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THE FUTURE OF BIOTECHNOLOGY: ACCELERATING GENEEDITING ADVANCEMENTS THROUGH NON-EXCLUSIVE LICENSES AND OPEN-SOURCE ACCESS OF CRISPR-CAS9

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THE FUTURE OF BIOTECHNOLOGY: ACCELERATING GENE-EDITING ADVANCMENETS THROUGH NON-EXCLUSIVE LICENSES AND OPEN-SOURCE ACCESS OF CRISPR-CAS9.

By Emily N. Rissberger[1]

From the immune system of bacteria comes a promising new gene-editing technology, CRISPR-Cas9. Discovered in 2012, CRISPR-Cas9 has already been named one of the fastest, easiest, and cheapest gene-editing technologies. With this reputation, CRISPR-Cas9 shows promise in the research and treatments of a wide array of diseases. Cancer, blood disorders, blindness, AIDS, Cystic Fibrosis, Muscular Dystrophy, Huntington's disease, and even COVID-19 to name a few.

This relatively new technology has brought hope to researchers, doctors, and patients alike. However, current biotechnology licensing practices could hinder CRISPR-Cas9's groundbreaking potential. This article examines common biotechnology licensing practices, specifically the practices of two of the largest CRISPR-Cas9 patent holders, The University of Berkeley and The Broad Institute of MIT and Harvard. After each institution's respective CRISPR-Cas9 discovery the two battled it out to determine which institution discovered CRIPR-Cas9 first and whether patent infringement existed. Eventually, both institutions were granted their desired patents and quickly ensured the future of their technologies, created independent companies to control the licensing of CRISPR-Cas9 patents. This article refers to such companies as "surrogate companies" and explains the function of these entities as the gatekeeper of valuable patent rights through overinclusive exclusive licenses.

This article offers solutions to existing exclusive licenses without losing sight of the important relationship between research institutions and surrogate companies. Providing limited field of use licenses, rather than overinclusive exclusive licenses, of CRISPR-Cas9 patented technology will ensure a wider range of the human genome be discovered. Limited licenses allow companies to focus on specific goals, reducing the possibility of a gene therapy being overlooked and underdeveloped. This article goes further, suggesting the biotechnology industry adopt an open-source access model like the one used in the software industry. Such a model could prove beneficial for

[1] Tech Edge JD Candidate, Santa Clara University School of Law, 2022. The author thanks her friends and family for their unwavering support and guidance through the research and writing process and the editors of the *Santa Clara High Technology Law Journal* for their helpful edits.

companies looking to expand product offerings while still maintaining profits. Historically low-profit diseases like tropical diseases could become more desirable to companies based on collaboration and reduced R&D costs from employing open-source practices.

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INTRODUCTION

The ability to modify genes "easily and efficiently . . . holds immense promise to transform basic science, biotechnology, and medicine."[2] CRISPR-Cas9 is one of the promising technologies in gene editing. With promising results in sickle cell disease trials and opportunities to treat genetic diseases such as cystic fibrosis and muscular dystrophy, CRISPR-Cas9 is the future of medicine.[3] Unfortunately, the potential of this revolutionary technology is dwindling, with CRISPR-Cas9 patent owners putting profits over accessibility and broad application.

The biotechnology industry provides hope for the future of disease management and treatments. However, the industry is currently riddled with patent thickets (multiple over-inclusive patents covering the same area of technology), over-inclusive licenses, and a profit over progress mindset that currently inhibits the industry's revolutionary potential. As a relatively new industry, biotechnology can take inspiration from the software industry's open-source model, providing public access to research and encouraging collaboration to create the future of biotechnology.

I. AN INTRODUCTION TO GENE EDITING

Genome-editing (gene-editing) is a group of technologies that allow genetic material to be altered.[4] Editing occurs at a particular location in the genome that allows scientists to change an organism's DNA.[5] Gene-editing has been used to genetically modify crops to improve yields, prevent disease, and survive droughts.[6] Crops that have undergone such editing are genetically modified organisms or GMOs.[7] Gene-editing is also used to research and treat diseases

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[1] Patrick D. Hsu, Eric S. Lander, Feng Zhang, *Development and Applications of CRISPR-Cas9 for Genome Engineering,* CELL, 1262, 1263 (June 5, 2014).

[3] Emily Mullin, *Fresh Off Her Nobel Prize Win, Jennifer Doudna Predicts What's Next for CRISPR*, Future Human (Oct. 12, 2020), https://futurehuman.medium.com/fresh-off-her-nobel-prize-win-jennifer-doudna-predicts-whats-next-for-crispr-1fea0225c41d.

[4] *What are genome editing and CRISPR-Cas9?*, U.S. NATIONAL LIBRARY OF MEDICINE (June 23, 2020), https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/.

[5] *Id.*

[6] *What is genome editing?*, yourgenome (Aug. 23, 2017), https://www.yourgenome.org/facts/what-is-genome-editing.

[7] *What is a GMO?*, yourgenome (Feb. 17, 2017), https://www.yourgenome.org/facts/what-is-a-gmo.

currently "being explored in research on a wide variety of diseases, including single-gene disorders such as cystic fibrosis, hemophilia, and sickle cell disease . . . and more complex diseases such as cancer and AIDS."[8]

A. How Gene-Editing Works

On a basic level, gene-editing is the process of slicing and dicing genetic material to change the structure of targeted DNA.[9] More specifically, an enzyme referred to as an "engineered nuclease" cuts a genome in a specific location.[10] After being cut, the cell naturally repairs itself.[11] This repair process is where the "editing" occurs.[12] During the repair process, some of the DNA may be lost or added around the site of the cut.[13] These deletions or additions affect the function of the DNA.[14] To remove DNA, an engineered nuclease cuts either side of the section to be removed.[15] To repair this cut, the DNA recognizes the damage done and joins the ends of the two cuts together.[16] To insert a new section of DNA, an engineered nuclease cuts a specific location and introduces a modified piece of the previously cut DNA into the location. [17] The cell uses this modified piece to fill in the cut section.[18]

II. CRISPER-CAS9: A REVOLUTIONARY GENE EDITING TECHNOLOGY

There are several kinds of engineered nucleases used in gene-editing. One of the most commonly used engineered nucleus is CRISPR-Cas9, originally discovered in bacteria that use CRISPR-Cas9 to destroy invading viruses.[19] CRISPR stands for "clustered

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[8] *What are genome editing and CRISPR-Cas9?, supra* note 3.
[9] *What is genome editing?*, *supra* note 5.
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *What is genome editing?*, *supra* note 5.
[15] *Id.*
[16] *Id.*
[17] *What is genome editing?*, *supra* note 5.
[18] *Id.*
[19] Thomas Gaj, Shannon J. Sirk, Sai-Ian Shui, & Jia Liu, *Genome-Editing Technologies: Principles and Applications*, Cold Spring Hard Perspect Biol, (Dec. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5131771/. *See also,* University of Zurich. *New Bacterial Defense Mechanism of the CRISPR-Cas System Uncovered*, ScienceDaily (July 18, 2017), https://www.sciencedaily.com/releases/2017/07/170718113722.htm.

regularly interspaced short palindromic repeats,"[20] and Cas9 represents CRISPR-associated protein 9.[21] CRISPR can be accompanied by other Cas proteins such as Cas12, Cas14, CasX, and CasY.[22] However, this article's main focus is on CRISPR-Cas9 and will stick to referring only to the Cas9 protein system. To utilize CRISPR-Cas9, researchers create a guide sequence of RNA which is attached to the DNA sequence being edited.[23] The guide RNA shows the Cas9 protein where to cut the DNA, and the Cas9 protein proceeds with the cut. [24] Once cut, researchers manipulate the cell's DNA repair mechanism to either add or delete genetic material.[25] Researchers can also change DNA by "replacing an existing segment with a customized DNA sequence."[26]

A. CRISPR-Cas9 in Use

CRISPR-Cas9 can be used either by editing cells that have been removed from the body or injecting the gene-editing system directly into the body.[27] The latter process has been used in a clinical trial to treat Leber's Congenital Amaurosis (LCA10), a rare cellular mutation that disables light-sensing cells in the retina.[28] LCA10 is also

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[20] *What are genome editing and CRISPR-Cas9?*, *supra* note 3.
[21] Heidi Ledford & Ewen Callaway, *Pioneers of Revolutionary CRISPR Gene Editing Win Chemistry Nobel,* Nature (Oct. 7, 2020), https://www.nature.com/articles/d41586-020-02765-9.
[22] Fiona Mischel, *Who Owns CRISPR in 2021? It's Even More Complicated Than You Think*, Synbiobeta (Apr. 27, 2021), https://synbiobeta.com/who-owns-crispr-in-2021-its-even-more-complicated-than-you-think/.
[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] *What are genome editing and CRISPR-Cas9?, supra* note 3.
[27] *See* Rob Stein, *In A 1st, Scientists Use Revolutionary Gene-Editing Tool To Edit Inside A Patient*, NPR (Mar. 4, 2020), https://www.npr.org/sections/health-shots/2020/03/04/811461486/in-a-1st-scientists-use-revolutionary-gene-editing-tool-to-edit-inside-a-patient. *See also* Rob Stein*, He Inherited A Devastating Disease. A CRISPR Gene-Editing Breakthrough Stopped It,* NPR (June 26, 2021), https://www.npr.org/sections/health-shots/2021/06/26/1009817539/he-inherited-a-devastating-disease-a-crispr-gene-editing-breakthrough-stopped-it.
[28] Rob Stein, *In A 1st, Scientists Use Revolutionary Gene-Editing Tool To Edit Inside A Patient*, NPR (Mar. 4, 2020), https://www.npr.org/sections/health-shots/2020/03/04/811461486/in-a-1st-scientists-use-revolutionary-gene-editing-tool-to-edit-inside-a-patient.

one of the most common causes of childhood blindness.[29] Microscopic droplets carrying the CRISPR-Cas9 gene-editing system were injected into the patient's eye in hopes of repairing the gene mutation.[30] This procedure demonstrates CRISPR-Cas9's ability to "open entire[ly] new areas of medicine and lead to a whole new class of therapies for diseases that are not treatable any other way."[31]

Currently, "one of the biggest challenges with applying CRISPR clinically so far, [] is being able to deliver it systemically and get it to the right place."[32] In June of 2021, early data indicated direct injection of CRISPR-Cas9 into a patient's bloodstream was a success.[33] CRISPR-Cas9 was injected directly into the bloodstream of patients with transthyretin amyloidosis, a rare inherited disease that produces misshapen proteins that attack important tissues and nerves.[34] Amyloidosis deteriorates the body, eventually leading to death.[35] The amyloidosis treatment is the first instance of CRISPR-Cas9 being injected directly into a patient's bloodstream.[36] The injection of CRISPR-Cas9 into the bloodstream significantly reduced the levels of destructive proteins in patients.[37] Injecting directly into a patient bloodstream could help overcome CRISPR-Cas9's delivery challenges, opening the door to further treatment of diseases that affect tissue not located near possible injection sites.[38]

B. The Institutions Behind Discovering CRISPR-Cas9

The CRISPR-Cas9 engineered nuclease is "faster, cheaper, more accurate, and more efficient than other existing genome editing methods."[39] CRISPR-Cas9 has the potential to transform the way scientists study disease and the human genome. This makes it a highly

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[29] Bill Holton, *Vision Tech: Several Gene Therapies for Blindness Reach Clinical Trials*, American Foundation for the Blind, (Nov. 2019), https://www.afb.org/aw/20/11/16815.
[30] *Id.*
[31] *Id*. (alteration in original).
[32] Rob Stein*, He Inherited A Devastating Disease. A CRISPR Gene-Editing Breakthrough Stopped It,* NPR (June 26, 2021), https://www.npr.org/sections/health-shots/2021/06/26/1009817539/he-inherited-a-devastating-disease-a-crispr-gene-editing-breakthrough-stopped-it.
[33] *Id.*
[34] Stein*, He Inherited, supra* note 31.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *What are genome editing and CRISPR-Cas9?, supra* note 3.

desirable technology that has been mired with intellectual property ("IP") rights disputes.[40] UC Berkeley and the Broad Institute of MIT and Harvard (hereinafter "Broad" or "Broad Institute") are the main contenders in the fight for CRISPR-Cas9 IP rights.[41] Both parties claim the IP rights to CRISPR-Cas9 technology.

In 2012, Berkeley Professor of Chemistry, Jennifer Doudna, and her team developed the CRISPR-Cas9 technology,[42] applying to patent their discovery with the USPTO in May of the same year.[43] At the same time, a team at the Broad Institute was researching human gene-editing CRISPR technology.[44] The Broad Institute team's first application of CRISPR-Cas9 in eukaryotic cells used a guide that combined two RNA molecules, while the UC Berkeley team's CRISPR relied on a single RNA rather than two to accomplish the same result.[45] This single-molecule guide RNA is now the standard tool in the field.[46]

The Broad Institute team filed a patent for its CRISPR technology in December of 2012.[47] Although the UC Berkeley team had applied seven months prior, the Broad Institute team was awarded its CRISPR patent[48] first because the Broad Institute paid to expedite their application.[49] As of 2013, the USPTO has operated under a first-to-file system.[50] This system would have alleviated the resulting legal battle between UC Berkeley and the Broad Institute.[51]

Consequently, in 2016 the UC Berkeley team requested that the U.S. Patent Trial and Appeal Board (PTAB) begin an interference proceeding to determine which team was entitled to CRISPR-Cas9 rights.[52] These proceedings found no interference between the

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[40] Mischel, *supra* note 21.
[41] *Id.*
[42] Mark Summerfield, *Who Will Get the CRISPR Patent?,* Patentology (Jan. 17, 2016), https://blog.patentology.com.au/2016/01/who-will-get-crispr-patent.html.
[43] U.S. Patent No. 10,266,850 (issued Apr. 23, 2019).
[44] Jon Cohen, *The Latest Round in the CRISPR Patent Battle has an Apparent Victor, but the Fight Continues*, ScienceMag (Sept. 11, 2020), https://www.sciencemag.org/news/2020/09/latest-round-crispr-patent-battle-has-apparent-victor-fight-continues.
[45] *Id.*
[46] *Id.*
[47] Summerfield, *supra* note 41.
[48] U.S. Patent No. 8,697,359 (issued Apr. 15, 2014).
[49] Summerfield, *supra* note 41.
[50] *Id.*
[51] Mischel, *supra* note 21.
[52] Summerfield, *supra* note 41.

CRISPR-Cas9 patents for gene and animal cells held by the Broad Institute and the patent application for gene editing in all environments filed by UC Berkeley.[53] In 2018, a Federal Circuit affirmed the U.S. Patent Board's finding[54] allowing the Broad Institute to "maintain its extensive CRISPR patent portfolio."[55] This decision did not interfere with UC Berkeley's patent application which was eventually granted. [56]

Recently in September of 2020, the PTAB ruled that "the Broad Institute has 'priority' in its already granted patents for uses of the original CRISPR system in eukaryotic cells."[57] Such a patent covers potentially lucrative applications in humans and lab-grown human cells.[58] However, UC Berkeley is still hopeful that the ruling will lead to the "PTAB [ ] recogniz[ing] that the [UC Berkeley] team was first to invent the CRISPR-Cas9 technology in eukaryotic cells."[59]

The European Patent Office ("EPO") has added complexity to the already complex CRISPR-Cas9 patent battle. In 2012, the EPO favored UC Berkeley, granting the university its CRISPR-Cas9 patents before Broad due to a technical issue on Broad's application. [60] However, more recently in 2021, the EPO has revoked two of UC Berkley's CRISPR-Cas9 patents based on an invalid priority claim.[61] Although this article focuses on the CRISPR-Cas9 battle in the United States, these EPO decisions provide insight into the ever-changing gene-editing patent landscape. This article focuses on United States

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[53] Public Affairs, *UC Files Appeal to Revive CRISPR Patent Interference*, Berkeley News (July 26, 2017), https://news.berkeley.edu/2017/07/26/uc-files-appeal-to-revive-crispr-patent-interference/.

[54] *Regents of Univ. of California v. Broad Inst., Inc.,* 903 F.3d 1286, 1296-97 (Fed. Cir. 2018).

[55] Kevin Noonan, *Federal Circuit Affirms PTAB in Appeal of CRISPR Interference,* JDSupra.com, (Sep. 11, 2018), https://www.jdsupra.com/legalnews/regents-of-the-university-of-california-52116/.

[56] *Id*.

[57] Cohen, *supra* note 43.

[58] *Id*.

[59] *Id*.

[60] Vincent M. Grandpré & Felicia Lozon, *Making Sense of the Battle for the CRISPR-Cas9 Patent Rights*, Osler (Mar. 15, 2021), https://www.osler.com/en/resources/critical-situations/2021/making-sense-of-the-battle-for-the-crispr-cas9-patent-rights.

[61] Chrisitane G. Espino & Fangli Chen, *UC Berkeley CRISPR Patent Revoked in Europe Due To Invalid Priority Claim,* 11 Nat'l L. Rev. (May 24, 2021), https://www.natlawreview.com/article/uc-berkeley-crispr-patent-revoked-europe-due-to-invalid-priority-claim.

patent law in analyzing the current CRISPR-Cas9 landscape. However, the above information on the EPO shows the complexity of this revolutionary technology and the potential ownership issues that can arise when research is conducted globally.

C. The Extensive CRISPR-Cas9 Patent Portfolios of UC Berkeley and Broad Institute of MIT and Harvard

Despite the ongoing patent dispute between UC Berkeley and Broad Institute, both institutions have managed to accumulate large CRISPR-Cas9 patent portfolios. With both UC Berkeley and Broad Institute holding CRISPR patents "a third party wishing to utilize the technology in eukaryotic cells (encompassing everything from yeast to man) would need a license from *both* the University [of California Berkeley] and Broad [Institute]."[62] Multiple companies have been founded on UC Berkeley and Broad's initial CRISPR IP rights, specifically Caribou Biosciences (UC Berkeley) and Editas Medicine (Broad).[63] These "for-profit surrogate companies"[64] act as the patent owner, functioning as the "gatekeepers" to the CRISPR-Cas9 gene-editing industry.[65] The surrogate model allows universities and institutions to maximize profits while minimizing licensing risks.[66] With a surrogate company dealing with licensing, universities and institutions are free to focus on research and development to expand their patentable technologies further.[67]

Currently, UC Berkeley holds the United States' largest CRISPR-Cas9 patent portfolio,[68] gaining 18 CRISPR-Cas9 related patents in 2019.[69] As of May 2021, UC Berkeley owns 44 CRISPR-

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[62] Noonan, *supra* note 54.
[63] Mischel, *supra* note 21.
[64] Lisa M. Krieger, *How UC-Berkeley's CRISPR License Could Limit Innovation,* The Mercury News (Feb. 16, 2017), https://www.mercurynews.com/2017/02/16/how-uc-berkeleys-crispr-license-could-limit-innovation/.
[65] Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, Surrogate Licensing, and Scientific Discovery,* 355 SCIENCE 698, 698 (2017).
[66] *Id.*
[67] *Id.*
[68] Public Affairs, *UC Now Holds Largest CRISPR-Cas9 Patent Portfolio*, Berkeley News (Oct. 1, 2019), https://news.berkeley.edu/2019/10/01/uc-now-holds-largest-crispr-cas9-patent-portfolio/.
[69] Robert Sanders, *UC Rings Out 2019 with its 20th CRISPR Patent*, Berkeley News (Dec 31, 2019), https://news.berkeley.edu/2019/12/31/uc-rings-out-2019-with-its-20th-crispr-patent/.

based patents in the United States.[70] This collection of patents can be used by nonprofits and academic institutions for non-commercial research and educational purposes as part of UC Berkeley's open-licensing policy.[71] Commercial use of these patents is exclusively licensed to Caribou Biosciences ("Caribou").[72] Caribou sublicenses UC Berkeley's CRISPR patents to "strategic partners who are "recognized leaders in many market sectors."[73] One such partner is Intellia Therapeutics Inc., another UC Berkeley surrogate company created for CRISPR-Cas9 application in human therapeutic.[74]

Similar to UC Berkeley, Broad Institute also requires an exclusive license to use its CRISPR IP for human therapeutic research and development.[75] Broad Institute only waives the need for a written license for institutions looking to use its CRISPR-Cas9 IP for academic and non-profit research.[76] Under its "inclusive innovation" model, an alternative term for the exclusive license model, Broad Institute licenses its CRISPR-Cas9 technology to a primary licensee.[77] After a specified time, non-competitors of the primary licensee may apply for a CRISPR-Cas9 license by presenting Broad Institute with a development plan.[78] This development plan explains how the company will use Broad Institute's CRISPR IP.[79]

The primary licensee has access to this development plan to ensure the plan does not infringe on the primary licensee's exclusive

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[70] Robert Sanders, *UC Berkeley Will Auction NFTs of Nobel Prize-Winning Inventions to Fund Research*, Berkeley News (May 27, 2021), https://news.berkeley.edu/2021/05/27/uc-berkeley-will-auction-nfts-of-nobel-prize-winning-inventions-to-fund-research/.

[71] Public Affairs, *CRISPR portfolio now at 14 and counting*, Berkley Research (Sep. 17, 2019), https://vcresearch.berkeley.edu/news/crispr-portfolio-now-14-and-counting.

[72] Public Affairs, *UC Now Holds Largest CRISPR-Cas9 Patent Portfolio*, Berkeley News (Oct. 1, 2019), https://news.berkeley.edu/2019/10/01/uc-now-holds-largest-crispr-cas9-patent-portfolio/.

[73] Licences, Caribou Biosciences, https://cariboubio.com/#licenses.

[74] Sanders, *UC Rings*, *supra* note 68.

[75] Information About Licensing CRISPR Systems, Including for Clinical Use, Broad Inst., available at https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-edi (last visited Sept. 10, 2021).

[76] *Id.*

[77] Information About Licensing CRISPR Systems, *supra* note 74.

[78] *Id.*

[79] *Id.*

CRISPR-Cas9 license.[80] If a primary licensee has plans to apply CRISPR-Cas9 to the same genes or diseases as its noncompetitor who submitted a development plan, then the non-competitor becomes a competitor and cannot obtain a CRISPR license.[81] This model "enable[s] the primary licensee to devote sufficient investment to develop CRISPR-based genome editing technology to treat human diseases, while supporting broad development of medicines to reach many patients."[82]

Both UC Berkeley and Broad Institute's licensing schemes risk excluding innovative companies from accessing CRISPR-Cas9 technology. With an exclusive license over UC Berkeley's vast CRISPR-Cas9 patent collection, Caribou has the discretion to choose which companies can sublicense and use UC Berkeley's revolutionary technology. Broad Institute's "inclusive innovation" licensing model, in practice, does not support the broad development of medicines. This model gives its primary licensee, Editas Medicine, run by "Feng Zhang of the Broad Institute of MIT and Harvard,"[83] close to exclusive control over the CRISPR industry. UC Berkeley and Broad Institute's licensing practices make it difficult for companies not affiliated with UC Berkeley or Broad Institute to enter the CRISPR market.

III. EXCLUSIVE LICENSING AND THE BIOTECHNOLOGY INDUSTRY

The exclusive licensing schemes used by UC Berkeley and Broad Institute diminish the incentive for the academic community to research CRISPR-Cas9 application in gene-editing. Although academic and non-profit use of both institutes' patents is allowed, the researchers and academics who use these patents "don't have the right to market and sell products derived from their research."[84] An additional roadblock to CRISPR-Cas9 access is surrogate company approval requirements. The exclusive licenses granted to UC Berkeley and Broad Institute's respective surrogate companies prohibit academic and nonprofit use of CRISPR-Cas9 for human therapeutics and treatment without the approval of the exclusive licensee.[85] The surrogate model also disadvantages the patent owners, restricting UC

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[80] *Id.*
[81] *Id.*
[82] Id.
[83] Sharon Begley, *Exclusive CRISPR Licenses Slow Development of Therapies, Legal Experts Argue,* STAT (Feb. 16, 2017), https://www.statnews.com/2017/02/16/crispr-exclusive-licenses/.
[84] Krieger, *supra* note 63.
[85] Contreras & Sherkow, *supra* note 64, at 698.

Berkeley and Broad Institute's ability to grant similar licenses to other companies without approval from their respective surrogate companies.[86]

A. Congress' Push to Make Federally Funded Research Accessible and the Exclusive Licensing That Followed

Before 1980, open science prevailed in biotechnology, with researchers "more inclined to share scientific findings rather than shroud them in secrecy."[87] Some researchers from the 20th century biomedical community even viewed patenting biomedical discoveries as unethical.[88] The social norms in the scientific community during this time were rooted in communalism which discouraged claiming property rights over inventions and keeping discoveries secret.[89]

Unfortunately, in a bid to "encourage the development of commercializ[ing] products", the United States Congress enacted the Bayh-Dole Act in 1980 along with several other pro-patent right acts.[90] These new laws allowed for the commercialization of publicly funded research, replacing the scientific community's communalism norm with commercialization.[91] The Bayh–Dole Act ushered in a new era of federally funded research, allowing inventions created from federally sponsored research to be owned by universities and institutions[92] rather than being assigned to the federal government.[93]

The act created a pathway to lucrative income by commercializing university-developed technology.[94] This new revenue stream, which currently makes over $6 billion per year, led to a rise in licensing activity among academic institutions.[95] By creating a uniform patent policy among federal agencies, the inventor protections created by the Bayh-Dole Act incentivized universities and

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[86] *Id*. at 700.
[87] Yann Joly, *Open Source Approaches in Biotechnology: Utopia Revisited*, 59 ME. L. REV. 385, 391 (2007).
[88] *Id*.
[89] *Id.*
[90] Joly, *supra* note 86.
[91] *Id*.
[92] Vladimir Drozdoff & Daryl Fairbairn, *Licensing Biotech Intellectual Property in University–Industry Partnerships*, COLD SPRING HARBOR PERSPECT MED. 1, 1 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355252/.
[93] *Bayh-Dole Act: Regulations Impacting Ownership of Patent Rights*, University of Wisconsin-Madison Research, https://research.wisc.edu/bayhdole/ (last visited Sept. 23, 2021).
[94] *Id*.
[95] Drozdoff & Fairbairn, *supra* note 91 at 1.

institutions to develop their research into lifesaving treatments.[96] For example, the Bayh-Dole Act made it possible for the University of Michigan to create radioimmunotherapy, a treatment for a once incurable form of follicular non-Hodgkin's lymphoma, out of Michigan's pre-existing research.[97] While the Bayh–Dole Act made federal-funded research more accessible to taxpayers[98], the era following saw an increase in exclusive licensing schemes and surrogate companies.

B. Exclusive Licensing Limits CRISPR-Cas9's Potential

The large patent portfolios of both UC Berkeley and Broad are at the root of the exclusive licensing problem. The overinclusive patents used by these institutions create a patent thicket inhibiting the further development of CRISPR-Cas9 technology and applications. A patent thicket occurs when multiple patents state broader claims than the actual invention discovered.[99] When multiple patents cover the same area of technology, as is the reality of the CRISPR patent landscape, a thicket of existing patent rights develops.[100] This thicket requires potential developers to obtain rights from each patent holder to minimize patent infringement liability.[101]

The exclusive licenses used by UC Berkeley and Broad Institute further inhibit the full potential of CRISPR-Cas9 innovations, holding back genome research and development. An exclusive license is a contract that allows a licensee to exclusively exercise one or more of a patent owners' rights for a specific period.[102] License agreements are important to define the scope of rights being transferred and to lay out the compensation for those rights.[103] License agreements also establish the risk each party takes on in carrying out the agreement.[104]

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[96] *Landmark Law Helped Universities Lead the Way*, AUTM, https://autm.net/about-tech-transfer/advocacy/legislation/bayh-dole-act.
[97] *Id.*
[98] *Id.*
[99] Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps*, 23 SANTA CLARA HIGH TECH. L.J. 271, 281-82 (2012).
[100] *Id*.
[101] *Id*.
[102] Drozdoff & Fairbairn, *supra* note 91, at 5.
[103] *Id.* at 2.
[104] *Id.*

Licensing rights, such as, exclusive licenses, are typically limit by field of use restrictions.[105] These restrictions inhibit a licensee's ability to exploit all fields of use of one technology, safeguarding against one licensee controlling all preventive, diagnostic, and therapeutic use for diseases in humans, animals, and plants.[106] Although exclusive licenses are common in biotechnology, the exclusive licenses granted to Caribou and Editas by their respective founding institutions differ from the industry standard.

Instead of granting the exclusive use of one gene or a section of a genome, the exclusive licenses UC Berkeley and Broad Institute use cover "every gene in the human body and every gene known to humankind."[107] One company is unlikely to research every aspect of the human genome, meaning certain gene therapies could go undeveloped or ignored.[108] CRISPR-Cas9 patents and exclusive licenses covering all known genes in both plant and animal cells create an impossibility "for researchers to invent around"[109] the patents owned by UC Berkeley and Broad Institute.

Exclusive licenses covering the whole human genome restrict the use of CRISPR technology to certain profitable genes selected by surrogate companies and their sublicensees. This prevents CRISPR-Cas9 from being used to develop less profitable gene therapies, hindering the technology's full potential. Similar to for-profit companies, surrogate companies focus on profitability when deciding which genes to develop and which companies to grant sublicenses to.[110] Currently, within human therapeutics, surrogate companies are focused on researching CRISPR-Cas9 effects on cancer, stem cells, sickle cell anemia, and cystic fibrosis.[111] These diseases make up only a fraction of CRISPR-Cas9's potential application in improving genetic diseases. This for-profit model inhibits the development of less profitable therapies, leaving the treatment of rare diseases or diseases

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[105] *See generally* Jeffrey P. Somers, *Biotech Patent Licensing: Key Considerations in Deal Negotiations*, MORSE (Jan. 15, 2003) https://www.morse.law/news/biotech-patent-licensing.

[106] *See id.*

[107] Begley, *supra* note 82.

[108] Jun Tong, *The CRISPR Patents and Their Hindrance to Innovation*, JIPEL Blog (Apr. 5, 2017) https://blog.jipel.law.nyu.edu/2017/04/the-crispr-patents-and-their-hindrance-to-innovation/.

[109] Joly, *supra* note 86, at 390.

[110] Contreras & Sherkow, *supra* note 64, at 699.

[111] *See* Clara R. Fernandez, *Eight Diseases CRISPR Technology Could Cure,* LABIOTECH.EDU (Sept. 13, 2021), https://www.labiotech.eu/crispr/crispr-technology-cure-disease/.

that affect disadvantaged communities unresearched or worse, undiscovered.[112]

Gene-editing industry members, such as Editas' co-founder George Church, believe exclusive licensees "have the potential to impede research into therapeutic genome editing."[113] The monopoly of therapeutic gene editing goes against the Patent and Trademark Law Amendments Act, a federal regulation created in 1980 to "promote the utilization of inventions arising from federally supported research or development."[114] Through this act, the public can petition for patents based on government-funded research to be licensed reasonably, allowing the patent to be utilized to its full potential.[115] The issue of patent accessibility has reached the highest court in the land with the Supreme Court of the United States, emphasizing the purpose of patents, "which exist to promote creation."[116]

The tragedy of the anticommons, first used by Heller and Eisenberg in 1998, identifies the problem with over-inclusive licensing.[117] The tragedy of the anticommons is the idea that many exclusive rights over a single resource will lead to the underutilization of the resource.[118] This tragedy perfectly describes the accessibility issue created by UC Berkeley and Broad Institute's CRISPR-Cas9 licensing scheme. Because of the over-inclusive licensing of CRISPR-Cas9 patents to surrogate companies, which in turn sublicense rights to others, the use of CRISPR-Cas9 is limited to the most profitable gene applications. This over fragmentation of patent rights deters innovation and makes the application of less profitable genes unlikely to be explored. Abandoning the surrogate exclusive license model is realistic and can help UC Berkeley and Broad further develop the CRISPR gene-editing industry. Non-exclusive licensing schemes have been used by universities determined to promote innovation.[119] Gene-splicing patents issued to Stanford University in 1980 were never exclusively licensed but still managed to promote innovation, leading

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[112] Contreras & Sherkow, *supra* note 64 at 700.
[113] Begley, *supra* note 82.
[114] *See generally* 35 U.S.C. § 200.
[115] Begley, *supra* note 82.
[116] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576, 589 (2013).
[117] George Balabanian, *Open-Source Licensing in Biotechnology and Pharmaceuticals: Possibilities and Challenges* 1, 14 (Apr. 23, 2012), https://ssrn.com/abstract=2977588.
[118] *Id.*
[119] Begley, *supra* note 82.

to the creation and expansion of the biotechnology industry.[120] Similarly, CRISPR technology has the potential to further advance the biotechnology industry if the industry's current exclusive licensing practices are altered.

C. *Alternatives to Exclusive Licenses.*

In 2006, a set of points were drafted to help research universities navigate the technology licensing of research tools. [121] Over 100 universities worldwide endorsed the *Nine Points to Consider in Licensing University Technology (*the *Nine Points),* including the University of California (of which UC Berkeley is a campus)[122], Harvard, and MIT.[123] To encourage the further development of licensed technologies, Point Two of the *Nine Points* instructs universities to structure exclusive licenses that encourage the development and use of licensed research tool technology.[124] CRISPR is generally thought of as a broadly applicable platform technology rather than an research tool that enables downstream research.[125] However, recently, researchers have begun exploring CRISPR as a research tool, expanding the gene editing technology past its current therapeutic purpose.[126] With research tooling capabilities, UC Berkeley, and Broad Institute should consider the *Nine Points* when structuring CRISPR licenses.

To implement Point Two, UC Berkeley and Broad Institute could issue narrowly drawn exclusive licenses to their surrogate companies, allowing for broader research and development of the human genome. [127] To be "mindful of the impact of granting overly

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[120] *Id.*

[121] California Institute of Technology et al., *In the Public Interest: Nine Points to Consider in Licensing University Technology* (Mar. 6, 2007), http://www.autm.net/AUTMMain/media/Advocacy/Documents/PointstoConsider.pdf.

[122] *The parts of UC*, University of California, https://www.universityofcalifornia.edu/uc-system/parts-of-uc.

[123] *James K. Woodell and Tobin L. Smith, T*echnology Transfer for all the Right Reasons*, TECH & INNOVATION 296, 298 (2017). See also, Nine Points to Consider in Licensing University Technology, AUTM, https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university.*

[124] *Id*. at 300.

[125] Contreras & Sherkow, *supra* note 64 at 700.

[126] Zach Winn, *Using CRISPR as a Research Tool to Develop Cancer Treatments,* MIT News (Apr. 23, 2021), https://news.mit.edu/2021/ksq-crispr-cancer-0423.

[127] California Institute of Technology et al., *supra* note 120, at 2.

broad exclusive rights,"[128] UC Berkeley and Broad Institute should limit the coverage of their exclusive licenses to select genes in the human genome, rather than allowing surrogate companies extensive control over all genes each institutions respective patents cover. This will allow the surrogate companies to continue their profit-focused research and development while encouraging a wider range of CRISPR-Cas9 gene therapies to be developed.[129]

Alternatively, UC Berkeley and Broad Institute can meet Point Two without abandoning exclusive licensing by including performance milestones in their existing exclusive licenses.[130] Providing performance milestones will encourage surrogate companies to align with UC Berkeley and Broad Institute's individual development goals while preserving the surrogate-university relationship. Milestones for CRISPR-Cas9 licenses could include requiring surrogates to apply CRISPR-Cas9 to specific genes or specific diseases within a reasonable timeline.

UC Berkeley and Broad Institute could also include sublicensing requirements for surrogate companies to "address unmet market or public health needs."[131] Currently, Caribou and Editas have full discretion to sublicense CRISPR-Cas9 technology.[132] Implementing sublicensing requirements would allow Caribou and Editas to continue sublicensing while narrowing their discretion, requiring sublicenses to be given for genes or diseases the surrogates are not developing. Sublicensing requirements would not only preserve the surrogate exclusive license model but also allow wider CRISPR-Cas9 application.

Another way to broaden CRISPR-Cas9 development while continuing to grant exclusive licenses is by reserving the licensor's right to license within the scope of the exclusive license.[133] UC Berkeley and Broad Institute could use reserved rights to license CRISPR-Cas9 for use in areas that the surrogate companies are not interested in or do not have the resources to fully develop. Broad Institute's current "inclusive innovation" model already allows for licenses to be given to third parties but only if the primary licensee is not interested in pursuing the same CRISPR applications.[134] With the

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[128] *Id.*
[129] Tong, *supra* note 107.
[130] California Institute of Technology et al., *supra* note 120, at 3.
[131] *Id.*
[132] Krieger, *supra* note 63.
[133] *Id*.
[134] Begley, *supra* note 82. *See also* Information About Licensing CRISPR System, *supra* note 74.

reserved right, Broad Institute could license its CRISPR technology to a third party without presenting the third party's development plan to Editas. This allows for broader application of CRISPR by multiple companies and encourages Editas to sublicense to more third parties because sublicensing gives them more control than licensing by Broad.

A nonexclusive license could also be an alternative to UC Berkeley and Broad's current overreaching exclusive licenses. Nonexclusive licenses generally allow the licensee to use patent rights without giving the licensee control over the enforcement or licensing of such rights.[135] This licensing scheme allows the patent owner to grant the same rights to several parties.[136] These licenses are most commonly seen used for platform technologies with wide applications in different fields of use.[137] The application potential of CRISPR-Cas9 can be compared to such platform technologies. However, with the additional liability risk that comes with developing genetic therapies, nonexclusive licenses are riskier than the exclusive licenses UC Berkeley and Broad Institute currently use.[138]

IV. OPEN-SOURCE IN THE BIOTECHNOLOGY INDUSTRY

The biotechnology industry should model future licensing after the software industry's open-source model to "enable researchers to improve the efficiency of research and decrease the transactions costs involved."[139] Open-source licensing is common in software code, which primarily relies on copyright protection.[140] Although the biotechnology industry relies on patent protections, rather than copyright protections, open-source licensing is still a potential solution to allow for wide access to innovative biotechnologies. In software, the shift from "secret, copyrighted, and carefully litigated"[141]code to collaboration and free distribution of source code and data allowed the industry to accelerate development.[142] An open-source approach could similarly benefit to the biotechnology industry, helping resolve the

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[135] Drozdoff & Fairbairn, *supra* note 91, at 5.
[136] *Id.*
[137] Drozdoff & Fairbairn, *supra* note 91, at 5.
[138] *See generally i**d.***
[139] Nolan-Stevaux, *supra* note 98, at 279.
[140] Andrew C. Oliver, *Open Source History Foretells the Future of Pharma and Omics,* Lucidworks, (June 27, 2018), https://lucidworks.com/post/open-source-history-foretells-the-future-of-pharma-and-omics/.
[141] *Id*.
[142] *Id*.

patent thicket problem and anticommons dilemma previously discussed.[143]

The most common open-source licenses are the General Public License (GPL) and the Berkeley Software Distribution License (BSD).[144] GPLs are copyleft licenses that allow freedom to share and change free software.[145] The less restrictive BSD allows free use of the BDS code if the required notices accompany the code.[146] Open-source licenses can still provide a level of secrecy. Software creators looking to maintain secrecy can make BSD-licensed code private "since proprietary software that includes the BSD notice can be distributed in object code so that it may be maintained in secret."[147] Although not entirely convertible to the biotechnology industry, open-source license models like GPL and BSD can work as guides in creating open-source licenses that benefit biotechnology.

There is a growing interest in the biotech industry to venture into the world of alternative business models.[148] Open-source research and development is one alternative model that is gaining traction. Unlike the software industry, when used in the biotechnology field, open-source is a catch-all term to identify a scientific collaboration business model.[149] Open source promotes sharing, rather than exclusivity, in the search for revolutionary, affordable medicine.[150] With more open-source access to research and development, less profitable disease therapies will have a better chance of gaining needed attention. Open-source practices could result in companies placing equal importance on medical advancement and profitability of new drugs therapies when deciding what information to release or which research to pursue.[151]

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[143] Nolan-Stevaux, *supra* note 98, at 282.
[144] Nolan-Stevaux, *supra* note 98, at 280.
[145] Nolan-Stevaux, *supra* note 98.
[146] *Id.* at 281.
[147] *Id.*
[148] Steven J. Vaughan-Nichols, *Medicine Needs to Embrace Open source*, ZDNet (June 10, 2019), https://www.zdnet.com/article/medicine-needs-to-embrace-open-source/.
[149] Joly, *supra* note 86, at 393.
[150] Vaughan-Nichols*, supra* note 147. *See generally,* Joly, *supra* note 86.
[151] Ruth Reader, *How Open-Source Medicine Could Prepare Us for the Next Pandemic,* Fast Company (Apr. 30, 2020) https://www.fastcompany.com/90498448/how-open-source-medicine-could-prepare-us-for-the-next-pandemic.

A. Examples of Open-Source Biotechnology Research and Development

In 2015, Pfizer discovered that its rheumatoid arthritis drug, Enbrel, reduced the risk of Alzheimer's by 64%.[152] Rather than making their discovery accessible to outside companies or researchers, Pfizer buried the results.[153] Pfizer claimed the results did not meet "rigorous scientific standards" and did not want others to be led astray.[154] In reality, Pfizer took advantage of the accepted exclusivity plaguing the biotech industry, putting profit potential over development. Pfizer's decision to put commercial incentives above valuable Alzheimer's data, positive or negative, shows how the greater biomedical industry is disadvantaged by the rejection of open-source collaboration.[155]

Pfizer, UC Berkeley, Broad Institute and the larger biotechnology community are making use of current biotechnology practices that, unfortunately, could have disastrous consequences for future innovation. The problem with UC Berkeley and Broad Institute's exclusive licenses is the inability for research to be developed in less profitable gene therapies to begin with. Gene applications that could benefit less profitable diseases, such as tropical diseases that typically affect poor or developing countries, are not enticing to large companies looking for the next "blockbuster drug."[156] This is because the commercial model Western companies operate under only works if a drug can be sold at a price and quantity that can cover the cost of R&D.[157] This model fails with tropical diseases because, generally, few tropical disease patients can afford to pay a price that will recover a company's high R&D costs.[158] The disadvantage less profitable diseases have is evident by the lack of newly developed tropical disease drugs.[159] It is estimated that only around 1% of newly developed drugs are for tropical diseases, such as African sleeping sickness, dengue fever, and leishmaniasis.[160]

Fortunately, the biomedical industry may be pushed into accepting open-source research and development in the near future.

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[152] Vaughan-Nichols, *supra* note 147.
[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] Balabanian, *supra* note 116, at 18.
[157] Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, PLOS Med (Dec. 28, 2004), https://doi.org/10.1371/journal.pmed.0010056.
[158] *Id.*
[159] Maurer, Rai & Sali, *supra* note 156.
[160] *Id.*

The recent global pandemic has assisted in accelerating open-source collaboration. Thanks to Chinese researchers openly publishing the COVID-19 genetic sequence, pharmaceutical companies and researchers were able to find existing drugs that have been repurposed to fight the virus and develop new vaccines quickly.[161] The COVID-19 pandemic is an incredible example of how open-source can benefit companies' profits and public's health. Advocates for open-source are hoping that the pandemic's "open-source model can be replicated to address other challenges in biomedical research."[162]

Even before the pandemic, some pharmaceutical companies were slowly moving toward open-source development. Offering a company's intellectual property to the public risks losing out on profits and credit, but diseases that affect poor populations, like tropical diseases, do not provide large profits to begin with.[163] Tropical diseases impact roughly one-sixths of the worlds population,[164] yet pharmaceutical companies devote little time and resources toward cures because such diseases lack economic incentives.[165] Tropical diseases are less commercially attractive because they take resources away from the research and development of "profitable" diseases that affect countries with rich populations willing and able to pay "blockbuster" drug prices.[166]

The Tropical Disease Initiative (TDI) is a web-based open-source drug development project tapping into the underdeveloped and less profitable tropical disease market.[167] Collaboration between researchers from laboratories, universities, institutes, and corporations work together to explore under-researched tropical diseases benefiting populations traditionally ignored by the biomedical industry.[168]

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[161] Reader, *supra* note 150.
[162] *Id.*
[163] Robert A. Guth, *Glaxo Tries a Linux Approach*, Wall Street Journal (May 26, 2010), https://www.wsj.com/articles/SB10001424052748703341904575266583403844888.
[164] *Neglected Tropical Diseases (NTDs)*, CDC, (Last updated Sep 14, 2018), https://www.cdc.gov/globalhealth/newsroom/topics/ntds/index.html.
[165] Balabanian, *supra* note 116, at 18.
[166] Tim Smedley, *Is it Fair to Accuse the Pharma Industry of Neglecting Tropical Diseases?*, The Guardian (Oct. 15, 2015, 7:47 AM), https://www.theguardian.com/sustainable-business/2015/oct/15/pharma-industry-neglecting-tropical-diseases-snake-bite.
[167] Balabanian, *supra* note 116, at 19.
[168] *Id.*

Similarly, the Medicines for Malaria Venture (MMV), working toward new Malaria treatments, shipped hundreds of its Malaria Boxes to 200 researchers in 30 countries.[169] The compounds in the Malaria Box that were used by one researcher "identified promising compounds that attacked the Plasmodium falciparum malaria parasite [leading] to further drug development work."[170] The same researcher even found compounds active against parasites unrelated to Malaria that could protect against a parasite that causes childhood blindness.[171] The Malaria Box and MMV's other projects, the Pathogen Box and the Pandemic Response Box, show a realistic open-source research model.[172] These boxes show the move from commercial drug research and development toward a collaborative model where intellectual property is shared instead of guarded.

MMV also collaborated with GlaxoSmithKline and St. Jude Children's Research Hospital to create a list of 20,000 potential antimalarials now logged in an open chemical database curated by the European Bioinformatics Institute.[173] Open-Source Pharma Foundation, founded in 2018, is also an open-source "success story." In 2019, the OSPF team took a generic diabetes drug into "Phase 2B clinical trials as a tuberculosis treatment."[174] Typically a new drug would cost $500 million to develop,[175] but OSPF's tuberculosis treatment required under $50,000 and took less than a year to develop, showing the cost and time efficiency of collaborative research.[176]

B. The Biotechnology Industry's Hesitation Toward Open-Source

Understanding why open-source was widely accepted in the software industry can help address the hesitation to adopt similar practices in other industries.[177] In the early stages of the industry, software was the "Wild West of the legal world."[178] The unknown of

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[169] Mark Peplow, *Open-Source Drug Discovery Takes Aim at Malaria and Neglected Diseases*, Chemical and Engineering News (Jan. 29, 2019), https://cen.acs.org/pharmaceuticals/drug-discovery/Open-source-drug-discovery-takes-aim-at-malaria-and-neglected-diseases/97/i5.
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] Peplow *supra* note 168.
[174] Reader, *supra* note 150.
[175] Balabanian, *supra* note 116, at 16.
[176] Reader, *supra* note 150.
[177] *See generally* Balabanian, *supra* note 116, at 11.
[178] *Id.*

the industry allowed open-source to flourish, largely due to the inability of legislators, regulators, and policy-makers to comprehend the new software frontier.[179]

Generally, the more reliant a field is on vested intellectual property interests, "the more resistant that field will be to the idea of open-source models."[180] Relying heavily on already existing and well-regulated intellectual property protection, the biotechnology industry's ability to explore new methods of sharing information and collaborating is limited. Open-source systems utilized by the software industry are not directly transferable to biotechnology.[181] The notable differences between software and biotechnology create an exciting opportunity to customize open-source projects to fit specific biotechnology research.[182]

Moving from tightly held secrets to open access is a radical idea for many companies. The Biological Innovation for Open Society (BiOS) initiative, created in 2005, is an open-source biological technologies project looking to promote open-source development in biotechnology, create new legal mechanisms to protect open-source developments, and provide intellectual property analysis to protect against patent liability.[183] BiOS is working to accelerate companies' open-source acceptance, with protections specific to biotechnology.[184] Projects like BiOS and other open-source research companies receiving public recognition provide promise for the biotechnology industry moving toward more open-source collaboration.

Critics of open-source research fear that the lack of standards within an open-source process will deteriorate the quality of future scientific findings.[185] This fear is unfounded given that open-source projects are not only constantly "peer-reviewed" but also continuously "peer improved".[186] With additional quality safeguards such as industry-developed Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices the fear of lackluster research and discovery becomes even less credible.[187]

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[179] *See generally id.*
[180] *Id* at 11.
[181] Peplow, *supra* note 168.
[182] *See generally* Peplow, *supra* note 168.
[183] Balabanian, *supra* note 116, at 21-22.
[184] Nolan-Stevaux, *supra* note 98, at 303-04.
[185] Balabanian, *supra* note 116 at 24.
[186] Balabanian, *supra* note 116, at 25.
[187] *Id.*

C. Benefits to Open-Source in the Biotechnology Industry

Benefits to an open-source model include the elimination of errors in research. Open access to research and findings "encourages an open, critical discussion in order to foster higher quality research."[188] Increased accessibility also allows for maximal early-stage development.[189] Receiving outside input during the early research phases, rather than after the initial discovery, will benefit the efficiency of the research and potentially cut down on research costs.[190] Open databases and access to new research tools or promising therapeutics could allow neglected diseases to be properly studied.[191] Cutting back on cost will lead to better research for diseases and treatments affecting poor populations and developing nations.[192]

Further economic benefits to implementing open-source in the biotechnology industry include reduced duplicate research.[193] Transparency cuts down excessive costs where research being perused by one has already been studied by another.[194] Fear of profit loss in an open-source model is mitigated by making up profits that would have been generated through complementary goods and services.[195] Providing public access to technology and research companies can also boost their reputation as being innovative and socially conscious.[196] Interest from the public could also lead to volunteer labor, further cutting down the cost of research.[197] Overall, open-source promises thorough review, revision, and modification by combining the know-how from a wide pool of interested parties.[198]

CONCLUSION

In the past few years, CRISPR-Cas9 has developed a reputation as the future of gene editing, becoming a mainstream gene-editing technology. During this time, UC Berkeley and Broad Institute have established themselves as pioneers in the CRISPR-Cas9 industry. With court judgments and esteemed awards, UC Berkeley and Broad Institute have legitimate evidence to establish ownership of their

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[188] Joly, *supra* note 86, at 398.
[189] *Id.* at 399-404.
[190] *Id.* at 399-400.
[191] *Id.*
[192] *Id.*
[193] *Id.*at 400.
[194] Joly, *supra* note 86, at 400.
[195] *Id.*
[196] *Id.* at 400.
[197] *Id.*
[198] Balabanian, *supra* note 116, at 25.

respective intellectual property, were they to be misused or stolen. The extensive legal battle between the two institutions found Broad Institute the "victor," legitimizing its claim to its extensive CRISPR-Cas9 patent portfolio.[199] This past year, UC Berkeley has also solidified its place as a CRISPR pioneer, with the university's biochemist, Jennifer Doudna, receiving the 2020 Nobel Prize in Chemistry[200] for developing CRISPR-Cas9.[201] This recognition makes both institutions' ability to provide open-source access to select CRISPR-Cas9 gene applications possible and realistic, as it is evident that CRISPR-Cas9 therapy or treatment will have been a product of UC Berkeley or Broad Institute's intellectual property.

The CRISPR industry is still relatively new, being first discovered in 2012.[202] Understandably, universities wish to keep intellectual property rights protected by licensing to surrogate companies. This surrogate licensing system gives universities more control over how their CRISPR-Cas9 technology is being used, while mitigating the risk associated with IP licensing. However, the current surrogate model used by the leaders of the CRISPR-Cas9 industry heavily restricts access to this revolutionary technology. Exclusive licenses are a common practice in biotechnology and should not be completely discarded from the universities' intellectual property rights toolkit. However, while licenses are an important tool for protecting intellectual property, universities must change their current exclusive license system to allow more than just a handful of companies access to CRISPR-Cas9.

While countless alternatives to exclusive licensing exist, open-source collaboration provides numerous benefits and has already gained popularity as a useful tool in COVID19 research. Open-source should not eliminate licensing altogether. The open-source method is not a threat to the blockbuster drug development model, which is currently the standard in the biomedical industry.[203] Companies can continue to use patents to protect the most commercially promising

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[199] *Regents of the Univ. of Cal. v. Broad Inst., Inc.,* 903 F.3d 1286, 1296-97 (Fed. Cir. 2018).

[200] UC Berkeley is beginning to auction off nonfungible tokens (NFTs) for the patent disclosures at the heart of two Nobel Prize-winning inventions from its research labs. One of the NFTs will be for the 2020 Nobel in Chemistry given to UC Berkeley's Jennifer Doudna for her discovery of CRISPR-Cas9 gene editing.

[201] Ledford & Callaway, *supra* note 20.

[202] Summerfield, *supra* note 41.

[203] Balabanian, *supra* note 116, at 18.

intellectual property, while open-source collaboration can fill in the gaps of less profitable but still vital, research and development.

UC Berkeley and Broad Institute's extensive CRISPR-Cas9 patent portfolios could benefit from allowing selective open-source access. To suggest these institutions completely give up their intellectual property rights over CRISPR-Cas9 application would be naive. However, ignoring the move toward collaboration within the biotechnology field is also naive. UC Berkeley and Broad Institute should limit their exclusive licenses to select gene applications and allow open-source access to less profitable genes that otherwise may go ignored or unexplored otherwise. Broader access to CRISPR-Cas9 intellectual property is in the best interest of the patent owner and the greater public because it encourages innovation, breeds healthy competition, and allows for CRISPR technology to be applied to a larger range of the human genome.