Early Action for Equitable Access: Protecting Access to Medicine in University Licensing

Tess McMullin
Robert Hunter
Nicholas Merrill

Prepared for Universities Allied for Essential Medicines (UAEM) by Georgetown Law Intellectual Property and Information Policy (iPIP) Clinic student attorneys under the supervision of Shweta Kumar pursuant to DC App. R. 48 in Spring 2024. Subject to editing by UAEM.
Executive Summary

In 2022, taxpayers funded $97 billion in federal research grants for universities across the United States, a typical investment for the U.S. The resulting innovations—which often provide the basis for essential, lifesaving drugs—are then patented and licensed to pharmaceutical companies on opaque terms. Universities often grant licensees control over the pricing and distribution of essential medicines, while inventors retain little to no power to ensure equitable access for the public. These pharmaceutical companies then sell those lifesaving drugs to the public at exorbitant costs, claiming that they need to recoup the costs of research and development, much of which was already covered by the public.

To investigate this issue, we analyze current licensing practices of universities’ technology transfer offices (“TTOs”), beginning with an overview of the legislative history of the Bayh-Dole Act, and its statutory requirements. To highlight the need for equitable licensing practices, we then focus on case studies of essential drugs developed by universities with federal funding: Norvir, Xalatan, Xtandi and Casgey. The National Institutes of Health’s (“NIH”) refusal to utilize its march-in rights for Norvir, Xalatan, and Xtandi underscores the importance of intervention at the licensing stage to negotiate for accessible terms. Finally, by drawing upon information published by university TTOs (such as pledges, affordable access plans, and model licensing agreements), we evaluate whether the major university recipients of federal funding are compliant with Bayh-Dole’s commitment to equitable licensing practices.

Next, we examine UAEM’s Equitable Technology Access Framework (“ETAF”). Publicly funded research institutions (“PFRIs”) have an ethical obligation to provide for the public benefit. UAEM provides guidance on best practices to fulfill this obligation through the ETAF, which universities and other PFRIs are encouraged to adopt. This section provides an overview of the ETAF and its goals. Other organizations with differing interests in the transfer and proliferation of patented technologies have published their own, at times competing, recommendations to universities. Most notable amongst these is the widely utilized Nine Points to Consider in Licensing University Technology (“Nine Points”), a set of licensing guidelines heavily encouraging the commercialization of intellectual property rights. This section compares the ETAF to the Nine Points and other notable technology transfer frameworks. We then analyze the legal efficacy of the ETAF, including contractual enforceability and compliance with existing FDA and patent laws, and recommend revisions to the ETAF. Finally, we consider the political viability of the ETAF by identifying key stakeholders in technology transfer policies and their shared interests and likely points of conflict.

The final section is our FOI advocacy toolkit. State and federal FOI laws permit individuals to request public records from government agencies. Activists and coalitions such as UAEM can use FOI laws to request licensing agreements between public university TTOs and their licensees. The toolkit consists of an overview of FOI laws, information typically exempt from disclosure requirements, and available recourse if fulfillment of a request is delayed, denied, or over-redacted. The toolkit also provides a guide to submitting California Public Records Act (“CPRA”) requests and includes a model CPRA request for such licensing agreements and other relevant information. This section concludes with an analysis of whether tech transfer agreements by private universities receiving government funding are subject to FOI laws.
# Table of Contents

**Executive Summary** ........................................................................................................... 2  

I. Current University Practices ................................................................................................ 5  
   A. The Bayh-Dole Act ............................................................................................................ 5  
      1. History .......................................................................................................................... 5  
      2. Requirements ................................................................................................................ 9  
      3. March-In Rights ........................................................................................................... 10  
   B. The Failure of March-in Rights .......................................................................................... 12  
      1. Norvir ............................................................................................................................ 12  
      2. Xalatan .......................................................................................................................... 13  
      3. Xstandi ........................................................................................................................... 13  
      4. Casgevy ......................................................................................................................... 15  
   C. Statements and Model Licenses ....................................................................................... 17  
      1. Top Funding Recipients ............................................................................................... 17  
      2. Model Licenses ............................................................................................................. 17  

II. The Equitable Technology Access Framework .................................................................... 20  
   A. Overview and Background of the ETAF .......................................................................... 20  
   B. Alternative Transfer Frameworks .................................................................................... 22  
      1. The Nine Points to Consider in Licensing University Technology .................................. 22  
      2. The Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies ........................................................................................................ 22  
      3. The Global Access Licensing Framework ...................................................................... 23  
      4. Summary ....................................................................................................................... 24  
   C. Relevant Stakeholders ....................................................................................................... 25  
      1. Brand Name Pharmaceutical Companies ....................................................................... 25  
      2. Universities ..................................................................................................................... 26  
      3. University Researchers .................................................................................................. 27  
      4. Generic Drug Manufacturers ......................................................................................... 29  
      5. The Public ....................................................................................................................... 29  
      6. Patient Advocacy Groups ............................................................................................... 30  
   D. Analysis and Revision of the ETAF ................................................................................ 30  
      1. Principle IV – Step-In Rights ......................................................................................... 31  
      2. Principle V – Reach Through Clauses .......................................................................... 35  
      3. Principle VI - Waiver of FDA Market and Data Exclusivity .......................................... 36  

III. Freedom of Information Advocacy Toolkit ...................................................................... 40  
   A. The Presumption of Transparency .................................................................................. 40  
   B. The California Public Records Act ................................................................................... 41  
      1. Overview ....................................................................................................................... 41  
      2. The CPRA in a Nutshell ................................................................................................. 42  


I. Current University Practices

Current university licensing practices fail to ensure that essential drugs developed with federal research grants (i.e., taxpayer dollars) are priced reasonably. Meanwhile, the price of essential drugs continues to fuel the U.S. healthcare crisis. 3 out of 10 American adults report not taking their medication as prescribed due to costs. That needs to change. The Bayh-Dole Act created a right for the government to “march in” and ensure that medicines developed using federal funding are available to the public on reasonable terms. But government agencies refuse to recognize affordability as a barrier to patients securing the drugs they need. We can no longer rely on the government to exercise its march-in rights to ensure that these drugs are affordable. Intervention must occur earlier, at the licensing stage.

A. The Bayh-Dole Act

1. History

Many essential medicines are developed by or with the help of researchers at universities across the United States. The National Institute of Health ("NIH"), Centers for Disease Prevention and Control ("CDC"), Biomedical Advanced Research and Development Authority ("BARDA"), and the Department of Defense ("DOD") commonly fund biomedical research. In 2022, these agencies supplied more than $97 billion in research and development funding to universities. Patented inventions made with such federal funding are subject to the Bayh-Dole Act. In the 40+ years since the Act was passed, the number of patents issued each year has risen substantially, including patents developed using federal funds ("Bayh-Dole Patents"). While Bayh-Dole Patents comprise a relatively small percentage of all patents awarded by the USPTO, they account for 15 percent of patents in biotechnology and 8 percent of pharmaceuticals. Bayh-Dole Patents cover many of the medicines on which Americans rely—between 1997 and 2005, 24 percent of the 252 new FDA approved drugs were developed at universities.

The passage of the Bayh-Dole Act dramatically changed the way that universities interact with the patent system in the United States. Bayh-Dole allows universities, non-profit organizations,
and small businesses to retain intellectual property rights for inventions developed through federally funded research. It standardized the previously overlapping and contradictory federal agency policies regarding ownership of these patents. According to its legislative history, Congress intended for the Act to facilitate the use of federally funded inventions, promote their commercialization and public availability, and protect the public from non-use or unreasonable use of inventions. In this report, we focus on Bayh-Dole as it relates to universities and their licensing practices.

Bayh-Dole also establishes a public right in these inventions through the creation of march-in rights. Should the university or its licensees not take effective measures to achieve practical application of the invention, or action is necessary to alleviate health or safety needs, or other requirements of Bayh-Dole are not being met, Section 203 of the Act allows the federal agency funding an invention to “march in” and require the invention to be licensed to others upon reasonable terms for the circumstances. March-in rights allow the government to ensure that inventions developed through federal funding are available to the public on reasonable terms. In the over 40 years since Bayh-Dole’s enactment, the government has not once utilized its march-in rights.

“[U]niversities should neither profit nor lose when providing research services to the Federal Government.” — Birch Bayh (D-IN).

The legislative history of the Bayh-Dole Act reveals that access to medicine was at the forefront of the motivations for passing the Act. Lawmakers’ statements emphasize the unique role of universities in the Act’s structure. Prior to the passage of the Act, one of its sponsors, Senator Birch Evan Bayh (D-IN), expressed in communications with the Office of Management and Budget that he supported their proposition that “universities should neither profit nor lose when providing research services to the Federal Government.” When discussing the proposed Act in a letter to the president, multiple members of Congress, including the then Speaker of the House Thomas P. O’Neill (D-MA), shared that they wanted universities to continue to be “viewed as a unique resource,” and not be treated as “commercial organizations.” The National Association of College and University Business Officers supported the bill due to its belief that it would bring federally funded research into wider public use, while simultaneously “safeguarding the public interest by the inclusion of Sec. 203 march-in rights.” In a letter to fellow senators, the Act’s sponsors, bipartisan senators Bayh, Dole (R-KS), Chales Mathias (R-MD), and Dennis DeConcini (D-AZ), hoped to garner support by stating “many people have been condemned to needless suffering because of the refusal of agencies to allow universities sufficient rights to

---

13 Id.
16 Letter from Milton Goldberg to Birch Bayh, with comments on S. 2496 (Dec. 21, 1978) (Link).
bring new drugs and medical instrumentation into the marketplace.”17 The materials suggest that the Act's purpose is to encourage utilization of inventions arising from government-supported university research for the public benefit – through market availability and reasonable pricing.

Despite these drafters’ clearly expressed intentions, some universities and pharmaceutical companies argue that encouraging universities to partner with private industry to commercialize federally funded inventions was the main goal of the Bayh-Dole Act.18 Congress, working on minimal evidence, believed that many innovations funded by the government remained unavailable to the public due to lackluster commercialization efforts.19 Some university officers who testified before the Senate opined that private companies lacked an incentive to invest in commercializing a federally funded invention because they believed that competitors would reap the profits of its development for free.20 Many universities’ technology transfer offices (“TTOs”) adopt this view.21 Because these stakeholders believe that the purpose of Bayh-Dole was to facilitate pharmaceutical industry-academia licensing partnerships, they view the Act as incredibly successful in achieving its goals.22 Even more troubling is the seeming change of heart of the Act’s drafters. While the legislative history suggests that access to affordable medicine was a main concern, 20 years after the Act’s passing, Senators Bayh and Dole published an op-ed arguing that “Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government.”23 The senators’ op-ed makes clear that Bayh-Dole is a victim of mission drift, a move away from the goals established at its inception.24 When reviewing and interpreting statutes, however, courts center their analysis on the internal legislative process at the time of drafting, regardless of subsequent retrospection about legislative intent by drafters.25

Following its enactment, many universities established or expanded TTOs in order to efficiently patent, license, and market their technologies.26 Bayh-Dole created an opportunity for many research institutions to exploit new sources of income, and many universities began to focus their research efforts on areas with potential for significant industrial applications.27 While the

17 Dear Colleague letter from Bob Dole, Birch Bayh, Charles Mathias, and Dennis DeConcini (Sept, 6, 1978) (Link).
18 Guidelines for Technology Transfer, AUTM (Link); The Bayh-Dole Act: Spurring American Biopharmaceutical Innovation, PhRMA (Link).
21 See e.g., Innovation Partnerships, University of Michigan, (Link); From Idea to Industry, Duke University (Link); Licensing Process, Stanford University (Link).
22 Bayh-Dole Act, AUTM (Link).
27 Mowery, Nelson, Sampat & Ziedonis at 104 (Link).
Bayh-Dole Act may have been an economic success — it is said to have contributed to $1.3 trillion in national economic growth, 4.2 million jobs, and 11,000 university start-up companies since its implementation — not all of its aims have been achieved. Equitable licensing practices are necessary to prevent the “needless suffering” that the Act set out to eradicate. While new drugs and medical instrumentation may be in the marketplace due to Bayh-Dole, they remain inaccessible at exorbitant costs set by pharmaceutical companies, and unchecked by the licensing universities. Public concerns regarding the ties between federally funded research universities and the private sector have been present since the 1970s. The standard post-Bayh-Dole licensing practice, in which a new biomedical product is patented by a university and exclusively licensed to a pharmaceutical company for development and distribution, creates barriers to equitable access. Universities receive hundreds of millions of dollars from pharmaceutical companies in exchange for exclusive licenses. Typically, once the invention is licensed to the company, the university has no power over pricing and distribution. While the drugs may be entering the market, exorbitant prices prevent patients from receiving the medication they need.

Those who laud the effects of Bayh-Dole often point to the rise in patents and drug approvals stemming from universities that receive federal funds, but these metrics are not an accurate measure of the effectiveness of Bayh-Dole, as they obfuscate other contributing factors. Other factors include: (1) industrial interest in academic research, (2) the desire of many universities to exploit new sources of income, and (3) the growth in academic research in areas with the potential for significant industrial application. Additionally, while it was once the standard in the pharmaceutical industry that a single product was covered by a single patent, the average number of patents per drug has been increasing. Drug companies have built large patent portfolios around a drug, some with hundreds of patents, to serve as a barrier to the launch of generic equivalents. Not only do these superfluous patents extend drug companies’ monopolies far beyond the twenty years of protection intended under U.S. patent law, they also make litigation harder. The more patents asserted for a drug, the more time and resources necessary for a generic company to challenge the drug’s exclusivity, and the greater the

While new drugs and medical instrumentation may be in the marketplace due to Bayh-Dole, they remain inaccessible at exorbitant costs set by pharmaceutical companies, and unchecked by the licensing universities.

---

29 Contreras at 446 (Link).
30 In 2016, UCLA received $520 million of the proceeds for the prostate cancer drug Xtandi. Teresa Watanabe, UCLA will get hundreds of millions for rights to prostate cancer drug, L.A. Times, Mar 4, 2016 (Link).
31 Contreras at 485 (Link).
32 Bayh-Dole Innovations, AUTM (Link).
33 Mowery, Nelson, Sampat & Ziedonis at 104 (Link).
34 On Point Analytics, Patent Proliferation: A 30-Year Increase in the Number of Patents Per Drug (Sept. 12, 2016) (Link).
35 Id., I-MAK, Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices (Link) (Hereinafter “I-MAK”).
36 I-MAK (Link).
chances that at least one patent will be found valid in court.\textsuperscript{37} The predatory patent practices of pharmaceutical companies must be halted at the licensing stage.

2. Requirements

Bayh-Dole sets forth multiple requirements that universities must comply with in order to benefit from its provisions. According to section 202 of the Bayh-Dole Act, for universities to benefit from the Act’s vesting of patent rights, several requirements must be met:

- The university must disclose the invention to the federal funding agency in a reasonable time.\textsuperscript{38}
- A university that elects title rights must file a patent application prior to any statutory bar date.\textsuperscript{39}
- If the university elects to retain title to the invention, it must do so within two years following disclosure to the agency, but at least 60 days before any statutory bar date. If the university elects title rights in an invention, the federal agency shall have a nonexclusive, non-transferable, irrevocable, paid-up license to practice on behalf of the U.S. throughout the world.\textsuperscript{40}
- The federal agency may require periodic reporting on the utilization or efforts at obtaining utilization of the university, the licensees, or assignees for the subject invention.
- The patent application for the subject invention and any final patent issued must include a statement that the invention was made with government support and that the government has certain rights in it.
- Any profits earned by the university in relation to the invention shall be utilized for the support of further scientific research or education.
- Universities should prioritize granting licenses to small business firms, if feasible.\textsuperscript{41}
- Licensees must commit that inventions will be manufactured substantially in the U.S.\textsuperscript{42}

Universities’ compliance with Bayh-Dole is difficult to measure. Federal oversight of Bayh-Dole is decentralized, with each funding agency responsible for administering the law as it applies to grants and contracts.\textsuperscript{43} To that end, the requirements of Bayh-Dole are largely self-regulating, as

\textsuperscript{37} On Point Analytics, Patent Proliferation: A 30-Year Increase in the Number of Patents Per Drug (Sept. 12, 2016) (Link).
\textsuperscript{38} A “reasonable time” is considered two months from the time the university’s patent counsel is informed of the invention. 35 U.S.C. § 202(c)(1)(2); 37 C.F.R. §401.14(c)(1)(2).
\textsuperscript{39} If an invention is disclosed, then the patent for it must be filed within one year, or else be barred from patenting that invention. 35 U.S.C. §102(b).
\textsuperscript{40} These licenses are commonly used to ensure subcontractors can continue researching after a grant is awarded without having to wait for an official subcontract to be drafted. See Univ. of S. Fla. Bd. of Trustees v. United States, 92 F.4th 1072, 1083 (Fed. Cir. 2024).
\textsuperscript{41} The Small Business Administration defines a “small business” either in terms of average number of employees or average annual receipts over time. 13 C.F.R. § 121.201. Bayh-Dole merely suggests that small businesses should be prioritized, but does not mandate it.
\textsuperscript{42} However, in individual cases, the funding agency can waive this requirement if US manufacturing is not commercially feasible or if the university attempted but was unsuccessful in securing a licensee that would substantially manufacture the drug in the United States. 35 U.S.C. § 204. While seeking a formal waiver is preferred, licensees in violation of this requirement are not in danger of a funding agency revoking its exclusive status or exercising its march-in rights. Alan S. Gutterman, Business Transactions Solutions § 209:23. Bayh-Dole Act—Preference to US manufacturing requirements (Apr. 2024).
\textsuperscript{43} United States General Accounting Office (1998), TECHNOLOGY TRANSFER: Administration of the Bayh-Dole Act by Research Universities. (Link).
the primary responsibility is placed on universities to comply voluntarily.\textsuperscript{44} Agency activity is limited to collecting and managing information that the universities submit, and this information is specifically exempted from Freedom of Information Act (FOIA) requests in the Bayh-Dole Act.\textsuperscript{45} Universities also do not make this information publicly available. In order to ensure that Bayh-Dole serves its purpose, more must be done.

3. March-In Rights

While Bayh-Dole creates rights for universities, it also ensures a federal interest in subject inventions via march-in rights. The previous requirements of Bayh-Dole only apply to universities seeking to license their patents, but march-in requirements attach to the invention and any resulting patent, applying to anyone involved with the subject invention, including licensees and assignees.\textsuperscript{46} Under section 203's march-in provision, a funding agency has discretion to intervene and require that a patent for a drug developed using federal funds be licensed or licensed to additional companies if the original licensee fails to make the drug publicly available on reasonable terms.\textsuperscript{47} Section 203 provides a list of scenarios where the use of march-in rights by may be advisable:

- (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.\textsuperscript{48}

While the statute does not define "practical application of the invention," some scholars have argued that in similar contexts of statutory interpretation, including remedying monopolistic markets and determining the bounds of an agency's power,\textsuperscript{49} courts have interpreted "reasonable terms" to include reasonable prices.\textsuperscript{50} The language of the march-in provision clearly authorizes the funding agency to march-in when the price of a drug becomes unreasonable.

\textsuperscript{44} Id.
\textsuperscript{45} Id. See 35 U.S.C. § 205.
\textsuperscript{46} Michael Henry Davis & Peter S. Arno, Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research, 75 Tul. L. Rev. 631, 675 (2001) (Link) (Hereinafter “Davis & Arno”).
\textsuperscript{47} 35 U.S.C. § 203.
\textsuperscript{48} As previously mentioned, this requirement can be waived. 35 U.S.C. § 204.
\textsuperscript{49} See e.g. Byars v. Buff City News Co., 609 F.2d 843, 864 (6th Cir. 1979), American Liberty Oil Co. v. Federal Power Commission, 301 F.2d 15, 18 (5th Cir. 1962), Commercial Solvents Corp. v. Mellon, 277 F. 548, 549 (D.C. Cir. 1922).
\textsuperscript{50} Davis & Arno at 652 (2001) (Link).
Yet, the National Institutes of Health (NIH) refuses to consider price as a factor when assessing march-in petitions for essential medicines. Since Bayh-Dole’s enactment, parties have filed five march-in petitions in hopes of increasing public access to essential medicines: Cellpro Ceprate SC, Norvir, Xalatan, Fabrazyme, and Xtandi.\(^5\) The NIH has denied every petition.

In 1997, Cellpro, Inc. asserted that a march-in was necessary to alleviate the health and safety needs that had arisen following the Delaware district court’s holding that their stem cell separation device, the Ceprate SC, infringed on patents owned by the Johns Hopkins University and licensed to Baxter Healthcare, and enjoined its sale.\(^5\) Despite the fact that Cellpro was the only company that had an FDA approved device commercially available, the NIH found that Hopkins and Baxter met the standard for practical application by being “available to the public on reasonable terms.”\(^5\)

Following manufacturing difficulties that left Fabrazyme, a bi-weekly injection to treat Fabry disease,\(^5\) in critically short supply, Dr. C. Allen Black submitted a march-in request for the drug on behalf of his patients in 2010.\(^5\) The Mount Sinai School of Medicine developed the drug and exclusively licensed it to Genzyme Corporation, who began to ration the doses after mishaps at their facilities led to reduced production.\(^5\) The NIH determined that a march-in proceeding was unnecessary, arguing that it would not properly alleviate the problem, blaming the years of clinical trials and regulatory approval that would be required of a third-party manufacturer’s product before it could reach patients.\(^5\) While the supply returned to normal in 2012, many patients suffered from the reduced dosages sold by Genzyme during the supply squeeze.\(^5\) As of March 2024, a case is currently pending in the Massachusetts district court in which two dozen patients impacted by the Fabrazyme shortage seek damages from Genzyme for the injuries they suffered.\(^5\)

Activist groups filed march-in petitions for Norvir, Xalatan, and Xtandi for the same central reason—the prices for the drugs were too high. Each of these petitions is analyzed in turn below. The NIH’s consistent refusal to utilize its march-in rights demonstrates the need for early intervention in the drug-licensing timeline to ensure essential medicines are affordable.

---

\(^5\) National Institutes of Health, Policies & Reports [Link].
\(^5\) National Institutes of Health, Determination In the Case of Petition of Cellpro, Inc. (Aug. 1, 1997) [Link].
\(^3\) Id. (citing 37 C.F.R. § 404.3(d)).
\(^4\) Fabrazyme, Drugs.com (last updated June 22, 2023) [Link].
\(^5\) National Institutes of Health, Determination In the Case of Petition of Fabrazyme (Dec. 1, 2010) [Link].
\(^6\) Id.
\(^7\) Id.
\(^8\) Zoey Becker, Fabrazyme Litigation Back in Play for Sanofi’s GEnome as Appeals Court Overturns Dismissal of 2020 Lawsuit, Fierce Pharma (Feb. 20, 2024) [Link].
\(^9\) Wilkins v. Genzyme, No. 22-1782 (1st Cir. 2024) [Link]. The U.S. District Court for the District of Massachusetts dismissed the claim for lack of standing. On February 15, 2024, the Court of Appeals for the First Circuit reversed and remanded for most plaintiffs, holding that those plaintiffs had standing.
B. The Failure of March-in Rights

Norvir, an HIV/AIDS drug, costs four to ten times more in the United States than in other high-income countries.\(^6^0\) Xalatan, a glaucoma drug, costs two to five times more in the United States than in 13 other high income countries.\(^6^1\) Xtandi costs between $160,000 and $180,000 per patient annually.\(^6^2\) The NIH has declined to utilize its march-in right to make these essential medicines more accessible to the patients who need them, relying on the standard that if a drug is actively being marketed and prescribed by physicians, then it is available to the public on reasonable terms, regardless of cost.\(^6^3\) Regardless of the fact that patients must be able to afford their drugs to achieve practical use, NIH argues that regulating drug prices is the prerogative of Congress, and that exercising the “extraordinary remedy” or march-in rights is not appropriate in these contexts.\(^6^4\)

This section reviews march-in petitions on Norvir, Xalatan, and Xtandi, and it also analyzes the potential utility of a march-in petition on Casgevy, a newly FDA approved therapy for sickle cell diseases developed using CRISPR/Cas-9 technology. These drugs, which were and are covered by Bayh-Dole patents, represent essential care for vulnerable people within the U.S. and abroad. Analyzing these cases reveals hard truths about licensing practices and the profit-driven motives of universities.

1. Norvir

Between 1988 and 1993, Abbott Laboratories utilized federal funds to develop Norvir, a drug for the treatment of patients with HIV/AIDS.\(^6^5\) Advocates petitioned for the NIH to utilize its march-in right to address the affordability of the Norvir in the United States following Abbot increasing the price from $2.14 per 100 mg gel tablet to $10.72 per tab.\(^6^6\) The annual cost of the drug per patient went from roughly $9,387 to $46,935.\(^6^7\) Activists argued that this pricing structure was “unreasonable, anticompetitive, and threatens the health and safety of people with AIDS.”\(^6^8\) In response, Ted Poehler, then Vice Provost for Research at the John Hopkins University, provided a statement on behalf of the Association of American Universities (“AAU”) on the matter: “to use march-in rights to address drug pricing is a misapplication of the statute.”\(^6^9\) The NIH agreed, putting the anti-competitive issue to the Federal Trade Commission to investigate and denying

---

\(^{6^0}\) Knowledge Ecology International, 15 Frequently Asked Questions about the 2012-2013 Ritonavir March-in Petition (Link).

\(^{6^1}\) Knowledge Ecology International, Several March-in and Royalty Free Rights Cases, under the Bayh-Dole Act (Link).


\(^{6^3}\) Elias A. Zerhouni, NIH response to Xalatan March-In Petition (Sept. 17, 2004) (Link).

\(^{6^4}\) Elias A. Zerhouni, NIH response to Norvir March-In Petition (July. 29, 2004) at 1 (Link).

\(^{6^5}\) Id.

\(^{6^6}\) Id. at 3; National Institute of Allergy and Infectious Diseases, Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonvair (Jan. 29, 2004) at 6 (Link).

\(^{6^7}\) National Institute of Allergy and Infectious Diseases, Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonvair (Jan. 29, 2004) at 6 (Link).

\(^{6^8}\) Id. at 7.

\(^{6^9}\) Ted Poehler, Statement on Norvir March-in Petition (May 25, 2004) (Link) at 3.
the march-in petition. In making this determination, the NIH refused to consider price as a barrier to the practical application of Norvir.

2. Xalatan

Utilizing NIH grants, Columbia University, in collaboration with Pharmacia Corporation, developed Xalatan, a medication for the treatment of high eye pressure, most commonly utilized by people suffering from glaucoma. Dr. Laszlo Z. Bito at Columbia University received over $4 million in grants from the National Eye Institute at the National Institutes of Health to fund the research that resulted in Xalatan. Pfizer acquired Pharmacia Corp. and began selling the drug at astronomical prices in the United States. In 1999, the New York Times published a story revealing that French pharmaceutical giant Sanofi produces Xalatan’s active ingredient in Hungary for less than one percent of the drug’s sales price in the United States. In filing the march-in petition, activists focused on the disturbing truth that the American price for Xalatan was two to five times the average price in most European countries, despite American taxpayers funding its development. Similar to its decision regarding the Norvir petition, the NIH declined to exercise its march-in rights due to its belief that Pfizer had “met the standard for achieving practical application of the applicable patents by its manufacture, practice, and operation of [Xalatan] and the drug’s availability and use by the public.” Once again, the NIH refused to consider price when measuring practical application.

3. Xtandi

In recent years, Xtandi, a prostate cancer drug developed by researchers at UCLA, has been at the center of debates over university licensing practices. An examination of its history and controversy reveal the ways in which student organizers can impact universities’ licensing practices. Using NIH and DOD funding, UCLA developed Xtandi (enzalutamide), a late-stage prostate cancer drug. UCLA claims that the work that led to its development began in 2000. UCLA received over $93,788,979 in NIH funding from 2000-2005. In 2005, UCLA licensed Xtandi’s patent to Medivation Inc. and its sub-licensee, Astellas Pharmaceuticals, who were responsible for marketing and selling the drug worldwide. It was subsequently sold at exorbitant prices, leaving many patients unable to afford the benefits of this publicly funded

70 Elias A. Zerhouni, NIH response to Norvir March-In Petition (July, 29, 2004) at 4 (Link).
71 Id. at 5.
72 Elias A. Zerhouni, NIH response to Xalatan March-In Petition (Sept. 17, 2004) (Link) at 1; Xalatan, Xalatan (Link).
73 Essential Inventions, Inc., Petition to use authority under Bayh-Dole Act to promote access to latanoprost (Jan. 29, 2004) (Link) at 2.
74 Id. at 3.
75 Jeff Gerth and Sheryl Gay Stolberg, Drug Companies Profit From Research Supported by Taxpayers (Apr. 23, 2000) (Link).
76 Essential Inventions, Inc., Petition to use authority under Bayh-Dole Act to promote access to latanoprost (Jan. 29, 2004) (Link) at 3.
77 Elias A. Zerhouni, NIH response to Xalatan March-In Petition (Sept. 17, 2004) (Link) at 5.
80 Aggregating RPGs - Non SBIR/STTR funds granted in the fiscal years 2000-2005. (Link).
81 UCLA, UCLA Sells Royalty Rights Connected with Cancer Drug to Royalty Pharma, (Link); Pfizer acquired Medivation in 2016, Pfizer Completes Acquisition of Medivation | Pfizer. (Link).
drug. Patients pay over $15,000 for a supply of 120 capsules.\textsuperscript{82} Medicare spent $1.4 billion on Xtandi in 2019, about $98 per dose.\textsuperscript{83} Prostate cancer mainly impacts senior men, the average age at diagnosis is between 65 to 68 years old.\textsuperscript{84} High out-of-pocket costs for Xtandi can be prohibitively expensive for these individuals, many of whom live on a fixed income.\textsuperscript{85}

Robert Sachs, a former attorney, became involved in the Xtandi march-in petition after he was prescribed the drug to treat the prostate cancer that had metastasized into some of his bones in 2020.\textsuperscript{86} He experienced sticker shock at the $740 monthly cost, the co-pay price after his Medicare and supplemental insurance coverage.\textsuperscript{87} In his comments on the Guidance Framework for Considering Exercise of March-In Rights, Sachs wrote “As a…eight year advanced prostate cancer survivor who has personally benefited from the fruits of federally funded research, I deeply appreciate the role the Bayh-Dole Act has played in fostering innovation and bringing new drugs to market…At the same time the public interest requires that innovations paid for by US taxpayers be affordable and broadly accessible.”\textsuperscript{88}

The NIH denied Sach’s march-in petition. The NIH’s response contained very similar language to the Norvir and Xalatan petitions, stating that Xtandi is available to the public on “reasonable terms,” despite its exorbitant costs.\textsuperscript{89} Discussing the result with the Los Angeles times, he said “after almost a year and a half, for them to send us a two-page letter that could have been written a week after we filed our petition and just contained boilerplate is hard to understand.”\textsuperscript{90}

The failure of march-in efforts and the continued inaccessibility of Xtandi motivated student members of UAEM’s UCLA chapter to organize and advocate for the university to adopt equitable licensing practices.\textsuperscript{91} These efforts were successful, and UCLA’s TTO adopted an Affordable Access Provision to be utilized in future license agreements.\textsuperscript{92} The new Affordable Access Provision, however, does not apply retroactively to Xtandi licenses.

\textsuperscript{83} Engelberg, Acom, & Kesselheim (Link).
\textsuperscript{84} Hong W. Chin, Jyung Kim, Gregory Rasp & Boris Hristov, Prostate Cancer in Seniors, 32 Fed. Pract. 41S (2015) (Link).
\textsuperscript{85} Patients for Affordable Drugs, June 2023 Cancer Drug Prices Report (June 14, 2023) (Link).
\textsuperscript{87} Id.
\textsuperscript{88} Robert Sachs, Comments of Robert Sachs on Guidance Framework for Considering Exercise of March-In Rights (Feb. 1, 2024) (Link).
\textsuperscript{89} Lawrence A. Tabak, NIH Decision Xtandi March-In Request, (Mar. 21, 2023) (Link).
\textsuperscript{90} Michael Hiltzik, Column: Biden Says He Wants to Bring Down Drug Prices. His Actions Tell a Different Story, L.A. Times (Mar. 24, 2023) (Link).
\textsuperscript{91} Ambika Verma, Student-Led Activism Transforming the Access to Medicines Movement, Think Global Health (Mar. 15, 2021) (Link).
\textsuperscript{92} UCLA TDG, UCLA Considers Underserved Populations When Licensing Medical Research Discoveries (Mar. 18, 2022) (Link).
Despite the controversy surrounding Xtandi’s exorbitant costs and UCLA’s pledge to consider underserved populations when licensing medical technologies, the Regents of the University of California and its licensees remain litigious over Xtandi’s patents. In December 2022, Astellas Pharma Inc., Medivation Prostate Therapeutics LLC, and the Regents of the University of California, filed a complaint in the U.S. District Court for the District of New Jersey against Sun Pharmaceutical Industries Inc., an Indian corporation that manufactures and sells generic pharmaceutical products.\textsuperscript{93} Sun Pharma had filed an Abbreviated New Drug Application (“ANDA”) seeking approval from the FDA to market generic versions of 40 and 80 mg enzalutamide.\textsuperscript{94} Astellas and its co-plaintiffs alleged that Sun Pharma’s distribution of a generic version of Xtandi would infringe the patent that covers Xtandi’s active ingredient, enzalutamide (“the ‘517 patent”), for which Medivation has an exclusive license and enforcement rights.\textsuperscript{95} While the case settled in October of 2023—with the co-plaintiffs and Sun agreeing to drop all claims related to the ‘517 patent\textsuperscript{96}—the suit highlights the continued efforts of exclusive license holders and universities to block more affordable generics from entering the market.

While the current situation regarding Xtandi may seem bleak, there is hope on the horizon. The patents covering the drug in the U.S. expire in 2027 and the FDA has already tentatively approved two generic versions of enzalutamide.\textsuperscript{97} Newly developed technologies, such as Casgevy, will serve as a test on whether universities are actually implementing equitable access provisions that they have claimed to support.

4. Casgevy

Newly developed Bayh-Dole patents for life saving drugs, such as Casgevy, will likely face a similar fate as Norvir, Xalatan, and Xtandi if early intervention at the licensing stage does not occur. On December 8, 2023, the FDA approved Casgevy, a one-time gene therapy developed by CRISPR Therapeutics and Vertex Pharmaceuticals, for patients 12 or older suffering from sickle cell disease.\textsuperscript{98} Sickle cell disease (“SCD”) is a rare but debilitating group of inherited lifelong red blood cell disorders, in which the red blood cells of the patient become crescent-shaped, causing serious complications including strokes, infections, and pain.\textsuperscript{99} SCD affects about 100,000 people in the United States and millions worldwide.\textsuperscript{100} The disease disproportionately impacts black people—it is estimated that about one out of every 365 black babies is born with SCD.\textsuperscript{101} Not only does Casgevy represent the first cell-based therapy for patients with SCD, it is also the first FDA-approved treatment developed utilizing the CRISPR/Cas9 genome editing technology.\textsuperscript{102}

The treatment process involves drawing stem cells from the patient, editing the genes of those stem cells with Casgevy, administering chemotherapy to the patient to kill the older, sickled

\textsuperscript{93} Complaint, Astellas Pharma. v. Sun Pharma., Case No. 2:22-CV-07357 (D.N.J. 2022) (\textsuperscript{Link}).
\textsuperscript{94} Id.
\textsuperscript{95} Astellas, Pfizer Settle Patent Suit Over Sun’s Copies of Xtandi. (\textsuperscript{Link}).
\textsuperscript{96} Id.
\textsuperscript{97} Id.
\textsuperscript{98} James Love, How Soon Could President Biden Enable Generic Competition to Xtandi? Very Quickly, If There Is the Will, Bill of Health (Mar. 28, 2023) (\textsuperscript{Link}).
\textsuperscript{99} FDA, FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease (Dec. 8, 2023) (\textsuperscript{Link}).
\textsuperscript{100} National Institutes of Health, Sickle Cell Disease - What Is Sickle Cell Disease? (Aug. 30, 2023) (\textsuperscript{Link}).
\textsuperscript{101} CDC, Data & Statistics on Sickle Cell Disease (May 2, 2022) (\textsuperscript{Link}).
\textsuperscript{102} Id.
cells, and finally transplanting gene-edited disease-free cells back into the patient.103 The intensive treatment will also require hospitalization for weeks to months.104 Casgevy is a first-of-its-kind procedure that offers hope to the millions impacted by SCD, but the price will be prohibitive for many. Kyle Smith, a 35 year old who has been suffering from the symptoms of SCD his entire life, said on the prospect of Casgevy, “just the idea of an opportunity to lessen your pain and have less crises and less hospitalizations is always appealing.”105 One thing holds him back. He is worried that his insurance company will not cover the full $2.2 million cost of treatment.106 And patients are not the only ones concerned about Casgevy’s price—UK regulators recently expressed hesitancy to recommend that the therapy be offered by the National Health Service due to the high cost of treatment.107

Casgevy is made with CRISPR technology covered by patents owned by Broad Institute of the Massachusetts Institute of Technology and Harvard University (“Broad Institute”) and was developed with an NIH grant.108 The Broad Institute has exclusively licensed its CRISPR portfolio to Editas Medicine,109 which in turn entered into a non-exclusive license agreement with Vertex for $100 million, with the possibility of additional licensing fees.110 A portion of these payments will be sent to the Broad Institute.111

CRISPR (“clustered regularly interspaced short palindromic repeats”) technology allows research scientists to selectively modify the DNA of organisms,112 and it has revolutionized biology research, medicine, and biotechnology.113 The University of California, Berkeley (“Berkeley”) and the Broad Institute have been entangled in a patent dispute for over a decade about the ownership of CRISPR technology.114 The Berkeley team requested a patent interference proceeding—an administrative trial to determine which of two or more parties claiming rights over a common patent was the first to invent it—which the USPTO’s Patent Trial

103 Lauren Gardner & Katherine Ellen Foley, Landmark Gene-Editing Therapy Approved: Here’s What You Need to Know, POLITICO (Dec. 8, 2023) (Link).
104 Id.
105 Sarah Jones, The Fight to Pay for Gene Therapy, Intelligencer (Feb. 29, 2024) (Link).
106 Id.
111 CURRENT REPORT Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934- Editas Medicine, Inc. UNITED STATES SECURITIES AND EXCHANGE COMMISSION. (Dec. 12, 2023) (Link).
112 CRISPR (Link).
114 In June 2012, researchers Jennifer Doudna of the University of California, Berkeley and Emmanuelle Charpentier, then working at the University of Vienna, published a scientific paper outlining how CRISPR, with the assistance of the enzyme Cas9, can be utilized as a tool to edit genes. In January 2013, a group of scientists led by Feng Zhang at the Broad Institute announced their method to use CRISPR-Cas9 to edit mammal cells. The Berkeley team filed their patent application a few months prior to the Broad Institute’s filing, yet the United States Patent and Trademark Office (“USPTO”) granted the Broad Institute a patent on their CRISPR technology in April 2014. See Catherine Jewell, The Battle to Own the CRISPR–Cas9 Gene-Editing Tool (Apr. 2017) (Link).
and Appeal Board (“PTAB”) granted in April 2015.\textsuperscript{115} In 2022, the PTAB held that the Broad Institute had priority over the Berkeley team for the use of a single RNA CRISPR-Cas9 system that functions in eukaryotic (plant, animal, or human) cells.\textsuperscript{116}

The battle over the CRISPR patents is far from over. The current complicated licensing schemes and uncertainty over ownership may deter further companies from utilizing the CRISPR technology to develop innovative essential medicine. This is in direct opposition to the objective of Bayh-Dole. \textbf{Both Berkeley and Broad need to alter their licensing practices to ensure the CRISPR technology is accessible to researchers,} and create a clear path for commercialization for the drugs developed through its application.

\section*{C. Statements and Model Licenses}

\subsection*{1. Top Funding Recipients}

Many top research institutions that produce patented medical technology receive federal funding for the development of those technologies, binding those institutions to the requirements of Bayh-Dole.\textsuperscript{117} The University of California, Los Angeles (“UCLA”) and Massachusetts Institute of Technology (“MIT”) top the list of Bayh-Dole biotechnology holders, and 22 of the top 25 institutions are research universities.\textsuperscript{118} Major funding agencies include the National Institutes of Health (“NIH”), the Department of Defense (“DOD”), and the Department of Energy (“DOE”).\textsuperscript{119}

The licensing practices of many of the top funding recipients remain elusive. \textbf{Table A1} is a catalog of the top 20 recipients of federal funding and the public approach of their respective TTOs (or functional equivalent) to public socially responsible licensing principles.\textsuperscript{120} Of the top 20, six have published model licenses, which are analyzed separately.

\subsection*{2. Model Licenses}

Select technology transfer offices (“TTOs”) have made their model licensing agreement publicly available. \textbf{Table A2} analyzes the model licenses’ compliance with Bayh-Dole and their commitment to socially responsible licensing practices.

Model licenses vary widely in their commitment to improving access to health care technologies for vulnerable populations. Many of the top funding recipients do not disclose a model licensing scheme or pledge any sort of commitment to socially responsible licensing practices. Michigan, Duke, and Stanford endorse AUTM’s licensing practices. The most equitable licensing

\begin{itemize}
\item \textsuperscript{115} \textit{Id.} The Patent Interference Procedure system was superseded by the Leahy-Smith America Invents Act in March 2013. The United States now operates on a “first to file” system, rather than “first to invent,” but because this dispute arose before 2013, the patent interference procedure governs. \textit{Interference Proceedings}, Legal Information Institute (\textit{Link}).
\item \textsuperscript{116} Broad Institute v. Regents of the University of California, No. 106,115 (P.T.A.B. Feb. 28, 2022) (\textit{Link}).
\item \textsuperscript{117} There are various databases to track government grants, including USAspending.gov, NIH RePORTER, and SAM.gov. These sources are helpful to track which universities are more or less compliant than others. See Francie Diep, \textit{One Scientist Neglected His Grant Reports. Now U.S. Agencies Are Withholding Grants for an Entire University}, The Chronicle of Higher Education (Apr. 10, 2024) (\textit{Link}).
\item \textsuperscript{118} Abdulla & Corrigan (\textit{Link}).
\item \textsuperscript{119} \textit{Id.}
\item \textsuperscript{120} Data based on 2023 statistics, sorted by RPGs - Non SBIR/STTR funding mechanism NIH awards by location and organization - NIH research portfolio (\textit{Link}).
\end{itemize}
policies—those of Berkeley and Harvard, and UCLA’s Affordable Access Plan—allege to prioritize the possibility for further development, use, and beneficial social impact over maximizing profits. These institutions’ TTOs pledge to mandate licenses that provide a plan for protecting underserved populations globally. Without access to the actual licensing agreements, the public has no way to ensure that the universities are enacting these commitments in practice.

The reporting requirements in the model licenses also vary, but most universities require their licensees to report on commercialization efforts annually. These reports are not available publicly, so there is no way to ensure that the licensees are complying with the model license. A FOI request may also be able to bring this information to light.

UCLA’s Affordable Access Plan, adopted following students’ organizing over Xtandi, commits to encouraging UCLA’s licensees to develop and implement plans for supporting affordable access to the drug in low and middle-income countries. It encourages collaborations with governments and nonprofits in order to do so.¹²¹ This is very similar to Harvard’s Global Access Provision, which commits to promoting affordable access to its drug patents in developing countries.¹²² Unlike UCLA and Harvard, Berkeley, Boston University, and Northwestern include affordable access provisions (with near identical language to UCLA and Harvard) in their model licenses, rather than being a separate document.¹²³ While these universities commit to equitable licensing practices in low and middle income countries (“LMICs”), their affordable access plans do not address underserved populations within the United States. Similarly, the non-suit provisions are limited to suits brought in LMICs. The current model licenses of the universities analyzed do nothing to ensure that essential medicines are accessible and affordable to U.S. patients.

Since the passage of the Bayh-Dole Act, universities have become increasingly litigious over their patents. From 1990 to 2019, universities were plaintiffs in 574 infringement actions in the US and involved in 813 patent disputes at the USPTO.¹²⁴ While Boston University’s model license includes a non-suit provision, it initiated the most patent infringement suits (42) of any university.¹²⁵ The entire University of California system, which includes Berkeley and UCLA, followed with 37 suits.¹²⁶ Universities are most commonly involved in infringement litigation as co-plaintiffs with licensees.¹²⁷

All of the licenses analyzed purport to comply with the objective of Bayh-Dole: for drugs to be commercially available to the public on reasonable terms. Not a single license, however, provides a definition of “reasonable terms.” As evidenced by the NIH’s refusal to march-in, price is not currently a consideration when assessing reasonable terms. Universities have the power

¹²¹ UCLA Affordable Access Plan (Link).
¹²³ See Berkeley Model License (Link); Boston University Model License (Link); Northwestern Model License (Link).
¹²⁴ Grazia Sveva Ascione, Laura Ciucci, Claudio Detotto & Valerio Sterzi, Universities involvement in patent litigation: an analysis of the characteristics of US litigated patents, 127 Scientometrics 6855, 6862 (2022) (Link).
¹²⁵ Id. at 6863.
¹²⁶ Id.
¹²⁷ Id.
to change this. By explicitly defining “reasonable terms” in their licenses to include affordability within the United States, universities can have more control over the pricing of the drugs developed with federal funds.

The licensing agreements that TTOs make publicly available are simply samples, and the licensee can negotiate terms that are satisfactory to both parties. While SLRPs are present in the model licenses of these universities, there is no certainty that they are actually being integrated into the final licensing contracts between the university and licensees. Further, the pledges to equitable access are oftentimes buried on a university’s TTO website—difficult to find unless one is specifically looking for it. Universities must publicize these pledges. Posting them on public platforms like WestLaw Practical Law\textsuperscript{128} or GitHub\textsuperscript{129} would allow equitable practices not only to be more accessible, but also enable TTOs of other universities to become better informed.

\textsuperscript{128} WestLaw Practical Law supplies legal templates, checklists, and how-to guides for lawyers to provide a starting point for drafting documents.
\textsuperscript{129} GitHub is a platform that allows developers to create, store, and manage code. It is commonly used for open source development projects. (\textsuperscript{Link}).
II. The Equitable Technology Access Framework

A. Overview and Background of the ETAF

Licensing agreements can be critical tools to effectuate necessary change in the university technology transfer system. Activists and organizations who wish to promote equitable practices in the development and delivery of essential medicine must be able to recognize what effective licensing policies and provisions entail. UAEM provides one such lens to interpret licensing agreements through the Equitable Technology Access Framework. The ETAF is a technology transfer framework that builds off of UAEM’s previous licensing framework, the Global Access Licensing Framework (GALF). The modifications to UAEM’s recommendations for TTOs comes in part from a recognition that the modalities through which universities commercialize their technologies had changed in the years since GALF was drafted. Though this paper focuses largely on university licensing, the ETAF also addresses technology transfer made by the creation of a spin-off company, product development partnerships, and research commissioned by a third party.

Access to medicine is at the core of UAEM’s very formation. UAEM was founded at Yale in 2001 due to “the access to medicines crisis” and “the realisation that universities can have an enormous impact on global access to their medical innovations.”¹³⁰ In the two decades that have followed, UAEM has expanded to over 100 universities in 20 different countries. Through this expansion access to medicine remains core to UAEM’s focus. UAEM’s mission is “to promote access to medicines and medical innovations, change norms and practices in academic patenting and licensing, and empower students to advocate for a biomedical R&D system that works for everyone.”¹³¹ The ETAF is a reflection of these beliefs.

The ETAF has three goals:¹³²

1. To improve global equitable access to health technologies,
2. Promote further development of health technologies, and
3. Improve transparency of health technology transfer.

In addition to these goals, the ETAF offers nine principles that TTOs should abide by to promote the equitable exchange of IP rights.¹³³ These principles reflect UAEM’s belief that “global availability and affordability of health technologies should be the primary purpose of technology transfer.”

¹³¹ About Us, Universities Allied for Essential Medicine (Link).
¹³³ Id.
technologies should be the primary purpose of technology transfer.” The ETAF principles are:

1. Social responsibility to the public
2. Limit monopolies
3. Retain IP rights
4. Include step-in rights
5. Include reach-through clauses
6. Limit data and market exclusivities
7. Commit to full sharing of all data and research findings
8. Ensure full transparency of all public funding sources and amounts
9. Implement robust accountability and transparency mechanisms

An additional motivation that underscores the ETAF is its increased attention to mechanisms through which equitable access obligations can be enforced. UAEM adopted the ETAF in 2021, following the recognition that universities were shirking their global access commitments. In a 2022 article, UAEM North America board member Dr. Reshma Ramachandran highlights the disconnect between the obligations that students and advocates had convinced universities to adopt and the policies TTOs had actually effectuated. Universities had taken steps such as shrinking the “subset of drugs, diseases and countries to implement the adopted global access licensing principles,” thereby minimizing the impact of their public commitments to global access. Dr. Ramachandran also notes the utility that the transparency surrounding university COVID-19 licensing practices had in determining which universities had adopted equitable access practices for COVID-19 technologies developed through their publicly funded research. This transparency then allows for equitable access activists to seek accountability from the majority of universities that instead adopted weaker, time-limited licensing guidelines such as those developed by AUTM.

The ETAF is clearly strengthened by UAEM’s experiences with universities and their TTOs. Influences from past TTO practices, such as those Dr. Ramachandran noted, can be seen in the ETAF’s principles. This includes a focus on providing broad guidance on technology transfer

---

134 Equitable Technology Access Framework (Link).
135 Step-In rights are contractual rights that allow one contracting party to “step-in” and take over the rights and obligations of the other party to the agreement. Step-In rights are discussed in greater detail in part D below.
136 Reach-through clauses provide a licensor limited rights over downstream uses of their technology, commonly in the form of royalty payments. Reach-through clauses are discussed in greater detail in part D below.
138 Id. (Link).
139 Id.
140 Id.
policies such that universities cannot as easily avoid their scope, recommendations for enforcement mechanisms to mitigate inequitable practices should they arise, and demands for transparency to support heightened accountability.

**B. Alternative Transfer Frameworks**

In a field as vast and lucrative as technology transfer, there are multiple entities providing guidance to universities on how technology should be licensed. To better understand the ETAF and how it compares to other licensing frameworks, an examination of those alternative frameworks is essential.

1. **The Nine Points to Consider in Licensing University Technology**

AUTM (previously the Association of University Transfer Managers) is an advocacy group representing the interests of several university technology transfer offices, whose stated objectives include moving technology from basic research laboratories, such as those at universities, to commercial partners capable of transforming technology into products.\(^{141}\) AUTM has members from over 800 universities, but is most influential at those universities where its board of directors are employed. Currently AUTM’s board includes members from Georgetown, Cornell, Caltech, Duke, Lakehead University, NYU, Boston Children’s Hospital (a Harvard Medical School teaching hospital), Stanford, John Hopkins, Jackson State University, and Louisiana State University.\(^{142}\) Their guidance to TTOs, outlined in the Nine Points to Consider in Licensing University Technology (“Nine Points”), puts considerably more weight on financial incentives for universities than for ensuring access to medicine. Due to its widespread adoption, and the conflicting beliefs of AUTM and UAEM, the Nine Points serves as a critical point of contrast against which the ETAF must be compared.

While the Nine Points never directly sets out goals, it does claim to be one of many methods of both (1) “nurturing future research,” as well (2) “using the innovations of university research to provide the broadest possible benefit to the public.”\(^{143}\) Given that the Nine Points is only presented as one method of accomplishing these broad aims, it is fair to assess what goals AUTM and the signatories are advancing based on the content of the points and AUTM’s mission and values. AUTM regularly claims that the commercialization of research is a public benefit, presenting the argument that taking inventions from lab to marketplace increases the public’s access to essential technologies.\(^{144}\) Further, AUTM suggests that successful commercialization of publicly funded research incentivizes universities to pursue future research.\(^{145}\) Therefore, from AUTM’s perspective, two implicit goals of the Nine Points can be fulfilled through one means, commercialization.

2. **The Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies**

AUTM has also signed onto the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (“Statement of Principles”), a set of principles focused on global technology access that are more narrowly adopted by only six universities (Boston

---

141 Nine Points to Consider in Licensing University Technology, AUTM (Mar. 2007) (Link) (Hereinafter Nine Points); About Technology Transfer & the Bayh-Dole Act, AUTM (Link).

142 AUTM, AUTM Board of Directors (Link).

143 Nine Points (Link).

144 AUTM, AUTM Better World Project, YouTube (July 11, 2022) (Link); What is the Technology Transfer Process?, AUTM (Link).

145 *Id.*
3. The Global Access Licensing Framework

UAEM sets out its own global access policy recommendations in the Global Access Licensing Framework (“GALF”). These recommendations have been phased out in favor of the ETAF since 2021, but exemplify the evolution of UAEM’s access goals. The GALF has two goals:

1. Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. This includes protecting access to the final end product needed by patients (e.g. formulated pills or vaccines).

2. Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research.

To accomplish those goals the GALF presents four strategies which can be summarized as:

1. Support generic competition by removing legal barriers in resource limited countries.

2. Include proactive licensing provisions to ensure follow-on patents do not block generic production.

3. Universities should issue non-exclusive licenses and reserve rights to practice licensed technology.

4. Licensing policies should be transparent and based off of clear, trackable metrics to ensure global access is being supported.

The GALF has two major features distinguishing it from the ETAF. First, the GALF focuses on global accessibility. Its recommendations are geared towards policies that can promote access to medicine where it is most needed, such as developing nations. This is made clear in Strategy Second is that it is strictly focused on licensing provisions, whereas the ETAF also includes strategies for working within other transfer modalities that TTOs deal with.

147 Id.
149 Leslie Friday, Moving Medical Advances into Developing Nations, BU Today (Nov. 17, 2009) (Link).
4. Summary

Though UAEM believes that “global availability and affordability of health technologies should be the primary purpose of technology transfer,” even a cursory review of AUTM’s frameworks makes clear that this understanding is not universal.\(^{151}\) Under the Nine Points, the public interest is best served by incentivizing universities to conduct research. To do so, the Nine Points places a heavy emphasis on policies that will maximize the financial gains of universities and other research institutions. This includes a focus on concepts which are designed to minimize the costs incurred. For example, Point 3 recommends a limitation on the licensing of future improvements.\(^{152}\) Future improvements or follow-on inventions are modifications, alterations or enhancements that improve the use of a licensed technology. AUTM suggests not licensing these—despite their potential to improve the efficacy or reduce the cost of an essential medicine—because these developments could be licensed at cost in the future. In the Nine Points, AUTM argues that licensing future improvements “may effectively enslave a faculty member’s research program to the company, thereby exerting a chilling effect on their ability to receive corporate and other research funding and to engage in productive collaborations with scientists employed by companies other than the licensee.”\(^{153}\) Or simply put, to AUTM, not receiving the maximum compensation for these developments is akin to enslavement and liable to prevent future research.\(^{154}\)

Perhaps the provisions left out of the Nine Points, rather than the ones included, are more illustrative of their values. The Nine Points do not require accountability, transparency, or limitations on the creation of predatory monopolies. They only recommend that universities receiving public funds consider addressing the unmet needs of those most in need. The ETAF and Nine Points do not appear to be the same category of licensing frameworks. The ETAF is an equitable access framework, whereas the Nine Points are commercialization recommendations for universities that merely allude to a measure of equitable values.

Despite the progress that the Statement of Principles’ updated views on equitable access represent, they are focused on developing nations and use language that is non-binding on the Universities’ actions, such as “we will make vigorous efforts to,” rather than simply saying “we will.”\(^{155}\) Perhaps most egregious of all the non-committal language in the Statement of Principles is Principle 4, which contains the document's only enforcement mechanism. The signatory universities commit that they will “strive to preserve our institutions’ future rights to negotiate effective global access terms through implementation of such measures as notice requirements coupled with “agreements to agree.”\(^{156}\) Agreements to agree are notoriously unenforceable, really representing no real agreement at all.\(^{157}\) Therefore the statement lacks meaningful

\(^{151}\) Equitable Technology Access Framework (Link).

\(^{152}\) Nine Points (Link).

\(^{153}\) Id.

\(^{154}\) Id.

\(^{155}\) Id.

\(^{156}\) Id.

\(^{157}\) See Adjustrite Systems, Inc. v. GAB Business Services, Inc., 145 F.3d 543, 548 (2d Cir. 1998) (stating an agreement to agree “is a mere proposal, and neither party has an obligation to negotiate further”) (Link).
enforcement mechanisms. Instead, the statement of Principles opts to recommend to include march-in right provisions, which as discussed previously have never been enforced.

A comparison between the ETAF Principles and similar provisions of the alternative frameworks classified by the subject matter they discuss, is provided in Table A3.

**C. Relevant Stakeholders**

The ETAF focuses its recommendations on TTOs, however the impact from its adoption is far more pervasive. In addition to TTOs, numerous other interests are impacted by equitable access to medicine. An examination of those stakeholders’ interests can help UAEM better target its advocacy when discussing the ETAF. A comparison of the key interests of stakeholders can be found in Table A4.

**1. Brand Name Pharmaceutical Companies**

Brand Name Pharmaceutical Company (Brand) opposition to equitable practices could prove a challenge for UAEM. The pharmaceutical industry is the largest lobbying group in the United States spending $381,425,889 in 2023–over $139,000,000 more than the second highest industry, electronics manufacturing.\(^{158}\) Between 2001 and 2019 over a quarter of all new drugs approved by the FDA had their origins in academic research.\(^{159}\) From 2010 to 2019 NIH funding contributed to 99.4 percent (all but two) of the drugs that received federal approval.\(^{160}\) These factors create an environment where pharmaceuticals can reap large profit margins utilizing public funding for their research.

Due to this strong connection between TTOs and Brand name pharmaceutical companies, equitable access can significantly impact pharmaceutical profit margins. If TTOs abide by Principles II and IV of the ETAF, the prohibitions against monopolies and exclusivity drastically reduce the profits that brand name pharmaceutical companies can earn. Competition in the market leads to both a reduction in prices due to competition and a division of sales amongst their competitors.

Brands have an incentive to adopt equitable access policies rather than allow the federal government to fulfill such measures on their behalf. As drug prices become an ever increasing point of public concern the federal government has begun to take a more interventionist role in setting prices between Brands and certain patients.\(^{161}\) Under the Inflation Reduction Act of 2022, the Biden administration will conduct negotiations to reduce the prices of select high-cost drugs that Medicare will pay. Given the large populous that this covers the federal government is in a powerful negotiating position and has the potential to receive particularly favorable rates.\(^{162}\) These negotiations have overwhelming political support, but are also currently not well-known among the public.\(^{163}\) Beyond the Medicare negotiations, the FTC has also pushed Brand companies to delist patents improperly added to the FDA ‘Orange Book’ to combat high drug

\(^{158}\) *Industries*, Open Secrets (2023) (Link).


\(^{160}\) Id.


\(^{162}\) Id.

\(^{163}\) *People Overwhelmingly Support Medicare Drug Price Negotiations, but Most Don’t Realize It’s Happening*, KFF (Jan. 31, 2024) (Link)
prices.\(^{164}\) While this effort is currently targeted at patents for select drug categories, the FTC has already identified over 100 improperly listed patents and multiple Brands have been forced to delist their patents.\(^{165}\) Brands could avoid further implementation of similar programs by adopting and publicizing equitable access programs. Though they may lose some revenue initially, that is likely to represent a smaller loss than they could expect to face should they lose more control over their ability to set prices independently or face stricter scrutiny prior to listing patents with the FDA.

Lastly, publicly traded companies have fiduciary duties to their shareholders. Violations of these obligations can lead to costly lawsuits against the corporation.\(^{166}\) One duty that often shuts down discourse related to socially conscious decision making is the duty to maximize shareholder value.\(^{167}\) However, these two principles are not actually at odds. Corporate decision making is held to the “business judgment rule,” a relatively permissive legal standard that simply requires corporate decision makers to behave with care, good faith, and in a manner that one could reasonably expect to be in the corporation’s best interest.\(^{168}\) Due to the open ended nature of the business judgment rule, courts have upheld a broad range of charitable corporate actions as reasonable business decisions.\(^{169}\) Much of the presumption that corporations have an absolute duty to generate as much money for its shareholders as possible is merely predicated on short-term thinking whereas the business judgment rule permits long-term planning as well. So long as a reasonable explanation for adopting more equitable technology transfer standards could be found, a Brand’s fiduciary duties would not bar them from doing so. The list of potential justifications for adopting equitable transfer policies is vast, but could include a desire to improve public perception of the Brand to increase future sales, a belief that universities are more willing to license to Brands that adopt equitable practices, or an understanding that a positive public image may allow the Brand to attract top talent to join their employ.

2. Universities

Universities receive sizable financial compensation from licensing patented technologies to pharmaceutical manufacturers. Using Xtandi as an example, UCLA received $6.5 million in the drug’s first three months on the market in 2012.\(^{170}\) Four years later UCLA received $520 million following Royal Pharma’s acquisition of Xtandi’s royalty rights.\(^{171}\) Large payouts for licensing patents that become successful drugs clearly incentivises universities to adopt licensing provisions which

---

\(^{164}\) FTC, FTC Files Amicus Brief in Asthma Inhaler Patent Dispute (Mar. 22, 2024) (Link)

\(^{165}\) Kate Goodwin, Three Companies Relent to FTC Demands, Delist Patents from FDA’s Orange Book, Biospace (Dec. 22, 2023) (Link)

\(^{166}\) Shareholder Derivative Suit, Cornell Legal Information Institute (Link)

\(^{167}\) Oliver Hart & Luigi Zingales, Companies Should Maximize Shareholder Welfare Not Market Value, 2 J.L. Fin. & Acct. 247 (2017) (Link); Lynn Stout, Corporations Don’t Have to Maximize Profits, N.Y. Times (Apr. 16, 2015) (Link)

\(^{168}\) Business Judgment Rule, Cornell Legal Information Institute (Link).

\(^{169}\) See, e.g., A. P. Smith Manufacturing Co. v. Barlow, 98 A.2d 581 (business judgment rule protects corporate decision to make charitable donation to a university) (Link).

\(^{170}\) NOTE 3 — COLLABORATION AGREEMENTS, SEC.gov (Sep. 30, 2012) (Link).

\(^{171}\) David Schwartz, UCLA Gets a Huge Payday in Billion Dollar Royalty Monetization Deal for Prostate Drug, Tech Transfer eNews (Mar. 9, 2016) (Link).
maximize the royalties that they will eventually earn. Most often, these are provisions that align with Brand interests and create barriers between consumers and access to medicine.

Beyond just direct payments for technology transfer, pharmaceutical companies also utilize their wealth to exert soft power over universities. Universities receive grants and other donations from pharmaceutical companies. These serve to further build relationships and tie the universities and pharmaceutical companies together.\(^{172}\) Despite the financial control that pharmaceutical companies can exert over them, as the patent holders, universities have considerable control over market entry when licensing their technology. Pharmaceutical companies have no means of bringing a drug reliant on university research to market unless they can reach a deal with the university. As such, finding areas where pharmaceutical interests diverge from those of the university creates an opportunity to advance more equitable goals.

Universities are also more sensitive to non-financial incentives than pharmaceutical companies. Prestige and public opinion are considerations which universities take seriously. UAEM has demonstrated that pressure from within the university community can result in universities making some strides towards adopting more equitable practices. Following the backlash over the pricing of Xtandi and pressure from UAEM and other equitable access advocates UCLA adopted the “Affordable Access Plan.”\(^{173}\)

In adopting the ETAF, universities may miss out on some of the financial windfall that exploitative technology transfer can provide, but damaging relations with members of their community through the negative publicity that such agreements attract could cost even more in the long run if university donors shy away from making contributions. By comparing the information provided by a university in its financial report to disclosures that the university’s TTO makes in its annual report, information on the impact of a school’s received donations and patent portfolio revenue can be gleaned.\(^{174}\) For example, at its peak for the past decade, UCLA's income from the fees and royalties of licensed patents was $78.3 million in the 2015 fiscal year.\(^{175}\) That same year UCLA had $6.5 billion in total revenue of which $285 million came from private gifts.\(^{176}\) Even at the height of Xtandi’s income, UCLA’s entire patent portfolio represented just over one percent of the university's total revenue, and less than a third of what it received from donors.

### 3. University Researchers

While it is easy to think of universities as a monolith, the incentives that affect researchers on a university’s staff may not perfectly align with those of their employer. Researchers actually see

---

\(^{172}\) Can Pharmaceutical Companies Ethically Sponsor Medical Education?, Tech Target: Pharma News Intelligence (Sep. 19 2023) (Link).

\(^{173}\) MEDICINES PATENT POOL – CONSIDERING UNDERSERVED POPULATIONS WHEN LICENSING INTELLECTUAL PROPERTY, Regents of the University of California (Dec. 15, 2020) (Link).

\(^{174}\) This information is available for all of the top NIH funded research universities in Table A1. The amount of information provided by TTOs varies, however at least a disclosure of the total revenue generated from their patents for the year is typically available. A further investigation utilizing freedom of information requests may be able to obtain more of the information that public universities’ TTOs used to produce these reports.

\(^{175}\) Technology Commercialization Report, University of California (2015) (Link) (The 2015 University of California’s annual report on patent commercialization provides information on each university in the system’s patent income, as well as the income for each of the top 25 earning inventions. Commercialization reports for 2013 to 2022 are available from the University of California. (Link))

very little of the profits that their discoveries earn at market. While some universities do have policies that distribute royalties amongst inventors, this is typically far a tiny fraction of the drug’s overall earnings.\(^{177}\) For example, at UCLA, under the Patent Policy for the University of California school system, inventors of a patented technology receive 35 percent of the net royalties and fees associated with licensing that technology.\(^{178}\) That 35 percent is then split between all named inventors on the patent application within the University of California system. For Xtandi, which UCLA licensed with a 10 percent royalty agreement, all inventors shared only 3.5 percent of total sales the discovery earned. While in the case of Xtandi, the most successful biotechnology product to come from the California school system, that still represents a great fortune, for most other technologies that reach the market, the inventors can only expect to see a pittance. Worse yet, this represents the most lucrative position for University researchers. Students and postdoctoral candidates, who perform a great deal of the research that is ultimately licensed away, typically are not included in royalty sharing programs at all, but instead receive either a stipend or fixed salary that is not incentivized by the commercialization of their research.\(^{179}\) Because the majority of university research staff see little to no return on the licensing of their inventions they are likely to be less motivated by the reduced drug revenues that may result from promoting equitable access.

Researchers also have non-financial incentives to consider when considering changes to current technology transfer paradigms. Academia is well known for the emphasis it places on status. The adage of “publish or perish” that has been the bane of scholars for generations, has quickly transformed into a “patent or perish” dynamic for those in scientific fields. The ability to obtain a vast and profitable patent portfolio can be instrumental in advancing an academic down their professorship path.\(^{180}\) The adage of “publish or perish” that has been the bane of scholars for generations, has quickly transformed into a “patent or perish” dynamic for those in scientific fields.

Especially in the realm of biotechnology not all researchers are PhDs. A significant portion of physicians who are academically affiliated with universities are engaged in research.\(^{181}\) Physicians who develop and patent medical innovations are held to a heightened set of ethical standards by the American Medical Association.\(^{182}\) These include two particularly relevant obligations, physicians should:\(^{183}\)

1. Not use patents (or other means, such as trade secrets or confidentiality agreements) to limit the availability of medical innovations. Patent protection should not hinder the goal of achieving better medical treatments and technologies.”

---

\(^{176}\) Patent Policy, University of California (Oct. 1, 1997) (Link).
\(^{180}\) Paul Sandberg, Morteza Gharib, Patrick T. Harker, & Sudeep Sarkar, *Changing the academic culture: Valuing patents and commercialization toward tenure and career advancement*, 111 PNAS 18, 6542 (Apr. 28, 2014) (Link).
\(^{181}\) Alyssa Browne, *Demographic Characteristics and Work Experiences of Physician Scientists in the U.S.*, AAMC (Link).
\(^{182}\) AMA Code of Medical Ethics: V,VII (Link).
\(^{183}\) Id.
2. Not allow patents to languish. Physicians who hold patents should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.

Not using intellectual property protections to hinder access to medicine is precisely in line with the ETAF’s Principle III on the avoidance of monopolies. In comparison the second obligation to utilize licensing agreements to promote development and usage of technology is reminiscent of Point 2 of the Nine Points. Depending on how a physician interprets their ethical duties they could serve as a strong ally for the ETAF amongst university researchers. Perhaps the most notable historical examples of disseminating medical technologies on moral grounds rather than for profit has come from physician researchers such as Jonas Salk and his release of the polio vaccine or Frederick Banting doing the same for insulin.  

4. Generic Drug Manufacturers

Generic drug manufacturers have many incentives to support universities adopting the ETAF. The ETAF seeks to remove barriers to access which often correspond with barriers that prevent generic drugs from entering the market. Most notably, should a university adopt principle V into their licensing agreements and require all licensees and sublicensees to revoke applicable FDA exclusivity periods, generic manufacturers could begin selling generic versions of the drug years earlier than if brand name manufacturers maintained their maximum exclusivity period. Further, generic manufacturers would not have any direct relationship with the original licensor and would therefore not be obligated to waive their own exclusivity rights, allowing them to still obtain 180-day exclusivity rights.

That said, generic drug manufacturers are not in the business of equitable access. Generic manufacturers can and will take opportunities to limit access to medication in situations where it benefits them financially. For example, numerous instances of “pay-for-delay,” where a generic manufacturer accepts payment from a Brand in exchange for not bringing a generic drug to market, arise. Despite pay-for-delay often violating antitrust law and being a costly detriment to all patients seeking affordable medicine, generic manufacturers are willing to collude with Brands when it fits their economic interests, ultimately making them unpredictable potential partners in advancing the ETAF.

5. The Public

82% of Americans believe that prescription drug prices are unreasonable.

The most important stakeholder under the ETAF is the public. The licensing and development of technology should seek to serve the public benefit, particularly in the case of PFRIs where public funding finances part or all of the research cost. The ETAF is intended to provide for the public benefit and therefore the stakeholders with the most to gain from the implementation of the ETAF are the public. Access to essential medicine is becoming a more widespread topic of discussion and the influence held by the broader American populace has the potential to result in significant reform in the coming years.

185 See, e.g., FTC v. Actavis, Inc., 570 U.S. 136 (2013) (Link) (finding that the FTC can bring suit for reverse payment patent settlements). See also Impax Lab’y’s, Inc. v. Fed. Trade Comm’n, 994 F.3d 484 (5th Cir. 2021) (Link) (finding a pay to delay scheme to be an unjust antitrust violation).
The public’s impact is already being felt. In his 2024 State of the Union, President Joe Biden spent considerable time discussing the costs of essential medicines, and claimed to be “ending” the high price of prescription pharmaceuticals in the United States. This should come as no surprise considering that approximately 82 percent of Americans believe that prescription drug prices are unreasonable. Because the public still overwhelmingly blames Brands for these prices, that is where political efforts are currently being directed. Continued advocacy on alternative causes for inflated drug prices, like technology transfer policies could produce improved results as the public’s interest in drug prices grows.

6. Patient Advocacy Groups

Patient advocacy groups (PAGs) represent a sophisticated and coordinated population interested in advancing the cause of patients suffering from a specific condition. These groups serve both as lobbying organizations striving to advance policy and public funds for the benefit of its representatives, as well as more traditional advocacy such as funding relevant research. PAGs have historically been successful in driving research and expediting development. That said, two factors make PAGs a more nebulous partner for the UAEM to work with when advancing the ETAF. First, PAGs are also known to have close connections with drug and device manufacturers. These connections range from relationships that focus on finding patients to serve in clinical research trials, to more nefarious arrangements such as significant non-disclosed financial support from pharmaceutical companies. Second, PAGs often are in place to advance the research done on a disease where successful treatment strategies remain elusive. In these cases, PAGs are likely to view the advancement of research as a far more pressing concern than the affordability of hypothetical future treatments. PAGs may therefore be apprehensive to support the ETAF if they worry equitable access may inhibit research to any degree.

---

186 Joe Biden, State of the Union Address (2022) (Link).
187 Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, Public Opinion on Prescription Drugs and Their Prices, KFF (Aug. 21, 2023) (Link).
188 Yumin Gao, The Role of Patient Groups in Driving Innovation in Cardiovascular Disease Research and Therapeutic Development, American Heart Association (Link).
189 Margaret Goldberg, Patient Advocacy Groups and Innovators Must Partner to Advance New Treatments, STAT (July 6, 2021) (Link).
190 Id.
192 See Gao (Link). 
III. Freedom of Information Advocacy Toolkit

A. The Presumption of Transparency

Most TTOs operate behind a veil of secrecy. As discussed earlier, even those that share model licensing agreements do not readily disclose the contents of their actual contracts. An access to medicine advocate can use Freedom of Information ("FOI") laws to request technology transfer agreements ("TTAs") and related communications between public universities and licensees. Because public universities are organized under state law, they are subject to all the requirements of state FOI statutes. UAEM can use these licenses to determine the popularity of exclusive vs. non-exclusive licenses, adherence to model licensing language, compliance with the Bayh-Dole Act, and the existence of contractual provisions designed to guarantee affordable access.

FOI laws establish a presumption that government records are open to the public. Broadly speaking, they require that government agencies disclose "public records" in response to descriptive requests. Depending on the specific statute, agencies must respond within a designated time frame. Disclosure requirements are subject to certain exemptions, which can take the form of express exceptions or catchall provisions limiting disclosure that would be contrary to the public interest.

States began passing FOI laws as early as 1866, when Nebraska granted citizens the right to inspect public records during business hours. 100 years later, the federal statute—the Freedom of Information Act ("FOIA")—passed. FOI laws are grounded in democratic political theory. That is, in order for voters to make informed judgments about their elected leaders, they must have access to public records. Consistent with the spirit of open access, anyone can use FOI laws, although they are particularly useful to journalists, academics, and activists. In 1974, the Watergate Scandal underlined the dangers of government secrecy and spurred amendments that strengthened FOIA by adding procedural safeguards.

---

194 See, e.g., Cal. State Univ. v. Superior Ct., 90 Cal. App. 4th 810 (Cal. Ct. App. 2001) (finding that records of private donors who had licensed luxury suites on university property were public records subject to disclosure).
195 FAQ, FOIA.gov (last visited Mar. 6, 2024) (Link).
196 Id.
197 See, e.g., 5 U.S.C. § 552(6) (20 days to respond); Cal. Gov’t Code § 7922.535(a) (10 days to respond).
199 LaMont Rainey, Watchfulness in the Citizen: A Guide to Nebraska’s Sunshine Laws, Nebraska Legislature (May, 2023) (Link).
200 FOIA, U.S. Department of Justice Archives (last visited Mar. 21, 2024) (Link).
201 Halstuk at 512.
202 Id.
203 Id at 533 ("For example, search and copying fees were made uniform among the agencies; agencies were required to respond to information requests within ten days or face lawsuits; and agencies were
In 2022 alone, the University of California received 570 utility patents.\textsuperscript{204} The University reaps enormous profit from its patented technology—particularly its pharmaceutical innovations.\textsuperscript{205} For example, UCLA received a cash payment of $1.14 billion when it licensed Xtandi to Royalty Pharma.\textsuperscript{206} As discussed earlier, UCLA and UC Berkeley developed Xtandi and CRISPR, respectively, using federal funds. Because of the University of California’s considerable influence in biomedical patenting and its status as a public research university, this section will focus on the California Public Records Act (“CPRA”).

**B. The California Public Records Act**

1. Overview

California passed its own FOI statute—the CPRA—in 1968.\textsuperscript{207} More than 35 years after the CPRA’s passage, Californians amended their constitution to guarantee a right to public information. Article I, § 3(b) (“Sunshine Amendment”) provides that “[t]he people have the right of access to information concerning the conduct of the people’s business, and, therefore, the meetings of public bodies and the writings of public officials and agencies shall be open to public scrutiny.”\textsuperscript{208} The Sunshine Amendment mandates broad interpretation of statutory provisions requiring disclosure, and narrow interpretation of statutory provisions requiring nondisclosure.\textsuperscript{209}

To submit a CPRA request, one must contact a state or local agency and “reasonably” describe an identifiable record or records.\textsuperscript{210} The agency must make the record(s) available on payment of copying fees.\textsuperscript{211} The agency is not permitted to consider the purpose of the request—so long as the requester reasonably describes a disclosable record, the custodian must make the record available.\textsuperscript{212} The agency has an affirmative obligation to aid the requester in the production of records—including “providing suggestions for overcoming any practical basis for denying access to the records or information sought.”\textsuperscript{213} Under “unusual circumstances,” the agency has the option to notify the requester and claim a fourteen-day extension.\textsuperscript{214} Unusual circumstances may include the need to search for records at another facility, a “voluminous”

---

\textsuperscript{204} The University of California Ranks No. 1 in Higher Education for U.S. Patents, University of California (Apr. 26, 2023) (Link).


\textsuperscript{206} Phil Hampton, UCLA Sells Royalty Rights Connected with Cancer Drug to Royalty Pharma, UCLA Newsroom (Mar. 4, 2016) (Link).

\textsuperscript{207} California Public Records Act FAQs, Commission on Peace Officer Standards and Training (last visited Mar. 21, 2024) (Link).

\textsuperscript{208} Cal. Const. Art. I, § 3(b)(1).


\textsuperscript{210} Cal. Gov’t Code § 7922.530.

\textsuperscript{211} Id.

\textsuperscript{212} Cal. Gov’t Code § 7922.530.

\textsuperscript{213} Cal. Gov’t Code § 7922.600.

\textsuperscript{214} Cal. Gov’t Code § 7922.535(b).
quantity of responsive documents, the need to consult with another agency, or the need to compile data. An agency may not delay or obstruct the production of records.

2. The CPRA in a Nutshell

1. Anyone can submit a request—that is, the requester does not need to be a resident of California or a citizen of the U.S.

2. The agency has ten days to respond, but can sometimes ask for a 14 day extension.

3. The agency is obligated to assist in identifying records.

4. If the records exist electronically, the requester may ask for them to be transmitted in electronic form.

5. The judicial and legislative branches are exempt from the CPRA.

5. The responding agency may charge copying fees equal to the actual cost of duplication, and access is contingent on payment. However, agencies may relax disclosure requirements and reduce/waive fees to “allow for faster, more efficient, or greater access to records.”

3. Exemptions

All public records are disclosable unless an exemption applies. If a portion of the document is protected by an exemption, the agency is still obligated to disclose any “reasonably segregable portion.” The fact that parts of a requested document fall within the terms of an exemption does not justify withholding the entire document. The CPRA has several express exemptions, including, but not limited to:

1. Trade secrets.

2. Personal medical information.

---

217 No provisions in the CPRA (Cal. Gov’t Code § 7920 to § 7931) impose a residency requirement for CPRA requests.
218 Cal. Gov’t Code § 7922.570.
222 Cal. Gov’t Code § 7922.525.
223 CBS, Inc. v. Block, 42 Cal. 3d 646, 653 (Cal. 1986).
224 Cal. Gov’t Code § 7930.205.
3. Certain information related to law enforcement and crime victims.\textsuperscript{226}

4. Social Security numbers.\textsuperscript{227}

5. “Official records” when a designated “public version” has been made available.\textsuperscript{228}

6. Disclosure that would violate privacy rights enshrined in Article I, §1) of the California Constitution.\textsuperscript{229}

In refusing to disclose a pharmaceutical licensing agreement, a TTO might rely on one or several exemptions, including (1) trade secrets, and (2) the “catchall” exemption, which includes deliberative process privilege.

4. University Responsiveness

The University of California’s Office of the President publishes guidelines for record requests.\textsuperscript{230} Below is a summarized review:

1. Provide specific information about records and attempt to describe unnamed records with as much specificity as possible.

2. Ideally, requests should be in written (or email) form.

3. Copying costs are $.20 per page.

4. A requester can inspect records prior to duplication, during business hours.

According to MuckRock—a nonprofit devoted to acquiring, sharing, and analyzing public records—the University of California system has a relatively poor track record of responding to CPRA requests in a timely manner. MuckRock collects data relating to response time and success rate. Across California generally, the average response time is 95 days, and the average success rate is 41.81\%.\textsuperscript{231} However, MuckRock’s “success rate” includes requests where the agency claims that no responsive documents exist.\textsuperscript{232} Assuming that the information access coordinators are operating in good faith, these instances should be excluded from the “success rate,” because they do not reflect non-compliance with the CPRA.

MuckRock’s user submissions suggest that requesters have had success acquiring contracts from the UC system. For example, UCLA disclosed an agreement between itself and a concert

\textsuperscript{226} Cal. Gov’t Code § 7930.100.
\textsuperscript{227} Cal. Gov’t Code § 7922.200.
\textsuperscript{228} Cal. Gov’t Code § 7922.205.
\textsuperscript{229} Cal. Gov’t Code § 7939.100
\textsuperscript{230} Office of Public Records Guidelines for Access, University of California Office of the President (last visited Mar 20, 2024) (Link).
\textsuperscript{232} Id.
performer,\textsuperscript{233} and well as its contracts with PepsiCo and Coke.\textsuperscript{234} Notably, the latter contract includes a provision noting that buyer and seller will comply with the CPRA, and that the contract is a public record.\textsuperscript{235} It also was not marked as confidential or privileged.\textsuperscript{236}

Below is a table summarizing MuckRock-collected data about some of the UCs’ responsiveness to CPRA requests. “Success Rate” has been adjusted to exclude queries resulting in “no responsive documents.” The sample sizes are relatively small, as noted in the chart. Further, the data does not account for queries that may have been poorly written or sought patently exempted information. However, the data can provide a rough idea of where resources can most effectively be spent. For example, UCLA is much faster and more responsive than Berkeley. The table was last updated as of March 22, 2024.

<table>
<thead>
<tr>
<th>University</th>
<th>Average Response Time (Days)</th>
<th>Approximate Success Rate</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California</td>
<td>79</td>
<td>67%</td>
<td>24</td>
</tr>
<tr>
<td>UC Berkeley</td>
<td>210</td>
<td>29%</td>
<td>65</td>
</tr>
<tr>
<td>UC San Francisco</td>
<td>393</td>
<td>58%</td>
<td>31</td>
</tr>
<tr>
<td>UC Los Angeles</td>
<td>60</td>
<td>60%</td>
<td>35</td>
</tr>
<tr>
<td>UC Irvine</td>
<td>104</td>
<td>55%</td>
<td>22</td>
</tr>
<tr>
<td>UC Davis</td>
<td>43</td>
<td>71%</td>
<td>17</td>
</tr>
</tbody>
</table>

C. The Trouble with Private Universities

Because FOI laws are directed at public agencies, they are inapplicable to private universities. However, an access to medicine advocate might be able to find a way to acquire TTAs between private universities and pharmaceutical companies. As described earlier, the Bayh-Dole Act creates a public stakehold in federally funded technology by establishing march-in rights and carving out a license for the federal government. By this rationale, one could argue that these licenses are public records. Further, large private universities are intertwined with state governments in other ways.\textsuperscript{237} Using the CPRA’s definition as an example, a “public record” is “any writing containing information relating to the conduct of the public’s business prepared,

\textsuperscript{233} PinkPantheress and UCLA Agreements, MuckRock (last visited Mar. 7, 2024) (Link).
\textsuperscript{235} Id.
\textsuperscript{236} Id.
owned, used, or retained by any state or local agency regardless of physical form or characteristics.” An agreement between a private university and pharmaceutical company would not be “prepared by” the government, but it does relate to the conduct of the public’s business. There is a chance that the record could be used or maintained by a government agency, but it would be difficult to find out. While the Bayh-Dole Act obligates certain disclosures to the federal government—such as whether a university elects to retain patent rights—it does not obligate disclosure of contracts that transfer patent rights.

Unfortunately, the Bayh-Dole Act itself provides little help. Section 200(c)(5) requires “periodic reporting on...utilization or efforts at obtaining utilization,” but explicitly exempts such disclosures from FOIA. If an agency invoked (c)(5) to deny disclosure of TTAs, an access to medicine advocate could argue that licenses are not equivalent to utilization data—rather, they merely provide the framework for utilization of publicly-funded technology. A dive into the legislative history of (c)(5) is slightly illuminating. In a statement submitted to Congress, Donald Dunner—then president of the American Patent Law Association—argued that “[t]his confidentiality is needed in part to protect the patentability of subject inventions in certain absolute novelty countries and regions of the world.” That is, he worried that disclosure of technical data would preclude patentability in other countries. Fortunately, this concern appears unrelated to contractual provisions between universities and pharmaceutical companies. Even if such provisions contained compromising technical data, a disclosing agency could easily redact any relevant portions and provide the remaining provisions to a requester (as they are required to do under the federal FOIA statute).

One way to acquire information about TTAs between private universities and pharmaceutical companies is Securities and Exchange Commission (“SEC”) filings.

One way to acquire information about TTAs between private universities and pharmaceutical companies is Securities and Exchange Commission (“SEC”) filings. In particular, the Global Healthcare Innovation Alliance Accelerator (“GHIAA”)—a global nonprofit that advocates for equitable access to medical products—has had considerable success acquiring TTAs that have been made public through SEC filings. GHIAA has a large database of provisions, including TTAs between universities and for-profit entities. While SEC filings may reveal the existence of a licensing or collaboration agreement, the downside of this approach—compared to FOI requests—is that the disclosure advocate has no control over which information is disclosed.

---

238 Cal. Gov’t Code § 7920.530.
241 President’s Industrial Innovation Program: Hearings on H.R. 6033, H.R. 6934, H.R. 3806 and H.R. 2414 Before the Comm. on Courts, Civil Liberties, and the Administration of Justice and the Comm. on the Judiciary, 9th Cong. 123 (statement of Donald Dunner).
242 5. U.S.C. § 552(b) (noting that “[a]ny reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt”).
243 Annual filings, such as 10-K forms, and filings triggered by specified events, such as 8-K forms, are likely to be instructive. Exchange Act Reporting and Registration, SEC.gov (last visited Mar. 20, 2024) (e.g., companies must file a “current report” when they enter into a “material definitive agreement.”) (Link).
244 Provision Database Methodology, Global Healthcare Innovation Alliance Accelerator (last visited Mar. 20, 2024) (Link).
245 All Agreements, Global Healthcare Innovation Alliance Accelerator (last visited Mar. 20, 2024) (Link).
Whether companies file contracts with the SEC depends on a variety of factors, and an advocate may not have access to specific, sought-after provisions.

Another source of transparency is patent law itself, which requires the USPTO to record any “assignment, grant or conveyance” of a patent or patent application upon request. While a patent holder is not necessarily obligated to disclose such conveyances, the USPTO encourages recording to protect parties to the transaction by establishing a chain of title and “in order to give third parties notification of equitable interests or other matters relevant to the ownership of a patent or application.” A disclosure advocate can use the USPTO’s Patent Assignment Search to (1) identify Bayh-Dole Patents, (2) investigate a patent’s ownership chain, and, more rarely (3) find information about licensees. For example, a search for Xtandi’s ownership chain reveals an assignment to Astellas Pharmaceuticals, executed in 2012. Similarly, a search for the first CRISPR patent reveals (1) the technology’s Bayh-Dole origins (2) the assignment from the inventor to the Broad Institute.

---

246 See, e.g., Exchange Act Reporting and Registration, SEC.gov (last visited Mar. 20, 2024) (e.g., companies must file a “current report” when they enter into a “material definitive agreement.”) (Link).
250 A funding agency, such as the NIH, should be listed as an assignee of the Bayh-Dole patent, as a university electing to retain title to a Bayh-Dole patent must grant a confirmatory license to the funding agency. See, e.g., License to the United States Government, U.S. Patent No. 14,054,414 (Link).
253 Assignment from Feng Zhang to the Broad Institute & The Massachusetts Institute of Technology, U.S. Patent No. 14,054,414 (Link).
IV. Conclusion

Essential medicines must be accessible to all, particularly underserved communities. Despite Bayh-Dole’s success in bringing drugs to market, the system is broken. Public and private universities license essential medicines to profit-motivated pharmaceutical companies, which then spend billions of dollars on marketing before passing those costs to patients. The goal of Bayh-Dole was not rote privatization, but to balance the need to incentivize innovation and the ability for the public to access life-saving treatments. The public—and patients in particular—have a real stake in federally-funded research. This is particularly true when public universities develop vital technologies. Prohibitively priced pharmaceuticals are an insufficient return on the public’s investment.

The ETAF outlines exactly how universities can promote equity and affordability. Compared to alternative frameworks—such as AUTM’s Nine Points—the ETAF centers the public’s, rather than the university’s, interest in life saving medicines. Because the ETAF reflects anti-monopolistic principles contrary to the financial interests of universities and pharmaceutical companies, it is particularly important that other stakeholders—such as patient advocacy groups and generic drug manufacturers—use their voices to exert pressure on behalf of patients. While each principle in the ETAF reflects a commitment to accessibility, UAEM can take certain steps to ensure that incorporation of certain ETAF principles is less likely to encounter legal obstacles.

Several universities have made strides by sharing model licensing language. While this is commendable, it is not enough. TTOs should do everything they can to ensure that model language is negotiated into licensing agreements. Additionally, model language should be easy to find. For an access to medicine advocate, university transparency is essential. An advocate can use state FOI laws to request licensing agreements between public universities and pharmaceutical companies. By pulling back the veil on licensing practices, an advocate can exert greater pressure on universities to promote equity, access, and affordability.
## Appendix

### Table A1. Top University Funding Recipients & Socially Responsible Licensing Plans

<table>
<thead>
<tr>
<th>University</th>
<th>Location</th>
<th>Public/Private</th>
<th>2023 NIH Funding</th>
<th>Model License?</th>
<th>Statement/Commitment on TTO website?</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC SAN FRANCISCO</td>
<td>CA</td>
<td>Public</td>
<td>$613,512,315</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>JOHNS HOPKINS UNIVERSITY</td>
<td>MD</td>
<td>Private</td>
<td>$609,518,263</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>UNIVERSITY OF MICHIGAN</td>
<td>MI</td>
<td>Public</td>
<td>$534,179,671</td>
<td>No</td>
<td>Endorses AUTM's Nine Points</td>
</tr>
<tr>
<td>UNIVERSITY OF PENNSYLVANIA</td>
<td>PA</td>
<td>Private</td>
<td>$532,826,406</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>UNIVERSITY OF PITTSBURGH</td>
<td>PA</td>
<td>Public</td>
<td>$515,123,914</td>
<td>Yes</td>
<td>See analysis of model license below</td>
</tr>
<tr>
<td>COLUMBIA UNIVERSITY</td>
<td>NY</td>
<td>Private</td>
<td>$512,673,005</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>WASHINGTON UNIVERSITY</td>
<td>MO</td>
<td>Private</td>
<td>$495,867,866</td>
<td>Not publicly available</td>
<td>No</td>
</tr>
<tr>
<td>UC LOS ANGELES</td>
<td>CA</td>
<td>Public</td>
<td>$482,787,923</td>
<td>Affordable Access Provision</td>
<td>See analysis of Affordable Access Provision below</td>
</tr>
<tr>
<td>YALE UNIVERSITY</td>
<td>CT</td>
<td>Private</td>
<td>$478,361,691</td>
<td>Yes</td>
<td>See analysis of model license below</td>
</tr>
<tr>
<td>DUKE UNIVERSITY</td>
<td>NC</td>
<td>Private</td>
<td>$463,110,068</td>
<td>Yes</td>
<td>Endorses Licensing Principles from AUTM</td>
</tr>
<tr>
<td>STANFORD UNIVERSITY</td>
<td>CA</td>
<td>Private</td>
<td>$457,798,980</td>
<td>No</td>
<td>Endorses Licensing Principles from AUTM</td>
</tr>
<tr>
<td>UC SAN DIEGO</td>
<td>CA</td>
<td>Public</td>
<td>$418,552,842</td>
<td>Exclusive License Agreement Template (coming soon)</td>
<td>No</td>
</tr>
<tr>
<td>UNIVERSITY OF WASHINGTON</td>
<td>WA</td>
<td>Public</td>
<td>$394,300,729</td>
<td>Yes</td>
<td>See analysis of model license below</td>
</tr>
<tr>
<td>UNIVERSITY OF NORTH CAROLINA</td>
<td>NC</td>
<td>Public</td>
<td>$372,261,364</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CHAPEL HILL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMORY UNIVERSITY</td>
<td>GA</td>
<td>Private</td>
<td>$346,449,098</td>
<td>Yes</td>
<td>See analysis of model license below</td>
</tr>
<tr>
<td>UNIVERSITY OF WISCONSIN-MADISON</td>
<td>WI</td>
<td>Public</td>
<td>$339,500,865</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>NORTHWESTERN UNIVERSITY</td>
<td>IL</td>
<td>Private</td>
<td>$309,026,808</td>
<td>Yes</td>
<td>See analysis of model license below</td>
</tr>
</tbody>
</table>
Model Licenses

For each license, the following information is provided:

Background Information
- The location of the university
- Amount of federal funding received in 2023
- Whether the university is private or public. \(^{254}\)

Bayh-Dole Requirements
- **Objective**: If the licensing agreement commits to the objective of Bayh-Dole: “to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions...and protect the public against nonuse or unreasonable use of inventions.”\(^{255}\)
- **Federal License**: If the agreement acknowledges the Federal agency’s right to a nonexclusive, non-transferable, irrevocable, paid-up license. \(^{256}\)
- **Progress Reporting Requirement**: The frequency of licensees reporting commercialization progress to the university required.
- **Small Business Preference**: If the agreement acknowledges Bayh-Dole’s preference for licensees to be a small business. \(^{257}\)
- **U.S. Manufacturing Preference**: If the agreement acknowledges the requirement for the licensee to make reasonable efforts to manufacture the medical technology to be substantially in the United States. \(^{258}\)

Socially Responsible Licensing Provisions
- **Affordable Access Plan**: If the agreement incorporates any type of plan for the equitable distribution of the licensed technology in Low-and-Middle-Income Countries (“LMICs”), as identified by the World Bank.
- **Non-Suit Provision**: Whether the PFRI maintains a right to decline pursuing a patent infringement action against any third party engaged in the manufacture, sale, or importation of the licensed technology in LMICs.

---

\(^{254}\) The private status of a university impacts its obligations under FOIA and state FOI laws, as discussed in [Section 3](#).

\(^{255}\) 35 U.S.C § 200.

\(^{256}\) 35 U.S.C § 202.

\(^{257}\) *Id.*

\(^{258}\) 35 U.S.C § 204.
Table A2. Comparison of University Model Licenses

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>UNIVERSITY OF PITTSBURGH</td>
<td>PA</td>
<td>$515,123,914</td>
<td>Public</td>
<td>Yes (Art. 3)</td>
<td>Yes (2.2)</td>
<td>Annually (5.3)</td>
<td>Yes (6.1)</td>
<td>Yes (2.2)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>UC LOS ANGELES</td>
<td>CA</td>
<td>$482,787,923</td>
<td>Public</td>
<td>Annually (Appendix A)</td>
<td>No</td>
<td>Yes (3.2)</td>
<td>No</td>
<td>Yes (3.2)</td>
<td>No</td>
<td>Yes 11(d)</td>
</tr>
<tr>
<td>YALE UNIVERSITY</td>
<td>CT</td>
<td>$478,361,691</td>
<td>Private</td>
<td>Yes (1.4)</td>
<td>Yes (3.2)</td>
<td>Annually (4.2)</td>
<td>No</td>
<td>Yes 11(d)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>UNIVERSITY OF WASHINGTON</td>
<td>WA</td>
<td>$394,300,729</td>
<td>Public</td>
<td>Yes (5.1)</td>
<td>Yes (2.8)</td>
<td>Annually (5.3)</td>
<td>No</td>
<td>Yes (2.8)</td>
<td>Yes (3.2)</td>
<td>Yes (7.6)</td>
</tr>
<tr>
<td>EMMORY UNIVERSITY</td>
<td>GA</td>
<td>$346,449,098</td>
<td>Private</td>
<td>Yes (6.2)</td>
<td>Yes (Definitions)</td>
<td>Annually (4.1)</td>
<td>No</td>
<td>Yes (2.8)</td>
<td>Yes (2.5)</td>
<td>No</td>
</tr>
<tr>
<td>BOSTON UNIVERSITY</td>
<td>MA</td>
<td>$148,174,655</td>
<td>Private</td>
<td>Yes (3.02)</td>
<td>Yes (2.0.5)</td>
<td>Annually (3.01(F))</td>
<td>Yes (3.01(G))</td>
<td>Yes (6.01)</td>
<td>Yes (General Terms)</td>
<td>Yes (2.07)</td>
</tr>
<tr>
<td>UC BERKELEY</td>
<td>CA</td>
<td>$120,870,509</td>
<td>Public</td>
<td>Yes (1.3)</td>
<td>Yes (1.6)</td>
<td>Semi-Annual (8.1)</td>
<td>Yes (3.4)</td>
<td>Yes (3.5)</td>
<td>Yes (4.9)</td>
<td>No</td>
</tr>
<tr>
<td>HARVARD UNIVERSITY</td>
<td>MA</td>
<td>$72,858,332</td>
<td>Private</td>
<td>Yes (3.1.1)</td>
<td>Yes (2.1.2)</td>
<td>Annually (3.3), Quarterly (5.1.1)</td>
<td>Yes (6.4)</td>
<td>No</td>
<td>Yes - Global Access Provisions</td>
<td>Yes (7.2)</td>
</tr>
<tr>
<td>NORTHWESTERN UNIVERSITY</td>
<td>IL</td>
<td>$37,701,299</td>
<td>Private</td>
<td>Yes (Art. IV)</td>
<td>Yes (WITNESSETH)</td>
<td>Annually (4.3)</td>
<td>Yes (Exhibit B)</td>
<td>Yes (2.2)</td>
<td>Yes (2.8)</td>
<td>Yes (9.2)</td>
</tr>
<tr>
<td>CARNEGIE MELLON UNIVERSITY</td>
<td>PA</td>
<td>$32,652,761</td>
<td>Private</td>
<td>Yes (4)</td>
<td>Yes (2.8)</td>
<td>Annually (Attachment B)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

259 UCLA has not published a model license, but has released its Affordable Access Provision, which states in relevant part: “As part of its public mission to bring products to the marketplace, UCLA strives to enable underserved populations, which have limited access to adequate quantities of medical innovations arising from UCLA’s laboratories, to have access to these innovative products. Licensees are encouraged to consider these populations’ interests when marketing and selling Licensed Products.” “UCLA Considers Underserved Populations When Licensing Medical Research Discoveries,” UCLA Technology Development Group (Link).
Table A3. Comparison of Licensing Framework Provisions
Frameworks are presented in order of how effective their requirements for TTOs are at implementing equitable access to medicine. Green indicates a more effective framework and red a less effective approach.

<table>
<thead>
<tr>
<th>Concept</th>
<th><strong>ETAF</strong>&lt;sup&gt;260&lt;/sup&gt;</th>
<th><strong>GALF</strong>&lt;sup&gt;261&lt;/sup&gt;</th>
<th><strong>Statement of Principles</strong>&lt;sup&gt;262&lt;/sup&gt;</th>
<th><strong>Nine Points</strong>&lt;sup&gt;263&lt;/sup&gt;</th>
</tr>
</thead>
</table>
| Responsibility to the (global) public | Principle I. Social responsibility to the public.  
The ETAF recognizes social responsibility as its foremost principle. The primary objective is to reimburse the public for their investment, via contributions to the public good. | G.1 Access to medicines and health-related technologies for all is the primary purpose of technology transfer of health-related innovations. | 1. In our negotiations with potential licensees we will make vigorous efforts to develop creative and effective licensing strategies that help to promote global access to health-related technologies  
5. We will further support the development of new health-related technologies aimed at diseases that disproportionately burden individuals in the developing world. | Point 9. Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.  
The Nine Points only recommends considering providing aid to those members of the global public most in need. |
| Limit Monopolies             | Principle II. Limit monopolies.  
Principle VI. Limit data and market exclusivities.  
Under the ETAF, exclusive licensing is a form of monopoly, which creates barriers to access that should be avoided in favor of nonexclusive agreements.  
Regulatory exclusivities enforce similar monopolies | S.1 Support generic competition by removing legal barriers in resource limited countries.  
S.3 Universities should issue non-exclusive licenses and reserve rights to practice licensed technology. | 2. Our intellectual property should not become a barrier to essential health-related technologies needed by patients in developing countries. | Point 2. Exclusive licenses should be structured in a manner that encourages technology development and use.  
Point 8. Be mindful of the implications of working with patent aggregators  
The Nine Points suggests that “exclusive license[s] often [are] necessary and appropriate,” as they believe |

---

<sup>263</sup> Nine Points to Consider in Licensing University Technology, AUTM (Mar. 2007) (Link).
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>and prevent competition from generic products</td>
<td></td>
<td></td>
<td>The only time it advises against exclusive licensing is when a licensee would not readily be able to put the technology to work. This is further evident in its prohibition on patent aggregators being limited to “patent trolls” and entirely permissive of monopolists who market a drug.</td>
<td></td>
</tr>
<tr>
<td>Retain IP Rights &amp; Rights to Address Licensee Actions</td>
<td>Principle III. Retain IP rights.</td>
<td></td>
<td>4. We will strive to preserve our institutions’ future rights to negotiate effective global access terms through implementation of such measures as notice requirements coupled with “agreements to agree.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Principle IV. Include step-in rights.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Principle V. Include reach-through clauses.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The ETAF seeks more options to address failures to fulfill equitable obligations.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share Research with Scientific Community</td>
<td>Principle VII. Commit to full sharing of all data and research findings.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[^260]: ETAF
[^261]: GALF
[^262]: Statement of Principles
[^263]: Nine Points
<table>
<thead>
<tr>
<th>Concept</th>
<th>ETAF\textsuperscript{260}</th>
<th>GALF\textsuperscript{261}</th>
<th>Statement of Principles\textsuperscript{262}</th>
<th>Nine Points\textsuperscript{263}</th>
</tr>
</thead>
</table>
| Transparency  | Principle VIII. Ensure full transparency of all public funding sources and amounts.  
Principle IX. Implement robust accountability and transparency mechanisms.  
The ETAF values effective use of public funding for the public benefit. Transparency is critical to ensuring that the equitable obligations of those who receive public funding are met. | S.4 Licensing policies should be transparent and based off of clear, trackable metrics to ensure global access is being supported. | 6. We will work together to develop and apply meaningful metrics to evaluate the success of our efforts to facilitate global access and support continued innovation with particular relevance to global health.  
7. We will share with one another our collective experiences from working with our licensees; educate others and encourage their consideration, endorsement and application of the principles articulated in this statement. | Point 4. Universities should anticipate and help to manage technology transfer related conflicts of interest (Internal Transparency).  
The Nine Points views funding as an incentive to innovate and not the source of an obligation for transparency (transparency and accountability could in fact prevent universities from seeking the most lucrative licensing terms available). |
| Follow-on Inventions | S.2 Include proactive licensing provisions to ensure follow on patents do not block generic production.  
G.2 Technology transfer should preserve future innovation by ensuring that intellectual property does not act as a barrier to further research. | | | Point 3. Strive to minimize the licensing of “future improvements.” |
| Litigation     | 3. In those cases where we pursue patent rights, we will negotiate license agreements that draw upon a variety of strategies that seek to align incentives among all stakeholders to promote broad access to health-related technologies in developing countries. | | | Point 6. Enforcement action should be carefully considered  
The Nine Points discourages litigation to protect the reputation of universities as a whole. This restricts a method of enforcing equitable access obligations. |
Table A4. Summary of Select Stakeholder Interests in Equitable Licensing

Cell colors provide a spectrum of how each interest in a given subject is likely perceived by the given stakeholder, spanning from a strong positive interest (green) to a negative interest (red).

<table>
<thead>
<tr>
<th>Stakeholder Type</th>
<th>High Brand Name Drug Prices</th>
<th>Quantity of research performed</th>
<th>Positive Public Perception</th>
<th>Prestige</th>
<th>Waiver of FDA NDA exclusivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name Drug Companies</td>
<td>Higher drug prices result in higher profits for brands.</td>
<td>The more research that universities are engaged in the more likely that a discovery can result in a profitable licensed drug.</td>
<td>While some consumers may choose to avoid products from a Brand with a negative reputation, the presence of regulatory monopolies in the drug space leaves most with no option.</td>
<td>Prestige plays some role in physician medication selection</td>
<td>NDA exclusivity periods extend the length of time Brands can charge monopolistic pricing. Relinquishing them would be a foreseeable loss of profit.</td>
</tr>
<tr>
<td>Universities</td>
<td>Universities receive royalties from drugs licensed to brands. Royalties represent only a subset of both the drug’s net revenue and the university’s overall income, but can still be a substantial sum.</td>
<td>More research will lead to an increase in larger patent portfolios that can produce both profit and prestige.</td>
<td>Public perception impacts universities ability to attract donations from private donors.</td>
<td>Prestige is instrumental in allowing universities to attract funding and talent.</td>
<td>The waiver of NDA exclusivities will only impact drug pricing after a drug’s patent term has lapsed. At this point the university has no royalty interest in a drug. The only cost of requiring waiver is that Brands will likely negotiate for reduced royalty rates to mitigate losses.</td>
</tr>
<tr>
<td>University researchers</td>
<td>Researchers can often receive a portion of the university’s income from licensed drugs. This is typically not available to the entire research team and only amounts to a fraction of the royalty revenue.</td>
<td>More research being performed as a result of licensing deals incentivizing research offers more opportunities for researchers to obtain positions and funding from universities.</td>
<td>Public perception for researchers is a relatively insignificant consideration for researchers. The perception of those within their industry is more important.</td>
<td>Prestige is one of the most powerful motivators for academics, as it is a near necessity to obtain recognition and advancement.</td>
<td>Waiver of exclusivities has no impact on researchers</td>
</tr>
</tbody>
</table>

- Higher drug prices result in higher profits for brands.
- The more research that universities are engaged in the more likely that a discovery can result in a profitable licensed drug.
- While some consumers may choose to avoid products from a Brand with a negative reputation, the presence of regulatory monopolies in the drug space leaves most with no option.
- Prestige plays some role in physician medication selection.
- NDA exclusivity periods extend the length of time Brands can charge monopolistic pricing. Relinquishing them would be a foreseeable loss of profit.
- Universities receive royalties from drugs licensed to brands. Royalties represent only a subset of both the drug’s net revenue and the university’s overall income, but can still be a substantial sum.
- More research will lead to an increase in larger patent portfolios that can produce both profit and prestige.
- Public perception impacts universities ability to attract donations from private donors.
- Prestige is instrumental in allowing universities to attract funding and talent.
- The waiver of NDA exclusivities will only impact drug pricing after a drug’s patent term has lapsed. At this point the university has no royalty interest in a drug. The only cost of requiring waiver is that Brands will likely negotiate for reduced royalty rates to mitigate losses.
- Researchers can often receive a portion of the university’s income from licensed drugs. This is typically not available to the entire research team and only amounts to a fraction of the royalty revenue.
- More research being performed as a result of licensing deals incentivizing research offers more opportunities for researchers to obtain positions and funding from universities.
- Public perception for researchers is a relatively insignificant consideration for researchers. The perception of those within their industry is more important.
- Prestige is one of the most powerful motivators for academics, as it is a near necessity to obtain recognition and advancement.
- Waiver of exclusivities has no impact on researchers.
<table>
<thead>
<tr>
<th>Generic Drug Manufacturers</th>
<th>High Brand Name Drug Prices</th>
<th>Quantity of research performed</th>
<th>Positive Public Perception</th>
<th>Prestige</th>
<th>Waiver of FDA NDA exclusivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic drug manufacturers can only enter the market once the monopoly pricing period has ended. While high Brand drug pricing may indicate high demand or price elasticity, more generics entering the market will eventually drive prices down.</td>
<td>Generic drugs only tangentially stem from research. Generic manufacturers are unlikely to be incentivized by the abundance of drugs that they can produce 20 or more years away.</td>
<td>Generics are seldom identifiable by consumers and the public.</td>
<td>Generic prestige is a relatively minor consideration even within the healthcare industry.</td>
<td>A licensor requiring a brand name drug company to waive regulatory exclusivities is a major boon for generics, allowing them to enter the market earlier without any costs or sacrifices.</td>
<td></td>
</tr>
<tr>
<td>The Public</td>
<td>Drug pricing is a major point of public concern, with 82% finding prices unreasonable and 28% having trouble paying for their prescriptions.</td>
<td>The public has an incentive to see more research turn into useful drugs and technology.</td>
<td>N/A</td>
<td>N/A</td>
<td>Generics being on the market earlier will result in reduced drug costs for the public sooner.</td>
</tr>
<tr>
<td>Patient Advocacy Groups</td>
<td>Patient advocacy groups tend to support the notion that reduced cost to consumers leads to reduced drug research and availability. Therefore, they are willing to accept high pricing for the chance at treatments for the patients they represent.</td>
<td>Patient groups’ top priority is typically advocating for additional research and funding for treatments aiding the patients they represent.</td>
<td>Public perception is important to PAGs impacting their ability both to advocate and receive donations from the public. That said the close relationship between PAGs and Brands indicates that some reputational harm is acceptable in advancing other aims.</td>
<td>More prestigious PAGs will have the ability to receive more donations and likely be able to work more closely with Brands on treatment development</td>
<td>Requiring Brands to waive ODE may decrease their interest in manufacturing a drug to treat rare conditions. Many patient groups advocate on behalf of patients with conditions that are applicable for ODE.</td>
</tr>
</tbody>
</table>

---


265 Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023) (Link).
<table>
<thead>
<tr>
<th>Institution</th>
<th>Information Practices Officer(s)</th>
<th>Email Address</th>
<th>Mailing Address</th>
<th>Office Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC Los Angeles</td>
<td>Robert Baldridge</td>
<td><a href="mailto:records@ucla.com">records@ucla.com</a></td>
<td>10920 Wilshire Blvd., Mail Code #143348 Los Angeles, CA 90095-1433</td>
<td>(310) 794-8741</td>
</tr>
<tr>
<td>UC Berkeley</td>
<td>Liane Wong</td>
<td><a href="mailto:pra@berkeley.edu">pra@berkeley.edu</a></td>
<td>University of California, Berkeley Office of Legal Affairs 200 California Hall, MC #1500 Berkeley, CA 94720-1500</td>
<td>(510) 664-4615</td>
</tr>
<tr>
<td>UC San Francisco</td>
<td>Brenda Gee DePeralta</td>
<td><a href="mailto:bgee@chanoff.ucsf.edu">bgee@chanoff.ucsf.edu</a></td>
<td>Office of the Chancellor University of California, San Francisco Box 0402, S24 San Francisco, CA 94143</td>
<td>(415) 476-4317</td>
</tr>
<tr>
<td>UC San Diego</td>
<td>Anastasia Chase, Paula Johnson</td>
<td>No email address listed, but there’s a Record Request Portal</td>
<td>Policy &amp; Records Administration, University of California, San Diego, 9500 Gilman Drive, #0014 La Jolla, CA 92093-0014</td>
<td>(858) 534-2552</td>
</tr>
<tr>
<td>UC Davis</td>
<td>Heather Urzua</td>
<td><a href="mailto:publicrecords@ucdavis.edu">publicrecords@ucdavis.edu</a></td>
<td>Office of Campus Counsel Offices of the Chancellor and Provost University of California, Davis One Shields Avenue Davis, CA 95616-8558</td>
<td>(530) 752-5527</td>
</tr>
<tr>
<td>UC Irvine</td>
<td>Thea Bullock</td>
<td><a href="mailto:pra@uci.edu">pra@uci.edu</a></td>
<td>Public Records Office University of California, Irvine 254 Multipurpose Science &amp; Technology Irvine, CA 92697-1430</td>
<td>(949) 824-2312</td>
</tr>
</tbody>
</table>
Dear [name of custodian of records]:

Under the California Public Records Act ("CPRA"), we are writing on behalf of Universities Allied for Essential Medicine ("UAEM") to request a copy of public records, as defined by Government Code § 7920.530 and 7920.545, detailed below. We request the following records:

Any agreement between the University and a pharmaceutical company that provides for the licensing, assignment, commercialization, manufacture, and/or sale of [technology], including but not limited to any patents associated with said [technology].

Any communications or correspondence, including but not limited to emails, reports, minutes, or memoranda, relevant to the licensing of [technology or medicine] or the negotiation of licensing provisions, including but not limited to any communications pertaining to affordable access, that include any of the following search terms:

- [Subject technology]
- [Numbers of any known patents associated with subject technology]
- Royalt! AND [subject technology]
- Exclusiv! AND [subject technology]
- Access AND [subject technology]
- Pric! AND [subject technology]
Please note that the CPRA permits for the request of records by description of content in lieu of listing specific documents. The University must search their records to find any such documents that will meet the provided criteria.

Optional: As a non-profit student coalition, we request that you waive fees. We have limited resources and will use the information to further the public’s understanding of how universities license patents for essential medicine. We will not use the information for commercial purposes.

Optional maximum fees: If you are unable to waive fees and anticipate duplication costs in excess of [maximum fee that requester is willing to pay], please contact us so that we can decide which documents we would prefer for you to disclose.

We would prefer that the public records be transmitted electronically, by email attachment, if possible.

California Government Code § 7922.535 provides that you have ten days to determine if the public records are disclosable. If you allege that all or a portion of the public records are exempted by law, you must notify us of your reasons within ten days. Government Code § 7922.525(b) further provides that you must redact and send any “reasonable segregable portion.”

If we can provide clarification that will help expedite your response, please contact us at [phone number or email address], pursuant to Government Code § 7922.600.

Thank you for your attention to this matter.

Sincerely,

[Name]
[Title]
[Company Name]
[Address]
[City, State ZIP Code]