USE OF BENEFIT CORPORATIONS TO ACCELERATE ACCESS TO AFFORDABLE VACCINES

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Abstract: Low- and middle-income countries face the heaviest burden from vaccine-preventable diseases, yet many of these countries cannot afford critical vaccines. Vaccines are often protected by patents so that pharmaceutical companies can recoup development costs. Consequently, vaccine manufacturers in developing countries must wait until the patents expire to produce lower-cost generic vaccines. Additionally, when the development of new vaccines relies on existing patents, such development is hindered. Benefit corporations offer an opportunity for the private and public sectors to align interests in accelerating critical vaccine development. Vaccine developers, restructured as benefit corporations, could commit to both special licensing agreements with developing country vaccine manufacturers and product development partnerships to accelerate access to affordable vaccines in low- and middle-income countries. In exchange, the public sector could reserve research and development funding opportunities for these benefit corporations.

INTRODUCTION

Ensuring access to vaccines is a global health priority.1 To achieve this goal, existing vaccines protected by patents must be made affordable for low- and middle-income countries (LMICs).2 Additionally, new vaccines, even if unprofitable, must be developed for emerging diseases that are disproportionately affecting LMICs.3 Children need access to vaccines to have a fair chance of surviving past the age of five.4 In 2017, an estimated 19.4 million children lacked access to routine

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1 ACCESS TO MEXI. FOX UND., ACCESS TO VACCINES INDEX 2017, at 9.
2 See, e.g., Swathi Padmanabhan et al., Intellectual Property, Technology Transfer and Manufacture of Low-Cost HPV Vaccines in India, 28 NATURE BIOTECHNOLOGY 671, 671 (2010) (stating that the price for Gardasil, Merck’s patent-protected vaccine for human papilloma virus (HPV), must drop from $171 to $2 per dose to be accessible in India).
4 See Mark E. McGovern & David Canning, Vaccination and All-Cause Child Mortality from 1985 to 2011: Global Evidence from the Demographic and Health Surveys, 182 AM. J. EPIDEMIOLOGY 791, 795 (2015) (showing that children with no vaccination coverage have a twenty-four percent higher risk of mortality than children with complete vaccination coverage).
vaccines. Consequently, vaccine-preventable diseases cause almost two million deaths annually among children under the age of five. The greatest utility for vaccines is in LMICs, where the disease burden is the heaviest. Yet these are the countries where access is limited due to the high cost of vaccines. Although efforts by developing country vaccine manufacturers (DCVMs) to make affordable generic versions have reduced the costs of some vaccines, others remain protected by patents, creating a barrier to low-cost development. While patents are critical for vaccine developers to recoup their significant investment costs, they also delay the development and introduction of affordable generics into LMICs.

Additionally, the World Health Organization (WHO) has identified over thirty diseases for which there is no active research and development by pharmaceutical companies as urgently needing a vaccine. Some not-for-profit organizations have addressed this challenge by providing funding to vaccine companies to develop necessary but unprofitable vaccines. Nevertheless, the limited profit potential for vaccines principally demanded in LMICs often does not provide a sufficient incentive for companies to invest their resources in development. Lack of investment in research and development for diseases disproportionately affects LMICs and indicates a misalignment between the public and private sectors. The global health community and pharmaceutical companies have pursued ambitious initiatives to remedy this imbalance, but these initiatives have failed to keep up with endemic and emerging diseases.

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5 ACCESS TO MED. FOUND., supra note 1, at 7.
6 Id. at 5.
7 Crager, supra note 3, at e85.
8 Id. (stating that notwithstanding other barriers, the price of new vaccines significantly impedes LMICs from adopting new vaccines).
9 See Padmanabhan et al., supra note 2, at 671 (explaining that DCVMs reduced the price of the Hepatitis B vaccine from between fifty and eighty dollars per dose to $0.30 per dose, and stating that patents might be a barrier for DCVMs seeking to develop generic HPV vaccines).
10 Kevin Outterson & Aaron S. Kesselheim, Market-Based Licensing for HPV Vaccines in Developing Countries, 27 HEALTH AFF. 130, 131 (2008).
11 ACCESS TO MED. FOUND., supra note 1, at 21.
12 See, e.g., Brittany Meiling, As Killer Virus Outbreaks Hit Unprecedented Levels, Nonprofit Hands $37.5M to Themis to Tackle Lassa/MERS Vaccines, ENDPOINTS NEWS, (Mar. 6, 2018, 7:01 P.M.), https://endpts.com/as-killer-virus-outbreaks-hit-unprecedented-levels-nonprofit-hands-37-5m-to-themis-to-tackle-lassa-mers-vaccines/ (discussing the partnership between a non-profit and an Austrian biotechnology company to develop vaccines for Lassa fever and Middle East respiratory syndrome).
13 See, e.g., David M. Bishai et al., Product Development Partnerships Hit Their Stride: Lessons from Developing a Meningitis Vaccine for Africa, 30 HEALTH AFFAIRS 1058, 1061 (2011) (explaining that multinational pharmaceutical companies did not commit to the development of an affordable meningitis vaccine because the profit margin was too low).
14 See Yaniv Heled et al., Why Healthcare Companies Should Be(come) Benefit Corporations, 60 B.C. L. REV. 73, 84 (2019) (stating that there is significantly more investment in finding cures for diseases in rich countries than for diseases in poor countries).
15 See WHO, 2018 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN 1, https://www.who.int/immunization/global_vaccine_action_plan/SAGE_GVAP_Assessment_Report_2018_EN.pdf?ua=1 (listing various achievements in vaccine coverage around the world, but also listing significant outbreaks of vaccine-preventable
Benefit corporations offer a unique opportunity for pharmaceutical companies to align their interests with public health priorities. A benefit corporation is a for-profit entity with public interest goals it must consider when making decisions. Although regular corporations could similarly consider public interest goals when making decisions, restructuring as a benefit corporation signals to the market that the company is prioritizing public interest goals. Nonetheless, reincorporating as a benefit corporation is not without risks, as it is uncertain how legislatures will hold such entities accountable for their public interest goals in the future.

To encourage pharmaceutical companies to reincorporate as benefit corporations and consider global health goals, the public sector could reserve research and development funding expressly for benefit corporations. By doing so, pharmaceutical companies could more closely align themselves with the global health community to accelerate access to existing vaccines and development of critical new vaccines. Part I of this Article provides background on vaccines, patent protection, and benefit corporations. Part II discusses the potential impact of benefit corporations on patent protection for vaccines. Finally, Part III argues that benefit corporations can align interests between vaccine innovators and the global health community by committing to product development partnerships and special licensing agreements.

I. VACCINES, PATENTS, AND BENEFIT CORPORATIONS

Vaccines play a significant role in the public health sector. Patent protection enables companies to recoup investment costs following the time-consuming and expensive vaccine development process. Benefit corporations, a relatively new corporate form, are being explored as a means to align pharmaceutical companies with public health goals. Section A provides background on the impact of

diseases); see, e.g., ACCESS TO MED. FOUND., supra note 1, at 27–28 (discussing GSK’s collaboration with PATH Malaria Vaccine Initiative and the Gates Foundation to develop a malaria vaccine).

16 See Heled et al., supra note 14, at 80–81 (arguing for the use of the benefit corporate structure to address the disconnect between the private and public sectors in the healthcare market).


18 Chu, supra note 17, at 168.

19 Briana Cummings, Benefit Corporations: How to Enforce a Mandate to Promote the Public Interest, 112 COLUM. L. REV. 578, 579–80 (2012).


21 Heled et al., supra note 14, at 80–82.

22 See infra notes 25–101 and accompanying text.

23 See infra notes 102–145 and accompanying text.

24 See infra notes 146–169 and accompanying text.

25 ACCESS TO MED. FOUND., supra note 1, at 7.

26 Stanley Plotkin et al., The Complexity and Cost of Vaccine Manufacturing—an Overview, 35 VACCINE 4064, 4068 (2017) (explaining that vaccine development costs hundreds of millions of dollars and requires upwards of fifteen years of work, pharmaceutical companies recoup profit over a twenty-year patent term); Outterson & Kesselheim, supra note 10, at 131.

27 Heled et al., supra note 14, at 80–82.
vaccination on global health.\textsuperscript{28} Section B offers an overview of patent protection for vaccines.\textsuperscript{29} Lastly, Section C explores the impact of benefit corporations on the pharmaceutical sector.\textsuperscript{30}

\textbf{A. Impact of Vaccination on Global Health}

Vaccination has transformed global health over the past century by dramatically reducing premature deaths from infectious diseases.\textsuperscript{31} Vaccines have significantly reduced early childhood deaths in particular, but mortality rates for children under five years old are still high in low-income countries.\textsuperscript{32} Population growth and increased urbanization, among other factors, have contributed to a relentless demand for vaccines.\textsuperscript{33}

By 2023, the global vaccine market is expected to be worth more than fifty billion dollars.\textsuperscript{34} Several multinational pharmaceutical corporations dominate the vaccine market and account for eighty percent of vaccine sales globally.\textsuperscript{35} The vaccine market is highly segmented: pharmaceutical companies derive most of their profit from high-cost low-volume sales in high-income countries, and donor organizations pay for low-cost high-volume supplies for low-income countries.\textsuperscript{36} Donor organizations include intergovernmental and governmental organizations as well as private foundations, non-profit organizations, and public-private partnerships that finance bulk vaccine purchases for LMICs.\textsuperscript{37} Middle-income countries have largely

\textsuperscript{28} See infra notes 31–51 and accompanying text.

\textsuperscript{29} See infra notes 52–86 and accompanying text.

\textsuperscript{30} See infra notes 87–101 and accompanying text.

\textsuperscript{31} See Alexandra Minna Stern & Howard Markel, The History of Vaccines and Immunization: Familiar Patterns, New Challenges, 24 HEALTH AFF. 611, 611 (2005); Eileen Murphy, Weakened Defenses, JOHNS HOPKINS PUB. HEALTH, (2002), https://magazine.jhsph.edu/2002/fall/vaccines.html (estimating that 12 million lives per year are saved by vaccines for smallpox, diphtheria, pertussis, measles, tetanus, and hepatitis B).

\textsuperscript{32} See Stern & Markel, supra note 31, at 611 (stating that infectious diseases that were especially fatal to children have been curbed in industrialized countries due to the proliferation of vaccines); Max Roser, Child Mortality, OUR WORLD IN DATA, https://ourworldindata.org/child-mortality (last visited Dec. 31, 2019) (stating that globally, mortality of children under the age of five has decreased from 36.2% in 1900 to 4.2% in 2015, but remains high in low-income countries such as 14% in Chad and 11% in Nigeria).

\textsuperscript{33} WHO, supra note 15, at iv.


\textsuperscript{36} See Shawn Gilchrist, Pull Mechanisms for Value-Added Technologies for Vaccines, OPTIMIZE: IMMUNIZATION SYS. & TECH. FOR TOMORROW 1, 3 (2009) (explaining that the vaccine markets in high-income countries are more lucrative for pharmaceutical companies than those in low-income countries).

\textsuperscript{37} See Vaccination Funding Landscape, GIVEWELL (Nov. 2012), https://www.givewell.org/international/charities/vaccination-organizations (including donor organizations such as UNICEF, Gavi, WHO, and MSF).
been left to negotiate their own prices, often resulting in more limited vaccine schedules than in low-income countries.\footnote{\textsc{médecins sans frontières}, \textit{The Right Shot: Bringing Down Barriers to Affordable and Adapted Vaccines} 1, 4 (2d ed. 2015) (stating that donor organizations generally do not negotiate lower vaccine prices for middle-income countries, and as such often pay higher prices for essential vaccines and exclude certain vaccines from their immunization schedules) [hereinafter \textsc{médecins sans frontières}, \textit{The Right Shot}].}

It is estimated that for every dollar spent on infant vaccinations, ten dollars are saved in healthcare costs, making vaccines exceptionally cost-effective.\footnote{Bourree Lam, \textit{Vaccines Are Profitable, so What?}, \textit{The Atlantic} (Feb. 10, 2015), https://www.theatlantic.com/business/archive/2015/02/vaccines-are-profitable-so-what/385214/.} As such, the public health sector seeks to expand access to immunization, especially in low-income countries that carry a disproportionately heavier disease burden.\footnote{See \textit{Vaccines Save 20 Million Lives, $350 Billion in Poor Countries Since 2001}, \textit{Medical Xpress}, (Sept. 1, 2017), https://medicalxpress-com.cdn.ampproject.org/c/s/medicalxpress.com/news/2017-09-vaccines-million-billion-poor-countries.amp (noting Gavi’s support contributing to vaccination of 580 million children in 73 poor countries); Gilchrest, \textit{supra} note 36, at 2 (stating that there is a higher burden from vaccine-preventable diseases in LMICs than in high-income countries).} Donor organizations, like Gavi, the Vaccine Alliance (Gavi), have been critical forces in this effort.\footnote{\textsc{gavi, the vaccine all.}, \textit{The 2016-2020 Investment Opportunity} 4 (2016).} Gavi was created in 2000 as a public-private partnership to expand global access to vaccines by co-financing vaccine supplies for low-income countries that have a gross national income per capita of less than $1,580.\footnote{Subhashini Chandrasekharan et al., \textit{Intellectual Property Rights and Challenges for Development of Affordable Human Papillomavirus, Rotavirus and Pneumococcal Vaccines: Patent Landscaping and Perspectives of Developing Country Vaccine Manufacturers}, 33 \textit{Vaccine} 6366, 6366 (2015); K.E. Gallagher et al., \textit{Status of HPV Vaccine Introduction and Barriers to Country Uptake}, 36 \textit{Vaccine} 4761, 4761 (2018).} As a country approaches this threshold, it enters into a five-year transition period during which the country’s co-financing commitment increases as Gavi’s decreases.\footnote{\textsc{gavi, the vaccine all.}, \textit{supra} note 41, at 10–11 (stating that Gavi-supported countries have a five-year graduation phase).} Countries then “graduate” from Gavi’s program and independently finance their immunization programs.\footnote{See, \textit{e.g.}, \textit{id.} at 11 (explaining that Ghana will “graduate” from Gavi support and will no longer receive support from Gavi after 2020).}

To incentivize pharmaceutical companies to sell vaccines at lower prices, Gavi and similar bulk purchasers have a pooled procurement strategy.\footnote{\textsc{médecins sans frontières}, \textit{The Right Shot}, \textit{supra} note 38, at 23. Besides Gavi, other bulk purchasers include the Pan American Health Organization and the United Nations International Children’s Emergency Fund.} Generally, the bulk purchaser-negotiated prices for vaccines are a small fraction of the prices in high-income countries.\footnote{See \textit{id.} at 25–26 (explaining that pharmaceutical companies offer tiered pricing to reduce prices for low-income countries).} For example, the human papillomavirus (HPV) vaccine, for which Merck has created a formula, costs Gavi approximately $4.50 per dose as compared to $168.10 to $217.11 per dose in the United States.\footnote{\textit{Vaccines for Children Program (VCP)}, \textsc{Ctrs. for Disease Control and Prevention}, https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html (last updated Mar. 1, 2019) (stating that the Gardasil price in the United States ranges from $168.10 to $217.11).} To lower
costs further, Gavi purchases over half of its vaccines from DCVMs, such as the Serum Institute of India (SII). The SII’s vaccine for measles, mumps, and rubella (MMR), for example, costs only 5% of the equivalent vaccine produced by Merck.

In addition to making existing vaccines affordable, it is essential that vaccine developers are properly incentivized to develop new critical vaccines. Multinational pharmaceutical companies have shown renewed interest in the development of new vaccines after the market success of the Hepatitis B, meningitis, and HPV vaccines and, importantly, patents play an important role in incentivizing pharmaceutical companies to develop viable treatments.

### B. Patent Protection for Vaccines

Patents are an effective way to incentivize innovation. By issuing a patent, the government grants a limited monopoly for twenty years. Until the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) by the World Trade Organization (WTO), it was challenging for inventors to protect their technologies in developing countries. After TRIPS, all WTO member countries, including developing countries, were required to establish basic patent systems. TRIPS, however, provided a caveat that countries could issue compulsory licenses as needed, such as to address public health emergencies.

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49 MEDECINS SANS FRONTIÈRES, THE RIGHT SHOT, supra note 38, at 59 (showing that Merck’s MMR vaccine price is $19.91 and SII’s is $1.03).

50 See ACCESS TO MED. FOUND., supra note 1, at 21, 23 (arguing that companies lack incentives for developing crucial vaccines and that improving affordability of vaccines would expand vaccine coverage).

51 Lam, supra note 39; see Outterson & Kesselheim, supra note 10, at 131 (explaining that pharmaceutical companies are incentivized to develop vaccines because of the patent rent earned during their limited monopoly on a new vaccine); Kayleigh E. McGlynn, The Role of Patents in the Fight Against Superbugs: Are Patent Laws Discouraging Investment in Promising Superbug Treatments, B.C. INTELL. PROP. & TECH. F. 1, 2 (2016), http://bciptf.org/wp-content/uploads/2017/02/McGlynn-IPTF-Blog-Post-Final.pdf.


53 Id. at 11–13. Patents must be new, useful, and non-obvious and encompass patentable subject matter. See id. (stating that patentable subject matter includes processes, machines, and compositions of matter; however, notably for vaccines it excludes products of nature).

54 Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 9, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 [hereinafter TRIPS]; see Padmanabhan et al., supra note 2, at 671 (explaining that prior to TRIPS, developing countries generally did not grant patents to pharmaceutical companies for their products).


56 Id.
Although patents incentivize vaccine development, they also introduce barriers to producing generic versions of newly patented vaccines and to developing novel vaccines that rely on existing technologies.\textsuperscript{57} The twenty-year limited monopoly provided by a patent is often crucial for vaccine developers to recoup their investment from long and expensive development cycles.\textsuperscript{58} Since the 1990s, developers have increasingly protected their vaccines with patents, such as those covering vaccine compositions, process technologies, methods of using the vaccine, and dose regimens.\textsuperscript{59} Patent holders in the vaccine market include academic and research institutions as well as government entities and for-profit companies.\textsuperscript{60} There are often dozens of patents held by various entities for a single vaccine.\textsuperscript{61} For example, the HPV vaccine is covered by at least eighty-one U.S. patents held by eighteen entities, creating an extremely complex patent landscape.\textsuperscript{62} Oftentimes, the patent holder licenses the patent for limited uses.\textsuperscript{63}

1. Patents & Licensing for Generic Vaccines

Post-TRIPS, DCVMs cannot infringe on patents without permission.\textsuperscript{64} As such, to create a generic version of a vaccine, a DCVM must navigate complex patent landscapes and obtain the necessary licenses.\textsuperscript{65} Generally, pharmaceutical companies voluntarily license their technology to DCVMs for the development of generic versions.\textsuperscript{66} In such a voluntary licensing agreement, a pharmaceutical company licenses the relevant technologies to the DCVM and transfers know-how for manufacturing processes.\textsuperscript{67} In exchange, the DCVM usually pays royalties to the pharmaceutical company and is restricted to selling the generic version in its own

\textsuperscript{57} See, e.g., Padmanabhan et al., supra note 2, at 671–72 (explaining that the complex patent landscape for the HPV vaccine is a barrier to developing generic versions); Bishai et al., supra note 13, at 1061 (explaining that development of an affordable meningitis vaccine hinged on a license from the National Institute of Health at well-below market price); GORDON, supra note 52, at 4. MÉDECINS SANS FRONTIÈRES, A FAIR SHOT FOR VACCINE AFFORDABILITY: UNDERSTANDING AND ADDRESSING EFFECTS OF PATENTS ON ACCESS TO NEWER VACCINES 5 (2017) [hereinafter MÉDECINS SANS FRONTIÈRES, A FAIR SHOT].

\textsuperscript{58} Milstien & Kaddar, supra note 55, at 360; Plotkin, supra note 26, at 4068 (noting that development of vaccines often takes at least fifteen years and two-hundred million dollars); GORDON, supra note 52, at 5.


\textsuperscript{60} Catherine Saez, Access to Vaccines, Patents Growing Concerns, Panellists Say, INTELL. PROP. WATCH (Oct. 6, 2014), https://www.ip-watch.org/2014/06/10/access-to-vaccines-patents-growing-concerns-panellists-say/.

\textsuperscript{61} Padmanabhan et al., supra note 2, at 672.

\textsuperscript{62} Id.

\textsuperscript{63} GORDON, supra note 52, at 24.

\textsuperscript{64} Id. at 671.

\textsuperscript{65} MÉDECINS SANS FRONTIÈRES, A FAIR SHOT, supra note 57, at 10.

\textsuperscript{66} Id. at 32.

\textsuperscript{67} Id.; Sean McElligott, Addressing Supply Side Barriers to Introduction of New Vaccines to the Developing World, 35 AM. J.L. & MED. 415, 419 (explaining that manufacturing vaccines requires significant technological know-how that is kept secret by innovators to maintain their market power).
country or a specific geographic region.\textsuperscript{68} On the other hand, advocates for greater vaccine accessibility have proposed alternatives such as compulsory licenses and market-based licenses.\textsuperscript{69}

Some global health professionals have advocated for the issuance of compulsory licenses when pharmaceutical companies refuse to voluntarily license critical technologies, which is authorized by TRIPS at a country’s discretion.\textsuperscript{70} Thailand, for example, issued a compulsory license for antiretroviral drugs to combat the AIDS epidemic.\textsuperscript{71} Currently, compulsory licenses have not yet been issued for patents covering vaccines.\textsuperscript{72} Some have argued that these licenses should be issued for HPV vaccines because HPV disproportionately impacts LMICs and a duopoly has maintained a relatively high price for the vaccines.\textsuperscript{73}

As a compromise between voluntarily licensing by pharmaceutical companies and compulsory licensing, some have proposed market-based licensing to expand access to affordable vaccines while still compensating developers for their research and development.\textsuperscript{74} For example, the “Generic Open (GO) License,” a market-based licensing system, proposes that DCVMs should automatically produce generic versions of patented vaccines exclusively in LMICs in exchange for a royalty paid to the innovator company, based on profits within that country.\textsuperscript{75}

2. Patent Blocking for New Vaccines & Product Development Partnerships

Patents can impede the development of new vaccines when such vaccines depend on unexpired patented technologies.\textsuperscript{76} These patents are often referred to as “blocking patents.”\textsuperscript{77} This issue arises when universities, national institutes of health, and pharmaceutical companies hold patents on a particular technology that is critical to develop a particular new vaccine.\textsuperscript{78}

Product development partnerships (PDPs) have been successful in overcoming patent blocking.\textsuperscript{79} In the vaccine market, a PDP is a collaboration between

\textsuperscript{68} Id.
\textsuperscript{69} Peter Maybarduk & Sarah Rimmington, Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine?, 35 AM. J. L. & MED. 323, 323 (2009); Outterson & Kesselheim, supra note 10, at 132, 134.
\textsuperscript{70} Maybarduk & Rimmington, supra note 69, at 323; Outterson & Kesselheim, supra note 10, at 132; TRIPS, supra note 54.
\textsuperscript{71} Outterson & Kesselheim, supra note 10, at 132.
\textsuperscript{72} See id. at 133 (stating that Brazil and Thailand utilized compulsory licenses for essential medicines).
\textsuperscript{73} Maybarduk & Rimmington, supra note 69, at 323. Merck and GSK are the sole producers of the HPV vaccine. Id.
\textsuperscript{74} Outterson & Kesselheim, supra note 10, at 134.
\textsuperscript{75} Id.
\textsuperscript{76} Médecins Sans Frontières, A Fair Shot, supra note 57, at 26–27. Describing multiple types of “blocking IP” for biological materials, processes, and devices.
\textsuperscript{77} Id. at 7; see Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCI. 698, 698–99 (1998) (explaining how patents on existing technologies can affect downstream development of new technologies).
\textsuperscript{78} Saéz, supra note 60.
\textsuperscript{79} See, e.g., Bishai et al., supra note 13, at 1061 (discussing how a PDP secured a license to a technology owned by the NIH that was essential to developing a low-cost meningitis vaccine).
C. Benefit Corporations

Benefit corporations stand to help structurally align private sector activities with public sector goals in the pharmaceutical industry.\textsuperscript{87} As of December 23, 2019, thirty-eight states offer the option to incorporate as a benefit corporation, including Delaware, where the majority of Fortune 500 corporations are registered.\textsuperscript{88} In Delaware and in most states, incorporators must state the corporation’s purpose, where the default is “engaging in any lawful purpose.”\textsuperscript{89} There is a common misconception that a corporation’s general purpose must be to maximize shareholder value.\textsuperscript{90} As such, critics argue that the benefit corporation structure is unnecessary because existing incorporation statutes do not limit corporations from stating a socially

\textsuperscript{80} Richard T. Mahoney, \textit{Product Development Partnerships: Case Studies of a New Mechanism for Health Technology Innovation}, 9 HEALTH RES. & POL’Y SYS. 1, 2 (2011); see e.g. ACCESS TO MED. FOUND., supra note 1, at 10 (noting that a PDP developed an affordable meningitis vaccine that was necessary for public health but had low commercial value).

\textsuperscript{81} Bishai et al., supra note 13, at 1060.

\textsuperscript{82} Id.

\textsuperscript{83} Id. at 1061.

\textsuperscript{84} Id. at 1059.

\textsuperscript{85} Id. at 1058.

\textsuperscript{86} See infra notes 106–111, 127–134 and accompanying text.

\textsuperscript{87} Heled et al., supra note 14, at 80–82; see Cummings, supra note 19, at 579–80 (stating that the first benefit corporation statute enacted was in Vermont in 2010).


\textsuperscript{89} Chu, supra note 17, at 168–69.

\textsuperscript{90} Id. at 169.
beneficial purpose. Moreover, as of 2009, thirty-three states had already enacted “other-constituency statutes” authorizing corporate directors to contemplate the interests of groups other than shareholders in operating standard corporations. Nonetheless, the benefit corporate structure has gained traction as a way for corporations to formally pursue goals other than profit maximization.

In the healthcare market, the public sector can incentivize pharmaceutical companies to restructure as benefit corporations to qualify for funding opportunities. Two examples of such an arrangement are Cooperate Research and Development Agreements (CRADAs) and Program-Related Investments (PRIs). CRA-DAs enable federal agencies and private organizations to jointly commercialize new technologies by sharing the costs of research and development. Similarly, PRIs allow donor organizations to invest in activities related to their charitable missions, thus expanding the pool of investment money available for activities promoting social causes.

Still, even if vaccine developers elect to become benefit corporations, it remains unclear whether they would also adopt patent strategies that balance recouping investment with accelerating the availability of affordable vaccines in LMICs. Nonetheless, because DCVMs have repeatedly demonstrated their ability to dramatically reduce vaccine prices, a key part of a pharmaceutical benefit corporation’s strategy would likely be to license critical technologies to DCVMs. In the

91 Id. at 157, 172.
93 See Cummings, supra note 19, at 590 (stating that benefit corporation statutes provide protection to directors when they consider public interest goals in their decision-making process); Status Tool, supra note 88 (showing that the number of states with benefit corporation statutes has increased from zero states in 2009 to thirty-eight states by the end of 2019).
94 See Eiser & Field, supra note 20, at 651–52 (proposing that federal agencies could give preference to benefit corporations for CRADAs).
95 See id. (discussing CRADAs); e.g., Paul Brest, Investing for Impact with Program-Related Investments, STAN. SOC. INNOVATION REV. 19, 19–20 (2016) (discussing the Gates Foundation’s use of PRIs to incentivize vaccine developers to create lower-cost vaccines).
96 Eiser & Field, supra note 20, at 652.
97 Brest, supra note 95, at 19, 21.
98 See McElligott, supra note 67, at 425 (stating that weak intellectual property environments discourage investment in research and development); Michael Messinger & Casey Berger, Early Patenting Questions for Public Benefit Corporations, LAW 360 (Mar. 12, 2018), https://www.law360.com/articles/1019094/early-patenting-questions-for-public-benefit-corporations (positing that benefit corporations will consider their public interest goals when deciding on their patent strategies).
99 See Padmanabhan et al., supra note 2, at 671 (stating that DCVMs reduced the cost of Gardasil from $171 for a three-dose regime to $2 per dose, and the Hepatitis B vaccine from between $50 and $80 per dose to $0.30 per dose).
100 Crager, supra note 3, at e86; see, e.g., Padmanabhan et al., supra note 2, at 671 (stating that the Hepatitis B vaccine retailed at between $50 and $80 per dose, but following competition by DCVMs, the price decreased to less than $0.30 per dose).
absence of such agreements, however, DCVMs’ ability to produce affordable generic versions of vaccines may be limited by patent barriers.101

II. BENEFIT CORPORATIONS’ IMPACT ON PATENT PROTECTION

Benefit corporations may provide a means to overcome patent barriers and improve access to existing and new vaccines in low- and middle-income countries (LMICs).102 On the other hand, using the benefit corporate structure to produce such effect may result in unintended consequences.103 Section A discusses how benefit corporations can overcome patent barriers to increase vaccine availability and affordability through licensing agreements and product development partnerships (PDPs).104 Section B then explores challenges in using benefit corporations to address patent barriers in the vaccine market.105

A. How Benefit Corporations Can Overcome Patent Barriers to Increase Vaccine Availability and Affordability

To make vaccines more affordable, developing country vaccine manufacturers (DCVMs) could increasingly manufacture generic versions of existing vaccines, and PDPs could take the lead in developing new vaccines that have a demonstrated public health demand.106 To engage in these activities, pharmaceutical companies and other entities need to cooperate with benefit corporations to secure licenses to essential components of vaccines.107 Although DCVMs have been able to successfully manufacture affordable, generic versions of some vaccines, patent protections remain a barrier to producing affordable vaccines for certain diseases, such as HPV.108 Additionally, PDPs have tried to engage private-sector companies to

101 Padmanabhan et al., supra note 2, at 671–72, 676 (explaining that there are likely patent barriers to developing a generic version of the HPV vaccine, and that generally patent barriers impede development of generic vaccines).

102 Id. at 671 (stating that DCVMs generally need access to patented technologies to develop generic vaccines); ACCESS TO MED. FOUND., supra note 1, at 10 (discussing the success of PDPs developing vaccines at low costs); Messinger & Berger, supra note 98 (positing that benefit corporations will consider their public interest goals when deciding on their patent strategies); Outterson & Kesselheim, supra note 10, at 134 (proposing Generic Open Licenses as a way for DCVMs to manufacture affordable vaccines in their countries while still ensuring that vaccine developers recoup their investment costs).

103 McElligott, supra note 67, at 425 (discussing the value of intellectual property and the financial risks involved in weakening intellectual property strategies).

104 See infra notes 106–134 and accompanying text.

105 See infra notes 135–145 and accompanying text.

106 Padmanabhan et al., supra note 2, at 671 (discussing DCVMs’ success in reducing the price of the Hepatitis B vaccine from between fifty and eighty dollars per dose to $0.30 per dose); Bishai et al., supra note 13, at 1058 (discussing a PDP’s success in developing an affordable meningitis vaccine).

107 See Chandrasekharan et al., supra note 42, at 6366 (explaining that patents hinder manufacturers from producing generic versions of a vaccine); Bishai et al., supra note 13, at 1061 (stating that MVP collaborated with the NIH, which granted a nonexclusive license to SII at well below market price).

108 Chandrasekharan et al., supra note 42, at 6366; Padmanabhan et al., supra note 2, at 671, 676.
develop critical vaccines despite their low commercial value. PDPs benefit from pharmaceutical companies’ cooperation because these companies often hold patents covering technologies necessary for the development of vaccines. Pharmaceutical companies, though, are generally not interested in vaccines with low commercial value because they are unable to recoup their investment.

1. Licensing Agreements for Affordable Generic Vaccines

Improved licensing agreements between vaccine developers and DCVMs are essential to producing affordable generic vaccines. Following TRIPS, DCVMs must navigate a complex patent landscape to obtain licenses for all relevant technologies to produce a generic vaccine. For example, the existing HPV vaccines are protected by eighty-one patents held by eighteen different entities. As such, vaccine developers, restructured as benefit corporations, could address this challenge by streamlining their licensing agreements. One promising option is a Generic Open (GO) License, which creates an automatic license for newly patented vaccines for exclusive use in LMICs. Under the GO License, DCVMs could automatically purchase the rights to produce generic versions of patent-protected vaccines exclusively in LMICs in exchange for a reasonable royalty paid to the vaccine developer.

Importantly, the GO License balances the need for vaccine developers to recoup development costs while accelerating affordable generic production. Under this license, vaccine developers would retain an exclusive monopoly for the patent term in high-income countries, where a developer can garner the majority of the profits. Additionally, vaccine developers would receive a reasonable royalty based on the profits that DCVMs accrue in LMICs.

The importance of licensing agreements is demonstrated by the current challenges surrounding access to the HPV vaccine in LMICs. Although the HPV vaccine is widely available in high-income countries, access remains limited in

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109 See, e.g., Bishai et al., supra note 13, at 1060 (stating that pharmaceutical companies from Europe and the United States declined to engage in MVP, and that a European biotechnology company initially committed to MVP but withdrew when it needed to commit its resources to other projects).

110 See, e.g., Sandra L. Shotwell, Patent Consolidation and Equitable Access: PATH’s Malaria Vaccines, HANDBOOK OF BEST PRACTICES, 1789, 1790–91 (showing that for malaria vaccines the majority of patents were held by a private-sector company).

111 See, e.g., Bishai et al., supra note 13, at 1060 (explaining that pharmaceutical companies from Europe and the United States would not engage in the MVP because of the low vaccine price).

112 See Outterson & Kesselheim, supra note 10, at 134 (discussing license agreements that will support innovation while simultaneously promoting generic production).

113 Padmanabhan et al., supra note 2, at 672.

114 See infra notes 121–126 and accompanying text.

115 See Messinger & Berger, supra note 98 (indicating that benefit corporations will consider their public interest goals in their patent management strategies).


117 Id.

118 Id.

119 Id.

120 Id.

121 Padmanabhan et al., supra note 2, at 671.
developing countries where the disease burden is the greatest.\textsuperscript{122} Merck and GSK have a duopoly on HPV vaccines, and they provide HPV vaccines to Gavi for $4.50 and $4.60 per dose, respectively.\textsuperscript{123} To be cost-effective for immunization programs in LMICs, studies have suggested that the HPV vaccine needs to cost approximately $2.00 per dose, less than half of its current price.\textsuperscript{124} As such, the price of the HPV vaccine has impeded several LMICs from introducing or sustaining programs for the vaccine.\textsuperscript{125} DCVMs have lowered the price of other vaccines, and they could do the same for the HPV vaccine if a license agreement such as the GO License were available.\textsuperscript{126}

2. Engaging Vaccine Developers In Product Development Partnerships

PDPs also play an important role in developing vaccines that are critical for global health but lack strong commercial potential.\textsuperscript{127} As the world confronts an increasing number of disease outbreaks, benefit corporations and PDPs provide an avenue to focus on the health care needs of neglected populations.\textsuperscript{128} Pharmaceutical companies restructured as benefit corporations could be incentivized through preferential grants from the public sector to participate in PDPs and similar research and development efforts.\textsuperscript{129}

The Meningitis Vaccine Project (MVP) is a successful PDP that demonstrates the great potential of combining resources and expertise to confront disease outbreaks.\textsuperscript{130} After a devastating meningitis outbreak in the mid-1990s, the public health sector recognized the pressing need for a vaccine to protect against future outbreaks, and the Gates Foundation contributed seventy million dollars to WHO and PATH to create the MVP.\textsuperscript{131} Ultimately, the MVP was able to produce a meningitis vaccine at one tenth of the typical cost of vaccine development and with a market price of only $0.50 per dose.\textsuperscript{132} The MVP was successful, in part, because

\textsuperscript{123} \textit{MÉDECINS SANS FRONTIÈRES, THE RIGHT SHOT}, supra note 38, at 41–42.
\textsuperscript{124} \textit{Id.} at 44.
\textsuperscript{125} \textit{Gallagher} et al., supra note 42, at 4765 (explaining that there is uncertainty over whether LMICs that are no longer eligible for Gavi support will introduce or sustain HPV vaccination programs).
\textsuperscript{126} Padmanabhan et al., supra note 2, at 671.
\textsuperscript{127} \textit{See Mahoney, supra note 80, at 2} (discussing various PDPs developing vaccines for malaria, tuberculosis, and dengue); \textit{ACCESS TO MED. FOUND.}, supra note 1, at 10 (discussing MVP, a PDP that developed a low-cost meningitis vaccine despite “low commercial potential”).
\textsuperscript{129} \textit{See ACCESS TO MED. FOUND.}, supra note 1, at 10 (noting that the MVP developed a critical meningitis vaccine that had limited commercial value); Eiser \& Field, supra note 20, at 651–52 (discussing the incentive of public sector grants for pharmaceutical companies that incorporate as benefit corporations).
\textsuperscript{130} Bishai et al., supra note 13, at 1058.
\textsuperscript{131} \textit{Id.} at 1059.
\textsuperscript{132} \textit{Id.} at 1058; \textit{ACCESS TO MED. FOUND.}, supra note 1, at 10.
it was able to license patented technologies at affordable prices from the U.S. government.\footnote{Bishai et al., supra note 13, at 1061; Heller & Eisenberg, supra note 77, at 699.} The MVP demonstrates that private and public sector collaboration is one way to successfully develop vaccines that have low commercial value but are crucial from a public health perspective.\footnote{Bishai et al., supra note 13, at 1058.}

**B. Challenges in Using Benefit Corporations to Address Patent Barriers for Vaccine Availability and Affordability**

Although benefit corporations provide a promising solution to current barriers affecting the availability of affordable vaccines, there are some challenges that need to be addressed.\footnote{See Lam, supra note 39 (discussing that a new vaccine development must be lucrative to attract industry attention); Saez, supra note 60 (explaining that DCVMs could take advantage of the research and development investments of multinational pharmaceutical companies).} First, lenient licensing agreements may not be a sustainable business model and could provide unfair advantages to DCVMs.\footnote{See Saez, supra note 60 (explaining that DCVMs should invest in their own research and development for new vaccines).} This is because, unlike vaccine developers, DCVMs do not incur significant research and development costs to produce generic drugs.\footnote{Outterson & Kesselheim, supra note 10, at 131.} If granted immediate licenses without geographic restrictions, DCVMs could sell their generics for substantially less than vaccine developers’ equivalent products.\footnote{Id.} If developers lack such a financial incentive, vaccine development would slow down.\footnote{Lam, supra note 39. New vaccine development slowed down significantly in the 1970s and 1980s because profit margins for vaccines were low compared to other pharmaceutical markets. Id.} Moreover, if DCVMs are immediately granted a license to produce a generic version, they may choose not to cultivate their own research and development capabilities and instead may free-ride on pharmaceutical companies’ capabilities.\footnote{Saez, supra note 60.} Nonetheless, this concern can be allayed by entering into licensing agreements exclusively in LMICs, where vaccine developers do not earn many profits.\footnote{See McElligott, supra note 67, at 420 (stating that vaccine developers earn most of their profits from high-income countries).}

Second, a lack of economic incentive may prevent vaccine developers from engaging in PDPs.\footnote{Bishai et al., supra note 13, at 1062.} Arguably, market forces will direct the right actors for PDPs based on each actor’s opportunity costs.\footnote{Id.} Corporations must assess whether participating in a PDP makes economic sense given the opportunity costs.\footnote{Id.} Although PDPs may present sound economic opportunities for DCVMs, this may not be the case for multinational pharmaceutical companies that can choose to dedicate resources to more profitable projects.\footnote{Id. at 1060, 1062.}

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\begin{enumerate}
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\item \footnote{Lam, supra note 39. New vaccine development slowed down significantly in the 1970s and 1980s because profit margins for vaccines were low compared to other pharmaceutical markets. Id.}
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\item \footnote{Id.}
\item \footnote{Id.}
\item \footnote{Id. at 1060, 1062.}
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III. BENEFIT CORPORATIONS CAN ALIGN INTERESTS BETWEEN VACCINE INNOVATORS AND THE GLOBAL HEALTH COMMUNITY

Patent protection hinders affordable access to existing and new vaccines.146 Due to patent monopolies, developing country vaccine manufacturers (DCVMs) are impeded from making lower cost generic versions of recently developed vaccines.147 This is especially concerning for vaccines like the HPV vaccine because women in low- and middle-income countries (LMICs) are disproportionately at risk for HPV compared to those in high-income countries.148 The patent barriers indicate a misalignment between the private and public sectors in the vaccine market.149 The private sector must secure patent protection to recoup costs for expensive vaccine development but the public sector is falling behind in providing affordable access to critical vaccines in LMICs.150

Benefit corporations may offer a way for the private and public sectors to mutually benefit from aligned goals in the vaccine market.151 Vaccine developers, restructured as benefit corporations, could formally commit themselves to improving access to vaccines in LMICs and implement patent strategies to advance this goal.152 In exchange, the public sector could reduce the cost and risk of vaccine development by reserving funding streams exclusively for vaccine developers that are incorporated as benefit corporations.153

As benefit corporations, vaccine developers could also demonstrate their commitment to vaccine accessibility in LMICs by revamping their patent management strategies.154 First, vaccine developers could pursue licensing agreements like the Generic Open License, which would provide an opportunity for DCVMs to produce affordable generic versions of patent-protected vaccines exclusively in LMICs.155 This shift would have minimal impact on vaccine developers’ bottom line because the majority of their profits are garnered from high-income countries, and would significantly reduce vaccine prices in LMICs by creating lower cost

146 Médecins sans frontières, A Fair Shot, supra note 57, at 2.
147 See, e.g., Padmanabhan et al., supra note 2, at 671 (discussing the patent barriers to developing generic vaccines after TRIPs).
148 Id.
149 See Heled et al., supra note 14, at 80–82 (arguing that there is a disconnect between the private and public sector in the pharmaceutical market).
150 Outterson & Kesselheim, supra note 10, at 131; see ACCESS TO MED. FOUND., supra note 1, at 21 (stating that the WHO has identified thirty-two critical diseases for which there is no research or development for a new vaccine).
151 Heled et al., supra note 14, at 80–82.
152 See Messinger & Berger, supra note 98 (describing how benefit corporations will align their patent management strategies with their stated public interest goals).
153 See Eiser & Field, supra note 20, at 651–52 (proposing that federal agencies could give preference to benefit corporations for federal research grants).
154 See Messinger & Berger, supra note 98 (positing that benefit corporations will consider their public interest goals when deciding on patent strategies).
155 See Outterson & Kesselheim, supra note 10, at 134 (proposing Generic Open Licenses so vaccine developers can maximize profits in high-income countries while still providing DCVMs with opportunity to manufacture lower cost generic versions of the vaccine in LMICs in exchange for a reasonable royalty payment).
generic options. Second, vaccine developers could prioritize cooperation with PDPs that are developing critical new vaccines. WHO has identified thirty-two emergent diseases for which there is currently no research or development for critical vaccines. Vaccine developers, especially those in Europe and the United States, have the most advanced resources to tackle these novel challenges. Vaccine developers, in exchange for public financing, could more fully commit their resources to participating and following through with initiatives like PDPs.

The public sector would need to create mechanisms to ensure that vaccine companies undertaking such commitments are able to recoup their investments with a reasonable profit margin. Otherwise, companies may move out of the vaccine market to pursue more lucrative opportunities. The public sector could offer significant grants for new vaccine development to replace vaccine developers’ reliance on patent protection to recoup investments. Such grants could be partially funded by the savings that the public sector would accrue from purchasing low-cost generic vaccines in LMICs. Longer term, improved vaccine coverage will result in significant savings to the healthcare systems in LMICs, and such savings can be channeled into grants to develop new critical vaccines.

Although benefit corporations are only required to consider their public interest goals when making decisions, this alone may be enough to shift patent management strategies in the vaccine market. Some pharmaceutical companies, such as GSK, have already committed themselves to developing a malaria vaccine under a not-for-profit model because the majority of the research is funded by donor foundations. The benefit corporation may be the next natural step to more broadly

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156 Padmanabhan et al., supra note 2, at 671; see Gilchrist, supra note 36, at 3 (explaining that the vaccine markets in high-income countries are more lucrative for pharmaceutical companies than those in low-income countries).

157 See Bishai et al., supra note 13, at 1060 (discussing the challenge of engaging pharmaceutical and biotechnology companies for PDPs developing affordable critical vaccines).

158 ACCESS TO MED. FOUND., supra note 1, at 21.

159 See Bishai et al., supra note 13, at 1062 (stating that the meningitis vaccine was relatively easy to develop, but that future vaccines will require higher level of expertise).

160 See id. (discussing pharmaceutical companies’ reluctance to commit to PDPs because of the opportunity costs, indicating that more public sector financing could encourage such companies to participate in PDPs).

161 See Lam, supra note 39 (arguing that if pharmaceutical companies do not make adequate profits in the vaccine market then they will shift their resources to more lucrative markets).

162 Id.

163 See Eiser & Field, supra note 20, at 651–52 (proposing that federal agencies could give preference to benefit corporations for federal research grants).

164 See MÉDECINS SANS FRONTIÈRES, THE RIGHT SHOT, supra note 38, at 11 (showing that brand-name vaccines are more expensive than generic versions of the same vaccine).

165 See Lam, supra note 39 (stating that immunization programs are one of the most cost-effective health interventions: one dollar invested in infant immunization saves approximately ten dollars in future healthcare costs).

166 DEL. CODE ANN. tit. 8, §§ 361–368 (2019); see Messinger & Berger, supra note 98 (indicating that benefit corporations will reconsider their patent management strategies in light of public interest goals).

167 ACCESS TO MED. FOUND., supra note 1, at 27–28.
align private and public sector goals in the vaccine market. Arguably, the vaccine market demands such alignment to ensure that advances in vaccine technology benefit the populations that need these vaccines the most.

CONCLUSION

Vaccines play a unique role in global health, protecting not only individuals, but ultimately, the global population. Thus, there is a strong shared interest in making vaccines widely available, especially where vaccine-preventable diseases are most prevalent. Yet, certain vaccines remain out of reach for LMICs where the disease burden is the heaviest. Benefit corporations provide one way to recognize the shared interest in making vaccines affordable and widely available. Vaccine developers, restructured as benefit corporations, could commit to special licensing agreements with DCVMs for production of low-cost generic vaccines in LMICs and to engagement in PDPs for critical new vaccines. With time, the public sector would accrue significant savings from purchasing generic vaccines and from improved vaccine coverage and could use these savings to invest heavily in future vaccines. Public sector investment would decrease pharmaceutical companies’ risks and costs for vaccine development, and thus reduce their reliance on expansive intellectual property protection to recoup costs. Given the long development cycles of vaccines, the benefit corporate structure would secure an arrangement of special licensing and engagement in PDPs from the private sector in exchange for increased public sector financing, thereby stimulating affordable vaccine development.

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168 See Heled et al., supra note 14, at 80–81 (proposing the benefit corporate structure as a way to align public health interests and private sector incentives); Bishai et al., supra note 13, at 1058 (discussing the success of a PDP for an affordable meningitis vaccine); McElligott, supra note 67, at 421–22 (discussing how the government is substantially involved in the vaccine market).

169 See Crager, supra note 3, at e85 (stating that LMICs are disproportionately affected by vaccine-preventable diseases).