit described above were about credit given in published work, allocated either through co-authorship or through references in the acknowledgements section of a paper. A "fleshy CV," of course, also measures value largely in terms of publications.

Scientists in the Network indeed publish regularly. A search of the leading scientific citation index shows that over 80 percent of the scientists that led a Network lab in 2016 have authored scientific articles, with over six in ten having published articles on influenza.[190] This is particularly impressive given the vast geographic diversity present in the Network, and the fact that many of the national labs are funded more for surveillance than research, and include flu only as one disease among many that they study.[191] Publications records also appear to be in fact linked to funding in the way Network participants suggest: scientists in more well-resourced labs, and

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186 *See supra* note 185 and accompanying text.

187 *See* Interview with Terry Besselaar, *supra* note 118. Often, in interviews, scientists would also praise a particular scientist as especially skilled, or having contributed in particularly important ways to the Network, offering an example of the importance of informal reputational circuits to scientific reputation. For example, several scientists went out of their way to praise the efforts of the Chinese CC, in particular for quickly releasing all of its data on H7N9, on the same day that the outbreak was publicly announced. *See* Interview with Anne Kelso, *supra* note 134; Interview with Michael Shaw, *supra* note 121. As this suggests, I was myself becoming part of the reputational circuit.

188 A key WHO official described the main motivation for scientists in the Network as "recognition of involvement in public health," which she noted comes in significant part through both official recognition of Network labs. Interview with Terry Besselaar, *supra* note 118.

189 Interview with John McCauley, *supra* note 59.

190 Appendix C, Table 3.

191 *See id.* For reasons described in the Appendix, this is also likely an underestimate of their contributions.

especially in the research-intensive CCs, tend to publish more.[192] Both descriptions by Network participants and publishing patterns, then, confirm the importance of scientific publishing to the modality of work undertaken in the Network.

C. Crisis

When avian influenza emerged, however, the normal practices of the Network were put under intense new pressure. The rapid response to H5N1 in Hong Kong significantly slowed its spread to other regions. But as expected,[193] H5N1 evolved and re-emerged. It underwent reassortments and mutations that made it tougher, and more deadly to a range of animals, including humans.[194] By early 2004, it had killed millions of birds in Thailand and Vietnam, and dozens of people.[195] WHO warnings about the virus became increasingly ominous, particularly as human cases turned up that could not immediately be traced to poultry.[196] The symptoms in humans were also worryingly similar to those of the 1919 flu—not just fever and coughing, but also encephalitis, acute respiratory distress, and internal bleeding.[197]

Indonesia reported its first case in 2005, and soon became the epicenter of the disease in humans, with an average of five new cases reported each month.[198] The fatality rate was thought to be above 80%.[199] The median age of victims was just twenty years.[200] The result was acute fear of a very deadly pandemic that quickly began to radiate into political circles.[201]

The Indonesian government scrambled to respond, and soon found—to its great frustration—that it was unable to buy

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192 The mean number of influenza publications for heads of Network labs generally is 17.5, but for CC heads it is 176. Appendix C, Table 2; *see also id.* at Figure 1. The number of influenza publications by scientists based in North America and Europe is also much higher than, for example, the number by scientists based in Latin America and Africa. *See id.* at Table 4.

193 Rosenwald, *supra* note 7, at 183 (citing Robert Webster, then head of the CC at St. Jude).

194 *See* Laurie Garrett, *The Next Pandemic?*, 84 FOREIGN AFF. 3, 11–12 (2005); Osterholm, *supra* note 3, at 25.

195 Reynolds, *supra* note 9, at 38; *see also* Garrett, *supra* note 194, at 12.

196 Garrett, *supra* note 194, at 13–14.

197 *Id.* at 14.

198 Endang R. Sedyaningsih et al., *Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia*, 37 ANNALS ACAD. MED. SING. 482, 483 (2008).

199 *Id.* at 484. The fatality rate for H5N1 is now thought to be closer to 50%. *See* Garrett, *supra* note 194, at 3.

200 Sedyaningsih et al., *supra* note 198, at 484.

201 *See, e.g.*, Garrett, *supra* note 194, at 3–4.

antiviral medicines, or H5N1 vaccines (to ship when they were completed), because wealthy countries had pre-purchased all the available supply of both.[202] In addition, the Indonesian Health Minister discovered that one H5N1 vaccine being prepared by an Australian company was based upon an Indonesian strain that had been contributed to the Network—and that Indonesia was considered to have no rights either to the samples or to the resulting vaccines.[203] Finally, the Minister also learned that research on Indonesian H5N1 strains had been presented at international scientific meetings, with neither the permission nor participation of Indonesians.[204] Though Indonesia had been contributing virus samples to the Network since the 1960s, in January 2007, the country announced that it would cease its contributions to the Network until these concerns were addressed.[205]

As the Indonesian crisis quickly revealed, there were no mechanisms in place to ensure adequate global supply of vaccines in the case of a pandemic, and nearly all manufacturing capacity was concentrated in the global North.[206] This virtually ensured that developing countries would have little if any access to vaccines in a pandemic. In the firestorm of intense advocacy that emerged thereafter, concern about patents, including in the Network, also became a key focus. Though some of those at the center of the Flu Network seem to have known that sporadic patenting was happening before, that fact was not widely known until now. Particularly influential was a report commissioned by an NGO that was advising developing countries, that identified many patent applications related to H5N1, including some coming from WHO labs, that made use

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202 *See* SITI FADILAH SUPARI, IT'S TIME FOR THE WORLD TO CHANGE, IN THE SPIRIT OF DIGNITY, EQUITY, AND TRANSPARENCY: DIVINE HAND BEHIND AVIAN INFLUENZA 40–42 (2008); Sedyaningsih et al., *supra* note 198, at 486.

203 SUPARI, *supra* note 202, at 35–37.

204 Sedyaningsih et al., *supra* note 198, at 485. A WikiLeaks cable from John Heffern, then Deputy Chief of Mission in Jakarta, confirms the importance of the disrespect perceived by Indonesian scientists. *See Indonesia - Avian Influenza Sample Sharing Update*, WIKILEAKS (Apr. 13, 2007, 08:51AM), http://www.wikileaks.org/plusd/cables/07JAKARTA1053_a.html [https://perma.cc/N785-ZYGX] ("Endang explained that NIHRD researchers want peer respect in the international research community.")

205 SUPARI, *supra* note 202, at 25, 34–35; Sedyaningsih et al., *supra* note 198, at 486.

206 World Health Org., Mapping the Global Vaccine Manufacturing Workforce: Preliminary Results of a Survey Among Vaccine Manufacturers 5 (2011) (unpublished draft report), http://www.who.int/phi/news/Draft_Survey_Report_Phases1-2.pdf [https://perma.cc/K376-6RJD] (last visited Aug. 4, 2014).

of strains contributed by developing countries.[207] The report warned that such patents "are resulting in a much more complex and limiting field of intellectual property claims than has ever before existed for influenza vaccine,"[208] and that flu-related patents had already shown the potential to hinder government efforts to prepare for a pandemic.[209] Existing patents could in fact restrict or slow access to vaccines and therapeutics in a pandemic,[210] though only one identified patent suite held by a Network lab could have this power.[211] In the wake of the recent campaigns to overcome patent barriers to HIV/AIDS medicines, and patent mappings such as this one, developing countries nonetheless found much reason for suspicion. As the Indonesian Health Minister saw it, if the Network's benefits were distributed according to market logic, Indonesia would be foolish to not to take its samples directly to companies in exchange for vaccines. She in fact explored such a deal, to give viruses to a private company, and obtain vaccines for the state in exchange.[212]

There was an immediate outcry when Indonesia suspended its cooperation with the Network, because of the dangerous consequences for both flu surveillance and the collection of vaccine viruses.[213] What followed was a five year long, very high-profile global negotiation at the WHO to create a new framework for the sharing of possible pandemic viruses,[214] in-

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207 EDWARD HAMMOND, THIRD WORLD NETWORK, SOME INTELLECTUAL PROPERTY ISSUES RELATED TO H5N1 INFLUENZA VIRUSES, RESEARCH AND VACCINES 9 (2009). The report was commissioned by Third World Network, which was a key NGO providing support to developing country governments during the negotiation. *See* Interview with Sangeeta Shashikant, Legal Advisor, Third World Network, in Geneva, Switz. (Nov. 4, 2011). For more on these patents see Appendix B.2.

208 HAMMOND, *supra* note 207, at 2.

209 For example, the report recounts an incident in which the U.S. government was forced to threaten to use its march-in rights to get a license from MedImmune for Sanofi to produce an H5N1 influenza vaccine, a privilege that other governments would not have had. HAMMOND, *supra* note 207, at 28.

210 *See* Appendix B.2.

211 *See* Appendix B.1 at 6–7 (describing St. Jude's reverse genetics patents, and the fact that the public sector was permitted to freely use this suite of patents—licensed to a company called Medimmune—during the avian flu scare).

212 *See, e.g.*, SUPARI, *supra* note 202, at 27–28.

213 *See, e.g.*, Richard C. Holbrooke & Laurie Garrett, Op-Ed., *'Sovereignty' That Risks Global Health*, WASH. POST, Aug. 10, 2008, at B7.

214 Discussions were early on limited to viruses of pandemic potential, excluding those related to seasonal flu. *See, e.g.*, World Health Org., Director-General, Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, 3, U.N. Doc. No. A/PIP/IGM/4 (Oct. 9, 2007) [hereinafter IGM-4], http://apps.who.int/gb/pip/pdf_files/PIP_IGM_4-en.pdf [http://perma.cc/33N7-VPFL] (last visited Aug. 4, 2014). This was in order to focus attention on the issue of greatest public health

volving hundreds of health officials and high-level government officials, including Ambassadors to the U.N.[215]

Country positions of course differed from one another and evolved over time, but broadly speaking, developing and developed countries were divided by two key issues. The first was the nature of any benefit sharing. Developing countries insisted that companies who benefitted from the Network should be legally bound to contribute a certain amount of vaccines and treatments to countries in need, and (for some) also to facilitate the production of vaccines in developing countries through transfer of technology and licensing of any relevant IP.[216] Developed countries supported the creation of a fund and stockpile through WHO to improve access to vaccines, but insisted that any benefit sharing through the Network should be voluntary.[217]

The second issue of major contention regarded intellectual property. Developing countries took the position that Network labs (and initially also any third-party recipients) should be broadly forbidden to seek IP on Network materials, and also on

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concern, and to limit the complexity of the negotiations. Interview with Keiji Fukuda, *supra* note 137.

215 *See, e.g.*, World Health Org., List of Participants of the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses, U.N. Doc. No. A/PIP/IGM/DIV/2 Rev. 1 (Nov. 22, 2007), http://apps.who.int/gb/pip/pdf_files/PIP_%20IGM_DIV2Rev1.pdf [https://perma.cc/Z8WM-AE6S] (listing representatives from 109 countries, the United Nations, and other agencies and organizations); World Health Org., List of Participants in Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: Sharing of Influenza and Access to Vaccines and Other Benefits, U.N. Doc. No. A/PIP/OEWG/DIV/1 Rev. 1 (May 11, 2010), http://apps.who.int/gb/pip/pdf_files/OEWG1/PIP_OEWG%20_DIV1Rev1.pdf [https://perma.cc/4UBT-A9Y8] (last visited Aug. 4, 2014) (listing representatives from 79 countries).

216 See, for example, Indonesia's Proposal requiring benefit sharing, and technology and know-how transfer. World Health Org., Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, 3–4, U.N. Doc. No. A/PIP/IGM/5 (Nov. 19, 2007) [hereinafter Indonesia Proposal], http://apps.who.int/gb/pip/pdf_files/PIP_IGM_5-en.pdf [https://perma.cc/8HY2-CMW6] (last visited Aug. 4, 2014). See also, for example, Thailand's Proposal requiring legally binding obligations on manufacturers to contribute vaccines, as well as suggesting technology transfer and know-how requirements. World Health Org., Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, 6–8, U.N. Doc. No. A/PIP/IGM/6 (Nov. 19, 2007) [hereinafter Thailand Proposal], http://apps.who.int/gb/pip/pdf_files/PIP_IGM_6-en.pdf [https://perma.cc/7YQE-3VG2] (last visited Aug. 4, 2014).

217 *See, e.g.*, World Health Org., Secretariat, Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, 3, U.N. Doc. No. EB 126/4 (Dec. 10, 2009) [hereinafter Secretariat Report], http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_4-en.pdf [https://perma.cc/5NUV-B8P8] (last visited Aug. 5, 2014).

broadly defined derivatives thereof.[218] Developed countries, in turn, resisted any restrictions on IP either within or outside the network.[219]

A third set of tensions that emerged during the negotiations related to the practices of scientists within the Network. Developing countries wanted clear commitments that Network labs and third-party recipients would acknowledge the contributions of the scientists in national labs, and seek to involve these scientists in subsequent work.[220] Scientists also became more aware of the existence of patents inside of the Network during the negotiations, and the matter raised concerns. As Alan Hay described, suspicions emerged that "some people were making a lot of money out of" patents related to their Network work.[221] Others reported that there were suspicions from some in developing countries that the CCs were selling viruses to industry.[222] Although there is no evidence that either was correct,[223] it spoke to an emerging mistrust in the Network—particularly coming from developing countries and their scientists—that began to threaten its practices of free information sharing.

With so many contentious issues on the table, the negotiations were protracted and difficult. Commentators expressed deep concern that the process would fail, leaving the Network

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218 *See, e.g.*, Thailand Proposal, *supra* note 216, at § 12(a)(viii) (prohibiting recipients of GISRS materials, inside or outside the Network, to assert IP rights on any products derived from, or that incorporate, GISRS materials); Indonesia Proposal, *supra* note 216, at 4 (same).

219 Developed countries, for example, insisted on a narrow definition of GISRS materials, and rejected the notion that anything except wild-type viruses—which would not generally be subject to patents as such—could be excluded from IP protection. World Health Org., Director-General, Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits, Outcome of the resumed Intergovernmental Meeting, 12, U.N. Doc. No. A62/5 Add.1 (May 18, 2009), http://apps.who.int/gb/ebwha/pdf_files/A62/A62_5Add1-en.pdf [https://perma.cc/24LL-YTNL] (last visited Aug. 5, 2014); IGM-4, *supra* note 214, at app. 3 paras. 4, 7, 30.

220 *See, e.g.*, Indonesia Proposal, *supra* note 216, at 4 (discussing credit and involvement); World Health Org., Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, 3–23, U.N. Doc. No. A/PIP/IGM/7 (Jan. 4, 2008) [hereinafter Africa proposal], http://apps.who.int/gb/pip/pdf_files/PIP_IGM_7-en.pdf [https://perma.cc/QA89-N5E9] (same).

221 Interview with Alan Hay, *supra* note 101.

222 Interview with Masato Tashiro, *supra* note 116.

223 As noted in Appendix B, the only evidence I have found of any Network lab earning income from patents involves the reverse genetics patents at St. Jude, which are not specific to influenza and arguably stem from basic research that was much broader than the CC's Network activities. *See* Appendix B at 7.

fundamentally undermined.[224] The 2009 "swine flu" pandemic, caused by an H1N1 virus, however, played a critical role in reigniting the negotiations. It increased the salience of the risk of a new flu pandemic, and generated renewed political will to find a resolution.[225] Two new co-chairs were appointed at this point, who brought the parties back together and engaged in unprecedented outreach to industry, who were brought in to speak directly to negotiators.[226]

A key breakthrough in the negotiation was described by one co-chair as "almost philosophical."[227] As he recounted, it came at a moment when all participants came to agree "that the principle of both virus sharing and benefits sharing should go together," and that the "idea was . . . to make the system a fair system," and to ensure that the benefits—mainly vaccines—to be shared would go not to individual countries, but to the WHO.[228] At a key moment, the logic of reciprocity that characterized the Network, then, was reestablished.

The final breakthrough came in April 2011, when with the final hours of the negotiation running out, the new co-chairs gathered together key countries—the United States, United Kingdom, France, Germany, Finland, Australia, Canada, China, Brazil, Indonesia, India, Egypt, and Turkey—to propose a "take-it-or-leave it" package with three key elements.[229] Two were "music to the ears of the developing countries": Industry would contribute half of the running costs of the Network to the

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224 *See, e.g.*, David P. Fidler, *Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1 and Pandemic Influenza H1N1*, PLOS MED., May 2010, at 1, 3 ("The negotiating path that could lead to a new global access framework for influenza vaccines is not apparent . . . ."); Rachel Irwin, *Indonesia, H5N1, and Global Health Diplomacy*, GLOB. HEALTH GOVERNANCE, 2010, http://eprints.lse.ac.uk/28272/1/Irwin_Indonesia_and_Global_Health_Diplomacy.pdf [https://perma.cc/L6TQ-PPD2] (noting that "[a]s the virus-sharing negotiations have continued for three years without resolution, some of the urgency and political will has been lost").

225 Interview with Juan José Gómez Camacho, Permanent Representative of Mex. to the United Nations, in Geneva, Switz. (Nov. 18, 2011) (remarking that "after H1N1 . . . the awareness and the pressure for these processes to be finished obviously increased, because it was clear that we were not playing with hypothetical games"); Interview with Gaudenz Silberschmidt, Head of Int'l Aff., Swiss Fed. Office of Pub. Health, in Geneva, Switz. (Nov. 17, 2011) (remarking that H1N1 "made it easier to move to real commitments in the . . . negotiations"). Silberschmidt has worked for the WHO since 2012, and gave the interview in his previous role working for the Swiss government.

226 Interview with Juan José Gómez Camacho, *supra* note 225; Interview with Gaudenz Silberschmidt, *supra* note 225.

227 Interview with Juan José Gómez Camacho, *supra* note 225.

228 *Id.*

229 *See id.*

WHO, and would donate a certain amount of real-time production of pandemic vaccines to the WHO.[230] The third was critical for developed countries: the Framework would include no compulsory transfers of patents or know-how from companies, which developing countries had demanded.[231] While IP restrictions are imposed inside the Network, there are no mandatory IP-related conditions imposed by the Network on outsiders.[232] One by one, each country announced that they were willing to take the deal.[233] The lone hold-out was the United States. The next morning, the United States announced that it too would agree. According to sources intimately involved in the negotiations, but who did not wish to be named, the about-face was the result of late-night phone calls between negotiators and the CEOs of various multinational companies, who in turn reached out to U.S. officials in Washington who had not been aware that the industry supported the deal.

The result was the path-breaking Pandemic Influenza Preparedness Framework, or "PIP Framework," officially adopted by the WHO General Assembly a few weeks later.[234] The Framework included important new rules, but also codified existing rules inside of the Network. As such, it is an excellent place to look to understand what was critical to the Network's reconstruction, as well as what aspects of the Network's rules are most important to its operation.

D. Reconstruction and Rules

The crisis in 2007 was triggered primarily by tensions between developing and developed countries, rather than among Network scientists, and its resolution required significant innovations in the Network's legal framework. The informality that had once characterized virus exchanges in the Network was replaced by a highly formal system requiring licenses to accompany the transfer of all potential pandemic strains. The Framework developed two "standard material transfer agreements," which operate as running contracts that mandate certain responsibilities for those who receive viruses from the Network, one for insiders, and another for Network outsiders.

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230 *See id.*

231 *See id.*

232 As I will note, firms have an option, in fulfilling their benefit sharing obligations, to contribute benefits via voluntary licensing instead of vaccine or drug donations, but this is not mandatory.

233 *See* Interview with Juan José Gómez Camacho, *supra* note 225.

234 PIP Framework, *supra* note 131.

All transfers of virus material to non-Network entities are governed by the outsider license. Over substantial opposition from developed countries, these contracts were rendered legally enforceable: disputes are to be referred to binding international arbitration.[235] The most important obligation of the license applies to manufacturers of vaccines that benefit from the Flu Network, who are obliged to commit to benefit sharing in return. While firms have options, it is widely believed that they will chose to meet their obligations by donating approximately 10% of their real time production in a pandemic to the WHO, and reserving another 10% of such production "at affordable prices" to the WHO.[236] These goods are to be distributed by the WHO according to public health need.[237] Industry that benefits from the Network also must contribute financially to the Network, to "improv[e] global pandemic influenza preparedness and response," to the tune of approximately $23 million a year.[238]

For insiders, a separate contract was drafted, supplemented by standard terms of reference for Network labs.[239] These agreements largely track practices in the Network that had evolved informally. In their emphasis, however—and in particular in a much-debated provision over IP—they are revealing. Three salient obligations for labs emerge from the Framework.

The first highlights the importance to Network scientists of recognition and collaboration. According to their model terms of reference, labs in the Network must "actively seek the participation of scientists . . . from originating laboratories and other

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235 PIP Framework, *supra* note 131, annex 2, art. 5, at 35; *see also* Interview with Sangeeta Shashikant, *supra* note 207 (discussing the United States' resistance to binding arbitration).

236 PIP Framework, *supra* note 131, annex 2, art. 4.1(A1), at 34. Other options include licensing and technology transfer to developing country manufacturers. Manufacturers of anti-retroviral medicines that rely on the GISRS will have a similar legal obligation, either for licensing or the donation of "at least X treatment courses of needed anti-retroviral medicine." *Id.* annex 2, art. 4.1(A3), at 34.

237 *Id.* art. 1.8, at 3 ("[T]he benefits arising from the sharing of H5N1 and other influenza viruses with human pandemic potential should be shared with all Member States based on public health risk and need.").

238 *Id.* art. 6.14.3.1, at 22. The amount is articulated at 50% of the running cost of the Network, so should increase as those running costs increase. *Id.* art. 6.14.3, at 21–22. Counter-intuitively, given the metric chosen, the "contribution" was intended not to help defray the existing running costs of the GISRS, but rather to "improv[e] global pandemic influenza preparedness and response." *Id.* art. 6.14.3.1, at 22. For more on its implementation, see *supra* note 153.

239 *Id.* annex 1, art. 1.1, at 29 (designating as subject to the license "influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO terms of reference").

authorized laboratories, especially those from developing countries, in scientific projects [and publications] associated with . . . clinical specimens . . . from their countries . . . ."[240]

The second highlights the tensions around IP that emerged in the Network. This rule was new, though it may not require significant departure from previous practice. It provides that Network labs "should" not seek to obtain IP "on" a carefully defined set of Network "biological materials."[241] The definition of biological materials includes not only wild viruses, but also virus isolates, modified candidate vaccine viruses, and certain cDNA.[242] The restriction thus clearly reaches certain patent-eligible subject matter.[243] Though couched in the discretionary language of "should," there is some evidence that the WHO is committed to treating the rule as mandatory.[244]

Third, the Framework imposes obligations on labs in the Flu Network to share materials and information, both with one another and with the general public.[245] National labs are obligated specifically to "maintain active communication and collaboration with other members of the [Network]," as well as to inform WHO, national authorities, and the public quickly when potential pandemic strains emerge.[246] CCs are given special obligations to share information back to national labs, and "to ensure that up-to-date information and findings of public health significance are rapidly exchanged . . . ."[247]

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240 *Id.* annex 1, art. 5.2, at 30–31; *see also id.* annex 4, at 40–41 (same); *id.* annex 5, at 45, 48, 52 (same). Outsiders are also required to "appropriately acknowledge," for example in publications and presentations, the contributions of WHO laboratories that provide biological materials to the Network. *Id.* annex 2, art. 4.3, at 35; *see also id.* annex 1, art. 5.3, at 31 (requiring insider recipients to "acknowledge in presentations and publications" contributions by other Network scientists and laboratories).

241 *Id.* annex 1, art 6.1, at 31; *see also id.* art. 4.1, at 8 (defining "biological materials").

242 *See id.* art. 4.1, at 8.

243 Less clear is whether it bars patents of the sort that were previously obtained or sought by the Network. This depends on interpretation of both the Framework and the complicated claims of the relevant patents or applications. For an overview of existing evidence on Network patents and patent applications, see Appendix B.

244 *Compare* PIP Framework, *supra* note 131, annex 1, art. 6.1, at 31 ("Neither the Provider nor the Recipient *should* seek to obtain any intellectual property rights (IPRs) on the Materials") (emphasis added), *with* Interview with Sangeeta Shashikant, *supra* note 206 (noting that WHO Director General Chan reportedly gave countries personal assurances that GISRS labs would not seek such IPRs).

245 *See* PIP Framework, *supra* note 131, annex 4, at 41; *id.* annex 5, at 45.

246 *Id.* annex 5, at 51–52.

247 *Id.* annex 5, at 45; *see also id.* annex 5, at 46 (obliging CCs to share information about H and N subtyping, as well as gene sequences, not only with other CCs but also with originating labs).

All Network labs are also obliged to submit genetic sequence data to publicly available databases in a timely manner.[248] This codified a norm that emerged only in 2006, when a prominent influenza scientist who was not a member of a Network lab objected to the earlier practice of depositing Network sequence information in a password protected database at Los Alamos.[249] Only a limited number of labs, most of them WHO labs, had access to this site, perhaps reflecting the concerns of contributing countries, and perhaps arising out of the desires of some scientists to keep their information close to allow them to benefit through exclusive publications. Just a few months later, a powerful coalition of scientists, including the heads of the CCs, announced a new initiative to ensure that all H5N1 sequences would be quickly entered into public-access databases, housed in an organization created for the purpose, called the GISAID.[250] The new database, EpiFlu, binds all users of the data with a click-wrap contract to two key conditions, designed to address the fairness concerns raised by developing countries and their scientists in the negotiations. Recipients are first obliged to give credit to originating labs and make "best efforts" to collaborate with them, and second are required not to seek patents on any data or fraction of data obtained from EpiFlu.[251] EpiFlu has become the repository of choice for many Network labs, particularly in developing countries.[252] Some Network labs, including the CDC, however, prefer to use a public database that imposes no restrictions on users, when compatible with their obligations to those who share samples with the Network.[253]

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248 *See id.* annex 4, at 41; *see also id.* annex 5, at 46 (obliging CCs to share H and N and other gene sequences of potential pandemic viruses "to a publicly accessible database in a timely manner but no later than three months after sequencing is completed, unless otherwise instructed by the laboratory or country providing the clinical specimens and/or viruses").

249 Martin Enserink, *As H5N1 Keeps Spreading, A Call to Release More Data*, 311 SCI. 1224, 1224 (2006).

250 *See* Martin Enserink, *Pushed by an Outsider, Scientists Call for Global Plan to Share Flu Data*, 313 SCIENCE 1026, 1026 (2006). The Indonesians were also early adherents to the GISAID model. *See* SUPARI, *supra* note 202, at 20–21.

251 *See Registration Form for Individual Users*, GISAID, http://platform.gisaid.org/epi3/frontend#4b51bf [https://perma.cc/6WGL-SLZR]. This too is structured as a running contract, so that data may not be transferred to anyone not bound by the same agreement.

252 *See* Lisa Schnirring, *Pandemic Reveals Strengths of New Flu Database*, CTR. FOR INFECTIOUS DISEASE RESEARCH & POLICY (June 25, 2009), http://www.cidrap.umn.edu/news-perspective/2009/06/pandemic-reveals-strengths-new-flu-database [https://perma.cc/7N45-X7XC].

253 *See* Interview with Michael Shaw, *supra* note 121.

Distilling all of this and combining it with other information we have about the Network, we can discern a key set of rules that govern information exchange and use within and outside the Network, that, as far as evidence permits us to see, are often followed. Inside of the Network, labs are reciprocally obliged to share data and information with one another. These obligations reflect what leading scientists in the Network describe as longstanding practices of free exchange within the Network.[254] As Hay put it: "if somebody calls me up and asks me a question, I give them an answer. . . . Now who else gives information away freely? . . . [I]t's just a different way of thinking."[255] This norm was articulated also by others, who described rapid sharing of samples and information as "one of the most important rules" of the Network.[256] The archives also reveal that the expectation that viruses and data will be shared freely has a long history in the Network. Accusations that a scientist has failed adequately to share virus samples with others are taken very seriously, and with some umbrage.[257]

Information exchange is also seen as a primary benefit by scientists themselves. John McCauley, head of the London CC,

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254 *See* Interview with Alan Hay, *supra* note 101 (noting that giving "information freely" was the Network's responsibility); Interview with John McCauley, *supra* note 59 (remarking that "there has always been free exchange of human influenza viruses and exchange of other influenza viruses within the Network").

255 Interview with Alan Hay, *supra* note 101.

256 Interview with Marilda Siqueira, *supra* note 157.

257 Consider, for example, this exchange between C.H. Andrewes, a leading flu scientist at the World Influenza Centre at Mill Hill in London, and the coordinator of the Network in Geneva at the time, Dr. A. Payne. Andrewes writes, of a third influenza scientist, Dr. Magill: "I take great exception to Magill's statement that he has not had access to our strains or data. I have sent information on representative strains across the Atlantic and have offered others . . . . Over several years we got no tittle of information about his own serological studies—however, I won't rub that in." Letter from C.H. Andrewes to Dr. A.M.M. Payne, M.D. (June 8, 1953) (on file with author). At times, Andrewes took such complaints to the broader community of scientists. For example, in the summary influenza report produced by the Network in 1952, which would have been sent to all of the labs in the Network, Andrews included this statement: "In no instance, other than those mentioned above, has material been sent to the World Influenza Centre [from the United States], nor has any information come in as to the type of virus." C.H. Andrewes, Summary Report on Influenza 1951–52 to Dr. A.A.M. Payne (Mar. 12, 1952). Andrewes had underlined it for emphasis. Alarmed, Payne had written back noting that this sentence had to be omitted in the final report, since "the cooperating laboratories are entirely independent and are cooperating on a voluntary basis, and that therefore we have to be rather careful to retain their good will." Letter from Dr. A.M.M. Payne, M.D., to Dr. Andrewes (Mar. 25, 1952). When he learned that Andrewes had already sent these sentences as part of the draft report directly to the offending scientist, Payne followed up with a letter to that scientist seeking to smooth things out and to suggest better ways to report their information. *See* Letter from A.M.M. Payne to Dorland Davis (Apr. 7, 1952).

when asked about the benefits of being part of the Network particularly for those in countries that benefitted little or not at all from the seasonal flu vaccine, said: "I would suspect the benefit of joining in is actually *just* being part of the community and the Network and to actually know what's going on and therefore be able to advise when something happens."[258] Network scientists are also obliged to provide one another with credit and to affirmatively seek collaboration. Over and over again in interviews, Network scientists affirmed the importance of these rules of information sharing and acknowledgement, because they help ensure that all in the Network feel that their work is respected,[259] and avoid a "two-speed" system for information production or exchange that would leave some labs behind.[260]

Self-reported norms requiring sharing of information or credit might of course not be followed. Indeed, in interviews scientists noted that these norms are not always followed, though they tended to suggest that they were followed more often inside of the Network than outside of it.[261] There is no easy way to track whether credit is allocated appropriately in publications, because a baseline would be difficult to establish. We can, however, use empirical sources to trace the routine sharing of data and samples by Network labs and by influenza scientists more generally. Network labs routinely report their influenza virus sample collection in a WHO database, showing that they have collected many millions of virus samples over

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258 Interview with John McCauley, *supra* note 59.

259 Interview with JM Heraud, *supra* note 139; Interview with John McCauley, *supra* note 59; Interview with Marilda Siqueira, *supra* note 157; Interview with Masato Tashiro, *supra* note 116.

260 Interview with Catherine Thompson, Healthcare Scientist, Respiratory Virus Unit, Virus Reference Department, Public Health England, United Kingdom, in London, U.K. (Nov. 18, 2011).

261 *See* Interview with John McCauley, *supra* note 59 (describing examples of rapid sharing of important data and viruses on the Network before publication, and expressing the view that inside the Network, although not outside of it, it will "always be the case" that the "global good"—namely, sharing—will take precedence over more selfish motivations); *see also* Interview with Masato Tashiro, *supra* note 116 (in the Network our "first priority is to share, to give services [to promote] international health issues, rather than our private publication"). Others were somewhat less sanguine. For example, Alan Hay remarked dryly that "most people want to get something out of all the work they've done rather than pouring their information for nothing into the lap of someone else who can then write a very nice paper on it." Interview with Alan Hay, *supra* note 101. "Scientists," he concluded, "are just as bad as anyone else." *Id. See also* Nicholas Zamiska, *How Academic Flap Hurt World Effort on Chinese Bird Flu*, WALL ST. J., Feb. 24, 2006, at A6 ("All the scientists should collaborate, but there's still a lot of competition. . . . Scientists are human.").

the last two decades, and made basic information about these samples available to the public broadly.[262] Influenza scientists, including many in Network labs, also regularly upload influenza virus sequences on GISAID, with the number of shared samples from each WHO region quite high.[263] Thus, empirical sources can verify that there is a great deal of information sharing by the Network, and among influenza scientists generally.

III
THE MODEL OF OPEN SCIENCE

The existing IP literature offers us no model that can explain how and why the Flu Network operated well for decades. Here, I describe a model that can begin to, that of "open science."[264] Two decades ago, Partha Dasgupta and Paul David modeled open science as a coherent system of information production, one with currencies and mechanisms that allow it to produce high quality information in a manner that serves not only scientists' aims but also social aims. The Network's experience offers a validation of this basic thesis, along with some important correctives in our understanding of its allocative processes, particularly as open science moves beyond the single-state setting.

The basic model of open science, like the existing "IP without IP" literature, describes cooperation as a relatively simple affair. In the Network, it has been anything but. Cooperation here has not been a mere byproduct of scientific self-interest (as the open science model at times suggests). Nor can it be explained as the result of the norms, intrinsic interest, and technology that are critical to the IP without IP literature. Rather, sustaining it has required recourse to organizations and to law. In fact, the Network has used organizations and law to serve many of the functions that have been demonstrated to be important to cooperation among groups managing common-pool resources. Its experience lays the foundation for a more plausible account of how IP without IP can be sus-

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262 *See* Appendix D.

263 *See id.* Regional distinctions in the level of samples and sequences shared exist, as we would expect, but even in Africa, Latin America, and especially Asia, there is very extensive collection of influenza viruses and information. For details, see *id.*

264 *See* Dasgupta & David, *supra* note 42, at 499. It might also be called "public science," a term which would reflect the prominent role of the state in funding open science. "Reputational science" is another possible designation, to signal the importance of reputation in this mode of scientific production.

tained, even under strain and where undertaken by loose-knit groups.

A. The Basic Model of Open Science

A basic account of open science as a system of production begins with the foundational work of Robert Merton.[265] Merton, an influential sociologist, described science as a system of institutional control governed largely by norms.[266] One of the most important norms, he argued, was the rule that scientific results are the common property of all scientists.[267] Merton also proposed that science is characterized by a particular reward structure, which places a premium on the priority of discovery, and that awards recognition accordingly, so that "[r]ecognition and fame then become symbol and reward for doing one's job well."[268]

Partha Dasgupta and Paul David connected Merton's work to information economics, proposing that what Merton called "science" was in fact a particular model of public or open science. In this system, priority of discovery is the basis for reputation, and reputation in turn "is the fundamental 'currency' in the reward structure that governs the community of academic scientists."[269] Funding comes from patrons, typically governments.[270] When deciding which projects to fund, patrons rely heavily on scientific reputation, amassed through the decentralized processes of peer review and publication.[271] Compen-

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265 *Id.* at 487, 510. Michael Polanyi's account of the "Republic of Science" is an important precursor to their model. *See* Michael Polanyi, *The Republic of Science: Its Political and Economic Theory*, 1 MINERVA 54, 54 (1962).

266 ROBERT K. MERTON, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267, 269 (Norman W. Storer ed., 1973).

267 *Id.* at 274–75. The other three norms central to the Mertonian account are *universalism* (which requires that scientific claims are evaluated objectively); *distinterestedness* (which involves commitment to following the rules of science, rather than acting in narrow self-interest), and *organized skepticism* (which requires detached scrutiny of results and theories). *Id.* at 270, 275, 277.

268 MERTON, *Priorities in Scientific Discovery*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS, *supra* note 266, at 286, 294.

269 Dasgupta & David, *supra* note 42, at 498; *see also* Strandburg, *supra* note 42, at 92–95 (showing reputational reward to be an important factor in a scientist's decision to share a discovery).

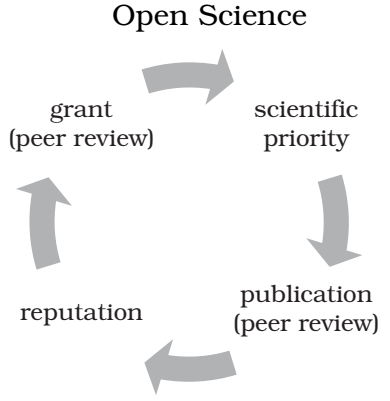
270 But compare William J. Broad, *Billionaires With Big Ideas Are Privatizing American Science*, N.Y. TIMES (Mar. 15, 2014), http://www.nytimes.com/2014/03/16/science/billionaires-with-big-ideas-are-privatizing-american-science.html [https://perma.cc/8ZME-AR4X], for a discussion of the significant, possibly growing role for foundations and philanthropists.

271 Dasgupta & David, *supra* note 42, at 491–92. These may be embodied, for example, in scientific peer review panels that score grant proposals, as well as influenced by the decentralized processes that generate publication records and

sation "consists of something like a flat salary for entering science, supplemented by rewards to winners of scientific competitions, with the proviso that the better is the performance, the higher will be the reward."[272] The system is "open" because scientists share their knowledge with one another freely and without charge.[273] In open science, then, "the use of others' output is encouraged and relatively cheap, with the cost being appropriate citation and possibly some reciprocity in sharing knowledge."[274]

Open science also has its own "cycle of investment and conversion,"[275] that can be visualized as a cycle in which capital is converted into reputation, and then back again, via intermediaries including publications and peer review. To show the distinctions, we can sketch market-exclusionary science as a parallel cycle that converts capital into patents, and back to capital, via intermediaries that include markets and patent offices.[276]

FIGURE ONE
THE CYCLES OF OPEN VS. MARKET-EXCLUSIONARY SCIENCE



scientific views about the relative importance and interest of different scientific questions. The allocation of NIH monies (about $30 billion per year), for example, relies on a peer-review process like this. For a good description, see Bhaven N. Sampat, *Mission-Oriented Biomedical Research at the NIH*, 41 RES. POL'Y 1729, 1732 & n.9 (2012).

272 Dasgupta & David, *supra* note 42, at 499.

273 *Id.* at 510.

274 Alfonso Gambardella & Bronwyn H. Hall, *Proprietary Versus Public Domain Licensing of Software and Research Products*, 35 RES. POL'Y 875, 877 (2006).

275 *See* BRUNO LATOUR & STEVE WOOLGAR, LABORATORY LIFE: THE CONSTRUCTION OF SCIENTIFIC FACTS 200 (1979).

276 This is adapted from a more materialist depiction of the cycles of credibility in science sketched by Latour and Woolgar. *See id.* at 201 fig.5.1.

Open science can this way be seen as a highly articulated system of information production, with processes that help it achieve the two primary values associated with markets: information gathering and investment allocation.

Much like the price system, cycles of credibility in open science (funding → publication → peer review → funding) help assemble and actuate widely dispersed information at relatively low cost. Scientists share their discoveries, and credit rather than permission is the prerequisite for building on the work of others. Because of this, the cost of identifying projects and collaborators is low, and scientists are free to invest their effort wherever they think that it will, via the cycles of open science, lead to the greatest scientific and reputational returns.[277] Desire for scientific priority encourages both diligent effort and the disclosure of discoveries, for to earn reputational points in open science it is important both to be first and to be *seen* to be first.[278] Disclosure, in turn, increases the chances that the scientists best suited to the task can evaluate and build upon the advances made by others.[279] In this way, the system addresses the central challenge to the efficiency of government funding: the quality of government information.[280] Indeed, when compared to a system of market exclusion, which

277 *See* Benkler, *Coase's Penguin*, *supra* note 23, at 405, 414–15. For example, a scientist need not pay or negotiate permission to write an article on H5N1. (She may need funding to pursue the research, and here peer review serves an important validation function.) Open science thus takes advantage of the efficiency advantages that open systems, such as free software, also have. *See id.* at 414 (describing how systems that permit self-nomination for creative work can plausibly allocate human creativity more effectively than more centralized systems, such as firms).

278 Dasgupta & David, *supra* note 42, at 499.

279 *Id.* at 500.

280 *See supra* notes 81–82 and accompanying text.

generates more secrecy about projects and collaborators, and which often requires licenses for particular lines of research, the open science system has plausible advantages in its ability to gather and make use of decentralized information.

Can open science appropriately direct investment toward social aims? David and Dasgupta argue that it can, because scientists operate "collectively as an 'agent' for the society at large," which is otherwise "incapable of screening scientists . . . [and] equally incapable of evaluating the relative importance of scientific discoveries."[281] As long as scientists do not abuse that trust by acting as a cartel, and as long as the political process respects scientific autonomy, open science can function "rather well in satisfying the requirement of social efficiency in the allocation of resources."[282] Indeed, they argue that it has an allocative advantage over the market-exclusionary system if research is highly uncertain.[283]

An examination of the Flu Network helps to validate the basic model, because the Network operates much as the model of open science suggests that it should. Scientists in the Network report sharing to be a central norm, and in fact share extensively. They describe functional systems of reputational rewards and sanctions that are linked to both scientific credibility and to the following of scientific norms. They also describe their own funding as relying upon reputation, as well as publications whose value is established by their peers.

The Network's experience also provides some support for the claim that open science "functions rather well in satisfying the requirement of social efficiency in increasing the stock of reliable knowledge."[284] Markets cannot reliably produce most of the kinds of goods that the Network produces, for the reasons described in Part I. The Network, though, has generated these goods both reliably and well over many decades. At certain critical moments, states have also responded to scientists' expert judgment that more resources are needed, and in-

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281 Dasgupta & David, *supra* note 42, at 505.

282 *Id.*

283 As described above, the market-exclusionary system is known to work poorly for basic R&D. *See supra* Section I. Open science, in contrast, may be particularly suited to such research. Expert judgment about the value of a line of work is likely a better signal than market returns where such returns are highly uncertain, far in the future, or unavailable because of the institutional limits of IP law. *See* Dasgupta & David, *supra* note 42, at 490.

284 *Id.* at 487.

creased the resources available to the WHO and the national labs.[285]

The Network's experience, however, also offers some important correctives to the basic model of open science. The Network's experience requires us to refine our understanding of the allocative processes of open science, and gives us a better understanding of its difficulties, particularly as we move beyond the single-state setting. It also demonstrates the critical role that organizations and law have played in sustaining the Network, particularly in times of strain.

B. Open Science in Practice: Allocation

The basic open science model offers a rudimentary account of how open science responds dynamically over time to social aims. Dasgupta and David assume that scientific interest coincides with social interest,[286] but do not explain why this must be. We might instead suspect that the two can diverge, leading scientists to prioritize projects that have high intrinsic interest (or that may provide the easiest path to striking results), but that do little to benefit the public. In the basic version of open science, states are also imagined as simply deferring to scientific judgment. Dasgupta and David recognize that states may not in fact defer, but have little to say about *why* states would defer, nor do they theorize mechanisms by which states could be held accountable for not so doing.[287]

In the Network, however, we can observe two subtle dynamics that may facilitate allocative success in open science. First, scientists describe motivation in the Network as not *solely* responsive to scientific interest. When asked why scientists contribute to the Network, many scientists described not only its scientific interest but also its public health importance.[288] And they reported that scientists in the Network generally cared about and were motivated by its public health consequences, perhaps particularly in the national labs that had fewer resources for research.[289] If both public health and scientific interest are values that dynamically constitute the research agenda of its scientists, then open science has an internal means to discipline scientists whose research verges

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285 *See supra* notes 142–46 and accompanying text.

286 Dasgupta & David, *supra* note 42, at 487–90.

287 *Id.* at 514–15 (noting that funders may be myopic, may fail to appreciate the importance of scientific autonomy to the system, and may fail to invest enough to allow open science to thrive).

288 *See* Interview with Alan Hay, *supra* note 101.

289 *See id.*

too far from work that could benefit the public. Scientific reputation, that is, could be expected not merely to reward scientists merely for scientific breakthroughs, but to reward scientists more if their breakthroughs were of more social significance.[290]

The status of public health as a value in the Network also helps explain how scientists gain the support of states. Scientists do not merely assert their scientific authority, but instead *argue* that their work is of social value. Sometimes they take their case directly to states. Scientists in the Network, for example, described designing and publishing scientific studies to help show states that influenza is a significant local health concern.[291] They also described the WHO accreditation of national labs as a means of gaining state buy-in, and reported directly communicating with states to stress the importance of the national labs' work when that was needed.[292] If states fail to respond, scientists also have some ability to discipline states, because their open publication practices can also help influence public opinion. The Network was, as described above, for many years very poorly funded.[293] Scientists only secured adequate resources for their work when states became more acutely concerned about the public health threat posed by influenza. In the wake of H5N1, though, prominent journalistic accounts—informed by influenza experts—were critical to gaining the attention of states.[294] As archival sources reveal, Network scientists have sometimes provided and urged the publication of information that their states wish to keep secret to spur them to action.[295] Here too, the fact that scientific

290 The prominence of public health as a value in the Network may not be reflective of open science more generally. A particle physicist would not explain her work in similar terms. Would she nonetheless perceive and describe a form of public interest that disciplines her work? Questions such as this can productively govern future inquiries into open science, and IP without IP generally, as Part IV describes.

291 *See supra* notes 154–55 and accompanying text.

292 *See supra* notes 159, 175 and accompanying text.

293 *See supra* note 146 and accompanying text.

294 *See* Garrett, *supra* note 194, at 3–4; Osterholm, *supra* note 3, at 31.

295 *See* Telegram to Dr. Payne from Dr. Mulder (July 13, 1957) (on file with author) (reporting influenza activity, and asking the WHO office to make such information public to provide "authoritative assistance against officials denying [the] epidemic spread of Asiatic influenza in Holland," which Dr. Mulder attributes to "economic reason[s]" and an "irresponsable [sic] attitude" toward the "outland"). Governments of course sometimes succeed at preventing reporting of outbreaks. China's reluctance to admit to the scale of its SARS epidemic was widely reported and criticized, and was a key part—along with the outbreak of H5N1—that led to the strengthening of a core WHO agreement that requires national governments to share with the WHO information about "all events which

values are linked with public values is important to the success of the Network.

The publicity of open science thus anchors a second mechanism that can facilitate allocative success in open science. Scientists can pressure states that fail to respond by appealing to public reason and public concern about the effectiveness of state action. This of course will be most effective at times and in states where public reason and political accountability are closely linked. More generally, open science presumes that states are themselves responsive to social aims via systems of political accountability. Mechanisms such as voting are a widely recognized means of providing such accountability and of setting social priorities.[296] In systems that are democratic, voting helps direct, and indeed define, social aims.[297]

But what of political systems that are not democratic? Here we come up against limits of the basic model. Open science seems unlikely to command the same support where states are not politically accountable, and/or where their legitimacy does not turn on their ability to provide research goods to their citizens. Many states do not, as described, provide much support for the Network's national labs.[298] This can be—and typically is—explained by Network participants as the result of simple resource constraints. But at least some of the time it may instead result from failures of political accountability at the national level. This is hardly a condemnation of the open science model. All systems of information production—including market exclusionary production—rely on a responsive and effective state.[299] But it suggests an important limitation on the claim that open science can in any simple fashion be relied upon to advance social aims in global perspective.

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may constitute a public health emergency of international concern within its territory." WORLD HEALTH ORG., INTERNATIONAL HEALTH REGULATIONS, art. 6 (2d ed. 2005), http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410_eng.pdf [https://perma.cc/L4YT-UZ2S].

296 In democratic states, voting is a key mechanism, for example. *See, e.g.*, KENNETH J. ARROW, SOCIAL CHOICE AND INDIVIDUAL VALUE 1 (1951) (contrasting "voting" and "markets" as different means for making social choices). The mechanisms to hold states accountable in non-democratic states are more obscure—forming part of the reason that the open science model faces challenges as it becomes more global.

297 *See* ELIZABETH ANDERSON, VALUE IN ETHICS AND ECONOMICS 158–59 (1990).

298 *See supra* notes 138–39 and accompanying text.

299 *See, e.g.*, Amy Kapczynski, *Intellectual Property's Leviathan*, 77 L. & CONTEMP. PROBS. 131, 140–44 (2014) (exploring the essential role of a "capable state" in IP law); *see also* Douglass C. North, *Institutions, Ideology, and Economic Performance*, 11 CATO J. 477, 477–81 (1991–1992) (exploring the role of institutions in facilitating efficient markets).

Open science also faces another difficulty when it moves beyond the single state setting. If politically accountable states invest in open science because they are responding to public opinion and democratic priority-setting, how can open science function to serve *global* social aims in the absence of something like a global state? The question begs the answer, one that is also etched into the contours of the Network. The crisis of the Network reflected some of the coordination problems that can occur in a multi-state setting: states want assurances that others will contribute, and that they will have access to benefits, if they are to contribute. Historically, the Network has also been funded predominantly by wealthy countries, who were also the recipients of the vaccines that are its most tangible benefit. The Network has served aims that can plausibly be called "global" in part because they were coterminous with the aims of wealthy countries. Frequently, however, countries are situated differently with respect to health problems.[300] In the absence of more global governance, open science will have difficulty generating investment in truly "global" priorities where the gains would be in the South but not the North.

This is in an important sense confirmed by the Network's experience. First, only because of our rudimentary system of global governance—in particular the organization of the WHO, and the availability of the international legal order that made the PIP Framework (and binding international arbitration) possible—could cooperation in the Network survive the H5N1 crisis. Second, that process managed not only to stabilize cooperation, but also to go some way toward ensuring that the benefits of the Network were more available around the world. The 10–20% share of pandemic vaccine allocated to developing countries in the PIP Framework is far less than what global justice would seem to require—but is also more than any existing transnational agreement has produced.[301] Open science, in sum, relies critically on international organizations and law to sustain cooperation between states when under strain. And it cannot claim to meet the demands of "global social aims" in a systematic and reliable way, without stronger

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300 This leads to the problem of so-called "neglected diseases," or those that primarily affect countries in the global South that are chronically underfunded. *See* Peter J. Hotez et al., *Eliminating the Neglected Tropical Diseases: Translational Science and New Technologies*, PLOS NEGLECTED TROPICAL DISEASES, Mar. 2, 2016, at 1–2.

301 *See* Meena Krishnamurthy & Matthew Herder, *Justice in Global Pandemic Influenza Preparedness: An Analysis Based on the Values of Contribution, Ownership and Reciprocity*, 6 PUB. HEALTH ETHICS 272, 280–82 (2013).

organizations and stronger legal frameworks at the international level that could help both define and pursue such aims.[302]

C. Open Science in Practice: Collaboration

The basic open science model, like the early IP without IP literature, describes cooperation in open science as fairly simple. It notes that open science is susceptible to tensions and failures, but sees these as largely self-correcting. For example, because researchers care intensely about priority, they may engage in wasteful races,[303] or costly fights over who has priority.[304] Scientists also may hoard data to preserve future publication opportunities,[305] or defect to the private market system if they are allowed to patent.[306] All but the last problem, Davis and Dasgupta predict, can be addressed by scientists via a kind of "outcasting," if they are in small-enough groups.[307] They will do this because "cooperative behavior furthers their self-interest in the race for priority, and denial of access to pools of shared information would place them at a severe disadvantage vis-a-vis competitors."[308] Defection to private science is more difficult to control, they suggest, presumably because exit dampens the power of reputational sanctions. This risk, they argue, can be prevented in the short term only

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302 The chronic underfunding of the WHO as an entity (as distinct from the Network as a sub-unit) is here a significant problem. The WHO itself has few resources that it can directly manage, and major donors can dictate priorities via earmarked contributions. *See supra* notes 148–50 and accompanying text.

303 Dasgupta & David, *supra* note 42, at 506–07. Scientists may, for example, see other scientists with a promising project and seek to duplicate it to win the race, when from a social perspective more diversity in project selection would have greater benefits. *Id.* at 507.

304 *Id.* at 501.

305 *Id.* at 500. Dasgupta and David also emphasize the risk of racing, wherein competition for a prize (here, priority), causes those involved to expend more effort than is justified by the value of the accelerated advance. *See id.* at 506–09. The problem of secrecy in science is well-documented. *See* Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, 8 INNOVATION POL'Y & ECON. 1, 6, 15–16 (2007); Eisenberg, *supra* note 42, at 216; Strandburg, *supra* note 42, at 91. It also has a long pedigree. Galileo and his compatriots, for example, sometimes reported their discoveries through the use of anagrams, so that they could establish priority while still reserving time to work out the details or to develop valuable extensions of their insights. *See* Merton, *Priorities in Scientific Discovery*, *supra* note 42, at 654.

306 Dasgupta & David, *supra* note 42, at 513.

307 *Id.* at 504; *see also* Oona Hathaway & Scott J. Shapiro, *Outcasting: Enforcement in Domestic and International Law*, 121 YALE L.J. 252, 308–10 (2011) (theorizing "outcasting" as a means of enforcing international law).

308 Dasgupta & David, *supra* note 42, at 504.

via a "pre-commitment" to sharing,[309] and over the longer term via cultural conditioning that would encourage young scientists to forego more lucrative private sector work.[310]

Science studies scholars have criticized Davis and Dasgupta's account of scientific behavior as "idealized"[311] and as divorced from the actual everyday experience of scientists.[312] The Network's experience, in particular, suggests that scientific collaboration in open science can be far more fraught than the basic account suggests.

This is in a sense not surprising, because open science in the Network cannot be described as occurring in a "close-knit" group. This is not primarily because scientists operate at a distance, but because the information that scientists need to accurately enforce open science norms is not always readily available throughout the Network.[313] Reputation circuits are imperfect, particularly for those at the periphery of the Network. A scientist in a national lab in Madagascar, for example, reported that his data had been used in published papers without proper acknowledgement, and that he had no effective means to retaliate.[314] Similar complaints were raised by Indonesian scientists[315] and by Chinese scientists.[316] While scien-

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309 *Id.* at 513.

310 *Id.* at 514–15 (describing, for example, conditioning to "value scientific inquiry for its own sake").

311 Philip Mirowski & Esther-Mirjam Sent, *Introduction*, *in* SCIENCE BOUGHT AND SOLD: ESSAYS IN THE ECONOMICS OF SCIENCE 50 (Philip Mirowski & Esther-Mirjam Sent eds., 2002). As they also recognize, David's more recent work is more nuanced. *See id.*; *see also* Paul A. David, The Republic of Open Science, SIEPR Discussion Paper No. 13-037 (June 14, 2014) (a more recent elaboration that treats open science in more historical and contingent fashion).

312 Mirowski & Sent, *supra* note 311, at 51; *see also* Stephen Turner, *Scientists as Agents*, *in* SCIENCE BOUGHT AND SOLD: ESSAYS IN THE ECONOMICS OF SCIENCE, *supra* note 311, at 380 (criticizing Merton and arguing that the empirical practices of scientists are more diverse, and involve more deviation from Merton's norms, than his account allows); DOMINIQUE VINCK, THE SOCIOLOGY OF SCIENTIFIC WORK: THE FUNDAMENTAL RELATIONSHIP BETWEEN SCIENCE AND SOCIETY 50–54, 111–19, 184–87 (2010) (similar); *see also* STEVEN SHAPIN, THE SCIENTIFIC LIFE: A MORAL HISTORY OF A LATE MODERN VOCATION 113–14 (2008) (similar).

313 *Cf.* Strahilevitz, *supra* note 27, at 365 n.31 ("[I]t is the community members' ability to monitor instances of noncooperation and communicate with fellow members about each member's reputation . . . rather than group size [that] frame the likely mechanisms by which cooperation might arise. Thus, the eBay auctioning network exhibits extremely impressive levels of user cooperation, despite its millions of members, thanks to an ingenious mechanism for tracking each user's reputation.").

314 *See* Interview with JM Heraud, *supra* note 139.

315 *See supra* note 204 and accompanying text.

316 *See* Zamiska, *supra* note 261, at A1 (describing a scientist in the Chinese Ministry of Agriculture who was angered by lack of credit for his work in a paper by a scientist from the U.S. CC at St. Jude).

tists in these examples could refuse to cooperate with those responsible, this sanction is costly to open science, and was clearly not always sufficient to change behavior.[317]

Decades ago, Merton coined the term the "Matthew effect" to designate the problem that eminent scientists receive disproportionate credit as compared to unknown researchers.[318] He argued that in science the reputationally rich tend to get richer, for example because they have memorable names, so tend to receive more credit than their co-authors. Plausibly, the ability to effectively sanction via reputational harms is also not evenly distributed. In the Network, the problem is amplified by its vast resource divides and divisions of labor. While scientists in national labs do engage in publishing, they are far less able to accrue reputational capital by publishing in top journals than are those in the CCs, so may be both less likely to get credit for their important data gathering work, and also less likely to exert the influence needed to successfully sanction others.

Scientists in the Network might be able to easily identify (if not sanction) failures to give credit to their work, because they routinely read papers in their field. But violations of other norms, such as those against patenting, are exponentially more difficult to detect. Before the H5N1 crisis, Network scientists began to develop suspicions about who held patents, but none understood precisely what labs in the Network held patents, much less exactly what they covered. Patent analysis was important because norms in the Network are not simple and binary. They require not that scientists associated with the Network never seek patents, but that they not seek patents on Network-related work.[319]

But patents are hard to interpret, and Network scientists have neither the time nor expertise to evaluate them. When the avian flu crisis ignited, NGOs and the WHO initiated patent mappings to help identify the bounds of the Network's patenting activities. These efforts took many months, and are still far from comprehensive.[320] The protracted and bitter fight that

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317 *See id.* at A6 (describing the difficulty of continuing cooperation); Interview with JM Heraud, *supra* note 139 (saying, of those who do not properly credit work, "my philosophy is that I know these people and I won't work anymore with these people. I am careful when I am sharing something.").

318 VINCK, *supra* note 312, at 114.

319 Some Network scientists defended patents if they were on their own scientific work, for example, as opposed to the work of the Network. *See, e.g.*, Interview with Alan Hay, *supra* note 101. Indeed, the rules of the new Framework only exclude patents on Network materials, carefully defined.

320 *See* Appendix B.

began in 2007 can be attributed in part to the fact that scientists have extreme difficulty knowing when others have defected from open science via patents. Where scientists cannot detect violations of open science norms, suspicion may take over.

Despite these difficulties, collaboration in the Network has persisted and expanded over time, and survived the challenges posed by the H5N1 outbreak. It thus provides us with a valuable opportunity to theorize the means by which IP without IP can be sustained in larger, loose-knit groups.

The two problems described above—the difficulty tracing and punishing violations of norms—have been managed in the Network not merely through the use of norms, nor via intrinsic motivations or technology. Critically, fights over both credit and patenting were solved in the Network with recourse to organizations and law.

The Network scientist who led the national lab in Madagascar, and who was not accurately credited, for example, turned to the WHO.[321] The problem was "fixed," he recounted, by the new click-wrap contracts that now mandate credit-sharing in the GISAID database.[322] The WHO, and codified agreements, have played a similar role in the credit disputes described by China.[323] The concerns raised over failure to credit were also a major component of the PIP Framework negotiations, which concluded with codified obligations to share built into standard material transfer agreements.[324]

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321 *See* Interview with JM Heraud, *supra* note 139; *see also supra* notes 250–53 and accompanying text (providing details on GISAID and EpiFlu's requirement for credit). For an example of scientists using the WHO to address disputes over sharing, see *supra* note 257.

322 *See* Interview with JM Heraud, *supra* note 139.

323 *See* Zamiska, *supra* note 316.

324 Medical and scientific journals have played an important clearinghouse role as well, by both codifying and enforcing norms about acknowledgement and appropriate sharing. In the Chinese example, the scientific journal in which the offending paper was also a key intermediary: the complaining party brought their concern to the editors, and the journal published a formal erratum, acknowledging the contributions of the local lab. *See* Elena A. Govorkova et al., *Author's Correction: Lethality to Ferrets of H5N1 Influenza Viruses Isolated from Humans and Poultry in 2004*, 80 J. VIROLOGY 6195, 6195 (2006). As this reflects, journals self-consciously play an intermediary role around issues of credit. For example, the International Committee of Journal Medical Editors has since 1978 published guidelines for scientific manuscript submission that includes an elaborate definition of who should count as an author. *See Defining the Role of Authors and Contributors*, INT'L. COMM. OF MED. JOURNAL EDITORS, http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html [https://perma.cc/KT2L-MRF4]. Recently, the ICMJE also proposed that journals create obligations on authors to share their datasets.

The WHO office also consciously facilitates reputational rewards for national labs that are more fine-grained than publication alone.[325] These help smooth over the resource inequities in the Network, and keep reputational rewards flowing to those activities that are essential to the Network's work.

Similarly, the tensions caused by the incursion of patents into the Network could not be resolved without the help of the WHO. The WHO facilitated a patent mapping that helped to identify how patents had been used, and then convened negotiations that resulted in a legal commitment that precluded patents on Network materials.[326] Among insiders, law is used with a light touch, to buttress what remains primarily informal and reputationally driven cooperation. It is the WHO, for example, that mediates any disputes about the terms of reference and PIP Framework between Network labs.[327] The Network's formal organizational structure, and its use of legal tools, have both intensified over time, as conflicts became more intense, and as the Network has grown in size and complexity.

Organizations and law help create infrastructure for more accurate monitoring and enforcement of norms in the Network. But their role reaches still broader. They help not just to "enforce" norms but also to adjust them, and to resolve disputes about their application. They redress concerns about fairness—such as those raised by the national labs—that are corrosive to cooperation over time. Critical to the reconstruction of the Network was also the benefit sharing agreement, which controls not Network participants, but the third-party firms that produce vaccines and medicines.

See Darren B. Taichman et al., *Sharing Clinical Trial Data — A Proposal from the International Committee of Medical Journal Editors*, 374 NEW ENGL. J. MED. 384, 384 (2016).

325 *See, e.g.*, Besselaar interview, *supra* note 118 (noting that more active national labs are rewarded with speaking slots at the biannual meetings, in part to "encourage[ ] the others that are possibly not as well developed to make efforts to reach that sort of stage," and describing the importance of thanking national labs and providing them with opportunities for training).

326 Like the relationship to patents in the Network, the relation to private funding is not a simple one, but one that must constantly be managed, via a kind of boundary-work that constructs a separation between open science and market-exclusionary science. *See supra* note 151 and accompanying text. This is not reflected in the basic model, which imagines that open science is exclusively funded by governments.

327 PIP Framework, *supra* note 131, annex 1, art. 7.2. This makes sense, if we consider the delicate balance of a system based upon reciprocity, and the possibility that too much formal legal obligation may disrupt forms of trust that are important to the workings of the open science system.

All of this suggests that an emphasis on "close-knittedness" leaves out functions that have been important to the success of open science in the Network. We can understand these functions better if we turn to the well-developed literature on the preconditions of successful cooperation in the material commons. This literature has been developed over decades by a group that has empirically tested Elinor Ostrom's theories of the conditions of sustainable community management of resources such as fisheries and grazing pastures.[328] The Ostrom group has identified a series of factors that are important to effective group management of a common pool resource: clearly defined boundaries for both the resource and the group; relatively low-cost monitoring; graduated sanctions (e.g., gossip for mild infractions but more serious consequences for more serious infractions); fair distribution of benefits and costs; group decision-making procedures; conflict resolution mechanisms; internal authority to organize to influence the rules; and "appropriate coordination" with outside groups where the group interacts with a multi-level system.[329]

In the Network, many of the factors that Ostrom and her followers stress as critical to group management of resources—which reach significantly beyond the simple monitoring and enforcement described in the open science model—would be absent without the support of the WHO, bolstered at key moments by legal agreements. It is the WHO, supported by contractual terms of reference and material transfer agreements, that creates the group boundaries of the Network. The WHO office also creates subtle means of recognition and rebuke, to supplement the sometimes crude and weak sanctions that

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328 *See* DIGITAL LIBRARY OF THE COMMONS, http://dlc.dlib.indiana.edu/dlc/ [https://perma.cc/WV98-YEGL].

329 David Sloan Wilson, Elinor Ostrom & Michael E. Cox, *Generalizing the Core Design Principles for the Efficacy of Groups*, 90S J. ECON. BEHAV. & ORG. S21, S21–S22 (2013). Ostrom first theorized a set of factors similar to this in 1990. ELINOR OSTROM, GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION 90–102 (1990). These were refined into the factors above via dozens of case studies. Michael Cox, Gwen Arnold & Sergio Villamayor-Tomás, *A Review of Design Principles for Community-Based Natural Resource Management* 15 ECOLOGY & SOC'Y 38, 38 (2010), http://www.ecologyandsociety.org/vol15/iss4/art38/ [https://perma.cc/7BNU-3YNH]. This account has been very influential in the resource management field, but it can also profitably be linked to a much broader literature on the evolution of governance, or the move from dyadic to triadic relations. *See* Alec Stone Sweet, *Judicialization and the Construction of Governance*, 32 COMPAR. POL. STUD. 147, 148–51 (1999). Ostrom and her followers, we might say, have been developing an account of when and why groups need governance, focusing on one specific context: the management of tangible resources.

scientists alone can mobilize. Informal rule-making and dispute settlement has long occurred in the Network, but as the Network grew, and particularly during the recent tensions, the elaboration of rules and resolution of disputes have been critically facilitated by the WHO, here too with important reliance on law. The WHO also plays an important role in modulating the terms on which outsiders can access the Network's materials and data. Formal law is especially important as regards this last function. The "outsider licenses," after all, are enforceable not via informal WHO dispute settlement, but via binding international arbitration.

Even this broader account, however, fails to account fully for what Network participants see as essential to their successful collaboration. As described in Part II, participants also regularly described the important role that the Network played in deliberately cultivating a sense of community, equality, and trust.[330] The WHO office does this in part by coming in to help resolve disputes and ensure norms are enforced. Also important, though, may be the normative power of its negotiations and legal agreements. The PIP Framework, for example, makes numerous references to the value of a "trust-based system," articulates the primacy of values such as "the protection of all people of the world from the international spread of disease," and describes the importance of a "fair, transparent, equitable and efficient framework" for virus sharing.[331] The WHO also facilitates trust through more mundane day-to-day activities that help keep the more distant national labs in personal contact with one another.[332]

We can make sense of this via the sizeable literature describing the difficulties of explaining collective action solely through rational actor models and the logic of self-interest. These models have long been known to have problems account-

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330 *See supra* notes 170–74 and accompanying text. The Flu Network's archive also suggests that activities to better connect the various nodes of the Network have long been a central component of its work, even at times when funding was very meager. Much of the archive is comprised of letters and memos about arrangements for visits that WHO officials or CC members are making to various laboratories, as well as efforts to bring scientists to WHO for training.

331 PIP FRAMEWORK, *supra* note 131, arts. 1.4, 1.9, at 3. *See also id.* art. 7.2.1, at 23–24 (references to a "trust-based system"); *id.* annex 3, arts. 1.1, 1.2, at 37 (same); *id.* art. 1.4, at 3 (universal protection from disease).

332 Interview with Wenqing Zhang, *supra* note 130 (describing how the WHO office holds global meetings for the national labs every two years in part for this purpose). It has also created a secure website dedicated to the GISRS where discussions occur, and regularly facilitates communication between the CCs, national labs, and ERLs. *Id.*

ing for stable collective action except under the most narrow of circumstances.[333] Trust, for example, is often critical to successful cooperation, because it permits individuals to contribute in the belief that others too will contribute, even where rules are sometimes broken and violations sometimes go unpunished.[334] And though the open science model might not predict it, participants in the Network see enforcement of norms in open science as inevitably imperfect. As one scientist put it, "if you don't trust [people], . . . and you are going to check where they are at each moment, then they cannot work anymore."[335]

The Network's success, as this all shows, was not sustained via norms and decentralized action alone. Rather, organizations and law stand in at crucial moments to help scientists in this loose-knit group not only monitor and enforce norms, but also to interpret and revise rules, resolve disputes, and define the boundaries of the group and exert control over the outside. Finally, organizations and law have also helped to foster trust, as well as what Elizabeth Anderson calls the "normativity of norms"—the "understanding of group members that they all *ought* to obey the standard of conduct defined by [the] norm . . . ."[336] The Network's experience, in fact, demonstrates the need to move beyond a simplified rational actor model of open science and IP without IP, as we begin to recognize the role that law and organizations play in sustaining both.

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333 *See* Elizabeth Anderson, *Beyond* Homo Economicus*: New Developments in Theories of Social Norms*, 29 PHIL. & PUB. AFF. 170, 177–81 (2000); Ernst Fehr & Simon Gächter, *How Effective Are Trust- and Reciprocity-Based Incentives?*, *in* ECONOMICS, VALUES, AND ORGANIZATION 337, 337–38 (Avner Ben-Ner & Louis Putterman eds. 1998).

334 *See* Anderson, *supra* note 333, at 175 ("Trust appears to be a key factor behind the willingness to cooperate. The norm of trust tells people to act as if they believe others will reciprocate their own cooperation. It is expressed in a persistent willingness to put oneself at risk, even in the face of short-term losses due to failures to reach cooperative equilibria with one's group."); *see also* Fehr & Gächter, supra note 333, at 338–40 (showing that trust in reciprocal behavior promotes the enforcement of contracts); Kahan, *supra* note 42, at 74 (same).

335 Interview with Sylvie Briand, Project Leader, Disease Monitoring, Assessment & Control, Global Influenza Programme (Nov. 11, 2011).

336 Anderson, *supra* note 333, at 171. *See also* Jane Mansbridge, *Starting With Nothing: On the Impossibility of Grounding Norms Solely In Self-Interest*, *in* Ben-Ner & Putterman eds., *supra* note 333, at 151–66 (concluding that rationality and self-interest alone cannot explain behavior).

IV
REORIENTING THE IP WITHOUT IP LITERATURE

The Network's example offers important lessons not only for those interested in open science but also for those concerned with information production more broadly. As Part I describes, critics have argued that there is no persuasive evidence that IP without IP can be sustained under pressure, where information value and capital costs are high, and/or where creators are loose-knit. To the contrary, as this study decisively shows, IP without IP can succeed under all of these circumstances.

The Network's example reveals that capital-intensive information production can occur without any recourse to IP, yet plausibly be reasonably effective and responsive to social aims if it combines a source of capital with processes like those described in the open science model. The two key processes here are 1) reputational circuits that help generate reliable signals of quality and value for funders, and 2) mechanisms that render the system accountable to public priorities.

These criteria are general, but will be helpful in structuring future inquiries into information production settings that are funded by government or other patrons. The point is not that such systems are inevitably effective and responsive, but rather that we can begin, by leveraging the model of open science, to inquire systematically into the conditions under which capital-intensive IP without IP systems can claim to be effective and normatively attractive.

The Network's example also shows that IP without IP can succeed in groups that are loose-knit, with the support of organizations and law. The commons-based strand of the literature has downplayed the need for management or compulsion in IP without IP, pointing out that because information is nonrivalrous, it escapes the problems of congestion and scarcity that afflict the material commons.[337] This however misses something important. The Flu Network produces a myriad of immaterial goods, but cannot be said to operate beyond scarcity, or without need for management or structures of command. It has characteristics of *both* significant openness—its information products are almost all freely shared with the public—and significant governance. The governance exists not to prevent the depletion of information, but to address tensions

337 Benkler, *Commons and Growth*, *supra* note 26, at 1554.

that can undermine the cooperation needed to produce high-quality, and socially oriented open science.

This is not to say, as some have suggested, that IP without IP inevitably relies upon forms of exclusion that "operate with an approximately equivalent effect" to IP itself.[338] Organizations and law in the Network operate not to support IP-like exclusions, but rather to support what we might call "Ostrom goods"—clear group boundaries, low-cost monitoring and effective sanctions, norm interpretation and revision, dispute settlement, and management of the boundary with the outside. They also help facilitate the cultivation of trust and public values, and normativity itself, working to support sharing despite a continued risk of defection, rather than to support exclusion.

Moreover, the Network did not reach for conventional IP law to stabilize cooperation. Rather, it made use of contract law, loosely with respect to insiders and more assertively with respect to outsiders. Conventional wisdom in the field of IP suggests that contract law is inadequate to support the production of information because it does not bind third parties generally.[339] This is a problem for the market-exclusionary model, because it depends on the ability to capture value broadly from third parties. But the Network exemplifies a different system of production—not a demand-side model that requires that users be prevented from free riding, but a supply-side model that requires the maintenance of incentives among a community of producers. Contract may be especially useful for such systems. Its flexibility means it can be used to codify a vast range of different rules, helping to clarify expectations and permitting legal recourse if cooperation ultimately breaks down.[340] Relations among Network insiders were anchored,

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338 Barnett, *supra* note 27, at 1754.

339 *See, e.g.*, Jane C. Ginsburg, *Creation and Commercial Value: Copyright Protection of Works of Information*, 90 COLUM. L. REV. 1865, 1917–21 (1990) (positing that contract law provides the original creator of a work with inadequate postdelivery control); Mark A. Lemley, *Intellectual Property and Shrinkwrap Licenses*, 68 S. CAL. L. REV. 1239, 1286 (1995) ("Intellectual property is only marginally susceptible to protection by contract alone, because it is very easy for third parties to duplicate an idea once it has become public. . . . Patent and copyright law both impose liability on third parties who could not have been expected to contract with intellectual property owners *ex ante*.").

340 As Karl Llewellyn described many years ago, "the major importance of legal contract is to provide a frame-work for well-nigh every type of group organization and for well-nigh every type of passing or permanent relation between individuals and groups, up to and including states—a frame-work highly adjustable, a frame-work which almost never accurately indicates real working relations, but which affords a rough indication around which such relations vary, an occasional guide in cases of doubt, and a norm of ultimate appeal when the relations cease in fact

particularly over time, by contracts such as these—contracts where individuals and groups bilaterally promised one another to adhere to certain rules.

Contracts can also be used to govern outsiders, if those outsiders can be identified and attracted into contractual relationships *ex ante*—as exemplified by the Network's "outsider license." These licenses require outsiders to the Network to follow certain rules, most prominently regarding benefit sharing. The result is a kind of control over outsiders that is less stringent than would be available if the Network held and exerted intellectual property rights (because those would bind third parties without prior agreement). But contract has been sufficient to sustain the Network, in part because the Network reliably generates benefits over time, access to which outsiders wish to maintain.[341] The "click-wrap" licenses that condition access to data from databases like GISAID similarly use contract to bind outsiders who access data from the Network.[342] Here too, contracts provide less comprehensive control than a more robust property right in this data would do, but have been enough to stabilize the Network.

The case study offered here confirms the value and viability of IP without IP, and can also help direct the next wave of developments in the field. This wave should focus its attention, at least initially, on other examples of IP without IP that are capital intensive and produce valuable social goods, especially if they are also loose-knit and exhibit sustained cooperation over time, despite threats from within and without. There are many other possible examples in the vein of open science. The most interesting will be those that in one way or another challenge the model described here.[343] Examples drawn from other

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to work." Karl N. Llewellyn, *What Price Contract? An Essay in Perspective*, 40 YALE L.J. 704, 736–37 (1931).

341 If patents were not so difficult to apply to the Network's work, and not so corrosive to its open science practices, then these might have been leveraged into still more assertive power over outsiders. One of the more intriguing possibilities that the Network's experience raises regards the potential for what we might call "common IP" to stabilize IP without IP practices.

342 *See supra* note 251.

343 For example, the open science model predicts that decentralized decision-making and open publication of research are critical to success. How then can we explain successful public scientific enterprises that require secrecy, or that employ far more centralized government control? Defense research is an example where secrecy may be standard, and where governments may exert more central control over allocation. National laboratories in the United States—which are directly government controlled, but some of which have produced an extraordinary number of Nobel prizes—would also make excellent subjects of study. A good example here is the Lawrence Berkeley Lab. Supported by the Department

domains—for example, involving state and philanthropic funding for the arts, journalism, and scholarship in the academy—would also be extraordinarily valuable.

We should also return to familiar examples in the field to consider them anew. For example, we should develop a better understanding of how examples studied earlier do—or do not—link creative effort to social aims. For example, does the reliance on in-kind labor bias Wikipedia to production of information that satisfies the relatively well-off, who have more leisure time—and if so, does the organization cultivate public values that could discipline this tendency, for example by insisting that priority be given to comprehensiveness?

Revisiting these examples will also allow us to consider whether mechanisms and tools used in open science also help to explain some of the success of these other communities. For example, creative groups that have been described as close-knit may, upon closer examination, rely on organizations and law in a manner not dissimilar from the Network.[344] Even information producers that appear to be closely connected may be "loose-knit" in the proper sense of the term, if it is difficult

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of Energy and managed by the University of California, it has thirteen Nobel Prizes associated with its work. *See About the Lab*, BERKELEY LAB, http://www.lbl.gov/about/ [https://perma.cc/5WNJ-5SU4]. Because the theory of open science suggests that it is most suited to basic research, we should also study examples where open science successfully reaches into the domain of "technology." The Network has some of this aspect, but still more interesting would be cases where the public sector takes on more conventionally technological tasks, such as late-stage drug development. We should also consider examples where the private sector undertakes basic R&D on a large scale. *See* SHAPIN, *supra* note 312, at 132–45 (describing basic R&D in Bell Labs, Eastman Kodak, and General Electric). Finally, the open science model, and the example of the Flu Network, suggests that the most significant problems in open science may relate to the ability of scientists to command adequate support from the state—particularly where support from multiple states is demanded. Studies of other transnational scientific networks that have been less successful than the Flu Network are important. Contrasting the Network to WHO's networks on foodborne infections, human African trypanosomiasis, and the more multi-purpose Global Outbreak Alert and Response Network (GOARN)—to name just a few possibilities—would be illuminating. Finally, studies of capital-intensive open science projects supported by multiple states would also be useful. Here, entities such as CERN, the large particle collider that is supported by twenty-one countries, would make excellent subjects. For a basic description of CERN, also known as the European Organization for Nuclear Research, see *About CERN*, http://home.web.cern.ch/about [https://perma.cc/EY7P-HD8Y].

344 *See, e.g.*, Loshin, *supra* note 21, at 138 (describing examples in which magicians who have revealed tricks to outsiders were ejected from illustrious magician organizations); *see also id.* at 125 (noting that societies such as the "International Brotherhood of Magicians" are important venues for sharing of knowledge among insiders); Oliar & Sprigman, *supra* note 21, at 1815 (noting that comedy clubs and booking agents refuse to book joke-stealers).

for creators to cheaply monitor and enforce norms. It would in fact not be surprising if this were often the case with respect to information goods, for example because the boundaries of information goods are notoriously hard to define.

Returning to consider Wikipedia and open source and free software anew, we can now see the significance of the organizational and legal structures that have emerged to sustain them. Wikipedia has developed a welter of specialized norms and organizationally mediated rules, backed up by formal dispute settlement systems and sanctions.[345] It is also supported by the Wikimedia Foundation, a legally constituted non-profit that employs close to 200 people,[346] with an annual budget of over $50 million.[347] Most prominent open source software projects are also supported by organizations.[348] These organizations play a variety of roles that resonate with the account of the Network offered here: they contract with participants and outsiders over rights and responsibilities, they set standards and facilitate collective decision-making, and they manage the assets and licensing strategies of these enterprises.[349]

Open source software and Wikipedia also can now be seen as relying heavily upon both organizations and law to help produce "Ostrom goods." Licenses help reinforce group norms and control outsiders by mandating sharing and sometimes credit,[350] thus helping to prevent forms of defection that would destabilize the community. They also help create group boundaries and prevent incursions from the outside. They are sup-

345 *See, e.g.*, JEMIELNIAK, *supra* note 32, at 7–8 (2014) (describing Wikipedia as relying upon "hundreds of rules, norms, policies, and guidelines"); *id.* at 17–22, 29–84 (describing ten different formal organizational roles, and active systems for monitoring, internal adjudication, and different levels of sanctioning); *id.* at 8 (describing Wikipedia as characterized by a degree of "regulation [that] is much higher than in many even explicitly bureaucratic organizations").

346 *Id.* at 129.

347 *See Wikimedia Foundation 2014-15 Annual Plan*, WIKIMEDIA FOUND. 3, http://upload.wikimedia.org/wikipedia/foundation/e/e0/2014-15_Wikimedia_Foundation_Plan.pdf [https://perma.cc/8DUT-WFBP] (last visited Aug. 30, 2014).

348 Jyh-An Lee, *Organizing the Unorganized: The Role of Nonprofit Organizations in the Commons Communities*, 50 JURIMETRICS 275, 288 (2009).

349 *Id.* at 290–96.

350 *See, e.g.*, *GNU General Public License*, GNU OPERATING SYS. (last updated June 29, 2007), https://www.gnu.org/licenses/gpl-3.0.en.html [https://perma.cc/GH22-8QNG] (the most prominent free software license, which requires contributors to share their developments under the same terms); *Wikipedia Copyrights*, https://en.wikipedia.org/wiki/Wikipedia:Copyrights [https://perma.cc/W9Q6-LV9K] (describing the license used by Wikipedia, which permits free reproduction and revision of the covered works, but requires attribution and the licensing of derivative works under the same licensing terms).

ported by organizations that help lower the cost of monitoring, enforcing, and revising group norms, and also—very prominently in the case of both Wikipedia and organizations like the Free Software Foundation—cultivate the values of the group.[351]

CONCLUSION

The importance of the case study here is not that it shows us another point on the spectrum of IP without IP. Rather, it allows us to see the field—and some of its most canonical examples—differently. It also decisively both proves the importance of, and reorients, this new literature.

It can no longer be said that IP without IP is limited to "niche" fields or products of low social value, nor that valuable forms of IP without IP are eventually replaced with a property model. The open science model described here identifies a sustainable, well-configured system that works very differently than does the market-exclusion model. The system has been durable over time, and can claim to do as well—and indeed at times far better—than IP at effectively producing information goods in response to social priorities. For more than six decades, the Network has produced data, analysis, and standardized inputs to critically important vaccines and diagnostics—when for reasons described in Part I, none of these could be well produced in markets. IP without IP does not only *work*, but it is essential to our collective well-being. Indeed, as this single example amply shows, it is essential to our very lives.

We must do more to understand open science, and the structures that permit it to work well, and that cause it to fail. The Network is a remarkable example of success, for example, but it has also struggled at times for state support, and has been buffeted by tensions from within and without. Even today, it cannot claim to be truly responsive to social aims at a global level—as in truth no system of information production, including the market exclusionary one, can. With other global diseases on the horizon, and other emergent global scientific priorities—climate change, for example—we urgently need a new literature that better maps the potential and limits of open science, particularly at the global level.

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351 *See, e.g.*, WIKIMEDIA FOUND. (last modified Nov. 26, 2016), https://wikimediafoundation.org/wiki/Home [https://perma.cc/5NWW-Q886] (describing the function and goals of the Wikimedia Foundation); FREE SOFTWARE FOUND., http://www.fsf.org/ [https://perma.cc/G248-M76V] (stating the mission of the Free Software Foundation).

The example and model described here can also help us better understand production of non-scientific goods, whether magic tricks, online encyclopedias, or legal scholarship itself. It offers us a window into how reputational systems, especially when linked to public-minded values, can help guide socially responsive information production. We can also move beyond a conception of IP without IP as requiring small communities, or, at the other end the spectrum, emerging in large online cohorts that operate with no governance at all. Many instances of IP without IP—plausibly the most important ones (i.e., that are under strain, and producing goods of high value)—will require concerted support from organizations and from law. We will see the kinds of solutions that have helped sustain the Flu Network much more broadly in high-stakes IP without IP, I believe, if we look for them. And only by training our eyes differently to look for these interventions, can we learn better how to sustain them.

APPENDIX A

RESEARCH METHODOLOGY

The case study method, like other methods, has certain advantages and disadvantages.[352] A case study, or "an intensive study of a single unit for the purpose of understanding a larger class of units,"[353] is particularly well-suited to generating theories and to "clarifying previously obscure theoretical relationships."[354]

The main purpose of the case study here is an exploratory one. I use the example of the Network to theorize the conditions under which IP without IP may be viable, particularly in high-stakes settings, where information production is expensive and temptations to defect substantial. The primary sources of data for understanding the operations, rules, and motivations of actors in the Network, as well as the recent crisis and reconstruction, are interviews, textual material on the Network (from the WHO archives,[355] as well as current documents available on the WHO website), and databases and secondary materials that facilitated tracing of the activity of Network members.

I conducted thirty-six semi-structured interviews, recruiting participants through a supplemented snowball method.[356] Interviews were conducted in November 2011, and in October 2013 to June 2014. Each interview typically lasted between

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352 For an account of the impossibility of achieving all analytic goals at the same time, and a general framework for understanding the value and limits of different quantitative and qualitative social science methods, see ADAM PRZEWORSKI & HENRY TEUNE, THE LOGIC OF COMPARATIVE SOCIAL INQUIRY 20–23 (1970) (describing trade-offs among accuracy, generality, parsimony, and causality).

353 John Gerring, *What Is a Case Study and What Is It Good For?*, 98 AM. POL. SCI. REV. 341, 342 (2004).

354 Timothy J. McKeown, *Case Studies and the Limits of the Quantitative Worldview*, *in* RETHINKING SOCIAL INQUIRY: DIVERSE TOOLS, SHARED STANDARDS 153 (Henry E. Brady & David Collier eds., 2004). Put another way, case studies have an advantage in "exploratory" as opposed to "confirmatory" research. Gerring, *supra* note 353, at 349–50.

355 The WHO archives are accessible through the WHO library in Geneva, and include a selection of internal papers from WHO offices from the 1940s to the 1980s. Library and Information Networks for Knowledge, *About Us*, WORLD HEALTH ORG., http://www.who.int/library/en/ [https://perma.cc/4KGY-GJGE].

356 Snowball sampling is "a method for generating a field sample of individuals possessing the characteristics of interest by asking initial contacts if they could name a few individuals with similar characteristics who might agree to be interviewed." JOHN LOFLAND ET AL., ANALYZING SOCIAL SETTINGS: A GUIDE TO QUALITATIVE OBSERVATION AND ANALYSIS 43 (2006). I did not rely on referrals alone, but used the WHO's list of Network laboratories, and the assistance of an NGO participant closely involved in the negotiations, to seek some representativeness among the interviewees, for example on basis of geography and type of participant.

forty-five minutes and an hour, and all but five (according to the wishes of the subjects) were recorded and transcribed. Interviewees included seventeen scientists in Network labs (eight who worked in CCs, eight who worked in national labs, and one with experience in an ERL), six WHO officials with responsibilities related to the Network, three private sector actors familiar with the Network, eight ambassadors or members of missions that participated in the PIP Framework negotiations, and two NGO participants closely involved in the Framework negotiations. Each interviewee was asked whether they were comfortable speaking on the record and being cited and quoted in research. Nearly all agreed to speak on the record, with some also asking to review quotations before publication (which I agreed to do).

Once I developed an understanding of the basic dynamics of the Network and negotiations, I sought representation from important constituent interests, which for the Network meant seeking scientists working in different regions of the world, and in national labs as well as CCs and the WHO central office. In seeking interviews with negotiators, I focused on those who were acknowledged by others as important to, or particularly involved in, the negotiations, and I also sought to speak to representatives from both the global North and South. I was relatively successful in both regards, speaking to scientists in Network labs from Latin America, Africa, East and Southeast Asia and Australia, and the US and Europe.

Important limitations on the sample should be noted. It is neither a random nor strictly representative sample. Interviews were conducted in English, limiting interviewees to those who are very comfortable in English (which many but not all Network scientists are), and for all scientists except those in Geneva and London, were conducted on the telephone. Finally, I particularly sought out scientists who had been involved in the Network for a long time, in positions that gave them an overview of the Network's activities and rules. It was relatively more difficult to interview heads of national labs, reflecting both language barriers and some of the structure of the Network itself. The Network is most interconnected at the CC level, and has some national labs that are only loosely integrated into its activities. This—along with the limits on who was willing and able to speak with me—meant that the sample includes disproportionate representation from those involved with the CCs and the WHO office, who may in turn be better resourced and less likely to emphasize problems affecting na-

tional researchers, perhaps particularly in resource-poor settings. Nonetheless, participants in both national labs and CCs did acknowledge similar problems in the Network, perhaps aided by the recent negotiations which made many of those problems a matter of public record.

One major limitation of interview-based research is that people may inaccurately report facts, their own views, or their motivations. Memories are inaccurate, people do not always clearly perceive events or their own state of mind, and people are more likely to report more socially acceptable behavior and less likely to report less socially acceptable behavior.[357] Where possible, I therefore sought to triangulate interview data with other evidence, for example from the PIP Framework or WHO archives, or from the Web of Science[358] and the databases that track and make visible the sharing activities of the Network.[359] I also rely on the Network's recent crisis and renegotiation to help trace the processes and conditions that are most essential to the Network.[360] Because the negotiations were intense and contentious, the resulting rules can be thought of as a kind of revealed preference, which can usefully be triangulated with the historical and experiential accounts of how the Network operates.

Finally, generalizing from case-based research is challenging.[361] Recognizing this, I primarily use the example here to refute deterministic theories (such as those suggesting that IP without IP cannot succeed where information is high value or

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357 *See* H. RUSSELL BERNARD, RESEARCH METHODS IN ANTHROPOLOGY: QUALITATIVE AND QUANTITATIVE APPROACHES 247 (4th ed., 2006). This may be particularly so when interviewees are speaking "on the record." *Cf. id.* at 245–50 (discussing several of the difficulties in maintaining factual accuracy that may arise from interview-based research). Notably, however, the accounts of those few interviewees who wished to remain anonymous did not differ in significant ways from those who were willing to be publicly cited.

358 *See infra* Appendix C.

359 *See infra* Appendix D.

360 Studying examples that involve failure or crises facilitate what case study methodologists call "process tracing," which relies on within-case variance to help to isolate the causes of an outcome in that case. *See* David Collier, James Mahoney & Jason Seawright, *Claiming Too Much: Warnings about Selection Bias*, *in* RETHINKING SOCIAL INQUIRY: DIVERSE TOOLS, SHARED STANDARDS 92–93 (Henry E. Brady & David Collier eds., 2004). The goal of process tracing is to connect the various phases of a policy process or change, in a way that permits us to determine why a particular outcome occurred. *See* Alexander L. George & Timothy J. McKeown, *Case Studies and Theories of Organizational Decision Making*, *in* 2 ADVANCES IN INFORMATION PROCESSING IN ORGANIZATIONS 34–41 (1985).

361 *See* Collier, Mahoney & Seawright, *supra* note 360, at 96–98.

cannot succeed over time and under pressure),[362] and to elaborate new theories (for example of certain potential failures of open science, and certain conditions of success for high-stakes "IP without IP").

362 Case studies can empirically refute deterministic theories, because a theory that asserts that "X is not possible" can be disproven if a single instance of X can be shown to exist. *See* Gerring, *supra* note 353, at 350.

APPENDIX B

PATENTS IN THE NETWORK AND IN INFLUENZA MORE GENERALLY

This Appendix gathers and analyzes evidence of patenting practices related to influenza in the Network, and in the public and private sectors more generally. Patent searches are resource- and time-intensive, but fortunately, several published reports have mapped patents related to pandemic influenza. I draw significantly upon them, because they provide good evidence of the Network's orientation toward patenting. Given the importance of and interest in recent pandemic strains, if the Network is patenting extensively, it would almost certainly be visible in this domain. A broader secondary literature provides some additional evidence of patenting, particularly about patents that may hinder responses to a pandemic.

1. *Patenting in the Network.*

There is very little evidence of patenting activity among the labs that make up the Network. Before getting into the evidence, it is worth noting—both on methodological grounds, and for reasons that are important to the problems that patents created for the Network—that it is in fact extraordinarily difficult to determine with precision the extent of patenting in the Network, or in influenza generally. Methods for searching patents, particularly globally, are highly imperfect, and there are particular difficulties with searching for patents in the genomics area.[363] When looking contemporaneously, one often only has patent applications rather than examined patents to review, and applications themselves are not published immediately.[364] But applications are commonly rejected or substantially narrowed upon examination.[365] Patent claims are

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363 For example, as one of the attempts to map genomic pandemic influenza patents described, digital patent searches are only possible in a small number of jurisdictions. *See* INFLUENZA GENOME TECHNOLOGY LANDSCAPE REPORT, PATENT LENS, http://www.bios.net/daisy/influenza/ext/navaggregator/navaggregator [https://perma.cc/QZ5Z-SJAN] [hereinafter PATENT LENS REPORT]. And "[e]ven for those jurisdictions with some searching facility, finding DNA or protein sequences disclosed in or claimed in patents is extraordinarily difficult if not impossible," because of the variety of ways that such sequences can be claimed, and the lack of search infrastructures adequate to track these variable techniques of claiming. *Id.*

364 *See, e.g.*, 35 U.S.C. § 122(b) (2012) ("[E]ach application for a patent shall be published, in accordance with procedures determined by the Director, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under title.").

365 *See, e.g.*, PATENT LENS REPORT, *supra* note 363 (documenting the narrowing of influenza sequence patent claims in examination); WORLD INTELL. PROP. ORG.,

difficult to interpret,[366] and in the genomics area often tend to be especially so, not only because of the limits of language and ambiguity of doctrine, but also because it may be very difficult to predict the possible consequences of a patent until later scientific developments emerge.[367]

If it is hard for experts in patent law to determine the import of patenting in the Network, it is still more difficult for scientists in the Network. In interviews, some Network scientists exhibited their understanding of patents by questioning the obviousness of certain patents,[368] expressing concerns about patent quality that mirror recent debates,[369] and making distinctions between the legitimacy of different kinds of patents; for example, patents on organisms (disfavored) versus patents on scientific methods or products such as monoclonal antibodies (more acceptable or even desirable, though only for non-Network work).[370] But it was also clear that even those scientists most comfortable discussing patents were rarely if ever intimately familiar with the claims of particular patents. Interviews, while a good source of information about how scientists *perceive* patents in the Network—an issue that turns out to be critical—are a poor source of the fact of the matter.

Fortunately, the task of determining the role that patents have played in the Network is facilitated by four publicly available patent mappings that were conducted in the aftermath of

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WIPO PATENT SEARCH REPORT ON PANDEMIC INFLUENZA PREPAREDNESS (PIP)-RELATED PATENTS AND PATENT APPLICATIONS 8 (2011) (explaining the challenges presented for mapping by the withdrawal of applications, the rejection of patent applications, and the narrowing of the scope of claims in patent applications) [hereinafter WIPO 2011 REPORT].

366 *See* Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1748, 1791–92 (2009).

367 On some of these points, see Lori B. Andrews & Laura A. Shackelton, *Influenza Genetic Sequence Patents: Where Intellectual Property Clashes with Public Health Needs*, 3 FUTURE VIROLOGY 235, 238–39 (2008) (describing unresolved issues in the interpretation of genomics patents on highly changeable viruses).

368 Interview with John McCauley, Director of the WHO Collaborating Centre for Reference and Research on Influenza, United Kingdom (Nov. 18, 2011).

369 *Id.* (criticizing a patent as obvious, and noting the fact that often "you just let everything go till it's challenged. Nobody challenges because it's too expensive.").

370 *Id.*; Interview with Alan Hay, former Director of the WHO Collaborating Centre for Reference and Research on Influenza, United Kingdom (Nov. 18, 2011); Interview with Michael Shaw, Senior Advisor for Laboratory Science, WHO Collaborating Centre for Reference and Research on Influenza (Feb. 5, 2014) (expressing a policy at CDC against patenting "a naturally occurring virus," but distinguishing these from "patents on our techniques"); *see also* Interview with JM Heraud, Head, Virology Unit and National Influenza Center, Madagascar (Feb. 6, 2014) (objecting to patents on virus sequences as "against science"); Interview with Julian Druce, Head, National Influenza Centre, Australia (Oct. 16, 2013) (similar).

the avian flu outbreak.[371] Most of them limit their searches to patents and patent applications relevant to recent pandemic influenza strains, and all reflect the difficulty of finding patents outside of those few jurisdictions that make patents available online. They each also use slightly different techniques to define and find relevant patents. The result is that even after these substantial reviews, no definitive accounting of Network-held patents and their implications is possible.

However, by triangulating between these reports and interviews, one can develop a clear, if general, picture of the role of patents in the Network over time. Scientists with a long history in the Network report that patents were unheard of in most of its history.[372] The patent mappings show that as early as the mid-1990s, a few Network labs did begin to seek patents related to their influenza work.[373] Over the years, such patents

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371 The World Intellectual Property Organization undertook an extensive patent mapping in 2011 to identify patents and patent applications "in connection with the H5N1 and H1N1 pandemic virus." WIPO 2011 REPORT, *supra* note 365, at 3. This review searched U.S., European, and PCT patents and patent applications, dividing potentially relevant patents into two categories. The first were patents that clearly claimed either parts of the H5N1 and H1N1 viruses themselves or a "derivative of the virus, for diagnostic, therapeutic or prophylactic purposes." *Id.* at 3; *see also id.* at 17 (describing "Group 1" patents in further detail). Note that patent applications may not have been granted or may have been narrowed if granted. *Id.* at 4–5, 8. A second report by CAMBIA focused more narrowly on U.S. patents and patent applications claiming either isolated genetic sequences or expressed proteins of H5N1 viruses. *See* PATENT LENS REPORT, *supra* note 363. This study used search techniques complementary to those used by WIPO, relying on searches based upon flu genetic sequences themselves (instead of keyword searches, which would miss patents that did not use key terms, such as "H5N1"). A third report was prepared by Edward Hammond for the Third World Network, and searched the WIPO international patent application database for claims that mention H5N1. EDWARD HAMMOND, SOME INTELLECTUAL PROPERTY ISSUES RELATED TO H5N1 INFLUENZA VIRUSES, RESEARCH AND VACCINES 3 (2009) [hereinafter HAMMOND STUDY]. The patent applications were included in the study if the claims could be classified as covering medicines, vaccines, microbes, peptides, nucleic acids, or immunoassays. *Id.* at 4. A fourth report prepared by the WHO Initiative for Vaccine Research cast the broadest net, looking for patents related to many dimensions of vaccine technology, such as processes involved in influenza vaccine production, and adjuvants used to make vaccines more potent. MAPPING OF INTELLECTUAL PROPERTY RELATED TO THE PRODUCTION OF PANDEMIC INFLUENZA VACCINES, WORLD HEALTH ORGANIZATION INITIATIVE FOR VACCINE RESEARCH (Oct. 23, 2007) [hereinafter IVR REPORT 2007].

372 *See* Interview with Ian Gust, former member of WHO expert committee on virus diseases (Oct. 16, 2013); Interview with Anne Kelso, Director of the WHO Collaborating Centre for Reference and Research on Influenza, Australia (Oct. 29, 2013); Interview with John McCauley, *supra* note 368.

373 Two of the earliest patents found in the mappings are: U.S. Patent No. 5,824,536 (filed June 17, 1996) (assigned to St. Jude) and U.S. Patent No. 5,976,551 (filed June 7, 1995) (assigned to Pasteur Institute in Paris). This does not provide definitive evidence of the date when patenting by Network labs began. Existing mappings focus largely on existing patents. But because patents expire

emerged only sporadically, sought by individual labs rather than the Network as an entity, with just a few labs and very few patents involved. While each mapping found at least one patent or patent application stemming from a Network lab in their relevant pool of patents, collectively they show patenting activity in only five out of the more than 100 labs associated with the Network, with fewer than 20 total patents and patent applications, and more than half of these stemming from one influenza lab with close ties to the animal sector, at St. Jude. Patents stemming from the Network are dwarfed, in every case, by the much larger number of patents from other entities. Only two patent applications by Network labs identified in these mappings include in their claims natural nucleotide sequences of Network viruses (an important issue when controversies emerged over whether patents were being obtained on "Network material" itself).[374]

Interpreting and generalizing the claims of the 20 pandemic-strain related patents and patent applications identified as associated with the Network is difficult, but they tend to fall into two subsets. One subset claims selections or modifications of influenza virus components designed to elicit a better immune response for vaccines or therapeutics,[375] and the other claims ways to stabilize or maximize the production of vaccine viruses.[376] The latter category includes one notable suite of patents held by St. Jude that are important to a pro-

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after a term of twenty years, 35 U.S.C. § 154(a)(2) (2012), these mappings are not a good source of information about patenting practices in the 1980s or earlier.

374 *See* HAMMOND STUDY, *supra* note 371, at 5, 15 (within discussion of patent applications including H5N1 genetic material, identifying two patent applications by Network labs that included natural virus sequences, one in the context of claims involving DNA vaccines and the other in the context of claims involving monoclonal antibodies and potent HA molecules); *see also* PATENT LENS REPORT, *supra* note 363 (within mappings of patents and patent applications claiming influenza nucleotide sequences, listing no patents or patent applications by Network labs that exclusively claim natural virus sequences).

375 For example, a patent application by St. Jude, WO 2007/019094 A3, uses reverse genetics to design specific changes to HA molecules that induce greater vaccine potency. Claim 7 of the application does claim a strain that came from the Flu Network, but only insofar as it includes the modified HA molecules. A subsequent and similar patent application by St. Jude, WO 2008/033105 A8, claims very potent HA molecules that can induce the production of antibodies that are to be used for diagnosis and therapy. *See* Hammond Study, *supra* note 371, at 15. Note that patent applications may not have been granted or may have been narrowed if granted.

376 In the second category, U.S. Patent No. 6,951,754 (filed Apr. 27, 2001) (assigned to St. Jude), claims broadly and generally reverse genetics techniques to produce compositions of various influenza genes and viral components, which is an efficient method for producing vaccine viruses.

cess known as reverse genetics.[377] These patents are general in nature, covering processes important to new techniques for building viruses from scratch, and in this sense are not directly related to influenza or the work of the Network.[378] These patents may well be relevant to the production of pandemic vaccines, because they cover the process used by the Network to create reference strains for pandemic vaccines.[379] In recognition of the sensitivity of the access to medicine issues posed by these patents—and perhaps also the fact that some of them are held by a CC—MedImmune has publicly announced that it will license these patents to government organizations and developing countries at no cost to develop vaccines for public health purposes.[380]

With the exception of these reverse genetics patents (which were not perceived as the result of Network work) the sporadic patents that Network labs have secured have apparently generated no revenue for the Network or its labs, nor impinged directly on its activities.[381] CC participants described a few

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377 *See* IVR REPORT 2007, *supra* note 371, at 18–19; Anatole Krattiger et al., *Intellectual Property Management Strategies to Accelerate the Development and Access of Vaccines and Diagnostics: Case Studies on Pandemic Influenza, Malaria and SARS*, 2 INNOVATION STRATEGY TODAY 67, 94–96 (2006). Influenza reverse genetics is the process by which scientists choose which HA and NA genes they will express in a particular virus strain, relying on their chosen HA and NA genes to be expressed from pre-designed plasmids, rather than resorting to natural assortment between different HA and NA strains like in conventional virus production. *See Reverse Genetics, Flu (Influenza)*, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (Jan. 14, 2011), https://web.archive.org/web/20140710042216/https://www.niaid.nih.gov/topics/Flu/Research/basic/Pages/ReverseGeneticsIllustration.aspx [https://perma.cc/8UY2-T99Q].

378 The technique is, however, critical to Network's work creating seed strains for pandemic vaccines. There are many patents beyond those belonging to St. Jude that are relevant to the process of reverse genetics, and the suite of relevant patents was assembled by a private company—which licensed the St. Jude's patents among others—called MedImmune. Press Release, MedImmune, *MedImmune Expands Patent Estate for Reverse Genetics with New Rights from Mount Sinai School of Medicine* (Dec. 7, 2005), *available at* http://www.prnewswire.com/news-releases/medimmune-expands-patent-estate-for-reverse-genetics-with-new-rights-from-mount-sinai-school-of-medicine-55415082.html [http://perma.cc/WG9A-7WGJ].

379 IVR REPORT 2007, *supra* note 371, at 18.

380 *See id.* MedImmune requires licensing fees for commercial producers of vaccines, and recently was acquired by AstraZeneca with uncertain implications for these policies. *Id.* at 19.

381 *See, e.g.*, Interview with Michael Shaw, *supra* note 370 (reporting that the CDC has no revenue stream coming from the CDC's diagnostic patents); Interview with Alan Hay, *supra* note 370 (stating that "generally throughout the Network, people aren't patenting anything that really impinges on the Network"); Interview with John McCauley, *supra* note 368 (indicating, vis-à-vis the emergence of patenting in the viruses and genomics, "I don't think within the Network it changed much in practice"). While the reverse genetics patents at St. Jude's were licensed,

patents that could theoretically have interfered with Network work, for example because they covered techniques related to flu diagnosis. Why did Network labs seek these patents? A lead scientist at the CDC, one of the few labs to hold such patents, described the reasons as "defensive."[382] More specifically, he described them as intended to prevent private firms from taking unfair advantage of the Network's work.[383] More broadly, they may also be intended to preserve freedom to operate for Network labs,[384] though there is no obvious evidence that patents, held by public or private entities, have interfered with the Network's work to date.

The recent seeking of patents by Network labs reflects—in attenuated fashion—a broader shift in attitudes toward patents that occurred in public scientific institutions in the 1980s and 1990s.[385] Government entities and academic institutions rarely patented before this period, and many had policies against patenting. The broader trend has been described as the result of factors that include the rise of biotechnology, expansions in the scope of patentability, and legislative shifts (particularly in the United States, where the Bayh–Dole Act

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they are not influenza specific, and the head of the CC there also suggested that any revenues that came to their lab from this patent would only be indirect, because the revenues go to St. Jude generally, which then sets the overall budgets for sub-units such as the influenza lab. *See* Interview with Richard Webby, Faculty, St. Jude Children's Research Hospital and Director, WHO Collaborating Center for Studies on the Ecology of Influenza in Animals and Birds (May 22, 2014).

382 Interview with Michael Shaw, *supra* note 370. This is consistent with what others from some CCs also perceived. *See, e.g.*, Interview with Alan Hay, *supra* note 370.

383 Dr. Shaw from the CDC reported, for example, that there had "been situations where we've sort of been caught, . . . [where] we had published some sequences of primers that were useful for sequencing of influenza viruses and a fairly large multinational company started marketing them." Interview with Michael Shaw, *supra* note 370. In response to this, the CDC has occasionally taken out patents on techniques the CC there has developed; for example, for a real-time PCR assay used in diagnosing influenza strains. These seem to be U.S. Patent No. 8,568,981 (filed July 20, 2012) (concerned with methods of detecting various influenza strains using different PCR primers) and U.S. Patent No. 8,241,853 (filed Aug. 13, 2008) (a continuation-in-part, specifically including probes that can detect variations of the H5 and H7 types of influenza).

384 *See, e.g.*, Interview with Alan Hay, *supra* note 370 (reporting that while the CDC had sought IP related to Network materials, that they had always insisted that the "reason they took out patents on things was to prevent others doing so. And so it was to protect the Network.").

385 *See, e.g.*, David C. Mowrey et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh–Dole Act of 1980*, 30 RES. POL'Y 99, 103–04 (2001) (giving evidence of the expansion of patenting by universities in these decades).

was passed to encourage patenting of the results of federal research).[386]

2. *The Broader Context: Patenting in the Public and Private Sectors Generally*

The Network's approach is clearly distinct from the more general trend in influenza. As these same patent mappings also show, patenting in connection with pandemic influenza viruses has grown dramatically in recent years, particularly around the re-emergence of H5N1. This explosion of patents includes applications and granted patents for genetic sequences, and those that are directed to primers, probes, diagnostic tests, and vaccine technologies.[387] The public and especially academic sector outside of the Network has actively participated in this new patent race, with a particularly high share of sequence patents (though altogether these are relatively few), and a more minor but not trivial share of patents that relate to vaccine production and manufacture.[388]

These mappings are incomplete and do not reveal, in particular, whether public sector and academic institutions seek to profit from such patents, or rather also view them as defensive in nature. However, they do make clear that many public sector institutions have begun to seek patents that could cover key vaccine components or processes.

In the private sector, patents related to vaccines are common, reflecting the broad importance of patents in the business model of the pharmaceutical and biotechnology industries. Patents related to vaccines may be multiple and fragmented,

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386 *Id.* at 100, 116.

387 *See* HAMMOND STUDY, *supra* note 371, at 4 (showing that 36% of patent applications for influenza vaccines filed between 1983 and September 2008 have been filed since January 1, 2006); Krattiger et al., *supra* note 377, at 94–104 (collecting granted patents on sequences and important techniques for vaccine production, etc.); PATENT LENS REPORT, *supra* note 363 (documenting granted patents on genetic sequences, reassortment viruses, and amino acid sequences); WIPO 2011 REPORT, *supra* note 365, at 3–4, 20, 23 (identifying 73 patent applications directly or indirectly related to the H5N1 and H1N1 viruses that claim virus sequences, isolated antigens, and sequences included in patents on novel vectors, vaccines, and adjuvants); IVR REPORT 2007, *supra* note 371 (documenting 123 patents relevant to the production of pandemic influenza vaccines).

388 For sequence patents, see, for example, U.S. Patent No. 6,685,946 (filed Sep .19, 2002), U.S. Patent No., U.S. Patent No. 6,287,570 (filed Nov. 28, 1998), and U.S. Patent No. 6,824,784 (filed May 8, 2003). *See also* PATENT LENS REPORT, *supra* note 363. The other patent mappings do not break out the public sector specifically, but tallying them reveals that public sector institutions account for less, and in certain cases significantly less, than a third of the patents identified. *See* HAMMOND STUDY, *supra* note 371; IVR REPORT 2007, *supra* note 371; WIPO 2011 REPORT, *supra* note 365.

and relate not to single vaccines but to broader systems that are used in processes of many different vaccines.[389] This is broadly reflected in influenza, particularly in recent years.

The most common form of influenza vaccine, grown in eggs, is more than sixty years old, and therefore unpatented.[390] However, there have been extensive efforts to improve the manufacturing and efficacy of vaccines, resulting in many patents (mostly—but not only—held by the private sector), that could potentially be critical to the production of vaccines in a pandemic.[391] The clearest example of a key patent stake is the suite of patents assembled by MedImmune that cover the process of reverse genetics, described above.[392] Several therapeutic drugs that target the influenza virus are also covered by patents, but in forms far less complex than the patent landscape for influenza vaccines.[393]

As this shows, the Network exists at one end of a spectrum: private sector entities have patented aggressively around influ-

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389 *See* Hillary Greene, *Patent Pooling Behind the Veil of Uncertainty: Antitrust, Competition Policy, and the Vaccine Industry*, 90 B.U. L. REV. 1397, 1404–05 (2010).

390 IVR REPORT 2007, *supra* note 371, at 3.

391 For example, improvements in the conventional process (that, for example, create higher yield) are under patent, at least in some countries. *Id.* at 3–5. In a pandemic setting, the use of adjuvants, which increase immune response and thus allow for smaller doses, may be critical, and many are under patent. *Id.* at 10–13 (discussing adjuvant-related patents, most of which are held by private companies). Cell-based techniques to grow viruses outside of eggs also are the subject of many patents, particularly—but not only—by private sector companies. *Id.* at 5–10. Of the 27 such patents identified in the IVR report, five were held by the University of California (which is home to a scientist who is a leader in the science of cell-based manufacture), one by the patenting entity of Wisconsin University, and three by St. Jude. Notably, even in the absence of patents, regulatory requirements may make it difficult to use cell-based techniques without the cooperation of the entity holding the original cell-line. *Id.* at 6. Live-activated vaccines ("FluMist" in the United States), which are administered as nasal sprays, are built on backbones of modified strains that give the vaccine virus its attenuated quality, and so patents could be important barriers to production of certain such vaccines. *See id.* at 13–15.

392 *See supra* note 377 and accompanying text.

393 For example, the most well-known such drug is oseltamivir phosphate (Tamiflu), which according to the FDA Orange Book was until recently covered by two patents: U.S. Patent No. 5,866,601 (filed June 6, 1995) and U.S. Patent No. 5,763,483 (filed Dec. 27, 1996). FDA ORANGE BOOK OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, N021087, http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=003&Appl_No=021087&Appl_type=N [https://perma.cc/2CQB-65RP]. The Orange Book is not comprehensive. (For example, it excludes process patents. 21 C.F.R. § 314.53(b)(1).) However, the landscape is clearly less complex than the landscape for vaccines, which may be impacted by patents on nucleotide or amino acid sequences, other intermediaries, on reverse genetics, on cell-based or other manufacturing processes, as well as on other techniques to optimize or test their efficacy.

enza, public sector entities outside of the Network have patented in significant numbers, and Network labs have patented hardly at all. Notably, the fact that private, and some public entities, have sought patents does not contradict the point above that the market-exclusionary mode is inadequate to generate the information goods we need to address influenza. Much of the work resulting in patents, in both the private and public sectors, has received substantial public funding, as described above. Patents do create some profit opportunities—for example, if a pandemic occurs—and companies rationally seek them for this reason. Nonetheless, we cannot expect patents alone to provide adequate incentives for the range of information goods that we need to address influenza, for the reasons detailed in Part I.

APPENDIX C

PUBLICATION RECORD OF CURRENT HEADS OF NETWORK LABS

The following reports instances of publications where the current head of a national lab, regulatory lab, or CC was at least a co-author. The data is up to date as of November 2, 2016.

The data was compiled by searching for each head of a national lab, regulatory lab, or CC[394] as an author in the Web of Science database.[395] Web of Science is a citation index system maintained by Thomson Reuters that indexes journals, books, and conference proceedings from all scientific disciplines and many social sciences and arts and humanities disciplines. It has over 90 million records of scholarly work.[396] It aspires to index the world's most important research, covering publications from 80 different countries, and has nearly 1 billion cited references.[397]

The search sought to capture potential authorship (or co-authorship) in all publications with no past time limits. The number of publications was found by searching in Web of Science Advanced Search for (1) a given author's last name and first and middle initials and (2) his or her country of residence. The search was then repeated with the topic "influenza" to see how many of those publications included the word in their titles.[398] For common names that returned an inordinate number of results, the results were limited according to the author's institution or via the Web of Science "Article Groups" feature, which attempts to identify unique authors via a propri-

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394 *Global Influenza Surveillance and Response System (GISRS)*, WHO INFLUENZA, http://www.who.int/influenza/gisrs_laboratory/en [https://perma.cc/BCA5-RFM3].

395 *Web of Science*, CLARIVATE ANALYTICS, http://clarivate.com/scientific-and-academic-research/research-discovery/web-of-science/ [https://perma.cc/GM8E-KLCF].

396 *Web of Science*, CLARIVATE ANALYTICS, http://wokinfo.com/citationconnection/ [https://perma.cc/PAE5-5ED6].

397 *Id.*, *Web of Science All Databases Help*, https://images.webofknowledge.com/WOKRS516B3/help/WOK/hp_additional_resources.html [https://perma.cc/YFU7-25CU].

398 For general publication counts, a search query of the following form was used: "AU=([author's last name and initials]*) AND CU=([author's country])", where "AU" indicates the author field and "CU" the country field. For "Influenza Publication" counts, a search query of the following form was used: "AU=([author's last name and initials]*) AND CU=([author's country]) AND TS=(inluenza)", where "TS" indicates the topic field. For "Other Publication" counts, the influenza publication counts were subtracted from the general publication counts.

etary algorithm.[399] The results are not exact, since they are inflated by the publication counts of other authors with the same last name and initials as the authors in question. Because Web of Science catalogues authors by last name and initials, this effect is impossible to avoid. Limiting the search results to the author's country of residence helps attenuate the effects.

There are three additional noteworthy limitations to the data generated. First, the publications selected for indexing in the Web of Science are likely skewed towards the global North. Second, the tenure duration and activity level of a NIC head impact his or her ability to compile a publication record. Third, many important influenza scientists have been affiliated previously with the Network but are not the current head of a lab, or are affiliated with the Network but not the head of a lab. The results below should be understood as illustrative of the dynamics of publication in the Network, and generally as underestimates of both individuals' total publications and of the role of Network scientists in publishing.

399 *Article Groups*, THOMSON REUTERS, http://images.webofknowledge.com/WOKRS522_2R1/help/WOS/hp_results_tellmemore.html [https://perma.cc/39QH-4SEX].

TABLE ONE
Publications by Country & Head[400]*:*

Country	Head Name	Lab	Influenza Publications	Other Publications
Afghanistan	Gulam Eshan Sharifi	Central Public HealthLaboratory	0	0
Albania	Silvia Bino	Institute of Public Health	0	47
Algeria	Fawzi Derrar	Institut Pasteur d'Algérie	0	1
Argentina	Elsa Baumeister	Instituto Nacional de Enfermedades Infecciosas	23	8
	Jorge Camara	Instituto de Virologia	0	3
	Osvaldo Uez	Intituto Nacional de Epidemiologia	10	0
	Country Total		33	11
Australia	Julian Druce	Victorian Infectious Diseases Reference Laboratory	12	31
	David Smith	PathWest Laboratory	24	23
	Dominic Dwyer	Westmead Hospital	95	209
	Ian Barr ¥	Victorian Infectious Diseases Reference Laboratory	151	25
	Mandvi Bharadwaj ǂ	Therapeutic Goods Administration Laboratories	3	53
	Country Total		285	341
Austria	Franz X. Heinz	Medical University of Vienna	20	173
Bahrain	Amjad Zaed	Public Health Laboratory	0	0
Bangladesh	Mahmudur Rahman	Institute of Epidemiology	10	35
Belarus	Natalia Gribkova	Republican Research & Practical Center for Epidemiology and Microbiology	0	0
Belgium	Isabelle Thomas	Scientific Institute of Public Health	8	111
Brazil	Wyller Alencar de Mello	Instituto Evandro Chagas	0	0
	Marilda Siqueira	Instituto Oswaldo Cruz	37	67
	Terezinha Maria de Paiva	Instituto Adolfo Lutz	0	0
	Country Total		37	67
Bulgaria	Neli Korsun	National Centre of Infectious and Parasitic Diseases	4	9
Cambodia	Philippe Dussart	Institut Pasteur in Cambodia	2	5
Cameroon	Richard Njouom	Centre Pasteur du Cameroun	9	49

400 ¥ denotes heads of WHO Collaborating Centres, with a total of six such individuals: Barr, Shu, Odagiri, McCauley, Katz, and Webby. ǂ denotes heads of Essential Regulatory Laboratories, with a total of four such individuals: Bharadwaj, Odagiri, Engelhardt, and Ye. All others are heads of NICs.

Canada	Yan Li	Health Canada Canadian Science Center for Human and Animal Health	50	41
Central African Republic	Emmanuel Nakouné	Institute Pasteur de Bangui	0	0
Chile	Rodrigo Fasce	Instituto de Salud Publica de Chile	16	10
China	Yuelong Shu [v]	Chinese National Influenza Center	125	5
	Janice Lo	Centre for Health Protection	3	22
	Country Total		128	27
Colombia	Juliana Barbosa Ramirez	Instituto Nacional de Salud de Colombia	1	2
Costa Rica	Jenny Lara	Laboratorio Nacional de Influenza	3	2
Côte d'Ivoire	Hervé Kadjo	Institut Pasteur de Côte d'Ivoire	0	0
Croatia	Vladimir Drazenovic	Croatian Institute of Public Health	8	10
Cuba	Betsy Acosta Herrera	Instituto de Medicina Tropical	4	2
Czech Republic	Martina Havlickova	National Instituteof Public Health	19	11
Democratic People's Republic of Korea	K. Dong Guy	Central Hygienic Antiepidemic Station	0	0
Denmark	Thea Kølsen Fischer	Statens Serum Institut	7	59
Ecuador	Alfredo Bruno Caicedo	Instituto Nacional de Higiene y Medicina Tropical	0	0
Egypt	Marwa Abdalhamid	Egyptian Holding Company for Biological Products and Vaccines	0	0
	Amel Mohamed Naguib	Central Public Health Laboratory	1	5
	Country Total		1	5
El Salvador	Mónica Jeannette Barahona de Gámez	Laboratorio Central Ministerio de Salud Pubilca	0	0
Estonia	Natalja Kuznetsova	Laboratory for Communicable Diseases	0	8
Fiji	Eric Rafai	Center for Communicable Disease Control	0	6
Finland	Niina Ikonen	National Institute for Health and Welfare	27	2
France	Bruno Lina	Centre de biologie etde pathologie	114	121
	Martine Valette	Centre de biologie et de pathologie	53	75
	Sylvie Van der Werf	Institut Pasteur	0	0
	Country Total		167	196

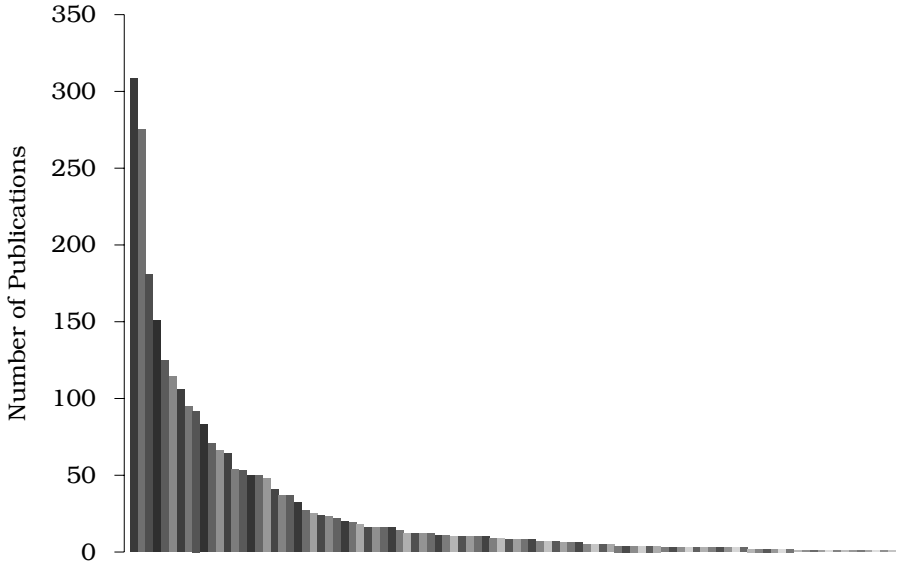
French Guiana	Dominique Rousset	Institut Pasteur de la Guyane	0	11
French New Caledonia	Dominique Baudon	Pasteur Institute	0	0
Georgia	Ann Machablishvili	National Influenza Center	1	1
Germany	Brunhilde Schweiger	Robert Koch-Institute	83	59
Ghana	William Ampofo	National Influenza Laboratory	18	45
Greece	Andreas Mentis	Institut Pasteur Hellénique	7	133
	Nikolaos Malisiovas	National Influenza Center	11	27
	Country Total		18	160
Guatemala	Leticia Castillo Signor	Centro Nacional de Influenza	0	0
Honduras	María Luisa Matute	Laboratorio Nacional de Vigilancia de la Salud	2	3
Hungary	Istvan Jankovics	B. JohanNational Center for Epidemiology	16	37
Iceland	Arthur Löve	Landspitali - University Hospital	3	35
India	Usha Soren Singh	National Influenza Center	0	22
	Ranjana Deshmukh	Acharya Donde Marg	3	3
	D T Mourya	National Institute of Virology	0	88
	CountryTotal		3	113
Indonesia	Pretty Multihartina	Center for Biomedical and Basic Technology of Health	1	0
Iran	Talat Mokhtari-Azad	Iranian National Influenza Center	12	32
Iraq	Imam M. Aufi	National Influenza Centre	0	0
Ireland	Cillian De Gascun	National VirusReference Laboratory	0	0
Israel	Michal Mandelboim	Ministry of Health	37	10
Italy	Maria Rita Castrucci	Istituto Superiore di Sanità	48	1
Jamaica	Sandra Jackson	University of the West Indies	1	10
Japan	Takato Odagiri ¥ ǂ	National Institute of Infectious Diseases	106	105
Jordan	Aktham Haddadin	Laboratory Directorate	1	8
Kazakhstan	Gauhar Nusupbaeva	National Reference Laboratory for Control of Viral infections	0	0
Kenya	Japeth Magana	Center for Virus Research	4	2
Kuwait	S. Al-Mufti	Ministry of Public Health	0	9
Kyrgyzstan	Gulbarchyn Saparova	National Virology Laboratory	0	0
Laos	Phengta Vongphrachanh	National Centre for Laboratory and Epidemiology	8	16

Latvia	Natalija Zamjatina	Riga East University Hospital	0	1
	Gatis Pakarna	Riga East University Hospital	0	1
	Country Total		0	2
Lebanon	Pierre Zalloua	National Influenza Centre	0	76
	Nisrine Jamal	National Influenza Centre	0	0
	Country Total		0	76
Lithuania	Vilnele Lipnickiene	National Public Health Surveillance Laboratory	0	3
Luxembourg	Matthias Opp	Laboratoire National de Santé	5	12
Madagascar	Jean-Michel Heraud	Institut Pasteur de Madagascar	16	22
Malaysia	Zainah Saat	Institute of Medical Research	6	15
	Jamal I-Ching Sam	University of Malaya	0	2
	Country Total		6	17
Malta	Christopher Barbara	Virology Laboratory of Mater Dei Hospital	0	13
Mauritius	Sanjiv Rughooputh	Central Health Laboratory	0	50
Mexico	Irma Lopez Martinez	Instituto de diagnóstico y Referencia Epidemiologicos	1	5
Moldova	Constantin Spinu	National Influenza Center	0	3
Mongolia	Y. Buyanjargal	National Center for Communicable Diseases	0	0
Morocco	Amal Barakat	Institut National d'Hygiène	3	1
Myanmar	Htay Htay Tin	National Health Laboratory	1	7
Nepal	Geeta Shakya	National Public Health Laboratory	2	27
Netherlands	Marion Koopmans	National Influenza Centre	66	139
New Zealand	Margaret C. Croxson	Auckland City Hospital	0	60
	Sue Huang	National Influenza Centre	5	68
	Country Total		5	128
Nicaragua	Angel Balmaceda Echeverria	Centro Nacional de Diagnóstico y Referencia	0	0
Nigeria	D. Olaleye	College of Medicine Ibadan	4	31
Norway	Olav Hungnes	Norwegian Institute of Publich Health	32	17
Oman	Amina Al Jardani	Central Public Health Laboratory	0	0
Pakistan	Birjees Mazher Kazi	National Institute of Health	3	10
Panama	Brechla Moreno	Instituto Conmemorativo Gorgas de Estudios de la Salud	1	21
Papua New Guinea	Amanda Lang	Institute of Medical Research	0	0
Paraguay	Cynthia Vazquez	Laboratorio Central de Salud Publica	3	5

Peru	Victoria Guttierez Peceros	Instituto Nactional de Salud	0	0
Philippines	Socorro P Lupisan	Department of Health	2	13
Poland	Lidia B. Brydak	National Influenza Centre	64	0
Portugal	Raquel Guiomar	National Influenza Reference Laboratory	12	5
Qatar	Ajayeb Al-Nabet	Hamad Medical Corporation	0	1
Republic of Korea	Kisoon Kim	Korea National Institute of Health	0	0
Romania	Costin Cernescu	National Influenza Centre in the Institute of Virology	0	31
	Viorel Alexandrescu	Cantacuzino Institute	4	38
	C. Apetrei	Lasi University of Medicine & Pharmacy	0	66
	Country Total		4	135
Russia	Petr Grigorievich Deryabin	Ministry of Health of the Russian Federation	8	15
	Elena Ivanova Burtseva	Ministry of Health of the Russian Federation	16	4
	Anna A. Sominina	Research Institute of Influenza	5	1
	Country Total		29	20
Senegal	Mbayame Niang	Institut Pasteur de Dakar	10	67
Serbia	Jasminka Nedeljkovic	Institute of Immunology	6	103
	Vera JerantPatic	Institute of Public Health	0	3
	Country Total		6	106
Singapore	Raymond Tzer Pin Lin	National Public Health Laboratory	12	60
Slovakia	Edita Staroňová	Public Health Authority of the Slovak Republic	1	0
Slovenia	Katarina Prosenc	National Laboratory for Health, Environment and Food	10	13
South Africa	Diana Hardie	University of CapeTown	1	30
	Florette Treurnicht	National Institute for Communicable Diseases	10	33
	Country Total		11	63
Spain	Tomàs Pumarola	Universidad de Barcelona	54	132
	Inmaculada Casas	Centro Nacional de Microbiología	3	9
	Francisco Pozo	Centro Nacional de Microbiología	2	3
	Raúl Ortiz de Lejarazu	Universidad de Valladolid	0	0
	Country Total		59	144
Sri Lanka	Jude Jayamaha	Medical Research Institute	0	0

Sudan	Hayat Salah Eldin Khogali	Federal Ministry of Health	0	0
Sweden	Mia Brytting	Public Health Agency Sweden	14	42
Switzerland	Samuel Cordey	University of Geneva Hospitals	1	24
Syria	Hazzaa Al Khalaf	Public Health Laboratories	0	1
Tanzania	Fausta Mosha	National Influenza Laboratory	0	2
Thailand	Malinee Chittaganpitch	National Institute of Health	41	8
Trinidad and Tobago	Victoria Moris-Glasgow	Caribbean Epidemiology Centre	0	0
Tunisia	Amine Slim	Laboratoire de Microbiologie	6	46
Turkey	Gulay Korukluoglu	National Influenza Centre	11	46
Uganda	Julius Lutwama	Uganda Virus Research Institute	4	44
Ukraine	Alla Mironenko	L.V.Gromashevsky Institute of Epidemiology & Infectious Diseases	5	3
UK	Pamela Molyneaux	Aberdeen Royal Infirmary	0	35
	Peter Coyle	Royal Victoria Hospital	3	75
	William Carman	Gartnavel General Hospital	9	73
	Maria Zambon	Health Protection Agency	181	35
	John McCauley [¥]	WHO Collaborating Centre for Reference and Research on Influenza	92	86
	Othmar Engelhardt [‡]	National Institute for Biological Standards and Control	25	1
	Country Total		310	305
US	H.F. Maassab	University of Michigan	71	30
	Jacqueline Katz [¥]	CDC	275	27
	John Janda	Viral and Rickettsial Disease Laboratory	0	10
	L. Grady	New York State Department of Health	1	37
	Richard Webby [¥]	WHO Collaborating Center for Studies on the Ecology of Influenza in Animals	308	22
	Zhiping Ye [‡]	FDA	50	6
	Country Total		705	132
Uruguay	Hector Chiparelli	Departamento de Laboratorio de Salud Publica	2	12
Venezuela	Esperanza Briceño	Instituto Nacional de Higiene	0	8
Vietnam	Le Quynh Mai	National Institute of Hygiene and Epidemiology	22	11
	Nguyen Thanh Long	Pasteur Institute	7	89
	Country Total		29	100
Zambia	Mwaka Monze	University Teaching Hospital	3	36

FIGURE ONE
Publication Distribution (influenza-only publications):



Publication Statistics:

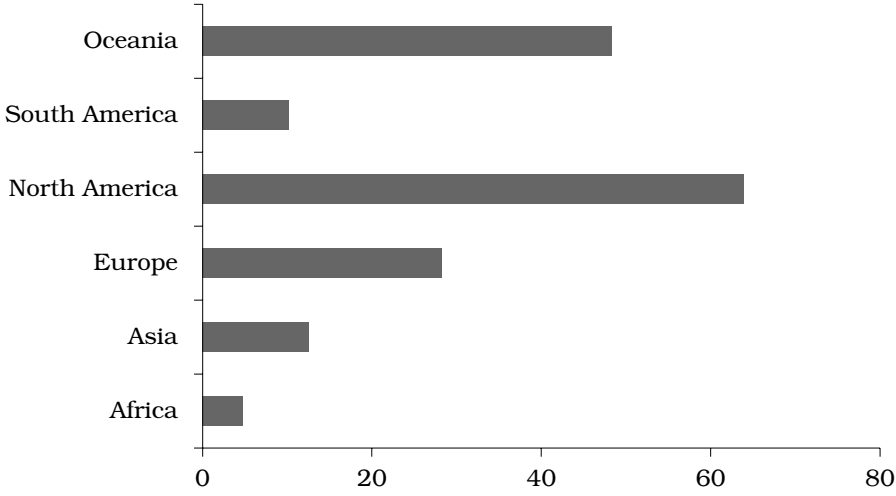
TABLE 2

Influenza Publications	Mean	Median
All Network Lab Heads	17.53	3
Head of CCs	176.17	138
Head of Regulatory Labs	46	37.5
Head of National Labs	10.79	2

TABLE 3

	Influenza	All
Total Number of Publications by All Heads	2700	6612
Percent Publications by Heads of CCs	39.15%	20.07%
Percent of Heads Without Any Publications	36.36%	18.83%

TABLE 4
NETWORK HEAD'S AVERAGE NUMBER OF INFLUENZA PUBLICATIONS BY REGION[401]



401 For this and the next figure, the following countries were grouped as Africa: Algeria, Cameroon, Central African Republic, Côte d'Ivoire, Egypt, Ghana, Kenya, Madagascar, Mauritius, Morocco, Nigeria, Senegal, South Africa, Sudan, Tanzania, Tunisia, Uganda, and Zambia.

The following countries were grouped as Asia: Afghanistan, Bahrain, Bangladesh, Cambodia, China, Democratic People's Republic of Korea, India, Indonesia, Iran, Iraq, Israel, Japan, Jordan, Kazakhstan, Kuwait, Kyrgyzstan, Laos, Lebanon, Malaysia, Mongolia, Myanmar, Nepal, Oman, Pakistan, Philippines, Qatar, Republic of Korea, Singapore, Sri Lanka, Syria, Thailand, Turkey, and Vietnam.

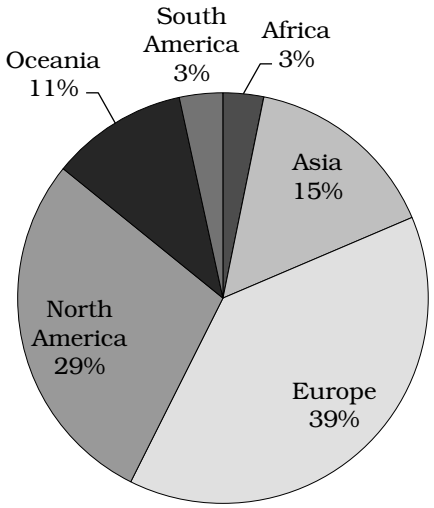
The following countries were grouped as Europe: Albania, Austria, Belarus, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Moldova, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK, and Ukraine.

The following countries were grouped as North America: Canada, Costa Rica, Cuba, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nicaragua, Panama, Trinidad and Tobago, and United States.

The following countries were grouped as Oceania: Australia, Fiji, French Guiana, French New Caledonia, New Zealand, and Papua New Guinea.

The following countries were grouped as South America: Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela.

TABLE 5
GISRS HEADS' TOTAL INFLUENZA PUBLICATIONS:
SHADE BY REGION



APPENDIX D

INFLUENZA SAMPLES COLLECTED AND SEQUENCES SHARED BY EACH COUNTRY

The following reports the number of influenza samples received and collected by Network laboratories worldwide, as reported to the Network through WHO FluNet,[402] as well as influenza virus sequences shared on GISAID EpiFlu by laboratories across the world, which include (but are not limited to) Network labs.[403] This data is up to date as of October 17, 2016.

The FluNet data was compiled by searching the FluNet interactive database[404] for the category "Influenza laboratory surveillance data from any week." For the date range, the search used a range from week 1 of 1995 to week 40 of 2016. This data reports the number of recorded influenza virus samples collected/received as reported to the Network within each country, where each instance of collection or receipt is tallied as a unit.

The GISAID data was compiled by searching the EpiFlu database[405] for the "collection date" from 1/1/1995 to 10/7/2016, and selecting every "originating laboratory" from an individual country. This data is the number of influenza sequences shared on the GISAID network for all users to access, where each sequence shared is tallied as a unit.

There are four noteworthy observations in this data.

First, there is extensive sharing of genetic sequences by influenza scientists, and even more extensive reporting of sample collection by WHO labs. The number of shared sequences on GISAID from each WHO region is quite high; even the region contributing the fewest sequences (South-East Asia—11 countries) had 1/10 of the number of sequences of the region contributing the most (Europe—53 countries). Furthermore, Network labs in every WHO region reported collecting hundreds of thousands of samples during the last 20 years.

Second, there is regional differentiation in terms of sample collection and data sharing, consistent with observations made

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402 *FluNet Database*, WHO, http://apps.who.int/flumart/Default?ReportNo=12 [https://perma.cc/2ZJQ-BEAK].

403 *About GISAID*, GISAID INITIATIVE, http://platform.gisaid.org/epi3/frontend - 17a8de [https://perma.cc/B2E6-FTNU] (click "About GISAID" on the top navigation bar).

404 *FluNet Database*, *supra* note 402.

405 *EpiFlu Database*, GISAID INITIATIVE, http://platform.gisaid.org/epi3/frontend - 17a8de [https://perma.cc/B2E6-FTNU] (click "EpiFlu™ DATABASE").

by Network scientists. Generally, there are more samples reported and shared from Europe and US labs, and relatively fewer samples reported and shared from countries with resource-poor labs.

Third, despite this differentiation, even in Africa, Latin America, and especially Asia, there is very extensive reporting and sharing of influenza sequence information. In fact, Asia's contribution is on par with (and regarding viruses, exceeds) contributions from Europe and the US, while Africa and Latin America's contributions are within the same order of magnitude as contributions from Europe and the US.

Fourth, overall, the number of specimens received and collected in FluNet looks consistent with the number of sequences shared on GISAID for each country. This seems to suggest that collecting and sharing influenza samples are generally correlated. However, it is noteworthy that Mexico, Japan, Austria, Ukraine, Germany, Sweden, Ireland, and Moldova all made significant contributions to GISAID (>100 samples), but were not recorded as making any collections in FluNet; this is true for a few more countries with less significant GISAID contributions, as well. These countries may be reporting their sample collection in another database.

Regional Comparisons:

Region	Total Sequences Shared in GISAID	Total Viruses Collected in FluNet
Americas	16,726	5,342,118
Western Pacific	13,890	3,523,758
Europe	17,143	901,826
Eastern Mediterranean	1,149	344,982
Africa	2,643	321,490
South-East Asia	1,788	259,968

Region	Percent of countries with no GISAID contributions	Top country's GISAID contribution percent
Americas	31%	76%
Western Pacific	26%	27%
Europe	11%	19%
Eastern Mediterranean	29%	30%
Africa	53%	14%
South-East Asia	45%	33%

WHO Africa Region:

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Africa	2,643	321,490
South Africa	363	60,123
Madagascar	288	11,445
Ghana	281	24,621
Kenya	274	29,824
Cameroon	226	15,485
Senegal	208	35,900
Mali	180	20,141
Tanzania	148	14,254
Côte d'Ivoire	121	13,725
Zambia	81	8,234
Mozambique	68	2,284
Ethiopia	67	3,420
Mauritius	59	6,211
Algeria	55	9,085
Uganda	47	18,243
Nigeria	45	11,649
Burkina Faso	43	2,441
Congo	40	333
Rwanda	31	8,506
Togo	8	2,462
Central African Republic	7	3,986
Niger	3	1,051
Democratic Republic of the Congo	0	14,942
Sierra Leone	0	1,782
Angola	0	1,134
Mauritania	0	209
Benin	0	0
Botswana	0	0
Burundi	0	0
Cape Verde	0	0
Chad	0	0
Comoros	0	0
Equatorial Guinea	0	0
Eritrea	0	0
Gabon	0	0
Gambia	0	0

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Guinea	0	0
Guinea-Bissau	0	0
Lesotho	0	0
Liberia	0	0
Malawi	0	0
Namibia	0	0
Sao Tome and Principe	0	0
Seychelles	0	0
South Sudan	0	0
Swaziland	0	0
Zimbabwe	0	0

WHO Americas Region:

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Americas	16,726	5,342,118
United States	12,653	3,821,974
Brazil	1,302	86,253
Chile	494	155,986
Argentina	437	23,015
Mexico	339	0
Canada	322	1,187,428
Peru	151	10,326
Trinidad and Tobago	147	0
Paraguay	117	2,698
Guatemala	108	3,024
Costa Rica	90	4,914
Colombia	81	0
Dominican Republic	81	0
Bolivia	79	0
El Salvador	60	13,381
Honduras	56	8,794
Panama	52	6,422
Uruguay	47	896
Ecuador	42	4,732
Nicaragua	25	0
Jamaica	15	6,536
Venezuela	14	1,153
Haiti	9	0
Barbados	5	0

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Cuba	0	4,565
Suriname	0	21
Antigua and Barbuda	0	0
Bahamas	0	0
Belize	0	0
Dominica	0	0
Grenada	0	0
Guyana	0	0
Saint Kitts and Nevis	0	0
Saint Lucia	0	0
Saint Vincent and the Grenadines	0	0

WHO Western Pacific Region:

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Western Pacific	13,890	3,523,758
China	3,757	2,994,997
Japan	3,603	0
Australia	3,155	160,638
Singapore	860	32,325
Laos	572	15,961
Vietnam	553	23,025
New Zealand	494	50,468
Cambodia	214	24,710
Mongolia	138	33,455
South Korea	122	98,245
Malaysia	113	19,596
Philippines	108	67,194
Fiji	99	1,802
Papua New Guinea	49	1,342
Brunei	17	0
Micronesia	15	0
Nauru	7	0
Solomon Islands	7	0
Palau	4	0
Kiribati	3	0
Cook Islands	0	0
Marshall Islands	0	0
Niue	0	0

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Samoa	0	0
Tonga	0	0
Tuvalu	0	0
Vanuatu	0	0

WHO Europe Region:

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Europe	17,143	901,826
Spain	3,249	14,009
United Kingdom	1,547	13,406
Austria	1,333	0
Norway	1,104	30,558
France	990	343,671
Russia	777	271,225
Portugal	753	0
Ukraine	671	0
Italy	631	56,888
Ireland	543	0
Greece	503	41,414
Germany	449	0
Netherlands	419	4,862
Turkey	323	18,240
Sweden	321	0
Romania	314	23,542
Slovenia	244	5,898
Kazakhstan	242	0
Finland	218	1,271
Belgium	211	5,814
Bulgaria	180	0
Denmark	164	14,930
Iceland	150	0
Moldova	148	0
Serbia	145	952
Latvia	131	7,318
Georgia	128	0
Lithuania	122	1,416
Estonia	120	4,739
Slovakia	111	0
Israel	105	494

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Hungary	100	0
Luxembourg	99	0
Czech Republic	93	0
Switzerland	87	3,045
Albania	60	0
Kyrgyzstan	57	0
Poland	51	38,134
Cyprus	51	0
Macedonia	35	0
Montenegro	34	0
Malta	32	0
Belarus	31	0
Croatia	23	0
Armenia	19	0
Bosnia and Herzegovina	18	0
Tajikistan	7	0
Andorra	0	0
Azerbaijan	0	0
Monaco	0	0
San Marino	0	0
Turkmenistan	0	0
Uzbekistan	0	0

WHO South-East Asia Region:

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
South-East Asia	1,788	259,968
Bangladesh	585	28,507
Nepal	378	13,050
Thailand	325	33,889
India	224	120,123
Indonesia	215	30,630
Sri Lanka	61	28,478
Bhutan	0	4,658
Myanmar	0	438
Maldives	0	195
North Korea	0	0
Timor-Leste	0	0

WHO Eastern Mediterranean Region:

Country	Sequences shared on GISAID	Total Viruses collected in FluNet
Eastern Mediterranean	1,149	344,982
Egypt	347	93,951
Jordan	231	8,844
Oman	162	30,242
Morocco	98	8,733
Bahrain	88	3,831
Iran	79	87,016
Pakistan	39	14,746
Saudi Arabia	23	0
Iraq	22	15,781
Tunisia	18	11,341
Afghanistan	18	7,120
Qatar	12	61,162
Syria	6	72
United Arab Emirates	5	0
Lebanon	1	1,770
Sudan	0	373
Djibouti	0	0
Kuwait	0	0
Libya	0	0
Somalia	0	0
Yemen	0	0

APPENDIX E

TOP PUBLISHERS IN THE INFLUENZA FIELD

The following table seeks to identify the 100 most prolific authors and their number of publications in the influenza field. The data is up to date as of September 25, 2016.

The data was compiled by searching for the topic of "influenza" in the Web of Science database. The search captured authorship (and co-authorship) in all publications for published articles with no past time limits. The results were then filtered to return the top 100 authors in terms of publication output. The results again are subject to important limitations, mirroring those described in Appendix C. Because of these, the method likely underestimates actual representation of the Network among these prolific authors.[406] Even without this consideration, 7% of the top-100 prolific researchers are Network lab heads (bolded in the below).

Top-100 Influenza research publishers and their number of publications[407]*:*

Author	**Publications**
Webster RG	766
Kawaoka Y	502
Palese P	343
Garcia-Sastre A	338
Osterhaus ADME	336
Peiris JSM	288
Suzuki Y	280
Klenk HD	262
Li Y	249
Katz JM	248
Doherty PC	243
Webby RJ	242
Guan Y	235
Kida H	234
Fouchier RAM	231
Rimmelzwaan GF	224
Murphy BR	223

406 For example, Nancy Cox, Richard Webster, and Masato Tashiro have been key members of the Flu Network for many years, but are not bolded here because they are not current heads of Network labs.

407 Bolded authors denote heads of WHO Collaborating Centres, Essential Regulatory Laboratories, and national labs in September 2016.

Author	Publications
Swayne DE	222
Chen HL	215
Cox NJ	215
Lamb RA	211
Compans RW	205
Zhang Y	205
Skehel JJ	202
Tumpey TM	196
Wang J	191
Cowling BJ	188
Monto AS	182
Suzuki T	169
Hayden FG	167
Subbarao K	166
Scholtissek C	164
Wang Y	164
Taubenberger JK	158
Finelli L	156
Kim JH	155
Tashiro M	153
Edwards KM	152
Capua I	149
Chen Y	148
Gao GF	148
Li J	146
Viboud C	145
Couch RB	143
Shu YL	142
Laver WG	141
Suarez DL	141
Klimov A	140
Uyeki TM	140
Liu Y	137
Rott R	137
Zambon M	137
Yuen KY	136
Krug RM	135
Zhdanov VM	134
Air GM	133
Kendal AP	133
Kilbourne ED	133
Nichol KL	133

Author	Publications
Wang W	133
Chan KH	132
Oxford JS	132
Glezen WP	129
Katze MG	126
Ludwig S	124
Govorkova EA	123
Klimov AI	122
Schild GC	122
Shay DK	122
Fry AM	121
Poland GA	119
Brown IH	117
Zhang L	117
Treanor JJ	116
Donis RO	115
Lina B	115
Esposito S	114
Gubareva LV	114
Haller O	114
Kuiken T	114
Nakamura K	114
Zhang J	114
Braciale TJ	113
Chen Z	113
Zimmerman RK	113
Belshe RB	112
Stallknecht DE	111
Donatelli I	109
Odagiri T	109
Simonsen L	109
Wiwanitkit V	109
Bridges CB	108
Potter CW	108
Dimmock NJ	107
McCullers JA	107
Wright PF	107
Perez DR	106
Sakoda Y	106
Li X	105
Alexander DJ	104