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Unpacking Open Source Bio

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For at least a quarter of a century, life science researchers around the world have undertaken initiatives loosely based on principles, goals, and institutional structures derived from the open source software (OSS) movement—approaches that I term "open source bio." Yet open source bio lacks a clear definition and set of guiding principles. Given public calls for greater openness in life science research, it is useful to understand how open source bio projects have fared over the past quarter century: how they were structured, what they hoped to achieve, and, as social and policy experiments, whether or not they were successful. This Article analyzes twelve life science research projects that have claimed to operate on an open source basis. It distills the common structures, features, and goals of these heterogeneous projects and evaluates them in terms of three organizing principles of open source: (1) their provision of access to enabling technology, (2) their treatment of intellectual property (IP), and (3) their mode of technology development. It concludes with observations and recommendations regarding directions for future open source bio projects and the prospects for meaningful open source bio projects in the future.

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INTRODUCTION

During the COVID-19 pandemic, researchers at Texas Children's Hospital and Baylor College of Medicine announced that they had developed a patent-free vaccine

that would be distributed throughout the world on an "open source" basis.[1] Over 100 million doses of the vaccine were manufactured and distributed for use in India.[2] This accomplishment earned the Texas team's leaders, Drs. Peter Hotez and Maria Elena Bottazzi, widespread accolades and a nomination for the Nobel Peace Prize.[3] The unexpected announcement and success of the Texas vaccine drew renewed global attention to the use of open source approaches to life science research and development—what I term "open source bio."[4]

But what is open source bio? Is it free access to research results? The posting of data on public websites? The relinquishment of intellectual property (IP) rights? The sharing of biological materials? The conduct of research through crowdsourcing and peer production? All of these practices are occurring throughout the scientific community, and many of them are referred to as open source.

The open source bio movement is, to a degree, part of a much larger and more diffuse set of activities known as "open science." As the British Royal Society observed in 2012, "[m]uch of the remarkable growth of scientific understanding in recent centuries is due to open practices; open communication and deliberation sit at the heart of scientific practice."[5]

The term open *source* is, of course, borrowed from open source software (OSS), a now-widespread method of software distribution in which the human-readable programming language (source code) of a software program "can be freely accessed, shared, modified, and improved."[6] OSS, which arose from the computer hacker culture of the 1960s and 1970s,[7] has become pervasive in many segments of the software market, from operating systems (Linux and Android) to programming languages (Python and JavaScript) to web servers (Apache) to media players (VLC) to web authoring (WordPress) to large language models (Llama).[8] A significant

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1. *See infra* Section II.L.

2. *See id.*

3. Karen Brooks Harper, *From Obscurity to a Nobel Prize Nomination: Houston Scientists Acclaimed for Their Patent-Free COVID-19 Vaccine*, TEX. TRIB. (Feb. 10, 2022, 5:00 AM), https://www.texastribune.org/2022/02/10/corbevax-texas-coronavirus-vaccine/ [https://perma.cc/646Y-WNUY].

4. These initiatives have been referred to as open source biology, open source biotechnology, open source drug discovery, and open source medicine—practices that this Article collectively refers to as "open source bio." For a brief discussion of terminology, see Geertrui Van Overwalle, *Uncorking Trade Secrets: Sparking the Interaction Between Trade Secrecy and Open Biotechnology*, *in* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH 246, 253–54 (Rochelle C. Dreyfuss & Katherine J. Strandburg, eds., 2011).

5. THE ROYAL SOC'Y, SCIENCE AS AN OPEN ENTERPRISE 13 (2012).

6. Stéphane Couture, *Free and Open Source Software*, *in* THE HANDBOOK OF PEER PRODUCTION 155, 155 (Mathieu O'Neil, Christian Pentzold & Sophie Toupin eds., 2021).

7. *Id.* at 155–56.

8. *See* Pratiyush, *15 Open-Source Projects That Changed the World*, MEDIUM (Mar. 16, 2024), https://medium.com/@pratiyush1/15-open-source-projects-that-changed-the-world-26ecb8abee97 [https://perma.cc/7JW2-QPL7]; Sara Ana Cemazar, *The Ultimate List of 15 Best Open-Source Software in 2024*, ROCKET.CHAT (Apr. 20, 2023), https://www.rocket.chat/blog/open-source-software-list [https://perma.cc/PR39-5P7N]; Nivas Jayaseelan, *LLaMA 2: The New Open Source Language Model*, E2E NETWORKS LTD.

amount of software used in life sciences research today is also OSS, including a wide range of bioinformatics and medical informatics programs[9] and the Nobel Prize winning AlphaFold3 AI protein-prediction tool.[10]

Yet in contrast to OSS, for which a precise set of defining criteria has been promulgated,[11] open source bio lacks a clear definition and set of guiding principles. While a plethora of definitions have emerged over the years, they exhibit little consensus or consistency, as illustrated by the various attempts that are collected in the Appendix. Perhaps the greatest unifying feature of these proposals is their desire to translate the success of open models in the software industry to the domain of life science research.[12] Over the past two decades, scholars and commentators have debated the suitability of open source development approaches for life sciences research and product development.[13]

(Aug. 7, 2023), https://www.e2enetworks.com/blog/llama-2-the-new-open-source-language-model [https://perma.cc/V44T-7UVK].

9. *See* Michele K. Herman, Jane Eckels, Joanne Montague, Jordan J. Bowler & Nicole Orlov, *Open Source and Bioinformatics*, *in* BIOINFORMATICS, MEDICAL INFORMATICS AND THE LAW 44 (Jorge L. Contreras, A. James Cuticchia, & Gregory J. Kirsch eds., 2022).

10. Ewen Callaway, *AI Protein-Prediction Tool Alphafold3 Is Now More Open*, 635 NATURE 531 (2024).

11. The nonprofit Open Source Institute (OSI) has developed, maintains, and applies a precise set of criteria defining what it means for software to be open source. *See History of the OSI*, OPEN SOURCE INITIATIVE, https://opensource.org/history (last updated Oct. 2018) [https://perma.cc/2WUB-TUUP]. Nevertheless, debates over the openness of software programs that claim to be OSS abound. *See, e.g.*, Stefanu Maffuli, *'Open Source' AI Isn't Truly Open — Here's How Researchers Can Reclaim the Term,* 640 NATURE 9 (2025). One court has even held that a party's inaccurate promotion of its software as "free and open source" constituted actionable false advertising. Neo4J, Inc. v. Purethink, LLC, No. 5:18-cv-07182-EJD, 2021 U.S. Dist. LEXIS 115090, at *41–44 (N.D. Cal. May 18, 2021), *aff'd* No. 21-16029, 2022 U.S. App. LEXIS 6494 (9th Cir. Mar. 14, 2022). *See infra* note 194 and accompanying text (discussing politician Al Gore's alleged misuse of the term "open source" for political gain).

12. *See, e.g.*, Michael Stebbins, Miranda Bain, Rena Conti, Nicholaos Krenteras, Nicoleta Krenteras, Jaykumar Menon & Bernard Munos, *Adopting an Open-Source Approach to Pharmaceutical Research and Development*, DAY ONE PROJECT 1, 6 (2020), https://fas.org/wp-content/uploads/2020/10/Adopting-an-Open-Source-Approach-to-Pharmaceutical-Research-and-Development.pdf [https://perma.cc/43G5-YYT3] ("The information technology (IT) sector provides a successful precedent for an open-source approach" to biomedical research.).

13. *See, e.g.*, Dan Burk, Josh Lerner & Michael Meurer, *Open Source Genomics*, 8 B.U. J. SCI. & TECH. L. 254 (2002); David W. Opderbeck, *The Penguin's Genome, or Coase and Open Source Biotechnology*, 18 HARV. J.L. & TECH. 167, 171 (2004); Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer*?, 6 MINN. J.L. SCI. & TECH. 169 (2004); Arti K. Rai, *"Open and Collaborative" Research: A New Model for Biomedicine*, *in* INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES: SOFTWARE AND BIOTECHNOLOGY 131 (Robert W. Hahn ed., 2005) [hereinafter Rai, *Open and Collaborative*]; Bernard Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NATURE REVS. DRUG DISCOVERY 723 (2006); Sara Boettiger & Brian D. Wright, *Open Source in Biotechnology: Open Questions*, 1 INNOVATIONS: TECH., GOVERNANCE, GLOBALIZATION 43, 46–47 (2006); JANET HOPE, BIOBAZAAR: THE OPEN SOURCE REVOLUTION AND

In the wake of the COVID-19 pandemic, public calls for greater openness in life science research have increased. As one prominent group of academics and policy experts recommended to the incoming Biden administration in 2020:

> We must move . . . towards a world in which pharmaceutical R&D is carried out collaboratively, cooperatively, transparently, flexibly, and efficiently. An important step is making key aspects of pharmaceutical R&D—especially publicly funded R&D that is supported or conducted by government—open source.[14]

For all of these reasons, it is useful to review and understand how open source bio projects have fared over the past quarter century: how they were structured, what they hoped to achieve, and, as social and policy experiments, whether or not they were successful. Without a more concrete understanding of these measures, the open source label risks becoming little more than, in the words of Antony Taubman, a "meme" that is "loosely applied to any kind of life sciences innovation that one happens to prefer."[15]

This Article analyzes a set of twelve distinct approaches to open source bio and distills from them a set of common structures, features, and goals against which it interrogates each of the projects. It then assesses how closely each of them hews to the characteristics of open source and seeks to draw useful recommendations regarding directions for future open source bio projects.

I. THE ELEMENTS OF OPEN SOURCE

As Andrew Katz has aptly observed, "[o]penness abounds" in modern society.[16] There are "open" movements for everything from software and equipment to politics and democracy.[17] While distilling from this mélange a set of common principles is not easy, open source projects in software and bio loosely share a set of three characteristics that, broadly speaking, can be said to constitute the basic elements of open source development: (1) access to enabling technology (the "source code" in

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BIOTECHNOLOGY 156 (2008); Julien Pénin & Jean-Pierre Wack, *Research Tool Patents and Free-Libre Biotechnology: A Suggested Unified Framework*, 37 RSCH. POL'Y 1909 (2008); Arti K. Rai, *Critical Commentary on 'Open Source' in the Life Sciences*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 213 (Geertrui van Overwalle ed., 2009); Antony S. Taubman [sic], *Several Kinds of 'Should' The Ethics of Open Source in Life Sciences Innovation*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES, *supra*, at 219; Minna Allarakhia, *Open Source Biopharmaceutical Innovation - A Mode of Entry for Firms in Emerging Markets*, 6 J. BUS. CHEMISTRY 11, 25 (2009).

14. Stebbins et al., *supra* note 12, at 3 (the authors include Michael Stebbins, Miranda Bain, Rena Conti, Nicholaos Krenteras, Nicoleta Krenteras, Jaykumar Menon, and Bernard Munos).

15. Taubman, *supra* note 13, at 230–31.

16. Andrew Katz, *Everything Open*, *in* OPEN SOURCE LAW, POLICY AND PRACTICE 512, 512 (Amanda Brock ed., 2022).

17. *Id.* at 512–13.

OSS), (2) a liberal grant of IP rights, and (3) decentralized or distributed technology development.[18]

A. Access to Enabling Technology

A computer program's "source" code is a version of the program written in a human-readable programming language, such as C++, PERL, or Python.[19] Access to a program's source code is necessary to understand the program's logical structure, to diagnose and correct errors in the program, and to modify it. Access to source code is thus enabling—it allows the user to build upon and improve the program.[20]

But in order to run on a computer, source code is typically compiled or interpreted into machine-readable binary "object" code. Most proprietary software is licensed and distributed in object code form only, while the uncompiled source code is retained as a closely held secret by its owner.[21] It is not practical, or even possible in most cases, for a person to understand the structure of, let alone modify, executable software in object code form.[22]

Beginning in the 1970s, a group of computer programmers—self-styled hackers[23]—rebelling against the restrictive practices of their corporate and institutional employers, began to share source code with one another.[24] This informal practice began the "free software," and later the "open source software" (OSS), movements.[25] A key motivation for making source code accessible was the enhancement of a software developer's freedom to learn from, use, and create new software based on existing programs.[26] Thus, a defining characteristic of OSS is that the source code of a software program is made available, usually for free and from a publicly accessible site, and anyone has the right to read, use, and modify that source code.[27]

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18. For OSI's list of defining features of OSS, see *The Open Source Definition (Annotated)*, OPEN SOURCE INITIATIVE, https://opensource.org/definition-annotated (last updated Feb. 16, 2024) [https://perma.cc/H5Z3-QCXN].

19. *See* JORGE L. CONTRERAS, INTELLECTUAL PROPERTY LICENSING AND TRANSACTIONS: THEORY AND PRACTICE 576 (2022) (providing examples) [hereinafter CONTRERAS, LICENSING].

20. *Id.* at 575–76.

21. *Id.* at 577.

22. *Id.*

23. *See* STEVEN LEVY, HACKERS: HEROES OF THE COMPUTER REVOLUTION 23–24 (1984) (defining the "hacker ethic" as "anything that might teach you something about the way the world works - should be unlimited and total").

24. *See* Richard Stallman, *The GNU Operating System and the Free Software Movement*, *in* OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION 53, 57, 60 (Chris DiBona, Sam Ockman & Mark Stone eds., 1999).

25. For the distinction between free software and open source software, see *infra* notes 185–86 and accompanying text.

26. I have previously referred to this as the programmer's liberty-based interest. Jorge L. Contreras, *The Evolution of Open Source Biotech – From Liberty to Justice*, *in* A HUMAN-CENTERED APPROACH TO HEALTH INNOVATIONS: RECONCILING INTELLECTUAL PROPERTY WITH HUMAN RIGHTS (Lisa Biersay, Thomas Pogge & Peter Yu eds., forthcoming 2025) [hereinafter Contreras, *Liberty to Justice*].

27. *Id.*

Life sciences projects also include a range of technologies that are needed to enable others to understand and advance a particular line of research. Enabling technologies in the life sciences can include software, and many life science researchers already use and develop OSS in their labs.[28] As artificial intelligence models continue to grow in sophistication and "in silico" testing of compounds becomes increasingly practical, open source bio will increasingly merge with OSS. But these are traditional OSS projects that need not be analyzed under the new rubric of open source bio.

Likewise, many life sciences labs regularly make large quantities of data available to the public, and the production of "open data" in the sciences has evolved from a voluntary laboratory practice to a binding federal policy.[29] In this tradition, the Human Genome Project released all of its genomic sequence data to public databases soon after it was generated,[30] a practice that continues to represent a norm in genomics and related fields.[31]

But scientific data represents a particular state of the world measured at a particular point in time: the amount of carbon in the air over Denver on a given day or the rate at which a drug is metabolized by a patient carrying a particular genetic variant. While essential to understanding scientific phenomena, data is not (or *should* not be) manipulated, altered, or improved upon in the same way as software. As such,

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28. *See* Allarakhia, *supra* note 13, at 16–17. Many early proponents of open source bio were themselves computer and data scientists who turned their attention to the emerging fields of bioinformatics and computational biology. *See* David Singh Grewal, *Before Peer Production: Infrastructure Gaps and the Architecture of Openness in Synthetic Biology*, 20 STAN. TECH. L. REV. 143, 147–48 (2017); Munos, *supra* note 13, at 724; Rai, *Open and Collaborative, supra* note 13. As explained by Maurer et al., "computing and computational biology are converging. In the same way that programmers find bugs and write patches, biologists look for proteins ('targets') and select chemicals ('drug candidates') that bind to them and affect their behavior in desirable ways. In both cases, research consists of finding and fixing tiny problems hidden in an ocean of code." Maurer et al., *supra* note 13, at 171.

29. In 2013, the U.S. Office of Science and Technology Policy (OSTP) directed all federal agencies with research budgets in excess of $100 million "to develop a plan to support increased public access to the results of research funded by the Federal Government." Memorandum from John P. Holdren, Dir., Exec. Off. of the President, Off. of Sci. & Tech. Pol'y, to the Heads of Executive Departments and Agencies, Increasing Access to Results of Federally Funded Scientific Research 2 (Feb. 22, 2013). A few months later, President Obama issued an Executive Order instructing the Office of Management and Budget (OMB) to develop a federal open data policy that would ensure the availability and usability of all nonsensitive government data. Exec. Order No. 13,642, 78 Fed. Reg. 28,111 (May 9, 2013).

30. *See* Kathryn Maxson Jones, Rachel A. Ankeny & Robert Cook-Deegan, *The Bermuda Triangle: The Pragmatics, Policies, and Principles for Data Sharing in the History of the Human Genome Project*, 51 J. HIST. BIOLOGY 693, 747 tbl.1 (2018).

31. *See* Jorge L. Contreras & Bartha M. Knoppers, *The Genomic Commons*, 19 ANN. REV. GENOMICS & HUM. GENETICS 429 (2018); Jones et al., *supra* note 30, at 695–99; Jorge L. Contreras, *Bermuda's Legacy: Policy, Patents, and the Design of the Genome Commons*, 12 MINN. J.L. SCI. & TECH. 61 (2011); Jane Kaye, Catherine Heeney, Naomi Hawkins, Jantina de Vries & Paula Boddington, *Data Sharing in Genomics--Re-Shaping Scientific Practice*, 10 NATURE REVS. GENETICS 331 (2009); Toronto International Data Release Workshop Authors, *Prepublication Data Sharing*, 461 NATURE 168 (2009).

in many cases, data may function less as an enabling technology than software source code.

Biomedical research projects uniquely diverge from computer science research in their dependence on the generation, testing, manipulation, and observation of tangible biological ("wet") materials. These include reagents, tissue samples, cell lines, seeds, pathogens, model organisms, synthetic molecules, and more. Unlike digital and intangible resources, biological materials are rivalrous—they cannot be reproduced indefinitely at a negligible cost. They occupy physical space. They are often perishable and degrade over time. They may require special handling—refrigeration, fixation, humidity control, and light exposure. They are frequently subject to regulations surrounding biohazards, exports, animal welfare, and informed consent, not to mention institutional policies governing materials transfer, handling, custody, and return.

Researchers in the biological sciences have for decades shared tangible materials with colleagues.[32] In the 1940s, researchers from Oxford famously shipped mold cultures to academic and government researchers in the United States to develop penicillin.[33] Similar norms of sharing have been documented among researchers studying the *c. elegans* worm[34] and mouse genomics.[35] Yet while projects like these evidence the sharing of biological materials among researchers at different institutions and even different countries, such sharing has typically been limited to collaborators who are known to one another and are operating under a common research protocol or institutional materials transfer agreement (MTA).[36]

Thus, a key feature of "open source" bio projects is their broad sharing of enabling technologies not only in digital form but also as tangible biological materials.

B. Broad Licensing of Intellectual Property

As observed by Andrew Katz, "An evident feature of *opens* is that they are intended to remove restrictions to use (including modification and reuse) and

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32. *See* HOPE, *supra* note 13, at 212 (describing informal sharing of research materials by biologists).

33. Roswell Quinn, *Rethinking Antibiotic Research and Development: World War II and the Penicillin Collaborative*, 103 AM. J. PUB. HEALTH 426, 427 (2013). *See also* GRAHAM DUTFIELD, THAT HIGH DESIGN OF PUREST GOLD: A CRITICAL HISTORY OF THE PHARMACEUTICAL INDUSTRY, 1880-2020 250–52 (2020).

34. *See* Jones et al., *supra* note 30, at 708–10.

35. Paul N. Schofield, Tania Bubela, Thomas Weaver, Lili Portilla, Stephen D. Brown, John M. Hancock, David Einhorn, Glauco Tocchini-Valentini, Martin Hrabe de Angelis & Nadia Rosenthal, *Post-Publication Sharing of Data and Tools*, 461 NATURE 171, 171 (2009) (noting need for improvement of sharing practices).

36. *See* CONTRERAS, LICENSING, *supra* note 19, at 451–55. One important point to note about materials sharing is that it is usually conducted with respect to nonhuman biological samples: seeds, model organisms, pathogens, synthetic DNA constructs, reagents, and the like. The sharing of human samples, even ones that have been "de-identified," introduces numerous legal and ethical complications that have generally limited this practice to collaborating laboratories operating under a common institutional review board (IRB) protocol.

access."[37] In other words, open source projects generally make their output broadly available to users and permit the adaptation of that output for the user's purposes. Thus, OSS developers, who retain the copyright in their software code,[38] grant licenses to anyone who wishes to use, modify, or distribute that code.[39] These licenses are typically granted via self-executing, publicly accessible agreements that become effective when the user downloads or uses the software, much like consumer shrinkwrap or clickwrap agreements.[40] These legal instruments have been termed public licenses,[41] and their enforceability has been validated by courts both in the United States and Europe.[42]

One of the best known and most widely deployed OSS license is the GNU General Public License (GPL).[43] The GPL, first designed by computer hacker Richard Stallman, is intended to preserve the right of software developers to modify software source code and thus imposes strict requirements on those who download and modify code licensed under the GPL.[44] In short, if software code is licensed under the GPL, then anyone who redistributes that code, or any modified version of that code, or any larger program into which that code has been incorporated, must distribute it under the GPL.[45] Thus, like a biological virus, the GPL propagates itself from user to user, program to program. Richard Stallman coined the term "copyleft" (the opposite of "all rights reserved" copyright) to describe the licensing strategy embodied by the GPL.[46]

Many corporate users considered the copyleft provisions of the GPL to be undesirable because GPL code could theoretically infect any proprietary code with which it is combined, making the entire combined work (i.e., both the open source and the proprietary code) available on an open source basis.[47] As a result, alternative OSS licenses that impose fewer restrictions on users have emerged over the years. Among the most popular of these are the BSD license, the MIT License, the Mozilla Public License, and the Apache Public License.[48]

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37. Katz, *supra* note 16, at 513 (emphasis in the original).

38. OSS is not contributed to the "public domain." *See* Stallman, *supra* note 24, at 58–59.

39. *What Is Open Source?*, OPENSOURCE.COM, https://opensource.com/resources/what-open-source [https://perma.cc/DW7W-QHC6].

40. *See* CONTRERAS, LICENSING, *supra* note 19, at 592.

41. *Id.*

42. *See* Heather J. Meeker, *Open Source and the Age of Enforcement*, 4 HASTINGS SCI. & TECH. L.J. 267 (2012).

43. *GNU General Public License*, GNU OPERATING SYS., https://www.gnu.org/licenses/gpl-3.0.en.html (last updated June 29, 2007) [https://perma.cc/WD8L-EJ8U] [hereinafter GPL v3.0].

44. *See* CONTRERAS, LICENSING, *supra* note 19, at 608–09.

45. This structure is referred to as "ShareAlike" by the Creative Commons licenses. *See id.* at 595–96.

46. Stallman, *supra* note 24, at 59.

47. *See* CONTRERAS, LICENSING, *supra* note 19, at 609–10 (discussing the "viral" nature of GPL and the perceived threat to commercial software).

48. *Open Source Licenses by Category*, OPEN SOURCE INITIATIVE, https://opensource.org/licenses/category (last updated Nov. 2, 2022) [https://perma.cc/S7PJ-G9LQ].

Though most OSS licenses grant rights primarily under the copyrights in computer code, some address patent issues as well. For example, the GPL and Mozilla licenses require a contributor to an OSS program to grant users a license under its patents that claim any portion of the program, even if originally written by somebody else.[49] In contrast, the Apache OSS license requires a contributor to grant users licenses under the contributor's patents, but only with respect to its own contributions to the OSS program, and not contributions made by others.[50]

Patents have been a staple feature of the life science research landscape since at least the late nineteenth century.[51] Nevertheless, there has long been a degree of ethical and professional unease among medical researchers and practitioners at the award of exclusive rights to discoveries that have the potential to cure disease, alleviate suffering, and improve human health.[52] But it was not until the confluence of two major events in the 1980s and 1990s that "access to medicines"—and the access barriers that patents could create—became a global concern:[53] the AIDS epidemic and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[54] The former made it clear that the latest medical discoveries were needed by populations around the world, and the latter required countries, rich and poor, to adopt protective IP regimes that permitted drug companies to exercise exclusive rights in their products globally. The high cost of lifesaving drugs in even the poorest countries led to public calls to enable generic drug manufacturers to enter the market and supply drugs at a lower cost.[55]

Open source bio projects have, to a degree, arisen in response to these considerations. That is, their granting of broad, public rights to use the IP underlying scientific discoveries enables less costly manufacturing and distribution of life science products and, in turn, more affordable access to those products by populations around the globe. In prior work, I have characterized this aspect of open source bio as one grounded in distributive justice.[56]

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49. *See* GPL v3.0, *supra* note 43, § 11, para. 3.

50. *See Apache License, Version 2.0*, APACHE SOFTWARE FOUND. (Jan. 2004), https://www.apache.org/licenses/LICENSE-2.0 [https://perma.cc/H8H5-N25V].

51. *See* DUTFIELD, *supra* note 33, at 174–203; Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV. 257, 282–83 (2013).

52. *See* DUTFIELD, *supra* note 33, at 164; Beauchamp, *supra* note 51, at 282; Katherine J. Strandburg, *Derogatory to Professional Character? The Evolution of Physician Anti-Patenting Norms*, *in* CREATIVITY WITHOUT LAW: CHALLENGING THE ASSUMPTIONS OF INTELLECTUAL PROPERTY (Kate Darling & Aaron Perzanowski eds., 2017).

53. *See* Ellen 't Hoen, *The Revised Drug Strategy: Access to Essential Medicines, Intellectual Property, and the World Health Organization*, *in* ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY 127, 127 (Gaëlle Krikorian & Amy Kapczynski eds., 2010); Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, 3 INNOVATION POL'Y & ECON. 91, 92–93 (2003).

54. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

55. *See* 't Hoen, *supra* note 53, at 131–32.

56. Contreras, *Liberty to Justice*, *supra* note 26.

C. Decentralized Development

Early OSS developers found that releasing their source code encouraged others to modify it and then share those modifications with the original developers. Self-organized communities of developers emerged around different OSS programs, leading to the rapid growth and improvement of those programs. As Eric Raymond, one of the founders of the OSS movement, observed in his seminal work *The Cathedral and the Bazaar*, "[W]hile coding remains an essentially solitary activity, the really great hacks come from harnessing the attention and brainpower of entire communities."[57] Raymond analogizes OSS development to the chaotic yet commercially effective environment of "a great babbling bazaar,"[58] a system that he contrasts with the highly structured and regimented "cathedral" environment that characterized software development within corporate organizations.[59] Later theorists have termed the OSS-distributed model of technology development "peer production."[60]

Yet not all OSS projects are chaotic and freewheeling bazaars; many of the largest and most successful OSS projects have evolved formalized hierarchies and managerial structures. There must be a leader to decide which modifications submitted by masses of independent developers will be accepted into the canonical code base and which will not. Raymond characterizes this as a "benevolent dictator" model, and it has led to the success of projects as large as the Linux kernel (famously led and overseen by Linus Torvalds).[61]

One form of directed peer production has come to be known as crowdsourcing, the practice of "outsourcing a task to a 'crowd,' which is generally a distributed group of often unknown participants."[62] Unlike an ongoing OSS project that takes advantage of distributed peer production, crowdsourcing usually connotes a more discrete task that is assigned without regard to community formation or continuity of engagement.[63]

Both distributed development and crowdsourcing approaches have been used in open source bio projects, as illustrated by the examples in Part II.

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57. ERIC S. RAYMOND, THE CATHEDRAL AND THE BAZAAR 62 (1999).

58. *Id.* at 30; *see also* HOPE, *supra* note 13, at 109 (OSS development "is an example of spontaneous, decentralized ordering of transactions.").

59. RAYMOND, *supra* note 57, at 29 ("I believed that the most important software . . . needed to be built like cathedrals, carefully crafted by individual wizards or small bands of mages working in splendid isolation . . . .").

60. *See* YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 62 (2006) ("[S]ystems that depend on individual action that is self-selected and decentralized, rather than hierarchically assigned.").

61. RAYMOND, *supra* note 57, at 123–25.

62. Katherine M. A. Reilly & Matthew L. Smith, *The Emergence of Open Development in a Network Society*, *in* OPEN DEVELOPMENT: NETWORKED INNOVATIONS IN INTERNATIONAL DEVELOPMENT 15, 27 (Matthew L. Smith & Katherine M. A. Reilly eds., 2013).

63. *Id.*

II. THE LANDSCAPE OF OPEN SOURCE BIO

This Part describes twelve past and current life science research projects that have been characterized, by themselves or others, as "open source."[64] An analysis and comparison of these projects follows.

A. International Genetically Engineered Machine (iGEM) Competition

One of the first open source bio projects arose in the field of synthetic biology—the creation of interchangeable biochemical "parts" from DNA sequences that encode for specific biological functions[65] (synthetic biology was itself referred to in the late 1990s as "open source biology").[66] In 2003, a group of MIT faculty taught a seminar in which students were required to design synthetic biology parts.[67] The next year, MIT reframed this activity as a competition among students from MIT and four other U.S. universities, which they named the International Genetically Engineered Machine (iGEM) competition.[68] Competition entries were collected and cataloged by the organizers and combined with existing biological parts to form the Registry of Standard Biological Parts.[69] The next year, DNA samples from the Registry were distributed to the competing teams.[70] In 2023, the competition included over 400 teams from forty-five countries,[71] and the Registry currently contains more than 75,000 biological parts.[72] In 2024, iGEM discontinued the collection of DNA samples from competing teams, who are now only required to submit digital DNA sequence information, which can easily be synthesized by commercial partners.[73]

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64. The projects selected for analysis were identified using online searches for "open source" and related terms in connection with biological research projects. Only projects implemented in the field are discussed. Academic proposals, such as the Tropical Disease Initiative (TDI) discussed in Maurer et al., *supra* note 13, while valuable contributions to the literature, are not reviewed. This Article does not aspire to be comprehensive in its coverage. For one early census of open source bio projects, see Minna Allarakhia, D. Marc Kilgour & J. David Fuller, *Modelling the Incentive to Participate in Open Source Biopharmaceutical Innovation*, 40 R&D MGMT. 50 (2009) (cataloging 39 different biopharmaceutical research projects meeting the authors' definition of "open source").

65. *See* Grewal, *supra* note 28, at 152–53.

66. Luis Campos, *The BioBrick™ Road*, 7 BIOSOCIETIES 115, 117 (2012).

67. *See* Linda Kahl, *What is iGEM? (Part 3): Insights from iGEM's History*, IGEM BLOG, https://blog.igem.org/blog/2019/9/18/what-is-igem-part-3 (last updated June 7, 2023) [https://perma.cc/JN4S-VSUC].

68. *See id.*; Christina D. Smolke, *Building Outside of the Box: iGEM and the BioBricks Foundation*, 27 NATURE BIOTECHNOLOGY 1099 (2009).

69. Kahl, *supra* note 67.

70. *Id.*

71. *Celebrating 20 years of iGEM at the 2023 Grand Jamboree*, IGEM BLOG (Nov. 8, 2023), https://blog.igem.org/blog/2023/11/8/celebrating-20-years-of-igem-at-the-2023-grand-jamboree [https://perma.cc/BPM2-M93M].

72. *The Heart of Synthetic Biology*, IGEM, https://igem.org [https://perma.cc/W7UA-DYW5].

73. *DNA Submission*, REGISTRY OF STANDARD BIOLOGICAL PARTS, https://parts.igem.org/DNA_Submission [https://perma.cc/PT67-B5DX].

Nevertheless, iGEM continues to send each team a kit containing over 1000 DNA samples that may be used for educational and competition purposes.[74]

To compete, teams are required to agree to the program's "Get & Give (& Share)" policy, which is explained as follows:

> The Registry is an open community that runs and grows on the "Get & Give (& Share)" philosophy. Users get parts, samples, data, and tools from the Registry to work on their synthetic biology projects. They'll give back to the Registry the new parts they've made, as well as data and experience on new and existing parts. Finally, users will share experience and collaborate in the Registry's open community through their wikis, the forums, and other social tools.[75]

As such, the Registry operates on an informal, open source basis, though without a formal contractual basis. iGEM is reported to share biological parts from the Registry with academic researchers upon request, also without formal agreements.[76]

B. BioBricks Foundation

Encouraged by the success of the iGEM competition, several of the same researchers at MIT helped to create the independent BioBricks Foundation to promote the use of standardized biological parts, or "biobricks," more broadly.[77] The Foundation promoted standardization efforts relating to biological parts, the creation and maintenance of a public repository for parts (a "synthetic biology commons"),[78] and the development of formal licensing agreements for contributing parts to the repository.[79]

The licensing framework adopted by the Foundation in 2010 owes much to the GPL and other OSS licenses, though it lacks the "copyleft" features of the GPL.[80] Specifically, each contributor to the Repository must agree not to assert patents, copyrights, or other IP rights against any use of the contributed part, and each user of a part must acknowledge the original contributor when redistributing that part.[81]

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74. *The iGEM Distribution 2.0*, IGEM, https://technology.igem.org/distribution [https://perma.cc/SD4H-D7EQ].

75. *Help: Philosophy*, REGISTRY OF STANDARD BIOLOGICAL PARTS (emphasis omitted), https://parts.igem.org/Help:Philosophy [https://perma.cc/7RR7-Z5UU]; *see* Vinoo Selvarajah, Abigail Sison & Linda Kahl, *A Look Back on the History of the iGEM Distribution*, IGEM BLOG, (Apr. 19, 2023), https://blog.igem.org/blog/2023/4/19/a-look-back-on-the-history-of-the-igem-distribution [https://perma.cc/8KWL-36PB].

76. *See* Jane Nielsen et al., *Provenance and Risk in Transfer of Biological Materials*, 16 PLOS BIOLOGY 1, 4 (2018).

77. Campos, *supra* note 66, at 118–21.

78. Arti Rai & James Boyle, *Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons*, 5 PLOS BIOLOGY 389, 391 (2007).

79. *See* Grewal, *supra* note 28, at 174–87 (history of BioBricks Foundation); Campos, *supra* note 66.

80. *See* Grewal, *supra* note 28, at 174–87 (detailed discussion of the development of the Biobrick agreements and comparison to GPL).

81. *The BioBrick™ Contributor Agreement, Version 1 (January 2010)*, BIOBRICKS

Unlike the iGEM Registry, the BioBricks repository has received few contributions.[82] David Campos describes resistance to the registry's open source, public domain nature by corporate researchers, noting the emergence of alternative synthetic biology registries that are more protective of contributors' IP.[83] Thus, while the iGEM student competition continues to thrive, its commercial counterpart seems to have achieved little uptake.

C. Biological Innovation for Open Society (BiOS)

The Biological Innovation for Open Society (BiOS) initiative, launched in 2003 by the Center for the Application for Molecular Biology to International Agriculture (CAMBIA) in Canberra, Australia, was an early open source bio project focused on agricultural genomics.[84] To facilitate collaborative development, BiOS created an open web platform called BioForge that was based on the popular SourceForge OSS development platform.[85] The first technology that CAMBIA made available through BioForge was Transbacter, a tool that enabled the transfer of genes into plant DNA using modified bacterial vectors.[86] Transbacter was intended as an alternative to gene transfer technology that used the patented Agrobacterium.[87]

BiOS distributed Transbacter, together with associated reagent kits, at no cost to users around the world.[88] Recipients were required to enter into a GPL-based license that required them to share improvements to the Transbacter technology with, and not to assert IP rights against, other users.[89] An associated technology support agreement also required for-profit companies to pay a fee based on their location and size.[90]

FOUND., https://biobricks.org/wp-content/themes/bbf2016/bpa-sample.php [https://perma.cc/NA7Q-QBS9]. The BioBrick agreements currently reside at *Users*, BIOBRICKS FOUND., https://biobricks.org/bpa/users/ [https://perma.cc/N6WG-4TGR].

82. As of August 27, 2024, there were only thirty-seven contributions to the BioBrick registry. *See Find a Part*, BIOBRICKS FOUND., https://biobricks.org/bpa/find-a-part/ [https://perma.cc/RW9F-LR39] (search conducted by author).

83. Campos, *supra* note 66, at 123–24.

84. *See* Carina Dennis, *Biologists Launch 'Open-Source Movement'*, 431 NATURE 494 (2004).

85. Richard Jefferson, *Science as Social Enterprise: The CAMBIA BiOS Initiative*, INNOVATIONS: TECH., GOVERNANCE, GLOBALIZATION, Fall 2006, at 13, 31.

86. *Id.* at 34–37. Eventually, BiOS hoped to expand its activities to a wide range of life science innovations, including plant and animal-breeding tools, genetic resources, human therapeutics, and environmental technologies. *See* Dennis, *supra* note 84.

87. *See* Nele Berthels, *Case 8. CAMBIA's Biological Open Source Initiative (BiOS)*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES, *supra* note 13, at 194, 198.

88. Jefferson, *supra* note 85, at 27, 37.

89. *Id.* at 29–30; Berthels, *supra* note 87, at 199–200 ("[I]mprovements made to enabling technology – which are protected by IP – are shared among other BiOS licensees, but the products or materials made, created or obtained by using an enabling technology, do not fall under this provision.").

90. Hassan Masum, Karl Schroeder, Myra Khan & Abdallah S. Daar, *Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies*, *in* OPEN

Transbacter was licensed to more than fifty companies in the agricultural genetics industry, including Monsanto, Dupont, Pioneer, Bayer, BASF, and Syngenta. But while corporate users were willing to use the technology, a collaborative development community, such as those seen in the OSS area, never emerged around Transbacter or any other technology on BioForge.[91] As a result, few additional projects were initiated, and the platform has largely faded from view, with CAMBIA shifting its focus to a patent searching tool for biotechnology inventions.[92]

D. Open Source Seed Initiative (OSSI)

As noted by Keith Aoki, between the 1980s and the 1990s, the treatment of plant genetic resources shifted from a view of these resources as a "common heritage" of mankind to a view that they constitute "sovereign property."[93] As a result, plant breeders and farmers have become increasingly constrained in their ability to access seed varieties (germplasm) bearing new traits.[94] While some germplasm is freely available without restriction from the U.S. National Plant Germplasm System (NPGS), germplasm containing the most advanced and desirable traits is no longer available from the NPGS.[95] Moreover, given that NPGS releases germplasm without any restrictions whatsoever, breeders who obtain NPGS germplasm are free to develop slight improvements that they can then protect with their own IP, thereby limiting access over the long term.[96]

In response to this situation, the Open Source Seed Initiative (OSSI) was launched in 2014 by a group of plant breeders, farmers, seed companies, nonprofit organizations, and policymakers with the goal of "promoting and maintaining open access to plant genetic resources worldwide."[97] OSSI initially released thirty-seven cultivars of fourteen crop species under an open source "pledge" that states the following:

> You have the freedom to use these OSSI seeds in any way you choose. In return, you pledge not to restrict others' use of these seeds or their

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DEVELOPMENT: NETWORKED INNOVATIONS IN INTERNATIONAL DEVELOPMENT, *supra* note 62, at 113, 116; Berthels, *supra* note 87, at 201.

91. Jefferson, *supra* note 85, at 32 (characterizing group engagement with the project as "miniscule"); *see also* Masum et al., *supra* note 90, at 117–18 (discussing low usage of BioForge).

92. *See* Masum et al., *supra* note 90, at 118–19.

93. Keith Aoki, *"Free Seeds, Not Free Beer": Participatory Plant Breeding, Open Source Seeds, and Acknowledging User Innovation in Agriculture*, 77 FORDHAM L. REV. 2275, 2275 (2009).

94. *See* Claire H. Luby, Jack Kloppenburg, Thomas E. Michaels & Irwin L. Goldman, *Enhancing Freedom to Operate for Plant Breeders and Farmers through Open Source Plant Breeding*, 55 CROP SCI. 2481 (2015).

95. *Id.* at 2484.

96. *Id.* at 2484–85.

97. *Id.* at 2485. This effort was long in germinating. The first proposed OSS-inspired license for plant germplasm was released in 1999 by Tom Michaels, at the Ontario Agricultural College, University of Guelph. *See* HOPE, *supra* note 13, at 304–07; Luby et al., *supra* note 94, at 2485.

> derivatives by patents, licenses or other means, and to include this Pledge with any transfer of these seeds or their derivatives.[98]

By requiring that recipients of its seeds commit to abide by these "share-alike" terms, OSSI seeks both to ensure that the germplasm that it distributes remains accessible to all, and that subsequent users do not capture important traits with their own IP. Nevertheless, the OSSI pledge approach has been criticized as lacking in legal enforceability,[99] thereby placing germplasm into what has been termed an 'unprotected commons' where improvements are subject to appropriation by private interests.[100] As such, some authors have questioned whether existing legal protections for plant breeders in many countries (so-called "plant breeders rights") may already be sufficient to achieve the flexibility that is desired by OSSI.[101] In any event, it is not yet clear whether the OSSI approach has gained appreciable uptake in the market.[102]

E. Addgene

By the early 2000s, the administrative burden on individual labs of sharing biological materials[103] led to the emergence of intermediary clearinghouses, the most prominent of which is Addgene. Launched in 2004, Addgene is a nonprofit entity that stores DNA plasmids[104] and other biological materials on behalf of laboratories and then provides samples of those materials to other laboratories that request them.

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98. Luby et al., *supra* note 94, at 2486. It is notable that OSSI had previously engaged a law firm to develop a formal licensing agreement but found the agreement to be too lengthy and complex for its intended audience. *Id.*

99. While commentators have questioned the enforceability of OSSI's pledge (*see* Luby et al., *supra* note 94, at 2486 ("The OSSI Pledge will function analogously to an open source software license, although it is likely not legally enforceable."); MICHAEL ANDREAS KOCK, INTELLECTUAL PROPERTY PROTECTION FOR PLANT RELATED INNOVATION: FIT FOR FUTURE? 227 (2022) ("The pledge—although legally hardly enforceable—is intended to create a moral obligation.")), there are various theories under which pledges such as this could be recognized as legally enforceable obligations. *See* Jorge L. Contreras, *Patent Pledges as Portfolio Management Tools: Benefits, Obligations and Enforcement*, *in* A MODERN GUIDE TO PATENTING: CHALLENGES OF PATENTING IN THE 21ST CENTURY (Nikolaus Thumm & Knut Blind eds., forthcoming 2025).

100. KOCK, *supra* note 99, at 228; Niels Louwaars, *Open Source Seed, a Revolution in Breeding or Yet Another Attack on the Breeder's Exemption*? 10 FRONTIERS IN PLANT SCI. 1, 5 (2019).

101. Louwaars, *supra* note 100, at 6 ("If it is the intent to create openness toward genetic resources, then the breeder's exemption in the plant breeder's rights system, which is the dominant protection system in almost all countries already, fulfils these needs. . . .").

102. *Id.* at 2.

103. *See* Andy Tay, *Share and Share Alike*, 625 NATURE 841, 842 (2024).

104. *See Plasmid*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/Plasmid (last updated Feb. 28, 2025) [https://perma.cc/77GW-V9QT] ("A plasmid is a small circular DNA molecule found in bacteria and some other microscopic organisms. . . . Scientists use recombinant DNA methods to splice genes that they want to study into a plasmid. When the plasmid copies itself, it also makes copies of the inserted gene.").

Addgene charges between $85 and $250 per plasmid, depending on the sample size, type, and whether the requester is a nonprofit or for-profit entity.[105] As of August 2024, Addgene advertised that it holds nearly 150,000 different plasmids on behalf of more than 6000 laboratories, and that it has shipped more than two million orders to more than a hundred different countries.[106]

Addgene, as a clearinghouse for biological materials, makes no representations or warranties about the materials that it distributes. Instead, it has automated a process for enabling a providing laboratory and a requesting laboratory to enter into a standardized materials transfer agreement (MTA) covering the materials.[107] Three varieties of MTA are currently offered: nonprofit, for-profit, and OpenMTA. The nonprofit and for-profit MTAs restrict the recipient in numerous ways, including by limiting its use of materials to internal research, prohibiting transfers of the material, requiring the recipient to notify the providing lab if it files a patent application covering a modification or method of manufacturing the material, and prohibiting the recipient from charging for modifications of the material (other than a reasonable shipping and handling fee).[108] The OpenMTA, which was added recently, lacks most of these restrictions but must be requested specifically by the providing laboratory.[109]

Notably, none of the Addgene MTAs include an IP license or commitment. Thus, the user of Addgene material is required to obtain a separate license under any patents held by the material owner.[110]

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105. *See Where Can I Find Pricing Information?*, ADDGENE, https://help.addgene.org/hc/en-us/articles/206133505-Where-can-I-find-pricing-information [https://perma.cc/Q5VC-4CNJ]. Until recently, Addgene only made materials available to nonprofit entities, a practice that limited its scope. *See* Linda Kahl, Jennifer Molloy, Nicola Patron, Colette Matthewman, Jim Haseloff, David Grewal, Richard Johnson & Drew Endy, *Opening Options for Material Transfer*, 36 NATURE BIOTECHNOLOGY 923, 924 (2018).

106. ADDGENE, https://www.addgene.org [https://perma.cc/T227-G4HC].

107. *How Do I Place an Order? Does Addgene Accept Orders by Fax, Phone or Email?*, ADDGENE, https://help.addgene.org/hc/en-us/articles/205436319-How-do-I-place-an-order-Does-Addgene-accept-orders-by-fax-phone-or-email.

108. *See Technology Transfer Overview*, ADDGENE, https://www.addgene.org/techtransfer/#request-process [https://perma.cc/Y4Q5-VD3W] [hereinafter *Addgene Sample Documents*].

109. *See What Is the OpenMTA?*, ADDGENE https://help.addgene.org/hc/en-us/articles/360042153872-What-is-the-OpenMTA [https://perma.cc/HM8A-KBFY] ("If you are interested in potentially making your materials available under the OpenMTA to your colleagues in both industry and academia to be used for any lawful purpose, including commercial purposes, please inform your technology transfer or other legal office of your interest and have them contact techtransfer@addgene.org to initiate the requisite deposit agreements.") (emphasis omitted)).

110. The Addgene Nonprofit and For-profit MTAs grant licenses only for internal research use and disclaim any implied licenses. *See Addgene Sample Documents*, *supra* note 108. The OpenMTA is more permissive and appears to authorize commercial use and sale of materials. Nevertheless, even its authors discourage its use with patented materials. *See* Kahl et al., *supra* note 105, at 926 (suggesting that OpenMTA is most suitable for use with unpatented materials or those for which patents have expired).

F. Center for Regenerative Medicine (CReM)

Around 2012, the Center for Regenerative Medicine (CReM) at Boston University initiated a program that it referred to as Open Source Biology, which it defines as "the sharing of reagents, ideas, databases and expertise without boundaries or exclusivity."[111] While CReM originally sent biological materials to requesting laboratories at no charge, it recently added an administrative charge of $600 to such shipments, reportedly at the suggestion of its federal grant funder.[112]

CReM distributes stem cells and other biological materials pursuant to a signed MTA that limits their usage to internal, noncommercial research and prohibits further transfers.[113] Boston University and CReM have not made public commitments regarding patents but have represented that they typically license patents covering CReM's research on a nonexclusive basis.[114]

G. Medicines for Malaria Venture (MMV) Open Boxes

The Medicines for Malaria Venture (MMV) is a Geneva-based nonprofit organization that was formed in 1999 to support research on antimalarial drugs.[115] In addition to funding malaria research at nonprofit and for-profit laboratories, MMV has made available a number of research tools known as "boxes" to the disease research community.

An MMV box is a library of known chemical compounds that have demonstrated some level of activity against a particular pathogen, together with associated metabolic, pharmacokinetic, and safety data.[116] These compounds, which have been chemically characterized and, in some cases, undergone testing and various stages of regulatory review, are useful both to develop drugs targeting the pathogen and to investigate potential activity against other diseases (so-called drug repurposing).[117]

MMV created its Malaria Box in 2011 with 400 compounds found to be active against malaria.[118] Between 2011 and 2015, MMV provided more than 250 Malaria Boxes free of charge to researchers around the world.[119] In 2015, MMV launched a

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111. *Welcome to the CReM*, CTR. FOR REGENERATIVE MED., https://crem.bu.edu/about-us/ [https://perma.cc/5SHC-5BWX].

112. *See* Contreras, *Liberty to Justice, supra* note 26.

113. BU/BMCC Ctr. for Regenerative Med., Induced Pluripotent Stem (iPS) Cell Material Transfer Agreement – US Transfer ONLY (June. 8, 2016) (on file with author).

114. *See* Contreras, *Liberty to Justice, supra* note 26.

115. *See Our History*, MEDS. FOR MALARIA VENTURE, https://www.mmv.org/about-us/what-we-do/our-history [https://perma.cc/WFP6-L4WC].

116. *See* Thomas Spangenberg, Jeremy N. Burrows, Paul Kowalczyk, Simon McDonald, Timothy N. C. Wells & Paul Willis, *The Open Access Malaria Box: A Drug Discovery Catalyst for Neglected Diseases,* 8 PLOS ONE 1, 1–2 (2013).

117. *See id.*

118. *See id.*; Wesley C. Van Voorhis et al., *Open Source Drug Discovery with the Malaria Box Compound Collection for Neglected Diseases and Beyond*, 12 PLOS PATHOGENS 1, 5 (2016).

119. MEDS. FOR MALARIA VENTURE, ANNUAL REPORT 2016, at 27 [hereinafter MMV 2016 ANNUAL REPORT].

Pathogen Box containing compounds that targeted a broader range of diseases[120] and distributed nearly 320 of these through 2019.[121] In 2019, shortly before the COVID-19 pandemic, MMV, in partnership with the Drugs for Neglected Diseases initiative (DNDi), launched a Pandemic Response Box targeting diseases including Zika and Ebola,[122] and more recently launched a COVID Box.[123]

While MMV distributes its boxes free of charge to any researcher deemed to have a legitimate use, it also stipulates in its Terms of Use that "[b]ox recipients are expected to share data resulting from research on the molecules from the box in the public domain within 2 years of its generation."[124] This approach thus creates a hybrid ShareAlike commitment:[125] A researcher obtains a free set of biological *materials* and is in turn required to release resulting *data* to the public.

H. Open Source Malaria (OSM)

In 2011, researchers in Sydney, working with international collaborators, launched the Open Source Malaria (OSM) project with funding from MMV. The project's goal was "taking public domain compounds that have shown good activity in killing the malaria parasite in cells and improving the properties of those molecules in order to discover a compound that can enter Phase I clinical trials."[126] The project has identified potentially useful therapeutic compounds, as reflected in several scientific publications.[127] As of 2019, over 300 individuals participated in four project campaigns.[128]

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120. *Id.* at 26.

121. MEDS. FOR MALARIA VENTURE, ANNUAL REPORT 2019, at 9 [hereinafter MMV 2019 ANNUAL REPORT].

122. *Id.* at 35.

123. *About the COVID Box*, MEDS. FOR MALARIA VENTURE, https://www.mmv.org/mmv-open/covid-box/about-covid-box [https://perma.cc/6BQF-JTPL].

124. *Pandemic Response Box Supporting Information*, MEDS. FOR MALARIA VENTURE, https://www.mmv.org/mmv-open/pandemic-response-box/pandemic-response-box-supporting-information [https://perma.cc/4E3P-KPHB]; *see, e.g.*, *Malaria Box Terms & Conditions*, MEDS. FOR MALARIA VENTURE, https://www.mmv.org/mmv-open/malaria-box/malaria-box-terms-conditions [https://perma.cc/JQJ2-3V66] [hereinafter *MMV Terms*].

125. *See infra* note 170.

126. OpenSourceMalaria, *The Story So Far in the Open Source Malaria (OSM) Project*, OPENWETWARE, https://openwetware.org/wiki/OpenSourceMalaria:Story_so_far (last updated Jan. 20, 2014) [https://perma.cc/8A8P-JX4C]; *see also* Murray N. Robertson, Paul M. Ylioja, Alice E. Williamson, Michael Woelfle, Michael Robins, Katrina A. Badiola, Paul Willis, Piero Olliaro, Timothy N. C. Wells & Matthew H. Todd, *Open Source Drug Discovery – A Limited Tutorial*, 141 PARASITOLOGY 148, 149 (2014).

127. *See, e.g.*, Edwin G. Tse, et al., *An Open Drug Discovery Competition: Experimental Validation of Predictive Models in a Series of Novel Antimalarials*, 64 J. MED. CHEMISTRY 16,450 (2021); Alice E. Williamson et al., *Open Source Drug Discovery: Highly Potent Antimalarial Compounds Derived from the Tres Cantos Arylpyrroles*, 2 ACS CENT. SCI. 687 (2016).

128. Matthew H. Todd, *Six Laws of Open Source Drug Discovery*, 14 CHEMMEDCHEM 1804, 1805 (2019).

All OSM results are released under the Creative Commons CC-BY-3.0 license.[129] In addition, OSM has published a set of guiding principles known as the Six Laws, which encapsulate the technical, organizational, and legal philosophy of the project.[130] The Six Laws are the following:

(1) All data are open, and all ideas are shared;
(2) Anyone can take part at any level of the project;
(3) There will be no patents;
(4) Suggestions are the best form of criticism;
(5) Public discussion is much more valuable than private email;
(6) The project is bigger than, and is not owned by, any given laboratory.

What these statements may lack in legal precision, they make up for in sincerity. They also show a clear link to the underlying philosophy of the OSS movement and attempt to define both the legal and cultural aspects of a large, collaborative project.

I. Open Source Drug Discovery (OSDD)

In 2008, the Indian Council of Scientific and Industrial Research (CSIR) launched the Open Source Drug Discovery (OSDD) project to harness open source methods to identify new drug candidates for diseases including tuberculosis, malaria, and HIV.[131] To do so, it developed a web-enabled interactive open source platform on which it could post current design challenges for drug development. Then, researchers from across India could post data and proposals relevant to those challenges, with monetary incentives offered for useful contributions.[132] OSDD claims that it has involved more than 50 Indian universities in more than 100 research projects and has identified more than 60 potential drug targets.[133] Among OSDD's accomplishments, a 2012 Norwegian study lists its curation of a re-annotation of *Mycobacterium* tuberculosis genome, generation of eleven models for prediction of antituberculosis activity, and creation of a chemical repository of small molecules.[134]

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129. The CC suite of licenses, which were designed for online content rather than new technologies, grants the user rights in copyrights but remains silent regarding patents. *See Attribution 3.0 Unreported*, CREATIVE COMMONS, https://creativecommons.org/licenses/by/3.0/legalcode [https://perma.cc/LH6C-6KPM]. The CC-BY-3.0 license permits free use and redistribution of the licensed content, provided that the original copyright owner(s) are acknowledged.

130. Robertson et al., *supra* note 126, at 149; Todd, *supra* note 128, at 1805.

131. Seema Singh, *India Takes an Open Source Approach to Drug Discovery*, 133 CELL 201 (2008); Anshu Bhardwaj et al., *Open source Drug Discovery—A New Paradigm of Collaborative Research in Tuberculosis Drug Development*, 91 TUBERCULOSIS 479 (2011).

132. Singh, *supra* note 131, at 201. *But see* Christine Årdal & John-Arne Røttingen, *Open Source Drug Discovery in Practice: A Case Study*, 6 PLOS NEGLECTED TROPICAL DISEASES 1, 9 (2012) (characterizing OSDD as a "highly successful crowdsourcing project" rather than an open source project).

133. *History of OSPF*, OPEN SOURCE PHARMA FOUND., https://www.ospfound.org/about.html#history [https://perma.cc/PDX2-7EX8] [hereinafter *History of OSPF*].

134. Årdal & Røttingen, *supra* note 132, at 5 tbl.2.

Though OSDD retains ownership of all resulting data,[135] this data, as well as methods, procedures, algorithms, and scripts, are made available for use, reuse, and modification under an online license.[136] And though OSDD does not reject the acquisition of patents, it claims that it will seek to utilize open source techniques alongside patenting of suitable technologies.[137]

J. Open Source Pharma Foundation (OSPF)

In 2018, the Open Source Pharma Foundation (OSPF) was established as an Indian nonprofit entity that would serve as the focus for global fundraising and the coordinator of collaborative research projects emerging from OSDD, particularly in the clinical trial phase.[138] OSPF maintains a research facility in Bangalore and has recently established business offices in New York and Paris. OSPF receives funding from a number of global health philanthropies, including the Wellcome Trust, Open Society Foundation, Rockefeller Foundation, and Tata Foundation, and has collaborative relationships with governmental research agencies in India, the United States, and Brazil.[139]

To date, OSPF has co-funded (with the Indian Council of Medical Research) an Indian Phase 2b clinical trial of metformin, an existing drug that is under study for repurposing for the treatment of tuberculosis.[140] It has committed that data from this trial will be made open and publicly available, and that all IP arising from the trial will be placed in the public domain.[141]

K. COVID Moonshot Consortium

Shortly after the outbreak of the COVID-19 pandemic, a group of crystallographers, virologists, computational biologists, and medicinal chemists in the United States, United Kingdom, Israel, Ukraine, and elsewhere, with funding from the Wellcome Trust, organized an ad hoc, crowdsourced collaboration known as the COVID Moonshot Consortium to explore designs for antiviral treatments for the disease.[142] Molecular designs were solicited from around the world via an open

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135. *Id.* at 9.

136. Bhardwaj et al., *supra* note 131, at 480.

137. Masum et al., *supra* note 90, at 119 ("Brahmachari has suggested the necessity of retaining patent protection alongside open source development, rather than in opposition to it . . . .").

138. *History of OSPF*, *supra* note 133.

139. *See* Stebbins et al., *supra* note 12, at 4.

140. Chandrasekaran Padmapriydarsini et al., *Randomized Trial of Metformin with Anti-Tuberculosis Drugs for Early Sputum Conversion in Adults with Pulmonary Tuberculosis*, 75 CLINICAL INFECTIOUS DISEASES 425 (2022).

141. *Selected Key Achievements*, OPEN SOURCE PHARMA FOUND., https://www.ospfound.org/achievements.html [https://perma.cc/RN5L-WC53].

142. *See* Melissa L. Boby et al., *Open Science Discovery of Potent Noncovalent SARS-CoV-2 Main Protease Inhibitors*, 382 SCI., Nov. 2023, at 1; Frank von Delft, John Chodera, Ed Griffen, Alpha Lee, Nir London, Tatiana Matviuk, Ben Perry, Matt Robinson, Mark Calmiano & Annette von Delft, Commentary, *A White-Knuckle Ride of Open COVID Drug Discover*y, 594 NATURE 330 (2021).

online platform,[143] resulting in the submission of more than 18,000 designs (with "community" contributions roughly equivalent in quality to those of the core group).[144] All submissions to the Consortium were "made openly available, explicitly free of IP restrictions."[145] Numerous companies provided services to the group free of charge, including x-ray crystallography, compound synthesis, web hosting, and computation.[146] Ultimately, the approved antiviral *ensitrelvir* (marketed by the Japanese pharmaceutical firm Shionogi as Xocova) was identified in part based on crystallographic data generated by the Consortium.[147]

L. Texas COVID Vaccine

Early in the COVID-19 pandemic, tropical disease specialists Peter Hotez and Maria Elena Bottazzi at Texas Children's Hospital and Baylor College of Medicine led a research effort to develop a low-cost COVID-19 vaccine.[148] Approximately $7 million in funding for the project came from a variety of state, federal, and international philanthropic sources.[149] The goal of the project, said Hotez, was "to save lives, not make a profit."[150]

The resulting vaccine was not patented. Instead, the Texas institutions provided potential manufacturers in countries such as India, Bangladesh, and Indonesia with reagents, antibodies, and other seed materials necessary to manufacture the vaccine, together with extensive documentation suitable for regulatory filings.[151] These materials were provided pursuant to nonpublic, "open source" licensing agreements under which licensees agreed to make milestone and royalty payments to the Texas

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143. Boby et al., *supra* note 142, at 1–2; *Contribute Your Designs*, POSTERA, https://covid.postera.ai/submit [https://perma.cc/E26S-3ZH8].

144. Boby et al., *supra* note 142, at 1.

145. *Id.* at 2; *COVID Project FAQ / About Us*, POSTERA (Mar. 2020), https://discuss.postera.ai/t/covid-project-faq-about-us/72 [https://perma.cc/738H-2WTT] ("Will there be any intellectual property restrictions? No. All intellectual property involving identities of compounds developed under this project will be made openly available in the public domain without patent or any other form of intellectual property restrictions.").

146. Boby et al., *supra* note 142, at 14.

147. *Id.* at 6.

148. *Texas Children's Hospital Center for Vaccine Development*, BAYLOR COLL. MED., https://www.bcm.edu/departments/pediatrics/divisions-and-centers/tropical-medicine/research/vaccine-development [https://perma.cc/6BG7-UX7R].

149. Evan Bush, *From Texas to India, a Patent-Free Covid Vaccine Looks to Bridge Equity Gaps*, NBC NEWS (Jan. 7, 2022, 10:42 AM), https://www.nbcnews.com/science/science-news/texas-india-patent-free-covid-vaccine-looks-bridge-equity-gaps-rcna10911 [https://perma.cc/6SBZ-BCRT].

150. Ella Fassler, *Open-Source Vaccines Got More Funding from Tito's Vodka than the Government*, VICE (Jan. 11, 2022, 10:00 AM), https://www.vice.com/en/article/akvk9j/open-source-vaccines-got-more-funding-from-titos-vodka-than-the-government [https://perma.cc/VP9Y-RE3H] (among others, the Texas effort received funding from a local vodka distiller).

151. Contreras, *Liberty to Justice, supra* note 26.

institutions.[152] Clinical trials, regulatory approval, and manufacturing were the responsibility of the licensee.[153]

One of the Texas licensees was the Indian pharmaceutical firm Biological E. Limited (BEL). In December 2021, BEL obtained emergency usage authorization from the Indian government for CORBEVAX, a recombinant protein sub-unit vaccine developed using the Texas materials.[154] As of June 2023, BEL had manufactured approximately 100 million doses of the vaccine for distribution in India.[155] This accomplishment was, as noted in the Introduction, viewed around the world as a significant validation of open source approaches to drug development, though the Texas program, with its bilateral licensing approach and limited distribution, appears to deviate significantly from commonly understood principles of open source development.

III. COMPARISON AND ANALYSIS

A. Attributes of Open Source Bio

As noted in Part I, three general organizing principles characterize open source projects across industries:

> ***(1) Access***—enabling technology should be made broadly accessible to interested parties everywhere
> ***(2) Intellectual property*** (IP)—should not restrict the use or modification of the technology
> **(3) *Technology development***—decentralized and distributed without geographic barriers

The remainder of this Section compares each of the open source bio projects described in Part II in terms of these three principles. Table 1 briefly summarizes the different projects' approaches.

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152. *See, e.g.*, Adam Taylor, *A New Coronavirus Vaccine Heading to India Was Developed by a Small Team in Texas. It Expects Nothing in Return*, WASH. POST (Dec. 30, 2021), https://www.washingtonpost.com/world/2021/12/30/corbevax-texas-childrens-covid-vaccine/ [https://perma.cc/4GMP-A8US] ("The ambition is to create a low-cost, open-source alternative to expensive and limited-supply mRNA vaccines for developing and under-vaccinated countries."); Brett Wilkins, *Texas Team Applauded for Giving What Big Pharma Refuses: A Patent-Free Vaccine to the World*, COMMON DREAMS (Dec. 30, 2021), https://www.commondreams.org/news/2021/12/30/texas-team-applauded-giving-what-big-pharma-refuses-patent-free-vaccine-world [https://perma.cc/9J9Z-GWDC] ("Corbevax . . . is an open-source alternative to Big Pharma's patent protected vaccines.").

153. *See* Contreras, *Liberty to Justice*, *supra* note 26.

154. *CORBEVAX Gets DCGI Approval*, BIOLOGICAL E. LTD., https://www.biologicale.com/Vaccines_Biologics/products.html [https://perma.cc/P87C-WAQL].

155. Jorge L. Contreras & Kenneth C. Shadlen, *Contrasting Academic Approaches to COVID-19 Vaccine Production and Distribution: What Can the Oxford and Texas Experiences Teach Us About Pandemic Response?*, 2 HEALTH AFFS. SCHOLAR 1, 2 tbl.1 (2024) (citing Airfinity data).

Table 1: Open Source Bio Project Comparison

Project	Start Year	Enabling Technology	Access to Technology	IP	Development Mode
iGEM	2003	Synthetic biology parts	Unrestricted	Viral nonenforcement	Open uncoordinated
BioBricks	2010	Synthetic biology parts	Unrestricted	Permissive nonenforcement	Open uncoordinated
BiOS	2003	Transbacter gene transfer tool	Unrestricted	Viral nonenforcement (with some charges)	Open uncoordinated
OSSI	2014	Seed germplasm	Unrestricted	Viral nonenforcement	Open uncoordinated
Addgene	2004	DNA plasmids	Unrestricted (paid)	No commitment	Open uncoordinated
CReM	2012	iPSC lines	Unrestricted (paid)	Licensed	Open uncoordinated
MMV	2011	Validated compounds	Unrestricted	Data sharing only	Open uncoordinated
OSM	2011	[data only]	Unrestricted	Permissive nonenforcement	Managed peer production
OSDD	2008	[data only]	Unrestricted	Licensed	Managed peer production
OSPF	2018	[data only]	Unrestricted	Permissive nonenforcement	Collaboration
COVID Moonshot	2020	[data only]	Unrestricted	Permissive nonenforcement	Managed peer production
Texas Vax	2020	Vaccine, data	Restricted	Licensed	Collaboration

1. Access to Enabling Technology

As noted in Part I, by analogy to the availability of computer source code in OSS projects, open source bio projects should make tangible biological materials that are necessary to conduct research broadly available to the research community. Many of the projects described in Part II do so. BiOS and CReM shipped a range of reagents and other biological tools to laboratories requesting them, and MMV and iGEM created standardized kits containing hundreds of different biological compounds that they provided to large numbers of recipients.[156]

Of course, the software industry once depended on physical artifacts as well. Computer programs were stored on magnetic or optical media, and the only practical

156. *See supra* Sections II.A, C, F & G.

way to share them before the widespread availability of broadband Internet connectivity was by exchanging physical media. Even Richard Stallman's GNU project began with programmers mailing magnetic tapes or floppy diskettes to one another.[157] But those days are a distant memory in the software world and are rapidly becoming obsolete in many areas of biology as well. For example, the field of genomics today is largely computational, with no need to share physical DNA samples beyond the laboratories and clinics conducting initial sequencing.[158] Thus, when considering the sharing of enabling technologies in open source bio projects, the requirement to make biological materials broadly available has diminished. As noted in Section II.A, the iGEM competition no longer requires contestants to submit physical DNA samples of their biological parts. It is easier for the competition administrators simply to synthesize those parts from the contestants' digital sequence listings.[159] Likewise, crowdsourced projects like OSDD did not distribute tangible materials to the thousands of students and other volunteers working on its research challenges. Rather, it provided, and received, enabling technology in digital form only.[160] The same was true more recently of the crowdsourced COVID Moonshot, which rapidly synthesized any compounds that showed promise in digital form.[161] As Elinor Ostrom and Charlotte Hess aptly observed two decades ago, modern biology has largely become an information science.[162]

Yet, while the shift to digital biology has begun, it is not complete. Some projects, such as OSSI, continue to distribute physical germplasm to seed manufacturers and breeders.[163] Fields like agriculture, infrastructure, and equipment still depend on the replication of physical materials rather than laboratory synthesis from digital files. Likewise, the synthesis of more complex molecules such as proteins, cell lines, model organisms, and biologic drugs remains challenging, if not beyond the capabilities of current technology.[164] As a result, the Texas vaccine project shipped samples of its protein-based COVID-19 vaccine to potential manufacturers in India, Bangladesh, and elsewhere.[165]

In the not-too-distant future, technology may be sufficiently advanced that large-scale collaboration will be possible entirely at the digital level. But until then, some open source bio projects may need to continue to make biological materials available

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157. *See* Stallman, *supra* note 24, at 58, ("[I]n early 1985 . . . I announced that I would mail a tape [of the GNU Emacs program source code] to whoever wanted one . . . .").

158. *See* Vera Laub, Kavi Devraj, Lena Elias & Dorothea Schulte, *Bioinformatics for Wet-Lab Scientists: Practical Application in Sequencing Analysis*, 24 BMC GENOMICS, no. 382, 2023, at 1; Richard A. Gibbs, Commentary, *The Human Genome Project Changed Everything*, 21 NATURE REVS. GENETICS 575 (2020).

159. *See supra* note 73.

160. Årdal & Røttingen, *supra* note 132, at 4.

161. *See supra* notes 142–147 and accompanying text.

162. Charlotte Hess & Elinor Ostrom, *A Framework for Analysing the Microbiological Commons*, 58 INT'L SOC. SCI. J. 335, 335 (2006).

163. *See supra* notes 97–99 and accompanying text.

164. *See* Anne Trafton, *New Technology Enables Fast Protein Synthesis*, MIT NEWS (May 28, 2020), https://news.mit.edu/2020/faster-protein-synthesis-0528 [https://perma.cc/U8SP-QJR6] (describing advances in technology).

165. *See supra* Section II.L.

and, as shown by the experience of CReM,[166] may be required to charge recipients a modest fee unless they have access to significant external funding, as was MMV for its box programs.[167]

It is notable that in all but one of the open source bio projects that distributed biological materials, these materials were made available to any researcher requesting them (sometimes for a fee). The Texas vaccine project, however, only shared materials with selected global manufacturers that entered into licensing agreements with the organizing institutions.[168] This approach, which supported the Texas institutions' ability to charge royalties to those manufacturers, more closely resembles traditional university technology transfer than an open source bio approach.

2. Intellectual Property

As discussed in Section I.B, OSS developers generally retain copyright in their software but license it to users on permissive terms. Though copyright is not relevant to most open source bio projects, those projects handle rights in data and patents in similar ways.[169] The IP approaches of the open source bio projects reviewed can broadly be grouped into the following four categories.

a. Viral Nonenforcement

With this form of commitment, the provider of data/materials commits not to enforce IP rights against users and, in turn, requires that users impose the same nonenforcement commitment on subsequent recipients of the data/materials or derivatives thereof. In this sense, the commitment resembles the copyleft structure of the OSS GPL and the ShareAlike Creative Commons licensing option.[170] Programs adopting a "viral nonenforcement" approach to IP have done so via a pledge requirement (e.g., iGEM's "Get & Give (& Share)" policy and OSSI's seed pledge)[171] as well as more formal agreements (e.g., the BiOS agreement).

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166. *See supra* Section II.F.

167. *See supra* Section II.G.

168. Contreras, *Liberty to Justice*, *supra* note 26.

169. *But see* Boettiger & Wright, *supra* note 13, at 46–47 (suggesting that fundamental differences between copyright and patent make OSS models less transferable to biotechnology).

170. *Attribution-ShareAlike 4.0 International*, CREATIVE COMMONS, https://creativecommons.org/licenses/by-sa/4.0/ [https://perma.cc/TXD5-C4TQ] ("ShareAlike — If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original.").

171. As noted above, there are numerous mechanisms for giving legal force to unilateral patent pledges, notwithstanding the assumption (even by some licensors) that they lack enforceability. *See supra* note 98 and accompanying text.

b. Permissive Nonenforcement (Public Domain)

Programs adopting a permissive nonenforcement approach commit that they will not enforce IP rights in data/materials that they make available but do not impose downstream IP-related commitments on recipients or users of those data/materials. This structure is similar to that observed in permissive OSS licenses such as BSD.[172] Commentators have referred to this as a "public domain" approach, as it precludes any enforcement action by the IP owner.[173] However, a true public domain approach also allows subsequent users to appropriate and claim property interests in modifications or improvements to shared IP, which some commentators have found to be less desirable.[174]

In most cases, commitments of this form are articulated in general terms, such as the Open Source Malaria statement "there will be no patents" coupled with its use of the copyright-focused CC-BY licensing agreement,[175] and OSPF's statement that all IP arising from its trials will be placed in the public domain.[176] Other programs, such as the BioBricks Foundation, have adopted a more formalized, contractual approach that achieves a similar result.[177]

c. Data Sharing

Some programs make no official mention of IP and only require that recipients of shared data/materials make results obtained using those data/materials publicly available. One such program is MMV, which states on its website that it expects recipients of its compound boxes to "deposit any Data in an open access public repository . . . within two (2) years of generating the Data."[178] Given the context (data sharing rather than IP), MMV's reference to the "open access public repository" likely means that data should be made available via a publicly accessible website, rather than requiring recipients to make any commitment regarding IP enforcement.[179]

d. Restrictive License

Some programs retain IP rights in their data/materials and license them to users on terms that may include monetary payments and restrictions on use. In the case of CReM, materials are provided pursuant to a materials transfer agreement and are

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172. *See* CONTRERAS, LICENSING, *supra* note 19, § 19.2.3.

173. *See, e.g.*, Grewal, *supra* note 28, at 186; Rai & Boyle, *supra* note 78, at 389.

174. *See, e.g.*, Grewal, *supra* note 28, at 186; Rai & Boyle, *supra* note 78, at 389; KOCK, *supra* note 99, at 228; Louwaars, *supra* note 101, at 5.

175. *See supra* Section II.H.

176. *See supra* Section II.J.

177. *See supra* Section II.B. Some authors have distinguished the BioBricks approach from a true "public domain" approach, given its more limited restraint on future activity. *See* Rai & Boyle, *supra* note 78, at 389 (referring to BioBricks as a "commons" approach).

178. *See MMV Terms*, *supra* note 124.

179. *Id.*

individually priced.[180] Boston University and CReM have not made public commitments regarding patents but have represented that they typically license patents covering CReM's research on a nonexclusive basis.[181]

While OSDD sponsors the crowdsourced screening of drug candidates and makes the resulting data publicly available, it strictly controls access to and use of that data.[182] Likewise, OSDD leaves open the possibility that it will seek patent protection on its discoveries and does not make any commitment regarding the licensing of those patents.[183]

While the Texas Vaccine project has publicly disavowed patenting, it nevertheless provides biological material, data, and regulatory information to manufacturers under a nonpublic licensing agreement that requires payments of undisclosed amounts. Addgene, which makes biological materials available to users for a fee, limits the use of those materials to internal research activities and prohibits the onward transfer of materials.[184]

3. Development Mode

The third major attribute of open source bio projects is their development methodology. As noted in Section I.C, OSS projects may range from broadly distributed peer-to-peer communities to hierarchical and managed development efforts. There is likewise heterogeneity among the twelve open source bio projects that were reviewed.

The development mode most frequently observed among these open source bio projects was what I term "open uncoordinated" development, in which project participants make data and/or materials available to others without a defined goal or project plan. In essence, anyone who obtains project data/materials is free to use them for their own purposes, but development activity is not coordinated or directed in any significant manner. Thus, iGEM competitors are free to create biological parts with functions of their own choosing,[185] seed breeders may develop any traits they wish using germplasm from OSSI, and researchers obtaining iPSC cells from CReM may conduct research independent from CReM and other recipients of similar cells. In many ways, this mode resembles that which arises from open data projects, in which it is hoped that freely available data will be useful to others without knowing what those uses will be.

The second development mode is what I refer to as "managed peer production," in which a project organizer defines specific tasks and enables decentralized,

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180. *See* Contreras, *Liberty to Justice, supra* note 26, at 6.

181. *Id.* at 12.

182. *See* Årdal & Røttingen, *supra* note 132, at 9.

183. Masum et al., *supra* note 90, at 119 ("Brahmachari has suggested the necessity of retaining patent protection alongside open source development, rather than in opposition to it . . . .").

184. *See supra* note 110 and accompanying text.

185. This is in contrast to the original iGEM seminar at MIT, in which students were asked to create a "blinking light" using biological components. *See Class Aims to Engineer Blinking Life in the Lab*, MIT NEWS (Feb. 13, 2003), https://news.mit.edu/2003/blinkers; Campos, *supra* note 66, at 118.

independent parties, usually self-selected, to work toward the completion of those tasks. This is a common mode for OSS development, in which a project (like Linux) has a recognized manager who oversees the overall direction of the project, resolves disputes, and decides which contributions to fold into the main project and which to reject. Thus, the organizers of the COVID Moonshot project posed a specific research question and solicited contributions from the global research community. Likewise, OSDD posed specific research questions to a large group of Indian university students and faculty.[186] It is also possible that open, uncoordinated projects can, at times, take on attributes of managed peer production projects. For example, MMV distributed its compound boxes to researchers around the globe to pursue their own research interests. Then, in 2016, some of the organizers of the Open Source Malaria Project conducted a competition in which participants used compounds from MMV's malaria and pathogen boxes to develop a predictive model for identifying inhibitors of an ion pump on the malaria parasite's surface.[187]

A third development mode is most aptly referred to as "private collaboration." In this mode, collaborators are selected by an organizer or organizers and invited to participate, rather than the project being open to the research community at large. While the results of a private collaboration may be released to the public, the work is performed only by the selected collaborators. Thus, OSPF's co-sponsored Phase 2 clinical trial of the antimalarial metformin was conducted at five carefully selected sites in India.[188] Opening a highly regulated activity such as a clinical trial to open, global participation would be impractical. Likewise, the Texas vaccine project was carried out primarily by Texas Children's Hospital and Baylor College of Medicine, which provided data and materials to selected manufacturing partners abroad, rather than making them available to all comers.[189] In this respect, the Texas project, notwithstanding its adoption of the open source label, was not dissimilar to Oxford University's collaboration with pharmaceutical company AstraZeneca.[190]

B. Is Open Source Bio Open Source?

The comparative analysis contained in Section III.A and the application of the three distilled principles of open source bio to the twelve projects described in this Article beg the question which of these twelve projects can fairly be characterized as "open source." One way to answer this question is to ask whether a particular project embodies the three attributes of open source projects discussed in Part I (access to enabling technology, lack of IP prohibitions, and decentralized development). The

186. OSDD has been characterized as a crowdsourcing project rather than an open source project largely because of its treatment of IP, rather than its distributed development structure. *See* Todd, *supra* note 128, at 1805 ("The Open Source Drug Discovery project in India was, despite its name, operating a crowdsourcing initiative as opposed to something that was open source."); Årdal & Røttingen, *supra* note 132, at 9 ("[R]ather than a strictly defined open source project, . . . OSDD is actually a highly successful crowdsourcing project . . . .").

187. *See* Tse et al., *supra* note 127.

188. Padmapriydarsini et al., *supra* note 140, at 426.

189. *See supra* note 148.

190. *See* Contreras & Shadlen, *supra* note 155.

following assessment tool draws on the characterization of activities that is presented in Section III.A:

Access: Are biological materials made broadly accessible to interested parties everywhere (for free or at a nominal charge)? If so, this attribute of open source projects is satisfied.

IP: Is the use, modification, or further distribution of the technology restricted? Using the framework developed in Section III.A.2, projects adopting copyleft nonenforcement, permissive nonenforcement, and data sharing approaches can be said not to impose such restrictions and thus satisfy this open source attribute. Projects that adopt a formal nonpublic licensing structure do not possess this attribute (though projects that require licensing agreements but purport to disavow patenting may straddle the line between open source and not). Finally, projects that are silent regarding IP usage, while not imposing express restrictions, do not offer assurances of unencumbered usage and also straddle the line between open source and non-open source.

Development: Based on the framework presented in Section III.A.3, projects adopting an open, uncoordinated, and managed peer production mode of development satisfy this attribute of open source, while private collaborations do not.

Table 2 below summarizes the extent to which the twelve projects described in this Article satisfy the requirements of an open source bio project, as defined above.

Table 2: Assessment of Open Source Nature of Open Source Bio Projects

Project	**Access** Is enabling technology made broadly accessible to interested parties everywhere?	**IP** Is use and modification of the technology unrestricted by IP?	**Development Mode** Is technology development decentralized ?	**Is it open source?**
iGEM	✓	✓	✓	✓
BioBricks	✓	✓	✓	✓
BiOS	✓	✓	✓	✓
OSSI	✓	✓	✓	✓
Addgene	✓	▽	✓	▽
CReM	✓	▽	✓	▽
MMV	✓	✓	✓	✓
OSM	Data	✓	✓	✓
OSDD	Data	▽	✓	▽
OSPF	Data	✓	✗	▽
COVID Moonshot	Data	✓	✓	✓
Texas Vax	✗	▽	✗	✗

Legend

✓ Yes ▽ Partially ✗ No

As shown in Table 2, some of the analyzed projects might not, under the proposed criteria for open source, qualify as open source bio projects. Thus, projects such as CReM and Addgene, which use MTAs that limit the permitted uses of biological materials and OSDD, which reserves the right to impose licensing terms on users of its materials, could fall short of open source principles. OSPF, in its clinical trial work, selects particular collaboration partners rather than allowing distributed development work to proceed. Most notably, the Texas vaccine project, despite advertising itself as open source, does not make biological materials broadly available or utilize distributed forms of development. As a result, notwithstanding its merits as a philanthropic effort and a global health initiative, the Texas vaccine project is not an open source project, strictly speaking.

The real question, then, is whether definitions of open source matter, or whether this is merely an issue of semantics. As Antony Taubman observes, the question is:

> [W]hether 'open source' is a coherent and enabling concept for biotech innovation: is it a badge of approval for behaviour we like, or can the experience of open source software development act as a heuristic for the construction, analysis or retrospective validation of distinct forms of research and development in the life sciences? [191]

In the software world, it turns out, terminology relating to OSS matters deeply. The term "open source," in fact, arose from an early divide between adherents of Richard Stallman's "free software" movement and more corporate-minded software developers, as represented by Eric Raymond.[192] As a result of the rift between these two camps, Raymond began to refer to "open source" software as distinct from "free software."[193] Likewise, groups perceived to be co-opting the OSS designation for corporate or political purposes have been the subjects of public criticism and sometimes ridicule, as was Al Gore's presidential campaign, which ill-advisedly advertised that its website was "open source."[194] Beyond issues of political appropriation, OSI's detailed criteria for OSS license compatibility are important because they indicate whether or not a software program distributed under a particular license can effectively be incorporated into an OSS program.[195] But issues of license compatibility are not (yet) as germane to the bio world.[196] So the question

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191. Taubman, *supra* note 13, at 23.

192. *See* RAYMOND, *supra* note 57, at 71; Couture, *supra* note 6.

193. RAYMOND, *supra* note 57, at 205.

194. *See* Joel Deane, *Gore's 'Open Source' Blasphemy*, ZDNET (Apr. 7, 1999, 5:00 PM), https://www.zdnet.com/article/gores-open-source-blasphemy/ [https://perma.cc/5G8E-9E8S]; Aram Sinnreich (@aramsinn.bsky.social), BLUESKY (Nov. 22, 2024, 8:13 AM), https://bsky.app/profile/did:plc:acbfcnn77ho54pzkjhwhrmpi/post/3lbk2meozjb2t (noting Al Gore's use of "open source" during his campaign).

195. *See* Rômulo Meloca, Gustavo Pinto, Leonardo Baiser, Marco Mattos, Ivanilton Polato, Igor Wiese & Daniel M. German, *Understanding the Usage, Impact, and Adoption of Non-OSI Approved Licenses*, PROCS. 2018 ACM/IEEE 15TH INT'L CONF. ON MINING SOFTWARE REPOSITORIES 270 (2018).

196. There may come a time when biological parts can be combined to perform complex biological functions, as envisioned by the BioBricks Foundation, thereby requiring license

remains whether adhering to a definition of open source principles can actually improve the development and distribution of life science technologies. If so, then the identification of particular projects to those principles could make a difference.

C. Analysis: Is Open Source Fit for Bio?

As noted in the Introduction, commentators have been discussing the application of open source approaches to life science research and development for more than two decades.[197] Now, with the benefit of a quarter century of attempts, it is worth asking whether open source approaches are well-suited to the life science arena and how, if at all, future efforts toward open source bio should proceed.

1. The Goals of Open Source Bio

In assessing the success of open source bio, it is useful first to consider what goals open source bio projects seek to achieve. As noted in Section I.A, the OSS movement emerged as an effort to free researchers from the constraints imposed by corporate intellectual property and nondisclosure agreements—what I have referred to as the "liberty" interest in open source.[198] Lakhani and von Hippel identified three primary motivations for firms to participate in OSS projects: the direct benefits that they can obtain in terms of enhanced development resources and early access to technology, indirect benefits such as improving employee skills, and signaling expertise and market presence to others.[199] To what degree do these factors incentivize organizations to participate in open source bio projects?

Life sciences researchers have displayed an interest in removing IP and contract-based barriers to their own research, as indicated by the widely used Addgene platform.[200] Plant genetics researchers, operating in an environment of stringent IP enforcement and secrecy, have also been attracted to open source models such as OSSI. Similar sentiments appear to motivate the continued success of the iGEM competition, in which competitors remain largely unencumbered in developing new biological parts. Nevertheless, there does not appear to be a groundswell of support for similar open sharing structures from researchers at companies and academic institutions, suggesting perhaps that protectionist IP norms have been accepted to a degree.

A second underlying motivation for open source bio projects has been the promotion of broader public access to life science technologies, particularly in underserved communities and the global south—what have been characterized as

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compatibility among combined parts.

197. *See supra* note 13 and accompanying text.

198. Contreras, *From Liberty to Justice*, *supra* note 26.

199. Karim R. Lakhani & Erik von Hippel, *How Open Source Software Works: "Free" User-to-User Assistance,* 32 RSCH. POL'Y 923 (2003).

200. *See* Anthony Cova, Chiara DeNatale & Andrew Baltus, *From Bench to Worldwide: How Addgene Built a Global Resource for Material Sharing*, 2 TECH. TRANSFER & ENTREPRENEURSHIP 85, 85 (2015) (noting prior frustration of Addgene founders with obtaining research materials for their labs).

distributive justice concerns.[201] Projects such as the MMV boxes, Open Source Malaria, and the Texas COVID vaccine were all aimed at fostering the availability of health technologies in low-income economies and making them available without the rent-seeking that often accompanies IP-encumbered solutions.

A third motivation for open source bio projects, which most directly borrows from the success of the OSS movement, has been to harness the power of large developer communities to tackle difficult scientific and technological problems, thereby enhancing innovation in these areas.[202] Projects like OSDD and the COVID Moonshot thus sought, with some success, to harness the power of the distributed peer-production features of OSS.[203]

Table 3 below roughly classifies each of the twelve open source bio projects discussed in this Article based on which of these three appears to have been its primary motivation.

Table 3: Underlying Motivations for Open Source Bio Projects

Project	Primary Motivation
iGEM	Developer freedom
BioBricks	Developer freedom
BiOS	Developer freedom
OSSI	Developer freedom
Addgene	Developer freedom
CReM	Developer freedom
MMV	Access
OSM	Access
OSDD	Enhanced Innovation and Access
OSPF	Access
COVID Moonshot	Enhanced Innovation
Texas Vax	Access

In assessing existing open source bio projects, and in proposing new ones, little attention has been paid in the literature to the underlying motivations for an open source approach. Thus, while the iGEM Registry of Biological Parts has probably not resulted in any new cures for an infectious tropical disease, it has undoubtedly

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201. *See* Contreras, *Liberty to Justice*, *supra* note 26.

202. *See* Allarakhia et al., *supra* note 64, at 53 ("Where products require a broad range of knowledge types, integration efficiency is maximized when separate firms that specialize in distinctive knowledge areas are linked by strategic alliances. Consequently, companies are reconsidering their strategies with respect to biopharmaceutical research and development including the use of open source-based consortia to manage these knowledge complexities." (citations omitted)).

203. Another motivation hypothesized for organizations to engage in open source bio projects is the ability to preview new areas for commercial exploitation at a low cost. *See* Allarakhia, *supra* note 13, at 25. Despite its theoretical plausibility, this motivation was not evident in the projects examined in this Article. *Id.*

enhanced synthetic biology education and, hence, research. As such, it has arguably achieved one of its goals. By identifying promising compounds used against certain targets, OSDD and the COVID Moonshot also achieved a goal that might not have been possible without a broadly distributed and decentralized approach borrowed from OSS.

It is the goal of broader access to medicines that appears to be the most challenging to crack using open source approaches. As Ken Shadlen and I discuss in prior work, it is possible that different, better funded development models could achieve a greater impact on public health.[204] But these arguments are based on a limited sample, and further experimentation may prove otherwise. Suffice it to say that disentangling the goals and methods of an open source bio project is likely to clarify its analysis significantly.

2. Successes and the Law of Small Numbers

Open source bio, broadly construed, is not without its successes. Addgene, though it is still largely confined to academic and noncommercial research, has demonstrated the feasibility of broad, global sharing of simple biological materials (DNA plasmids) without the need for protracted contractual wrangling among institutional legal departments and technology transfer offices. Other materials sharing systems—iGEM, CReM, and MMV—have distributed thousands of biological samples to laboratories around the world, thus advancing research in ways that are hard to measure. Likewise, OSSI has contributed to the diversification of seed germplasm in the global food supply, though, again, its direct results are difficult to quantify.

Some projects—OSM, OSDD, OSPF, and the COVID Moonshot—have made modest, though measurable,[205] contributions toward the development of human therapeutics for deadly diseases such as malaria, tuberculosis, and COVID-19. And the Texas vaccine project, though it is probably the least "open" of the projects considered in this Article, produced a working vaccine that was administered to millions of patients—the most notable success story to date.[206]

To some, these successes may sound unimpressive. Yet it is worth noting that the twelve projects discussed in this Article are among the most prominent open source bio projects that have emerged during the last quarter century. Only twelve! While there are doubtless more projects that have attracted less attention in the press and

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204. *See* Contreras & Shadlen, *supra* note 155 (comparing the Texas vaccine project with the vaccine development program undertaken by Oxford University and AstraZeneca).

205. Measuring the impact of open science and open IP projects is inherently challenging, as it is often difficult to know whether and how innovations are used when they are freely available. In contrast, the impact of innovations subject to IP rights that must be formally licensed are easier to track through licensing agreements and reporting by licensees. *See* Jorge L. Contreras, *The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 2021 UTAH L. REV. 833, 916 [hereinafter Contreras, *Open COVID Pledge*].

206. *See supra* note 150–156 and accompanying text.

academic literature,[207] it would be surprising if there have been more than fifty such projects in the life science arena overall.

Software, on the other hand, is very different. According to Statista, by December 2022, there were 2.5 million open source JavaScript projects around the world.[208] And on GitHub, one of the main OSS development platforms, developers started 52 million new open source projects in 2022 alone.[209] Thus, for every Linux and Apache, there are *millions* of failed or discontinued OSS projects. As a result, comparisons between life science and software projects are, from a statistical standpoint, immensely unfair.

3. The Materials Challenge

As noted above, life science research differs substantially from software development in that many life science projects require the exchange of biological materials. This exchange is costly, time-consuming, and legally intensive. While projects like Addgene have greatly streamlined the process for simple DNA plasmids,[210] it remains to be seen whether the same efficiencies can be achieved for more complex compounds.[211] Legal and ethical challenges multiply when biological materials are sourced from human subjects—a difficulty that does not exist in the world of software code.

However, as noted in Section III.A.1, the decreasing cost of laboratory synthesis potentially reduces the importance of sharing biological materials when compounds can be synthesized cheaply from digital sequence listings. Thus, while the inherent physicality of life science research might, at first glance, appear to impose barriers to the practice of open source bio, those barriers are rapidly falling.

4. Know-How and Knowledge Transfer

One of the frequent critiques of open patent initiatives is that patent rights alone seldom enable the production of complex technology products.[212] Biomedical

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207. *See* Allarakhia et al., *supra* note 64 (cataloging thirty-nine open source bio projects of the early 2000s).

208. Lionel Sujay Vailshery, *Total Number of Open Source Projects and Project Versions Worldwide in 2023, by Ecosystem*, STATISTA (Jan. 9, 2024), https://www.statista.com/statistics/1268650/worldwide-open-source-projects-versions-ecosystems/ [https://perma.cc/AW47-PFYU].

209. Martin Woodward, *Octoverse 2022: 10 Years of Tracking Open Source*, GITHUB: BLOG, (Nov. 17, 2022), https://github.blog/news-insights/research/octoverse-2022-10-years-of-tracking-open-source/ [https://perma.cc/TGV7-AXJD].

210. The fact that Addgene and CReM charge recipients modest amounts to ship biological materials is not itself a significant barrier to usage. After all, even Richard Stallman charged other programmers $150 for copies of tapes containing the Emacs program. *See supra* note 157 and accompanying text.

211. Addgene advertises that it now carries viral vectors and recombinant antibodies in addition to DNA plasmids. ADDGENE, *supra* note 106.

212. *See* Jorge L. Contreras, Bronwyn H. Hall & Christian Helmers, *Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons*, 57 HOUS. L. REV. 61, 82–84

manufacturing requires a host of skills, techniques, and processes—trade secrets that are often closely guarded within corporate enterprises.[213]

This challenge, however, suggests that open source projects, which are inherently collaborative, might help. The Texas vaccine project made researchers in Texas available (remotely) to assist collaborators at manufacturing facilities in India and provided them with a wealth of information in support of regulatory clearances that would ordinarily be viewed as trade secrets.[214] Admittedly, this type of direct, hands-on assistance is far more difficult and costly to provide at scale than access to data or even biological materials.[215] But even less formal open source communities routinely pose questions and post suggested solutions on discussion boards and Slack channels. If a community is large and open to cooperation, then knowledge gaps can be bridged. As Eric Raymond wrote, "Given enough eyeballs, all bugs are shallow . . . ."[216]

5. Software vs. Bio Culture

One of the first scholars seriously to challenge the viability of open source bio was David Opderbeck. Opderbeck argued in 2004 that the norms of the life science research community, far from reflecting a Mertonian culture of openness and cooperation, are actually based on conformity and competition.[217] He goes on to observe that, for historical and practical reasons, there has never been a "hacker culture" in the biosciences, and one is unlikely to emerge.[218] More than twenty years later, Opderbeck's observations still ring true. Despite the occasional news story and academic article about "biohackers,"[219] the mainstream of life science research is still heavily institutional and corporate.

But does the sociological gap between software and biology preclude the establishment and growth of open source communities in the biosciences? Not necessarily. As noted above, the hacker culture of the 1970s led to the emergence of the OSS movement, but this is an origin story rather than a description of OSS today. While a hacker culture still exists around the edges of OSS, the vast majority of OSS

(2019).

213. W. Nicholson Price II, Arti K. Rai & Timo Minssen, *Knowledge Transfer for Large-Scale Vaccine Manufacturing*, 369 SCI. 912 (2020).

214. *See* Contreras, *Liberty to Justice, supra* note 26.

215. Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503, 1525–26 (2012).

216. RAYMOND, *supra* note 57, at 27 (emphasis omitted).

217. Opderbeck, *supra* note 13, at 190 (citing landmarks in the sociology of science, including 2 THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (Otto Neurath, Rudolf Carnap & Charles Morris eds., 2d ed. 1970) and HARRY COLLINS & TREVOR PINCH, THE GOLEM: WHAT EVERYONE SHOULD KNOW ABOUT SCIENCE (1st ed. 1993)).

218. *Id.* at 191*; see also* Boettiger & Wright, *supra* note 13, at 51 ("The culture of hackers that continues to fuel the advances of OS in software may not be replicable in the field of biology.").

219. *See* Morgan Meyer, *Biohacking*, *in* THE HANDBOOK OF PEER PRODUCTION 211 (Mathieu O'Neil, Christian Pentzold & Sophie Toupin eds., 2021).

development today is conducted within well-organized corporate and institutional settings.[220] Some have argued that the corporatization of OSS has diminished its potential or otherwise corrupted its essence, yet OSS continues as a major force in software development.[221]

The projects examined in this Article demonstrate that life science researchers can collaborate across institutions and national borders. For example, the COVID Moonshot, with organizers from the United States, United Kingdom, Israel, and Ukraine, received a large number of legitimate scientific contributions from around the world.[222] And the iGEM synthetic biology competition continues to grow, with 4500 attendees estimated to have attended its 2024 jamboree in Paris.[223] Active and engaged communities from around the world can form in the life sciences.

What's more, the institutional structure of modern life science research does not preclude the participation of individual researchers in open source projects. One need only look to the software industry to appreciate this. After all, open source developers today work at the largest technology companies in the world—Google, Microsoft, IBM/Red Hat, Oracle, and SAP.[224] While a vibrant underground hacker community still exists, the bulk of OSS development occurs within the framework of corporate laboratories. Thus, the institutional structure of life science research should not present an obstacle to the conduct of research and development on an open source basis.

6. Research vs. Development

Another dimension along which the suitability of open source approaches to life sciences research may vary is the stage in the product development life cycle, from basic scientific research to product manufacturing. It may be that basic research, such as the sequencing of the human genome, lends itself to decentralized collaboration without significant IP positions better than late stage product development that is closer to commercial markets and which requires more significant investment to pursue.[225] Thus, the iGEM student competitions in synthetic biology, which exemplify a successful open source bio approach, have few direct commercial applications. But, as shown by the Texas vaccine project, the production of a vaccine for broad administration may be less amenable to traditional open source approaches,

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220. BENJAMIN J. BIRKINBINE, INCORPORATING THE DIGITAL COMMONS: CORPORATE INVOLVEMENT IN FREE AND OPEN SOURCE SOFTWARE 2 (2020).

221. *Id.* at 3–4.

222. *See supra* note 142.

223. *2024 Grand Jamboree*, IGEM, https://jamboree.igem.org/2024/home [https://perma.cc/5LRF-ZY8J].

224. Kaye Timonera, *34 Top Open Source Software Companies Shaping 2024*, DATAMATION (Mar. 21, 2024), https://www.datamation.com/open-source/35-top-open-source-companies/ [https://perma.cc/XKJ5-XURQ].

225. *See* Boettiger & Wright, *supra* note 13, at 47 ("If the goal is open access to an end-product, not to a research tool (as in BiOS), then widespread delivery of the product may depend on engaging capital to get it from the lab out into the hands of consumers. The ability to leverage patent rights can, in some cases, play a critical role.").

notwithstanding the researchers' desire to promote broad access to the fruits of their research.

7. Economic Sustainability

Of course, the most forceful critique of open source bio is rooted in simple economics: It is hard to make money when something is freely shared with others. A corollary to this proposition is that without sufficient financial incentives, most technology development projects will not be undertaken.

Fear of financial unsustainability is what led the governmental funder of the CReM project to urge the program to charge for its iPSC lines.[226] It is also an alleged reason that the Gates Foundation urged Oxford University to abandon its initial foray into open source development of a COVID-19 vaccine in favor of a tiered pricing model.[227] By the same token, it is no surprise that few companies in the biopharma sector joined the COVID-19 patent pledges that attracted large firms in the digital innovation sector—there was simply too much money to be made.[228]

This being said, some commentators have viewed a lack of financially lucrative markets in certain fields as strong arguments for adopting open source approaches. For example, one of the first scholarly calls for open source bio cited the lack of commercial interest in tropical diseases as a reason that such an approach might succeed (i.e., commercial players would have little reason to oppose it, and even some incentives to join, given that the financial stakes are low).[229] Dana Klug and colleagues have recently made a similar argument for the viability of an open source approach to antibody development.[230]

Concerns about economic sustainability have clearly impeded the launch of open source bio projects. Whether these concerns are warranted is unclear. But if open source projects can accelerate the development of life science products or ensure that they are more equitably distributed, then the market need not be the only arbiter of the fate of such projects.

8. The High Stakes of Life Sciences Research

Finally, as Antony Taubman points out, the decentralized, loosely managed development environment of OSS may not translate well to fields of life sciences research that could impact human health and well-being.[231] Unlike a buggy piece of software, which can be thrown back to a bazaar of volunteer software programmers for repair, he notes, "[T]he release of a buggy open source vaccine or drug could

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226. *See supra* note 112 and accompanying text.

227. Robert Fortner, *AstraZeneca's Covid-19 (Mis)adventure and the Future of Vaccine Equity*, 379 BMJ, no. o2592, 2022, at 2.

228. *See* Contreras, *Open COVID Pledge*, *supra* note 205, at 898–99.

229. Maurer et al., *supra* note 13.

230. Dana M. Klug, Fahima I.M. Idiris, Mark A.T. Blaskovich, Frank von Delft, Christopher G. Dowson, Claas Kirchhelle, Adam P. Roberts, Andrew C. Singer & Matthew H. Todd, *There Is No Market for New Antibiotics: This Allows an Open Approach to Research and Development*, 6 WELLCOME OPEN RSCH. 146 (2021).

231. *See* Taubman, *supra* note 13, at 235–36.

yield a public health crisis . . . ."[232] As a result, Taubman notes that "[t]he kind of broad disclaimers typically found in software licensing (open source, free or otherwise) could not be sustained for much life sciences innovation."[233] These differences may or may not impact all forms of life sciences development (e.g., the iGEM student competition), but they have greater resonance when considering human vaccines and therapeutics.

D. Policy Options

As with many public projects, government can intervene at numerous levels: It can encourage open source activity via grants, tax incentives, procurement preferences, and the like.[234] It can also make direct investments in improving the technological and policy infrastructure supporting open source projects.[235] In the life sciences realm, I have previously enumerated the ways in which the National Institutes of Health have promoted collaborative research activities that have resulted in the public release of large quantities of scientific data.[236] Other examples of governmental and international encouragement of public-spirited life sciences projects include the Medicines Patent Pool and the Pool for Open Innovation Against Neglected Tropical Diseases.[237]

In addition, policy makers could consider the creation of legal preferences for open source bio projects and the products resulting from such projects. Such incentives could come in the forms of accelerated regulatory approval, reduced approval costs and fees, or even limited market exclusivities.[238]

Alternatively, Congress could enact limitations on patent liability for open source bio products, as it did in 1996 when it created an immunity for healthcare providers from infringement of medical treatment patents.[239] Legislative limitations on liability have been enacted in other situations that seek to promote innovation in critical national industries, such as the National Vaccine Injury Compensation Program,

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232. *Id.* at 235.

233. *Id.* at 236.

234. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544 (2019).

235. *See* Stebbins et al., *supra* note 12.

236. *See* Jorge L. Contreras, *Leviathan in the Commons: Biomedical Data and the State*, *in* GOVERNING MEDICAL KNOWLEDGE COMMONS 19 (Katherine J. Strandburg, Brett M. Frischmann & Michael J. Madison eds., 2017).

237. *See* Michael Mattioli, *Communities of Innovation*, 106 NW. U. L. REV. 103, 147–48 (2012).

238. Congress has fashioned a range of regulatory market exclusivities to encourage the development, for example, of pediatric drugs and drugs targeting rare diseases. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 111, 111 Stat. 2296, 2305–08 (codified as amended at 21 U.S.C. § 505(a)) (6-month pediatric drug market exclusivity); Orphan Drug Act, Pub. L. No. 97-414, § 2, 96 Stat. 2049, 2050–51 (1983) (codified as amended at 21 U.S.C. § 527(a)) (7-year market exclusivity for drugs targeting rare diseases).

239. *See* Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3067 (1996) (codified as amended at 35 U.S.C. § 287(c)).

created in 1988, to limit the liability of vaccine manufacturers for injuries arising from certain widely administered vaccine products,[240] and the Standards Development Organization Advancement Act of 2004, which eliminates antitrust treble damages for qualifying standards development organizations.[241] Any of these measures could encourage open source approaches to life science research and development in areas where it may be most helpful.

CONCLUSION

The twelve case studies examined in this Article illustrate the diversity of approaches that researchers in the life sciences have considered to be open source. While open source bio projects have not, by any measure, achieved the unprecedented market success of OSS,[242] this should not be viewed as a sign of failure. The life science and software industries are different. A literal transplantation of open source processes and goals from software to life science research is unlikely to be effective. As Arti Rai has noted, "[s]uccessful translation of open source principles into the life sciences will require far more than simple cutting and pasting."[243] Even Erik Raymond, one of the most prominent spokespersons for the OSS movement, has expressed skepticism about the application of OSS principles to other fields of endeavor.[244]

The findings of this Article reflect the heterogeneity of approaches that institutions and firms have taken in the life science arena when trying to fashion open source strategies. This heterogeneity reflects a spirit of policy experimentalism that may be necessary to achieve an optimal strategy for employing open source principles in life science research and development. The software world, far from being monolithic, has its own conflicts and deep philosophical divides, ranging from the vehement anti-property manifestos of Eben Moglen and Richard Stallman to the corporate profit strategies of firms like IBM and Microsoft.[245]

Yet even if open source bio never achieves the market acceptance of OSS, the case studies in this Article show that some gains are possible, and open source bio projects may have the potential to effect real benefits for both life science research and public health. More policy experimentation is needed.

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240. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34.

241. Standards Development Organization Advancement Act of 2004, Pub L. No. 108-237, § 213, 118 Stat. 661 (codified at 15 U.S.C. §§ 4301–05).

242. Despite its success, OSS itself is not without its doomsayers. *See* Rina Diane Caballar, *Open-Source Software Is in Crisis*, IEEE SPECTRUM, Nov. 13, 2024, https://spectrum.ieee.org/open-source-crisis [https://perma.cc/EGX9-A86S].

243. Arti K. Rai, *Critical Commentary on 'Open Source' in the Life Sciences*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS, *supra* note 13, at 217.

244. RAYMOND, *supra* note 57, at 225–27 ("I do not want to weaken the winning argument for open-sourcing software by tying it to a potential loser."); *see also* Allarakhia et al., *supra* note 64, at 52 ("it is reasonable to expect that the incentives driving participation in open source software endeavours efforts versus open source biopharmaceutical initiatives, as well as the rules of engagement that maximize chances of success, will likely differ.")

245. *See* BIRKINBINE, *supra* note 220, at 15–20.

Finally, it may be that open source bio, with its emphasis on distributed development and materials sharing, should be viewed as just one arrow in the quiver of open biology projects, rather than a prescription for the entire biopharmaceutical R&D enterprise. Amy Kapczynski, Richard Gold, and others have proposed alternative routes to open science,[246] which, together with better-established modes of open science, including open data, patent forbearance, and, of course, open source software itself, may all work together to enhance life science technology development, distribution, and access.

APPENDIX

Definitions of Open Source Bio
Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer*?, 1 PLOS MED. 183, 184 (2004). > What would open-source drug discovery look like? As with current software collaborations, we propose a Web site where volunteers use a variety of computer programs, databases, and computing hardware . . . . Individual pages would host tasks like searching for new protein targets, finding chemicals to attack known targets, and posting data from related chemistry and biology experiments. Volunteers could use chat rooms and bulletin boards to announce discoveries and debate future research directions. Over time, the most dedicated and proficient volunteers would become leaders.
Bernard Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NATURE REVS. DRUG DISCOVERY 723, 723 (2006). > [O]pen-source no longer refers to source code, but instead to the open origin of contributors.
Janet Hope, *Open Source Genetics: Conceptual Framework*, *in* GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 171, 179, 183–84 (Geertrui Van Overwalle ed., 2009). > Three key objectives of open source licensing are (1) credible commitment, (2) competition and, optionally, (3) copyleft. All three features are designed to encourage follow-on innovators to contribute to cumulative development of open source technologies . . . . 'Credible commitment' is about providing potential follow-on innovators with legally enforceable rights so they will have the confidence to invest in the initial technology and incorporate it into new developments. 'Competition' is about what hackers call 'software freedom,' which

246. *See* E. Richard Gold, *The Fall of the Innovation Empire and Its Possible Rise Through Open Science*, 50 RSCH. POL'Y, June 2021, at 1; Amy Kapczynski, *Order Without Intellectual Property Law: Open Science in Influenza*, 102 CORNELL L. REV. 1539 (2017).

in the present context might be thought of as 'technology freedom' or 'gene freedom': the right to use the technology, improve on it, and sell or otherwise distribute either the initial innovation or one's own improvements without incurring any ongoing obligation to the technology owner. Finally, 'copyleft' licences seek to extend these rights beyond the initial technology to follow-on innovations. A licensee who accepts a copyleft licence forgoes the usual right of excluding others from using any IP-protected improvements he or she might choose to distribute, but in return gains an assurance that he or she will have access to developments contributed by others.
Christine Årdal & John-Arne Røttingen, *Open Source Drug Discovery in Practice: A Case Study*, PLOS NEGLECTED TROPICAL DISEASES, Sept. 2012, at 1, 2 (citing Hassan Masum & Rachelle Harris, *Open Source for Neglected Diseases: Magic Bullet or Mirage?*, RESULTS FOR DEV. INST. (2011), https://r4d.org/wp-content/uploads/Open-source-high-res.pdf [https://perma.cc/BEP4-TGVQ]). 1. The project's data must be open access, meaning that anyone can view the data free-of-charge. 2. The project must provide a forum for open collaboration (across organizational and geographical boundaries). 3. The project must be governed by a set of rules that mandates the project's "openness".
Hassan Masum, Karl Schroeder, Myra Khan & Abdallah S. Daar, *Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies*, *in* OPEN DEVELOPMENT: NETWORKED INNOVATIONS IN INTERNATIONAL DEVELOPMENT 113, 122 (Matthew L. Smith & Katherine M.A. Reilly eds., 2013). [O]pen access to underlying information, open licensing practices, and open collaborative methods and platforms.
MEDS. FOR MALARIA VENTURE, ANNUAL REPORT 2015 26 (2016). Open Source: All project data and structures are laid bare and the wider community is invited to fully engage and offer support e.g. advice, synthesis, testing and in-kind technology.
Manica Balasegaram, Peter Kolb, John McKew, Jaykumar Menon, Piero Olliaro, Tomasz Sablinski, Zakir Thomas, Matthew H. Todd, Els Torreele & John Wilbanks, *An Open Source Pharma Roadmap*, PLOS MED., Apr. 18, 2017, at 1, 2. [R]adically transparent working practices pioneered in software development, such as the prepublication sharing of data and ideas, the possibility of participation in a project by anyone in real time, and a form of shared ownership that ensures that the underlying methods and data are public domain.

MICHAEL STEBBINS, MIRANDA BAIN, RENA CONTI, NICHOLAOS KRENTERAS, NICOLETA KRENTERAS, JAYKUMAR MENON & BERNARD MUNOS, FED'N OF AM. SCIENTISTS, DAY ONE PROJECT: ADOPTING AN OPEN-SOURCE APPROACH TO PHARMACEUTICAL RESEARCH AND DEVELOPMENT 3 (2020).

> First, an open-source approach would enable the entire scientific community to work together on challenges that are difficult for any single entity to solve (in keeping with the open-source mantra in software that 'with enough eyes, all bugs are shallow'). Second, an open-source approach would draw on the sum total of human knowledge, without being constrained by discipline-specific technical expertise, or being limited to knowledge with high profit potential. Third, an open-source approach would focus on creating universally accessible medicines and vaccines with substantial public-health benefits, even when those medicines and vaccines do not generate substantial revenue streams. Fourth, an open-source approach would create knowledge accessible to all, and accelerate the advance of science.