# "In The Public Interest": University Technology Transfer and The Nine Points Document—An Empirical Assessment

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*In 2007, eleven major U.S. research universities and the Association of American Medical Colleges signed an accord titled* In the Public Interest: Nine Points to Consider in Licensing University Technology. *It outlined a range of issues that universities should consider when licensing their technology to the private sector—from reservations of rights and limitations on exclusivity to limiting dealings with patent assertion entities to making medical technologies accessible at affordable prices. More than talking points, the document proposed specific contractual clauses intended to promote the educational and public welfare missions of universities. Today, more than a hundred academic institutions and associations around the world have signed the* Nine Points *document. Yet in the fifteen years since the document was created, there has been no systematic, empirical assessment of its effect on university licensing practices. This Article fills that gap with the first empirical study of the impact of the* Nine Points *document on university licensing practices. Through a review of 220 publicly available university technology licenses signed both before and after the adoption of the* Nine Points *document, this Article finds that while the document prompted the expansion of educational and non-profit research using patented university technology, it resulted in few changes relating to the promotion of public health or access to medical technologies. This mixed adoption of the*

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*recommendations made by the* Nine Points *document suggests that there is little consensus regarding the nature of the 'public interest' that the* Nine Points *document sought to promote. This Article recommends that a reorientation of university technology transfer policy may be in order—one that could be facilitated through greater engagement of academic faculty, senior administrators, students, alumni, and other institutional stakeholders in setting policy for university technology transfer.*

## INTRODUCTION

University technology development and transfer are significant economic activities in the United States. University-based research played a major role in the growth of the biotechnology, medical devices, software, and computer networking industries.[1] The licensing of university-owned patents has resulted in notable products and services ranging from the Gatorade® sports drink (University of Florida) to CRISPR-Cas9 gene editing (UC Berkeley and the Broad Institute of Harvard and MIT) to the Google search algorithm (Stanford). In 2020, 184 U.S. academic research institutions received more than 8,700 U.S. patents and applied for nearly 18,000 more.[2] During the same year, these institutions entered into more than ten thousand technology licensing and option agreements with private sector entities.[3] One research group recently estimated that university-developed technologies contributed between $333 billion and $1 trillion to the U.S. gross domestic product (GDP) between 1996 and 2020.[4]

Yet the business of academic technology transfer has not always been viewed favorably by the public. Beginning in the 1970s, fears emerged that the promise of

1. *See generally* NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., RESEARCH UNIVERSITIES AND THE FUTURE OF AMERICA: TEN BREAKTHROUGH ACTIONS VITAL TO OUR NATION'S PROSPERITY AND SECURITY 49 (2012); Yali Friedman, *Biotech's U.S. Birth*, SCI. AM. WORLDVIEW 54 (2009); Tammy D'Amato, Lindsey Gilroy & Scott Oldach, *From the Classroom to the Boardroom—How Universities Can Become the Flywheel for Economic Growth*, INTELL. PROP. TODAY, Sept. 2009, at 22.

2. AUTM, AUTM 2020 LICENSING ACTIVITY SURVEY 5 (2021) [hereinafter AUTM 2020 SURVEY]. For general discussions of university patenting patterns and practices, see, for example, Jennifer Carter-Johnson, *University Technology Transfer Structure and Intellectual Property Policies*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER 4, 6–8 (Jacob H. Rooksby ed., 2020); Lisa Larrimore Ouellette & Rebecca Weires, *University Patenting: Is Private Law Serving Public Values?*, 2019 MICH. ST. L. REV. 1329; Peter Lee, *Patents and the University*, 63 DUKE L.J. 1 (2013).

3. AUTM 2020 SURVEY, *supra* note 2, at 5.

4. Lori Pressman, Mark Planting, Carol Moylan & Jennifer Bond, ECONOMIC CONTRIBUTIONS OF UNIVERSITY/NONPROFIT INVENTIONS IN THE UNITED STATES: 1996–2020 (2022) [hereinafter ECONOMIC CONTRIBUTION REPORT] (estimates stated in 2012 dollars).

licensing revenue was causing universities to stray from their core educational and public missions.[5] Critics identified potential conflicts of interest between academic institutions and corporate sponsors as early as 1974, when an agreement between Monsanto and Harvard Medical School attracted significant public opprobrium.[6] Consumer advocate Ralph Nader echoed the fears of many in 2004 when he wrote:

> Academic science, with its custom of open exchange, its gift relationships, its willingness to provide expert testimony that speaks truth to power, its serendipitous curiosity and its nonproprietary legacy to the next generation of student-scientists, differs significantly from corporate science, which is ridden with trade secrets, profit-determined selection of research, and awesome political power to get its way, whether by domination or servility to its payers.[7]

Another public critic was journalist Jennifer Washburn, whose 2005 book, *University Inc.: The Corporate Corruption of Higher Education*, focused on the increasing commercialization of university research. Washburn highlighted transactions like UC Berkeley's multimillion-dollar deal with Novartis/Syngenta, which led to student and faculty protests on campus, as well as an investigation and hearings by the California State Senate.[8]

Against the backdrop of these critiques, representatives of thirteen major research institutions met at Stanford University in 2006 to hash out a set of guiding principles for their burgeoning technology licensing businesses.[9] Together, these institutions held patents covering some of the most important and profitable biotechnology, chemical, and electronic technologies in the world. Yet in March 2007, they produced a document that called for restraint in their commercial licensing practices. It urged academic institutions everywhere to recall their educational and public missions, and to refrain from pure profit-seeking when licensing patents to the private sector.

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5. *See, e.g.*, Peter Mikhail, Hopkins v. CellPro*: An Illustration that Patenting and Exclusive Licensing of Fundamental Science Is Not Always in the Public Interest*, 13 HARV. J.L. & TECH. 375 (2000); *see also* Eliot Marshall, *When Commerce and Academe Collide*, 248 SCIENCE 152 (1990) (identifying increasing ties between industry and academia during the 1980s).

6. *See* JENNIFER WASHBURN, UNIVERSITY, INC: THE CORPORATE CORRUPTION OF HIGHER EDUCATION 4–5 (2005); *see also* DANIEL S. GREENBERG, SCIENCE FOR SALE: THE PERILS, REWARDS, AND DELUSIONS OF CAMPUS CAPITALISM 2 (2007) (asking whether "today's commercial values [have] contaminated academic research, diverting it from socially beneficial goals to mercenary service on behalf of profit-seeking corporate interests?"); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

7. Ralph Nader, *Foreword* to SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST—HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH?, at xiii, xiv (2004).

8. *See* WASHBURN, *supra* note 6, at 3–24.

9. *See infra* Section II.A.

The seventeen-page document, titled *In the Public Interest: Nine Points to Consider in Licensing University Technology* (*Nine Points* document)[10], was a milestone in the field of academic technology transfer. One senior university official has referred to it as the "Pledge of Allegiance" for technology transfer,[11] and it is still referenced regularly in scholarly articles, government reports, and industry bulletins relating to academic technology transfer.

As of September 2021, 118 research institutions and associations around the world signed the *Nine Points* document.[12] To a significant degree, the document has become the symbol of a more public-spirited approach to university technology transfer. As observed by Professor David Winickoff, universities view the document as "a testament to the public values underlying technology transfer."[13] The *Nine Points* document has been endorsed by bodies including the National Research Council[14] and the Association of American Universities.[15] It has been held up at Congressional hearings as evidence of the academic community's commitment to the public good.[16] As Professor Winickoff characterizes it, the *Nine Points*

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10. STAN. UNIV., IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY (2007) [hereinafter NINE POINTS DOCUMENT], https://news.stanford.edu/news/2007/march7/gifs/whitepaper.pdf [https://web.archive.org/web/20211023163224/https://news.stanford.edu/news/2007/march7/gifs/whitepaper.pdf] .

11. *See Nine Points to Consider in Licensing University Technology with Kathy Ku*, AUTM ON AIR (Sept. 8, 2021), https://music.amazon.com/podcasts/ea3e863b-db18-47b7-9cc1-9f660d0ae276/episodes/57ea2bfa-c451-47a2-a937-4e4ae16c55bc/tech-transfer-ip-nine-points-to-consider-in-licensing-university-technology-with-kathy-ku? [https://perma.cc/5JC8-JU85].

12. AUTM, NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY, [hereinafter NINE POINTS SIGNATORIES] https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university [https://web.archive.org/web/20211025093425/https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university/] (last visited Oct. 25, 2021).

13. *See* David E. Winickoff, *Private Assets, Public Mission: The Politics of Technology Transfer and the New American University*, 54 JURIMETRICS 1, 32 (2013).

14. NAT'L RSCH. COUNCIL, MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST 6, 66, 72 (Stephen A. Merrill & Anne-Marie Mazza eds., 2011) [hereinafter NRC UNIVERSITY IP] (recommending adoption of principles stated in the NINE POINTS DOCUMENT, *supra* note 10).

15. AAU WORKING GRP. ON TECH. TRANSFER AND INTELL. PROP., STATEMENT TO THE AAU MEMBERSHIP ON UNIVERSITY TECHNOLOGY TRANSFER AND MANAGING INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST (2015) [hereinafter AAU STATEMENT], https://www.aau.edu/key-issues/aau-technology-transfer-working-group-statement-managing-university-technology-transfer [https://perma.cc/6KQM-5FPK].

16. *The Bayh-Dole Act (P.L. 96-517, Amendments to the Patent and Trademark Act of 1980)—The Next 25 Years: Hearing Before the H. Subcomm. on Tech. & Innovation of the H. Comm. on Sci. & Tech.*, 110th Cong. 15–18 (2007) (statement of Dr. Arundeep Pradhan, Chief Technology Transfer Official, Or. Health & Sci. Univ.); *The Role of Federally Funded University Research in the Patent System: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 10–11 (2007) (statement of Charles Louis, V.C. for Rsch., Univ. of Cal., Riverside); *see also* Winickoff, *supra* note 13, at 32 (first citing *Hearing Before the H. Subcomm. On Tech & Innovation*; *supra*; and then citing *Hearing Before the S. Comm. on the Judiciary*, *supra.*

document is "an act of public accountability" that "broadcast[s] the collective goals of the academic licensing community and its operating principles to the public."[17]

Yet more than just statements of principle, the *Nine Points* document proposes specific contractual clauses that are intended to promote the educational and public welfare missions of universities—clauses providing for the retention of internal research rights, limitations on the automatic licensing of improvements, and requirements that medical innovations be made broadly available at affordable prices.[18] As such, it is one of the first such policy statements to operationalize its drafters' conception of the public good with concrete textual recommendations.

The *Nine Points* document aspires to serve as a blueprint for future behavior by its signatories and all academic institutions. In this regard, its creators may have been inspired by other globally significant consensus documents such as the 1996 Bermuda Principles, an accord that continues to shape the practice of scientific data sharing today.[19]

But did the *Nine Points* document live up to its promise? Public critiques of university technology transfer practices have surged in recent years. As before, commentators have questioned whether universities have abandoned their public missions, focusing instead on earning profits from lucrative licensing deals.[20] These critiques have been especially acute in connection with recent biomedical innovations such as COVID-19 vaccines[21] and CRISPR gene editing technologies.[22]

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17. Winickoff, *supra* note 13, at 30.

18. *See infra* Section II.B.

19. The Bermuda Principles were created by a group of approximately fifty scientific and governmental leaders of the Human Genome Project and revolutionized the sharing of scientific data both among HGP participants and the public. *See* Kathryn Maxson Jones, Rachel A. Ankeny & Robert Cook-Deegan, *The Bermuda Triangle: The Pragmatics, Policies, and Principles for Data Sharing in the History of the Human Genome Project*, 51 J. HIST. BIOLOGY 693 (2018); Jorge L. Contreras, *Bermuda's Legacy: Patents, Policy and the Design of the Genome Commons*, 12 MINN. J.L. SCI. & TECH. 61 (2011).

20. *See* Brian L. Frye & Christopher J. Ryan, Jr., *Technology Transfer and the Public Good*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER, *supra* note 2, at 245; Ouellette & Weires, *supra* note 2; Rebecca S. Eisenberg & Robert Cook-Deegan, *Universities: The Fallen Angels of Bayh-Dole?*, 147 DAEDELUS 76 (2018); Sigrid Sterckx, *Patenting and Licensing University Research: Promoting Innovation or Undermining Academic Values?*, 17 SCI. & ENG'G ETHICS 45 (2009).

21. *See, e.g.*, Matthew Herder, E. Richard Gold & Srinivas Murthy, *University Technology Transfer Has Failed to Improve Access to Global Health Products During the COVID-19 Pandemic*, 17 HEALTHCARE POL'Y 15, 16 (2022) (pointing to "the divide between the university's stated principles to serve global health and technology transfer in practice" with respect to LNP technology incorporated into COVID-19 mRNA vaccines); Matthew Rimmer, *The People's Vaccine: Intellectual Property, Access to Essential Medicines, and the Coronavirus COVID-19*, J. INTELL. PROP. STUD. 1, 8 (2021) (discussing calls by student activists for universities to make their IP more available in the COVID-19 vaccine effort); Jorge L. Contreras, *The Open COVID Pledge: Design, Implementation and Preliminary Assessment of an Intellectual Property Commons*, 2021 UTAH L. REV. 833, 901 (describing student-led campaign to persuade universities to contribute vaccine-related intellectual property to the COVID-19 response).

22. *See, e.g.*, Knut J. Egelie, Sabina P. Strand, Berit Johansen & Bjorn K. Myskja, *The Ethics of Access to Patented Biotech Research Tools From Universities and Other Research Institutions*, 36 NATURE

One particular question raised by this ongoing debate is whether the *Nine Points* document had any measurable effect on university licensing practices. Did it temper the commercial tendencies of university licensing offices, or was it, as Professor Winickoff asks, merely an exercise in "optics"?[23] While various universities over the years have issued public statements espousing the values reflected in the *Nine Points* document,[24] no systematic, empirical assessment of its effect on university licensing practices has ever been conducted.[25] This Article fills that gap.

In order to gain a better understanding of the impact of the *Nine Points* document on university licensing practices, this study reviewed 220 publicly available university licenses signed both before and after the adoption of the *Nine Points* document. This Article describes its findings, both as to the nature of universities that have signed the *Nine Points* document, as well as its effect on university licensing provisions.

In short, this study finds that while the *Nine Points* document prompted the expansion of educational and non-profit research using patented university technology, it resulted in few changes relating to the promotion of public health or access to medical technologies. This mixed adoption of the recommendations made by the *Nine Points* document suggests that there is little consensus regarding the nature of the 'public interest' that the *Nine Points* document sought to promote.

The remainder of this Article proceeds as follows. Part I provides additional background regarding university patenting in the United States, the Bayh-Dole Act of 1980, and notable public disputes that contributed to the adoption of the *Nine Points* document. Part II describes, in greater detail, the process by which the *Nine Points* document was created and adopted, summarizes each of the provisions of the *Nine Points* document, and describes additional programs and mechanisms that

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BIOTECHNOLOGY 495 (2018) ("Exclusive licensing to a surrogate company granted by a university will, as for CRISPR-Cas9, create concentrated control of the use of the technology in a for-profit entity that has both short and long-term goals that are likely to be in conflict with the broad dissemination of the technology."); Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, Surrogate Licensing, and Scientific Discovery*, 355 SCIENCE 698 (2017) (discussing university exclusive licensing of CRISPR-Cas9 intellectual property).

23. Winickoff, *supra* note 13, at 40; *see also* Liza Vertinsky, *Universities as Guardians of Their Inventions*, 2012 UTAH L. REV. 1949, 2008 ("There is little evidence that informal measures such as [the NINE POINTS DOCUMENT, *see supra* note 10,] have been adequate to curtail universities' self-interested actions in the face of increasing competition for scarce resources.").

24. *See, e.g.*, James K. Woodell & Tobin L. Smith, *Technology Transfer for All the Right Reasons*, 18 TECH. & INNOVATION 295, 299–300 (2017) (describing numerous university commitments to the public interest and statements following the NINE POINTS DOCUMENT, *see supra* note 10).

25. One prior study of university socially responsible licensing practices relied primarily on interviews with university TTO officials at eleven universities in North America and Europe. *See* Thi-Yen Nguyen, Mohammad Shahzad & Juliana Veras, *Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America: Identifying Key Provisions to Promote Global Access to Health Technologies*, LES NOUVELLES, Sept. 2018, at 189.

were adopted in its wake. Part III describes the methodology and results of the empirical study of university licenses signed both before and after the publication of the *Nine Points* document. Part IV presents a discussion and analysis of these results. The Article concludes with recommended actions and areas for further study.

## I. UNIVERSITY PATENTING AND LICENSING IN THE UNITED STATES

### *A. Bayh-Dole and University Patenting*

Before World War II, research at many U.S. universities had little practical application.[26] But with the need to combat the technological advances being deployed to great effect by Germany, the United States mobilized its substantial research establishment for the war effort. Vannevar Bush, the Dean of MIT's School of Engineering and the founder of Raytheon, led the government's new Office of Scientific Research and Development, drawing on his longstanding ties to academia as he oversaw key wartime initiatives such as the development of radar and nuclear weapons.[27] During America's postwar economic boom, Bush continued to guide national research policy, and the Federal Government poured money into academic labs.[28] Between 1953 and 1980, federal non-defense R&D funding increased from $2.5 billion to $46.1 billion[29]—much of which was paid to America's research institutions.[30]

Though this bonanza of federal spending produced impressive research results, including multiple Nobel prizes for American scientists, relatively little academic research found its way into the commercial sector. Unlike Japan, where the government directly funded industrial research programs for semiconductors and consumer electronics, there was no straightforward pathway from U.S. academic laboratories to the marketplace.[31] The problem, many felt, resulted from the murky rules governing the handling of patents for federally-funded research—some federal funding agencies claimed ownership over inventions that they funded, others ceded rights to their grantees, and others did not specify one

26. For informative discussions of pre-WW2 R&D by U.S. academic researchers, see Bhaven N. Sampat, *Whose Drugs Are These?*, 36 ISSUES SCI. & TECH. 42 (2020); Carter-Johnson, *supra* note 2 at 1, 6, 8.

27. *See* Sampat, *supra* note 26, at 43.

28. *See id.* at 43–45.

29. A.A.A.S., HISTORICAL TRENDS IN FEDERAL R&D BY FUNCTION, FY 1953–2023 (2022), https://www.aaas.org/sites/default/files/202209/RDGDP.xlsx?adobe_mc=MCMID%3D59658429100983127920909863658838319045%7CMCORGID%3D242B6472541199F70A4C98A6%2540AdobeOrg%7CTS%3D1675782002 [https://perma.cc/BDP5-U4G7] (amounts stated in constant FY22 dollars).

30. *See R&D at Colleges and Universities*, A.A.A.S. (Oct. 2022) https://www.aaas.org/programs/r-d-budget-and-policy/rd-colleges-and-universities [https://perma.cc/V3DQ-Y5KP].

31. Thomas A. Massaro, *Innovation, Technology Transfer, and Patent Policy: The University Contribution*, 82 VA. L. REV. 1729, 1729–30 (1996).

way or the other.[32] The result of this lack of clarity was that few federally-funded inventions were being patented or used by the private sector.[33]

A proposed solution to this problem came in the form of legislation sponsored by Senators Birch Bayh (D-IN) and Bob Dole (R-KS) and supported by the research university community.[34] The resulting Patent and Trademark Law Amendments Act of 1980—more commonly known as the Bayh-Dole Act[35]—made a number of adjustments to the patent system focused on federally-funded academic research.

First, the Bayh-Dole Act provides that when an academic institution develops a patentable technology using federal research funding, the institution is entitled to patent the invention. Moreover, if the institution *fails* to seek a patent, it may lose rights to the invention. In effect, universities are penalized for *not* patenting their inventions.[36] Another section of the Bayh-Dole Act provides that any institution earning revenue from one of these patents must *share* some of its profits with the individual inventors.[37] The statute does not specify how much each inventor should get, but most universities have developed a three-way division of royalty licensing income among the inventors, their academic departments, and the university itself, after deducting overhead expenses.[38]

Critics point to the Bayh-Dole Act as a major factor in the commercialization of academic science,[39] while supporters credit it with saving the American technology economy.[40] In 2002, *The Economist* labeled the Act "the goose that laid

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32. *See* NRC UNIVERSITY IP, *supra* note 14, at 16; Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1676–77 (1996); GREENBERG, *supra* note 6, at 52–53.

33. *See* NRC UNIVERSITY IP, *supra* note 14, at 16 ("[V]ery little federally funded research was commercialized prior to 1980.").

34. *See* WALTER D. VALDIVIA, IS PATENT PROTECTION INDUSTRIAL POLICY? NOTES ON THE POLITICAL ECONOMY OF UNIVERSITY PATENTING 4 (2022).

35. Patent and Trademark Laws Amendment Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200–212).

36. 35 U.S.C. § 202(c)(3) (funding agreements with government funding recipients shall provide that "a contractor electing rights in a subject invention agrees to file a patent application prior to the expiration of the 1-year period referred to in section 102(b), and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times").

37. 35 U.S.C. § 202(c)(7).

38. *See* Carter-Johnson, *supra* note 2, at 26–27; Lisa Larrimore Ouellette & Andrew Tutt, *How Do Patent Incentives Affect University Researchers?*, 61 INTL. REV. L. & ECON. 1, 9–10 (2020).

39. *See, e.g.*, Eisenberg & Cook-Deegan, *supra* note 20; Ouellette & Weires, *supra* note 2; Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373 (2007); Rai & Eisenberg, *supra* note 6.

40. *See, e.g.*, Kristen Osenga, *Rembrandts in the Research Lab: Why Universities Should Take a Lesson from Big Business to Increase Innovation*, 59 ME. L. REV. 407 (2007); F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691 (2001); David C. Mowery, Richard R. Nelson, Bhaven N. Sampat & Arvids

the golden egg"—attributing much of America's technological relevance to this single piece of legislation.[41] But whichever side of this debate one favors, almost everyone would agree that the Bayh-Dole Act has substantially changed the world of university technology transfer.

### *B. TTOs and University Licensing*

Following the enactment of the Bayh-Dole Act, many universities established technology transfer offices (TTOs)[42] that were charged with overseeing the growing patent portfolios in university hands. While most universities operate their TTOs as internal units, sometimes falling under the jurisdiction of the university counsel or the office of the provost, others have established semi-autonomous entities (often structured as foundations) to hold intellectual property emerging from university labs.[43] Universities staff their TTOs with attorneys and business managers with expertise in patents, technology licensing and commercialization.[44]

In many cases, the most likely industrial licensee of a university invention is an established enterprise actively pursuing the development of products in the relevant field. Sometimes, however, established industrial partners may not exist, particularly when technologies are in new and emerging fields. In these cases, university researchers, working with external advisors and funders, may form start-up companies to commercialize the discoveries generated by their labs. According to survey data collected by the Association of University Technology Managers (AUTM), in 2020, over one thousand start-up companies were formed to exploit university-owned intellectual property.[45] These companies are sometimes referred

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A. Ziedonis, *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RSCH. POL'Y 99 (2001).

41. Opinion, *Innovation's Golden Goose*, ECONOMIST (Dec. 14, 2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose [https://web.archive.org/web/20201020011659/https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose]. *The Economist* appears to have retreated from this bullish assessment a few years later. *See Bayhing for Blood or Doling Out Cash?*, ECONOMIST (Dec. 24, 2005) ("[T]here is ample evidence that scientific research is being delayed, deterred or abandoned due to the presence of patents and proprietary technologies."), https://www.economist.com/science-and-technology/2005/12/20/bayhing-for-blood-or-doling-out-cash [https://web.archive.org/web/20210124071859/https://www.economist.com/science-and-technology/2005/12/20/bayhing-for-blood-or-doling-out-cash].

42. Such groups are variously known as technology transfer offices (TTOs), technology licensing offices (TLOs), technology venture and commercialization (TVC) offices, and even, in the case of the University of Utah, the Partners for Innovation, Ventures, Outreach & Technology (PIVOT) Center. *See* PIVOT CTR., https://pivotcenter.utah.edu [https://perma.cc/Y44T-98TK] (last visited Feb. 7, 2023). For ease of discussion, this article refers to all such groups as TTOs.

43. *See* David Orozco, *Assessing the Efficacy of the Bayh-Dole Act Through the Lens of University Technology Transfer Offices (TTOS)*, 21 N.C. J.L. & TECH. 115, 121, 135 (2019).

44. *See* Carter-Johnson, *supra* note 2, at 15–17. The Wisconsin Alumni Research Foundation (WARF) is one such foundation. *See* Orozco, *supra* note 43, at 135–37; *see* discussion *infra* Section I.C.2.

45. *See* AUTM 2020 SURVEY, *supra* note 2, at 5, 21.

to as university "spinouts," and AUTM data shows that in 2020 approximately sixteen percent of university technology licenses were granted to spinout companies.[46]

### *C. Public Concerns Over University Patents and Licensing*

As discussed in the Introduction, public objections to the ties between academia and the private sector began to emerge in the 1970s.[47] University administrators were keenly aware of these criticisms.[48] In addition to these generalized complaints, several specific incidents motivated leading research institutions to reconsider their technology transfer policies in the mid-2000s, culminating in the adoption of the *Nine Points* document in 2007.

#### *1. The Research Tool Controversy*

Some university inventions have proven to be of significant general applicability—"research tools" that can aid other researchers in a wide range of investigations. By the early 1990s, significant concerns had emerged regarding patents on key biomedical research tools including the polymerase chain reaction (PCR) and short DNA fragments known as expressed sequence tags (ESTs).[49] At least one high-level committee was formed to consider the issues raised by patented research tools,[50] and in 1998 Rebecca Eisenberg and Mark Heller cautioned that excessive patenting of biomedical research tools could lead to a counterproductive "anti-commons."[51] In 1999, the National Institutes of Health (NIH) published a set of non-binding guidelines encouraging its grant recipients to license patented research tools on a non-exclusive basis to promote their greatest utilization.[52]

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46. *See* AUTM 2020 SURVEY, *supra* note 2, supplemental data at 5, 14 (finding that of 10,050 license and option agreements, 1,601 were granted to start-up companies). In some cases, universities have granted sweeping, exclusive rights to these start-up companies, covering an entire portfolio of patents and all known applications of the resulting technologies. Jacob Sherkow and I have criticized this practice (which we refer to as "surrogate licensing") as it allows a university to avoid its public mission by outsourcing the exploitation of its patent rights to a for-profit company that does not necessarily share that mission. *See* Contreras & Sherkow, *supra* note 22.

47. *See* Mikhail, *supra* note 5; *see also supra* notes 5–8, and accompanying text.

48. *See* Ben Butkus, *Tech Transfer White Paper Authors Hope to Spur Debate, Socially Responsible Licensing*, GENOMEWEB, (Mar. 19, 2007), https://www.genomeweb.com/biotechtransferweek/tech-transfer-white-paper-authors-hope-spur-debate-socially-responsible-licensin#.YxvkQy2B0U5 [https://perma.cc/A6YH-59C3] (noting awareness of criticisms by Jennifer Washburn, among others, as prompting action by organizers of the NINE POINTS DOCUMENT, *supra* note 10).

49. *See* NAT'L RSCH. COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 43–46, 51–55 (1996) [hereinafter NRC RESEARCH TOOLS REPORT].

50. *See id.* at vii–viii.

51. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

52. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 60 Fed. Reg. 72090 (Dec. 23, 1999) [hereinafter NIH Research Tool Guidelines].

Notwithstanding these cautionary notes, universities continued to obtain and license patents covering research tools. In some cases, these patents were not perceived as significant barriers to scientific research.[53] Yet some holders of research tool patents began to explore different ways to monetize these patents, including by charging "reach-through" royalties based not on the use of the research tool itself, but upon revenue earned through products developed using the tool.[54] Though considered "inappropriate" under the NIH Guidelines,[55] the attempt to collect reach-through royalties became increasingly frequent and controversial, particularly in the biotechnology industry.[56]

### *2. The WARF Stem Cell Controversy*

Closely related to the research tool controversy was a situation involving the Wisconsin Alumni Research Foundation (WARF), the technology commercialization arm of the University of Wisconsin-Madison (UW).[57] WARF, established in 1925, granted its first commercial license to the Quaker Oats Company for a Vitamin D supplement intended to combat the childhood disease rickets.[58] Today, WARF reports that it has contributed nearly $4.1 billion to UW.[59] In addition to Vitamin D enrichment, WARF has licensed blockbuster products including the blood thinner warfarin,[60] making it one of the most successful university technology commercialization operations in the country.[61]

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53. *See* John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 289 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) ("[W]e find little evidence of routine breakdowns in negotiations over rights, although research tool patents are observed to impose a range of social costs and there is some restriction of access.").

54. *See* Alfred C. Server, Nader Mousavi & Jane M. Love, *Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools*, 1 HASTINGS SCI. TECH. L.J. 21, 62–63 (2009).

55. NIH Research Tool Guidelines, *supra* note 52, at 72091 ("Royalties on the sale of a final product that does not embody the tool, or other reach-through rights directed to a final product that does not embody the tool discourage use of tools and are not appropriate in these circumstances.").

56. *See* Server, Mousavi & Love, *supra* note 54, at 64 ("[R]each-through royalties have generated significant controversy."); Kimberlee A. Stafford, *Reach-Through Royalties in Biomedical Research Tool Patent Licensing: Implications of NIH Guidelines on Small Biotechnology Firms*, 9 LEWIS & CLARK L. REV. 699, 705 (2005) (noting increasing use of reach-through royalties by universities).

57. *See* Mark L. Gordon, *University Controlled or Owned Technology: The State of Commercialization and Recommendations*, LES NOUVELLES, Dec. 2004, at 152, 156.

58. *Id.*

59. *Strengthening UW-Madison with a Century of Support*, WARF, https://www.warf.org/about-warf/impact-on-uw-madison/ [https://perma.cc/PTM5-EX36] (last visited Feb. 7, 2023).

60. *See* Kevin Walters, *Of Rats and Men: Warfarin Becomes World Famous by 1955*, WARF (2015), https://www.warf.org/announcement/of-rats-and-men-warfarin-becomes-world-famous-by-1955/ [https://perma.cc/X57T-FDD9] (noting that the name "warfarin" is a portmanteau of "WARF" and the chemical compound "coumarin").

61. Carl Gulbrandsen, *WARF's Licensing Policy for ES Cell Lines*, 25 NATURE BIOTECH. 387, 387 (2007).

In 1998, UW researcher James Thompson and colleagues succeeded in creating the first long-lasting human embryonic stem cell (hESC) line. The hESC cells, and methods for producing them, were covered by a series of patents held by WARF and its wholly-owned subsidiary WiCell.[62] WARF's licensing program for its hESC cell line was controversial. Beginning in 2001, WARF charged academic researchers $5,000 to obtain hESC cells.[63] But pricing alone did not generate opposition to WARF's licensing program. Equally important were the restrictions that WARF placed on researchers' ability to share cell lines with collaborators[64] and to use them in research sponsored by the private sector.[65] Others were uncomfortable with the restrictions that WARF placed on particular uses of its hESC cells, such as embryo implantation and the creation of human embryos and human-nonhuman chimeras.[66]

Though WARF entered into more than 130 hESC licenses by 2005,[67] opposition to its licensing program steadily grew. Harvard molecular biologist Douglas Melton publicly called WARF's licensing terms "onerous, restrictive, and uncooperative."[68] In early 2006, at the urging of NIH, WARF reduced the price of its hESC cells from $5,000 to $500.[69] Nevertheless, much of the academic research community remained uncomfortable with WARF's hESC licensing program.

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62. For ease of reference, I refer simply to WARF as the holder and licensor of these patents. A good discussion of WARF's hESC patents and associated licensing practices can be found in Sean O'Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics*, 21 BERKELEY TECH. L.J. 1017 (2006); John M. Golden, *WARF's Stem Cell Patents and Tensions Between Public and Private Sector Approaches to Research*, 38 J.L. MED. & ETHICS 314 (2010); and Winickoff, *supra* note 13, at 21–23.

63. Other than this access fee, WARF did not charge academic researchers to operate under its hESC patents. Commercial researchers, on the other hand, were required to pay significant licensing fees. *See* Golden, *supra* note 62, at 319–20. This being said, some researchers complained about the $5,000 charge, as other suppliers of hESC cells, including Harvard University, charged nothing for them. *See* Jeanne F. Loring & Cathryn Campbell, *Intellectual Property and Human Embryonic Stem Cell Research*, 311 SCIENCE 1716, 1717 (2006).

64. According to Carl Gulbrandsen, WARF's former Managing Director, restrictions on the distribution of WARF hESC cells were imposed by exclusive licensing agreements that WARF had entered with Geron Corporation. *See* Interview with Carl Gulbrandsen, former Managing Dir., WARF (Mar. 19, 2020); *see also* Matthew Herder, *In (or Out of) the Marketplace of Ideas:* WARF v. Geron *and Lessons for Canada*, 11 DALHOUSIE J. LEGAL STUD. 196 (2002) (discussing WARF litigation and settlement with Geron over hESC technology).

65. *See* Golden, *supra* note 62, at 319–20; Amy Ligler, *Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research*, 1 DUKE L. & TECH. REV. 1, 5 (2001).

66. According to Dr. Gulbrandsen, these restrictions were imposed by WARF's institutional review board (IRB) on grounds of protecting human research subjects. Interview with Carl Gulbrandsen, *supra* note 64.

67. Sander Rabin, *The Gatekeepers of hES Cell Products*, 23 NATURE BIOTECHNOLOGY 817, 818 (2005).

68. Eli Kintisch, *Groups Challenge Key Stem Cell Patents*, 313 SCIENCE 281, 281 (2006).

69. *See* Loring & Campbell, *supra* note 63, at 1717; Golden, *supra* note 62, at 320.

### *3. Zerit and Access to Medicines*

One of the most heated debates in the area of academic technology transfer has concerned the accessibility (and affordability) of new biomedical products in the developing world. A typical licensing pattern for a new drug involves the discovery and patenting of a new compound by a university lab, followed by the university's licensing of that patent to a biotechnology or pharmaceutical company for further development, testing, regulatory approval, and commercialization.[70] Many such licenses are "exclusive," meaning that the university is contractually prohibited from granting rights under the patent to any other entity, and even from exploiting the patent itself, at least in the licensed field of use.[71] The principal rationale for granting exclusive rights is to induce the licensee to expend significant sums on the development of a commercial product by guaranteeing it the sole ability to profit from the commercialized invention to the exclusion of competitors.[72] Once the patented discovery is licensed to the company, decisions regarding the pricing and distribution of the resulting product are generally left to the discretion of the company.[73]

Thus, when a Yale University patent on the compound d4T (staudivine) was licensed to Bristol-Myers Squibb (BMS) in 1988, the company received exclusive rights to control the sale and marketing of the resulting anti-retroviral drug known as Zerit.[74] Zerit, a nucleoside reverse transcriptase inhibitor similar to AZT, soon became a critical part of the standard AIDS treatment regimen and by 1998 was the most frequently prescribed anti-retroviral drug in the world.[75] BMS priced Zerit between $10,000 and $15,000 per year.[76] However, when the international humanitarian organization Médecins Sans Frontières (MSF) asked BMS to permit

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70. *See, e.g.*, JORGE L. CONTRERAS, INTELLECTUAL PROPERTY LICENSING AND TRANSACTIONS: THEORY AND PRACTICE 175–76 (2022) [hereinafter CONTRERAS, IP TRANSACTIONS] (describing licensing practices for new drugs).

71. *See id.* at 173.

72. *See id.* at 175–76.

73. From 1989 to 1995, the U.S. National Institutes of Health (NIH) imposed "reasonable pricing" constraints on drugs that were developed under cooperative R&D agreements (CRADAs) between federal agencies and private industry. *See* Jorge L. Contreras, *What Ever Happened to NIH's "Fair Pricing" Clause?*, HARV. L.: BILL HEALTH (Aug. 4, 2020), https://blog.petrieflom.law.harvard.edu/2020/08/04/nih-fair-pricing-drugs-covid19/ [https://perma.cc/YTC9-VGS8]. This requirement was discontinued by NIH in the face of significant industry opposition. *Id.*

74. Donald G. McNeil, Jr., *Yale Pressed to Help Cut Drug Costs in Africa*, N.Y. TIMES (Mar. 12, 2001), https://www.nytimes.com/2001/03/12/world/yale-pressed-to-help-cut-drug-costs-in-africa.html [https://perma.cc/HLL3-U2KP].

75. Ashley J. Stevens & April E. Effort, *Using Academic License Agreements to Promote Global Social Responsibility*, LES NOUVELLES, Jun. 2008, at 85, 87.

76. *After an Uproar, Price of AIDS Drug Falls in Africa*, 35 YALE MED., Spring 2001, at 4, 4. *See generally* Julian Borger & Sarah Boseley, *Campus Revolt Challenges Yale over $40m AIDS Drug*, GUARDIAN (Mar. 13, 2001, 12:59 AM), https://www.theguardian.com/world/2001/mar/13/education.highereducation [https://perma.cc/6CDV-CAW4].

the Indian firm Cipla to import a generic version of Zerit into South Africa at a price of $350 per year, BMS refused.[77] The refusal sparked protests by Yale students and faculty, who pointed out, among other things, that Yale was earning approximately $40 million per year from patent royalties on Zerit.[78] As a result of this pressure, BMS agreed in March 2001 to make Zerit available in South Africa for one dollar per day and to permit generic versions to be sold as well.[79]

Yale was again in the limelight when, in 2006, it licensed a related compound known as Ed4T to Japanese pharmaceutical manufacturer Oncolys.[80] According to the student-led organization Universities Allied for Essential Medicines (UAEM), which emerged from the Zerit protests, Yale was forgetting the lessons that it had learned in 2001.[81]

In November 2006, UAEM produced a manifesto known as the Philadelphia Consensus Statement,[82] which was signed by nearly four hundred students, scientists, lawyers, and activists.[83] It called on universities to "promote equal access to university research" by requiring that exclusive licensing agreements ensure low-cost access to health-related innovations in the developing world, to promote research and development of neglected tropical diseases, and to measure the success of research programs based on their impact on human welfare.[84]

### *4. Socially Responsible Licensing*

The growing controversy over access to medicines prompted some universities to reconsider their patent licensing policies with an eye toward improving access for disadvantaged populations. One of the most prominent of these was the University of California Berkeley. In 2003, Berkeley initiated a Socially Responsible Licensing Program (SRLP) with the goal of promoting the "affordability and accessibility of drugs, therapies, diagnostics, crops, and vaccines

77. *After an Uproar, Price of AIDS Drug Falls in Africa*, *supra* note 76.

78. *Id.*; Borger & Boseley, *supra* note 76.

79. *After an Uproar, Price of AIDS Drug Falls in Africa*, *supra* note 76; Stevens & Effort, *supra* note 75. The Zerit controversy also prompted more general proposals for increasing access to medicines around the world. *See* Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005) (describing open source-based approach for university licensing of biomedical innovations).

80. *See* Erika Check, *Universities Urged to Do More for Poor Nations*, 444 NATURE 412, 413 (2006).

81. *Id.*

82. UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES, PHILADELPHIA CONSENSUS STATEMENT ON UNIVERSITY POLICIES FOR HEALTH-RELATED INNOVATIONS (2006) [hereinafter PHILADELPHIA STATEMENT], http://www.columbia.edu/cu/amsa/uaem/PhiladelphiaConsensusStatement.pdf [https://perma.cc/5Z4N-46JY].

83. Check, *supra* note 80, at 412.

84. PHILADELPHIA STATEMENT, *supra* note 82.

to the developing world by stimulating investment where it has been traditionally lacking under profit-motivated business models."[85]

Berkeley's SRLP achieved some notable early successes. For example, in the first few years of the program, the university granted royalty-free licenses to produce the malaria drug artemisinin, a handheld immune-diagnostic assay, and disease-resistant crops, all in least-developed countries.[86] In another deal, Berkeley partnered with the government of Samoa to isolate the gene for the AIDS drug Prostratin from the bark of the native mamala tree and to share any royalties with the people of Samoa.[87] By the end of 2005, Berkeley had completed ten different agreements under its SRLP.[88] Although there were calls for broader adoption of the Berkeley SRLP model,[89] few other universities followed Berkeley's lead during the mid-2000s.[90]

### *5. Universities and Patent Enforcement*

While universities were not traditionally aggressive enforcers of their intellectual property rights, by the late 1990s, some universities had begun to assert patents against alleged infringers with vigor. For example, in 1994, Johns Hopkins University sued CellPro, a manufacturer of devices used to purify stem cells in connection with a leukemia therapy.[91] The dispute resulted in a highly-publicized "march in" petition under the Bayh-Dole Act requesting that NIH authorize CellPro to continue to operate under Hopkins's patents to address unmet public health needs.[92] Twelve U.S. senators and twenty-five representatives wrote letters

85. Carol Mimura, *Technology Licensing for the Benefit of the Developing World: UC Berkeley's Socially Responsible Licensing Program*, 18 J. ASS'N U. TECH. MANAGERS 15, 16 (2006).

86. *See* Mimura, *supra* note 85, at 19.

87. Robert Sanders, *Landmark Agreement Between Samoa and UC Berkeley Could Help Search for AIDS Cure*, BERKELEY NEWS (Sept. 29, 2004), https://www.berkeley.edu/news/media/releases/2004/09/29_samoa.shtml [https://perma.cc/QPT7-6YRV].

88. Barry Bergman, *Research Patently in the Public Interest*, BERKELEYAN (Dec. 2, 2005), https://newsarchive.berkeley.edu/news/berkeleyan/2005/12/02_licensing.shtml [https://perma.cc/MCC4-7QWR].

89. *See* Stevens & Effort, *supra* note 75, at 89 (recommending that all academic institutions "make Socially Responsible Licensing a formal, stated institutional policy").

90. Bergman, *supra* note 88 ("Berkeley's program remains the exception among university licensing offices, even within the UC system.").

91. Johns Hopkins Univ. v. CellPro, Inc., 931 F. Supp. 303, 309 (D. Del. 1996), *aff'd in part, vacated in part*, 152 F.3d 1342 (Fed. Cir. 1998).

92. HAROLD VARMUS, NATIONAL INSTITUTES OF HEALTH, DETERMINATION *IN THE CASE OF PETITION OF CELLPRO, INC.*, (1997) [hereinafter *CELLPRO* DETERMINATION]*; see also* Mikhail, *supra* note 5; Kevin W. McCabe, *Implications of the* CellPro *Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-In Right?*, 27 PUB. CONT. L.J. 645 (1998); Gretchen Dunbar, "*Real as Pro Wrestling":* Johns Hopkins University v. CellPro *and the Federal Court's Power of Review in Patent Infringement Actions*, 18 SANTA CLARA HIGH TECH. L.J. 275 (2002).

in support of CellPro's petition.[93] Nevertheless, the petition was denied,[94] and the Federal Circuit ruled in 1997 that CellPro had willfully infringed the patents.[95]

Then, in 2000, the University of Rochester sued Searle, Monsanto, Pfizer, and Pharmacia for infringing a university patent allegedly covering the blockbuster Cox-2 inhibitor marketed as Celebrex®.[96] According to the *New York Times*, university officials bragged when they brought the suit, predicting that the patent "might become the most lucrative ever held by a university."[97] Yet the anticipated returns never materialized, as the asserted patent was invalidated for lack of written description.[98] About the patent, the district judge wrote in 2003 that "the inventors could no more be said to have possessed the complete invention claimed by the . . . patent than the alchemists possessed a method of turning base metals into gold."[99] Rochester's humiliating defeat became well-known within the TTO community.

In addition, by the mid-2000s, there was a growing awareness in the United States of the activity of patent assertion entities (PAEs)—so-called "patent trolls"—which acquire and assert patents for the primary purpose of earning revenue.[100] In his concurring opinion in *eBay v. MercExchange*,[101] the landmark 2006 case that redefined the standard for obtaining injunctive relief in patent cases, Justice Anthony Kennedy cautioned that such entities could use the threat of injunctions "to charge exorbitant fees" for patent licenses.[102]

The fact that universities, which generally produce no products, were obtaining an increasing number of patents that they sought to license on a revenue-generating basis led prominent intellectual property scholar Mark Lemley

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93. *See* Eliot Marshall, *NIH Nixes Appeal to Bypass Patent Law*, 277 SCIENCE 759 (1997).

94. *CELLPRO* DETERMINATION, *supra* note 92, at 8 ("It would be inappropriate for the NIH, a public health agency, to exercise its authorities under the Bayh-Dole Act to procure for CellPro more favorable commercial terms than it can otherwise obtain from the Court or from the patent owners. CellPro's commercial viability is best left to CellPro's management and the marketplace.").

95. *Johns Hopkins Univ.*, 152 F.3d 1342.

96. *See* Andrew Pollack, *University's Drug Patent Is Invalidated by a Judge*, N.Y. TIMES (Mar. 6, 2003), https://www.nytimes.com/2003/03/06/business/university-s-drug-patent-is-invalidated-by-a-judge.html [https://perma.cc/L9QM-EZBZ] (noting that Celebrex earned more than $3 billion per year); Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp. 2d 216, 224 (W.D.N.Y. 2003), *aff'd*, 358 F.3d 916 (Fed. Cir. 2004).

97. Pollack, *supra* note 96.

98. *Univ. of Rochester*, 249 F. Supp. 2d at 224.

99. *Id.* at 230.

100. *See* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 38 (2003) ("NPEs [PAEs] obtain and enforce patents against other firms, but either have no product or do not create or sell a product that is vulnerable to infringement countersuit by the company against which the patent is being enforced.").

101. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

102. *Id.* at 396 (Kennedy, J., concurring).

to ask in a 2006 speech whether universities are actually "patent trolls."[103] In the speech, Lemley observed, "[t]ime and again, when I talk to people in a variety of industries, their view is that universities are the new patent trolls. One even referred publicly to universities as 'crack addicts' driven by 'small-minded tech transfer offices' addicted to patent royalties."[104] Though many university TTO officials likely disagreed with Lemley,[105] they were certainly aware of the negative public light being shed on their patenting and licensing practices.[106]

In addition to the possibility that universities themselves were acting like PAEs, concerns existed over universities' licensing of technology *to* PAEs. In 1997, for example, Columbia University licensed several of its patents covering the MPEG-2 digital video compression standard to a patent pool known as MPEG LA. As it announced in a July 1997 press release, "Columbia University, the only academic institution in the patent pool . . . expects to begin receiving license fees from the technology as early as this year."[107] The director of Columbia's TTO reiterated that "the patent pool approach offers Columbia an excellent opportunity to receive significant royalty payments over the next few years."[108] With this focus on royalty revenue earned through the MPEG-2 pool, some observers asked whether Columbia had become part of a PAE.[109]

### *6. National Security and University Research*

The export of sensitive military technologies from the United States has long been restricted under a variety of regulatory regimes. During the Cold War, fears arose that scientific research conducted at American universities could be utilized

103. Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008) (reproducing 2006 speech delivered to the Licensing Executives Society and AUTM).

104. *Id.* at 615 (quoting Chuck Fish, Comments at the Fordham Annual Conference on International Intellectual Property Law & Policy (Apr. 22, 2006)).

105. *Id.* at 611 n.* (noting that many in his audience disagreed with the implication of this question).

106. In the acknowledgements to his article, Lemley expressly thanks two TTO officials who attended the Stanford meeting that led to the NINE POINTS DOCUMENT, *supra* note 10. Lemley, *supra* note 103, at n.* ("[T]hanking Carl Gulbrandsen (WARF) and Kathy Ku (Stanford); Lemley also thanks Lita Nelsen, the head of MIT's TTO, though she did not attend the Stanford meeting herself.").

107. *Justice Department Approves Digital TV Patent Pool; Columbia, Only University in Group, To Receive Fees*, COLUM. U. NEWS (July 1, 1997), http://www.columbia.edu/cu/pr/96_99/19161.html [https://perma.cc/L34W-WKEV].

108. *Id.*

109. *See* Julie Hopkins, *When Pools Act Like Trolls*, AUSTIN AM. STATESMAN, (Sept. 26, 2018, 11:04 PM), https://www.statesman.com/story/news/2013/11/27/hopkins-when-pools-act-like-trolls/9867637007/ [https://perma.cc/4P77-ZMPY], ("Some view MPEG LA as more of an offensive acting patent troll than a patent pool.").

by enemy states, thus endangering U.S. national security.[110] The academic community responded with concern that fundamental scientific research could be hampered by excessive restrictions on international collaboration. In 1985, President Reagan issued National Security Decision Directive 189 (NSDD-189), which provides that basic and applied research in science and engineering, as distinguished from proprietary research and industrial development, design, production, and product utilization, should remain free from export restrictions, so long as the relevant information is not classified.[111]

Concerns over the leakage of sensitive information from academic research centers again emerged after the September 11, 2001, attacks. While various federal agencies reaffirmed the validity of NSDD-189,[112] high-level discussions of the appropriate scope of oversight and control over academic research continued. In early 2006, with the backing of the House Committee on Science and Technology and the White House Office of Science and Technology Policy (OSTP), the National Science Foundation and the National Institutes of Health requested that the National Research Council's Committee on Science, Technology, and Law form an *ad hoc* Committee on a New Government-University Partnership for Science and Security. This eleven-member committee was charged with analyzing these issues and making recommendations regarding any new measures that should be taken to address them. One of the members of the committee was Arthur Bienenstock of Stanford University, who had also been actively engaged in discussions of university intellectual property policy. As discussed in Section II.A, Bienenstock was one of the organizers of the Stanford meeting in 2006 that led to the creation of the *Nine Points* document.

## II. CREATION OF THE *NINE POINTS* DOCUMENT

### *A. The Stanford Summit*

By July 2006, the issues described in Section I.C above were becoming the subjects of increasing discussion among university administrators and technology managers. In response, Arthur Bienenstock, Vice Provost and Dean of Research and Graduate Policy at Stanford University, together with Kathy Ku, the head of Stanford's TTO, felt that leading academic institutions could develop a consensus around appropriate responses to many of these issues. Bienenstock, in particular,

110. *See* NAT'L RSCH. COUNCIL NAT'L ACADS., SCIENCE AND SECURITY IN A POST 9/11 WORLD: A REPORT BASED ON REGIONAL DISCUSSIONS BETWEEN THE SCIENCE AND SECURITY COMMUNITIES 28 (2007) [hereinafter N.R.C. SCI. & SEC.].

111. NAT'L SEC. DECISION DIRECTIVES, NATIONAL POLICY ON THE TRANSFER OF SCIENTIFIC, TECHNICAL AND ENGINEERING INFORMATION (1985), https://irp.fas.org/offdocs/nsdd/nsdd-189.htm [https://perma.cc/P6XF-5NVF].

112. N.R.C. SCI. & SEC., *supra* note 110, at 30.

wished to ensure that both senior university research administrators as well as TTO directors and managers were involved in such a conversation, so that both commercial and broader programmatic perspectives on university technology licensing would be considered.[113]

Bienenstock and Ku convened a meeting at Stanford to which they invited both TTO and research policy officials from Berkeley, CalTech, Columbia, Cornell, Harvard, MIT, University of Illinois (both Chicago and Urbana-Champaign), University of Washington, WARF and Yale. In addition to these universities, the Association of American Medical Colleges, a trade association then chaired by David Korn, the former dean of Stanford Medical School, also participated. According to attendees, it was the first such meeting ever to be convened.

The organizers asked each attendee to be prepared to discuss his or her top two or three issues relating to university technology transfer. Twenty-five to thirty individuals attended.[114] They sat around a large round conference table and each person was given the opportunity to express his or her views in turn, after which the group engaged in a discussion which, according to attendees, was intense but cordial.[115]

One of the principal purposes of the meeting was to address concerns surrounding WARF's hESC licensing program. During the meeting, WARF's Managing Director, Carl Gulbrandsen, explained the rationales for the licensing practices that had attracted the ire of some researchers, and also that WARF had already amended some of these practices to be less onerous. It soon became apparent that the participants wished to discuss a broad range of issues affecting university technology transfer and the relationship between universities and the private sector, well beyond WARF. Some coordination among universities on these issues was viewed as desirable, so as to present a more consistent front to private entities with which universities were negotiating.[116] Finally, Carol Mimura, the head of Berkeley's TTO, and John Soderstrom, who led the Yale TTO, were particularly interested in humanitarian licensing and access to medicines issues.[117]

The initial goal of the Stanford meeting had not been to produce a document, but as consensus began to develop around certain principles, participants suggested that these be recorded. Small drafting groups were formed and over the following months these were refined and combined. By March 2007, the resulting *Nine Points*

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113. Interview with Arthur Bienenstock, V. Provost and Dean of Rsch. & Graduate Pol'y, Stanford University (March 2020).

114. *Id.*

115. *Id.*

116. The degree to which universities could legally engage in such coordination was also discussed, and at least one participant expressed concern about potential antitrust liability associated with such concerted action. *Id.*

117. *Id.*

document had been created and approved by twelve of the thirteen participants at the Stanford meeting.[118]

### *B. The Nine Points—Point-by-Point*

The *Nine Points* document not only articulates general principles applicable to academic technology licensing, it also proposes specific contractual text intended to implement many of those principles (Recommended Clauses). There are thirty-one distinct Recommended Clauses (some duplicated in Points 2 and 5), which are summarized below.

**Point 1—Universities should reserve the right to practice licensed inventions and to allow other non-profit and governmental organizations to do so**

As noted in Section I.C.3, above, many university technology licenses are exclusive, meaning that the licensed rights cannot be utilized by anyone other than the licensee. Without an express reservation of rights, exclusivity prevents even the owner of the licensed rights (i.e., the university) from practicing those rights. Thus, if a university practices a right that it has exclusively licensed to another, it may be found to infringe its own intellectual property. These considerations gave rise to three distinct suggestions in Point 1 of the *Nine Points* Document.

(a) Education. Under the first clause recommended by Point 1, a university licensor would reserve the right to practice licensed technology internally for educational purposes, and/or to permit other non-profit and governmental organizations to do so. This right is of clear relevance to universities, as many, if not most, university inventions are created by academic faculty who have either direct or indirect teaching responsibilities. Education is also a primary function of universities, making it imperative that the right to conduct this important activity be carefully preserved, notwithstanding a university's exclusive licensing of technology to third parties.[119]

(b) Research. Because academic researchers often continue to conduct research on technologies that their universities have licensed to others, it is important for universities to retain sufficient rights to conduct this research. Such contractual reservations of rights became even more important after the Federal Circuit's 2002 decision in Madey v. Duke University, which established that there is no general 'experimental use defense' that immunizes university researchers from

118. Columbia University has not signed the NINE POINTS DOCUMENT, *supra* note 10.

119. *See* Kepner-Tregoe, Inc. v. Vroom, 186 F.3d 283 (2d Cir. 1999) (professor's reservation of educational rights in exclusive license agreement was insufficient to conduct certain executive education and consulting activities).

claims of patent infringement.[120] The drafters of the *Nine Points* document expressly sought to counteract the effects of Madey by proposing contractual reservations to the exclusivity granted under typical patent licensing agreements for internal research purposes (including research sponsored by commercial entities), and as an additional option to extend these research rights to other nonprofit and governmental entities.[121]

(c) Materials Transfer. The WARF controversy discussed in Section I.C.2, above, highlighted for many universities the need to reserve the right to transfer tangible research materials (e.g., biological samples and chemical compounds) as well as computer software, databases and know-how, to third parties, particularly non-profit and governmental entities for research purposes. Point 1 thus suggests contractual language that permits universities to make such transfers notwithstanding the grant of exclusive rights to third party licensees.

Three sample clauses implementing these reservations of rights are included in the appendix to the *Nine Points* document.

**Point 2—Exclusive licenses should be structured in a manner that encourages technology development and use**

**Point 5—Ensure broad access to research tools**

Points 2 and 5 respond to the concerns discussed in Section I.C.1, above, regarding the exclusive licensing of university technology, and research tools in particular. Point 2 cautions that

> A license grant that encompasses all fields of use for the life of the licensed patent(s) may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is particularly troublesome if the licensee is not able or willing to develop the technology in fields outside of its core business.[122]

In some cases, however, the *Nine Points* document recognizes that exclusive licenses may be justified, such as "[w]hen significant investment of time and resources in a technology are needed in order to achieve . . . broad implementation"

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120. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (holding that the experimental use defense is "very narrow and limited to actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'").

121. The reference to corporate sponsorship of university research was likely a direct response to WARF's prohibition on the use of its licensed hESC lines for sponsored research. *See supra* Section I.C.4. For a general discussion of university sponsored research, see CONTRERAS, IP TRANSACTIONS, *supra* note 70, at 448–50.

122. NINE POINTS DOCUMENT, *supra* note 10, at 2. This issue is discussed by Contreras and Sherkow in the context of the foundational patents covering the CRISPR gene editing technology. Contreras & Sherkow, *supra* note 22, at 700 ("[T]he exclusive licenses granted to the institutions' surrogates for human therapeutics limit access to CRISPR as a platform technology, potentially hindering competition and creating innovation bottlenecks.").

of an invention.[123] In such cases, Point 2 counsels that "it is important that licensees commit to diligently develop the technology to protect against a licensee that is unable or unwilling to move an innovation forward."[124] These provisions seek to prevent a technology from lying dormant in the hands of an unproductive licensee, which would deprive others of the benefits of the technology.[125]

Concerns regarding research tools are related. The discussion in Point 5 cites the NIH Guidelines on Research Tools,[126] noting that "universities are expected to make research tools as broadly available as possible."[127] To this end, Point 5 suggests that exclusive licenses of research tools should be limited, though not prohibited outright.

Points 2 and 5 offer a total of twelve different Recommended Clauses to address this set of related concerns. These Recommended Clauses are grouped into six sub-categories based on their overall goals and approach:

(1) Milestone Penalties. Point 2 contains three related Recommended Clauses regarding a university's ability to terminate or limit a licensee's exclusivity if the licensee fails to meet contractual commercialization and development milestones. Such clauses, which can result in termination of the entire agreement, a particular licensed field of use, or the licensee's exclusivity in a particular licensed field of use incentivize a licensee to work diligently toward the achievement of mutually agreed commercialization milestones and permits a university to offer the technology to others if the licensee underperforms.

(2) Public Health/Medical Use. Responding specifically to the access issues raised by the Zerit controversy and related debates, Point 2 includes five Recommended Clauses that would permit a university to authorize third parties to operate within an exclusive licensee's field when necessary to address unmet market or public health needs, to require the licensee to grant sublicenses to address such needs, and to permit healthcare providers, clinical researchers and public health authorities to operate within the exclusive field. Some of these issues are also addressed under Point 9.

(3) Limit Sale but not Use. Points 2 and 5 recommend that, in some cases, the scope of an exclusive license could be limited to encompass only the sale of licensed

123. NINE POINTS DOCUMENT, *supra* note 10, at 2.

124. *Id.* at 3.

125. The risk is aptly illustrated by the unfortunate case of the University of Utah's patent on a gene associated with a fatal cardiac irregularity known as Long QT syndrome. The university granted an exclusive license of the patent to a company that soon went bankrupt, suspending all activity relating to the gene for two years, during which no other lab could perform diagnostic tests on the gene and invariably leading to loss of life. *See* Misha Angrist, Subhashini Chandrasekharan, Christopher Heaney & Robert Cook-Deegan, *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, 12 GENETICS MED. S111 (2010).

126. NIH RESEARCH TOOL GUIDELINES, *supra* note 52.

127. NINE POINTS DOCUMENT, *supra* note 10, at 5.

products, but not their use.[128] For example, if a university patent claims a genomic analysis technique,[129] the exclusive licensee would have the exclusive right to sell testing apparatus embodying that technique, but could not prevent individual labs from employing the technique with equipment that they created themselves or obtained from a third party.[130] Thus, the exclusive licensee could seek to enforce the licensed patent against a competing manufacturer of testing equipment, but not against a laboratory or hospital using that equipment, even if that use might otherwise be infringing. In this way, Clause 2(3) could achieve an outcome similar to Clause 2(2), but without limiting the scope of permitted use to healthcare or any other particular field. It also creates a broad, contractual research exemption to fill the gap left by *Madey v. Duke*,[131] permitting researchers to use patented technologies so long as they do not eventually sell products embodying those technologies.

(4) Non-Exclusive Licensing of Research Tools. Consistent with the NIH Guidelines, Points 2(4) and 5 recommend that broadly applicable research tools be licensed only on a non-exclusive basis. Such non-exclusive licensing is intended to make such tools as widely available as possible, notwithstanding the revenue that might be available to a university granting an exclusive license with respect to these tools. While this recommendation is stated strongly, it is not accompanied by any specific Recommended Clauses, as the result in question would simply be achieved by granting a license that is non-exclusive rather than exclusive.

(5) Professional Education and Training. Point 2 recommends that the scope of exclusivity be limited to permit an exclusively licensed technology to be used freely by third parties for professional education and training purposes. This proposed exclusion goes beyond Clause 1.a, which permits the use of an exclusively licensed technology by the licensor and other non-profit and governmental organizations for educational purposes. Clause 2(5) would extend that educational right to for-profit education and training providers, as well.

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128. The basis for this distinction arises from the exclusive rights granted to a patent holder under 35 U.S.C. 271 to make, use, sell, offer for sale or import a patented article. The Recommended Clause is directed to patent claims covering equipment and apparatus, but not necessarily to patent claims covering methods or processes.

129. The concerns expressed in this section of Point 2 seem to arise from public concerns over the patenting of human genes and the exclusive licensing of those genes to companies like Myriad Genetics. Myriad Genetics exploited its position as the sole authorized provider of BRCA1/2 diagnostic testing in the United States to prevent both further research on the technique and the use of the technique in multi-gene analysis. *See* Jorge L. Contreras, Association for Molecular Pathology v. Myriad Genetics*: A Critical Reassessment*, 27 MICH. TECH. L. REV. 1, 47–48 (2020) (describing controversial role of University of Utah in exclusive licensing of *BRCA* gene patents).

130. The *Nine Points* document also mentions equipment obtained by the user from the exclusive licensee, NINE POINTS DOCUMENT, *supra* note 10, at 3, but in actuality the use of that equipment would generally require no license at all, as the relevant patents would, in most cases, be exhausted upon the licensee's sale to the user. *See* Impression Prod., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017).

131. *See supra* note 120 and accompanying text.

(6) Quality Control. The final clause recommended by Point 2 is an exclusion from exclusivity to permit third parties to operate under a licensed technology in order to perform quality verification and control. This issue received significant attention in the years preceding the *Nine Points* document, particularly in the area of genetic testing for variants in the BRCA1/2 genes, which had been patented by the University of Utah and licensed exclusively to Myriad Genetics. Myriad, which was the only lab in the United States authorized to perform BRCA diagnostic testing, refused to permit third parties to conduct tests to confirm its results. Critics claimed that "false positive" results from Myriad could thus lead patients to receive unnecessary prophylactic surgery.[132]

**Point 3—Strive to minimize the licensing of "future improvements"**

The authors of the *Nine Points* document were concerned by contractual provisions that required a university to grant its licensee rights to future improvements of a licensed technology, at least without additional payment. Such provisions, the authors note, "may effectively enslave a faculty member's research program" to the licensee.[133] The *Nine Points* document thus advises universities to avoid contractual provisions that grant licensees automatic rights to improvements or follow-on inventions made at the university or by inventors at other institutions. Three Recommended Clauses are included, each limiting a licensee's right with respect to improvements to the licensed technology made by the university or others.

**Point 4—Universities should anticipate and help to manage technology transfer related conflicts of interest**

Point 4 recommends that university TTOs be sensitive to conflicts of interest that may arise between investigators and institutions, on one hand, and corporate sponsors and licensees, on the other. The issue of financial conflicts in the academic setting has increased in prominence over the years, and many academic institutions have adopted formal conflicts of interest policies and internal review processes.[134] Point 4, however, contains no specific suggestions regarding language for licensing agreements.

**Point 5—Ensure broad access to research tools**

See Point 2(4), above.

**Point 6—Enforcement action should be carefully considered**

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132. *See* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 702 F. Supp. 2d 181, 207 (S.D.N.Y. 2010), *aff'd*, 569 U.S. 576 (2013) ("Plaintiffs contend that as a result of the patents-in-suit, *BRCA1/2* genetic testing is one of the very few tests performed as part of breast cancer care and prevention for which a doctor or patient cannot get a second confirmatory test done through another laboratory.").

133. NINE POINTS DOCUMENT, *supra* note 10, at 4.

134. *See* Jorge L. Contreras & Marc D. Rinehart, *Conflicts of Interest and Academic Research*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER, *supra* note 2.

Point 6 concerns the enforcement of university-owned intellectual property against third parties. The participants at the Stanford meeting were well-aware of increasing patent enforcement activity by universities, including the University of Rochester's humiliating defeat a few years earlier.[135] These incidents raised awareness among university officials of the pitfalls of patent enforcement, particularly the potential reputational damage to the universities involved and to the university system in general.[136]

Point 6 thus begins by discouraging universities from initiating litigation except as a last resort, urging them to "be mindful of their primary mission to use patents to promote technology development for the benefit of society."[137] It further notes that "[l]itigation is seldom the preferred option for resolving disputes."[138] If litigation is initiated, "it should be with a clear, mission-oriented rationale for doing so—one that can be clearly articulated both to its internal constituencies and to the public."[139] These recommendations are directed at university decisions and, as such, do not translate to specific Recommended Clauses in university licensing agreements.

However, the same concerns exist with respect to litigation brought by university licensees. Under the procedural rules of standing and joinder, a patent owner may be joined involuntarily in an enforcement action brought by its exclusive licensee.[140] Thus, a university could suffer similar reputational harm if its licensee brought an ill-advised patent enforcement suit. Accordingly, Point 6 recommends that university licensing agreements require exclusive licensees to consult with, or obtain the permission of, the university prior to initiating patent infringement litigation.[141]

**Point 7—Be mindful of export regulations**

As noted in Section I.C.6, above, the national security implications of university research were the subject of intense, high-level discussions during the

135. *See supra* notes 96–99 and accompanying text.

136. NINE POINTS DOCUMENT, *supra* note 10, at 6 ("Under all circumstances, it reflects poorly on universities to be involved in 'nuisance suits.'"); *see also* Walter D. Valdivia, *Patent Infringement Suits Have a Reputational Cost for Universities*, BROOKINGS: TECHTANK (Nov. 10, 2015), https://www.brookings.edu/blog/techtank/2015/11/10/patent-infringement-suits-have-a-reputational-cost-for-universities-2/ [https://perma.cc/84CL-ZT3Q]; N.R.C. UNIVERSITY IP, *supra* note 14, at 7 ("Enforcement of IP rights against suspected infringers should be approached carefully to protect the institution's resources and reputation.").

137. NINE POINTS DOCUMENT, *supra* note 10, at 6.

138. *Id.*

139. *Id.*

140. *See* FED. R. CIV. P. 19; FED. R. CIV. P. 20; Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459 (1926) (an exclusive licensee should be able to join the patent owner, involuntarily if need be, to maintain suit).

141. Such a clause is relevant only with respect to exclusive licenses, as non-exclusive licensees typically do not have the right to initiate litigation to enforce licensed rights. *See* Rite-Hite Corp. v. Kelly Co., 56 F.3d 1538 (Fed. Cir. 1995).

period that the Nine Points document was under development. And several individuals involved in the national security discussion, principally Arthur Bienenstock from Stanford, were also key players in the development of the *Nine Points* document.[142] It is thus not surprising that Point 7 refers explicitly to export regulations in the context of university technology transfer and urges university TTOs to be particularly sensitive to export laws and regulations. Yet, despite the extensive body of federal regulations relating to technology exports, Point 7 is remarkably short, consisting of a single paragraph that has only one suggestion for university licensing agreements: that they require the licensee to comply with applicable export laws and regulations, something already required by law.[143]

**Point 8—Be mindful of the implications of working with patent aggregators**

Point 8 addresses the issues raised by the licensing of university patents to PAEs.[144] The *Nine Points* document suggests a contractual clause requiring licensees to operate under a business model that encourages commercialization and does not rely primarily on threats of infringement litigation to generate revenue. Such a clause would, in effect, prevent a university from licensing a technology to a PAE.

**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**

Point 9 addresses the access to medicines issues raised by Zerit and similar incidents in the 1990s and early 2000s.[145] In doing so, it seeks to codify the public interest principles pioneered by the Berkeley SRLP,[146] asking universities to refocus on their public missions in addition to considerations of financial gain in technology licensing transactions. Point 9 specifically encourages universities to include in relevant licensing agreements provisions ensuring that underprivileged populations have low- or no-cost access to adequate quantities of licensed medical innovations.

As the above discussion indicates, the *Nine Points* document was not a wholesale attempt to re-align university patent licensing practices with the public interest, as its title might suggest. Rather, the *Nine Points* document embodies a range of compromises across different substantive domains (exclusivity, materials transfer, enforcement, national security, and access to medicines), reflecting the different priorities and experiences of the *Nine Points* drafters. As shown in the next Part, this diversity of approaches has resulted in widely varying levels of uptake of the different *Nine Points* recommendations.

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142. N.R.C. SCI. & SEC., *supra* note 110.

143. *See* CONTRERAS, IP TRANSACTIONS, *supra* note 70, at 408–09 (discussing contractual "compliance with law" clauses).

144. *See supra* Section I.C.5.

145. *See supra* Section I.C.3.

146. *See supra* Section I.C.4.

## III. MEASURING THE NINE POINTS

In order to assess the impact of the *Nine Points* document on university technology licensing practices, the researchers undertook the first empirical study of the implementation of the contractual provisions recommended by the *Nine Points* document both before and after its adoption. The findings of this study are presented below.

### *A. Methodology*

The AUTM website identifies each signatory to the *Nine Points* document (Signatories).[147] As noted above, there were 118 Signatories as of September 2021. Based on Internet searches and other public data, this study independently determined for each Signatory: the entity type (academic/medical institution, service provider (e.g., law firm, advertising firm), company, association, or governmental entity) and its geographic location (United States, Canada, Latin America, Europe, Africa, Australia/New Zealand or Asia Pacific). This study also determined for each Signatory the year in which it signed the *Nine Points* document based on successive searches of past versions of the AUTM website using the Internet Archive (Wayback Machine).[148]

We next collected patent licensing agreements entered into by academic/medical institutions (both Signatories and non-Signatories) before and after the creation of the *Nine Points* document. Because patent licensing agreements are typically confidential, most are unavailable for public review. However, it is a requirement of Regulation S-K promulgated under the Securities Act of 1933 and the Securities Exchange Act of 1934[149] that publicly traded companies in the United States (registrants) file with the SEC "[e]very contract not made in the ordinary course of business [that] is material to the registrant,"[150] specifically including contracts "upon which the registrant's business is substantially dependent, as in the case of . . . any franchise or license or other agreement to use a patent, formula, trade secret, process or trade name upon which registrant's business depends to a material extent."[151] Thus, to the extent that an academic institution enters into a patent license agreement with a publicly-traded company to which the agreement is material (or a private company that later becomes publicly-traded), the agreement must be filed with the SEC, even though the academic institution itself has no SEC filing obligations. Accordingly, our primary source of agreements for this study was

147. *See* NINE POINTS SIGNATORIES, *supra* note 12.
148. INTERNET ARCHIVE: WAYBACK MACHINE, http://web.archive.org (last visited Feb. 7, 2023).
149. 17 C.F.R. § 229.601 (2021).
150. 17 C.F.R. § 229.601(b)(10)(i) (2021).
151. 17 C.F.R. § 229.601(b)(10)(ii)(b) (2021).

the public Electronic Data Gathering, Analysis, and Retrieval (EDGAR) database operated by the U.S. Securities and Exchange Commission.[152]

During the summer of 2020, we conducted searches on EDGAR to identify agreements in which academic institutions licensed patents to other parties.[153] We obtained 136 agreements meeting this criteria. We obtained an additional sixty-eight agreements from KTMine, a private database vendor, which also sourced these agreements from EDGAR. Fourteen agreements were provided to us by Professor Colleen Chien, who obtained them via a series of Freedom of Information Act (FOIA) requests to the SEC in 2015. Six agreements were obtained by the author through independent federal and state FOIA requests. We thus reviewed a total of 220 unique patent license agreements (Reviewed Agreements) to which eighty-five different academic institutions were parties.[154] A list of all 220 Reviewed Agreements is contained in Appendix 1.

We manually reviewed each Reviewed Agreement to determine its parties, date, exclusivity or non-exclusivity, industry sector, and whether the academic party was a signatory to the *Nine Points* document. We then reviewed the text of each Reviewed Agreement for the presence or absence of each of the thirty-one Recommended Clauses that are included in the *Nine Points* document (see Section II.B, above) as well as two clauses not recommended by the *Nine Points* document but relating to the Recommended Clauses, for a total of thirty-three coded clauses per Reviewed Agreement. Finally, we identified the total 2019 research budget for each U.S. academic institution that was either a Signatory or a party to one of the Reviewed Agreements based on data reported by the National Science Foundation.[155]

In addition to the collection and analysis of empirical data described above, we interviewed four individuals who were involved in the original 2006 meeting that

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152. U.S. Securities and Exchange Commission, EDGAR, https://www.SEC.gov/EDGAR/searchedgar/companysearch.html [https://web.archive.org/web/20230114013726/https://www.sec.gov/edgar/searchedgar/companysearch] (last visited Jan. 14, 2023). In most cases, agreements that are available on EDGAR have been granted "confidential treatment" by the SEC with respect to specific words and phrases deemed to be of competitive significance. *Id.* These words and phrases are thus redacted in the publicly available documents. *Id.* However, given the nature of this inquiry, these redactions did not have a material impact on our review of the agreements.

153. To conduct this search, we utilized a variety of related Boolean queries containing the terms "licens*" and "university" or "institut*."

154. Based on data obtained from the AUTM STATT database, we estimated that U.S. universities entered into a total of approximately 20,000 exclusive licensing agreements between 1992 and 2018. Our sample thus represents approximately 1% of the total set of such agreements, with a 90% confidence level and margin of error of 6%. *STATT: Statistics Access for Technology Transfer Database*, AUTM, https://autm.net/surveys-and-tools/databases/statt [https://perma.cc/9PWM-BRAH] (last visited Feb. 7, 2023).

155. N.S.., HIGHER EDUCATION RESEARCH AND DEVELOPMENT: FISCAL YEAR 2019 at 15–36, tbl.5 (2021) [hereinafter N.S.F. 2019 R & D REPORT], https://ncses.nsf.gov/pubs/nsf21314/assets/nsf21314.pdf [https://perma.cc/BU9N-KMJ6].

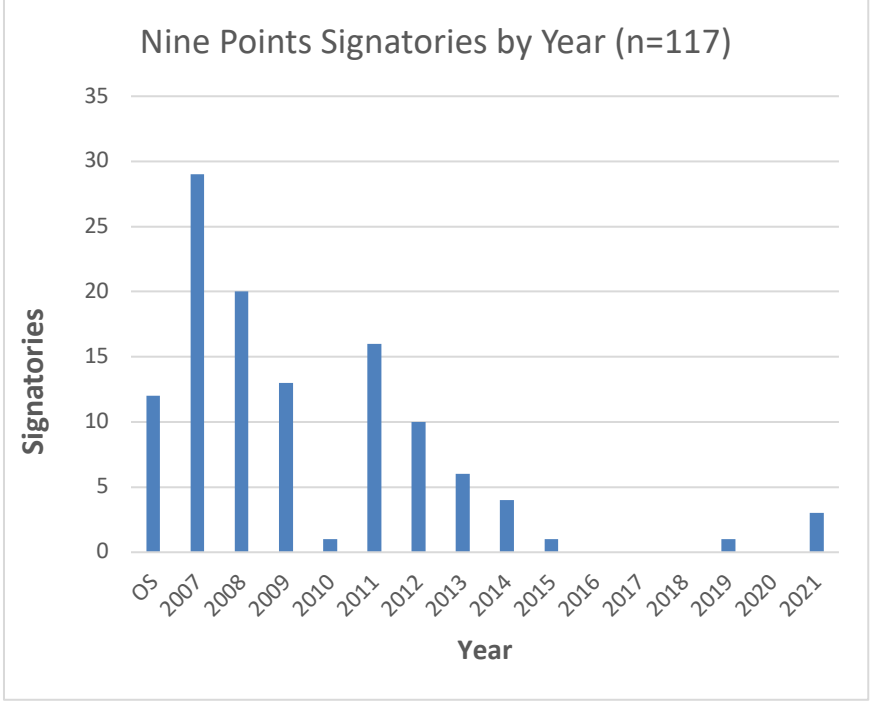
led to the adoption of the *Nine Points* document. These interviews were conducted via Zoom during the Spring of 2020 to collect background information on the meeting and its conduct that are not otherwise present in the written literature. The interviews were not intended to form the basis for generalizable hypotheses or conclusions.

### *B. Findings*

This Section III.B presents the findings of this study regarding the characteristics of the Signatories to the *Nine Points* document, the Reviewed Agreements, and the presence or absence of the Recommended Clauses in each of these agreements. An analysis of the implications of these findings follows in Part IV.

#### *1. Characteristics of the* Nine Points *Signatories*

As noted above, twelve entities—eleven U.S. universities and the AAMC—signed the *Nine Points* document in March 2007. Following its creation, 106 additional entities signed. *Figure 1* below illustrates the accession, by year, of additional entities to the *Nine Points* document (OS indicates the Original Signature date of March 6, 2007, and 2007 indicates signatures occurring between March 7 and December 31, 2007).



As shown in *Figure 1*, accession to the *Nine Points* document was highest in the years immediately following its creation (2007–2008), followed by a decline over the next few years (2009–2014), and a mere trickle thereafter. Institutions that adopted the *Nine Points* document in 2007 and 2008 were likely responding to the initial endorsement by the original twelve Signatories and subsequent encouragement by AUTM, which distributed the *Nine Points* document to its membership in 2007, urging "adoption and implementation by the wider community of universities."[156]

Some of the implications of the adoption rate of the *Nine Points* document are discussed in Section IV.A below.

The original Signatories to the *Nine Points* document were all major U.S. institutions. Though non-U.S. entities have subsequently signed the *Nine Points* document, the large majority of its Signatories (87, 74%) continue to be U.S.-based. Other geographies represented include Europe (12), Canada (5), Latin America (3),

156. Memorandum from Patrick L. Jones, AUTM Recommends Universities Review the 'Nine Points to Consider in Licensing University Technology' (2007). AUTM clearly viewed the NINE POINTS DOCUMENT, *supra* note 10, as a means for repairing damage to the public image of university technology transfer. *See* Memorandum from Patrick L. Jones, *supra.* As its President wrote in 2007, "[g]iven the current political environment that questions the motives and methods underlying our activities . . . it is important that the principles used to support our decision-making be recognized as serving the best interest of our nation—not just our individual institutions." *Id.*

China/Japan/Korea (3), India/Pakistan (2), and South Africa (2). Figure 2 below illustrates the geographic distribution of Signatories as of September 2021.

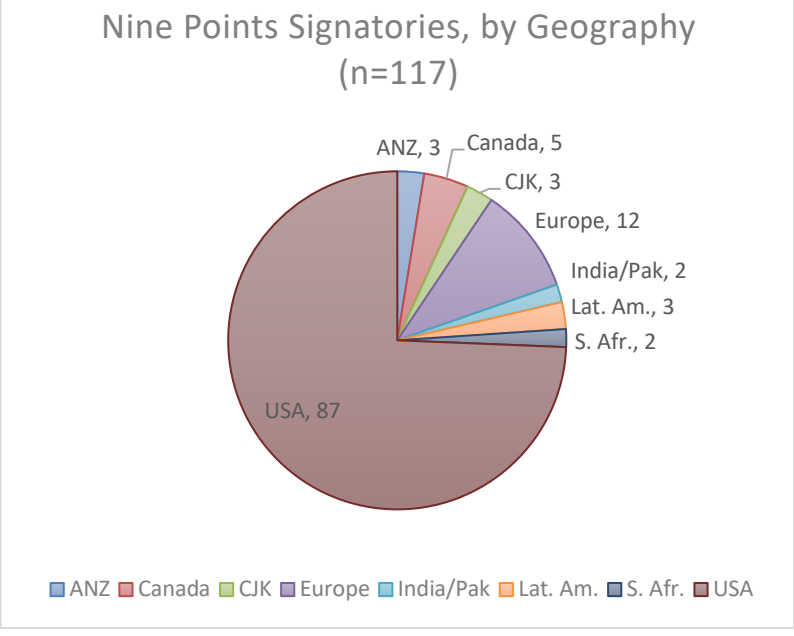



Figure 2

Given that the *Nine Points* document is directed specifically toward university licensing, the large majority of Signatories (96, 82%) are academic institutions, including universities and academic medical centers. Other Signatories include trade associations and organizations serving the academic community (8), service providers such as law firms and consultants (6), companies (4), government agencies (2), and a charitable foundation (1).[157] *Figure 3* below illustrates the breakdown of Signatories by entity type as of September 2021.

157. It is not clear what non-academic institutions signify by signing the NINE POINTS DOCUMENT, *supra* note 10. They may sign to show support for the principles espoused in the *Nine Points* document, to encourage universities to adopt the recommendations of the *Nine Points* document, or because they intend to modify their own patent licensing practices to conform to the recommendations of the *Nine Points* document.

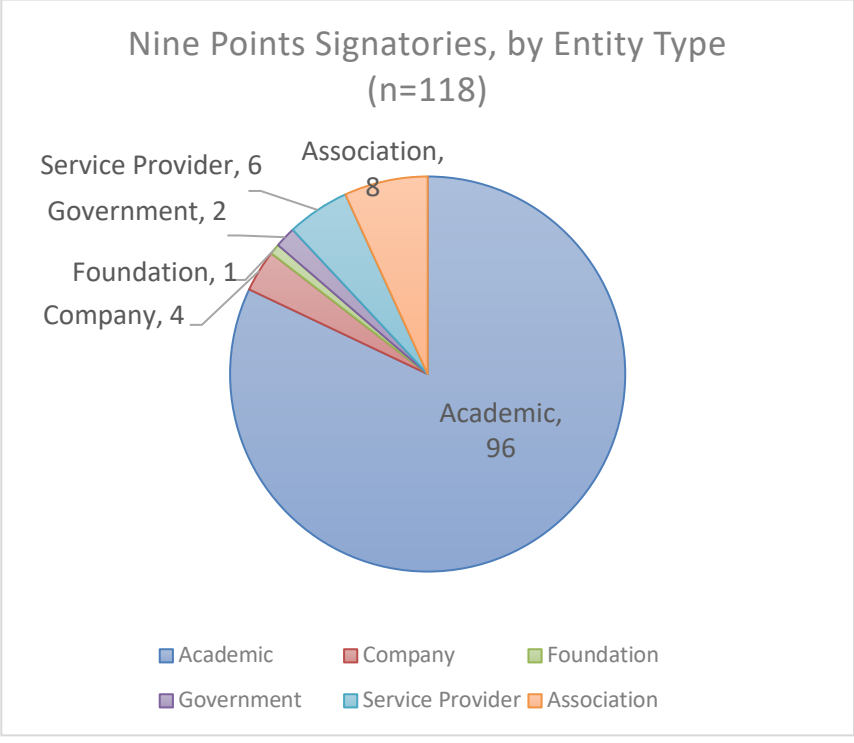



Figure 3

Combining geographical and sectoral data, the largest group of Signatories (75, 64%) consists of U.S.-based academic institutions, followed by non-U.S. academic institutions (21, 12%). One Korean and one European governmental agency are Signatories. Of the four for-profit companies that are Signatories, two are European, one is Chinese, and one is based in the United States. Service providers include four U.S. and two Canadian entities; and the eight trade associations include six U.S., one Canadian, and one Indian entity.

As described in Section III.A, we also identified the total 2019 research expenditures made by U.S.-based academic Signatories, which we use as a proxy for the general size of the institution's research enterprise. The original eleven academic Signatories were generally very large research institutions, with ten reporting annual research expenditures in excess of one billion dollars.[158] Over the years, however, a number of smaller research institutions signed the *Nine Points* document, so that by

158. For purposes of research expenditure reporting, University of Illinois Chicago and University of Illinois Urbana-Champlain report as a single entity, with combined expenditures of approximately $1.1 billion. *See* N.S.F. 2019 R & D REPORT, *supra* note 155.

2021, institutions with total research budgets of less than five million dollars had become Signatories.[159] At the same time, as discussed in Section IV.A, below, many of the largest research institutions in the United States have still not signed the *Nine Points* document.

### *2. License Agreement Characteristics*

As noted in Section III.A, we collected 220 unique Reviewed Agreements. The licensors in 140 Reviewed Agreements (63%) were academic institutions that have signed the *Nine Points* document (Signatories).[160] Academic institutions that have not signed the *Nine Points* document (non-Signatories) were licensors in the remaining eighty Reviewed Agreements (37%).

Reviewed Agreements had execution dates ranging from 1991 to 2018. A total of 118 of these Reviewed Agreements (54%) were executed prior to the creation of the *Nine Points* document in March 2007[161] and 102 (46%) were executed after that date. Of the 140 Reviewed Agreements to which Signatories were parties, 87 (63%) were executed prior to the licensor's signature of the *Nine Points* document and 53 (37%) were executed after to the licensor's signature of the *Nine Points* document. *Figure 4* illustrates the date range of the Reviewed Agreements by year.

159. See, for example, Worcester Polytechnic Institute and Boise State University. NINE POINTS SIGNATORIES, *supra* note 12; AUTM 2020 SURVEY, *supra* note 2.

160. Our focus is on university licensors only. While universities are sometimes licensees, these licensing agreements are seldom accessible to the public.

161. One agreement with a non-signatory having a stated execution date of March 15, 2007, was counted as being executed prior to the NINE POINTS DOCUMENT, *supra* note 10, given the likelihood that the agreement was drafted and negotiated prior to the formal March 6 date of the *Nine Points* document.

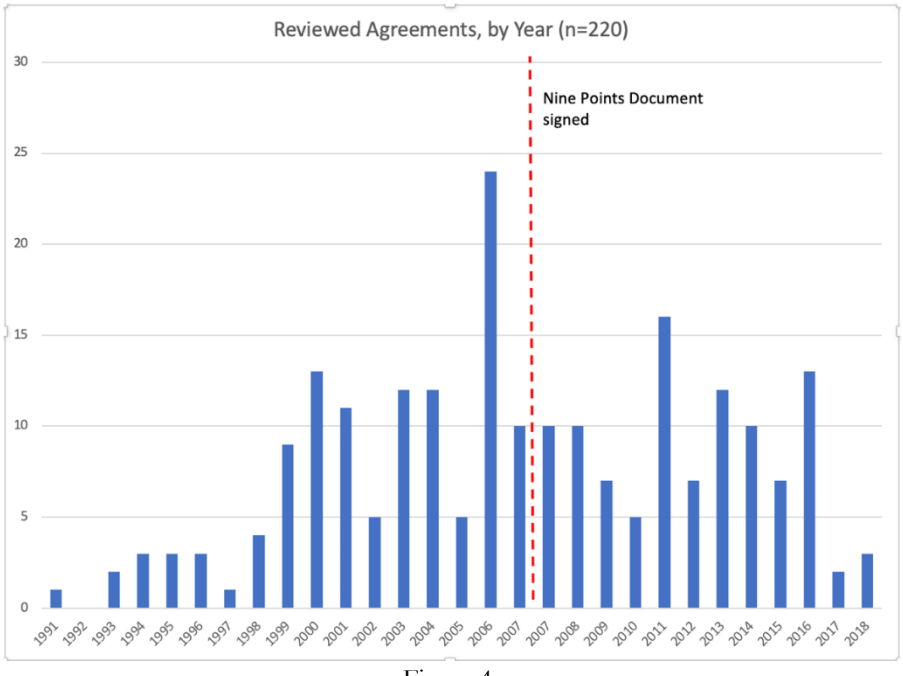



Figure 4

Eighty-five different academic institutions are licensors under the Reviewed Agreements. Of these, 36 (42%) are *Nine Points* document Signatories and 49 (58%) are non-Signatories. *Table 1* shows the sixteen academic institutions that are parties to five or more Reviewed Agreements, together with the year that such institutions became Signatories (if at all) and the number of Reviewed Agreements to which each such institution is a party.

Table 1
Top Institutional Parties to Reviewed Agreements

| Institution | Year Signed 9P* | No. of Reviewed Agreements | | |
|---|---|---|---|---|
| | | Pre-9P | Post-9P | Total |
| University of California (system) | OS | 10 | 5 | 15 |
| University of Texas (system) | 2007[162] | 2 | 8 | 10 |
| Johns Hopkins University | n/a | n/a | n/a | 7 |
| Stanford University | OS | 3 | 4 | 7 |
| University of Pennsylvania | 2009 | 6 | 0 | 6 |
| Wisconsin Alumni Research Fndn. | OS | 3 | 3 | 6 |
| California Inst. Technology | OS | 4 | 1 | 5 |
| Columbia University | n/a | n/a | n/a | 5 |
| Duke University | 2007 | 4 | 1 | 5 |
| Massachusetts Inst. Technology | OS | 4 | 1 | 5 |
| University of Colorado | 2007 | 2 | 3 | 5 |
| University of Florida | 2007 | 3 | 2 | 5 |
| University of Illinois | OS | 3 | 2 | 5 |
| University of Massachusetts | 2008[163] | 4 | 1 | 5 |
| University of Michigan | 2007 | 2 | 3 | 5 |
| University of Washington | OS | 3 | 3 | 5 |
| | | **50** | **37** | **102** |

* OS indicates an original signatory to the Nine Points document; "n/a" indicates an institution that has not signed the Nine Points document. Rows that are shaded indicate non-Signatories.

As shown in *Table 1*, two "top" academic licensors in our sample—Johns Hopkins and Columbia—are not Signatories. Of the remaining fourteen "top" licensors, only the University of Pennsylvania is a licensor on agreements all of which were signed prior to it becoming a Signatory to the *Nine Points* document. The remaining thirteen licensors were parties to Reviewed Agreements that were signed both before and after the licensor became a Signatory.

The vast majority of Reviewed Agreements (99%) involved the licensing of patents, often coupled with know-how or technical information. The large majority of Reviewed Agreements (211, 96%) included an exclusive license grant. The remainder were co-exclusive (2) or non-exclusive (7). The prevalence of exclusive licenses among Reviewed Agreements is not surprising. First, for a variety of commercial reasons, the large majority of university license agreements are

162. The University of Texas Health Science Center, San Antonio and University of Texas Medical Branch each signed the *Nine Points* document in 2007 (though not as original Signatories). University of Texas, Austin signed the *Nine Points* document in 2011.

163. The University of Massachusetts, Lowell signed the *Nine Points* document in 2008.

exclusive.[164] Second, our sample was derived largely from "material" agreements filed by licensees with the SEC, and an exclusive license is likely both to be more valuable to the licensee and to involve higher payments (thus more likely than a non-exclusive license to be material to the registrant).

We also manually coded the primary technical field to which each Reviewed Agreement relates. As shown in *Figure 5,* below, the large majority of Reviewed Agreements (182, 83%) relate to technologies in the biomedical/biopharma field, including genetics and genomics. Approximately 8% (16) of Reviewed Agreements concerned medical devices or medical techniques, while smaller numbers related to electrical and electronics (12), chemical and materials (7), and mechanical and manufacturing technologies (2).

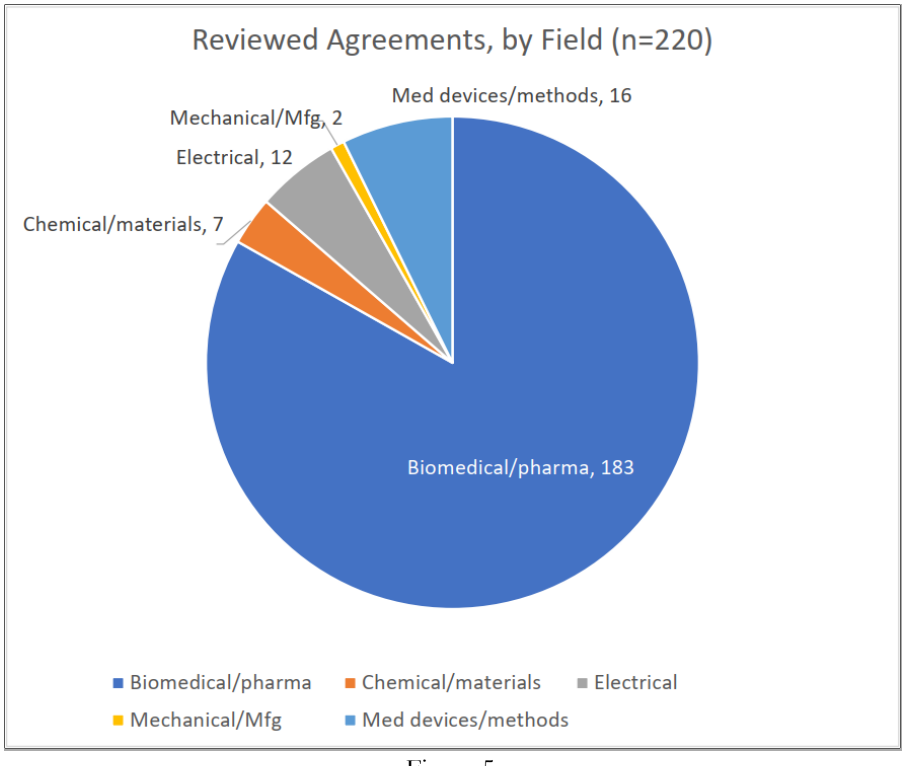



Figure 5

These figures are not entirely consistent with the overall distribution of technologies across university patents. For example, according to data compiled by the National Science Board, in 2016 issued university patents in the biomedical/pharma area represented approximately 41% of all patents issued, while

164. *See* Lemley, *supra* note 103, at 617 ("The overwhelming majority of university patent licenses are exclusive.").

medical technologies represented 10%, and other technologies represented the balance.[165] Thus, while biopharma inventions represent 41% of the patents obtained by universities, they represent more than 80% of all university commercial licenses, suggesting that inventions in this sector are perceived to have greater commercial potential than inventions in other technical areas.

### *3. Adoption of Recommended Clauses in University License Agreements*

As noted in Section III.A, we coded each Reviewed Agreement for occurrence or non-occurrence of each of the Recommended Clauses discussed in Section II.B.[166] We then compared the total occurrences of each such Recommended Clause across all Reviewed Agreements before and after March 16, 2007, the date on which the *Nine Points* document was released (*Nine Points* date). We further compared the occurrence of each Recommended Clause in Reviewed Agreements to which *Nine Points* document Signatories were parties, both before and after each such Signatory signed the *Nine Points* document, and to which non-Signatories were parties, both before and after the *Nine Points* date. Complete descriptive statistics reflecting these results are contained in the table in Appendix 2. Below is a summary of the frequencies at which each Recommended Clause occurred and how these frequencies varied based on *Nine Points* document signature status.

#### *a. Reserved Rights*

The Recommended Clauses under Point 1 relate to rights that a university licensor should reserve for education, research, and materials transfer when an exclusive license is granted. Universities could implement the first two of these clauses (education and research reservations) either reserving rights only for themselves (i.e., to use the licensed material internally for education and research purposes), or for all non-profit and governmental entities. The adoption of the *Nine Points* document appears to have had a significant effect on the utilization of these clauses.

Prior to the *Nine Points* document, 92 of 118 Reviewed Agreements (77%) included a reservation of rights for educational purposes, and 106 (89%) included a reservation of rights for research purposes. These rates increased after the *Nine Points* document to 90% and 96%, respectively, suggesting that the document impacted university practices positively.

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165. Nat'l. Sci. Bd., *Invention, Knowledge Transfer, and Innovation*, *in* SCIENCE & ENGINEERING INDICATORS 2018, at 19, tbl.8-1, https://www.nsf.gov/statistics/2018/nsb20181/report/sections/Invention-Knowledge-Transfer-and-Innovation/Invention-United-States-and-Comparative-Global-Trends#global-patent-trends-and-cross-national-comparison [https://perma.cc/W7JE-S3LN].

166. Recommended Clause 2(4) was not measurable (see below). Point 4 contains no Recommended Clauses. Point 5 is addressed together with Point 2.

Yet a more striking result emerges when comparing the reservation of rights as to the university licensor alone and as to all non-profit entities. Prior to the *Nine Points* document, 46% and 47% of Reviewed Agreements reserved educational and research rights, respectively, for the university licensor alone, while slightly fewer—32% and 43%, respectively—reserved rights for all non-profit entities. After the *Nine Points* document, however, the balance shifted notably toward reserving rights for all non-profit entities. Specifically, after the *Nine Points* document, 25% of Reviewed Agreements reserved educational and research rights for the university licensor alone, while 66% and 73%, respectively, reserved rights for all non-profit entities.

This shift is even more pronounced when the Reserved Agreements of Signatories are considered. Before the *Nine Points* document, 45% and 44% of Signatories' Reviewed Agreements reserved educational and research rights for the university licensor alone, while 37% and 48%, respectively, reserved rights for all non-profit entities. These rates are roughly comparable to those of all Reviewed Agreements. After the *Nine Points* document, however, the rate of Signatory Reviewed Agreements that reserved educational and research rights only for the university licensor dropped to 19%, while 72% and 79% of Reserved Agreements, respectively, reserved rights for all non-profit entities. These results with respect to Signatories are illustrated in Figure 6, below and indicate a clear shift post-*Nine Points* document toward reservations of rights intended to benefit all non-profit entities, as opposed to the licensor university alone.

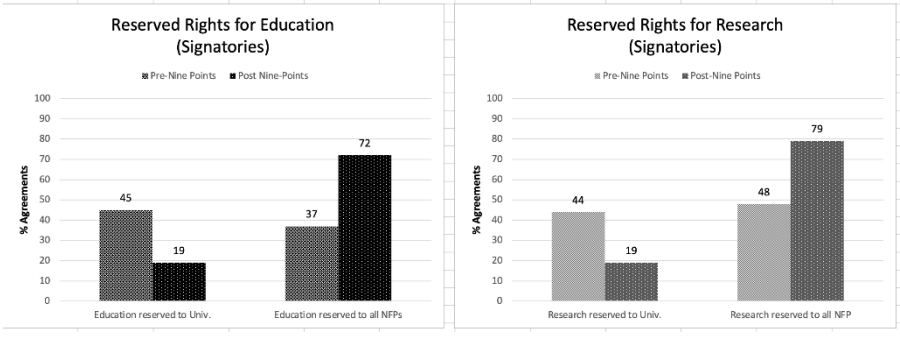


Figure 6

While the adoption of the *Nine Points* document appears to have triggered a significant shift among Signatories in the reservation of rights from the university licensor only to all non-profit entities, a similar, though smaller, shift was also observed among non-Signatories. Thus, for non-Signatories, rates of reservation for educational purposes to the university licensor decreased from 44% to 32% while rates of reservation to all non-profits increased from 30% to 59%, and rates for research purposes to the university licensor decreased from 47% to 32% while rates

of reservation to all non-profits increased from 40% to 65%. These effects suggest that the *Nine Points* document affected not only the behavior of Signatories, but also promoted industry-wide norms of academic technology transfer more broadly.

The rate of adoption of Recommended Clause 1.c (transfer of materials to academic/non-profit labs) was approximately half that of the other Recommended Clauses under Point 1, at 40% pre-*Nine Points* document and 44% post-*Nine Points* document. There was not a significant difference in the use of this Recommended Clause between Signatories and non-Signatories. It should be noted that materials transfer is relevant primarily to agreements in the biopharmaceutical sector, and less so in software, electronics, and other fields.[167]

*b. Limitations on Exclusivity*

As discussed in Section II.B, we classified the twelve different Recommended Clauses made under Points 2 and 5 into six categories. Each is reviewed below in view of its frequency of occurrence in the Reviewed Agreements.

(1) *Milestone Penalties*—The Recommended Clauses in category 2(1) impose various penalties on exclusive licensees that do not meet certain commercialization milestones. These penalties occurred in only 21% of all Reviewed Agreements at comparable rates pre- and post-*Nine Points* document and are generally associated with higher-value agreements in the biotechnology field. Overall occurrence rates for Signatories and non-Signatories were roughly identical (21%), suggesting little impact by the *Nine Points* document.

(2) *Public Health/Medical Use*—The Recommended Clauses in category 2(2) create exclusions from exclusivity for various public health and clinical uses. These clauses occurred in only 6% of Reviewed Agreements at rates between Signatories and non-Signatories that were not statistically significant.

(3) *Limit Sale, But Not Use*—Clause 2(3) grants the licensee exclusive rights to *sell* a licensed product, but this exclusivity does not extend to *use* of the licensed product (i.e., permitting research institutions to make use of patented methods, but prohibiting others from selling equipment or materials implementing those methods). Despite its creative approach to limiting licensee exclusivity, this clause did not appear in any of the Reviewed Agreements.

(4) *Research Tools*—Point 2(4) urges universities to grant non-exclusive licenses with respect to broadly applicable research tools. The contractual text associated with this recommendation is the license grant itself, which may be exclusive or non-exclusive. There were only seven non-exclusive licenses among the Reviewed Agreements. Because our textual coding methodology was not suited to determine whether the rights granted under any particular Reviewed Agreement

167. *See* CONTRERAS, IP TRANSACTIONS, *supra* note 70, at 451.

related to a broadly applicable research tool, it was not possible to determine how frequently research tools were licensed on an exclusive or non-exclusive basis.

(5) *Professional Education*—Recommended Clause 2(5) excludes from exclusive license grants the ability of for-profit third parties to practice the licensed rights for educational purposes (beyond the reservation for internal university educational purposes provided in Recommended Clause 1.a). This clause appeared in only 6% of Reviewed Agreements at comparable rates for Signatories and non-Signatories.

(6) *Quality Control*—Recommended Clause 2(6) excludes from exclusive license grants the ability of third parties to use the licensed rights for quality control and verification purposes. This clause occurred in no Reviewed Agreements.

*c. Improvements*

The Recommended Clauses under Point 3 are actually clauses that the *Nine Points* document recommends *avoiding* (i.e., clauses that would grant a licensee rights in technology improvements made by the university). Nearly all Reviewed Agreements (99%) omitted such clauses.

*d. Restraint in Patent Enforcement*

Recommended Clause 6 requires exclusive licensees to consult with or obtain the permission of the university prior to enforcing licensed rights against a third party. This clause appeared in only 3% of Reviewed Agreements. However, a similar clause (not recommended by the *Nine Points* document) that requires exclusive licensees only to *notify* the university prior to enforcing the licensed rights against a third party occurred in 97% of Reviewed Agreements at comparable rates pre- and post-*Nine Points* document and among Signatories and non-Signatories.

Recommended Clause 8 requires licensees to operate under a business model that encourages commercialization and does not rely primarily on threats of infringement litigation to generate revenue. This clause occurred in no Reviewed Agreements.

*e. Export Controls*

Recommended Clause 7 requires licensees to comply with applicable export laws and regulations. This clause appeared in only 4% of Reviewed Agreements.

*f. Access to Medicines*

Recommended Clause 9 seeks to ensure that underprivileged populations have low- or no-cost access to adequate quantities of licensed medical innovations. This clause occurred in no Reviewed Agreements.[168]

*Table 2* below summarizes the overall frequency with which the Recommended Clauses appeared in the Reviewed Agreements and the apparent impact of the *Nine Points* document on usage rates.

| Clause | Usage* | Impact of Nine Points |
|---|---|---|
| ***Reserved Rights*** | | |
| Education and research (1.a, 1.b) | High | Large shift by Signatories from reservation benefitting only university licensor to all non-profit and governmental entities |
| Materials transfer (1c) | Moderate | Low |
| ***Limits on Exclusivity*** | | |
| Milestone penalties (2(1)) | Moderate | Low |
| Public Health/Medical Use (2(2)) | Low | None |
| Limit Sale, But Not Use (2(3)) | None | None |
| Professional education 2(5)) | Low | None |
| Quality Control (2(6)) | None | None |
| ***Other*** | | |
| Improvements (3) | Very High | None |
| Restraints on Enforcement (6, 8) | Very Low | None |
| Export Controls (7) | Very Low | None |
| Access to Medicines | None | None |

Table 2

Effect of Nine Points Document on Recommended Clauses

* Very Low = less than 5%, Low = 5% to 14%, Moderate = 15% to 40%, High = 41% to 90%, Very High = greater than 90%

168. UCLA announced in 2020 that it would require all biomedical technology licensing agreements to include an "Affordable Access Plan" to "support[] affordable access to the UCLA patented drug in low- and middle-income countries." Memorandum from UCLA Off. of the President to Members of the Health Serv. Comm. at 1 (Dec. 2020) [hereinafter UCLA 2020 Xtandi Memorandum], https://Regents.UniversityofCalifornia.edu/regmeet/dec20/h12.pdf [https://perma.cc/6XP8-YWCL]. It is likely that any UCLA agreements containing this clause are too recent to have been included the Reviewed Agreements.

### *C. Subsequent University Licensing Trends*

The *Nine Points* document, which was widely discussed, focused attention on the public aspects of university licensing activities. As such, it both attracted endorsements by national groups and prompted further action by some universities. This Section III.C summarizes some of the major trends in university technology transfer following the release of the *Nine Points* document.

#### *1. External Endorsements of the* Nine Points *Document*

In 2011, a committee of the National Research Council undertook a formal study of "the organization, functioning, and effects of university technology transfer activities involving formal intellectual property rights."[169] The committee, which included at least two participants from the 2006 Stanford meeting,[170] made a number of findings and recommendations, among which was an endorsement of the *Nine Points* document and a set of nine recommendations that closely track the *Nine Points*.[171]

In 2014 and 2015, each of the Association of American Universities (AAU) and the Association of Public & Land-Grant Universities (APLU), respectively, formed a committee to examine issues surrounding the management of university technology in the public interest. In a three-page statement, the AAU's committee encouraged member institutions to "[r]eaffirm or affirm the university's commitment to adhering to technology transfer practices that best serve the public interest and which are guided by principles such as those outlined in the Nine Points document."[172] The APLU, in a seven-page statement, recommended that its members "review and support to the extent practical the [*Nine Points* document] and align IP management policies and practices with the Nine Points."[173]

#### *2. Socially Responsible Licensing Programs*

Following the release of the *Nine Points* document, several universities, encouraged by a range of constituents including the student-based group UAEM, continued to refine and expand their positions regarding the licensing of health-related technologies in the developing world.[174] This effort led to the release

169. NRC UNIVERSITY IP, *supra* note 14.

170. David Korn (Harvard) and Katherine Ku (Stanford). *See* NRC UNIVERSITY IP, *supra* note 14, at vi.

171. *See* NRC UNIVERSITY IP, *supra* note 14, at 6–7.

172. AAU STATEMENT, *supra* note 14, at 3.

173. APLU TASK FORCE ON MANAGING UNIV. INTELL. PROP., STATEMENT TO APLU MEMBERS OF RECOMMENDATIONS ON MANAGING UNIVERSITY INTELLECTUAL PROPERTY 2 (2015), https://www.aplu.org/wp-content/uploads/March2015TaskForceManagingUniversity IntellectualProperty.pdf [https://perma.cc/G3DZ-FS4L].

174. *Six Universities Adopt New Technology Transfer Principles Designed to Speed Access to Affordable Medicines in the Developing World*, YALENEWS (Nov. 9, 2009), https://news.yale.edu/2009/

in November 2009 of a new document titled *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies*, which was endorsed by two original *Nine Points* Signatories (Yale and Harvard), three later *Nine Points* document Signatories (Boston University, Oregon Health & Science University, and University of Pennsylvania), one non-Signatory (Brown University), and AUTM.[175] The goal of the 2009 Statement was to provide "a more concrete statement of goals as well as licensing practices [to] help to promote further progress in advancing health in developing countries."[176]

The 2009 Statement is four pages in length and articulates seven principles and strategies for the management and licensing of medical innovations so as to increase dissemination of these innovations to needy populations. These include both high-level aspirational goals, such as "appris[ing] potential commercial partners of our institutions' commitment to contribute to the health and well-being of populations throughout the developing world,"[177] as well as recommended contractual clauses, such as "[r]eserved or 'march-in' rights, mandatory sublicenses or non-assert provisions . . . [t]iered- or other appropriate pricing on a humanitarian basis (e.g., subsidized, at-cost or no-cost),"[178] some of which echo those of the *Nine Points* document, and others that go beyond it. Though this study did not focus on the particular contractual clauses recommended by the 2009 Statement, our coding of Reviewed Agreements for clauses responsive to Point 9 and other provisions of the *Nine Points* document would likely cover many of the recommendations of the 2009 Statement.

The 2009 Statement also included a number of ongoing evaluative, reporting, and evolutionary commitments. For example, the Statement provides that the signatories will "develop and apply meaningful metrics to evaluate the success of . . . efforts to facilitate global access," "cooperate in the creation of [a] compendium of best practices, tools and techniques; and [a] consistent means of reporting on our global access initiatives and activities" and "[r]evisit these principles on a biennial basis, to ensure that they reflect currently-understood best practices."[179] We are not aware of publicly available information indicating that these ongoing commitments have been followed in a systematic or collective

11/09/six-universities-adopt-new-technology-transfer-principles-designed-speed-access-affordabl [https://perma.cc/LW46-V4ZM].

175. STATEMENT OF PRINCIPLES AND STRATEGIES FOR THE EQUITABLE DISSEMINATION OF MEDICAL TECHNOLOGIES (2009) [hereinafter 2009 STATEMENT].

176. *Id.* at 1.

177. *Id.* at 2.

178. *Id.* at 3.

179. *Id.* at 4.

manner, though individual universities may have sought to address one or more of these commitments on their own.[180]

Interestingly, University of California Berkeley, which was an early leader in socially responsible licensing (see Section I.C.4), did not sign the 2009 Statement. It did, however, continue to pursue humanitarian licensing opportunities, particularly in the area of global health, through its own SRLP in the years following adoption of the *Nine Points* document.[181] Other universities also adopted socially responsible licensing programs following the adoption of the *Nine Points* document. One study conducted in 2015 reported the results of interviews with representatives of eleven Canadian, European, and U.S. universities, including several *Nine Points* document and 2009 Statement Signatories, each of which had a more or less formal socially responsible licensing policy.[182]

The development of the groundbreaking CRISPR-Cas9 gene editing technology by researchers at Berkeley and the Broad Institute of Harvard and MIT, among others, led to renewed interest in the humanitarian applications of university technology. As noted above, Berkeley and the Broad Institute were criticized for granting broad, exclusive licenses of their CRISPR technology to privately held "surrogate" companies unbounded by the public missions of the universities.[183] At the same time, the Broad Institute, at least, evidenced a desire to exclude the most controversial agricultural uses of its technology—the creation of sterile 'terminator' seeds, the development of species-destroying gene drives, and the commercialization of tobacco products—from the licenses that it granted.[184] This form of public-minded exclusion has been termed "ethical licensing."[185]

The COVID-19 pandemic also prompted some universities to liberalize their licensing programs with respect to COVID-related technologies. On April 7, 2020,

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180. *See, e.g.*, Tania M. Bubela & Timothy Caulfield, *Role and Reality: Technology Transfer at Canadian Universities*, 28 TRENDS BIOTECH. 447 (2010) (discussing non-financial metrics used to assess TTO at one Canadian university).

181. *See, e.g.*, Carol Mimura, Julie Cheng & Braden Penhoet, *Socially Responsible Licensing, Euclidean Innovation, and the Valley of Death*, 5 STAN. J.L. SCI. & POL'Y 1 (2011); Carol Mimura, *Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact*, *in* WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY 269 (Rochelle Dreyfuss, Harry First & Diane Zimmerman eds., 2010).

182. Nguyen, Shahzad & Veras *supra* note 25; *see also* UCLA 2020 Xtandi Memorandum, *supra* note 168 (describing UCLA Affordable Access Plan).

183. *See* Contreras & Sherkow, *supra* note 22.

184. *See* Christi J. Guerrini, Margaret A. Curnutte, Jacob S. Sherkow & Christopher T. Scott, *The Rise of the Ethical License*, 35 NATURE BIOTECH. 22 (2017); *see also* Aisling McMahon, *Biotechnology, Health and Patents as Private Governance Tools: The Good, the Bad and the Potential for Ugly?*, 3 INTEL. PROP. Q. 161 (2020) (describing Broad and other examples); Sapna Kumar & Ana Santos Rutschman, *Contractual Solutions to Overcome Drug Scarcity During Pandemics and Epidemics*, 40 NATURE BIOTECH. 301 (2022) (proposing a range of government-imposed contractual clauses that could be used to improve access and affordability of COVID-19 technologies).

185. Guerrini, Curnutte, Sherkow & Scott, *supra* note 184.

Harvard, MIT and Stanford announced a "COVID-19 Technology Access Framework" that reflects the sentiments of Point 9 of the Nine Points document.[186] As of October 2021, twenty additional U.S. research institutions and one non-U.S. university had also adopted this commitment.[187] The licenses to be granted under the Framework were to be both non-exclusive and royalty-free, designed to ensure broad access. It is unclear how many, and to whom, licenses have been granted under this framework, and with respect to what intellectual property.

Also in April 2020, AUTM released a set of COVID-19 Technology Licensing Guidelines that encourage intellectual property owners "to adopt a COVID-19 licensing strategy that facilitates rapid pandemic response by licensees and to make the execution of associated transactions a top priority."[188] The Guidelines then suggest that "where legally possible, this strategy is best accomplished by adopting time-limited, non-exclusive royalty-free licenses, in exchange for the licensees' commitment to rapidly make and broadly distribute products and services to prevent, diagnose, treat and contain COVID-19 and protect healthcare workers during the pandemic."[189] As of October 2021, nearly one hundred institutions had endorsed these Guidelines, though it is not clear from publicly-available information whether, and to what degree, such commitments led to any particular licensing agreements. This lack of transparency has led some commentators to question the degree to which universities take such altruistic sentiments seriously.[190]

### *3. Universities and Patent Assertion*

Points 6 and 8 of the Nine Points document urge universities to be cautious about engaging in patent enforcement litigation and licensing patents to third parties that are likely to focus on patent enforcement and litigation (i.e., PAEs). But, as

186. *COVID-19 Technology Access Framework*, STAN. OFF. TECH. LICENSING, https://otl.Stanford.edu/COVID-19-Technology-Access-Framework [https://perma.cc/32P6-MKJW] (visited Feb. 17, 2021) ("We are committed to implementing COVID-19 patenting and licensing strategies that are consistent with our goal of facilitating rapid global access. For most types of technologies, this includes the use of rapidly executable non-exclusive royalty-free licenses to intellectual property rights that we have the right to license, for the purpose of making and distributing products to prevent, diagnose and treat COVID-19 infection during the pandemic and for a short period thereafter.")

187. The same number of universities appeared in January 2021, suggesting that adoption of the Framework has more or less ceased.

188. *COVID-19 Licensing Guidelines*, AUTM, https://AUTM.net/about-tech-transfer/covid19/COVID-19-Licensing-Guidelines [https://perma.cc/J3ZG-2XGS] (last visited Feb. 7, 2023).

189. *Id.*

190. *See* Herder, Gold & Murthy, *supra* note 21, at 16 ("We show the divide between the university's stated principles to serve global health and technology transfer in practice."); Reshma Ramachandran, *Commentary: Fulfilling the Promise of Global Access Licensing Principles to Enable Equitable Access*, 17 HEALTHCARE POL'Y 37, 38 (2022) (highlighting the "pervasive failure of universities in implementing their public pledges to use licensing strategies that prioritize global access to technologies developed on their campuses").

noted in Section III.B.3, we observed no incorporation of these Recommended Clauses into university licensing agreements.

Notwithstanding the *Nine Points* document recommendations, the enforcement of patents by U.S. universities has continued to attract attention with high-profile lawsuits and enormous damages awards. In 2008, WARF began to assert one of its patents covering computer processors against chip manufacturers.[191] It achieved an early $110 million settlement with Intel, then an attention-grabbing damage award of $506 million against Apple.[192] The case prompted numerous outlets again to ask whether WARF is, indeed, a patent troll.[193] But WARF is not alone. In 2020, CalTech won a $1.1 billion award against Apple and Broadcom for Wi-Fi related patents,[194] and recently asserted the same patent against Samsung.[195]

Recent literature suggests that university-initiated patent litigation has increased since the adoption of the *Nine Points* document.[196] In a 2011 study, Professor Jacob Rooksby found that during 2009 and 2010 alone, thirty-three different universities had initiated patent infringement lawsuits.[197] In a 2020 study, Professors Teo Firpo and Michael Mireles found that, between 2000 and 2014,

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191. *See* Valdivia, *supra* note 136.

192. Wis. Alumni Rsch. Found. v. Apple Inc., No. l4-cv-062-wmc (W.D. Wis. July 25, 2017). This damages award was later reversed. *See* Blake Brittain, *Apple Defeats New Trial Bid After Overturning $506 Mln Patent Verdict*, REUTERS (May 11, 2022, 10:29 AM), https://www.reuters.com/legal/litigation/apple-defeats-new-trial-bid-after-overturning-506-mln-patent-verdict-2022-05-11/ [https://perma.cc/FHH4-ZMFZ].

193. *See, e.g.*, *Is WARF Trolling Apple?*, U.I.C. REV. INTELL. PROP. L. (Oct. 24, 2015), https://ripl.law.UIC.edu/news-stories/Is-WARF-trolling-Apple/ [https://perma.cc/LAF7-XBAF]; Laurel White, *'Is WARF a Patent Troll?' and Four Other Questions About the* Apple vs. WARF *Lawsuit, Answered*, CAP. TIMES (Oct. 15, 2015), https:madison.com/ct/news/local/writers/laurel-white/Is-WARF-a-patent-troll-and-four-other-questions-about-the-Apple-vs-WARF-lawsuit/article_4179a7c6-2c8f-55ed-ac13-6e8abe301519.html [https://perma.cc/E4MM-PBC4].

194. *See* Susan Decker, Ian Lopez & Matthew Bultman, *Caltech Wins a $1.1-Billion Patent Verdict Against Apple and Broadcom*, L.A. TIMES (Jan. 30, 2020, 1:59 PM), https://www.LATimes.com/business/story/2020-01-29/Caltech-Wins-a-1-1-Billion-Jury-Verdict-Against-Apple-and-Broadcom [https://perma.cc/P5-TH97].

195. *See* Andrew Karpan, *Caltech Sues Samsung After $1B Apple Patent Win*, LAW360 (Dec. 3, 2021, 10:20 PM), https://www.law360.com/articles/1445672/Caltech-Sues-Samsung-After-1B-Apple-Patent-Win [https://perma.cc/NXC8-YKWT].

196. *See, e.g.*, Teo Firpo & Michael S. Mireles, *Currents and Crosscurrents in Litigation of University and Nonprofit Related Patents: Is There a Coming Wave of Patent Litigation Involving Those Patents?*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER, *supra* note 2, at 309, 309 n.1 (collecting academic literature); Stan Gibson, *A Snapshot of University Patent Litigation*, PAT. LAW. BLOG (Dec. 11, 2015), https://patentlaw.jmbm.com/2015/12/A-Snapshot-of-University-Paten.html [https://perma.cc/ZM2J-AW9T]; Andrew Chung, *Schools that Sue: Why More Universities File Patent Lawsuits*, REUTERS (Sept. 15, 2015, 7:42 AM), https://www.Reuters.com/article/university-patents/Schools-that-Sue-Why-More-Universities-File-Patent-Lawsuits-idUSL1N11G2C820150915 [https://perma.cc/HFG4-2R97].

197. Jacob H. Rooksby, *University Initiation of Patent Infringement Litigation*, 10 J. MARSHALL REV. INTELL. PROP. L. 623, 660 (2011).

Boston University and CalTech, both *Nine Points* document Signatories, initiated around forty patent infringement suits each, and that, in general, such suits are on the rise.[198] Professors Firpo and Mireles suggest at least three different reasons that university-initiated patent litigation may further increase in the future: "[First,] some universities have begun to change their tenure policies to include consideration of commercialization activities performed by professors. Second, most TTOs have not been able to generate enough revenue to cover their own costs. Third, the federal government has been reducing funding for research."[199] Universities' assertion of patents does not end with third party infringers. In one recent study, Professor Brenda Simon has described the assertion of patents against university researchers after they moved to new institutions.[200]

With respect to the relationship between universities and PAEs, several post-*Nine Points* document studies have identified significant trafficking of patents between universities and PAEs. In 2012, Thomas Ewing and Professor Robin Feldman identified forty different universities (including six Signatories of the *Nine Points* document) that had licensed or transferred patents to Intellectual Ventures, a large PAE, or one of its holding companies.[201] Two more recent studies observe significant rates of patent sales by universities to PAEs.[202] This trend has caused AUTM to reconsider its position on universities transferring patents to PAEs notwithstanding the guidance contained in the *Nine Points* document.[203]

Most recently, in January 2021, the U.S. Department of Justice issued a favorable business review letter to a group of fifteen U.S. universities, including ten

198. Firpo & Mireles, *supra* note 196, at 316–17.

199. *Id.* at 318.

200. Brenda M. Simon, *Preserving the Fruits of Labor: Impediments to University Inventor Mobility*, 89 TENN. L. REV. 1 (2021); *see also* ORLY LOBEL, TALENT WANTS TO BE FREE: WHY WE SHOULD LEARN TO LOVE LEAKS, RAIDS, AND FREE RIDING 152–54 (2013) (describing litigation between universities and their research faculty).

201. Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1; *see also* Heidi Ledford, *Universities Struggle to Make Patents Pay*, 501 NATURE 471 (2013) (describing CalTech's exclusive license of fifty patents to Intellectual Ventures).

202. *See* Brian J. Love, Erik Oliver & Michael Costa, *U.S. Patent Sales by Universities and Research Institutions*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER, *supra* note 2, at 256, 266 ("[T]he vast majority of acquisitions [of patents from universities] appear to have been made with patent assertion in mind."); *see also* STEFANIA FUSCO, FRANCESCO LISSONI, CATALINA MARTINEZ & VALERIO STERZI, MONETIZATION STRATEGIES OF UNIVERSITY PATENTS THROUGH PAES: AN ANALYSIS OF US PATENT TRANSFERS (2019), https://dx.doi.org/10.2139/ssrn.3410086 [https://perma.cc/NGN5-HTV7] (identifying 326 patents transferred by universities to PAEs during preceding ten years).

203. *See* Paul Basken, *Under Financial Pressure, Universities Give Patent Buyers a Closer Look*, CHRON. HIGHER EDUC. (Oct. 25, 2013), https://www.chronicle.com/article/under-financial-pressure-universities-give-patent-buyers-a-closer-look/ [https://perma.cc/2NP5-ZJ6Z] (quoting AUTM's President).

Signatories of the *Nine Points* document, that proposed a new patent pool.[204] The pool, known as the University Technology Licensing Program (UTLP), would aggregate university-held patents covering physical science inventions, initially those relating to autonomous vehicles, the Internet of Things, and big data.[205] The UTLP has been criticized by observers, including the Electronic Frontier Foundation, which fears that the new pool will seek to license and assert patents of low quality in a manner that "sounds an awful lot like a patent troll."[206]

### *4. Export Controls*

Point 7 of the *Nine Points* document encourages universities to be vigilant about U.S. export control regulations. Issues relating to the export of technical and scientific know-how in violation of U.S. law have increased dramatically since the *Nine Points* document was created in 2007. Beginning in 2016, the U.S. government added numerous Chinese universities to its list of restricted entities to which sensitive information cannot be disclosed.[207] One recent survey of twenty-two U.S. colleges and universities found that 55% have withdrawn a scholarship or expelled a foreign student due to a failure to disclose a relationship with a foreign military, university, or government organization.[208] In addition, a number of high-profile incidents involving foreign technology disclosures have recently reinforced the importance of export control issues to university research.[209]

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204. *See* Letter from Michael F. Murray, Acting Principal Deputy Assistant Att'y Gen., U.S. Dep't of Just. Antitrust Div., to Garrard R. Beeney, Sullivan & Cromwell (Jan. 23, 2021) [hereinafter UTLP Review Letter] (universities include Brown; Caltech; Columbia; Cornell; Harvard, Northwestern; Princeton; State University of New York at Binghamton; University of California, Berkeley; University of California, Los Angeles; University of Illinois; University of Michigan; University of Pennsylvania; University of Southern California; and Yale).

205. *See* Letter from Garrard R. Beeney, Sullivan & Cromwell, to Makan Delrahim, Assistant Att'y Gen., U.S. Dep't of Just., Antitrust Div. 2 (Aug. 14, 2020) [hereinafter UTLP Request Letter].

206. Joe Mullin, *15 Universities Have Formed a Company That Looks a Lot like a Patent Troll*, ELEC. FRONTIER FOUND. (June 10, 2020), https://www.eff.org/deeplinks/2021/06/15-universities-have-formed-company-looks-lot-patent-troll [https://perma.cc/W8HW-CU74] ("Imagine this: a limited liability company (LLC) is formed, for the sole purpose of acquiring patents, including what are likely to be low-quality patents of suspect validity. Patents in hand, the LLC starts approaching high-tech companies and demanding licensing fees. If they don't get paid, the company will use contingency-fee lawyers and a litigation finance firm to make sure the licensing campaign doesn't have much in the way of up-front costs. This helps give them leverage to extract settlements from companies that don't want to pay to defend the matter in court, even if a court might ultimately invalidate the patent if it reached the issue. That sounds an awful lot like a patent troll. Unfortunately, this description also applies to a company that has just been formed by a consortium of 15 large research universities.").

207. *See* Yojana Sharma, *US Export Controls Raise Research Collaboration Concerns*, UNIV. WORLD NEWS (June 25, 2019), https://www.universityworldnews.com/post.php?story=20190625091615818 [https://perma.cc/DW63-MMHN].

208. *See, e.g.*, JAMES MOSES, EXPORT CONTROLS COMPLIANCE PRACTICES BENCHMARKS FOR HIGHER EDUCATION (2022 ed.).

209. In 2020, the chair of Harvard's chemistry department was charged with concealing the receipt of millions of dollars from the Chinese government and a Boston University researcher was

## IV. LICENSING IN THE SHADOW OF THE NINE POINTS

This Part IV addresses the implications of the findings presented in Section III.B, above, beginning with observations about the adoption of the *Nine Points* document itself and continuing with the use (or non-use) of particular Recommended Clauses in university licensing agreements.

### *A. Adoption and Non-Adoption of the* Nine Points *Document*

As discussed in Section III.B.1 above, the *Nine Points* document saw an initial period of high rates of adoption, followed by a steep decline. This pattern is not uncommon among public interest intellectual property projects.[210] The high levels of uptake during the initial period suggest an institutional desire to be part of a group that is attracting positive public reactions. By the same token, declining adoption after the initial surge suggests decreased promotion of the project by its creators, the emergence of more desirable, competing alternatives, and a recognition that declining to accede resulted in few negative consequences for holdouts.[211] One example of such a holdout is Columbia University, the only participant at the 2006 Stanford meeting that did not sign the *Nine Points* document. Columbia, with 2020 gross licensing income of nearly $45 million, and a total research budget of approximately one billion dollars, seems to have suffered little from its refusal to accede to the *Nine Points* document.

As shown in *Table 3*, other significant holdouts from the *Nine Points* document (shaded rows) include some of the largest universities and medical research centers in the United States.

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indicted for failing to disclose on a visa application that she was a lieutenant in the Chinese army. *See* Kate O'Keeffe & Aruna Viswanatha, *Chinese Military Turns to U.S. University to Conduct Covert Research*, WALL ST. J. (Feb. 23, 2020, 9:00 AM), https://www.wsj.com/articles/chinese-military-turns-to-u-s-university-to-conduct-covert-research-11582466400 [https://perma.cc/L232-FGHV]. In 2021, an Ohio State University professor was sentenced to 37 months in prison for making false statements to federal authorities about his research on behalf of the Chinese government. Press Release, U.S. Dep't of Justice, University Researcher Sentenced to Prison for Lying on Grant Applications to Develop Scientific Expertise for China (May 16, 2021), https://www.justice.gov/opa/pr/university-researcher-sentenced-prison-lying-grant-applications-develop-scientific-expertise [https://perma.cc/EY6X-RZGF].

210. *See, e.g.*, Contreras, *Open COVID*, *supra* note 21, at 896 (discussing Open COVID Pledge and the "initial burst of interest, followed by a steady decline in new pledge commitments"); *see also* Jorge L. Contreras, Bronwyn H. Hall & Christian Helmers, *Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons*, 57 HOUS. L. REV. 61, 73–76 (2019) [hereinafter Contreras, Hall & Helmers, *Eco-Patent*] (showing that the group formed in 2008 gained strong initial support with modest increases through 2011, after which no new members joined and was discontinued in 2016).

211. *See* Contreras, *Open COVID*, *supra* note 21, at 896 ("[E]ntities that adopted a 'wait and see' approach to the Pledge may have concluded, following its debut, that the benefits enjoyed by early adopters were not as significant as originally anticipated, and that negative effects from not joining did not materialize. As such, for these entities, the cost-benefit balance might continue to weigh in favor of not making the Pledge.").

Table 3

| **Institution** | **2020 Gross Licensing Income**[212] |
|---|---|
| University of Texas System | $362,712,828 |
| Memorial Sloan Kettering Cancer Ctr. | $265,284,478 |
| City of Hope Natl. Med. Ctr. | $165,523,000 |
| Massachusetts General Hospital | $142,906,417 |
| Princeton University | $134,338,003 |
| Mayo Foundation/Clinic | $117,885,888 |
| Stanford University | $114,022,678 |
| University of California System | $107,945,000 |
| Northwestern University | $105,321,475 |
| Massachusetts Inst. Tech. | $87,000,000 |
| Mount Sinai School of Medicine | $77,120,430 |
| Duke University | $65,267,643 |
| University of Houston | $59,116,380 |
| University of Florida | $58,695546 |
| Harvard University | $58,687,376 |
| Rockefeller University | $57,512,998 |
| University of Illinois Chicago/Urbana Champaign | $54,232,350 |
| Baylor College of Medicine | $53,123,532 |
| University of New Mexico | $52,341,706 |
| Columbia University | $43,517,319 |
| Brigham & Women's Hospital | $31,145,259 |
| University of Pennsylvania | $30,617,752 |
| Cedars-Sinai Medical Center | $30,200,000 |
| Johns Hopkins University | $27,395,520 |
| University of Washington | $27,364,553 |

Top 25 U.S. Academic Institutions by 2020 Gross Licensing Income and Signature Status

Yet even with the significant holdouts shown in *Table 3*, the adoption rate of the *Nine Points* document is impressive. AUTM reports technology transfer statistics for 183 U.S. academic institutions.[213] The seventy-five U.S. academic institutions that are *Nine Points* Signatories represent 41% of this total, a far greater portion than most other public interest patent-related projects. By way of comparison, the 2009 Statement on socially responsible licensing attracted twenty-one Signatories, the Eco-Patent Commons, a coalition of companies that committed not to assert patents against green/clean technologies, attracted only thirteen large industrial firms,[214] a tiny fraction of the total world industrial base,

212. Ass'n Univ. Tech. Managers, *supra* note 2.
213. *Id.*
214. *See* Contreras, Hall & Helmers, *Eco-Patent*, *supra* note 210, at 73–76.

and the Open COVID Pledge, a similar commitment with respect to technologies relevant to COVID-19, attracted thirty-two patent holders.[215] Even the Harvard-MIT-Stanford COVID-19 Technology Access Framework, aimed specifically at research universities, has attracted only twenty-four signatories from April 2020 to September 2021.[216]

It is possible, of course, that the adoption rate for the *Nine Points* document is higher than rates for these other programs because its requirements are more modest. The Eco-Patent Commons, Open COVID Pledge, and COVID-19 Technology Access Framework each require its participants to commit to making patents available for specified purposes at no charge. This goes far beyond the requirements of the *Nine Points* document, which merely suggests amendments to contractual language, most of which are beneficial to academic licensors.

### *B. The Question of Benefit*

When analyzing the *Nine Points* document, it is useful to recognize that the *Nine Points* document clauses are themselves heterogeneous. Though the *Nine Points* document is framed, at a high level, in terms of the "public interest," there is no clear indication which public interests are addressed. Thus, while some Recommended Clauses, such as those pertaining to public health, appear to be directed at broad public constituencies, others seem largely to benefit university licensors. For example, Point 3, which discourages universities from granting rights in university improvements to licensees, largely benefits the universities that incorporate such clauses in their agreements as it enables them to retain (and profit separately from) subsequently developed technology. Likewise, the clauses in category 2(1) give the university flexibility to replace or otherwise penalize an underperforming exclusive licensee, thereby enhancing the university's revenue and dissemination of the licensed technology. While the public might be an indirect beneficiary of the broader availability of a licensed technology, the university appears to be the primary beneficiary of such rights.

Point 5, on the other hand, encourages universities to refrain from granting exclusive rights with respect to broadly applicable research tools. Because exclusive licenses are generally more lucrative than non-exclusive licenses,[217] this recommendation could tend to reduce university revenue in favor of serving the public interest in the broad availability of research tools. Likewise, Point 9, relating to increasing the availability of health-related technologies for underserved

215. *See* Contreras, *Open COVID*, *supra* note 21, at 895.

216. *See COVID-19 Technology Access Framework*, *supra* note 186; *see also* Contreras, *Open COVID*, *supra* note 21, at 866 (discussing low uptake of Harvard-MIT-Stanford framework). Notably, Memorial Sloan Kettering Cancer Center, a major holdout from the *Nine Points* document, *see supra* tbl.1, has adopted the COVID-19 Technology Access Framework.

217. *See* CONTRERAS, IP TRANSACTIONS, *supra* note 70, at 176.

populations, has the public interest as its primary focus, with associated goodwill and reputational benefits to the university playing a secondary role.

*Table 4* offers an assessment of the primary beneficiary of each of the *Nine Points* Recommended Clauses.[218]

Table 4
Primary Beneficiaries of the *Nine Points* Recommended Clauses

| Point | Description | Primary beneficiary |
|---|---|---|
| 1.a.u | University reserved right for education | university |
| 1.a.n | All non-profit reserved right for education | public |
| 1.b | University reserved right for research | university |
| 1.b.n | All non-profit reserved right for research | public |
| 1.c | University right to transfer materials | university |
| 2(1) | Milestone penalties | university |
| 2(2) | Public health/medical use | public |
| 2(3) | Exclusive sale but not use | public |
| 2(4) | Research tool non-exclusivity | public |
| 2(5) | Third party education and training | university |
| 2(6) | Quality control | public |
| 3 | Licensing of future improvements | university |
| 4 | Conflicts of interest | university |
| 5 | Broad access to research tools | public |
| 6 | Consent to enforcement | public |
| 7 | Export regulations | University |
| 8 | Working with patent aggregators | Public |
| 9 | Availability of medical innovations | Public |

As shown in *Table 4*, clauses primarily benefitting universities and the public are split roughly evenly (8–10) in the *Nine Points* document. These "polarities" will be referenced in the discussion in Section III.C, below, regarding the occurrence rates of Recommended Clauses in university licensing agreements.

There are, of course, gray areas. For example, Point 4, which counsels universities to be vigilant as to conflicts of interest, benefits the university by helping it to steer clear of embarrassing or compromising conflict situations. By the same token, the public also stands to benefit from a reduction in conflicts of interest among university personnel and university licensees.

218. The foregoing analysis largely equates benefit with financial gain. Other constructions of benefit are, of course, possible. For example, Dr. Mimura explains that in Berkeley's SRLP, "social impact is valued as strongly as other outcomes such as licensing revenue." Mimura, *supra* note 85, at 17. Other university benefits such as reputation, student morale, alumni relations, government relations and donor development may also be balanced against direct financial gain from licensing agreements.

Finally, Clauses 1.a and 1.b present an interesting dichotomy. When these clauses reserve only the licensor university's right to conduct internal educational and research activities, the principal beneficiary is the university (as preserves for itself greater freedom to conduct its internal programs). While there may be a public benefit arising from allowing such educational and research activities to continue at the university (i.e., to the extent that the university is fulfilling a public mission of educating and conducting research beneficial to the public), the primary and most direct beneficiary of such clauses is the university itself. However, when these clauses reserve educational and research rights not only to the licensor university, but to all non-profit and governmental entities, then, assuming the university wishes to make these rights available, educational and non-commercial research may be conducted broadly under the licensed rights. As such, a clause that reserves rights for all non-profit and governmental entities to use the licensed rights serves a broader public interest than one that merely reserves rights to the licensor university.

Of course, the actual public benefit to be gained from the broad reservations of educational and research rights described in Clause 1 depends entirely on the willingness of the university licensor to grant sufficient rights to others, and the terms on which those rights are granted. That is, these clauses, which appear in licensing agreements between a university and an otherwise exclusive licensee, do not actually effectuate the rights reserved to third parties. To do so, the owner of the relevant rights (the university) must affirmatively grant such rights, either directly or through a public-facing license of some kind. Given the complexity of determining whether such rights have been granted, this study did not determine the extent to which universities actually granted such rights to others. Nevertheless, for the sake of analysis, these clauses are classified as benefitting the public interest on the assumption that a university including them in a negotiated licensing agreement would, on average, be willing to grant the relevant rights to the intended third parties or at least not to enforce its rights against them.

### *C. Occurrence of Recommended Clauses*

With the dichotomy between university-benefitting clauses and public-benefitting clauses in mind, it is possible to make some general observations about the occurrence of the Recommended Clauses in university licensing agreements.

#### *1. Reservations of Rights: A Shift Toward the Public Interest*

The most notable finding of this study is the strong effect that the *Nine Points* document appears to have had on university reservations of rights for education and research. While most Reviewed Agreements executed prior to the *Nine Points* document contained reservations of rights for education (78%) and research purposes (90%), the scope of that reservation changed dramatically after the *Nine*

*Points* document was signed. Whereas pre-*Nine Points* document agreements that included reservation clauses included roughly equivalent numbers of clauses that reserved education/research rights to only the licensor university versus all non-profit and governmental entities (46/47% versus 32/43%, respectively), Reviewed Agreements post-*Nine Points* document shifted significantly toward reservations for all non-profit and government entities (25/25% versus 66%/73%, respectively). The shift was even more pronounced for *Nine Points* document Signatories (19/19% versus 72/79% respectively).[219]

Given that a reservation for all non-profit/governmental entities is more directed toward the broader public interest than a reservation only for the university licensor, these findings show that the *Nine Points* document achieved a meaningful shift in university licensing practices toward the public interest in the areas of educational and research use even though, as noted in Section IV.B above, it is not clear how often those rights were affirmatively granted to other governmental and non-profit entities.

### *2. Public Health and Other Clauses-Correlation with University Benefit*

Except as discussed in Section IV.C.1 above with respect to Clauses 1.a and 1.b, the *Nine Points* document had few observable effects on university licensing practices. With respect to other Recommended Clauses, particularly those seeking to address public health issues (e.g., Clauses 2(2) and 9), and to limit their litigation of patents directly or through PAEs, university licenses generally followed the same patterns before and after the *Nine Points* document, both as to Signatories and non-Signatories. That is, except as noted above, Reviewed Agreements were most likely to include Recommended Clauses that benefit the university and were unlikely to include Recommended Clauses that benefit the public interest.[220]

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219. It is worth noting that Clause 2(5), which recommended a reservation of rights for educational purposes broadly, without limitation to non-profit and governmental entities, occurred very infrequently in the Reviewed Agreements. Clause 1.a, with the highest overall occurrence rate, permits a university to use an exclusively licensed technology for its own educational purposes, and often to authorize other non-profit entities to do so. But authorizing a for-profit third party to conduct educational activities may be more objectionable to potential licensees.

220. Two exceptions to this rule are Clause 2(5), a university-favorable clause that seldom appeared, *see supra* note 219, and Clause 7, relating to export controls, which may be viewed as legally superfluous. Clause 7 merely requires that a licensee comply with applicable export laws and regulations, a requirement that already exists by virtue of law whether or not required by agreement. Such "compliance with law" clauses are not uncommon in legal agreements, but their purpose is to create a breach of agreement if one party violates an applicable law, rather than to prescribe a party's conduct in any particular way. *See* CONTRERAS, IP TRANSACTIONS, *supra* note 70, at 408 ("While a contractual commitment . . . does not make compliance with applicable laws any more or less mandatory, it does establish that a party that fails to comply with applicable laws can be found to be in breach of contract, in addition to any liability that the non-complying party may have to regulatory or enforcement authorities.").

### *D. Discussion and Analysis*

The TTO officials that we interviewed for this Article believed that their university modified its licensing practices in response to the *Nine Points* document, usually to adopt a more public-spirited approach to technology transfer. Nguyen also report that TTO officials at several universities that claim to have socially responsible licensing programs report that contractual terms promoting the public interest are regularly incorporated into their licensing agreements.[221] If these statements are true, then why do we observe such a divergent pattern of adoption of Recommended Clauses from the *Nine Points* document? Given the prominence of the *Nine Points* document and its broad adoption by the academic community, this Section III.D considers why some Recommended Clauses were adopted broadly by the university licensing community and others were not.

#### *1. Which Public Interest? Education and Research versus Public Health*

As described above, the Recommended Clauses whose usage increased notably following the *Nine Points* document primarily seek to promote the public interests of education and research (Clauses 1.a, 1.b). Yet Recommended Clauses seeking to address issues of public health and access to medicines (Clauses 2(2) and 9), occurred rarely, if at all, both before and after the *Nine Points* document.

This divide between education, research, and public health suggests a difference in perspective regarding the nature of the "public interest" that universities sought to advance through the *Nine Points* document. The nature of the public interest can often be in the eye of the beholder.[222] Thus, universities may honestly believe that they are advancing the public interest by making their patented technology more available for educational and research purposes, while declining to adopt measures that would make those technologies more affordable or accessible to underserved populations. The diverse and somewhat incoherent nature of the *Nine Points* themselves—some promoting education and research, some promoting public health, some seeking to limit university litigation, and some promoting no more than prudent management practices—suggests that, even among the drafters of the *Nine Points* document, there was not clear agreement on the "public interest" that the document sought to advance.

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221. *See* Nguyen, Shahzad & Veras, *supra* note 25, at 193 tbl.2 (statements by Harvard and Yale representatives).

222. This point is illustrated by significant disagreement over the nature of the "public interest" in cases assessing the suitability of injunctive relief as a remedy in patent infringement cases. Under the standard established in *eBay v. MercExchange*, courts determining whether to issue an injunction must consider the effect of such an injunction on the public interest. In doing so, they have considered a range of interests including public health and safety, consumer welfare and choice, and the protection of property rights. *See* Jorge L. Contreras, *Injunctive Relief in U.S. Patent Cases*, *in* PATENT LAW INJUNCTIONS 1, 4 (Rafal Sikorski ed., 2018).

The COVID-19 pandemic has refocused public attention on issues of health equity and access. Many view these issues as the principal measures of public benefit that should be expected from technologies in the medical and biotechnology sectors, and consider universities as failing to serve the public interest unless they promote such access. As the President of UAEM recently wrote, "Universities have a moral and ethical responsibility to the public to openly share the intellectual property on the taxpayer-funded COVID-19 vaccines, therapeutics, and diagnostics we all paid to invent."[223] A recent commentary in the journal *Nature* amplifies these sentiments, declaring that scientific research in the "global public interest" should achieve the following goals:

- Prioritize public-health needs through structured, inclusive, transparent and informed processes
- Mandate, incentivize and facilitate rapid, open sharing of inputs, processes and outputs
- Provide timely access to health technologies that are safe, efficacious and offer therapeutic advances
- Ensure R&D meets the needs of subpopulations such as children, older people and those who might become pregnant
- Share all benefits equitably
- Build affordability, availability and suitability into the R&D process[224]

Statements like these reflect a view of the public interest that is embodied by access to and affordability of health-related technologies, and which largely discounts measures intended to increase educational and research uses of patented technologies.

### *2. Alternative Routes to Achieving Public Interest Goals*

The failure of universities to include public-health focused Recommended Clauses in their licensing agreements does not necessarily indicate a disregard for these issues. Rather, it is possible that universities have incorporated into their licensing agreements provisions directed toward the various issues raised by the *Nine Points* document, but which *differ* from the Recommended Clauses. That is, the Recommended Clauses are specific clauses that can accomplish particular goals

223. *UAEM 2020 U.S. University Report Card*, FREE THE VACCINE (Apr. 18, 2021), https://freethevaccine.org/2021/04/18/uaem-2020-u-s-university-report-card/ [https://perma.cc/96KT-7WJ9] (quoting Merith Basey).

224. Soumya Swaminathan, Bernard Pécoul, Hisham Abdullah, Christos Christou, Glenda Gray, Carel IJsselmuiden, Marie Paule Kieny, Mariana Mazzucato, Veronika von Messling, Bernhards Ogutu, John Reeder, John-Arne Røttingen, Renu Swarup, Marcel Tanner, Nísia Trindade Lima, Michelle Childs, Alex Harris, Els Torreele & Suerie Moon, *Reboot Biomedical R&D in the Global Public Interest*, 602 NATURE 207, 208 (Feb. 10, 2022).

within a licensing agreement, but those goals may also be accomplished by other means that are less amenable to standardization in a general document such as the *Nine Points* document. For example, in order to achieve the goals articulated in Point 9 relating to access to health-related technologies in the developing world, royalty rates may be structured to favor distribution of licensed products in low-income countries.[225] Milestone obligations may include regulatory approval for distribution of products in such countries or the actual distribution thereof. A licensee's territory may be limited to exclude low-income countries so that they may be supplied by an alternate vendor. We did not attempt to review the entirety of the Reviewed Agreements for all possible language addressing particular issues of concern to universities. Instead, we only determined whether the Reviewed Agreements incorporated the Recommended Clauses suggested by the *Nine Points* document. This study does not reflect these alternative approaches to achieving the goals of the *Nine Points* document.

Moreover, some public goals may be achieved through discretionary mechanisms that are not hard-wired into an agreement's text. For example, many university licensing agreements permit the licensor (i.e., the university) to select, in its sole discretion, the countries in which to seek patent protection for a particular technology. If it wishes to improve access to medical technologies in low-income countries, the university could simply elect not to seek protection in those countries, notwithstanding its licensee's wishes.[226]

Another non-textual mechanism available to university licensors is the selection of licensees at the outset. For example, a university could elect to grant a license to a manufacturer based in a developing country rather than an established global enterprise. Or, rather than including a prohibition on a licensee's pursuit of a patent monetization business model—the recommendation of Point 8—a university could choose (without memorializing that choice in writing) not to license its intellectual property to entities known to be PAEs.

Likewise, a university has the flexibility at the outset to decide whether it wishes to grant licenses on an exclusive or non-exclusive basis. The use of non-exclusive licensing for broadly applicable research tools is recommended both by the *Nine Points* document and NIH Guidelines, but, as discussed in Section III.B.3,

225. *See, e.g.*, Nguyen, Shahzad & Veras, *supra* note 25, at 194.

226. This approach was advocated by the 2009 Statement, *supra* note 174, at 2 ("Early publication and wide dissemination of results will be encouraged to reduce opportunities for interfering patents."), and some universities. *See* Nguyen, Shahzad & Veras, *supra* note 25, at 196 tbl.8 (statements by Harvard, Oxford, Yale). This being said, university decisions not to seek patent protection in certain countries would have only a limited impact on the patent coverage of most drugs, which are also covered by patents held by private firms. *See* Maya M. Durvasula, Lisa Larrimore Ouellette & Heidi L. Williams, *Private and Public Investments in Biomedical Research* 341, 344 n.12 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28349, 2021).

above, it is difficult to measure the degree to which this mechanism is used in practice.

Finally, even if a university wishes to incorporate a Recommended Clause in a licensing agreement, there is no assurance that the licensee will accept such a clause. While most university licensing agreements are initially drafted by university counsel, many are negotiated, some heavily. During negotiation, each party must assess and weigh the importance of each clause to which the other party objects and determine when to take a stand and when to concede. Though universities have some bargaining leverage in licensing negotiations, the large companies with which they negotiate often have the ability to fund university research programs for years to come. Universities must thus be sensitive to negotiating "too hard" and thus losing deals that might provide overall benefits for the institution.[227]

For all of these reasons, the presence or absence of particular Recommended Clauses may not tell the whole story with respect to the goals or practices of any particular university in any given situation. While one might interpret the findings presented above as suggesting that universities do not prioritize public health issues, this may not always be the case.

### *3. Commercialism and TTOs*

While university officials espouse the public interest missions of their institutions, TTO personnel may have a more directed focus on maximizing university licensing income. This focus is reinforced by the annual AUTM Licensing Activity Survey, which ranks TTOs on the basis of licensing income, startup formation, agreement completion, and other quantitative metrics.[228] Such rankings serve to highlight commercial TTO accomplishments to the exclusion of more public-oriented goals.

Moreover, a small but growing number of universities have implemented incentive compensation schemes to reward TTO personnel based on the achievement of metrics such as the number of license agreements completed, license income, and startup company formation.[229] To the extent that TTO personnel are personally remunerated for revenue-based achievements, then it is no surprise that revenue generation has become a primary goal of some TTOs.[230]

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227. *But see* UCLA 2020 Xtandi Memorandum, *supra* note 168, at 2 ("To date, UCLA . . . has been successful in incorporating [an Affordable Access Plan] provision in its biopharmaceutical license agreements and has received *minimal pushback* from its licensees." (emphasis added)).

228. *See* AUTM 2020 SURVEY, *supra* note 2.

229. *See* ASS'N UNIV. TECH. MANAGERS, 2017 AUTM SALARY SURVEY 85 (2018) (showing 39 of 172 responding institutions reported having an incentive compensation scheme, representing an increase of 33% over the prior biennial survey).

230. *See, e.g.*, E-mail from Tech Transfer Central to author (Nov. 9, 2021) (on file with author) ("[University] administrators are increasingly looking for a bottom-line return—courtesy of the TTO—to shore up lost research dollars and continue fueling the commercialization pipeline.").

Underscoring this point, a cursory review of recent training programs offered to university TTO personnel reveals an emphasis on sales and marketing skills. Below are a few illustrative examples of promotional materials targeted at TTO personnel, demonstrating this emphasis on commercial transactions and profit maximization:

> The knowledge you'll gain from this information-packed program will have a direct impact on your patent monetization strategies and decisions—and that can make a huge difference in the ultimate payout you receive.[231]

> By making a small investment in [marketing] skill sets your TTO will reap huge dividends in its ability to tell a compelling story about your innovations and attract the licensees, investors, entrepreneurs, and partners you need.[232]

> Learn powerful negotiating gambits such as Moonwalk, Circular Saw, Velvet Crowbar, Two-Step Dance, the Hindenburg, and many more.[233]

> [A] well-run royalty audit can potentially add hundreds of thousands of dollars in revenue to your bottom line.[234]

> Get the tools and guidance you need to successfully value, price, and negotiate technology licenses:
>
> - Get detailed explanations of royalty rate derivation models
> - Optimize the pricing of your IP
> - Negotiate lucrative licensing deals
> - Support infringement damages[235]

Interestingly, even the federal government appears to have embraced this commercial approach to technology licensing. One recent seminar for TTO personnel was titled "Marketing University Innovations: Strategies to Revitalize and

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231. E-mail from Tech Transfer Central to author (Apr. 18, 2022) (on file with author).

232. E-mail from Tech Transfer Central to author (Dec. 6, 2021) (on file with author).

233. E-mail from Tech Transfer Central to author (Dec. 23, 2021) (on file with author).

234. *Technology Transfer Tactics*, TECH TRANSFER CENTRAL (Jan. 13, 2023), https://techtransfercentral.com/category/technology-transfer-tactics/ [https://perma.cc/76F4-ZMQ8] (citing 15 TECHNOLOGY TRANSFER TACTICS, no. 15, Sept. 2021).

235. E-mail from Tech Transfer Central to author (Dec. 23, 2021) (on file with author).

Expand a High-Touch, Low-Tech Approach that Gets Results" and was led by a Senior Technology Transfer Manager from the National Cancer Institute.[236]

When the organizers convened the Stanford meeting in 2006, they insisted that it be attended by both TTO officials and university research administrators. This combination was important, because while TTOs may be motivated by the desire to enter into as many licensing agreements as possible, upper-level university administrators may have a broader view of the university's public mission. This combination of perspectives led to the *Nine Points* document. However, once the *Nine Points* document was signed, the day-to-day business of technology transfer returned to the TTOs, which exercise significant discretion in the implementation of university licensing arrangements. As such, a return to the public spirit of the *Nine Points* document may be needed to temper the commercial focus of many TTOs.

### *4. TTO Policy Advocacy and AUTM*

Beyond the negotiation of licensing agreements, TTOs have begun to exercise influence over broader university policy concerning technology transfer. Much of this influence comes through the efforts of AUTM, an industry trade association comprised largely of TTO personnel.[237] Though AUTM originally supported the *Nine Points* document,[238] that support has gradually waned and, by 2013, leadership of the organization was actively backpedaling on certain commitments made in the document.[239]

AUTM's advocacy efforts have increasingly sought to strengthen patent rights and erode mechanisms for granting broad access to patented inventions. In 2021 alone, AUTM issued formal statements (a) supporting regulations that would prevent the consideration of drug pricing as a ground for the exercise of march-in rights under the Bayh-Dole Act,[240] (b) opposing the World Trade Organization's proposed waiver of trade penalties against nations that issue compulsory licenses

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236. *See* Jesse Schwartz, *Marketing University Innovations: Strategies to Revitalize and Expand a High-Touch, Low-Tech Approach that Gets Results*, TECH TRANSFER ENEWS BLOG (Oct. 20, 2021), https://techtransfercentral.com/2021/10/20/marketing-university-innovations-strategies-to-revitalize-and-expand-a-high-touch-low-tech-approach-that-gets-results/ [https://perma.cc/8GM8-2S6M].

237. An excellent history of AUTM's advocacy role can be found in Christopher S. Hayter & Jacob H. Rooksby, *Policy Advocacy and Organizational Change at the Association of University Technology Managers (AUTM)*, *in* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER, *supra* note 2, at 131.

238. *See* Memorandum from Patrick L. Jones, *supra* note 156.

239. *See* Murray, *supra* note 204 (discussing reduction of AUTM's opposition to the transfer of patents to PAEs).

240. *See* Stephen J. Susalka, AUTM, Opinion Letter on AUTM's Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327) to National Institute of Standards and Technology (Mar. 28, 2021).

relating to COVID-19 vaccines,[241] and (c) advocating for the restoration of U.S. patent protection for products of nature, natural laws, and mental activities.[242]

AUTM has been joined in these advocacy efforts by other higher education associations,[243] as well as individual universities.[244] In 2021, AUTM, together with various trade associations and universities, formed an advocacy group called the Bayh-Dole Coalition, the mission of which is "protecting the Bayh-Dole Act and educating policymakers about the positive impacts of the law."[245] Whatever their technical merits, positions favoring stronger patent protection and decreased access to affordable drugs arguably run counter to at least the spirit, and in many cases the letter, of several points in the *Nine Points* document.

The most recent trends in AUTM's advocacy efforts may be explained by shifts in the organization's internal governance structure that began around 2014. As recounted by Professors Christopher Hayter and Jacob Rooksby, prior to 2014 AUTM's leadership was embodied by a board of directors and a rotating one-year presidency held by a member (a structure similar to that of many professional associations).[246] But in 2014 AUTM hired a full-time executive director (also answerable to the Board),[247] giving the organization a more consistent and coherent policy platform and the bandwidth to engage regularly in advocacy activities perceived to benefit its membership.[248]

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241. *See* Stephen J. Susalka, *Patent Waiver Strikes Damaging Blow to the Future of Innovation*, AUTM, https://autm.net/about-autm/media/press-releases/patent-waiver-strikes-damaging-blow-to-the-future [https://perma.cc/YL5S-H6AU] (May 6, 2021).

242. *See* Stephen J. Susalka, AUTM, Opinion Letter on AUTM's Comments on USPTO's Patent Eligibility Jurisprudence Study (Docket Number: PTO-P-2021-0032) to Andrew Hirshfeld, Commissioner for Patents (Oct. 14, 2021).

243. *See, e.g.*, Ass'n of Am. Univs., Ass'n of Pub. and Land-grant Univs., Council on Governmental Rels., Am. Council on Educ., Ass'n of Am. Med. Colls., Opinion Letter on Joint Association Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327) to Courtney Silverthorn, National Institute of Standards and Technology (Apr. 5, 2021) [hereinafter University Coalition Comments], https://www.cogr.edu/sites/default/files/JointAssocationComments_NIST%20NPRM.pdf [https://perma.cc/QY7R-X3HT] (supporting exclusion of pricing considerations from the exercise of march-in rights under the Bayh-Dole Act).

244. *See, e.g.*, comments filed by Yale, CalTech, University of California and WARF supporting the exclusion of pricing considerations from the exercise of march-in rights under the Bayh-Dole Act (collected by Knowledge Ecology International at https://www.keionline.org/35432 [https://perma.cc/DS8H-ECF5] ).

245. *About*, BAYH-DOLE COALITION, https://bayhdolecoalition.org/about/#members [https://perma.cc/7GLK-9Z8J] (visited Feb. 8, 2023); *see* Valdivia, *supra* note 34, at 4–5 ("The small coalition that designed and pushed for the Bayh-Dole reform has grown into a well-organized and powerful lobby that is a formidable defender of university patenting. Self-dubbed the Bayh-Dole Coalition, this group . . . skillfully connects its own interests to the public good by suggesting that patents are the nexus between universities and national innovation.").

246. *See* Hayter & Rooksby, *supra* note 237, at 140–41.

247. *Id.* at 140.

248. Based on data from the AUTM website, AUTM advocacy documents steadily increased from one or two per year from 2014 to 2016 to eleven by 2021. *Taking a Stand*, AUTM, https://

To a significant degree, the positions taken by AUTM in recent years have sought to strengthen patent protection and limit the broad availability of patented technologies. As such, AUTM's evolution into an influential lobbying and advocacy organization for university TTO interests has placed it at odds with the public-oriented sentiments expressed in the *Nine Points* document.

This being said, AUTM is, at its root, a membership organization, the role of which is to reflect the views and priorities of its members. And these members are, by and large, university TTO personnel. But do TTOs appropriately represent the interests of the broader academic community? In many areas—land use, curricular priorities, equity, diversity and inclusion, campus security, investment divestiture, and the like—university governance involves a broad range of stakeholders from faculty and students to alumni and local communities. Why, then, is university policy surrounding intellectual property and technology transfer set largely by small groups of non-academic business professionals who are often motivated by financial incentives?

The engagement of broader university constituencies in the formation of technology transfer policy could help to shift those policies back toward the public interest goals espoused by the *Nine Points* document. As demonstrated by the Zerit controversy[249] and the continuing efforts of UAEM to nudge universities toward greater public accountability,[250] many students care deeply about their universities' policies concerning technology transfer and intellectual property, particularly as they impact global health. Likewise, faculty members who are not directly involved in technology transfer activities often have strong views regarding university policy in this regard. Finally, as intuited by Arthur Bienenstock when planning the 2006 Stanford meeting,[251] senior academic and research leadership can view intellectual property policy within the broader context of universities' public missions and should thus have a greater voice in policy determinations.

Such multilateral policy advisory committees are not unknown to university governance. Today, many universities have investment advisory committees that help to guide institutional decisions regarding the divestiture of endowment funds linked to objectionable investments in fossil fuels, conflict minerals, firearms,

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autm.net/about-tech-transfer/advocacy/autm-speaks-out/ [https://perma.cc/7BSC-XXCL] (last visited Feb. 8, 2023).

249. *See* discussion *supra* Section I.C.3.

250. *See supra* notes 81–84 and accompanying text; *see also* Ramachandran, *supra* note 190, at 38–40 (reviewing UAEM campaigns).

251. *See* N.R.C. SCI. & SEC., *supra* note 110 and accompanying text.

tobacco, and oppressive regimes.[252] Some of these committees can include input from students, faculty, and alumni as interested stakeholders.[253]

Yet the author is not aware of any universities that have implemented permanent institutional mechanisms for fashioning technology transfer policy in a multilateral manner or that regularly seek input from interested stakeholder groups beyond the TTO. To date, this input has typically arisen in the midst of crisis situations, such as student protests over Yale's licenses for Zerit[254] and UCLA's licenses for the Pfizer drug Xerit.[255] Constituting permanent, multilateral decision-making bodies that are empowered to guide university policy concerning technology transfer could help to avoid such controversies by redirecting those policies away from purely commercial considerations and more toward the public interest goals espoused by the *Nine Points* document and broader university mission statements.

Moreover, if universities expressed dissatisfaction with the policy positions taken by AUTM, then those positions could be redirected toward a more public orientation. In the alternative, given that AUTM is, technically, a trade association for university "technology managers" (i.e., TTO personnel), then more generally focused university associations such as the Association of American Universities (AAU), the Association of Public and Land Grant Universities and the Association of American Medical Colleges (AAMC), one of the original *Nine Points* Signatories, could take a more active role in public policy debates over these issues, rather than simply following the lead of AUTM.[256]

### *5. Why Did They Sign?*

If universities have to a degree failed to adopt the recommendations of the *Nine Points* document, then why did so many universities sign it? Is it merely window dressing and reputation burnishing—a high-minded set of principles that adorns institutional websites without much cost or inconvenience?

Professor Winickoff offers a more cynical option, writing that "[i]f signatories to the document intended to enlighten their peers, they also intended to make

252. *See* George O. Aragon, Yuxiang Jiang, Juha Joenväärä & Cristian Ioan Tiu, Responsible Investing: Costs and Benefits for University Endowment Funds (Mar. 23, 2022) (unpublished working paper), https://papers.ssrn.com/sol3/Papers.cfm?abstract_id=3446252 [https://perma.cc/25UL-EBCL].

253. *Id.* at 8.

254. *See* discussion *supra* Section I.C.3.

255. *See* Memorandum from Univ. of Cal. L.A. Off. of the President to Members of the Health Servs. Comm. of the Univ. of Cal. Sys. 2–3, (Aug. 14, 2018), https://regents.universityofcalifornia.edu/regmeet/aug18/h4.pdf [https://perma.cc/VZD8-2KF4] (describing UCLA's formation of a Principles for Patenting and Licensing Intellectual Property in Medicine Task Force (of unspecified composition) to respond to advocacy efforts regarding Xtandi licensing).

256. *See, e.g.*, University Coalition Comments, *supra* note 243.

themselves more accountable to their publics, perhaps before those very publics (whether students, industry, local businesses, or the global sick) demanded stronger forms of control."[257] This statement suggests that universities, smarting from increasing public criticism, may have sought to appease critics by signing a document that paid lip service to public-minded ideals, but that in reality was intended to obviate calls for greater oversight of, or stricter control over, university activities. This tactic is not without precedent, and there is a long history of organizations voluntarily committing intellectual property to the public good in order to avoid public scorn, governmental regulation or adverse judicial action.[258]

Yet the participants in the 2006 Stanford meeting that led to the creation of the *Nine Points* document seem genuinely to have sought to improve at least some aspects of university technology licensing. This goal may have been achieved, at least in part, by the increased usage of clauses reserving non-profit rights for education and research.

But if the *Nine Points* document is less than perfect, and if it has failed to live up to its full promise, then that may be more a result of the manner in which it was conceived. Unlike more focused policy statements such as the 2009 Statement on humanitarian licensing, the organizers of the 2006 Stanford meeting did not convene in order to develop a consensus position on a single issue of pressing concern. Rather, as discussed in Section II.A, above, the direct impetus for the Stanford meeting was consternation over WARF's hESC licensing program. But the attendees at Stanford were each asked to bring their top two or three issues to the meeting, and these reflected a broad range of practical and policy concerns that had little relation to one another. The resulting document covered a smorgasbord of topics ranging from retained rights and limitations on exclusivity to conflicts of interest and export controls to global health and access to medicines. At some point, a title for the document was formulated, and it sought to unify these disparate elements under the banner of the "public interest." Yet that labeling exercise, while successful in terms of public messaging, did not accurately reflect what was really a grab bag of principles and contractual terms with little practical coherence.

Today, perhaps due to the explicit invocation of the public interest in its title, most references to the *Nine Points* document are directed to Point 9, concerning equitable access to medicines—a point that was never fully embraced by its Signatories. The document's more technical provisions pertaining to exclusivity, retained rights, future inventions, export controls, and conflicts of interest have largely been absorbed into internal TTO practice and seldom appear in the public

257. Winickoff, *supra* note 13, at 30.

258. *See, e.g.*, Contreras, *supra* note 21, at 864, 869–70 (discussing potentially self-interested patent pledges by Fortress and Moderna); Jorge L. Contreras, *Patent Pledges*, 47 ARIZ. ST. L.J. 543, 588–90 (2015) (discussing voluntary commitments made to refrain from asserting patents in order to avert governmental action).

discourse. Likewise, discussions of university patent enforcement and transactions with PAEs have largely evaporated as it has become increasingly clear that universities can earn windfalls by enforcing patents in litigation without significant public backlash.[259]

Given its origin and structure, it is not surprising that TTO officials did not substantially revise their contractual templates after their universities signed the *Nine Points* document. Today, the document is perceived to represent more a general spirit of public-minded stewardship over university technology than a pragmatic library of contractual clauses. And, as such, it may still have value. With respect to the public-interest oriented reservations of rights contained in Point 1, *Nine Points* document Signatories markedly altered their technology licensing practices toward a more public-benefit stance, and also appeared to influence non-Signatory universities to move in this direction.[260]

With respect to public health issues, Point 9 of the *Nine Points* document has served as a springboard for more focused and directly actionable initiatives such as the 2009 Statement and the COVID-19 Licensing Framework. And even if its title is not representative of the majority of its content, the *Nine Points* document, for the first time, announced to the world that leading universities considered their role to be one of public stewardship—a role that they have imperfectly fulfilled, but one to which they can, and should, continue to aspire.

### *E. Limitations and Future Directions for Study*

The study described in this Article is necessarily subject to a number of limitations. First, our sample of 220 university licensing agreements is slightly greater than one percent of the total estimated 20,000 university licensing and option agreements that have been signed during the period studied, resulting in an estimated margin of error of six percent.[261] A larger sample might produce more robust results.

More importantly, as described in Section II.A, the large majority of Reviewed Agreements were obtained from the SEC EDGAR database. University licensing agreements filed with the SEC have two significant constraints: the licensee must be a publicly traded company in the United States (or a company applying to have its stock listed on a U.S. stock exchange), and the agreement must be material to the company's business.[262] As a result, such agreements necessarily exclude licenses granted to non-U.S. entities, non-profit organizations, public companies for which the agreement is not material (e.g., large pharmaceutical firms), small companies that never went public (i.e., many university spinouts), and entities that seek to

259. *See* discussion *supra* Section III.C.3.
260. *See* discussion *supra* Section III.B.3.a.
261. *See* Contreras & Rinehart, *supra* note 134.
262. *See supra* notes 149–151 and accompanying discussion.

remain privately held (e.g., some PAEs). The exclusion of agreements with licensees in these categories could bias our results in various ways. For example, licenses to nonprofit organizations may have been more likely to include the Recommended Clauses of Point 9, and the exclusion of licenses to PAEs could skew results relating to Point 8. Moreover, the fact that our sample includes only "material" agreements may skew our results more heavily toward agreements that are the most heavily negotiated by licensees, resulting in terms that are more favorable to the licensees and less favorable to the university licensors. Future studies may benefit from the review of non-public agreements, to the extent that such agreements can be obtained from universities or their licensees.

The large majority of licensing agreements that we reviewed contained exclusive licenses. This is not surprising, as exclusive licenses are generally higher-value and more significant to licensees. Yet our results tell us little about non-exclusive licensing by universities. There are likely large categories of non-exclusive licenses in areas such as computer software and mobile apps that are not included in our sample. It is possible that the *Nine Points* clauses, or the principles set out in the *Nine Points* document, are reflected to a greater degree in non-exclusive licenses.

Additionally, like most studies of contractual terms, this study was limited to the review of executed agreements. We did not have access to initial or interim drafts of agreements or their negotiating history. Thus, our results do not account for contractual terms that might have been proposed by a university, but which were rejected by the licensee and thus omitted from the final agreement, or agreements that were negotiated but never executed. Further investigation of the negotiation history of university patent licensing agreements could offer additional insights into the practices and goals of universities in this area.

The scope of this study was limited to the measurable effect of the *Nine Points* document on the text of university licensing agreements. There are several other measures of university licensing that can be assessed, including the degree of dissemination of university technology in the field, the creation of products based on university technology, the returns earned by universities from their licensing activities, and the amount and type of intellectual property litigation in which universities engage. In addition, useful information could be gained from an investigation of the effects of university licensing programs that emerged after the *Nine Points* document, including the COVID-19 Technology Access Framework, the AUTM COVID-19 Licensing Guidelines, and the recently announced University Technology Licensing Program (UTLP).

## CONCLUSIONS

The *Nine Points* document was announced in 2007 with much fanfare. It attracted more than a hundred university Signatories in the United States and abroad

and, as such, has been among the most influential and highly cited documents in the field of academic technology transfer. Yet this study reveals that the impact of the *Nine Points* document has been limited. While Signatories and other university licensors adopted contractual provisions promoting educational and non-commercial research, they largely omitted terms seeking to promote public health and access to medicines or to constrain their own behavior, whether in terms of patent enforcement, interaction with PAEs, or attention to export regulations. In fact, in the years following the release of the *Nine Points* document, universities, led by the trade association AUTM, have increasingly advocated for broader patent protection and limitations on the government's ability to require low-cost access to medical technologies. This trend appears to run counter to the spirit of the *Nine Points* document.

While various extra-contractual mechanisms, ranging from the selection of licensees to decisions regarding where to seek patent protection, may enable universities to shape their technology licensing practices, these actions are difficult to assess empirically. Thus, unless they are visibly promoted by universities, such efforts may go unnoticed in the broader community.

The *Nine Points* document announced to the world that research universities collectively considered their role to be one of stewardship of publicly funded technology. While the promotion of educational and research goals may, indeed, serve the public interest, the COVID-19 pandemic has refocused public attention on issues of health equity and access. As a result, a reorientation of university technology transfer policy may be in order—a shift that may be facilitated through greater engagement of academic faculty, senior administrators, students, alumni, and other institutional stakeholders in setting policy for university technology transfer.

APPENDIX 1

Reviewed Agreements

| **Licensor** | **Licensee** | **Date** |
|---|---|---|
| University of Utah | Helix Technologies Incorporated | 8-Oct-91 |
| Massachusetts Institute of Technology | Metabolix, Inc. | 15-Jul-93 |
| University of Florida | Targeted Genetics Corporation | 25-Dec-93 |
| Medical College of Ohio | Targeted Genetics Corporation | 14-Mar-94 |
| University of Texas | Intron Therapeutics, Inc. | 20-Jul-94 |
| University of Utah | Myriad Genetics, Inc. | 23-Nov-94 |
| California Institute of Technology | Clinical Micro Sensors, Inc. | 8-Feb-95 |
| University of Pennsylvania | Care Management Science Corporation | 1-Apr-95 |
| UAB Research Foundation | Biohorizons Dental Implants, LLC | 29-Jun-95 |
| University of Pennsylvania | Myriad Genetics, Inc. | 13-Mar-96 |
| University of California | Scientific Learning Principles Corp. | 27-Sep-96 |
| Massachusetts Institute of Technology | Innogene Pharmaceuticals, Inc. | 11-Dec-96 |
| University of Colorado | GlobeImmune, Inc. | 18-Sep-97 |
| UAB Research Foundation | Novirio Pharmaceuticals, Ltd. | 20-Jun-98 |
| Louisiana State University | Hybridon, Inc. | 1-Jul-98 |
| University of California | Atherogenics Inc. | 17-Jul-98 |
| University of Colorado | Myogen, Inc. | 1-Sep-98 |
| Wisconsin Alumni Research Foundation | TomoTherapy Inc. | 22-Feb-99 |
| Trinity College Dublin | Inhibitex, Inc. | 8-Apr-99 |
| University of California | Digirad Corporation | 19-May-99 |
| University of Arizona | ProIX Pharmaceuticals, Inc. | 3-Jun-99 |
| University of Southern California | Bio-Management, Inc. | 14-Sep-99 |
| University of Illinois | Quark Biotech, Inc. | 15-Sep-99 |
| Children's Medical Center Corporation | Lakaro Biopharmaceuticals, Inc. | 18-Nov-99 |
| Duke University | Celsion Corporation | 20-Nov-99 |
| University of Illinois | Advanced Life Sciences | 2-Dec-99 |
| Johns Hopkins University | Zorax, Inc. | 28-Mar-00 |
| Columbia University | Sentigen Corp. | 10-Apr-00 |
| University of California | Allegro Cell Systems, Inc | 27-Apr-00 |
| Stanford University | Xenogen Corporation | 5-May-00 |
| University of California | Otonomy, Inc. | 19-May-00 |

| Licensor | Licensee | Date |
|---|---|---|
| California Institute of Technology | Insert Therapeutics, Inc. | 22-May-00 |
| University of Florida | OraGen, Inc. | 22-Jun-00 |
| University of California | Osmotics Corporation | 28-Jun-00 |
| University of British Columbia | Xenon Genetics Inc. | 1-Aug-00 |
| University of Washington | Lumera Corporation | 20-Oct-00 |
| Johns Hopkins University | Second Sight, LLC | 24-Oct-00 |
| Brigham Young University | Biopulse, Inc. | 1-Dec-00 |
| University of California | SIGA Technologies, Inc. | 6-Dec-00 |
| University of Miami | Utek Corporations | 1-Jan-01 |
| University College Cardiff and Velindre | Bioenvision Inc. | 9-Jan-01 |
| University of Maryland | Fluorometrix Corporation | 31-Jan-01 |
| University of California | Celladon Corporation | 10-Feb-01 |
| UT-Battelle | Micro Sensor Technologies, Inc. | 26-Mar-01 |
| Rutgers | Oxiquant, Inc. | 13-Apr-01 |
| Massachusetts Institute of Technology | Cardiomems, Inc. | 1-Aug-01 |
| Baylor College | Opexa Pharmaceuticals, Inc. | 5-Sep-01 |
| Harvard College | NanoSys, Inc. | 4-Oct-01 |
| University of British Columbia | Oncogenex Technologies Inc. | 1-Nov-01 |
| Johns Hopkins University | Paralex | 30-Nov-01 |
| Stanford University | Sunvax, Inc. | 1-Feb-02 |
| University of Pittsburgh | Medquest Products, Inc | 13-Feb-02 |
| Mount Sinai School of Medicine | Amicus Therapeutics, Inc. | 15-Apr-02 |
| Oregon Health & Science University | Oxiquant, Inc. | 26-Sep-02 |
| University of Connecticut Health Center | Deliatroph Pharmaceuticals, Inc. | 15-Nov-02 |
| University of Pennsylvania | Polymedix, Inc. | 3-Jan-03 |
| University of Zurich | Viventia Biotech, Inc. | 9-Jan-03 |
| Cornell University | Acorda Therapeutics, Inc. | 3-Feb-03 |
| UAB Research Foundation | Fluidigm Corporation | 7-Mar-03 |
| University of Pennsylvania | Acuity Pharmaceuticals, Inc | 31-Mar-03 |
| University of Massachusetts | CytRx Corporation | 15-Apr-03 |
| Columbia University | Viventia Biotech, Inc. | 23-Jun-03 |
| University of Maryland | Amicus Therapeutics, Inc. | 26-Jun-03 |
| Brookhaven Science Associates LLC | Circle Group Holdings Inc. | 22-Jul-03 |

| **Licensor** | **Licensee** | **Date** |
|---|---|---|
| Stanford University | XTL Biopharmaceuticals Ltd. | 12-Sep-03 |
| Children's Medical Center Corporation | Tengion, Inc. | 10-Oct-03 |
| Emory University | Medical Safety Technologies, Inc. | 30-Dec-03 |
| Cold Spring Harbor Laboratory | Alnylam Pharmaceuticals, Inc. | 30-Dec-03 |
| Boston University | Coley Pharmaceutical Group, Inc. | 23-Jan-04 |
| William Marsh Rice University | Natcore Technology, Inc. | 31-Mar-04 |
| Columbia University | Sentigen Biosciences Inc. | 27-May-04 |
| University of Iowa | Neurogenetics, Inc. | 15-Jun-04 |
| Tel Aviv University | Golden Hand Resources, Inc. | Jul-04 |
| Temple University | Save the World Air, Inc. | 1-Jul-04 |
| The Cleveland Clinic Foundation | Cleveland BioLabs, Inc. | 1-Jul-04 |
| University of South Carolina | BioStratum Incorporated | 27-Aug-04 |
| Duke University | Cellective Therapeutics, Inc. | 21-Sep-04 |
| Rutgers | Xstream Systems, Inc. | 13-Dec-04 |
| University of Florida | ViewRay, Inc. | 15-Dec-04 |
| University of Miami | Somaxon Pharmaceuticals, Inc. | 31-Jan-05 |
| Columbia University | Omnimmune Corp. | 1-Feb-05 |
| West Virginia University Research Corp. | IAS Communications Inc. | 17-Mar-05 |
| University of California | General Fiber, Inc. | 11-Jul-05 |
| California Institute of Technology | Methanotech, Inc. | 12-Jul-05 |
| Northwestern University | Nanosphere, Inc. | 1-Jan-06 |
| University of California | Urigen Holdings Inc. | 18-Jan-06 |
| University of Michigan | Glyconix Incorporated | 20-Jan-06 |
| University of Utah | Glycosan Biosystem, Inc. | 7-Feb-06 |
| University of Arkansas | IMARX Therapeutics, Inc. | 10-Feb-06 |
| University of Michigan | Vical Incorporated | 14-Feb-06 |
| Harvard College | Raindance Technologies, Inc. | 23-Feb-06 |
| Duke University | Precision Biosciences Inc. | 17-Apr-06 |
| Rockefeller University | Rosetta Genomics Ltd. | 4-May-06 |
| California Institute of Technology | DMFCC | 9-May-06 |
| University of Pennsylvania | Aegerion Pharmaceuticals, Inc. | 19-May-06 |
| Creighton University | SafeStitch LLC | 26-May-06 |
| Iowa State University Research Fndn. | Polyphenol Technologies Corporation | 12-Jun-06 |

| Licensor | Licensee | Date |
|---|---|---|
| Dartmouth College | Mascoma Corporation | 10-Jul-06 |
| Penn State | Spheric Technologies, Inc. | 20-Jul-06 |
| North Carolina A&T State | Materials Monitoring Technologies, Inc. | 2-Aug-06 |
| Harvard College | Tetraphase Pharmaceuticals, Inc. | 3-Aug-06 |
| University of Illinois | Acuity Pharmaceuticals, Inc | 3-Aug-06 |
| University of Texas | Introgen Therapeutics, Inc. | 30-Sep-06 |
| University of Alberta | Arcadia Biosciences, Inc. | 2-Oct-06 |
| Princeton University | TetraLogic Pharmaceuticals Corp. | 6-Oct-06 |
| Duke University | Phase Bioscience Inc. | 18-Oct-06 |
| University of Washington | Achaogen | 1-Dec-06 |
| Massachusetts Institute of Technology | Tempo Pharmaceuticals, Inc. | 21-Dec-06 |
| CBR Institute for Biomedical Research | Advanced Genetic Technologies, Inc. | 1-Jan-07 |
| University of Massachusetts | RXi Pharmaceuticals Corp. | 10-Jan-07 |
| University of Massachusetts | Rxi Pharmaceuticals Corporation | 10-Jan-07 |
| University of Minnesota | Expression Diagnostics | 24-Jan-07 |
| Wisconsin Alumni Research Foundation | Colby Pharmaceuticals Company | 26-Jan-07 |
| Temple University | Save the World Air, Inc. | 2-Feb-07 |
| Washington University in St. Louis | Modigene, Inc. | 2-Feb-07 |
| Wisconsin Alumni Research Foundation | Tecogen Inc. | 5-Feb-07 |
| University of Washington | Osmetech | 28-Feb-07 |
| Cold Spring Harbor Laboratory | RXi Pharmaceuticals Corp. | 15-Mar-07 |
| **NINE POINTS DOCUMENT SIGNED** | | Mar-07 |
| Tufts University | Digital Genomics, Inc. | 18-Jun-07 |
| University of Massachusetts | Anterios, Inc. | 13-Aug-07 |
| University of Florida | MAKO Surgical Corp. | 15-Aug-07 |
| Research Foundation of SUNY | Tempo Pharmaceuticals, Inc. | 31-Aug-07 |
| Johns Hopkins University | Signpath Pharmaceuticals, Inc. | 2-Oct-07 |
| Stanford University | Fundamental Applied Biology, Inc. | 3-Oct-07 |
| University of Southern California | Tocagen Inc. | 22-Oct-07 |
| University of Pittsburgh | Precision Therapeutics, Inc. | 1-Nov-07 |
| University College London Hospital | Coronado Biosciences, Inc. | 5-Nov-07 |
| Wisconsin Alumni Research Foundation | Enable IPC | 21-Nov-07 |

| **Licensor** | **Licensee** | **Date** |
|---|---|---|
| University of North Carolina at Chapel Hill | Epizyme, Inc. | 7-Jan-08 |
| University of Pennsylvania | Apellis AG | 28-Mar-08 |
| University of Texas | Miragen Therapeutics, Inc. | 21-Apr-08 |
| Massachusetts Institute of Technology | Parasol Therapeutics, Inc. | 28-Apr-08 |
| Viginia Commonwealth University | Synthetic Blood International, Inc. | 21-May-08 |
| Dartmouth College | Phytomedical Technologies, Inc | 30-Jun-08* |
| Research Foundation of SUNY | Artelo Biosciences, Inc. | 30-Jun-08* |
| University of California | Lantis Laser Inc. | 9-Jul-08 |
| Univ. North Texas Health Science Center | Signpath Pharmaceuticals, Inc. | 18-Aug-08 |
| Wisconsin Alumni Research Foundation | VistaGen Therapeutics, Inc. | 5-Dec-08 |
| California Institute of Technology | Immune Design Corp. | 1-Jan-09 |
| Johns Hopkins University | BIND Biosciences, Inc. | 17-Feb-09 |
| University of Missouri | Organovo, Inc. | 24-Mar-09 |
| Emory University | Alimera Sciences, Inc. | 16-Jul-09 |
| Johns Hopkins University | Hanes Newco, Inc. | 11-Oct-09 |
| University of Colorado | Viral Genetics, Inc. | 22-Nov-09 |
| Yale University | Rib-X Pharmaceuticals, Inc. | 3-Dec-09 |
| University of Washington | Genocea Biosciences, Inc. | 27-Jan-10 |
| Dartmouth College | Celdara Medical, LLC | 30-Apr-10 |
| Emory University | Inhibikase Therapeutics, Inc. | 8-Jun-10 |
| University of Kentucky | Biospherics, Incorporated | 22-Jun-10 |
| University of Chicago | BlackBox Semiconductor, Inc. | 30-Nov-10 |
| University of Michigan | Medgenics, Inc. | 31-Jan-11 |
| University of Arizona | Wildcap Energy, Inc. | 2-Mar-11 |
| Cornell University | Biopancreate, Inc. | 30-Mar-11 |
| Clemson University (Research Foundation) | Organovo, Inc. | 2-May-11 |
| University of Michigan | Heal Biologics, Inc. | 22-Jul-11 |
| Temple University | Save the World Air, Inc. | 1-Aug-11 |
| University of Pittsburgh | Exagen Diagnostics, Inc. | 2-Aug-11 |
| University of Utah | Salaries Pharmaceuticals, LLC | 3-Aug-11 |
| University of Zurich | Hookipa Biotech GmbH | 6-Oct-11 |
| University Health Network | VistaGen Therapeutics, Inc. | 24-Oct-11 |
| Notre Dame | Kraig Biocraft Laboratories, Inc. | 28-Oct-11 |

| Licensor | Licensee | Date |
|---|---|---|
| University of British Columbia | Advanced Inhalation Therapies | 1-Nov-11 |
| Cornell University | Stealth Peptides International Inc. | 3-Nov-11 |
| University of Texas | Peloton Therapeutics, Inc. | 21-Nov-11 |
| Columbia University | Trovagene, Inc. | 12-Dec-11 |
| Texas A&M University | Oragenics, Inc. | 20-Dec-11 |
| Stanford University | Ruga Corporation | 25-Jan-12 |
| University of Texas | arGEN-X BV | 15-Feb-12 |
| University of Texas | Intertech Bio Corporation | 2-Apr-12 |
| Fred Hutchinson Cancer Research Center | Actinium Pharmaceuticals, Inc. | 1-Jun-12 |
| Wisconsin Alumni Research Foundation | Cellular Dynamics International, Inc. | 6-Jun-12 |
| Emory University | Clearside Biomedical, Inc. | 4-Jul-12 |
| University of Arkansas | Cyto Wave Technologies, Inc. | 15-Dec-12 |
| Pennsylvania State Univ. | TNI BioTech, Inc. | 1-Jan-13* |
| University of North Carolina at Chapel Hill | Immune Design Corporation | 16-Jan-13 |
| Yale University | BIND Biosciences, Inc. | 31-Jan-13 |
| University of Zurich | Mirna Therapeutics, Inc. | 10-Mar-13 |
| University of Colorado | Syndax Pharmaceuticals, Inc. | 28-Mar-13 |
| University of California | Caribou Biosciences, Inc. | 16-Apr-13 |
| Brandeis University | BRI-Alzan Inc. | 1-May-13 |
| Stanford University | Fate Therapeutics, Inc. | 2-May-13 |
| Ohio State University | MicroLin Bio, Inc. | 6-Sep-13 |
| University of Iowa | AAVenue Therapeutics, LLC | 14-Oct-13 |
| University of Maryland | Tokai Pharmaceuticals, Inc. | 28-Oct-13 |
| University of Texas | AEMase Inc. | 24-Dec-13 |
| University of Basel | Hookipa Biotech AG | 1-Jan-14 |
| University of Massachusetts | Voyager Therapeutics, Inc. | 30-Jan-14 |
| University of Colorado | Ocugen, Inc. | 3-Mar-14 |
| University of California | Breathing Technologies, Inc. | 19-May-14 |
| Ohio State University | Cellectis | 1-Aug-14 |
| University of Kansas | Reata Pharmaceuticals, Inc | 26-Sep-14 |
| Old Dominion University | Electroblate, Inc. | 1-Oct-14 |
| Duke University | Editas Medicine, Inc. | 10-Oct-14 |
| University of Minnesota | Regenxbio, Inc. | 10-Nov-14 |

| **Licensor** | **Licensee** | **Date** |
|---|---|---|
| University of Minnesota | Cellectis Plant Sciences | 15-Dec-14 |
| University of Texas | Lung Therapeutics, Inc. | 8-Jul-15 |
| University of Florida | Audentes Therapeutics, Inc. | 28-Jul-15 |
| Cold Spring Harbor Laboratory | Asothera Pharmaceuticals, Inc. | 31-Jul-15 |
| Stanford University | Epinomics | 15-Oct-15 |
| University of Missouri | Solid GT, LLC | 15-Oct-15 |
| University of Washington | Solid GT, LLC | 16-Oct-15 |
| University of Texas | Codiak Biosciences, Inc. | 10-Nov-15 |
| McGill University | Iaso Biomed Inc. | 6-Jan-16 |
| University of Illinois | Ocugen, Inc. | 3-Feb-16 |
| University of Chicago | Evelo Biosciences | 10-Mar-16 |
| University of Michigan | Solid GT, LLC | 10-Mar-16 |
| Yale University | Protea Biosciences Group, Inc. | 12-Apr-16 |
| University of Southampton | Asothera Pharmaceuticals, Inc. | 18-Apr-16 |
| Rutgers | Biohaven Pharmaceuticals Holding Co. | 15-Jun-16 |
| University of Minnesota | Oxis Biotech, Inc. | 18-Jul-16 |
| University of California | Creative Medical Technologies, Inc. | 25-Aug-16 |
| University of California | TheRas, Inc. | 28-Sep-16 |
| University Health Network | AvroBio, Inc. | 4-Nov-16 |
| University of Illinois | G1 Therapeutics, Inc | 23-Nov-16 |
| Johns Hopkins University | Unity Biotechnology, Inc. | 28-Nov-16 |
| University of Chicago | Aridis Pharmaceuticals, Inc. | 13-Jun-17 |
| University of Pittsburgh | Immune Ventures, LLC | 26-Jun-17 |
| University of Texas | LogicBio Therapeutics, Inc. | 7-May-18 |
| Rockefeller University | Vir Biotechnology, Inc. | 31-Jul-18 |
| Northwestern University | Oncorus, Inc | 11-Dec-18 |

* Date rationalized

APPENDIX 2

Occurrence of Recommended Clauses in Reviewed Agreements

| | | N | 1.a.u | 1.a.n | 1.b.u | 1.b.n | 1.c | 2(1) | 2(2) | 2(3) | 2(5) | 2(6) | 3 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | All | 220 | 80 | 105 | 80 | 125 | 92 | 47 | 13 | 0 | 13 | 0 | 3 | 7 | 8 | 0 | 0 |
| 2 | All % | | 36% | 48% | 36% | 57% | 42% | 21% | 6% | 0% | 6% | 0% | 1% | 3% | 4% | 0% | 0% |
| 3 | All Pre-2007 | 118 | 54 | 38 | 55 | 51 | 47 | 26 | 8 | 0 | 8 | 0 | 1 | 2 | 5 | 0 | 0 |
| 4 | % | | 46% | 32% | 47% | 43% | 40% | 22% | 7% | 0% | 7% | 0% | 1% | 2% | 4% | 0% | 0% |
| 5 | All Post-2007 | 102 | 26 | 67 | 25 | 74 | 45 | 21 | 5 | 0 | 5 | 0 | 2 | 5 | 3 | 0 | 0 |
| 6 | % | | 25% | 66% | 25% | 73% | 44% | 21% | 5% | 0% | 5% | 0% | 2% | 5% | 3% | 0% | 0% |
| 7 | % Difference | | -20% | 33% | -22% | 29% | 4% | -1% | -2% | 0% | -2% | 0% | 1% | 3% | -1% | 0% | 0% |
| | | | | | | | | | | | | | | | | | |
| 8 | All Sigs | 140 | 49 | 70 | 48 | 84 | 61 | 30 | 10 | 0 | 9 | 0 | 3 | 4 | 7 | 0 | 0 |
| 9 | % | | 35% | 50% | 34% | 60% | 44% | 21% | 7% | 0% | 6% | 0% | 2% | 3% | 5% | 0% | 0% |
| 10 | Sigs Pre-9P | 87 | 39 | 32 | 38 | 42 | 35 | 17 | 6 | 0 | 5 | 0 | 1 | 2 | 4 | 0 | 0 |
| 11 | % | | 45% | 37% | 44% | 48% | 40% | 20% | 7% | 0% | 6% | 0% | 1% | 2% | 5% | 0% | 0% |
| 12 | Sigs Post-9P | 53 | 10 | 38 | 10 | 42 | 26 | 13 | 4 | 0 | 4 | 0 | 2 | 2 | 3 | 0 | 0 |
| 13 | % | | 19% | 72% | 19% | 79% | 49% | 25% | 8% | 0% | 8% | 0% | 4% | 4% | 6% | 0% | 0% |
| 14 | % Difference | | -26% | 35% | -25% | 31% | 9% | 5% | 1% | 0% | 2% | 0% | 3% | 1% | 1% | 0% | 0% |
| | | | | | | | | | | | | | | | | | |
| 15 | All Non-Sigs | 80 | 31 | 35 | 32 | 41 | 31 | 17 | 3 | 0 | 4 | 0 | 0 | 3 | 1 | 0 | 0 |
| 16 | % | | 39% | 44% | 40% | 51% | 39% | 21% | 4% | 0% | 5% | 0% | 0% | 4% | 1% | 0% | 0% |
| 17 | Non-Sigs Pre-9P | 43 | 19 | 13 | 20 | 17 | 15 | 11 | 3 | 0 | 4 | 0 | 0 | 0 | 1 | 0 | 0 |
| 18 | % | | 44% | 30% | 47% | 40% | 35% | 26% | 7% | 0% | 9% | 0% | 0% | 0% | 2% | 0% | 0% |
| 19 | Non-Sigs Post-9P | 37 | 12 | 22 | 12 | 24 | 16 | 6 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| 20 | % | | 32% | 59% | 32% | 65% | 43% | 16% | 0% | 0% | 0% | 0% | 0% | 8% | 0% | 0% | 0% |
| 21 | % Difference | | -12% | 29% | -14% | 25% | 8% | -9% | -7% | 0% | -9% | 0% | 0% | 8% | -2% | 0% | 0% |
| | | | | | | | | | | | | | | | | | |
| 22 | Change Diff. Sig v. Non-Sig | | -14% | 6% | -11% | 6% | 0% | 14% | 8% | 0% | 11% | 0% | 3% | -7% | 3% | 0% | 0% |
| 23 | Rate Diff. Sig v. Non-Sig | | -4% | 6% | -6% | 9% | 5% | 0% | 3% | 0% | 1% | 0% | 2% | -1% | 4% | 0% | 0% |

*Explanation of Variables*

Row 1 of *Table 2* shows the frequency with which each Recommended Clause appears in the full set of Reviewed Agreements, and Row 2 shows the percentage of all Reviewed Agreements in which each such Recommended Clause appears. Rows 3 and 5 show the frequency with which each Recommended Clause appears in Reviewed Agreements signed before and after the *Nine Points* date. A comparison of Rows 3 and 5 reveals the likely effect of the *Nine Points* document on the inclusion of a particular Recommended Clause in an agreement. Row 7 shows the difference in the normalized occurrence frequency of a Recommended Clause before and after the *Nine Points* date. Thus, a negative result in Row 7 indicates that the Recommended Clause appeared less frequently after the *Nine Points* date, a positive result indicates that the Recommended Clause appeared more frequently after the *Nine Points* date, and zero indicates that there was no measurable change in the occurrence of the Recommended Clause after the *Nine Points* date.

Rows 8 to 14 present the same statistics with respect to Reviewed Agreements to which *Nine Points* Signatories are parties, both before and after signing the *Nine Points* document. Row 14 thus reveals the likely effect of the *Nine Points* document on the licensing practices of Signatories. In contrast Rows 15 to 21 present these statistics with respect to Reviewed Agreements to which non-Signatories are parties. Thus, Rows 17 and 19 enable comparison of the frequency of occurrence of

particular Recommended Clauses both before and after the *Nine Points* date, hopefully illuminating general trends in university licensing practices over the period studied, independent of the *Nine Points* document (i.e., as a "control" set, when compared to the results involving Signatories).

Row 22 shows the difference between the occurrence rate differences in Row 14 (Signatories) and Row 21 (non-Signatories). That is, the figures in Row 22 are intended to compare changes in the rate of occurrence of particular Recommended Clauses after Signatories have signed the *Nine Points* document with changes in the rate of occurrence of those Recommended Clauses that may be attributable to general industry trends following the *Nine Points* date. In other words, Row 22 reveals the effect of the *Nine Points* document on the use of particular Recommended Clauses when compared to general industry trends. Row 23, in contrast, shows the absolute difference between the occurrence of a Recommended Clause between Signatories and non-Signatories.