

Winter 1-15-2018

Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine

Ana Santos Rutschman
Saint Louis University School of Law

Follow this and additional works at: <https://scholarship.law.slu.edu/faculty>

 Part of the [Government Contracts Commons](#), [Health Law and Policy Commons](#), and the [Intellectual Property Law Commons](#)

Recommended Citation

Ana Santos Rutschman, Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine, 127 YALE L.J.F. 651 (2018), <http://www.yalelawjournal.org/forum/vaccine-licensure-in-the-public-interest>.

This Article is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in All Faculty Scholarship by an authorized administrator of Scholarship Commons. For more information, please contact erika.cohn@slu.edu, ingah.daviscrawford@slu.edu.

Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine

Ana Santos Rutschman

ABSTRACT. Vaccines developed by the public sector are key to preventing future outbreaks of infectious diseases. However, the licensure of these vaccines to private-sector companies under terms that do not ensure both their availability and affordability compromises their development. This Essay analyzes the recent attempted licensing deal for a Zika vaccine between the U.S. Army and Sanofi, a French pharmaceutical company. The proposed grant of an exclusive license to Sanofi triggered widespread concern because none of its substantive terms were disclosed. While § 209 of the Patent Act imposes limitations on exclusive licensure, the Army released no information supporting its finding that exclusivity would serve the public interest with respect to the Zika vaccine. This proposed deal reflects the broader licensing opacity in the current regime, which undermines § 209's safeguards. The Essay proposes changes to the Patent Act to increase transparency and accountability in the licensing process, which would ultimately result in more affordable vaccines for outbreak diseases like Zika.

INTRODUCTION

In the two years since the Zika epidemic began sweeping the Americas, Zika vaccine development has made significant strides.¹ While there is still no commercially available Zika vaccine, several candidates have emerged as leading contenders, yielding promising results in clinical trials.² The vaccine developed by the U.S. Army was one such candidate, and it was widely considered

1. See, e.g., Stephen J. Thomas, *Zika Virus Vaccines—A Full Field and Looking for the Closers*, 376 *NEW ENG. J. MED.* 1883 (2017).

2. *Id.*

for a time the leading candidate in the field.³ In December 2016, the Army announced its intention to license the vaccine for private sector manufacturing,⁴ further cementing the status of this federally funded vaccine as the most likely candidate to enter the market ahead of any competitors. Several months later, however, the Biomedical Advanced Research and Development Authority (BARDA), an office in the Department of Health and Human Services, ended all contracts for Zika vaccine research and development (R&D).⁵ Shortly thereafter, Sanofi, a French pharmaceutical company working with the Army on Zika R&D announced that it would cease all work on the vaccine.⁶

Zika vaccine R&D stopped less than a year after the declaration of the end of the Zika outbreak by the World Health Organization (WHO).⁷ Since then, scientific evidence has confirmed a connection between the Zika virus and severe congenital and neurological problems.⁸ Future outbreaks are expected to increasingly burden women of childbearing age, in line with the outbreaks of 2015 and 2016. Moreover, the virus is still not fully understood, with recent research positing that Zika R&D might be of use in the study and treatment of certain types of cancer.⁹ Dwindling federal support for Zika R&D thus comes at a time in which the scientific understanding of Zika is largely incomplete. At the same time, the lack of vaccines leaves our health system ill-prepared to deal with future flare-ups of the Zika virus.

-
3. Jennifer Abbasi, *First Inactivated Zika Vaccine Trial*, 316 J. AM. MED. ASS'N 2588 (2016).
 4. U.S. Army Medical Research and Materiel Command, Intent to Grant an Exclusive License of U.S. Government-owned Patents, 81 Fed. Reg 89087 (Dec. 9, 2016), <http://www.gpo.gov/fdsys/pkg/FR-2016-12-09/pdf/2016-29514.pdf> [<http://perma.cc/7HHX-YSJ5>].
 5. See Peter Loftus, *Sanofi Stops Work on Two Zika Vaccines*, WALL ST. J. (Sept. 6, 2017), <http://www.wsj.com/articles/sanofi-stops-work-on-two-zika-vaccines-1504734084> [<http://perma.cc/2C4J-V26N>]. This is not the first time BARDA has discontinued vaccine R&D contracts. The same also happened with the anthrax vaccine in 2014. See BioPrepWatch, *BARDA to Descope PharmAthene SparVax Contract* (Apr. 9, 2014), <http://bioprepwatch.com/stories/510512242-barda-to-descope-pharmathene-sparvax-contract> [<http://perma.cc/FY7U-ZUHD>].
 6. Press Release, Sanofi Pasteur, *Sanofi Statement on Zika Vaccine License* (Sept. 1, 2017), <http://www.news.sanofi.us/Sanofi-Statement-on-Zika-Vaccine-License> [<http://perma.cc/8N3Y-8FCY>].
 7. See Debra Goldschmidt, *WHO Ends Zika Public Health Emergency*, CNN (Nov. 18, 2016), <http://www.cnn.com/2016/11/18/health/who-ends-zika-public-health-emergency/index.html> [<http://perma.cc/BP3J-CSQ4>].
 8. See *Zika Virus*, WORLD HEALTH ORG. (Sept. 6, 2016), <http://www.who.int/mediacentre/factsheets/zika/en> [<http://perma.cc/DHU9-D55R>].
 9. Maria Cohut, *Brain Cancer Could Be Treated with Zika Virus*, MED. NEWS TODAY (Sept. 5, 2017), <http://www.medicalnewstoday.com/articles/319272.php> [<http://perma.cc/4K3G-AKZA>].

Problems surrounding the development of Zika vaccines extend well beyond the realm of funding limitations. A closer look at the licensing process surrounding the Army's vaccine candidate reveals a deeper strain of legal and policy issues that would have affected the eventual availability and affordability of Zika vaccines: in late 2016, the Army made the decision to license its vaccine on an exclusive basis.¹⁰ Sanofi was chosen as the sole developer and manufacturer of the vaccine.¹¹ Under § 209 of the Patent Act, federally funded inventions must be licensed on a nonexclusive basis, absent compelling reasons to proceed otherwise.¹² In addition to granting a private-sector company an exclusive license, the Army failed to provide any reasons for this decision, thereby undermining § 209 safeguards.¹³ The result is that without robust competition, the exclusive licensee (in this case, Sanofi) will likely have fewer long-term incentives to innovate, as well as greater incentives to charge higher prices for the vaccine.

The exclusive licensing regime has also hindered short-term innovation. Now that the Army's only private-sector partner in this venture has pulled out due to funding cuts, R&D on the most promising Zika vaccine candidate has stopped. Had the Army chosen to work with multiple licensees, one of them could have carried on the work, even if more slowly.¹⁴

This Essay explores the problems surrounding the licensure of the Army's Zika vaccine, highlighting their salience in a world of declining funding for government-supported research.¹⁵ At a broader level, the Army case study sheds new light on problems that are likely to repeat themselves in the near future. Vaccines for imminent outbreaks of pathogens are currently in the early stages of R&D, and outbreaks of unknown pathogens will require the devel-

10. See U.S. Army Medical Research and Material Command, *supra* note 4.

11. *Id.* See also *Timeline of U.S. Army & Sanofi Zika Vaccine Collaboration*, KNOWLEDGE ECOLOGY INT'L, <http://keionline.org/zika-timeline> [<http://perma.cc/8AJ2-AXY2>].

12. 35 U.S.C. § 209(a) (2012) (allowing the grant of an exclusive or partially exclusive license only when it is a "reasonable and necessary incentive" to either "call forth the investment capital and expenditures needed to bring the invention to practical application" or "otherwise promote the invention's utilization by the public").

13. U.S. Army Medical Research and Material Command, *supra* note 4.

14. A considerable amount of innovation today takes place outside big pharmaceutical companies, within small or specialized startup companies. See, e.g., Jennifer Alsever, *Big Pharma Innovation in Small Places*, FORTUNE (May 13, 2016), <http://fortune.com/2016/05/13/big-pharma-biotech-startups> [<http://perma.cc/UV6K-P9LZ>].

15. See, e.g., Jeffrey Mervis, *Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%*, SCL (Mar. 9, 2017), <http://www.sciencemag.org/news/2017/03/data-check-us-government-share-basic-research-funding-falls-below-50> [<http://perma.cc/9EJE-QMTJ>].

opment of new vaccines.¹⁶ Against this backdrop, the Essay argues that the licensing framework presently applicable to federally funded innovation is inadequate. The current regime opens the door to licensing practices that harm the public interest, particularly in fields like vaccine R&D.

Part I traces the development of the Army's Zika vaccine from early to mid-2016, with a focus on the proposed exclusive licensing agreement that would have transferred rights over the vaccine to Sanofi. It situates this transfer within the context of the Patent Act, which establishes a strong preference for non-exclusivity when publicly funded research is transferred into the private sector. The Essay then argues that exclusive licensing deals like the one between the Army and Sanofi are detrimental to the public interest. Part II proposes two solutions. The first is a mechanism to ensure greater transparency (and corresponding accountability) when the government grants exclusive licenses in any domain: a set of small changes to the Patent Act requiring the disclosure of key terms in exclusive licenses. The second is narrowly designed to address specific problems in the specific field of vaccines treating or preventing underfunded diseases: the creation of a list of diseases for which federally funded vaccines would be automatically ineligible for § 209 exclusivity.

I. THE ARMY'S ZIKA VACCINE: DEVELOPMENT AND ATTEMPTED LICENSURE

A. *The Army's Zika Vaccine*

Operating under the Department of Defense, the Walter Reed Army Institute of Research (WRAIR) has a long history of generating biomedical technologies that are used both inside and outside the military. WRAIR's contributions have been especially notable in the development of vaccine technology: the Army has pioneered vaccines for diseases including hepatitis A and Japanese encephalitis and helped develop vaccines for HIV and malaria.¹⁷

In January 2016, as the Zika outbreak reached its apex, the Army decided to start Zika R&D, borrowing technology that it had originally developed for its Japanese encephalitis vaccine. The resulting Zika vaccine candidate—known as ZPIV (Zika Purified Inactivated Virus)—was developed in record time by any

16. *An R&D Blueprint for Action to Prevent Epidemics: Plan of Action*, WORLD HEALTH ORG. 21-22 (May 2016), http://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf [<http://perma.cc/XS9M-66UP>].

17. Nelson L. Michael, *WRAIR's Contribution to the Vaccine Enterprise*, WALTER REED ARMY INST. RES. 20 (Feb. 2, 2016), <http://www.hhs.gov/sites/default/files/WRAIR.pdf> [<http://perma.cc/4U6W-U9DB>].

R&D standards.¹⁸ In May 2016, the Army filed a patent application covering the vaccine,¹⁹ and in August 2016, the Army applied for a second patent.²⁰

With newly developed vaccine technology ready for human subject testing, the Army sought a partner to move the vaccine into the next stages of the R&D process. This is not an unusual move for government research organizations, which use a significant portion of their resources to further R&D on diseases that command scarce R&D attention from the private sector. Typically, these organizations end up sharing or transferring late-stage R&D duties to one or more parties, which may bring in increased technical and manufacturing capacity. In the case of the Zika vaccine, the Army signed a CRADA—a cooperative research and development agreement between a federal and non-federal party²¹—with the vaccines division of Sanofi, one of the world’s largest pharmaceutical companies.²²

Up to this point, the Army had engaged solely in preclinical development of the vaccine, with support from the National Institute of Allergy and Infectious Diseases (NIAID) and BARDA. Pursuant to the CRADA with Sanofi, the Army would share data collected during pre-clinical tests and release biological samples emerging from studies performed in nonhuman primates.²³ Sanofi would undertake phase II clinical trials and seek regulatory approval for the vaccine from the Food and Drug Administration (FDA), as well as the agency’s counterparts outside the United States.²⁴ In order to support phase II clinical trials, BARDA granted Sanofi \$43.2 million in September 2016,²⁵ and trials began two months later.²⁶

-
18. Annette M. Boyle, *Army Research Produces Zika Vaccine Candidate in Record Time*, U.S. MED. (Aug. 2016), <http://www.usmedicine.com/agencies/department-of-defense-dod/army-research-produces-zika-vaccine-candidate-in-record-time> [<http://perma.cc/CPZ3-J2DU>].
 19. *Zika Virus Vaccine and Methods of Production* (U.S. Provisional Patent Application 62/343,315).
 20. *Zika Vaccine and Methods of Preparation* (U.S. Provisional Patent Application 62/370,260).
 21. See 15 U.S.C § 3710a (2012) (outlining the legal structure of cooperative research and development agreements).
 22. This division, known as Sanofi Pasteur, has a record for drug overcharging in the field of vaccines. See *infra* note 44; see also SANOFI PASTEUR, <http://www.sanofipasteur.us> [<http://perma.cc/6XJU-TMR8>].
 23. Press Release, Sanofi Pasteur, Sanofi Pasteur Signs Research Agreement for Zika Vaccine (Jul. 6, 2016), <http://www.sanofipasteur.com/en/articles/Sanofi-Pasteur-Signs-Research-Agreement-for-Zika-Vaccine.aspx> [<http://perma.cc/GPA6-K6TC>].
 24. *Id.*
 25. Press Release, Sanofi Pasteur, BARDA Grants \$43.2 Million USD to Sanofi Pasteur for Zika (Sept. 26, 2016), <http://www.sanofipasteur.com/en/articles/BARDA-Grants-43.2-million>

In December 2016, the Army published a notice in the Federal Register of its intent to license both Zika vaccine patents to Sanofi.²⁷ Apart from an indication that Sanofi would be the exclusive licensee of the vaccine technology, no other information was provided.

Section 207 of the Patent Act allows federal agencies to “grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions,”²⁸ on either a royalty-bearing or a royalty-free basis, depending on the case.²⁹ Traditionally, these transfers of rights over patented inventions have been a staple of the dynamics of U.S. biomedical innovation. The government often jumpstarts basic scientific research, before handing over downstream research—the development of drugs and vaccines for commercialization—to private-sector companies.³⁰ The role of the public sector in promoting basic research is especially relevant in the case of diseases like Zika, where markets for the resulting vaccines are too small to attract private-sector investment,³¹ at least until a severe public health crisis.

However, the Patent Act also restricts the transfer of government-developed technologies in order to ensure that downstream development of these technologies furthers the public interest, rather than the commercial interests of the licensees. A preference for nonexclusive licenses represents the most significant of these restrictions. Although § 207 enables the federal government to grant both exclusive and nonexclusive licenses, § 209 restricts exclusive and partially exclusive licenses to cases in which exclusivity is “a reason-

-USD-to-Sanofi-Pasteur-for-Zika.aspx [http://perma.cc/G3KM-2TSW]. The contract itself between BARDA and Sanofi is not publicly available, though the contract number, Contract HHSO100201-6000039C, was released. *Id.*

26. See Press Release, National Institute of Allergy and Infectious Diseases, Testing of Investigational Inactivated Zika Vaccine in Humans Begins (Nov. 7, 2016), <http://www.niaid.nih.gov/news-events/testing-investigational-inactivated-zika-vaccine-humans-begins> [http://perma.cc/C3C2-86FV].
27. Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89,087 (Dec. 9, 2016).
28. 35 U.S.C. § 207(a)(2) (2012).
29. *Id.*; see also *id.* § 209(a)(1) (outlining when a federal agency may grant an exclusive or partially exclusive license).
30. See Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 NEW ENG. J. MED. 535, 540-41 (Feb. 10, 2011) (noting that over the past decades, the role of the public sector in downstream research has grown more than previously thought).
31. Cf. Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188 (June 22, 2002) (describing the disparity in research and development between more “profitable” diseases and neglected infectious diseases).

able and necessary incentive” to bring the innovation to the public.³² Specifically, an agency granting an exclusive license must also make a finding that

the public will be served by the granting of the license, as indicated by the applicant’s intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention’s utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention’s utilization by the public.³³

In addition to incentivizing commercialization and serving the public interest, exclusivity cannot “substantially lessen competition” or violate antitrust law.³⁴ Furthermore, in choosing the recipient of an exclusive license, federal agencies must give first preference to small business firms that match (or surpass) the capabilities of larger companies.³⁵

Government-developed vaccine technology may therefore be licensed to a single private-sector downstream developer, as the Army intended to do with Sanofi, but only as a last-resort measure. In a nutshell, exclusivity must be necessary to incentivize commercialization of the invention by the licensee—and, correspondingly, to guarantee public access to the invention.

In the case of the Zika vaccine, the government has not disclosed evidence as to whether exclusivity is necessary or not. In its exclusive license notice, the Army only provided the numbers of the provisional patent applications covering the vaccine, the identity of the intended licensee, and the exclusive nature of the license.³⁶ To be sure, the Army notice complied with the disclosure requirements that currently apply to transfers of publicly funded technologies.³⁷ But precisely because the Army disclosed neither substantive terms of the license nor any information supporting its finding that exclusivity would serve the public interest pursuant to § 209, it is impossible to gauge if exclusivity was appropriate in this particular case.

32. 35 U.S.C. § 209(a)(1) (2012). Further conditions imposed on exclusive and partially exclusive licenses are found in § 209(d).

33. 35 U.S.C. § 209(a)(2) (2012).

34. 35 U.S.C. § 209(a)(4) (2012).

35. 35 U.S.C. § 209(c) (2012).

36. Intent to Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89,087 (Dec. 9, 2016).

37. 35 U.S.C. § 209(e) (2012).

B. Critiquing the Current Notice Regime for Transfers of Publicly Funded Technology

While procedurally speaking, notices disclosing very little information facially comply with the requirements set forth in the Patent Act, the current notice regime fosters a culture of licensing opacity that undermines the safeguards established elsewhere in § 209. This was apparent in the case of the Army's Zika vaccine. Among the requests for more information submitted by several institutions, concerns with excessive pricing of the vaccine were paramount.³⁸ By precluding competition, an exclusive license enables a pharmaceutical company to charge higher prices for a drug than it otherwise would. An exclusive Zika vaccine may therefore reach the market with a price tag that is unaffordable to consumers who need it. For these reasons, it is important that a licensing agreement contain pricing provisions, ensuring that a newly developed vaccine is affordable to different populations both in the United States and abroad. The Army declined to disclose whether the license included any affordable pricing provisions: “[t]he U.S. Army lacks the means, expertise, and authority to define, implement, and enforce ‘affordable prices’ or to set price controls for a potential vaccine that will require great investment and face high risk of failure.”³⁹

The opacity of the current notice requirements can thus be used to shield government organizations from addressing substantive issues that affect the availability and affordability of innovative drugs. The expensive price and outcome uncertainty of drug R&D cannot serve as a basis for an unfiltered grant of exclusive rights over the drug—heightened costs and risk are inherent to drug development, as well as several other innovation processes. Exclusive licenses are only allowed if, after an assessment of the *actual* costs and the risk associated with the development of a specific drug, an agency concludes that exclusivity is the appropriate form of economic incentive for commercialization of the drug. The Army's failure to take pricing issues into account when assessing whether exclusivity was appropriate for the Zika vaccine is therefore likely to be

38. See, e.g., *Doctors Without Borders/Médecins Sans Frontières (MSF) Comments to the Department of Defense Notice of Intent to Grant an Exclusive License of U.S. Government-Owned Patents on a Zika Vaccine Candidate*, MÉDECINS SANS FRONTIÈRES 4 (Jan. 23, 2017), http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_letter_MSFCommentsstoFRNoticeREZikaVaxCandidateLicensing_ENG_2016_2.pdf [<http://perma.cc/LCA4-V6Q2>]; *An Exclusive License to Patents on a New Zika Vaccine to Sanofi Is Contrary to the Provisions of 35 U.S.C. 209(a)(1)*, KNOWLEDGE ECOLOGY INT'L 2 (Jan. 12, 2017), <http://www.keionline.org/sites/default/files/Zika-12Jan2016-KEI-AFSCME-PFAM-UAEM-BAKER-35USC209a1.pdf> [<http://perma.cc/ML2X-5FYF>].

39. Letter from Barry M. Datloff, Chief, U.S. Army Med. Research & Materiel Command, to James Love, Dir., Knowledge Ecology Int'l 2 (Apr. 21, 2017).

a violation of § 209 and its mandate that the exclusive licensee “promote the invention’s utilization by the public.”⁴⁰

The choice of Sanofi as the exclusive licensee for the Army’s vaccine is even more troubling for two reasons. First, the notice of intent to license the vaccine on an exclusive basis appeared in the Federal Register three months after Sanofi received \$43.2 million in funding from BARDA. From an economic perspective, BARDA’s grant mitigates the overall cost and risk of R&D falling on Sanofi. In turn, this weakens the rationale provided by the Army for not engaging in pricing considerations. And second, the grant also reinforces the concerns about further detrimental effects of exclusive licenses, if improperly granted: a private-sector company that has already received R&D funding from the public sector may charge monopoly-like prices for a drug, thereby taxing taxpayers twice.⁴¹

For example, Sanofi has also recently admitted to overcharging the Department of Veterans Affairs (VA) for vaccines.⁴² Initially, the company notified the VA that it had made a mistake calculating the price of the vaccines between 2007 and 2011, exceeding the federal ceiling price for drugs,⁴³ but a VA investigation concluded that Sanofi had overcharged it for a period of nine years, beginning in 2002. In April 2017, the Department of Justice announced that it had reached a settlement with Sanofi in the amount of \$19.8 million.⁴⁴

Within a few weeks of the settlement, the Centers for Disease Control and Prevention (CDC) announced a temporary (but total) depletion of Sanofi’s YF-VAX, the only FDA-approved yellow-fever vaccine in the United States.⁴⁵ The shortage has been attributed to a “manufacturing complication” that occurred

40. 35 U.S.C. § 209(a)(2) (2012).

41. See, e.g., Bernie Sanders, *Bernie Sanders: Trump Should Avoid a Bad Zika Deal*, N.Y. TIMES (Mar. 10, 2017) <http://www.nytimes.com/2017/03/10/opinion/bernie-sanders-trump-should-avoid-a-bad-zika-deal.html> [<http://perma.cc/N96S-ZNAX>].

42. Joel Schectman & Susan Heavey, *Sanofi to Pay \$19.8 Mln Over Claims of Drug Overcharges—U.S.*, REUTERS (Apr. 3, 2017, 4:24 PM), <http://www.reuters.com/article/sanofi-usa-idUSL2N1HB1PP> [<http://perma.cc/C2RJ-FXHQ>].

43. Veterans Health Care Act of 1992 § 603, 38 U.S.C. § 8126 (2012).

44. *Sanofi Pasteur Agrees to Pay \$19.8 Million to Resolve Drug Overcharges to the Department of Veterans Affairs*, DEP’T OF JUSTICE (Apr. 3, 2017), <http://www.justice.gov/opa/pr/Sanofi-pasteur-agrees-pay-198-million-resolve-drug-overcharges-department-veterans-affairs> [<http://perma.cc/R7QD-S8JE>].

45. *Announcement: Temporary Total Depletion of US Licensed Yellow Fever Vaccine Addressed by Availability of Stamaril Vaccine at Selected Clinics*, CTNS. FOR DISEASE CONTROL & PREVENTION (Apr. 18, 2017), <http://wwwnc.cdc.gov/travel/news-announcements/yellow-fever-vaccine-access> [<http://perma.cc/ERN6-Y7EG>].

while Sanofi transferred inventory to a new manufacturing facility.⁴⁶ Every year, 500,000 doses of Sanofi's vaccine are distributed to 4,000 civilian clinics, where they are administered to people traveling to areas where yellow fever is endemic, as well as to other sites where they are administered to members of the U.S. military who are exposed to this life-threatening disease.⁴⁷ To meet the demand for the vaccine in the United States, Sanofi has now begun importing a different vaccine, Stamaril, administered routinely in Europe and elsewhere, but currently unapproved for use in the United States.⁴⁸

While the CDC and FDA have backed this temporary strategy for ensuring the availability of a yellow fever vaccine in the United States,⁴⁹ the ongoing shortage points to broader concerns raised by sole-source manufacturing of drugs. In addition to pricing issues, exclusive exploitation of a vaccine may lead to a situation of market failure, in which a life-saving drug becomes unavailable to would-be consumers. This is especially problematic in the case of diseases like Zika, for which alternative drugs do not exist.

Sanofi's announcement in September 2017 that it would pause the development of the Army's Zika vaccine leaves several questions unaddressed, at least in the short term.⁵⁰ Furthermore, the evidence suggests that the choice of an exclusive license was poorly justified by the Army, and potentially flawed in its substantive parameters.

It should be noted, however, that Sanofi's decision to stop R&D on Zika is directly linked to the loss of BARDA's financial support, and BARDA has made it clear that it may resume funding Zika vaccine R&D if a new outbreak occurs.⁵¹ These problems are therefore likely to resurface in the medium and long runs, and perhaps even sooner than expected.⁵²

More generally, these issues are not specific to Zika vaccine development — all types of biomedical innovation, if covered by patents owned by the federal

46. Mark D. Gershman et al., *Addressing a Yellow Fever Vaccine Shortage—United States, 2016–2017*, CTDS. FOR DISEASE CONTROL & PREVENTION (May 5, 2017), <http://www.cdc.gov/mmwr/volumes/66/wr/mm6617e2.htm> [<http://perma.cc/MAC8-SAWM>].

47. *Id.*

48. *Yellow Fever Vaccine Access*, SANOFI PASTEUR (last updated Nov. 1, 2017), <http://www.sanofipasteur.us/vaccines/yellowfevervaccine> [<http://perma.cc/D6W7-XVVG>].

49. *Id.*

50. *Sanofi Statement on Zika Vaccine License*, SANOFI PASTEUR (Sept. 1, 2017), <http://www.news.sanofi.us/Sanofi-Statement-on-Zika-Vaccine-License> [<http://perma.cc/4U22-AGW2>].

51. Susan Scutti, *Sanofi Stops Work on Zika Vaccine While Others Forge Forward*, CNN (Sept. 7, 2017), <http://www.cnn.com/2017/09/07/health/sanofi-discontinues-zika-vaccine-development/index.html> [<http://perma.cc/3DNK-WFM2>].

52. The World Health Organization classifies Zika infection as one of three “serious diseases necessitating further action as soon as possible.” WORLD HEALTH ORG, *supra* note 16, at 22.

government, fall under the purview of § 207 and § 209.⁵³ The next Part considers possible solutions to the policy problems posed by the current regime.

II. LICENSURE IN THE PUBLIC INTEREST: THE CASE FOR TARGETED CHANGES TO THE PATENT ACT

A. *Changing the Licensing Culture To Ensure Affordability of Vaccines*

The attempted licensure of the Army's Zika vaccine in terms that potentially violate the normative framework for the transfer of government-developed technology has attracted considerable criticism from different domains.⁵⁴ In the heat of the debate, several institutions called for changes to the Army's Zika license, particularly with a view to making the vaccine available at affordable prices.⁵⁵ These proposed changes may be useful in informing future licensing negotiations between the government and the private sector.

The most comprehensive proposal focusing on pricing resulted from a joint effort by Médecins Sans Frontières/Doctors Without Borders (MSF) and Knowledge Ecology International (KEI). This proposal distinguishes between two markets for the Zika vaccine: the United States and developing nations abroad. In the case of the latter, MSF and KEI suggested that the Army should

require that Sanofi . . . disclose the steps it will take to enable the registration and availability of the vaccine at an affordable price in every country with a demonstrated need, according to the CDC/WHO, either

-
53. All publicly funded technologies, including vaccines, are also subject to march-in rights, which allow the government to require a licensee to sub-license the technology if the licensee fails to develop the technology, or to meet health and safety needs. See § 203(a)(1) and § 203(a)(2). While this regime falls outside the scope of this Essay, it should be noted that the government has never exercised march-in rights, even when under public pressure to do so. See Ryan Whalen, *The Bayh–Dole Act & Public Rights in Federally Funded Inventions: Will The Agencies Ever Go Marching In?*, 109 NW. U. L. REV. 1083 (2015).
54. See, e.g., Alison Kodjak, *States Fear Price if New Zika Vaccine Will Be More Than They Can Pay*, NPR (May 30, 2017), <http://www.npr.org/sections/health-shots/2017/05/30/529887446/states-fear-price-of-new-zika-vaccine-will-be-more-than-they-can-pay> [http://perma.cc/6H6X-8GR8]; Ed Silverman, *Lawmakers Ask U.S. Army to Hold a Hearing on Zika Vaccine Licensing*, STAT (June 14, 2017), <http://www.statnews.com/pharmalot/2017/06/14/lawmakers-army-zika-vaccine> [http://perma.cc/5HMH-3584].
55. See *US Department of Defense Announces Decision to Give Pharmaceutical Corporation Exclusive Rights on Taxpayer-Funded Zika Vaccine, Failing to Ensure Affordable and Sustainable Access*, MÉDECINS SANS FRONTIÈRES (Apr. 25, 2017), <http://www.msfacecess.org/about-us/media-room/press-releases/us-department-defense-announces-decision-give-pharmaceutical> [http://perma.cc/PH49-AH3F].

by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.⁵⁶

MSF/KEI then addressed the different configuration of the U.S. market, where taxpayer dollars have already offset part of the cost associated with the R&D undertaken by Sanofi. The proposal provides a formula for calculating an affordable price for the vaccine:

Sanofi agrees to make the vaccine available to the public in the U.S. at publicly disclosed prices no higher than the median price charged in the seven countries with the largest GDP, which have per capita incomes of at least half that of the U.S.⁵⁷

Under this approach, Sanofi would presumably be able to charge more for the vaccine in the United States than in smaller economies, but the mandatory price cap would prevent the company from asking for exorbitant amounts, ensuring that the vaccine is available to most consumers in the United States.

Both prongs of the MSF/KEI proposal mitigate the problems created by the grant of an exclusive license in a system that does little to promote ex ante negotiation of licensing terms that maximize the public interest. They are suitable ad hoc fixes when the ideal solution—a nonexclusive license—is no longer on the table. Considering the Army's self-professed lack of expertise to engage in pricing negotiations, the proposal puts forth two straightforward solutions that the Army may easily adopt if BARDA resumes funding of Zika R&D, rekindling Sanofi's interest in the exclusive license. More broadly, the proposal may also help guide future license negotiations by agencies that transfer federally funded vaccine technology to the private sector.

However, there remains a need for changes to the current regime as a whole, in ways that truly further the public interest. This is especially true when transfers of technology involve vaccines. With unpredictable outbreaks looming on the horizon,⁵⁸ vaccines play a crucial role both in preventing them

56. *KEI and Médecins Sans Frontières Propose Contractual Terms to Protect Access and Affordability of Zika Vaccine*, KNOWLEDGE ECOLOGY INT'L (July 25, 2017), <http://www.keionline.org/node/2842> [<http://perma.cc/P8E3-WEPP>].

57. Letter from James Love, Dir., Knowledge Ecology Int'l, et al., to Barry M. Datlof, Command Judge Advocate, U.S. Army Med. Research and Materiel Command (July 24, 2017), <http://www.keionline.org/wp-content/uploads/KEI-MSF-Army-Zika-Vaccine-Proposed-Text-Pricing.pdf> [<http://perma.cc/U6M3-L5JV>].

58. See Bryan Walsh, *The World Is Not Ready for the Next Pandemic*, TIME (May 4, 2017), <http://time.com/4766624/next-global-security> [<http://perma.cc/35SN-RJEC>].

and in mitigating their impact on health systems across the world.⁵⁹ Making sure that vaccine technology is transferred efficiently and fairly is imperative.

B. Proposed Changes to the Patent Act

Two improvements to the Patent Act's regulation of transfers of government-owned technology can help ensure fair and efficient access to vaccines. First, we should reform the notice requirement regime as a whole. And second, in order to avoid the specific drawbacks of exclusive licenses on vaccines for traditionally underfunded diseases, we should consider prohibiting exclusivity in certain circumstances.

A troubling lack of transparency characterizes the current notice requirement regime. Currently, § 209(e) establishes that federal agencies must give public notice of the intention to grant an exclusive license of an invention developed by the federal government. The notice must be given "in an appropriate manner" and at least fifteen days before the license is granted. Additionally, agencies must provide a comment period and "consider all comments" received during that window of time. But § 209 does not require agencies to make public any substantive terms of negotiated licenses. The opaque process of transferring federally funded technology leaves commentators and the public in the dark about the reach of the license.

This problem stretches beyond the lack of transparency of the negotiation process. As seen above, § 209 also requires agencies to make a finding that "the public will be served" by the license and that the "scope of exclusivity is not greater than reasonably necessary."⁶⁰ But it is impossible to have truly informed commentary on either of these points if no substantive information is provided. For the same reasons, opacity makes it harder for the agency to be held accountable for its exclusivity assessment (or lack thereof).

Consider the notice given for the Army's Zika vaccine: it has now been made clear that the Army does not negotiate affordable pricing provisions when transferring vaccine technology. Yet it should, as the main concern with exclusivity is that it will allow a company to charge more than is necessary for a drug. Simply put, failing to consider whether a vaccine will be available at affordable prices is licensing against the public interest.

In situations like this, the opacity of notice requirements may thus foster licensing practices contrary to § 209 that nonetheless are shielded from public

59. See John-Arne Røttingen et al., *New Vaccines against Epidemic Infectious Diseases*, 376 *NEW ENG. J. MED.* 610, 610-611 (Feb. 16, 2017).

60. 35 U.S.C. § 209(a)(2) (2012).

scrutiny for extended periods of time. To encourage public commentary—and to promote a licensing culture of greater accountability—we should therefore amend § 209(e) to include a core of substantive information that agencies must disclose when transferring federally funded inventions. Among the information that should be mandatorily provided, disclosure of pricing provisions (or lack thereof) is especially relevant. At a time when the cost of drugs and biopharmaceuticals attracts more public scrutiny than ever before, such a requirement would potentially nudge agencies to negotiate affordable prices (or standards for calculating affordable prices)⁶¹ before transferring vaccines and other health technologies out of the public sector. At the very least, in cases of agencies that maintain a practice of not negotiating pricing provisions, the mandatory disclosure of the inexistence of such provisions would have the advantage of enabling immediate public debate about the ultimate affordability of publicly funded technology. In addition to pricing issues, there are other types of provisions that should be disclosed by agencies when technology is transferred out of the public sector. In the context of exclusive licensing, for example, disclosing the term of the license is helpful to assess whether the measure of exclusivity is adequate to overturn the Patent Act's general preference for nonexclusive licenses.⁶² An alternative or concomitant step to creating a list of core information to be disclosed by agencies is to require them to provide a justification for exclusivity, including an explanation of how the license serves the public and why the scope of exclusivity is appropriate.

While such an amendment would be applicable to all types of technologies subject to § 209 transfers, there are certain technologies for which exclusive licenses might be especially problematic. This is the case of vaccines targeting diseases like Zika. From an R&D perspective, “mainstream diseases” command a great deal of funding, while others are outright unattractive due to expected low return (or no return) on investment. Zika funding plummeted throughout 2017,⁶³ even after all the attention brought by the 2015-2016 outbreak. The immediate interruption of R&D on the Army's Zika vaccine following BARDA's withdrawal of funding illustrates the pitfalls of trusting the development of the vaccine to a single entity. A possible lesson from the Zika case study is that there are some diseases for which the grant of exclusive licenses should not be allowed. The Patent Act already explicitly favors nonexclusive licenses,⁶⁴ as in-

61. Such as the standards exemplified by the KEI/MSF proposal, *supra* note 56.

62. This would facilitate compliance with the narrowly constructed admissibility of exclusive licenses for publicly funded technology set forth in 35 U.S.C. § 209(a).

63. See, e.g., Katie Worth, *As Zika Season Nears, States Brace for an End to CDC Funding*, PBS (Apr. 21, 2017), <http://www.pbs.org/wgbh/frontline/article/as-zika-season-nears-states-brace-for-an-end-to-cdc-funding> [<http://perma.cc/T8G9-AZ2M>].

64. 35 U.S.C. § 209(a).

licated above. And there have been instances in which federal agencies have granted nonexclusive licenses on vaccine technology: for example, in 2005 the National Institutes of Health granted eight nonexclusive licenses on rotavirus vaccines.⁶⁵

For diseases like Zika, it is therefore likely that the public interest is furthered if exclusivity is not allowed. However, a prohibition on exclusivity should be narrowly construed. Prime candidates for this list would be diseases that are not endemic to the United States, like Zika. In addition to ad hoc choices, the WHO and the CDC have lists of so-called “neglected tropical diseases,” which could be used as a basis for identifying diseases that should be encompassed by a prohibition on exclusivity.⁶⁶

CONCLUSION

The transfer of federally funded vaccine technology presents unique challenges in reconciling the need for private-sector R&D with the furtherance of the public interest when the resulting invention is brought to the market. As illustrated by the recent case of the Army-developed Zika vaccine, federal agencies often favor the granting of exclusive licenses, despite the Patent Act’s explicit preference for nonexclusivity. While the granting of exclusive licenses is not per se against the public interest, in practice several problems are likely to occur, from lack of competition and overpricing to concerns surrounding single-source manufacturing. This scenario is especially problematic in the context of vaccines for underfunded diseases. Two fixes could help mitigate these problems: first, notices of intent to license should contain a disclosure of core of substantive provisions, including pricing provisions; and second, the transfer of certain technologies should be treated in a more stringent way—specifically, the Patent Act should be amended to forbid exclusive licensing of vaccines for underfunded diseases.

Ana Santos Rutschman is the Jaharis Faculty Fellow in Health Law and Intellectual Property at DePaul College of Law. She recently consulted for the World Health Or-

65. *Rotavirus Vaccine: NIH Office of Technology Transfer*, in EXECUTIVE GUIDE TO INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES, NIH (2017), <http://www.ott.nih.gov/sites/default/files/documents/pdfs/casestudy13.pdf> [<http://perma.cc/ZFU5-JRBQ>].

66. *Neglected Tropical Diseases*, WORLD HEALTH ORG. (2017), http://www.who.int/neglected_diseases/diseases/en [<http://perma.cc/9A5C-5FFA>]; *Neglected Tropical Diseases*, CTRS. FOR DISEASE CONTROL AND PREVENTION (last updated Apr. 19, 2017), <http://www.cdc.gov/globalhealth/ntd/index.html> [<http://perma.cc/LA8P-L4YT>].

ganization during the Ebola and Zika crises. She is grateful to Ali Cooper-Ponte, Meenu Krishnan, Arjun Ramamurti, and Erin van Wesenbeeck for thoughtful comments and suggestions.

Preferred Citation: Ana Santos Rutschman, *Vaccine Licensure in the Public Interest: Lessons from the Development of the U.S. Army Zika Vaccine*, 127 YALE L.J. F. 651 (2018), <http://www.yalelawjournal.org/forum/vaccine-licensure-in-the-public-interest>.