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### 'In the Public Interest' - University Technology Transfer and the Nine Points Document – An Empirical Assessment

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**“IN THE PUBLIC INTEREST” -  
UNIVERSITY TECHNOLOGY TRANSFER AND THE NINE POINTS  
DOCUMENT – AN EMPIRICAL ASSESSMENT**

Jorge L. Contreras\*

*Draft 21 Dec. 2021*

ABSTRACT

*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.” The Nine Points document 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 refraining from dealing 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 one hundred academic institutions and associations around the world have signed the Nine Points document. Yet in the fourteen years since it 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 effect of the Nine Points document on university licensing practices. Through a review of 224 publicly available university patent licenses signed both before and after the adoption of the Nine Points document, this article finds that the document prompted few measurable changes in university licensing practices. Universities largely continued to include in their licensing agreements the contractual clauses that they had previously included, and did not, to any meaningful degree, add new clauses recommended by the Nine Points document. To the extent they did, such new clauses protected university interests rather than the public interest. The lackluster adoption of the recommendations made by the Nine Points document suggests that, by and large, universities have prioritized commercial interests over the public-oriented goals of the document. As such, 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.*

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## INTRODUCTION

University technology licensing is a significant economic activity in the United States. In 2020, 184 U.S. academic research institutions received more than 8,700 U.S. patents and applied for nearly 18,000 more.<sup>1</sup> During the same year, these institutions entered into more than ten thousand technology licensing and option agreements with the private sector.<sup>2</sup> University-based research played a major role in the growth of the biotechnology industry and has made significant contributions to industries such as computer software, medical devices and the Internet.<sup>3</sup> The licensing of university-owned patents has resulted in many 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).

Yet the business of academic technology transfer has not always been viewed favorably by the public. Beginning in the 1990s, fears emerged that the promise of licensing revenue was causing universities to stray from their core educational and public missions.<sup>4</sup> 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.<sup>5</sup> 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

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<sup>1</sup> Assn. Univ. Tech. Managers, AUTM 2020 Licensing Activity Survey at 5 (2021) [hereinafter AUTM 2020 Survey]. For general discussions of university patenting patterns and practices, see, e.g., Jennifer Carter-Johnson, *University Technology Transfer Structure and Intellectual Property Policies*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER 1, 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 (2019); Peter Lee, *Patents and the University*, 63 DUKE L.J. 1 (2013).

<sup>2</sup> AUTM 2020 Survey, *supra* note 1, at 5.

<sup>3</sup> See, generally, NATL. RES. COUNCIL, 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*, SCIENTIFIC AMERICAN – 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.

<sup>4</sup> 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); Eliot Marshall, *When Commerce and Academe Collide*, 248 SCIENCE 152 (1990) (identifying increasing ties between industry and academia during the 1980s).

<sup>5</sup> 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).

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.<sup>6</sup>

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.<sup>7</sup>

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.<sup>8</sup> 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.

The seventeen-page document, titled *In the Public Interest: Nine Points to Consider in Licensing University Technology* (the “Nine Points document”)<sup>9</sup>, 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,<sup>10</sup> and it is still referenced regularly in scholarly articles, government reports and industry bulletins relating to academic technology transfer.<sup>11</sup>

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<sup>6</sup> Ralph Nader, *Foreword* in SHELDON KRIMSKY, *SCIENCE IN THE PRIVATE INTEREST – HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH?* xiii, xiv (pbk. ed. 2004).

<sup>7</sup> WASHBURN, *supra* note 5, at 3-24.

<sup>8</sup> See Part II.A, *infra*.

<sup>9</sup> *In the Public Interest: Nine Points to Consider in Licensing University Technology*, Mar. 6, 2007, <https://news.stanford.edu/news/2007/march7/gifs/whitepaper.pdf> (visited Sep. 12, 2021) [hereinafter *Nine Points document*].

<sup>10</sup> See TechTransferIP Podcast with Lisa Mueller, *Nine Points to Consider in Licensing University Technology with Kathy Ku* (Sep. 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?> (interview with Kathy Ku, former head of Stanford’s Office of Technology Licensing).

<sup>11</sup> See sources cited in notes x, *infra*.

As of this writing, 118 research institutions and associations around the world have signed the Nine Points document.<sup>12</sup> 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.”<sup>13</sup> The Nine Points document has been endorsed by bodies including the National Research Council<sup>14</sup> and the Association of American Universities.<sup>15</sup> It has been held up at Congressional hearings as evidence of the academic community’s commitment to the public good.<sup>16</sup> As Professor Winickoff characterizes it, the Nine Points 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.”<sup>17</sup>

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.<sup>18</sup> 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.<sup>19</sup>

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<sup>12</sup> Assn. Univ. Tech. Managers, *Nine Points to Consider in Licensing University Technology*, <https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university> (visited Sep. 12, 2021) [hereinafter *Nine Points Signatories*].

<sup>13</sup> David E. Winickoff, *Private Assets, Public Mission: The Politics of Technology Transfer and the New American University*, 54 *JURIMETRICS* 1, 30 (2013)).

<sup>14</sup> NATL. RES. COUNCIL, *MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST* at 6, 66, 72 (Stephen A. Merrill & Anne-Marie Mazza eds., 2011) (recommending adoption of principles stated in the Nine Points document) [hereinafter *NRC University IP*].

<sup>15</sup> AAU Working Group on Technology Transfer and Intellectual Property, *Statement to the AAU Membership on University Technology Transfer and Managing Intellectual Property in the Public Interest*, Mar. 2015 [hereinafter *AAU Statement*].

<sup>16</sup> The Bayh-Dole Act (P.L. 96-517, Amendments to the Patent and Trademark Act 1980) -- *The Next 25 Years: Hearing Before H. Subcomm. on Tech. and Innovation, Comm. Sci. and Tech., 110th Cong. At 20-36 (2007)* (testimony of Dr. Arundee Pradhan, chief technology transfer official at Oregon Health and Science University); *The Role of Federally Funded University Research in the Patent System: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (2007)* (testimony of Charles Louis—Vice Chancellor for Research at University of California, Riverside) (both cited in Winickoff, *supra* note 13, at 32).

<sup>17</sup> Winickoff, *supra* note 13, at 30.

<sup>18</sup> See Part x, *infra*.

<sup>19</sup> 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

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.<sup>20</sup> These critiques have been especially acute in connection with recent biomedical innovations such as COVID-19 vaccines<sup>21</sup> and CRISPR gene editing technologies.<sup>22</sup>

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”?<sup>23</sup> While various universities over the years have issued public statements espousing the values reflected in the Nine Points document,<sup>24</sup> no systematic, empirical assessment of its effect on university licensing practices has ever been conducted.<sup>25</sup> This article fills that gap.

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& 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).

<sup>20</sup> See Brian L. Frye & Christopher J. Ryan, Jr., *Technology Transfer and the Public Good*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER 236, 236 (Jacob H. Rooksby ed., 2020); Ouellette & Weires, *supra* note 1; 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. & ENGINEERING ETHICS 45 (2009).

<sup>21</sup> See, e.g., Matthew Rimmer, *The People's Vaccine: Intellectual Property, Access to Essential Medicines, and the Coronavirus COVID-19*, J. INTELL. PROP. STUD. (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, \_\_ (2021) (describing student-led campaign to persuade universities to contribute vaccine-related intellectual property to the COVID-19 response).

<sup>22</sup> See, e.g., Knut J Egelie et al., *The ethics of access to patented biotech research tools from universities and other research institutions*, 36 NATURE BIOTECH. 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).

<sup>23</sup> Winickoff, *supra* note 13, at 40. See also Liza Vertinsky, *Universities as Guardians of Their Inventions*, 2012 UTAH L. REV. 1949, 2008 (2012) (“there is little evidence that informal measures such as [the Nine Points document] have been adequate to curtail universities’ self-interested actions in the face of increasing competition for scarce resources”).

<sup>24</sup> 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).

<sup>25</sup> 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. Thi-Yen Nguyen, Mohammad Shahzad & Juliana Veras, *Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America:*

In order to gain a better understanding of the impact of the Nine Points document on university licensing practices, this study reviewed 224 publicly available university licenses signed both before and after the adoption of the Nine Points document. This article describes our 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 found that university licensing practices changed very little in response to the Nine Points document. By and large, after the Nine Points document was signed, universities continued to adhere to their existing contractual language, with some minor alterations, most of which appear to protect the university's interests rather than promote the public good. But while adoption of the contractual provisions suggested by the Nine Points document has been lackluster, the Nine Points document has served as a launching pad for other, more ambitious, university licensing programs, and may thus exert its greatest influence as a model of norms for public interest initiatives in the university setting.

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 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 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.<sup>26</sup> But with the need to combat the technological advances being deployed to great effect by Germany, the U.S. 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

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*Identifying Key Provisions to Promote Global Access To Health Technologies*, LES NOUVELLES 189 (Sept. 2018).

<sup>26</sup> For informative discussions of pre-WW2 R&D by U.S. academic researchers, see Bhaven N. Sampat, *Whose Drugs Are These?*, 36 ISSUES IN SCI. & TECH. 42 (2020); Jennifer Carter-Johnson, *University Technology Transfer Structure and Intellectual Property Policies*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER 1, 6-8 (Jacob H. Rooksby ed., 2020).

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.<sup>27</sup> During America's post-War economic boom, Bush continued to guide national research policy and the Federal government poured money into academic labs. Between 1953 and 1980, federal non-defense R&D funding increased from \$2.2 billion to \$41.5 billion – much of which was paid to America's research institutions.<sup>28</sup>

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 in fields like semiconductors and consumer electronics, there was no straightforward pathway from U.S. academic laboratories to the marketplace.<sup>29</sup> 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 didn't specify one way or the other.<sup>30</sup> The result of this lack of clarity was that few federally-funded inventions were being patented or used by the private sector.<sup>31</sup>

The proposed solution to this problem came in the form of legislation sponsored by Senators Birch Bayh (D-IN) and Bob Dole (R-KS). The legislation that they introduced – the Patent and Trademark Law Amendments Act of 1980, more commonly known as the Bayh-Dole Act<sup>32</sup> -- 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. 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. The statute does not specify how much each inventor should get, but most universities have developed a rough three-way split of royalty

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<sup>27</sup> See Sampat, *supra* note 26.

<sup>28</sup> AAAS, Historical Trends in Federal R&D, By Function: Defense and Nondefense R&D, 1953-2017, <https://www.aaas.org/programs/r-d-budget-and-policy/historical-trends-federal-rd>.

<sup>29</sup> Thomas A. Massaro, Innovation, Technology Transfer, and Patent Policy: The University Contribution, 82 VA. L. REV. 1729, 1729-30 (1996).

<sup>30</sup> 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 5, at 52-53.

<sup>31</sup> See NRC University IP, *supra* note 14, at 16 (“very little federally funded research was commercialized prior to 1980”).

<sup>32</sup> Patent and Trademark Law Amendments Act, Pub. L. 96-517 (Dec.12, 1980), codified at 94 Stat. 3015, 35 U.S.C. §§ 200–212.

licensing income among the inventors, their academic departments, and the university itself, after deducting overhead for the TTO itself.<sup>33</sup>

Critics point to the Bayh-Dole Act as a major factor in the commercialization of academic science,<sup>34</sup> while supporters credit it with saving the American technology economy.<sup>35</sup> In 2002, *The Economist* labeled the Act “the goose that laid the golden egg” – attributing much of America’s technological relevance to this single piece of legislation.<sup>36</sup> 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)<sup>37</sup> 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.<sup>38</sup> Universities staff their TTOs with attorneys and business managers with expertise in patents, technology licensing and commercialization.<sup>39</sup>

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

<sup>33</sup> See Carter-Johnson, *supra* note 26, at 26-27; Lisa Larrimore Ouellette & Andrew Tutt, *How do patent incentives affect university researchers?*, 61 INTL. REV. L. & ECON. 105883 at 9-10 (2020).

<sup>34</sup> See, e.g., Eisenberg & Cook-Deegan, *supra* note 20; Ouellette & Weires, *supra* note 1; Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost*, 43 HOUS. L. REV. 1373 (2007); Rai & Eisenberg, *supra* note 5.

<sup>35</sup> 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 et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL’Y 99 (2001).

<sup>36</sup> *Opinion, Innovation’s golden goose*, ECONOMIST, Dec. 14, 2002.

<sup>37</sup> 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 <https://pivotcenter.utah.edu>. For ease of discussion, in this article refers to all such groups as TTOs.

<sup>38</sup> 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 (2019).

<sup>39</sup> See Carter-Johnson, *supra* note 26, at 15. The Wisconsin Alumni Research Foundation (WARF), discussed in Part x, *infra*, is one such foundation. See Orozco, *supra* note 38, at 135-37.

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.<sup>40</sup> These companies are sometimes referred to as university “spinouts”, and AUTM data shows that in 2020 approximately 16% of university technology licenses were granted to such spinout companies.<sup>41</sup>

### 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 1990s.<sup>42</sup> University administrators were keenly aware of these criticisms.<sup>43</sup> 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).<sup>44</sup> Various high-level committees were formed to consider the issues raised by patented research tools,<sup>45</sup> and in 1998 Rebecca Eisenberg and Mark Heller cautioned that excessive patenting of biomedical research tools could lead to a counterproductive “anticommons”.<sup>46</sup> In 1999, the National Institutes of Health (NIH) published a set of non-binding guidelines encouraging its grant recipients to

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<sup>40</sup> See AUTM 2020 Survey, *supra* note 1, at x.

<sup>41</sup> See AUTM 2020 Survey, *supra* note 1, supplemental data (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. Contreras & Sherkow, *supra* note 22.

<sup>42</sup> See notes x-y, *supra*, and accompanying text.

<sup>43</sup> See Ben Butkus, *Tech Transfer White Paper Authors Hope to Spur Debate, Socially Responsible Licensing*, BIOTECHTRANSFERWEEK, Mar. 19, 2007, <https://www.genomeweb.com/biotechtransferweek/tech-transfer-white-paper-authors-hopespur-debate-socially-responsible-licensing#.YVUMwC1h2Zw> (noting awareness of criticisms by Jennifer Washburn, among others, as prompting action by organizers of the Nine Points document).

<sup>44</sup> See NATL. RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 43-46, 51-55 (1996) [hereinafter NRC Research Tools Report].

<sup>45</sup> See NRC Research Tools Report, *supra* note 44, at vii-viii.

<sup>46</sup> Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

license patented research tools on a non-exclusive basis to promote their greatest utilization.<sup>47</sup>

Notwithstanding these cautionary notes, universities continued to obtain patents covering research tools. In most cases, these patents were not perceived as significant barriers to scientific research.<sup>48</sup> 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.<sup>49</sup> Though considered “inappropriate” under the NIH Guidelines,<sup>50</sup> the attempt to collect reach-through royalties became increasingly frequent and controversial, particularly in the biotechnology industry.<sup>51</sup>

## 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).<sup>52</sup> 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.<sup>53</sup> Today, WARF reports that it enters into approximately one hundred commercial licensing agreements per year and has contributed nearly \$3.4 billion to UW.<sup>54</sup> In addition to Vitamin D enrichment, WARF has licensed blockbuster

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<sup>47</sup> 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).

<sup>48</sup> 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) (“we 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”).

<sup>49</sup> 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).

<sup>50</sup> NIH Research Tool Guidelines, *supra* note 47, at 72,091 (“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”).

<sup>51</sup> See Server et al., *supra* note 49, at 64 (“reach-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).

<sup>52</sup> Wisconsin Alumni Research Foundation, ‘Our History’, <http://www.warf.org/about/index.jsp?cid=26>

<sup>53</sup> *Id.*

<sup>54</sup> WARF, Strengthening UW-Madison with a Century of Support, <https://www.warf.org/about-warf/impact-on-uw-madison/> (accessed Sep. 11, 2021).

products including the blood thinner warfarin,<sup>55</sup> making it one of the most successful university technology commercialization operations in the country.<sup>56</sup>

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.<sup>57</sup> WARF's licensing program for its hESC cell line was controversial. Beginning in 2001, WARF charged academic researchers \$5,000 to obtain hESC cells.<sup>58</sup> 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<sup>59</sup> and to use them in research sponsored by the private sector.<sup>60</sup> 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.<sup>61</sup>

Though WARF entered into more than 130 hESC licenses by 2005,<sup>62</sup> opposition to its licensing program steadily grew. Harvard molecular biologist Douglas Melton publicly called WARF's licensing terms "onerous, restrictive and uncooperative".<sup>63</sup>

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<sup>55</sup> See Kevin Walters, *Of Rats and Men: Warfarin Becomes World Famous by 1955*, WARF Decade by Decade (2015), <https://www.warf.org/announcement/of-rats-and-men-warfarin-becomes-world-famous-by-1955/> (noting that the name "warfarin" is a portmanteau of "WARF" and the chemical compound "coumarin").

<sup>56</sup> Carl Gulbrandsen, *WARF's licensing policy for ES cell lines*, 25 NATURE BIOTECH. 387, 387 (2007).

<sup>57</sup> 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.

<sup>58</sup> 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 57, 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).

<sup>59</sup> 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 into with Geron Corporation. Author's interview of Carl Gulbrandsen, 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).

<sup>60</sup> See Golden, *supra* note 57, 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).

<sup>61</sup> According to Dr. Gulbrandsen, these restrictions were imposed by WARF's institutional review board (IRB) on grounds of protecting human research subjects. Gulbrandsen interview, *supra* note 59.

<sup>62</sup> Sander Rabin, *The gatekeepers of hES cell products*, 23 NATURE BIOTECH. 817, 818 (2005).

<sup>63</sup> Eli Kintisch, *Groups Challenge Key Stem Cell Patents*, 313 SCIENCE 281, 281 (2006).

In early 2006, at the urging of NIH, WARF reduced the price of its hESC cells from \$5,000 to \$500.<sup>64</sup> Nevertheless, much of the academic research community remained uncomfortable with WARF's hESC licensing program.

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

One of the most heated debates in the area of academic technology transfer has concerned the accessibility 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.<sup>65</sup> 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 a particular field of use.<sup>66</sup> 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.<sup>67</sup> 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.<sup>68</sup>

Thus, when a Yale University patent on the compound d4T (stavudine) 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.<sup>69</sup> 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.<sup>70</sup> BMS priced Zerit between \$10,000 and \$15,000 per year.<sup>71</sup> However, when the international

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<sup>64</sup> See Loring & Campbell, *supra* note 58, at 1717; Golden, *supra* note 57, at 320.

<sup>65</sup> See, e.g., JORGE L. CONTRERAS, *INTELLECTUAL PROPERTY LICENSING AND TRANSACTIONS: THEORY AND PRACTICE* 147 (0.9 ed. 2021) (describing licensing practices for new drugs) [hereinafter CONTRERAS, *LICENSING AND TRANSACTIONS*].

<sup>66</sup> See CONTRERAS, *LICENSING AND TRANSACTIONS*, *supra* note 65, at Ch. 8 – Intro. (Exclusivity).

<sup>67</sup> See *id.* at Ch. 8.A (Exclusivity – Rationales and Policy).

<sup>68</sup> 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. This requirement was discontinued by NIH in the face of significant industry opposition. See Jorge L. Contreras, *What Ever Happened to NIH's "Fair Pricing" Clause?*, BILL OF HEALTH (Aug. 20, 2020), <https://blog.petrieflom.law.harvard.edu/2020/08/04/nih-fair-pricing-drugs-covid19/>.

<sup>69</sup> Donald G. McNeil, Jr., *Yale Pressed to Help Cut Drug Costs in Africa*, N.Y. TIMES, Mar. 12, 2001, p. A3.

<sup>70</sup> Ashley J. Stevens & April E. Effort, *Using Academic License Agreements to Promote Global Social Responsibility*, LES NOUVELLES, Jun. 2008, 85, 87.

<sup>71</sup> Yale School Med., *After an Uproar, Price of AIDS Drug Falls in Africa*, YALE MEDICINE MAGAZINE, Spr. 2001; Julian Borger & Sarah Bosely, *Campus revolt challenges Yale over \$40m Aids drug*, GUARDIAN, Mar. 13, 2001.

humanitarian organization Médecins Sans Frontières (MSF) asked BMS to permit the Indian firm Cipla to import a generic version of Zerit into South Africa at a price of \$350 per year, BMS refused.<sup>72</sup> The refusal sparked protests by Yale students and faculty, including the original discoverer of d4T, who pointed out, among other things, that Yale was earning approximately \$40 million per year from patent royalties on Zerit.<sup>73</sup> As a result of this pressure, BMS agreed in March 2001 to make Zerit available in South Africa for \$1 per day and to permit generic versions to be sold as well.<sup>74</sup>

Yale was again in the limelight when, in 2006, it licensed a related compound known as Ed4T to Japanese pharmaceutical manufacturer Oncolys.<sup>75</sup> 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.

In November 2006, UAEM produced a manifesto known as the Philadelphia Consensus Statement<sup>76</sup> which was signed by nearly four hundred students, scientists, lawyers and activists.<sup>77</sup> 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.<sup>78</sup>

#### 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 to the developing world by stimulating investment where it has been traditionally lacking under profit-motivated business models.”<sup>79</sup>

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

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<sup>72</sup> Yale School Med., *supra* note 71.

<sup>73</sup> Yale School Med., *supra* note 71; Borger & Bosely, *supra* note 71.

<sup>74</sup> Yale School Med., *supra* note 71; Stevens & Effort, *supra* note 70.

<sup>75</sup> See Erika Check, *Universities Urged to do More for Poor Nations*, 444 NATURE 412, 413 (2006).

<sup>76</sup> Philadelphia Consensus Statement on University Policies for Health-Related Innovations (Nov. 2006), <http://www.columbia.edu/cu/amsa/uaem/PhiladelphiaConsensusStatement.pdf> [hereinafter Philadelphia Statement].

<sup>77</sup> Check, *supra* note 75, at 412.

<sup>78</sup> Philadelphia Statement, *supra* note 76.

<sup>79</sup> Carol Mimura, *Technology Licensing for the Benefit of the Developing World: UC Berkeley’s Socially Responsible Licensing Program*, 18 J. ASSN. UNIV. TECH. MANAGERS 15, 16 (2006).

produce the malaria drug artemisinin, a handheld immune-diagnostic assay, and disease-resistant crops, all in least-developed countries.<sup>80</sup> 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.<sup>81</sup> By the end of 2005, Berkeley had completed ten different agreements under its SRLP.<sup>82</sup> Although there were calls for broader adoption of the Berkeley SRLP model,<sup>83</sup> few other universities followed Berkeley's lead during the mid-2000s.<sup>84</sup>

### 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 some 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.<sup>85</sup> 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.<sup>86</sup> Twelve U.S. senators and twenty-five representatives wrote letters in support of CellPro's petition.<sup>87</sup> Nevertheless, the petition was denied,<sup>88</sup> and the Federal Circuit ruled in 1997 that CellPro had willfully infringed the patents.<sup>89</sup>

Then, in 2000, the University of Rochester sued Searle, Monsanto, Pfizer and Pharmacia for infringing a university patent allegedly covering the blockbuster

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<sup>80</sup> See Mimura, *supra* note 79, at 19.

<sup>81</sup> Robert Sanders, Landmark agreement between Samoa and UC Berkeley could help search for AIDS cure, UC Berkeley Web Feature, Sept. 29, 2004.

<sup>82</sup> Barry Bergman, *Research patently in the public interest*, BERKELEYAN, Dec. 2, 2005.

<sup>83</sup> See Stevens & Effort, *supra* note 70, at 89 (recommending that all academic institutions "make Socially Responsible Licensing a formal, stated institutional policy").

<sup>84</sup> Bergman, *supra* note 82 ("Berkeley's program remains the exception among university licensing offices, even within the UC system").

<sup>85</sup> Johns Hopkins Univ. v. CellPro, Inc., 931 F. Supp. 303, 308 (D. Del. 1996), *aff'd* 152 F.3d 1342 (Fed. Cir. 1998).

<sup>86</sup> Harold Varmus, National Institutes of Health, Office of the Director, Determination in the Case of Petition of CellPro, Inc., Aug. 1, 1997 [hereinafter CellPro Determination]. See also Mikhail, *supra* note 4; Kevin W. McCabe, *Implications of the "CellPro" Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-In Right?*, 27 PUBLIC CONTRACT 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 (2001).

<sup>87</sup> See Eliot Marshall, *NIH Nixes Appeal to Bypass Patent Law*, 277 SCIENCE 759 (1997).

<sup>88</sup> CellPro Determination, *supra* note 86, at 6 ("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.")

<sup>89</sup> 152 F.3d 1342 (Fed. Cir. 1998).

Cox-2 inhibitor marketed as Celebrex<sup>®</sup>.<sup>90</sup> 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.”<sup>91</sup> Yet the anticipated returns never materialized, as the asserted patent was invalidated for lack of written description.<sup>92</sup> 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.”<sup>93</sup> 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.<sup>94</sup> In his concurring opinion in *eBay v. MercExchange*,<sup>95</sup> 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.<sup>96</sup>

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 professor Mark Lemley to ask in a 2006 speech, “Are Universities Patent Trolls?”<sup>97</sup> In the speech, Lemley observed, “Time 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.”<sup>98</sup> Though many university TTO officials likely disagreed with Lemley,<sup>99</sup> they were certainly aware of the negative public light being shed on their patenting and licensing practices.<sup>100</sup>

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<sup>90</sup> See Andrew Pollack, *University’s Drug Patent Is Invalidated by a Judge*, NY TIMES, Mar. 6, 2003 (noting that Celebrex earned more than \$3 billion per year).

<sup>91</sup> Pollack, *supra* note 90.

<sup>92</sup> *University of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216, 230 (W.D. NY 2003), *aff’d* 358 F.3d 916 (Fed. Cir. 2004).

<sup>93</sup> *Id.* at 230.

<sup>94</sup> See Fed. Trade Comm’n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, p. 38 (Oct. 2003) (“NPEs 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.”)

<sup>95</sup> *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

<sup>96</sup> 547 U.S. at 396 (Kennedy, J., concurring).

<sup>97</sup> 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).

<sup>98</sup> Lemley, *Universities*, *supra* note 97, at 615 (quoting Chuck Fish, Comments at the Fordham Annual Conference on International Intellectual Property Law & Policy (Apr. 22, 2006)).

<sup>99</sup> Lemley, *Universities*, *supra* note 97, at 611 n.\* (noting that many in his audience disagreed with the implication of this question).

<sup>100</sup> In the acknowledgements to his article, Lemley expressly thanks two TTO officials who attended the Stanford meeting that led to the Nine Points document. Lemley, *Universities*, *supra* note 97, at 611 n.\* (thanking 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).

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."<sup>101</sup> 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."<sup>102</sup> With this focus on royalty revenue earned through the MPEG-2 pool, some observers asked whether Columbia had become part of a PAE.<sup>103</sup>

### 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 by enemy states, thus endangering U.S. national security.<sup>104</sup> 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.<sup>105</sup>

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,<sup>106</sup> 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

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<sup>101</sup> Columbia Univ., Press Release: Justice Department Approves Digital TV Patent Pool; Columbia, Only University in Group, To Receive Fees, Jul. 1, 1997, [http://www.columbia.edu/cu/pr/96\\_99/19161.html](http://www.columbia.edu/cu/pr/96_99/19161.html).

<sup>102</sup> Columbia Univ., *supra* note 101.

<sup>103</sup> See Julie Hopkins, *When Pools Act Like Trolls*, AUSTIN AMERICAN-STATESMAN, Nov 27, 2013 (updated Sep 26, 2018), ("some view MPEG LA as more of an offensive acting patent troll than a patent pool")

<sup>104</sup> See Natl. Research Council, *Science and Security in a Post 9/11 World: A Report Based on Regional Discussions Between the Science and Security Communities 28* (2007) [hereinafter NRC Science & Security].

<sup>105</sup> National Policy on the Transfer of Scientific, Technical and Engineering Information, September 21, 1985.

<sup>106</sup> NRC Science & Security, *supra* note 104, at 30.

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 Part 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 Part 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, 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.<sup>107</sup>

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.<sup>108</sup> 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.<sup>109</sup>

One of the principal purposes of the meeting was to address concerns surrounding WARF's hESC licensing program. During the meeting, WARF's

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<sup>107</sup> Author's interviews, conducted March 2020.

<sup>108</sup> Author's interviews, conducted March 2020.

<sup>109</sup> Author's interviews, conducted March 2020.

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.<sup>110</sup> 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.<sup>111</sup>

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 document had been created and approved by twelve of the thirteen participants at the Stanford meeting.<sup>112</sup>

### *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 a total of twenty-four 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 Part x, 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. This right is of clear relevance to universities, as

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<sup>110</sup> 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. Author's interviews, conducted March 2020.

<sup>111</sup> Author's interviews, conducted March 2020.

<sup>112</sup> Columbia University did not sign the Nine Points document.

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.<sup>113</sup>

- (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 claims of patent infringement.<sup>114</sup> 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).<sup>115</sup>
- (c) *Materials Transfer.* The WARF controversy discussed in Part I.C.2, above, highlighted for many universities the need to reserve the right to transfer tangible research materials (e.g., biological and chemical compounds) as well as computer software, databases and know-how, to third parties, particularly non-profit and governmental entities. 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***

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<sup>113</sup> See *Kepner-Tregoe, Inc. v. Vroom*, 186 F.3d 283 (2d Cir. 1999) (professor's reservation of rights in exclusive license agreement was insufficient to conduct certain executive education and consulting activities).

<sup>114</sup> 307 F.3d 1351, x (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").

<sup>115</sup> 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 note x, *supra*. For a general discussion of university sponsored research, see CONTRERAS, LICENSING AND TRANSACTIONS, *supra* note 65, at 394-97.

Points 2 and 5 respond to the concerns discussed in Part 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.<sup>116</sup>

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” of an invention.<sup>117</sup> 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.”<sup>118</sup> These provisions seek to prevent a technology from being locked up in the hands of an unproductive licensee, which would deprive others of the benefits of the technology.<sup>119</sup>

Concerns regarding research tools are related. The discussion in Point 5 cites the NIH Guidelines on Research Tools,<sup>120</sup> noting that “universities are expected to make research tools as broadly available as possible.”<sup>121</sup> 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

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<sup>116</sup> Nine Points document, *supra* note 9, 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 (“the 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.”)

<sup>117</sup> Nine Points document, *supra* note 9, at 2.

<sup>118</sup> Nine Points document, *supra* note 9, at 3.

<sup>119</sup> 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 IN MED. S111 (2010).

<sup>120</sup> NIH Guidelines, *supra* note 47.

<sup>121</sup> Nine Points document, *supra* note 9, at 5.

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 products, but not their use.<sup>122</sup> For example, if a university patent claims a genomic analysis technique,<sup>123</sup> 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.<sup>124</sup> 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*,<sup>125</sup> permitting researchers

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<sup>122</sup> 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.

<sup>123</sup> 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, which 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).

<sup>124</sup> The Nine Points document also mentions equipment obtained by the user from the exclusive licensee, Nine Points document, *supra* note 9, 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 Products, Inc. v. Lexmark Intl., Inc.*, 581 U.S. \_\_\_\_ (2017).

<sup>125</sup> See notes x, *supra*, and accompanying text.

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 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 that of Clause 1.a, which permits a university licensor to use an exclusively licensed technology for its own educational purposes. Clause 2(5) extends that educational right to third parties, as well.
- (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. Opponents claimed that “false positive” results from Myriad could thus lead patients to receive unnecessary prophylactic surgery.<sup>126</sup>

### ***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

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<sup>126</sup> 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.”)

program” to the licensee.<sup>127</sup> The Nine Points document thus encourages 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.<sup>128</sup> Point 4, however, contains no specific suggestions regarding language for licensing agreements.

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

See Point 2, above.

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

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.<sup>129</sup> 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.<sup>130</sup>

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

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<sup>127</sup> Nine Points document, *supra* note 9, at 4.

<sup>128</sup> See Jorge L. Contreras & Mark D. Rinehart, *Conflicts of Interest and Academic Research*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER 143 (Jacob H. Rooksby ed., 2020).

<sup>129</sup> See notes x, *supra*, and accompanying text.

<sup>130</sup> Nine Points document, *supra* note 9, 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; NRC University Report, *supra* note 14, at 7 (“Enforcement of IP rights against suspected infringers should be approached carefully to protect the institution’s resources and reputation”).

to promote technology development for the benefit of society”.<sup>131</sup> It further notes that “[l]itigation is seldom the preferred option for resolving disputes.”<sup>132</sup> 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.”<sup>133</sup> 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.<sup>134</sup> 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.<sup>135</sup>

#### ***Point 7 – Be mindful of export regulations***

As noted in Part I.C.6, above, the national security implications of university research were the subject of intense, high-level discussions during the 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.<sup>136</sup> 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.

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

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<sup>131</sup> Nine Points document, *supra* note 9, at 6.

<sup>132</sup> Nine Points document, *supra* note 9, at 6.

<sup>133</sup> *Id.*

<sup>134</sup> See Fed. R. Civ. Pro. 19, 20; *Independent Wireless Telegraph Co v. Radio Corp of America*, 269 US 459 (1926) (an exclusive licensee should be able to join the patent owner, involuntarily if need be, to maintain suit).

<sup>135</sup> 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. Inc.*, 56 F.3d 1538 (Fed. Cir. 1995).

<sup>136</sup> NRC Science & Security, *supra* note 104.

Point 8 addresses the issues raised by the licensing of university patents to patent assertion entities.<sup>137</sup> 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 presented by Zerit and similar incidents in the 1990s and early 2000s.<sup>138</sup> In doing so, it seeks to codify the public interest principles pioneered by the Berkeley SRLP,<sup>139</sup> 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 embody 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.

### 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. Our findings are presented below.

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<sup>137</sup> See Part I.C.5, *supra*.

<sup>138</sup> See Part x, *supra*.

<sup>139</sup> See Part x, *supra*.

### A. Methodology

The AUTM website identifies each signatory to the Nine Points document (Signatories).<sup>140</sup> 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 (US, Canada, Latin America, Europe, Africa, Australia/NZ 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 (waybackmachine).<sup>141</sup>

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<sup>142</sup> 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”, 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.”<sup>143</sup> 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 the public Electronic Data Gathering, Analysis, and Retrieval (EDGAR) database operated by the U.S. Securities and Exchange Commission.<sup>144</sup>

During the summer of 2020, we conducted searches on EDGAR to identify agreements in which academic institutions licensed patents to other parties.<sup>145</sup> We obtained 136 agreements meeting these criteria. We obtained an additional 68 agreements from KTMine, a private database vendor, which also sourced these

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<sup>140</sup> See Nine Points Signatories, *supra* note 12.

<sup>141</sup> <http://web.archive.org>

<sup>142</sup> 17 CFR § 229.601.

<sup>143</sup> 17 CFR § 229.601(b)(10)(ii)(b).

<sup>144</sup> <https://www.sec.gov/edgar/searchedgar/companysearch.html>. 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. These words and phrases are thus redacted in the publicly-available documents. However, given the nature of this inquiry, these redactions did not have a material impact on our review of the agreements.

<sup>145</sup> To conduct this search we utilized a variety of related Boolean queries containing the terms “licens\*” and “university” or “institute\*”.

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 224 unique patent license agreements (Reviewed Agreements) to which 85 different academic institutions were parties.<sup>146</sup> A list of all 224 Reviewed Agreements is contained in the Appendix.

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 Recommended Clause included in the Nine Points document (see Part II.B, above).

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.<sup>147</sup>

## B. Findings

This Part 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

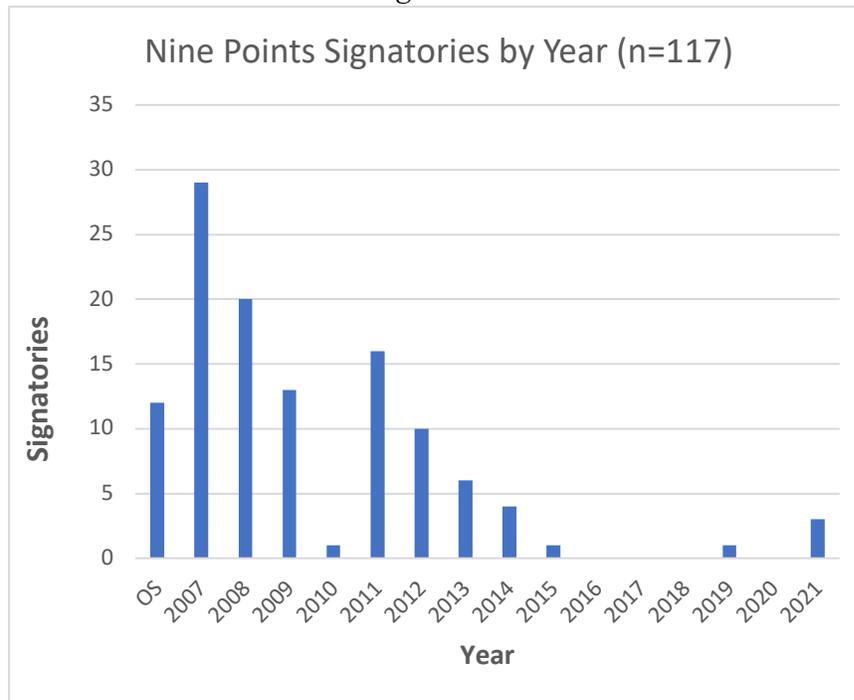
As noted above, twelve entities – eleven U.S. universities and the AAMC – signed the Nine Points document in March 2007. Following its creation, 106 additional entities signed the Nine Points document. *Figure 1* below illustrates the accession, by year, of additional entities to the Nine Points document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

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<sup>146</sup> Based on data obtained from the AUTM STATT database, it is 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 95% confidence level and margin of error of 7%.

<sup>147</sup> Natl. Sci. Fdn., Higher education R&D expenditures at higher education institutions in both survey populations, ranked by all R&D expenditures, by source of funds: FY 2019, [https://nces.nsf.gov/pubs/nsf21314#utm\\_source=miragenews&utm\\_medium=miragenews&utm\\_campaign=news](https://nces.nsf.gov/pubs/nsf21314#utm_source=miragenews&utm_medium=miragenews&utm_campaign=news) [hereinafter NSF 2019 R&D Report].

Figure 1



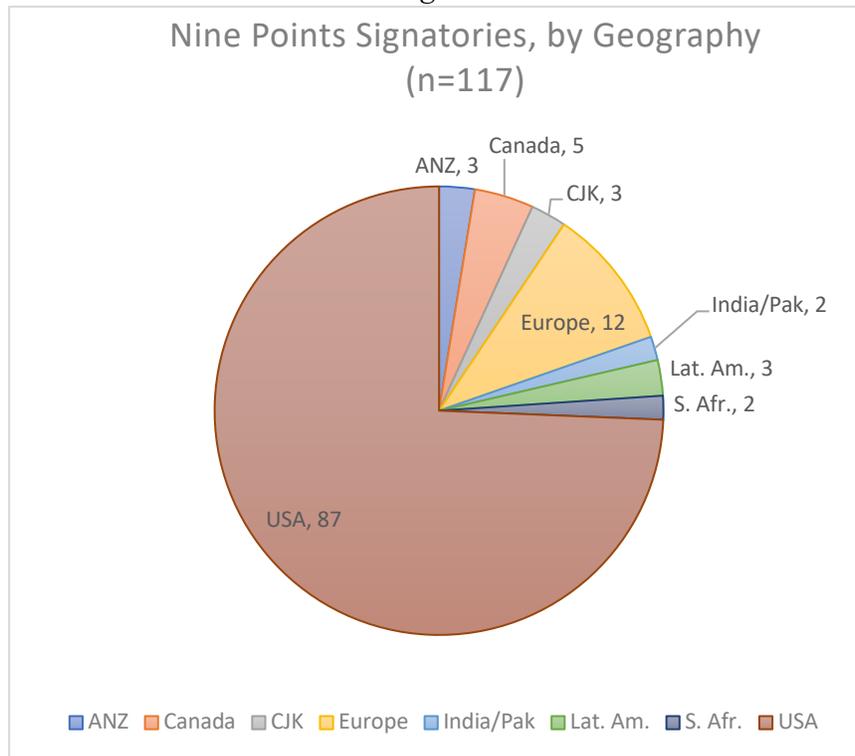
As shown in *Figure 1*, accession to the Nine Points document was highest in the years immediately following its creation (2007-2008), followed by a decline over the next few years (2009-2014), and a mere trickle thereafter. Institutions that adopted the Nine Points in 2007 and 2008 were likely responding 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.”<sup>148</sup>

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

The original signatories of the Nine Points 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), China/Japan/Korea (3), India/Pakistan (2) and South Africa (2). Figure 2 below illustrates the geographic distribution of Signatories as of September 2020.

<sup>148</sup> Patrick L. Jones, AUTM Recommends Universities Review the ‘Nine Points to Consider in Licensing University Technology’ (2007). AUTM clearly viewed the Nine Points document as a means for repairing damage to the public image of university technology transfer. As its President wrote in 2007, “Given 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.*

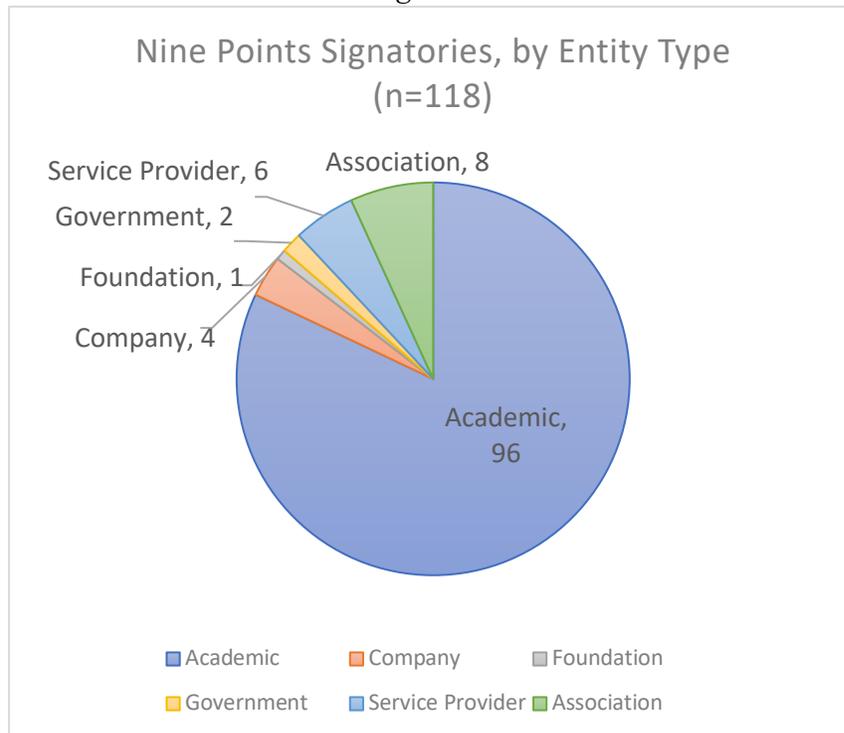
Figure 2



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).<sup>149</sup> Figure 3 below illustrates the breakdown of Signatories by entity type as of September 2020.

<sup>149</sup> It is not clear what non-academic institutions signify by signing the Nine Points document. 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 U.S. 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 Part 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.<sup>150</sup> Over the years, however, a number of smaller research institutions signed the Nine Points document, so that by 2021, institutions with total research budgets of less than \$5 million had become signatories.<sup>151</sup> At the same time, as discussed in Part IV.A, below, many of the largest research institutions in the U.S. have still not signed the Nine Points document.

<sup>150</sup> For purposes of research expenditure reporting, University of Illinois Chicago and University of Illinois Urbana-Champaign report as a single entity, with combined expenditures of approximately \$1.1 billion. See AUTM 2020 Survey, *supra* note 1; NSF 2019 R&D Report, *supra* note 147.

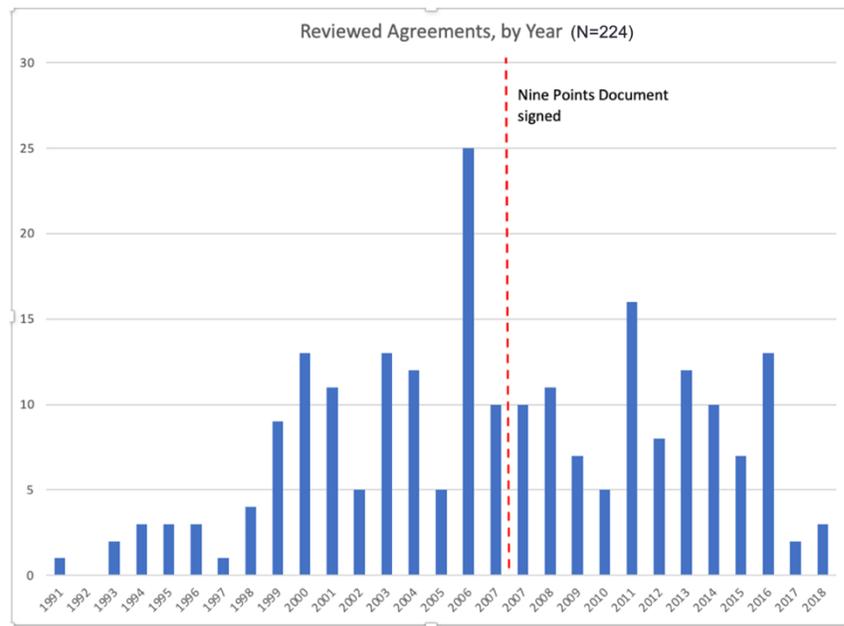
<sup>151</sup> E.g., Worcester Polytechnic Institute and Boise State University. AUTM, Nine Points Signatories, *supra* note 12; AUTM 2020 Survey, *supra* note 1.

2. License Agreement Characteristics

As noted in Part III.A, we collected 224 unique Reviewed Agreements. The licensors in 142 Reviewed Agreements (63%) were academic institutions that have signed the Nine Points document (Signatories).<sup>152</sup> The twelve original Signatories were licensors in 57 of these Reviewed Agreements (25% of the total). Academic institutions that have not signed the Nine Points document (non-Signatories) were licensors in the remaining 82 Reviewed Agreements (37%).

Reviewed Agreements had execution dates ranging from 1991 to 2018. A total of 120 of these Reviewed Agreements (54%) were executed prior to the creation of the Nine Points document in March 2007<sup>153</sup> and 104 (46%) were executed after that date. Of the 142 Reviewed Agreements to which Signatories were parties, 89 (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.

Figure 4



Eighty-five (85) different academic institutions are licensors under the Reviewed Agreements. Of these, 36 (42%) are Nine Points 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

<sup>152</sup> Our focus is on university licensors only. While universities are sometimes licensees, these licensing agreements are seldom accessible to the public.

<sup>153</sup> 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, given the likelihood that the agreement was drafted and negotiated prior to the formal March 6 date of the Nine Points document.

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	11	5	16
University of Texas (system)	2007 <sup>154</sup>	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 <sup>155</sup>	4	1	5
University of Michigan	2007	2	3	5
University of Washington	OS	3	3	5
		<b>51</b>	<b>37</b>	<b>102</b>

\* “OS” indicates an original signatory to the Nine Points document; “n/a” indicates an institution that has not signed the Nine Points document.

As shown in *Table 1*, two “top” academic licensors in our sample – Johns Hopkins and Columbia – are not Signatories to the Nine Points document. Of the remaining fourteen licensors, only the University of Pennsylvania is a licensor on agreements all of which were signed prior to its 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 large majority of Reviewed Agreements (215, 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 exclusive.<sup>156</sup> 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).

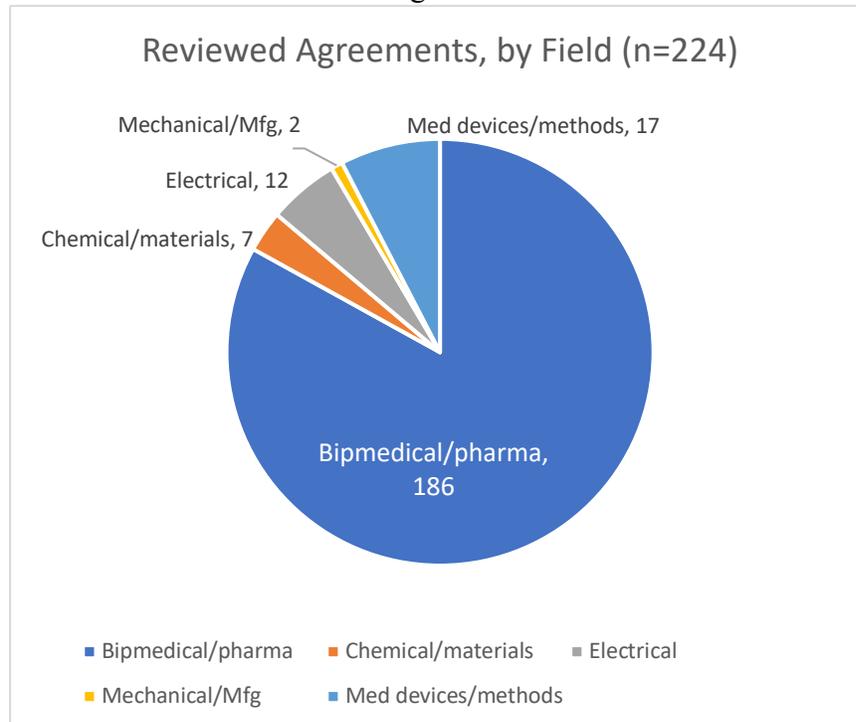
<sup>154</sup> The University of Texas Health Science Center, San Antonio and University of Texas Medical Branch each signed the Nine Points document in 2007 (though not as original Signatories). University of Texas, Austin signed the Nine Points document in 2011.

<sup>155</sup> The University of Massachusetts, Lowell signed the Nine Points document in 2008.

<sup>156</sup> See Lemley, *Trolls*, *supra* note 97, at 617 (“the overwhelming majority of university patent licenses are exclusive”).

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 (186, 83%) relate to technologies in the biomedical/biopharma field, including genetics and genomics. Approximately 8% (17) 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



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

As noted in Part III.A, we coded each Reviewed Agreement for occurrence or non-occurrence of each of the Recommended Clauses discussed in Part II.B. We then compared the total occurrences of each such Recommended Clause across all Reviewed Agreements before and after the 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 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. Descriptive statistics reflecting these results are contained in *Table 2* and graphically displayed in *Figure 6*. A discussion of the potential implications of these findings follows in Part IV.C, below.

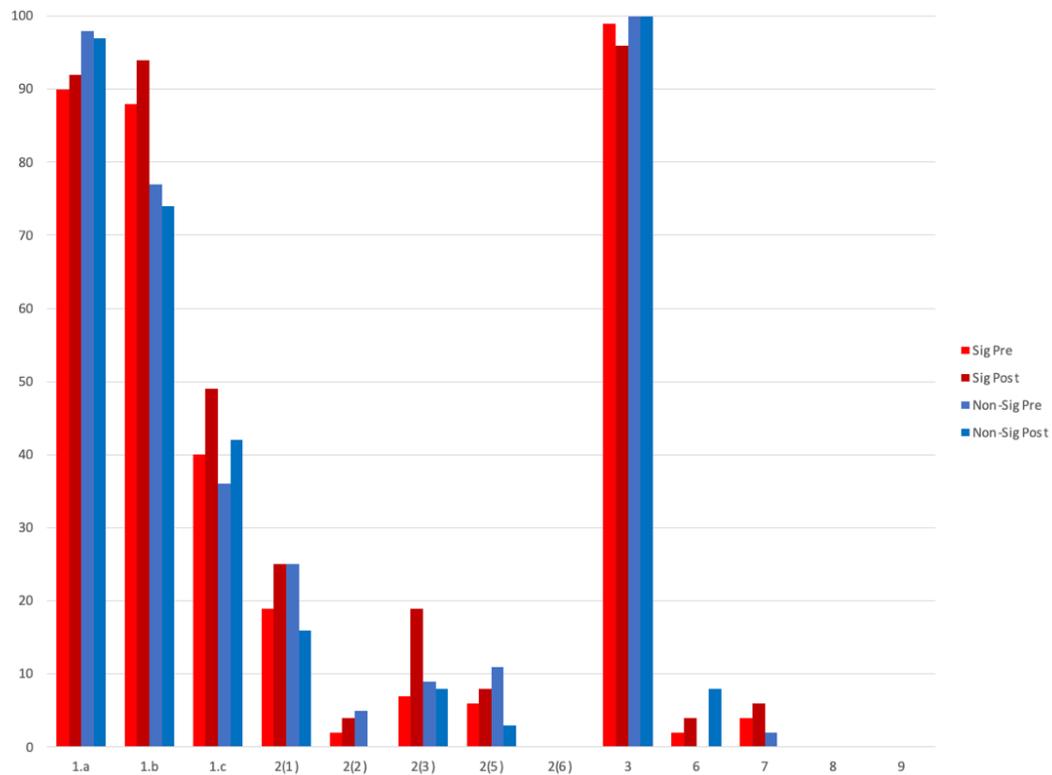
Table 2  
 Clause-by-Clause Comparison of Reviewed Agreements<sup>157</sup>

		N	1.a	1.b	1.c	2(1)	2(2)	2(3)	2(5)	2(6)	3	6.X	6	7	8	9
1	All	224	209	190	94	47	6	23	15	0	221	217	7	8	0	0
2	All %		93%	85%	42%	21%	3%	10%	7%	0%	99%	97%	3%	4%	0%	0%
3	All Pre-2007	120	112	102	49	26	4	8	9	0	119	116	2	5	0	0
4	%		93%	85%	41%	22%	3%	7%	8%	0%	99%	97%	2%	4%	0%	0%
5	All Post-2007	104	97	88	45	21	2	15	6	0	102	101	5	3	0	0
6	%		93%	85%	43%	20%	2%	14%	6%	0%	98%	97%	5%	3%	0%	0%
7	% Difference		0%	0%	2%	-2%	-1%	7%	-2%	0%	-1%	0%	3%	-1%	0%	0%
8	All Sigs	142	129	128	62	30	4	16	9	0	139	138	4	7	0	0
9	%		91%	90%	44%	21%	3%	11%	6%	0%	98%	97%	3%	5%	0%	0%
10	Sigs Pre-9P	89	80	78	36	17	2	6	5	0	88	86	2	4	0	0
11	%		90%	88%	40%	19%	2%	7%	6%	0%	99%	97%	2%	4%	0%	0%
12	Sigs Post-9P	53	49	50	26	13	2	10	4	0	51	52	2	3	0	0
13	%		92%	94%	49%	25%	4%	19%	8%	0%	96%	98%	4%	6%	0%	0%
14	% Difference		2%	6%	9%	6%	2%	12%	2%	0%	-3%	1%	2%	1%	0%	0%
15	All Non-Sigs	82	80	62	32	17	2	7	6	0	82	79	3	1	0	0
16	%		96%	75%	39%	20%	2%	8%	7%	0%	100%	95%	4%	1%	0%	0%
17	Non-Sigs Pre-9P	44	43	34	16	11	2	4	5	0	44	43	0	1	0	0
18	%		98%	77%	36%	25%	5%	9%	11%	0%	100%	98%	0%	2%	0%	0%
19	Non-Sigs Post-9P	38	37	28	16	6	0	3	1	0	38	36	3	0	0	0
20	%		97%	74%	42%	16%	0%	8%	3%	0%	100%	95%	8%	0%	0%	0%
21	% Difference		-1%	-3%	6%	-9%	-5%	-1%	-8%	0%	0%	-3%	8%	-2%	0%	0%
22	Change Diff. Sig v. Non-Sig		3%	9%	3%	15%	6%	13%	10%	0%	-3%	4%	-6%	3%	0%	0%
23	Rate Diff. Sig v. Non-Sig		-6%	15%	5%	1%	1%	3%	-1%	0%	-2%	2%	-1%	4%	0%	0%

<sup>157</sup> Recommended Clause 2(4) was not measurable (see below). Point 4 contains no Recommended Clauses. Point 5 is addressed together with Point 2.

Figure 6

Frequency of Recommended Clauses pre- and post-9 Points for Signatories and Non-Signatories



a. 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.

*b. Point by Point Results*

As shown in *Table 2* and *Figure 6*, the occurrence of Recommended Clauses in the Reviewed Agreements varies significantly. Below is a summary of the frequencies at which each Recommended Clause occurred and how these frequencies varied based on Nine Points signature status.

***Point 1 – Reserved Rights.*** The Recommended Clauses contained within Point 1 appear frequently in the Reviewed Agreements. Recommended Clause 1.a, in which a university retains the right to use an exclusively licensed technology for educational purposes, appeared in 209 of 224 Reviewed Agreements (93% [row 2]). The rate of occurrence is even higher (96%) when the seven non-exclusive agreements (as to which the clause is not relevant) are excluded.<sup>158</sup> This high rate of occurrence is comparable for both pre-Nine Points and post-Nine Points agreements (93% [rows 4, 6]). The rate is also comparable between Signatories and Non-Signatories to the Nine Points document. Clause 1.a appeared in 91% of Reviewed Agreements to which Signatories were parties [row 9] (96% when non-exclusive licenses are excluded from the total) and 96% of Reviewed Agreements to which non-Signatories were parties [row 16].

Recommended Clause 1.b (retained right for internal research purposes) also had high rates of adoption both before and after the Nine Points agreement (85%, rows 4, 6]). The rate of adoption of Recommended Clause 1.c (transfer of materials to academic/nonprofit labs) was approximately half that of the other Recommended

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<sup>158</sup> There were two co-exclusive agreements in our sample. Neither included the recommended Point 1 clauses. However, because such clauses are conceivably relevant in a co-exclusive (as opposed to a non-exclusive) license, it is not appropriate to exclude co-exclusive licenses from this count.

Clauses under Point 1, at 41% pre-Nine Points [row 4] and 43% post-Nine Points [row 6]. 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.<sup>159</sup>

Among Nine Points Signatories, the occurrence of all Point 1 Recommended Clauses increased slightly following adoption of the Nine Points document (2%, 6% and 9%, respectively [row 14]). Among non-Signatories, occurrence of Recommended Clauses 1.a and 1.b decreased slightly after the Nine Points Date, while use of Recommended Clause 1.c increased by 6% [row 21]. All of these changes are within the margin of error other than the 12% increase in the occurrence of Clause 1.c among Signatories.

The only significant difference in occurrence rates for Point 1 Recommended Clauses between Signatories and non-Signatories was in Clause 1.b, in which the Signatory occurrence rate (90% [row 9]) is 15 points [row 23] higher than the non-Signatory occurrence rate (75% [row 16]). The occurrence of Clauses 1.a and 1.c among Signatories each increased a net 3% after adoption of the Nine Points document when compared to the slight decrease among non-Signatories [row 22], which is within the margin of error. Only Clause 1.b shows comparative increased occurrence among Signatories in excess of the margin of error (9% [row 22]).

***Points 2 and 5 - Exclusivity.*** As discussed in Part II, we classified the twelve different Recommended Clauses made under Points 2 and 5 into six categories.

(1) *Milestone Penalties* – The Recommended Clauses in category 2(1) impose various penalties on exclusive licensees that do not meet certain commercialization milestones. Such penalties occurred in 21% of the Reviewed Agreements [row 2] at comparable rates pre- and post-Nine Points, and are generally associated with higher-value agreements in the biotechnology field. Occurrence rates for Signatories and non-Signatories were comparable (21% and 20%, respectively [rows 9 and 16]). Signatories increased usage of Clause 2(1) by 6% following execution of the Nine Points document [row 14], whereas usage among non-Signatories declined by 9% [row 21], resulting in a net increase among Signatories versus industry trends of 15% [row 22].

(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 3% of Reviewed Agreements [row 2].

(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. The clause occurred slightly more frequently among Signatories than non-Signatories (11% vs 8% [rows 9 and 16]), and saw a 12% increase among Signatories following adoption of the Nine Points document [row 14], with no

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<sup>159</sup> CONTRERAS, LICENSING AND TRANSACTIONS, *supra* note x, at Ch. 14.E.

meaningful change among non-Signatories [row 21]. This is one of the few detectable, if small, effects that may be attributable to the Nine Points document.

(4) *Research Tools* – Point 2 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 in our sample. Because our textual coding methodology was not suited to determine whether the rights granted under any particular Reviewed Agreement related to a broadly applicable research tool, it was not possible to determine how frequently research tools were licensed on a non-exclusive basis.

(5) *Education* – Recommended Clause 2(5) excludes from exclusive license grants the ability of third parties to use the licensed rights for educational purposes (beyond the reservation for internal university educational purposes provided in Recommended Clause 1.a). This clause appeared in 7% [row 2] of Reviewed Agreements at comparable rates for Signatories and non-Signatories. There was no discernable change in Signatory occurrences post-Nine Points [row 14], though the rate of non-Signatory occurrences dropped by 8% [row 21].

(6) *Quality Control* - Recommended Clause 2(5) 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.

**Point 3 – Improvements.** The Recommended Clauses under Point 3 limit a licensee’s rights in technology improvements made by the university. At least one of these clauses appeared in 99% of Reviewed Agreements at comparable rates pre- and post-Nine Points and among Signatories and non-Signatories.

**Point 5 – Research Tools.** See Point 2 above.

**Point 6 – 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% [row 2] 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 and among Signatories and non-Signatories.

**Point 7 – Export Controls.** Recommended Clause 7 requires licensees to comply with applicable export laws and regulations. This clause appeared in only 4% [row 2] of Reviewed Agreements.

**Point 8 – Patent Assertion Entities.** 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.

**Point 9 – Access to Medicines.** Recommended Clause 9 ensures that underprivileged populations have low- or no-cost access to adequate quantities of licensed medical innovations. This clause occurred in no 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 Part 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 of the National Academies undertook a formal study of “the organization, functioning, and effects of university technology transfer activities involving formal intellectual property rights.”<sup>160</sup> The committee, which included at least two participants from the 2006 Stanford meeting,<sup>161</sup> 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.<sup>162</sup>

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.”<sup>163</sup> 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.”<sup>164</sup>

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<sup>160</sup> NRC University Report, *supra* note 14.

<sup>161</sup> David Korn (Harvard) and Katherine Ku (Stanford). See NRC University Report, *supra* note 14, at vi.

<sup>162</sup> See NRC University Report, *supra* note 14, at 6-7.

<sup>163</sup> AAU Statement, *supra* note 15, at 3.

<sup>164</sup> APLU Task Force on Managing University Intellectual Property, Statement to APLU Members of Recommendations on Managing University Intellectual Property, Mar. 2015, at 2.

## 2. Socially Responsible Licensing

Following the release of the Nine Points document, several universities, encouraged by a range of constituents including the student group UAEM,<sup>165</sup> continued to refine and expand their positions regarding the licensing of health-related technologies in the developing world. This effort led to the release 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 Signatories (Boston University, Oregon Health & Science University and University of Pennsylvania), one non-Signatory (Brown University) and AUTM.<sup>166</sup> 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.”<sup>167</sup>

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”,<sup>168</sup> 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)”,<sup>169</sup> some of which echo those of the Nine Points document, and others that go beyond it. Though the study described in this article 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.”<sup>170</sup> We are not aware of publicly available information indicating that these ongoing commitments have been followed in a systematic or collective manner, though individual

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<sup>165</sup> Six Universities Adopt New Technology Transfer Principles Designed to Speed Access to Affordable Medicines in the Developing World, YaleNews, Nov. 9, 2009.

<sup>166</sup> Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (2009) [hereinafter 2009 Statement].

<sup>167</sup> 2009 Statement, *supra* note 166, at 1.

<sup>168</sup> 2009 Statement, *supra* note 166, at 2.

<sup>169</sup> 2009 Statement, *supra* note 166, at 3.

<sup>170</sup> 2009 Statement, *supra* note 166, at 4.

universities may have sought to address one or more of these commitments individually.<sup>171</sup>

Interestingly, University of California Berkeley, which was an early leader in socially responsible licensing (see Part 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.<sup>172</sup> 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 and 2009 Statement signatories, each of which had a more or less formal socially responsible licensing policy.<sup>173</sup>

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 Broad were criticized for granting broad, exclusive licenses of their CRISPR technology to privately held “surrogate” companies unbounded by the public missions of the universities.<sup>174</sup> 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.<sup>175</sup> This form of public-minded exclusion has been termed “ethical licensing”.<sup>176</sup>

The Covid-19 pandemic also prompted some universities to liberalize their licensing programs with respect to Covid-related technologies. On April 7, 2020, Harvard, MIT and Stanford announced a “COVID-19 Technology Access Framework” that reflects the sentiments of Point 9 of the Nine Points document.<sup>177</sup>

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<sup>171</sup> See, e.g., Tania M. Bubela & Timothy Caulfield, *Role and reality: technology transfer at Canadian universities*, 28 TRENDS IN BIOTECH. 447 (2010) (discussing non-financial metrics used to assess TTO at one Canadian university).

<sup>172</sup> See, e.g., Carol Mimura, Julie Cheng, & Braden Penhoet, *Socially Responsible Licensing, Euclidean Innovation, and the Valley of Death*, STAN. J. L. SCI. & POLICY, Sept. 2011; Carol Mimura, *Nuanced Management of IP Rights: Shaping Industry-University Relationships to Promote Social Impact*, in WORKING WITHIN THE BOUNDARIES OF INTELLECTUAL PROPERTY (Rochelle Dreyfuss, Harry First, Diane Zimmerman, eds., 2010).

<sup>173</sup> Nguyen, et al. *supra* note 25.

<sup>174</sup> See Contreras & Sherkow, *supra* note 22.

<sup>175</sup> See Christi J. Guerrini et al., *The rise of the ethical license*, 35 NATURE BIOTECHNOLOGY 22 (2017).

<sup>176</sup> *Id.*

<sup>177</sup> *COVID-19 Technology Access Framework*, STAN. OFF. TECH. LICENSING, <https://otl.stanford.edu/covid-19-technology-access-framework> (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

As of October 2021, twenty additional U.S. research institutions and one non-U.S. university had also adopted this commitment.<sup>178</sup> The licenses to be granted under the Framework are 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.<sup>179</sup> These 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.” 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.” As of October 2021, nearly one hundred institutions had adopted these Guidelines, though it is not clear from publicly-available information whether, and to what degree, such commitments led to any particular licensing agreements.

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

Notwithstanding the Nine Points 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.<sup>180</sup> It achieved an early \$110 million settlement with Intel, then an attention-grabbing damage award of \$506 million against Apple.<sup>181</sup> The case prompted numerous outlets again to ask whether WARF is, indeed, a patent troll.<sup>182</sup> But WARF is not alone. In 2020,

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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.”)

<sup>178</sup> The same number of universities appeared in January 2021, suggesting that adoption of the Framework has more or less ceased.

<sup>179</sup> Assn. Univ. Tech. Managers, <https://autm.net/about-tech-transfer/covid19/covid-19-licensing-guidelines>

<sup>180</sup> See Valdivia, *supra* note 130.

<sup>181</sup> Wisconsin Alum. Res. Fdn. v. Apple, Inc., Case No. 14-cv-062-wmc (W.D. Wis., Jul. 25, 2017).

<sup>182</sup> See, e.g., *Is WARF trolling Apple?*, UIC REV. INTELL. PROP. L., Oct. 24, 2015, <https://ripl.law.uic.edu/news-stories/is-warf-trolling-apple/>; Laurel White, *'Is WARF a patent troll?' and four other questions about the Apple vs. WARF lawsuit, answered*, CAPITAL TIMES, Oct. 15,

CalTech won a \$1.1 billion award against Apple and Broadcom for Wi-Fi related patents,<sup>183</sup> and recently asserted the same patent against Samsung.<sup>184</sup>

Recent literature suggests that university-initiated patent litigation has increased since the adoption of the Nine Points document.<sup>185</sup> In a 2011 study, Professor Jacob Rooksby found that during 2009 and 2010 alone, thirty-three different universities had initiated patent infringement lawsuits.<sup>186</sup> In a 2020 study, Professors Teo Firpo and Michael Mireles found that, between 2000 and 2014, Boston University and CalTech, both Nine Points Signatories, initiated around forty patent infringement suits each, and that, in general, such suits are on the rise.<sup>187</sup> 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.”<sup>188</sup>

With respect to the relationship between universities and PAEs, several post-Nine Points 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.<sup>189</sup> Two more recent studies observe significant rates of patent sales by universities to PAEs.<sup>190</sup> This trend has caused

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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://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).

<sup>183</sup> See Susan Decker, Ian Lopez & Matthew Bultman, *Caltech wins a \$1.1-billion patent verdict against Apple and Broadcom*, BLOOMBERG, Jan. 30, 2020.

<sup>184</sup> See Andrew Karpan, *Caltech Sues Samsung After \$1B Apple Patent Win*, LAW360, Dec. 3, 2021.

<sup>185</sup> 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 309, 309 n.1 (Jacob H. Rooksby ed., 2020) (collecting academic literature); Stan Gibson, *A Snapshot of University Patent Litigation*, PATENT LAWYER BLOG, Dec. 11, 2015, <https://patentlaw.jmbm.com/2015/12/a-snapshot-of-university-paten.html>; Andrew Chung, *Schools that sue: Why more universities file patent lawsuits*, REUTERS, Sept. 15, 2015, <https://www.reuters.com/article/university-patents/schools-that-sue-why-more-universities-file-patent-lawsuits-idUSL1N11G2C820150915>.

<sup>186</sup> Jacob H. Rooksby, *University Initiation of Patent Infringement Litigation*, 10 J. MARSHALL REV. INTELL. PROP. L. 623, 660 (2011).

<sup>187</sup> Firpo & Mireles, *supra* note 185, at 316-17.

<sup>188</sup> Firpo & Mireles, *supra* note 185, at 318.

<sup>189</sup> Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1 (2012). 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).

<sup>190</sup> 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 256, 266 (Jacob H. Rooksby ed., 2020) (“the vast majority of acquisitions [of patents from universities] appear to have been made with patent assertion in mind”); Stefanie Fusco et al., *Monetization Strategies of University Patents through PAEs: an Analysis of US Patent Transfers*,

AUTM to reconsider its position on universities transferring patents to PAEs notwithstanding the guidance contained in the Nine Points document.<sup>191</sup>

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 signatories of the Nine Points document, that proposed a new patent pool.<sup>192</sup> 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.<sup>193</sup> 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.”<sup>194</sup>

#### 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 signed in 2007. Beginning in 2016, the U.S. government has added numerous Chinese universities to its list of restricted entities to which sensitive information cannot be disclosed.<sup>195</sup> 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 indicted for

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2019 ISSI Conference Proceedings (2019) (identifying 326 patents transferred by universities to PAEs during preceding ten years).

<sup>191</sup> See Paul Basken, *Under Financial Pressure, Universities Give Patent Buyers a Closer Look*, CHRON. HIGHER ED., Oct. 25, 2013 (quoting AUTM’s President).

<sup>192</sup> Letter from Michael F. Murray, Acting Principal Deputy Assistant Attorney General, U.S. Dept. Justice Antitrust Division, to Garrard R. Beene, Sullivan & Cromwell, dated Jan. 23, 2021 [hereinafter UTLP Review Letter]. The requesting 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. *Id.*

<sup>193</sup> Letter from Garrard R. Beene, Sullivan & Cromwell, to Makan Delrahim, Assistant Attorney General, Antitrust Division, Department of Justice, dated Aug. 14, 2020 at 2 [hereinafter UTLP Request Letter].

<sup>194</sup> Joe Mullin, *15 Universities Have Formed a Company That Looks a Lot Like a Patent Troll*, Jun. 10, 2020, <https://www.eff.org/deeplinks/2021/06/15-universities-have-formed-company-looks-lot-patent-troll> (accessed Oct. 1, 2021) (“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.”).

<sup>195</sup> Yojana Sharma, *US export controls raise research collaboration concerns*, UNIVERSITY WORLD NEWS, Jun. 25, 2019.

failing to disclose on a visa application that she was a lieutenant in the Chinese army.<sup>196</sup> 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.<sup>197</sup> These highly-publicized incidents confirm that export control issues remain important to universities.

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

This Part IV addresses the implications of the findings presented in Part 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 Part 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.<sup>198</sup> 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.<sup>199</sup> 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 include some of the largest universities and medical research centers in the United States.

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<sup>196</sup> See Kate O’Keeffe & Aruna Viswanatha, *Chinese Military Turns to U.S. University to Conduct Covert Research*, WALL ST. J., Feb. 23, 2020.

<sup>197</sup> U.S. Dept. Justice, *University Researcher Sentenced to Prison for Lying on Grant Applications to Develop Scientific Expertise for China*, May 14, 2021.

<sup>198</sup> See, e.g., Contreras, *Open COVID*, *supra* note 21, at \*69 (discussing Open COVID Pledge and “initial burst of interest, followed by a steady decline in new pledge commitments”); Jorge L. Contreras, Bronwyn H. Hall & Christian Helmers, *Pledging Patents for the Public Good: Rise and Fall of the Eco-Patent Commons*, 57 HOUSTON L. REV. 61, 73-76 (2019) (group formed in 2008 gained strong initial support, with modest increases through 2011, after which no new members joined, and was discontinued in 2016).

<sup>199</sup> See Contreras, *Open COVID*, *supra* note 21, at \*69 (“entities 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*  
*Top 25 U.S. Academic Institutions by 2020 Gross Licensing Income and Signature Status*

Institution	2020 Gross Licensing Income <sup>200</sup>
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	\$58,695,546
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

Green = Signatory

Rose = Non-Signatory

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.<sup>201</sup> The 75 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,<sup>202</sup> a tiny fraction of the total world industrial base, and the Open COVID Pledge, a similar commitment with respect to technologies relevant to COVID-19, attracted 32 patent holders.<sup>203</sup> Even the Harvard-MIT-Stanford COVID-19

<sup>200</sup> AUTM 2020 Survey, *supra* note 1.

<sup>201</sup> AUTM 2020 Survey, *supra* note 1.

<sup>202</sup> Contreras et al., *Eco-Patent*, *supra* note 198, at 73-76.

<sup>203</sup> Contreras, *Open COVID*, *supra* note 21, at \*68.

Technology Access Framework, aimed specifically at research universities, has attracted only twenty-four signatories since its inception in April 2020.<sup>204</sup>

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 requires its participants to commit to make 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 are themselves heterogeneous. Though the Nine Points document is framed in terms of the “public interest”, several of its Recommended Clauses largely benefit university licensors. For example, Clauses 1.a and 1.b can be included in an exclusive licensing agreement to preserve a university’s right to conduct internal research and educational activities. While there may be some public benefit arising from allowing such research and educational activities to continue, the primary and most direct beneficiary of such clauses appears to be the university itself. Likewise, the clauses in category 2(1) give the university flexibility to replace 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 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, this recommendation could tend to reduce university revenue in favor of serving the public interest in broad availability of research tools. Likewise, Point 9, relating to increasing the availability of health-related technologies for underserved populations, has the public interest as its primary focus, with associated goodwill and reputational benefits to the university playing a secondary role.

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

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<sup>204</sup> Stanford Univ., Harvard Univ. Mass. Inst. Tech., COVID-19 Technology Access Framework, <https://otl.stanford.edu/covid-19-technology-access-framework> (visited Sept. 18, 2021). *See also* Contreras, *Open COVID*, *supra* note 21, at \*73-74 (discussing low uptake of Harvard-MIT-Stanford framework). Notably, Memorial Sloan Kettering Cancer Center, a major holdout from the Nine Points document (see Table 1), has adopted the COVID-19 Technology Access Framework.

the same token, the public also stands to benefit from a reduction in conflicts of interest among university personnel and university licensees.

Nevertheless, at a high level, it is possible to estimate, for each Recommended Clause, whether it principally benefits the university through reduced risk, increased flexibility, or higher revenue, or whether it principally benefits the public through broader access to technology or lower costs, usually at some direct cost or foregone opportunity to the university. *Table 4* offers an assessment of the primary beneficiary of each of the Nine Points Recommended Clauses.

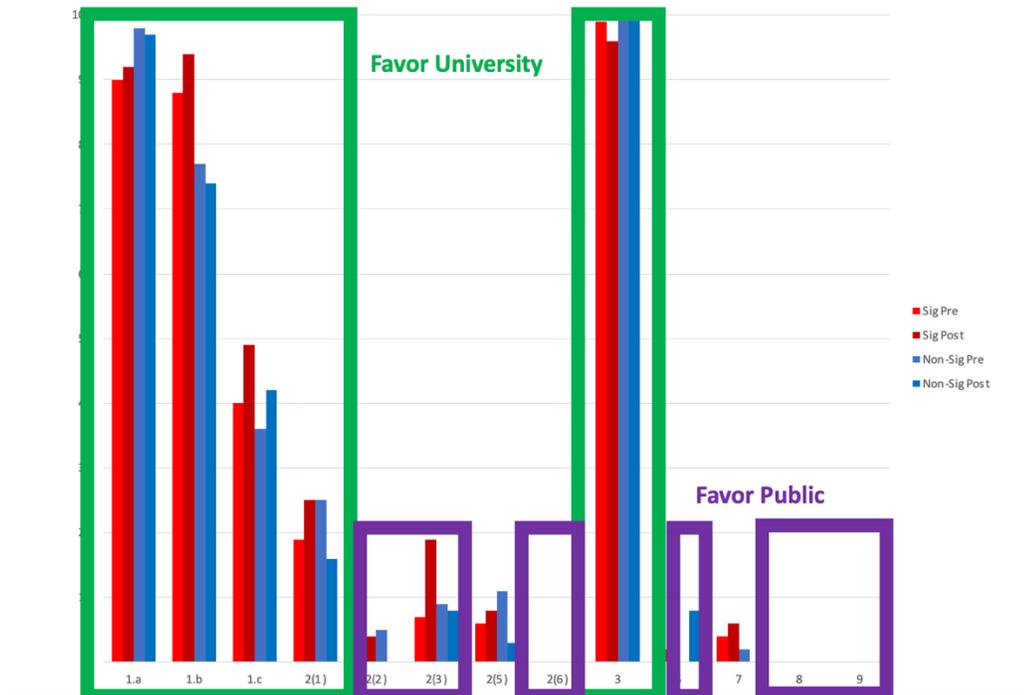
*Table 4*  
*Primary Beneficiaries of the Nine Points Recommended Clauses*

Point	Description	Primary beneficiary
1.a	University reserved right for education	university
1.b	University reserved right for research	university
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 evenly split in the Nine Points document, with eight groups of clauses in each such category. This breakdown is graphically illustrated in *Figure 7*, which overlays the classification of clauses as benefitting universities or the public against the frequency with which such clauses occurred among the Reviewed Agreements.

Figure 7

Frequency of Recommended Clauses pre- and post-9 Points



C. Occurrence of Recommended Clauses

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

a. Correlation with University Benefit

As suggested by *Figure 7*, university licenses are most likely to include Recommended Clauses that benefit the university and less likely to include Recommended Clauses that benefit the public. That is, those Recommended Clauses with the highest incidence benefit the university, while those with the lowest incidence benefit the public. It is not difficult to understand this result. Like all negotiating parties, universities draft licensing agreements to benefit themselves. Clauses that may benefit the public at some cost to the university appear to be less desirable and are thus far less frequent.

Only two university-favorable clauses had low occurrence rates. These were Clause 2(5), which excludes from a licensee’s exclusivity the university’s right to license others to use the licensed rights for educational purposes, and Clause 7, which requires a licensee to comply with applicable export regulations. One reason that Clause 2(5) may occur infrequently is that there is a low perceived need for it.

Clause 1.a, with the highest overall occurrence rate, already permits a university to use an exclusively licensed technology for its own educational purposes, a right that appears to be important to most universities. But authorizing a third party to conduct educational activities may be a less common requirement, and may also be more objectionable to potential licensees.

Clause 7, on the other hand, is a legally superfluous clause. It 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.<sup>205</sup>

The foregoing calculus equates benefit with financial gain. Other constructions of benefit are, of course, possible. For example, Dr. Momura explains that in Berkeley’s SRLP, “social impact is valued as strongly as other outcomes such as licensing revenue.”<sup>206</sup> 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. Yet these considerations do not appear to have had much impact on the occurrence of Recommended Clauses, even in licensing agreements to which the University of California is a party (see *Table 5*).

*Table 5*  
*University of California versus Overall Occurrences*

Point	Description	Primary beneficiary	Total Frequency (n=224)	UC Frequency (n=16)
1.a	University reserved right for education	university	93%	94%
1.b	University reserved right for research	university	85%	100%
1.c	University right to transfer materials	university	42%	69%
2(1)	Milestone penalties	university	21%	13%
2(2)	Public health/medical use	public	3%	0%
2(3)	Exclusive sale but not use	public	10%	13%
2(5)	Third party education and training	university	7%	6%
2(6)	Quality control	public	0%	0%
3	Licensing of future improvements	university	99%	94%
6	Consent to enforcement	public	3%	0%
7	Export regulations	university	4%	0%
8	Working with patent aggregators	public	0%	0%
9	Availability of medical innovations	public	0%	0%

<sup>205</sup> See CONTRERAS, LICENSING AND TRANSACTIONS, *supra* note 65, at 361 (“While a contractual commitment such as the one above 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.”)

<sup>206</sup> Momura, *supra* note x, at 17.

b. *Minimal Effect on Agreement Text*

In most cases, the creation and signature of the Nine Points document had little or no measurable impact on the text of university licensing agreements with either Signatories or non-Signatories. That is, for both frequent and infrequent Recommended Clauses, occurrence rates were comparable both pre- and post-Nine Points. Additionally, as illustrated by the example of University of California (Table 6), there were no discernable patterns in the occurrence of Recommended Clauses even among agreements signed by the same university licensor (i.e., the sixteen universities that were parties to five or more Reviewed Agreements), whether that university was a Signatory or a non-Signatory. These observations suggest that university TTO officers drafting and negotiating licensing agreements did not overhaul or add particular clauses to their licensing agreements in response to the adoption of the Nine Points document.<sup>207</sup> In large part, they continued doing what they were already doing.

This observation runs counter to various statements made by TTO officials when commenting on the Nine Points document and similar policy statements. For example, Nguyen et al. interviewed TTO officials at several universities and were told that once they created socially responsible licensing programs, contractual terms promoting socially responsible licensing practices were regularly incorporated into licensing agreements.<sup>208</sup>

D. *Discussion and Analysis*

Given the prominence of the Nine Points document and its broad adoption by the academic community, it is worth considering why its Recommended Clauses were adopted so infrequently in university licensing agreements and the other trends observed in university technology transfer have continued notwithstanding the aspirational statements in the Nine Points document.

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<sup>207</sup> One minor exception may be Clause 2(3), the “exclusive sale but not use” limitation, the occurrence rate of which increased slightly (12%) among Signatories after the signing of the Nine Points document, with no corresponding increase among non-Signatories. This is the only Recommended Clause, the occurrence of which increased meaningfully following signature of the Nine Points document. There are several possible explanations for this modest increase in usage. First, the clause is somewhat innovative. It seeks to achieve a public-oriented goal through a subtle adjustment of the scope of the license grant. By eliminating the licensee’s exclusivity on the use of a patented technique, the lack of exclusivity enables others to utilize that technique, either by creating their own process or using one obtained from an unlicensed source. At the same time, it ensures that the only authorized vendor of, say, test kits embodying the invention, is the licensee. Such a clause would generally be undesirable for commercial licensees, so a university’s inclusion of the clause would work against its own financial interest. Thus, while the rate of occurrence of Clause 2(3) increased among Signatories following their signing the Nine Points document, the overall rate of occurrence [19%] remains modest.

<sup>208</sup> See Nguyen, et al. *supra* note 25, at 193, Table 2 (statements by Harvard and Yale representatives).

### 1. *Alternative Routes to Achieving Nine Points Goals*

The absence of the Nine Points Recommended Clauses in university licensing agreements need not suggest a disregard for the principles espoused in the Nine Points document. Rather, it is possible that universities have incorporated into their licensing agreements clauses 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 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.<sup>209</sup> 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. Thus, our results do 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.<sup>210</sup>

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 wholly unrealistic recommendation of Point 8 – a university could choose not to license its intellectual property to entities known to be PAEs.

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<sup>209</sup> See, e.g., Nguyen, et al. *supra* note 25, at 194.

<sup>210</sup> This approach was advocated by the 2009 Statement, *supra* note x, at 2 (“Early publication and wide dissemination of results will be encouraged to reduce opportunities for interfering patents”) and some universities, Nguyen, et al. *supra* note 25, at 196, Table 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 Durvasula, Lisa Larrimore Ouellette & Heidi Williams, *Private and Public Investments in Biomedical Research*, 111 AEA PAPERS & PROCEEDINGS 341, 344 n.12 (2021).

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 Part III.B.3, 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 agree to do so. 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 undeniably 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.

For all of these reasons, the presence or absence of particular Nine Points Recommended Clauses may not tell the entire 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 act in a largely self-interested manner, adopting licensing provisions that benefit them and doing little to adopt provisions intended to benefit the public, this may not always be the case.

## 2. *Commercialism and TTOs*

While university research 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 numerical factors.<sup>211</sup> 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.<sup>212</sup> To the extent that TTO personnel

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<sup>211</sup> See AUTM 2020 Survey, *supra* note 1.

<sup>212</sup> Assn. Univ. Tech. Managers, 2017 AUTM Salary Survey 85 (2018) (39 of 172 responding institutions reported having an incentive compensation scheme, representing an increase of 33% over the prior biennial survey).

are personally remunerated for revenue-based achievements, then it is no surprise that revenue generation has become a primary goal of some TTOs.<sup>213</sup>

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 examples of promotional materials targeted at TTO personnel indicating the types of skills that they should seek to gain:

Though marketing expertise is sorely lacking at most TTOs, the good news is that marketing skills can be taught, practiced, and perfected. By making a small investment in these 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.<sup>214</sup>

Keen attention to detail can prepare you for more successful royalty audits ... [A] well-run royalty audit can potentially add hundreds of thousands of dollars in revenue to your bottom line.<sup>215</sup>

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<sup>216</sup>

Interestingly, even the federal government appears to have embraced this commercial approach to university licensing. One recent seminar for TTO personnel was titled “Marketing University Innovations: Strategies to Revitalize and Expand a High-Touch, Low-Tech Approach that Gets Results” and was led by a Senior Technology Transfer Manager from the National Cancer Institute.<sup>217</sup>

<sup>213</sup> See, e.g., Tech Transfer Central, Non-Monetary Metrics that Every TTO Should be Tracking: Measuring Your Collaborative Culture (promotional email received by the author on 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”).

<sup>214</sup> Tech Transfer Central, Marketing Boot Camp for university TTOs -- on-demand and share-able so you can build skills amongst your entire staff (promotional email received by the author on Dec. 6, 2021 – on file with author).

<sup>215</sup> Tech Transfer Central, Technology Transfer Tactics, September 2021, <https://techtransfercentral.com/category/technology-transfer-tactics/>.

<sup>216</sup> Tech Transfer Central, A how-to guide to calculating royalty rates in technology licensing (promotional email received by the author on Dec. 2, 2021 – on file with author).

<sup>217</sup> Tech Transfer Central, Marketing University Innovations: Strategies to Revitalize and Expand a High-Touch, Low-Tech Approach that Gets Results

When Arthur Bienenstock convened the Stanford meeting in 2006, he 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.

### 3. *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, the industry trade association comprised largely of TTO personnel.<sup>218</sup> Though AUTM originally supported the Nine Points document,<sup>219</sup> that support has gradually waned and, by 2013, leadership of the organization was actively backpedaling on certain commitments made in the document.<sup>220</sup>

AUTM's advocacy efforts have increasingly sought to strengthen patent rights and to 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,<sup>221</sup> (b) opposing the World Trade Organization's proposed waiver of trade penalties against nations that issue compulsory licenses relating to Covid-19 vaccines,<sup>222</sup> and (c) advocating for the restoration of U.S. patent protection for products of nature, natural laws and mental activities.<sup>223</sup>

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<https://techtransfercentral.com/marketplace/distance-learning/marketin...vitalize-and-expand-a-high-touch-low-tech-approach-that-gets-results/> (visited Oct. 21, 2021).

<sup>218</sup> 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 131 (Jacob H. Rooksby ed., 2020).

<sup>219</sup> See note 148, *supra*.

<sup>220</sup> See note 191, *supra*, and accompanying text (discussing reduction of AUTM's opposition to the transfer of patents to PAEs).

<sup>221</sup> Assn. Univ. Tech. Managers, AUTM's Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327) (Mar. 28, 2021).

<sup>222</sup> Assn. Univ. Tech. Managers, Patent Waiver Strikes Damaging Blow to the Future of Innovation (May 6, 2021).

<sup>223</sup> Assn. Univ. Tech. Managers, AUTM's Comments on USPTO's Patent Eligibility Jurisprudence Study (Docket Number: PTO-P-2021-0032) (Oct. 14, 2021).

AUTM has been joined in these advocacy efforts by other higher education associations,<sup>224</sup> as well as individual universities.<sup>225</sup> In 2021, AUTM, together with various trade associations and universities, formed the Bayh-Dole Coalition, an advocacy group devoted to “protecting the Bayh-Dole Act and educating policymakers about the positive impacts of the law”.<sup>226</sup> 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 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).<sup>227</sup> But in 2014 AUTM hired a full-time executive director (also answerable to the Board),<sup>228</sup> giving the organization a more consistent and coherent policy platform and the bandwidth to engage regularly in advocacy activities perceived to benefit its membership.<sup>229</sup>

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

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<sup>224</sup> See, e.g., Association of American Universities, Association of Public and Land-grant Universities, Council on Governmental Relations, American Council on Education, Association of American Medical Colleges, Joint Association Comments on 37 CFR Parts 401 and 404 (Docket ID Number: 201207-0327) (Apr. 5, 2021), [https://www.cogr.edu/sites/default/files/JointAssociationComments\\_NIST%20NPRM.pdf](https://www.cogr.edu/sites/default/files/JointAssociationComments_NIST%20NPRM.pdf) [hereinafter University Coalition Comments] (supporting exclusion of pricing considerations from the exercise of march-in rights under the Bayh-Dole Act).

<sup>225</sup> 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 at <https://www.keionline.org/354320>).

<sup>226</sup> Bayh-Dole Coalition, About, <https://bayhdolecoalition.org/about/#members> (visited Dec. 19, 2021).

<sup>227</sup> Hayter & Rooksby, *supra* note 218, at 140-41.

<sup>228</sup> *Id.* at 140.

<sup>229</sup> The following table shows the number of public policy statements issued by AUTM from 2014 to 2021 as listed on the AUTM website, <https://autm.net/about-tech-transfer/advocacy/autm-speaks-out/>

Year	Advocacy Documents
2014	1
2015	2
2016	1
2017	4
2018	5
2019	9
2020	7
2021	11

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 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<sup>230</sup> -- 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?

In contrast, 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 incident<sup>231</sup> and the continuing efforts of UAEM to nudge universities toward greater public accountability,<sup>232</sup> 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 Stanford meeting, 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.

Yet the author is not aware of any universities that have implemented formal institutional mechanisms for fashioning technology transfer policy in a multilateral manner or which seek input from interested stakeholder groups beyond the TTO. Constituting such multilateral decisionmaking bodies and empowering them to guide university policy concerning technology transfer could help to redirect those policies away from purely commercial considerations and more toward the public interest goals espoused by the Nine Points document.

In short, 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

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<sup>230</sup> [add citations]

<sup>231</sup> See notes x, *supra*, and accompanying text.

<sup>232</sup> See notes x, *supra*, and accompanying text.

of American Medical Colleges (AAMC) could take a more active role in public policy debates over these issues, rather than simply following the lead of AUTM.<sup>233</sup>

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

If universities have largely failed to adopt the recommendations of the Nine Points document and to adhere to its basic principles, 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 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.”<sup>234</sup> 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 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.<sup>235</sup>

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. If the Nine Points document is less than perfect, and if it has failed to live up to its 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 Part 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 smörgåsbord 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

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<sup>233</sup> See, e.g., University Coalition Comments, *supra* note 224.

<sup>234</sup> Winickoff, *supra* note 13, at 32.

<sup>235</sup> See, e.g., Contreras, *Open COVID*, *supra* note 21, at x (discussing potentially self-interested patent pledges by Fortress and Moderna); Jorge L. Contreras, *Patent Pledges*, 47 ARIZONA ST. L.J. 543, 588-90 (2015) (discussing voluntary commitments made to refrain from asserting patents in order to avert governmental action).

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 its title, most references to the Nine Points document are directed to Point 9 concerning equitable access to medicines.<sup>236</sup> 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 discourse. Likewise, discussions of university patent enforcement and transactions with PAEs have largely evaporated as it has become increasingly clear that universities can earn gigantic windfalls by enforcing patents in litigation without significant public backlash.<sup>237</sup>

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. The Nine Points document (at least Point 9) 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 224 university licensing agreements is slightly greater than one percent of the total estimated 20,000 university licensing agreements that have been signed during the period studied, resulting in a margin of error of 7%. A larger sample would produce more robust results.

More importantly, as described in Part II.A, the large majority of Reviewed Agreements were obtained from the Securities and Exchange Commission (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.<sup>238</sup> As a result, such agreements necessarily exclude licenses granted to non-U.S. entities,

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<sup>236</sup> [citations]

<sup>237</sup> See notes x, *supra*, and accompanying discussion.

<sup>238</sup> See notes x, *supra*, and accompanying discussion.

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 remain privately held (e.g., some PAEs). The exclusion of these agreement 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.

Additionally, like most studies of contractual terms, this study was limited to the review of executed agreements. This study 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 and 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 suggests that the Nine Points document prompted few measurable changes in university licensing practices. Universities largely continued to include in their licensing agreements the contractual clauses that they had previously included, and did not, to any meaningful degree, add new clauses recommended by the Nine Points document. To the extent they did, such clauses largely protected university interests rather than

the public interest. Nor did many universities heed the recommendations made by the Nine Points document regarding their own behavior, whether relating to patent enforcement, interaction with PAEs or attention to export regulations. In fact, since 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, exist for 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, for the first time, announced to the world that research universities collectively considered their role to be one of stewardship of publicly funded technology. The lackluster adoption of the recommendations made by the Nine Points document suggests that, by and large, universities have prioritized commercial interests over the public-oriented goals of the document. As such, 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

## Reviewed Agreements

Licensors	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	GlobelImmune, 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
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

Licensors	Licensee	Date
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
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
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	Collective Therapeutics, Inc.	21-Sep-04

Licensors	Licensee	Date
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 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
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

Licensors	Licensee	Date
Cold Spring Harbor Laboratory	RXi Pharmaceuticals Corp.	15-Mar-07
<b>NINE POINTS DOCUMENT SIGNED</b>		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
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
University of Chicago	Raindance Technologies, Inc.	9-Jun-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

Licensors	Licensee	Date
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
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
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	Electroplate, Inc.	1-Oct-14
Duke University	Editas Medicine, Inc.	10-Oct-14
University of Minnesota	Regenxbio, Inc.	10-Nov-14
University of Minnesota	Cellectis Plant Sciences	15-Dec-14
University of Texas	Lung Therapeutics, Inc.	8-Jul-15

Licensors	Licensee	Date
University of Florida	Audentes Therapeutics, Inc.	28-Jul-15
Cold Spring Harbor Laboratory	Asothera Pharmaceuticals, Inc.	31-Jul-15
Stanford University	Epionomics	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