# DECONSTRUCTING THE MTA PROCESS TO FOSTER SHARED INNOVATIVE ACTIVITY IN ACADEMIC SCIENCE

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#### ABSTRACT

This Article examines the interaction between patent law, contract law, and academic science. Emerging literature suggests that academic science is at an all-time high but that barriers remain in place preventing the full realization of the increased innovation. This Article will address two specific barriers negatively affecting academic science: the deterioration of the sharing ethos in universities, teaching hospitals, and research laboratories, and the increase in complexity and volume of material transfer agreements (MTAs). These are interrelated: as the sharing ethos decreases, the number of MTAs increases. Conversely, if the MTA process becomes less demanding then shared innovative activity in academic science is better supported. The so-called "open science" culture, which has largely disappeared in the last twenty or so years, will be one step closer to a current practice in academic science.

Accordingly, this Article seeks to reinvigorate the sharing ethos by deconstructing the MTA process to better understand the deal-breaking and non-collaborative terms, both in academic-to-academic transfer and academic-to-industry or industry-toacademic transfer. Through careful analysis of MTAs for materials, research tools, and data, three particularly sticky aspects of the negotiation of MTAs are identified: ownership of any resulting IP, indemnification, and right to timely publish laboratory results. With the new understanding of why these three contract terms are particularly hard to agree upon, most notably in industry-to-academy transfers, this Article concludes with policy recommendations for when and how parties can overcome these barriers. These recommendations will help move forward parties in drawn out or stalemate transfers. This is turn will help foster shared innovative activity.

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### I. INTRODUCTION

Academic science is changing. No longer are universities, teaching hospitals, and research laboratories content to be "pure scientists," leaving the commercialization of their scientific innovation to industry partners. Instead, these academic institutions are entering the market, armed with their science and new understanding of the potential value of it.<sup>1</sup>

In just the past six years, New York University has received approximately \$650 million on royalties for Remicade, an autoimmune disease-treating pharmaceutical developed by a professor of microbiology.<sup>2</sup> The total income over the life cycle of Remicade to date is estimated at \$1 billion.<sup>3</sup> Similarly, Northwestern University has received around \$700 million on what a chemistry professor called pregabalin, and

<sup>&</sup>lt;sup>1</sup> For clarity and consistency, I will use the term "academic institution" to refer to the general class of non-commercial scientists at universities, teaching hospitals, and research laboratories. I will use the individual terms when only referring to just that particular type of academic institution.

<sup>&</sup>lt;sup>2</sup> See Karen W. Arenson, Manhattan Drug Research Benefits University, May 8, 2007, available at http://www.nytimes.com/2007/05/08/nyregion/08mbrfs-drug.html?\_r=0.

<sup>&</sup>lt;sup>3</sup> Richard Perez-Pena, *Patenting Their Discoveries Does not Pay Off for Most University, a Study Says*, NYTimes, Nov. 20, 2013 (*available at* www.nytimes.com/2013/11/21/education/patenting-their-discoveries-does-not-pay-off-for-most-universities-a-study-says.html).

Pfizer now markets as "Lyrica," currently the most effective treatments for seizures.<sup>4</sup> And just last April, a judge increased a previous \$1.17 billion patent infringement jury verdict against Marvell Technology Group to \$1.54 billion in favor of Carnegie Mellon University.<sup>5</sup>

But while there are other academic institutions such as the University of California,<sup>6</sup> Yale,<sup>7</sup> Florida State University,<sup>8</sup> and Columbia University<sup>9</sup> that have discovered similar "big hits," these large royalties are like obtaining the winning lottery ticket. The odds are never favorable, and big payouts are rare. Even so, many will compete for the chance of that one big hit.

In 2007 more than 150 U.S. universities had technology transfer offices, yet only thirteen of these offices reported licensing income of \$25 million or more.<sup>10</sup> A recent study found that in any year, roughly seven out of eight universities do not make enough licensing revenue to cover the cost of running its technology transfer office.<sup>11</sup> Beyond the numbers, there are mixed feelings about academic institutions commercializing its discoveries. Some noncommercial scientists and industry partners believe there are ethical concerns when academic institutions and commercial opportunities mix, and others believe that commercialization of faculty output is a distraction from the main goal of academic institutions (namely to teach and conduct basic research).<sup>12</sup>

Thomas Jefferson once remarked that it is difficult but paramount that we draw "a line between the things which are worth to the public the embarrassment of an

<sup>&</sup>lt;sup>4</sup> See Jon Van, Drug Find Worth \$700 Million, Chicago Tribune, March 10, 2008, available at http://articles.chicagotribune.com/2008-03-10/business/0803090219\_1\_gaba-richard-silverman-drug-

companies (explaining that Dr. Silverman's discovery is the "chemist's version of a PowerBall ticket").

<sup>&</sup>lt;sup>5</sup> See http://chronicle.com/blogs/ticker/jp/judge-adds-366-million-to-patent-lawsuit-award-for-carnegiemellon-u.

<sup>&</sup>lt;sup>6</sup> To be precise, it all started when a biochemist and professor at the University of California, San Francisco earned himself a \$65 million paycheck in 1980 when his co-founded company, Genentech, did its initial public offering. ELIZABETH POPP BERMAN, CREATING THE MARKET UNIVERSITY: HOW ACADEMIC SCIENCE BECAME AN ECONOMIC ENGINE (Princeton University Press 2012), p. 7, 14. Genentech's patents covering recombinant DNA (an emblematic gene spicing method) earned UCSF and Stanford close to \$225 billion. Center for Technology Innovation at Brookings, at 10. Genetech ushered in the modern day era of biotech entrepreneurship, and many universities and its faculty rushed to follow suit.

<sup>&</sup>lt;sup>7</sup> Yale was one of the first with its breakthrough technology on the antiretroviral (HIV) pharmaceutical Zerit that earned more than \$250 million. *Berman*, at 95.

<sup>&</sup>lt;sup>8</sup> Florida State University brought in \$350 million for cancer-treating drug therapy Taxol. *Id.* 

<sup>&</sup>lt;sup>9</sup> Columbia University had two recent "blockbusters": \$790 million for patents covering a method to insert DNA into eukaryotic cells, see Jeff Gerth & Sheryl Gay Stolberg, *Medicine Merchants: Birth of a Blockbuster; drug Makers Reap Profits on Tax-Backed Research*, New York Times, April 23, 2000 (*available at* www.nytimes.com/2000/04/23/us/medicine-merchants-birth-blockbuster-drug-makers-reap-profits-tax-backed.html), and \$20 million for glaucoma eye drop Xalatan, see \_\_\_\_\_.

<sup>&</sup>lt;sup>10</sup> Berman, at 94. (Update numbers).

<sup>&</sup>lt;sup>11</sup> Richard Perez-Pena, *Patenting Their Discoveries Does not Pay Off for Most Universities, a Study Says*, NYTimes, Nov. 20, 2013 (*available at* www.nytimes.com/2013/11/21/education/patenting-their-discoveries-does-not-pay-off-for-most-universities-a-study-says.html).

<sup>&</sup>lt;sup>12</sup> Peter Lee explains that "the unique norms, incentives, and missions of universities suggest that academic inventions fit uncomfortably in a patent system predicated on exclusive rights and profit maximization." Peter Lee, *Patents and the Universities*, 63 DUKE L.J. 1, 4 (2013).

exclusive patent."<sup>13</sup> The "line" in academic science of when to patent an invention was once highly revered, even feared, but is now quite murky. The success stories of NYU and Carnegie Mellon, among others, have motivated academic institutions to not only protect their faculty output via the patent system, but to actively seek infringers. Simply put, academic institutions are acting like their industry counterparts.<sup>14</sup>

With the increase of academic patenting and understanding of the value of faculty output, much change has occurred in academic science. Most positively, the public is enjoying the fruits of increased innovation: cancer treating drug therapies, a new process to isolate cancer-specific genes, stem-cell research to possibly cure previously untreatable autoimmune diseases, and the Google search engine among many others. This groundbreaking academic innovation has also lead to another positive change: a substantial amount of money poured back into research and development.<sup>15</sup>

But as evidenced by the relatively low revenue of most university technology transfer offices, as well as the "valley of death" (the period in-between academic science discoveries and the time those discoveries reach the public through some new product or process), there are still many barriers that noncommercial scientists and academic institutions face.

Some of these barriers are not new. For example, there has long been a cultural and ethical clash between administration, faculty, and industry over the most appropriate use of faculty time and research funds, as well as how and how much academic institutions should be partnering with industry partners. That said, this particular barrier between academic science and industry science is narrower now than it is has been in decades, maybe ever.

Moreover, it is now also understood that "shared innovative activity tends to characterize the early phase of establishment of an industry."<sup>16</sup> But it is this last part, the recent understanding of the value of shared innovative activity and its potential to start new industries, that is most at risk because of new barriers. Two such barriers are the focus of this Article: the decline in the once robust sharing ethos, and, related to this decline, the increase in both the sheer number and the complexity of material transfer agreements (MTAs).

MTAs cover everything from cell lines, plasmids, and transgenic animals to plant varieties, bacteria, data, and laboratory tools. The ability to make new discoveries in part depends on the sharing of research tools, materials, and data, but the sharing ethos among academic institutions, which was once very much alive, particularly in the biological field, is declining.<sup>17</sup>

<sup>&</sup>lt;sup>13</sup> Article 1, Section 8, Clause 8, Document 12, Letter from Thomas Jefferson to Isaac McPherson, *available at* http://press-pubs.uchicago.edu/founders/documents/a1 8 8s12.html.

<sup>&</sup>lt;sup>14</sup> See, e.g., Lee, *supra* note \_\_\_\_, at 5 (stating that "academic science has become more aggressive, and universities have begun behaving more like typical commercial entities"); Mark Lemley, *Are Universities Patent Trolls*? 18 FORDHAM IP, MEDIA & ENTERTAINMENT L.J. 611, \_\_\_\_ (2008).

<sup>&</sup>lt;sup>15</sup> Many of the grants that fund this research and development require the academic institutions to direct revenues back into research and development efforts. Conditions of Bayh-Dole Act. Also, many professors donate a portion of their share to their university. *See, e.g.*,

<sup>&</sup>lt;sup>16</sup> Katherine J. Strandburg, User Innovator Community Norms: At the Boundary Between Academic and Industry Research, 77 FORDHAM L. REV. 2237, 2245 (2009) (quoting Meyer).

<sup>&</sup>lt;sup>17</sup> See J.H. Reichman & Paul F. Uhlir, A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment, 66 LAW & CONTEMP. PROBS. 315, 323 (2003) (explaining that "access to data is everywhere becoming more dependent on negotiated

In prior decades, industry used the patent system for applied science while academic institutions focused on basic science and shared results through publication. While academic science has never been "open access," meaning in academic science "unfettered access,"<sup>18</sup> at points it has been termed "open science." Open science commonly refers to science that is timely published with full and honest details, that does not have intellectual property restrictions, and is highly transparent pre-and postpublication that is most often accomplished through the free and quick sharing of data and deliberations within the working research team.<sup>19</sup>

But now that academic institutions understand that they have the potential, just as industry does, to make millions, they too are using the patent system to exclude others from their discoveries. Scholars have voiced concern that patents on research tools, especially in particular areas like biomedical science may slow down downstream research activity.<sup>20</sup>

The change in the sharing ethos is readily apparent in that research tools, data, and materials that were once shared freely and informally-with no contract in place or at least one with desirable terms-are now only transferred when a contract is executed. The MTA went from a relatively rare occurrence to an everyday practice in academic institutions. It is estimated that large academic institutions execute thousands of MTAs annually and spend over a hundred thousand dollars managing MTAs.<sup>21</sup> Smaller academic institutions report executing hundreds of MTAs annually,  $2^{22}$  with the collective academy spending millions annually in the management of MTAs.<sup>23</sup>

MTA requests are so numerous and taxing on resources that researchers and faculty members are simply ignoring MTA requests.<sup>24</sup> There are also troubling numbers reported by technology transfer offices that MTAs between academic institutions and industry partners fail to be timely negotiated and/or executed because of different perspectives on what terms are reasonable.<sup>25</sup> This makes the MTA negotiation process even more daunting.

This Article contributes to the growing academic science literature by focusing on transfers that can help reinvigorate the sharing ethos by making it easier to share materials, tools, and data. Instead of ignoring MTA requests or having grants expire,

transactions between private stakeholders" and that the "sharing norms of the past" are being negatively affected). See also Lee, supra note \_\_\_\_, at 36 (explaining that "[t]he rise in patenting following the Bayh-Dole Act has challenged traditional norms of openness and communal sharing" and that academic science has largely shifted from the "communalistic norms" of the early twentieth century").

<sup>&</sup>lt;sup>18</sup> Peter Lee, Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law, 58 EMORY L. REV. 889, 906 (2009) [hereinafter Lee, Contracting to Preserve Open Science]. The term "open access" in the software context, the context it most often refers, is commonly defined as "works that are freely available over the internet." See also Andres Guadamuz Gonzalez, Open Science: Open Source Licenses in Scientific Research, 7 N.C. J. L. & TECH. 321, 330 (2006). <sup>19</sup> See Id.

<sup>&</sup>lt;sup>20</sup> Id. at 901. See also Rebecca S. Eisenberg, Patents and Data-Sharing in Public Science, 15 INDUS. & CORP. CHANGE 1013, 1016 (2006).

<sup>&</sup>lt;sup>21</sup> http://www.vanderbilt.edu/cttc//cttc/sites/cttc.co/files/public/page/mtashare-ppt-website.pdf (hereinafter *Vanderbilt Presentation*)

<sup>&</sup>lt;sup>22</sup> http://ott.emory.edu/about/statistics/mta.html

<sup>&</sup>lt;sup>23</sup> See Vanderbilt Presentation, supra note \_\_\_\_, at \_\_\_\_.

<sup>&</sup>lt;sup>24</sup> Bring source up from below.

<sup>&</sup>lt;sup>25</sup> Wendy D. Streitz & Alan B. Bennett, Material Transfer Agreements: A University Perspective, p. 1 (available at http://www.ncbi.nim.nih.gov/pmc/articles/PMC523866/.

industry partners and academic institutions should use MTA requests to build relationships that could lead to shared innovative activity. I take one step in that direction by deconstructing the current MTA process and addressing the different types of MTAs, as well as identifying the terms that delay or completely quash MTA requests.

Different contract terms are at issue when the thing being transferred is to be used to support back-end collaboration versus front-end collaboration. There are also different considerations when the material being transferred involves an industry partner, as opposed to just two academic institutions.

I take these differences into account when making policy suggestions on how to better build the MTA process. Currently the only standardized MTAs are one-size fits all agreements that do not account for the difference in front-end and back-end relationships or the differences in one-shot or long-term contracts. The normative suggestions here will allow for more direct and efficient negotiations between parties, and will allow parties to once again focus on building back up the sharing ethos in academic science while also providing timely publication and pre- and post-publication transparency.

Part II will discuss the development of academic science. Part III will then identify existing barriers to innovation. This part will focus on the increased role of contract law, and, in particular, the MTA. It will introduce the current MTA process of various academic institutions to demonstrate the various approaches that serve to further muddle an already complicated process due to the nature of the transfers (human tissues or animals, for example). Part IV will then build the space for increased visibility and efficiency in MTAs in academic science. Part V concludes.

### II. THE DEVELOPMENT OF ACADEMIC SCIENCE

Before moving forward, it is important to better define collaboration in the academic science context. First, there is upstream or "front-end" collaboration. This is where an academic institution receives a grant or similar financial support from state or federal government or a private company to support basic research. For example, Dr. Mary-Claire King received financial support from the National Cancer Institute (NIC) to study heredity breast cancer, and, ultimately, it was Dr. King and her laboratory that proved that there is a single genetic mutation, breast cancer susceptibility gene 1 (BRCA1), located on chromosome 17 that is responsible for inherited breast and ovarian cancers.<sup>26</sup> Second, there is downstream or "back-end" collaboration. This is where a research institution is focusing on applying basic science discoveries to a product or process to bring to the market. After Dr. King's increased understanding and isolation of BRAC 1, the next step was to partner noncommercial scientists, such as Dr. King, with industry scientists to create a diagnostic screening process for BRAC 1.

<sup>&</sup>lt;sup>26</sup> See http://www.cancer.gov/aboutnci/servingpeople/cancer-research-progress/discovery/brca; see also https://www.washington.edu/alumni/columns/sept96/king1.html. At the time of identification, Dr. King was at the University of California Berkeley, but she has since moved to the University of Washington. After Dr. King's discovery, Dr. Mark Skolnick, again with funding from NIC, was the first to clone the gene and pinpoint its exact location. https://www.washington.edu/alumni/columns/sept96/king1.html.

Within these two types of collaboration there are two general types of contracts: one-shot contracts and long-term contracts. In a one-shot contract, whether in front-end or back-end relationships, the parties plan to interact just once. Dr. King's laboratory needed many research tools and materials, some of which likely were transferred from other laboratories.

In a long-term contract, again, regardless of the type of collaboration, the parties are working together over the course of weeks, months, or years on basic and/or applied science. These parties have a very different relationship, one that evolves and has layers of complexities, especially when compared to the one-shot relationship that is quick and focused on efficiency and managing expectations. After the discovery of BRAC1, and shortly thereafter BRAC2, Myriad Genetics collaborated with over 444 outside scientists in its endeavor to find the most effective diagnostic test and continued learning of BRAC1 and BRAC2.<sup>27</sup>

This Article addresses upstream and downstream research and development, with a focus on one-shot contracts.<sup>28</sup> The goal is to quickly share materials, tools, and data to further research and development with as little delay or headache as possible. Before addressing the specifics of the current MTA process, this next part will discuss the rise of academic science, tracing it roots and how it has changed over the past 100 years. This is important because it shows where academic science started, and specifically how parties once interacted with one another and the patent system. This can then be compared and contrasted to the current sharing ethos and interaction with the patent system that has lead to an increased MTA process.

#### A. The Rise of Academic Science

Historically, the long-standing rhetoric surrounding universities is that they are secluded high above the world in ivory towers.<sup>29</sup> They are divorced from the reality of the world and the market. In essence, universities were concerned about upstream research with little formal contracting with other universities or industry partners to support downstream development of basic science.

With this narrative about universities, it is not surprising that universities and industry parties have long been thought to be mutually exclusive.<sup>30</sup> While this is may

<sup>&</sup>lt;sup>27</sup> See https://www.myriad.com/lib/speaker-portal/Setting%20the%20Record%20Straight.pdf.

<sup>&</sup>lt;sup>28</sup> My next project is likewise focusing on upstream and downstream research and development, but with a look at fostering long-term collaborative contracts.

<sup>&</sup>lt;sup>29</sup> See Peter Lee, *Patents and the University*, 63 Duke L.J 1, 7 (2013) [hereinafter, Lee, *Patents and the University*]; Ritchie de Larena, p. 1374 ("Universities have a reputation for being isolated ivory towers [...]"). ; C.L. Max Nikias, Executive Vice President and Provost of the University of Southern California, Thirty-First Annual Earl V. Pullias Lecture, "Beyond the Ivory Towers: On Tomorrow's American Research University," available at http://www.president.usc.edu/speeches/beyond-the-ivory-towers-on-tomorrows-american-research-university/ ("We face increasing cynicism about the academy. Elite research universities have been criticized as being too divorced from the concerns of ordinary women and men, too insular, too wealthy, too inefficient, too expensive, too naïve about the realities of life beyond the ivory tower.").

<sup>&</sup>lt;sup>30</sup> Lee, *supra* note \_\_\_\_\_, at 7 ("The first phase of academic science's interactions with patent law was largely characterized by mutual exclusion.").

not be true in reality about universities and industry generally (or certainly in the founding of universities), it has been almost uniquely true in the patent world.<sup>31</sup>

The term "academic exceptionalism" is "the notion that the patent system should exclude the fruits of academic science or treat academic entities differently than other actors."<sup>32</sup> This differential treatment in the patent system is in part derived from the culture within academic science. This culture is sometimes referred to as "open science." Open science focus on transparency and the dissemination of tests and research results through publication. Open science does not mean open access or free access, but nevertheless has a core sharing ethos that is critical to supporting research and development.

In line with open science, faculty generally did not use the patent system.<sup>33</sup> This nonuse was furthered when universities actively discouraged faculty members from seeking patents covering their discoveries.<sup>34</sup> The long-standing norms of academic science center on the open availability and sharing of knowledge, often achieved through publication, that work to serve the public.<sup>35</sup> Accordingly, university scientists historically have relied on sharing research and materials, with the objective to place or keep any faculty output in the public domain.<sup>36</sup>

If a patent was sought, it was not for commercial purposes but rather to ensure quality control and widespread dissemination of the discovery.<sup>37</sup> And those that sought patents for the sake of the public interest, whether quality control or price control, did so with great caution. At this time, there was overwhelming skepticism regarding universities using the patent system on the faculty output.<sup>38</sup>

Early patent policies showed both this wariness to apply for patent protection and concern for the public's access to high quality products at fair prices. For example, Columbia University's patent policy in 1925 focused on ensuring quality control and maintaining fair and reasonable prices of any patented technology.<sup>39</sup> Similarly, MIT's

<sup>&</sup>lt;sup>31</sup> *Id*.

 $<sup>^{32}</sup>$  Id. at 1.

<sup>&</sup>lt;sup>33</sup> Lee, *supra* note , at 7 (explaining that while "U.S. universities have long served practical needs, academic norms often discouraged patenting). This negative view of the patent system was also shared by the Rockeller Foundation (an major source of support for universities in the twentieth century). For example, the Rockefeller Foundation threatened to pull its funding for Herbert Evans at University of California, Berkley "if he tried to benefit financially from his research through patents." Id. at 12. Jacques Loeb of the Foundation "warned that 'if the institutions for pure science go into the handling of patents I am afraid pure science will be doomed."" Id.

<sup>&</sup>lt;sup>34</sup> The Rockefeller Foundation, for example, threatened to pull its funding for Herbert Evans at University of California, Berkley "if he tried to benefit financially from his research through patents." Id. at 12. Jacques Loeb of the Foundation "warned that 'if the institutions for pure science go into the handling of patents I am afraid pure science will be doomed."" Id.

<sup>&</sup>lt;sup>35</sup> J.H. Reichman & Paul F. Uhlir, A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment, 66 Law & Contemporary Problems 315, 317 (speaking to the importance of "the open availability of scientific data[] and full disclosure of results through publication").

 $<sup>^{36}</sup>$  Id. at 5.

 $<sup>^{37}</sup>$  Id. at 7; see infra pages and notes for an example of a professor obtaining patent protection to ensure more access for a lifesaving discovery.

<sup>&</sup>lt;sup>38</sup> See e.g., JAMA 1948 report. <sup>39</sup> *Id*. At 13.

patent policy in 1932 contained the statement that MIT "shall hold and administer these rights for the ultimate benefit of the public."<sup>40</sup>

Patent policies further reflected the academic culture regarding patenting faculty output in the biomedical and public health fields. For example, in 1934, Harvard University had one of the most strongly worded patent policies, mandating that "[n]o patents primarily concerned with therapeutics or public health may be taken out by any member of the University, except with the consent of the President and Fellows; nor will such patents be taken out by the University itself except for dedication to the public."<sup>41</sup> This patent policy affirmed Harvard's earlier decision to not allow it or any of its professors to profit from any faculty research in the field of public health and therapeutics.<sup>42</sup> Yale had a similar policy explaining "it is, in general, undesirable and contrary to the best interests in medicine and the public to patent any discovery or invention applicable in the fields of public health or medicine."<sup>43</sup>

While other institutions such as St. Louis University and John Hopkins University at the time endorsed more of a "hands-off policy," both institutions in 1930 and 1933, respectively, had either an implied or express understanding that if a patent was obtained there was to be no personal financial gain.<sup>44</sup> Furthermore, the attitudes of both universities reflected many others, where institutions that did not have formal patent policies nevertheless were "definitely adverse to the patenting of any inventions" or at least had "a view to discouraging the acquisition of patents."<sup>45</sup>

Overall, this time period was marked by "[s]cientific investigators working in university and professional school laboratories [that were] concerned primarily with the formulation of new ideas and the understanding of nature and its laws. The discovery and development of patentable inventions [were] seldom conscious objectives of their research efforts."<sup>46</sup>

Because of this concern for mixing academic and commercial development, as well as only the rare patent application filed in order to quality control and ensure public access, courts perceived academic science as operating outside the scope of patent law.<sup>47</sup> This segregation between academic science from the patent system continued as courts encouraged only patenting of discoveries that are a reward to "inventors," (as opposed to a "pure scientist" whose discoveries are not patentable).<sup>48</sup>

This distinction is quite apparent when the Ninth Circuit in 1943 invalidated three university patents covering the irradiation (vitamin D enhancing) process, specifically noting that the patent system was not aimed at the "pure scientist."<sup>49</sup> A few years later, the Supreme Court held that "[h]e who discovers a hitherto unknown

<sup>&</sup>lt;sup>40</sup> *Id*. (citations omitted).

<sup>&</sup>lt;sup>41</sup> *Id.* at 13-14. (citations omitted).

<sup>&</sup>lt;sup>42</sup> *Id*.

 $<sup>^{43}</sup>$  *Id.* (citations omitted).

<sup>&</sup>lt;sup>44</sup> JAMA, at 500

<sup>45</sup> Id.

<sup>&</sup>lt;sup>46</sup><sub>47</sub> JAMA, at 497.

<sup>&</sup>lt;sup>47</sup> *Id.* at 14. *See also id.* at 7-8 (finding that "courts viewed academic science as falling outside the scope of patentability and afforded universities a rather privileged normative status within the paten system"). <sup>48</sup> *Id.* at 22.

<sup>&</sup>lt;sup>49</sup> Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 58 U.S.P.Q. (BNA) 293, 295 (9th Cir. 1943).

phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."<sup>50</sup> At the time, academic science was largely focused on studying and observing nature, and not trying to invent something new for a profit.

Certainly while universities are now "widely recognized as the core of this nation's science and technology system," placing heavy emphasis on the potential value of academic science was very new in the early twentieth century in the United States.<sup>51</sup> Accordingly, this segregation of academic science and the patent system was arguably relatively easy to achieve and maintain.

Moreover, prior to World War II the scope of academic science was modest.<sup>52</sup> In 1938, university research expenditure across the United States totaled just \$50 million.<sup>53</sup> This \$50 million did not come from the federal government except for a few isolated projects, but rather from industry partners and a few private organizations such as the Rockefeller Foundation and the Carnegie Corporation.<sup>54</sup> In the 1939-1940 academic year, "10 of the estimated 150 research universities in the United States performed \$9.3 million or 35% of the total of \$26.2 million in research performed in the natural sciences and engineering by the academic sector, while 35 of these 150 institutions performed \$16.6 million or 63% of the academic total."55 And universities such as Massachusetts Institute of Technology (MIT) and Berkley actively sought out partnerships and stayed responsive to the market so that they would have money to spend on research.<sup>56</sup>

But one particular pioneer in academic science emerged after WWI and before WWII. In 1925, Professor Harry Steenbock at University of Wisconsin-Madison founded the Wisconsin Alumni Research Foundation (WARF).<sup>57</sup> He created this nonprofit to manage the output of the University's faculty and described the WARF's mission as "protecting discoveries from crass commercialism,' 'using licensure to control the quality of the products and their advertising,' and licensing in a way that 'minimize[d] the monopolistic character of patents.""58 Further, the WALF focused on

<sup>&</sup>lt;sup>50</sup> Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948). 51

<sup>&</sup>lt;sup>52</sup> Berman, *supra* note , at 19. *See also* Atkinson & Blanpied, *supra* note , at 30, 34 ("Prior to the war, universities received virtually no federal funding for research, particular basic research, and the concept of such funding was viewed as a radical idea." Instead, "private universities obtained their research support from their endowments and from non-profit foundations, and state universities from state governments.").

<sup>&</sup>lt;sup>54</sup> Id. Consequently, there was synergy between universities and industry out of necessity for the universities, but it was on such a small scale that little has been made of it. This large dependency on industry funding, and to a bit of often scarce private funding, had already been a mainstay in the life of universities. As Peter Lee explains, "universities depended on local funding for revenue and thus had to be responsive to local economic and educational needs." Lee, supra note \_\_\_\_\_, at 8. Further, this led to "many early U.S. universities cultivat[ing] close connections with industry." Id. at 9.

<sup>&</sup>lt;sup>55</sup> Atkinson & Blanpied, *supra* note \_\_\_\_, at 34.

<sup>&</sup>lt;sup>56</sup> Berman, *supra* note \_\_\_\_, at \_\_\_\_.

<sup>&</sup>lt;sup>57</sup> Cite. Steenbock was arguably influenced by both the University of Toronto and the University of Minnesota, both whom decided to use the patent system to help ensure the safe dissemination of technology to the public. Lee, *supra* note , at 17.

<sup>&</sup>lt;sup>58</sup> Id.

two goals: "to bring additional 'margin of excellence' research funding to the [university] and to put the inventions of [university] faculty to work for the maximum benefit of society."<sup>59</sup>

Steenbock's motivation to start the WARF stemmed from his own invention, namely, a process of using ultraviolet radiation to enhance vitamin D in milk and other foods.<sup>60</sup> His discovery had the potential to eradicate rickets, a bone disease that particularly affected children and poorer populations.<sup>61</sup>

Going against the academic norm, Steenbock obtained four patents covering his irradiation technology.<sup>62</sup> Steenbock wrote in an early journal article that he decided to obtain patents "to protect the interest of the public in the possible commercial use of these findings."<sup>63</sup> There is additional evidence that he also wanted to preempt so-called "patent pirates" that would steal his technology, patent it, and then charge high fees to those who wanted to use their technology.<sup>64</sup>

Quaker Oats initially offered Steenbock \$900,000 for the rights to his patent (roughly \$12 million today), but he refused that offer,<sup>65</sup> and, ultimately the WARF entered into a licensing agreement with Quaker Oats and pharmaceutical companies to develop "a medicinal preparation of vitamin D called Viosterol."<sup>66</sup> Steenbock declined to accept any share of the licensing royalties.<sup>67</sup> Throughout the patenting of Steenbock's process and the WARF negotiations with Quaker Oats and other companies, the WARF received heavy criticism from the industry, news outlets, and even the U.S. Senate.<sup>68</sup> Arguably, the criticism was also a part of the Ninth Circuit decision in 1943 that invalidated three of the WARF patents on Steenbock's process.

Today, the WARF continues to manage the innovation of the University's faculty and the relationships with the industry, just as it continues to receive occasional backlash for the way that it commercializes technology. Most recently, the WARF received negative attention for its aggressive pricing structure of its stem cell licensing program.<sup>69</sup>

<sup>&</sup>lt;sup>59</sup> John M. Golden, *WARF's Stem Cell Patents*, 38 J.L. Med. & Ethics 314, 10 (2010) (need to get finalized copy).

<sup>&</sup>lt;sup>60</sup> Angela Shah, Xconomy, Q&A: How WARF Plans to Stay Relevant in Lean Times for Tech Transfer, December 20, 2013 (with Carl Gulbrandsen, WARF's Managing Director, and Leigh Cagan, WARF's Chief Technology Commercialization Officer) (available at http://www.xconomy.com/wisconsin/2013/12/20/qa-warf-plans-stay-relevant-lean-times-techtransfer/?single\_page=true).

<sup>&</sup>lt;sup>61</sup> Id.

<sup>&</sup>lt;sup>62</sup> U.S. Patent No. 1,680,818 (filed June 30, 1924), U.S. Patent No. 1,871,135 (filed Dec. 27, 1926), U.S. Patent No. 1,871,136 (filed Dec. 27, 1926), U.S Patent No. 2,057,399 (filed May 14, 1932).

<sup>&</sup>lt;sup>63</sup> Harry Steenbock, the Induction of Growth Promoting and Calcifying Properties in a Ration by Exposure to Light, 60 Science 224, 225 (1924).

<sup>&</sup>lt;sup>64</sup> Lee, *supra* note \_\_\_\_\_, at 18. There is evidence that Steenbock also wanted to protect Wisconsin local dairy industry and keep his vitamin D enhancing process away from the manufactures of oleomargarine ("the butter of the poor").

<sup>&</sup>lt;sup>65</sup> Shah. See also \_\_\_\_

<sup>&</sup>lt;sup>66</sup> Shah.

<sup>&</sup>lt;sup>67</sup> Lee, *supra* note \_\_\_\_, at 18, n.96 ("Steenbock later relented, partly at the urging of WARF, which argued that other inventors would not assign their patents to WARF without such inducement.").

<sup>&</sup>lt;sup>68</sup> *Id*. Cite additional sources.

<sup>&</sup>lt;sup>69</sup> See, e.g.,

While the WARF was garnering skepticism from some, other universities after WWII quickly sought to follow its model of using the patent system but having a separate entity handle the patenting process, maintenance, and licensing. In 1956 more than fifty incorporated organizations existed that were managing university patents.<sup>70</sup> The rush to create these separate organizations to handle faculty output demonstrates two points: (1) there was still anxiety about the university handling its own patents, and, (2), much changed for university research during WWII when the "power of science" ended the war, with \$1.89 billion dollars spent over the course of the six-year Manhattan Project.<sup>71</sup>

The Manhattan project employed more than 130,000, yet within this large number there were small teams of university researchers that played an integral role in the development of the atomic bomb. Teams of researchers were developed from professors at University of California-Berkeley, MIT, Columbia, Princeton, Chicago, Illinois, the Carnegie Institution of Washington, Iowa State, Virginia, Wisconsin-Madison, and the Rochester School of Medicine.

Beyond the Manhattan Project, nine universities had significant wartime contracts, totaling \$300 million spent just for university-specific research.<sup>72</sup> During wartime, the projects commissioned by the government generally allowed the contractors (in this case, universities) to retain ownership of the discovery, with the government retaining the right to use any discovery.<sup>73</sup>

The impact of university research and the legitimacy of federal funding for basic research going forward was memorialized in Vannevar Bush's (former Dean of Engineering at MIT) report "Science—the Endless Frontier" (SEF) to President Harry Truman in July 1945. SEF implored the government to fund basic scientific research at universities. For example, SEF reported that during WWI, the death rate from disease was reduced from 14.1 per thousand in WWI, to just .6 per thousand in WWII. It went on to report that many more citizens die annually than the total number of Americans killed in battle, and that even more are ill with no cure or adequate preventative measures. Accordingly, SEF concluded:

The responsibility for basic research in medicine and the underlying sciences, so essential to progress in the war against disease, falls primarily upon the medical schools and universities. Yet we find that the traditional sources of support . . . are diminishing and there is no immediate prospective of a change in this trend. [...] If we are to maintain the progress in medicine which has marked the last 25 years, the Government should extend financial support to basic medical research in the medical schools and in universities.<sup>74</sup>

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<sup>&</sup>lt;sup>71</sup> *Id*. Check these details on Manhattan Project and add in an article giving more details of the project.

<sup>&</sup>lt;sup>72</sup> Berman, *supra* note , at 20. "[...]MIT lead[] the pack with a whopping \$117 million in contracts." *Id.*<sup>73</sup> *Id.* at 99.

<sup>&</sup>lt;sup>74</sup> http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm#summary.

SEF repeatedly stated that the government must support university research, and that the "pool of knowledge on which industry could draw" was largely depleted during WWII.<sup>75</sup> Prior to WWII, America largely relied on Europe to supply it with the basic research required by industry, but afterwards it was clear that Europe would take a long time to rebuild. The United States had an opportunity to become a leader and to "rely on its own resources."<sup>76</sup>

President Truman and Congress listened to Bush and the SEF, and although government spending on university research did not remain at the high wartime levels, government spending has ever since been a major source of university research funding.<sup>77</sup>

# B. Congressional Support

As detailed above, prior to WWII, academic norms and culture were antagonistic to and wary of the patent system. And because university research was so modest, there were not that many opportunities to patent faculty inventions.<sup>78</sup> Moreover, the Supreme Court (and through it the federal government) was arguably also against academic patenting.

However the time period of 1950-1975 saw rapid increases in federal expenditures for research and development, and, concomitantly, higher numbers of patents issued to universities.<sup>79</sup> Federal expenditures supporting research and development made up 55% of all university research spending in 1953 and 73% in 1966.<sup>80</sup> In actual dollars, universities received approximately \$273 million in 1953, accounting for 5.3% of the total national research and development expenditures.<sup>81</sup> This percentage rose to 7.9% in 1965 and to 10% in 1970.<sup>82</sup>

As for patents, in the 1950s and 1960s, there were roughly fewer than 100 patents issued per year to universities, but in 1972 there were over 200 patents awarded to universities and in 1975 there were 300.<sup>83</sup> This means that between the mid-1960s and mid-1970s the number of issued patents to universities roughly tripled.

With this new funding and higher numbers of issued patents, the emerging practice of academic patenting continued to become more common and acceptable of a practice.<sup>84</sup> Academic science in the United States was thriving, with Americans dominating the Nobel Prizes awarded between 1950 and 1975, and with non-American

<sup>&</sup>lt;sup>75</sup> Atkinson & Blanpied, *supra* note \_\_\_\_, at 35 (explaining that Bush in the SEF used the metaphor of a pool of knowledge that was devastated by the war and needed to be replenished by American university research).

<sup>&</sup>lt;sup>76</sup> Id.

<sup>&</sup>lt;sup>77</sup> *Id*.

<sup>&</sup>lt;sup>78</sup> Berman, *supra* note \_\_\_\_, at 98 (explaining that university patenting was so infrequent "that it might never even occur to a faculty member to consider pursuing a patent").

<sup>&</sup>lt;sup>79</sup> Atkinson & Blanpied, *supra* note \_\_\_\_, at 36.

<sup>&</sup>lt;sup>80</sup> *Id.* at 37.

<sup>&</sup>lt;sup>81</sup> *Id*.

<sup>&</sup>lt;sup>82</sup> *Id*.

<sup>&</sup>lt;sup>83</sup> Berman, *supra* note \_\_\_\_, at 100.

<sup>&</sup>lt;sup>84</sup> It is important to note that academic patenting is still not accepted by many, and that each university (and faculty within each university) has its own unique view of academic patenting.

students flooding the American university system.<sup>85</sup> What also became apparent was that there was no overriding standard or rules to determine ownership of this federal supported university research.<sup>86</sup>

During the war, federally supported projects generally resulted in the universities keeping title to any discovery and the government retaining the right to use any such discovery. However, there was also a government-title approach, where the government could elect to keep title to any university discovery and patent it, or perhaps just let the invention go into the public domain.<sup>87</sup> After the war, various agencies were responsible for granting and overseeing particular federally supported projects, and each agency seemed to employ a different ownership policy. By at least one count, there were as many as twenty-six different agency policies.<sup>88</sup> Moreover, each decision within those agencies generally was made on a case-by-case basis.<sup>89</sup>

These conflicting patent ownership policies became a focus of various presidents and of Congress, with several attempts to clarify the law pertaining to government supported research.<sup>90</sup> These various attempts only provided rough guidance to agencies that were already working within their own specific framework, but the conflicting policies were only one source of strain on the sudden boom in academic science. While WWII brought a flood of research dollars into universities, the Vietnam War, particularly in the late 1960s, marked a time in significantly decreased resources for academic institutions.<sup>91</sup>

With many university professors openly protesting the war, and with "[a] sizeable segment of the anti-war movement h[olding] science and technology—and therefore scientists—at least nominally complicit in the devastation being visited upon Vietnam by the US armed forces, the federal research and development allocation decreased after 1974."<sup>92</sup> An interesting allegation is that then-President Lyndon Johnson "deliberately punished [US university faculty] by reducing their research support" due to their outspoken opposition to the war efforts.<sup>93</sup> Less controversially is Richard Nixon's general dislike of university faculty, affirmed by his disbanding of the presidential science advisory system in 1973.

<sup>&</sup>lt;sup>85</sup> Atkinson & Blanipied, *supra* note \_\_\_\_\_, at 37-38 (highlighting that "[t]he flowering of the US research universities during the quarter century following World War II also can be gauged in terms of intangible factors," such as Nobel Prizes and foreign students enrolling at US research universities).

<sup>&</sup>lt;sup>86</sup> See Berman supra note \_\_\_\_, at 95 (stating that while academic patenting "was on the rise, the practice of university patenting was also on shaky legal ground" and "its future [] uncertain."

<sup>&</sup>lt;sup>87</sup> Berman, *supra* note \_\_\_\_, at 99.

<sup>&</sup>lt;sup>88</sup> Wendy H. Schacht, The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology 2 (CRS Report for Congress, RL32076, Oct. 5, 2007).

<sup>&</sup>lt;sup>89</sup> Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 Houston L. Rev. 1374, 1378, (2005).

<sup>&</sup>lt;sup>90</sup> See *id.* at 1378, n.33. President Franklin D. Roosevelt in 1941 and President John F. Kennedy in 1963 issued executive orders to determine the best way to support innovation in both times of war and peace, and how to govern the disposition of any such resulting innovation when federal funds were contributed. *Id. See also* Berman, p. 95 (explaining that "the number of patents issued to universities roughly tripled between the mid-1960s and the mid-1970s").

<sup>&</sup>lt;sup>91</sup> Atkinson & Blanpied, *supra* note \_\_\_\_, at 39.

 $<sup>^{92}</sup>$  *Id*.

<sup>&</sup>lt;sup>93</sup> *Id*.

When Gerald Ford became president in 1975 after Nixon's resignation, he immediately acted to restore the relationship between government and science.<sup>94</sup> For the first time since 1968, federal funding for research and development increased.95 Moreover, Congress had hearings on reviving the presidential science advisory system that Nixon had disbanded, and, in 1976, President Ford signed the Science and Technology Policy, Organization and Priorities Act of 1976.<sup>96</sup> A part of this legislation was the creation of the Office of Science and Technology Policy (OSTP), with the director serving as the President's science advisory.<sup>97</sup>

Also during the mid-1970s there were resurgences from private industry and federal agencies to support research, and, furthermore, fostering of collaboration between science and industry.<sup>98</sup> With this resurgence, however, it again became evident that there was no clear ownership policy of federally funded academic science projects. Should the university keep title to any resulting patents, or should those potential patents belong to the agency or federal government at large that supported the research?

Legislative action was needed – and after several years of legislative debate on how to best support and incentive research and innovation, Senator Bayh in 1980 "managed to squeak [just that] [] through Congress" (even after having losing his bid for reelection).<sup>99</sup> The University and Small Business Patent Procedures Act signed by Jimmy Charter in December 1980, and commonly referred to as the Bayh-Dole Act, has profoundly impacted academic science.<sup>100</sup>

The Act affirmed that universities are allowed to patent any resulting inventions if several conditions are met.<sup>101</sup> These conditions include the university disclosing to the federal government the invention "within a reasonable time,"<sup>102</sup> as well as informing the federal government of any intent to obtain a patent<sup>103</sup> and providing updates when requested to do so.<sup>104</sup> Also, "the university must retain title," "share licensing proceeds with the inventors," and "the balance of licensing income must be used to support 'scientific research or education."<sup>105</sup>

With this new legislation, Congress actively wanted "to promote the utilization of inventions arising from federally supported research and development," as well as ensure "the public availability of inventions made in the United States . . . . "106 Furthermore, Congress aimed to encourage collaboration between nonprofit entities, including universities, and commercial industry entities.<sup>107</sup>

- <sup>95</sup> Id. <sup>96</sup> *Id*.
- $^{97}$  *Id.* at 40.
- <sup>98</sup> Id.
- <sup>99</sup> *Id.* at n.5.

<sup>&</sup>lt;sup>94</sup> Id.

<sup>&</sup>lt;sup>100</sup> Burman, *supra* note \_\_\_, at \_\_\_. <sup>101</sup> Ritchie de Larena, *supra* note \_\_\_, at 1375.

<sup>&</sup>lt;sup>102</sup> 35 U.S.C. 202(c)(1) (2000).

 $<sup>^{103}</sup>$  35 U.S.C. 202(c)(3)(2000).

<sup>&</sup>lt;sup>104</sup> Ritchie de Larena, *supra* note , at 1375.

<sup>&</sup>lt;sup>105</sup> Id.

<sup>&</sup>lt;sup>106</sup> 35 USC 200 (2006). Congress passed the Stevenson-Wydler Technology Act of 1980 declaring "a strong national policy supporting domestic technology transfer and utilization of the science and technology resources of the Federal Government." 15 USC 3701(8).  $^{107}$  Id.

Certainly a byproduct of the Bayh-Dole Act was an implicit (if not direct) push towards university patenting, but it was not the only catalyst of increased university patenting in 1980. The Supreme Court issued an opinion early that year that dramatically changed the rules of patenting for universities. In Diamond v. Chakrabarty, the Court construed the scope of the Patent Act to allow the patenting of "anything under the sun that is made by man."<sup>108</sup>

Previously the view towards "pure scientists" learning about and observing nature was performed outside the scope of the patent system, with only the reward of a patent going to "inventors." Chakrabarty changed this understanding, and opened the door for patents on microorganisms, and, later, patent protection of "more complex forms of life."109 Academic institutions quickly seized this change, with Harvard University in 1988 obtaining the first-ever patent on an animal.<sup>110</sup>

Another change to the patent system in the early 1980s was the creation of the Court of Appeals for the Federal Circuit in 1982. Congress added this specialized circuit court to oversee all patent appeals in the hopes of creating more uniformity and consistency in patent law.<sup>111</sup> While it is arguable that the Federal Circuit achieved this uniformity or consistency, it was quickly "a strong champion of patentholder rights."<sup>112</sup> These three changes altered the course of academic patenting, with significant increases in both academic patents applied for and issued, and quick increases in the number of university technology transfer offices.

At the thirty-year anniversary of the Bayh-Dole Act, many gave glowing reviews despite previously loud criticism with the Economist stating the Act was "[p]ossibly the most inspired piece of legislation in America over the past halfcentury."<sup>113</sup> The Economist further stated that with the "amendments in 1984 and augmentation in 1986, [it] unlocked al the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.<sup>1114</sup> Because of the Bayh-Dole Act, "universities across America became hotbeds of innovation [...] [and] [s]ince 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2.200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute \$40 billion annually to the American economy."<sup>115</sup>

Glowing reviews from the normally quite dour Economist, but this did not last long. Just a few years later, the Economist updated its view, finding that "[a] landmark law has allowed American universities to profit by patenting their innovations. But the costs are adding up."<sup>116</sup> Similarly, Fortune Magizine published an article entitled "The

<sup>&</sup>lt;sup>108</sup> Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting Sen. Rep. No. 1979 (1952).

<sup>&</sup>lt;sup>109</sup> Berman, *supra* note \_\_\_\_, at 109.

<sup>&</sup>lt;sup>110</sup> Id.

<sup>&</sup>lt;sup>111</sup> Cite Rutgers.

<sup>&</sup>lt;sup>112</sup> Lee, *supra* note , at 34 (internal citations omitted).

<sup>&</sup>lt;sup>113</sup> Innovation's Golden Economist, Dec. 12, 2002, at Goose, (available at http://www.economist.com/node/1476653).

 $<sup>^{114}</sup>$  Id.  $^{115}$  Id.

<sup>&</sup>lt;sup>116</sup> Baying for Blood or Doling out Cash?, Economist, Dec. 24, 2005, at 109 (available at http://www.economist.com/node/5327661).

Law of Unintended Consequences," arguing that the Bayh-Dole Act actually serves to keep university discoveries from being publically released to the scientific community.<sup>117</sup>

Likewise, scholars have criticized the Act, with perhaps the most common criticism that while universities (especially in the biomedical field) used to share research and tools, they are now not sharing and are instead seeking patents that block upstream research and innovation.<sup>118</sup> In an empirical study, it was found that over one-half of Columbia University's licensed patents covered research tools, and, further, that out of 62 surveyed universities, most of the licensed technology was indeed "embryonic."<sup>119</sup> This survey focused on university technology offices. In 1980, twenty-three universities had technology transfer offices (with at least another 50 universities set up with outside technology transfer managing organizations), and although numbers are hard to count, it seems as of 2012, there are likely at least 232 technology offices.<sup>120</sup>

### C. Explosion of Technology Transfer Offices

The Association of University Technology Managers (AUTM) publishes yearly surveys on academic science focusing on, among other things, patents issued and licenses executed by universities. It has done so since 1991, enabling scholars to track the scope and magnitude of technology transfer offices and the business going/coming out of them. When the past thirty years of reports are studied, it is evident that there has been a significant increase in patents issued in the last thirty years,<sup>121</sup> and, moreover, that there has been a similar increase in the number of university technology transfer offices.

<sup>&</sup>lt;sup>117</sup> De Lorena, *supra* note \_\_\_\_, at 1374, n.2 (quoting Clifton Leaf, The Law of Unintended Consequences, Fortune, Sept. 19, 2005

<sup>&</sup>lt;sup>118</sup> See, e.g., Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 ("Universities have taken the opportunity to file patent applications on basic research discoveries, such as new DNA sequences, protein structures, and disease pathways, that are primarily valuable as inputs into further research, thereby accelerating the encroachment of the patent system into what was formerly the domain of open science"); Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 608, 613 (2005) (explaining that prior to the Bayh-Dole Act, Internet inventions were not patented because universities "did not think patents were necessary or appropriate," but that now "universities [] are patenting early and often"); Jeffrey R. Armstrong, *Bayh-Dole Under Siege: The Challenge to Federal Patent Policy as a Result of* Madey v. Duke University, 30 J.C. & U.L. 619, 624 (2004) (noting that "each 'upstream' patent . . . allows its owners to set up a 'toll booth' on the road to product development, adding to the cost and slowing the pace of 'downstream' innovation").

<sup>&</sup>lt;sup>119</sup> Rai & Eisenberg, *supra* note \_\_\_\_\_, at 292, n.22 (quoting

<sup>&</sup>lt;sup>120</sup> It is hard to count actual "offices," but there are 232 universities and colleges that the Association of University Technology Managers (AUTM) includes on its list as those engaged in technology transfer activities (colleges and universities can subscribe to AUTM's services by paying a \$100 annual fee). http://www.autm.net/AM/Template.cfm?Section=FY2012\_Licensing\_Activity\_Survey&Template=/CM/ContentDisplay.cfm&ContentID=11435

<sup>&</sup>lt;sup>121</sup> Katherine J. Strandburg, *Curiosity-Driven Research and University Technology Transfer*, in University Entrepreneurship and Technology Transfer: Process, Design, and Intellectual Property 94 (Gary Libecap ed., 2005) (finding "clear evidence . . . that patenting at universities has increased drastically over the past 30 years") (hereinafter Strandburg, *Curiosity-Drive Research*).

Prior to 1983, AUTM found that twenty-seven universities had some sort of technology transfer office or program in place.<sup>122</sup> Between 1985 and 1990, thirty-seven universities added technology transfer offices,<sup>123</sup> and by 1999 that number increased to approximately 120.<sup>124</sup> This number has continued to grow, with another fifteen offices added by 2006.<sup>125</sup>

The 2012 AUTM U.S. Licensing Activity Survey Report ("2012 Survey") came out early this year, and showed growth in several areas of academic science. The 2012 Survey included 194 responses, including 161 universities, 32 hospitals and research institutes, and 1 third-party technology investment firm. This was a slight increase in response rate compared to 2011, up from 60 percent to 65 percent. I will highlight a few notable details of the 2012 Survey as it demonstrates the continued growth in academic science.

Invention disclosures for 2012 saw an increase of 8.6 percent, for a total of 23,741 disclosures.<sup>126</sup> Further, there was an even more significant increase in the number of issued patents. With 2011 seeing a 5 percent increase, 2012 increased by ten percent, for a total of 5,145 issued patents (and 22,750 patent applications). This number is even more significant when it is compared to that of 2008, totaling an increase in 56 percent in just 6 years. In 1979, the year before the Bayh-Dole Act was passed and the Supreme Court opinion *Chakrabarty*, universities received 264 patents.<sup>127</sup>

This increase in academic patenting is also reflected in the licensing activity of universities. Licensing increased by 5 percent for a total of 5,130 executed, and options to license increased by 8 percent for a total of 1,242 options executed.<sup>128</sup> These newly executed licenses and options brings the total number of active licenses and options to 40,007, an increase by 4 percent from 2011. It follows that licensing income also saw in a positive increase, with the total income up 6.8 percent, and 30.2 percent increase in royalties earned on sales of products. Combined with cashed-in equity and a catchall category of "other income," the total licensing income reported by the survey respondents was \$2.6 billion. While still quite impressive, it still is short of the all-time high recorded in 2008 at \$3.4 billion.<sup>129</sup>

These numbers look promising for universities, but the reality is that few university technology transfer offices hit it big with "blockbuster patents."<sup>130</sup> A recent study determined that over half of the offices do not generate enough to cover its own

<sup>129</sup> Abrams, Leung, & Stevens, *supra* note \_\_\_\_\_, at 2. (not sure if it is an all-time high, check this). <sup>130</sup> Cite needed. NYTimes article?

<sup>&</sup>lt;sup>122</sup> Tyler III, *supra* note \_\_\_\_, at 167, n78.

<sup>&</sup>lt;sup>123</sup> Berman, *supra* note \_\_\_\_, at 113.

<sup>&</sup>lt;sup>124</sup> Tyler III, *supra* note \_\_\_\_\_, at 167, n78.

 $<sup>^{125}</sup>_{126}$  Id.

http://www.autm.net/AM/Template.cfm?Section=FY2012\_Licensing\_Activity\_Survey&Template=/CM/ContentDisplay.cfm&ContentID=11435

<sup>&</sup>lt;sup>127</sup> Rai & Eisenberg, *supra* note \_\_\_\_, at 292.

http://www.autm.net/AM/Template.cfm?Section=FY2012\_Licensing\_Activity\_Survey&Template=/CM/ContentDisplay.cfm&ContentID=11435

operating costs, and only sixteen percent are self-sustaining.<sup>131</sup> Many of the offices barely break even after taking into account salaries of employees and legal fees.<sup>132</sup> But one thing is certain: university technology transfer offices, whether actually separate offices, program, or business organizations, "have become crucial organizations by providing a ready means to get university research results into the productive, commercial sector."<sup>133</sup>

# **III. EXISTING BARRIERS: THE GAP BETWEEN ACADEMIC SCIENCE** AND THE MARKET

It is easy to overlook existing barriers between academic science and the market given the incredible growth in funding, innovation, and sophistication of universities in the past century. Many of the barriers are ones that existed a century ago—for example, differing views about the ultimate mission of the university system, and how best to achieve it. And some of these barriers come with the increased patenting in academic science, for example, a fear that overpatenting in the life sciences will stall innovation and change the sharing norm,<sup>134</sup> as well as increased funding in particular academic disciplines.<sup>135</sup>

Certainly universities remain vigilant about the preservation of ideas and faculty discoveries for the benefit of the public, and, furthermore, the continued generation of such ideas and discoveries, but there is not a consistent message on how to best achieve those two missions.<sup>136</sup> "There are times when these two missions seem to conflict, making it difficult for federal labs, universities, hospitals and independent research institutions to maintain consistency."137

Compare those two missions with that of the unified mission in industry-make the biggest profit possible. Although industry scientists may work in laboratories that collaborate with large number of academic scientists, their end goal of producing a successful product or process makes for a very different work environment. Academic scientists operate under a more open environment with research results being published, whereas industry scientists are much more likely to keep their research results secret.<sup>138</sup>

<sup>&</sup>lt;sup>131</sup> Irene Abrams, Grace Leung, Ashley J. Stevens, How are U.S. Technology Offices Tasked and Motivated—Is It All About the Money? 17 Research Management Review 1, 1 (2009) (finding that "over half the technology transfer programs bring in less money than the costs of operating the program, and only 16% are self-sustaining, bringing in enough income that, after distributions to inventors and for research, there are sufficient funds to cover the operating costs of the program").

<sup>&</sup>lt;sup>132</sup> Cite. <sup>133</sup> *Id.* at 40.

<sup>&</sup>lt;sup>134</sup> Strandburg, *supra* note at 2250 ("Increased university patenting, particularly in the life sciences, has inspired fears that sharing norms would break down and research would be significantly slowed or stymied by the need to obtain preauthorization from research tool patentees.").

<sup>&</sup>lt;sup>135</sup> See Mangus Gulbrandsen & Jens-Christian Smedy, Industry Funding and University Professors' Research Performance, 34 Res. Pol'y 932, 940 (2005). Find some statistics here on various industries and carry down further to talk about culture changes.

<sup>&</sup>lt;sup>136</sup> http://www.ucop.edu/ott/faculty/overacad.html. See also: http://www.cogr.edu/Pubs\_intellectual.cfm. <sup>137</sup> Id.

<sup>&</sup>lt;sup>138</sup> Strandburg, *supra* note \_\_\_\_, at 2260 (suggesting that "the social benefits of research tool sharing are less clear when industry scientists are involved since they are more likely to keep their research results secret").

As one patent scholar and former academic scientist notes, "it is more difficult to stabilize and enforce norms of sharing in a community consisting of both academic and industry scientists than in a more homogenous academic research community."<sup>139</sup>

When academic and commercial institutions come together to share or transfer materials or technology, "the clash of internal academic goals" becomes most apparent. There are ethical concerns, with some "argue[ing] that university-industry interactions compromise objectively and that industry will try to unduly influence research topics, methods, results, and even the substantive reports themselves."<sup>140</sup> There are also several scholars that have written on the increase in academic commercialization and blamed it "for everything from increasing undergraduate tuition to destroying the public's trust in the objectivity of the advice and analysis it receives from professors."<sup>141</sup>

Another concern is simply the power of distraction. Universities and their respective faculty members should be focused on student experiences, teaching more generally, and basic research. Partnerships with industry may threaten collegiality within the university, encourage secrecy that goes against the basic norm of open sharing within academia, and delay publication.<sup>147</sup>

The overlap of university research and industry research is not new, but the norm is shifting where universities in particular disciplines are competing more with industry as opposed to just being the scientists establishing the groundwork for potentially new end products. Accordingly, university and industry institutions may be engaged in similar research, and the sharing and/or collaboration is more difficult with the academic missions at universities to share general knowledge with the public as well as now to profit. As a former president of Duke remarked "universities should do all that is reasonably possible to earn returns on inventions, and should not be timid in making prudent business arrangements to assure the largest fair return."<sup>143</sup>

The following sections will identify old and new barriers between faculty and university administration, and between the university and industry. I will then discuss the role of contract law in creating, and hopefully, helping to decrease barriers.

### A. Changing Culture of Open Science

After the Bayh-Dole Act was passed, universities began patenting their research discoveries and then also their research tools. This is troubling because of the importance in research tools to both upstream and downsteam innovation. It is shown that patenting decreases public access and increases price, and it is also generally accepted that scientists can do more meaningful and efficient work when given ready

 <sup>&</sup>lt;sup>139</sup> Strandburg, *supra* note \_\_\_\_\_, at 2260.
 <sup>140</sup> John E. Tyler III, *Advancing University Innovation: More Must Be Expected—More Must Be Done*, 10 MINN J.L. SCI. & TECH. 143, 158 (2009).

<sup>&</sup>lt;sup>141</sup> Abrams, Leung, & Stevens, *supra* note \_\_\_\_, at 4 (citing sources).

<sup>&</sup>lt;sup>142</sup> *Id.* at 158-59.

<sup>&</sup>lt;sup>143</sup> Lee, *supra* note \_\_\_\_, at 39 (citing Terry Sanford, *The University and Technology: New Paths and New* Perspectives, in 1 THE LAW OF BUSINESS AND LICENSING: LICENSING IN THE 1980S 1-63, 1-67 (Robert Goldsheider and Tom Arnold eds., 1989).

access to "gene fragments, disease models, and basic laboratory procedures."<sup>144</sup> Many scholars and scientists feared that the academic norms of open and free sharing of research tools would be eroded because of this new patenting practice of research tools.<sup>145</sup> The so-called patent thicket has already created blocking and holdout opportunities in many industries;<sup>146</sup> would the same happen in basic academic science?

Although it is hard to measure the impact of university patenting on the access and norms of sharing research and materials, recent empirical studies suggest that some of these fears as to research tools were somewhat overstated. As to the norm of sharing research tools despite potentially blocking patents, scholars are finding that "[s]cientists in both academia and industry routinely ignore patents on do-it-yourself research tools that can be 'homemade' in the laboratory."<sup>147</sup> This is consistent with previous academic norms and law that scientists act largely outside the scope of the patent system, both as to being eligible to patent and as to concerns about infringing others' patents.<sup>148</sup>

Ignoring patents is also consistent with the sharing ethos that is often talked about in the academy. Three academic technology transfer specialists write that "[i]n the health and agricultural sciences, biological materials were once freely and widely exchanged. But more and more, these materials have gained commercial value....<sup>149</sup> This has resulted in a significant change in the way that transfers are made in academic science. Transfers of materials are now accompanied by an MTA, and so while the practice of patenting "per se may not impede research tool sharing very significantly," this is not as true in the sharing of research materials.<sup>150</sup>

This is particularly so if the transfer of a research tool or particular material involves industry-to-academy transfer (compared to academic-to-academic transfer).<sup>151</sup> Instead of relying on the cheaper mechanism of publication to teach others the do-ityourself building of research tools, research materials must physically be transferred from one lab to another. Furthermore, publication is not exclusive to one scientist or any particular group, whereas sharing physical research materials is necessarily more finite and accordingly more costly.<sup>152</sup>

<sup>&</sup>lt;sup>144</sup> Lee, Contracting to Preserve Open Science, supra note \_\_\_\_, at 906 (explaining that this unfettered access to research tools would "suggest[] that perhaps research tools should be exempt from patenting and freely available in the public domain").

<sup>&</sup>lt;sup>145</sup> Strandburg, *supra* note \_\_\_\_\_, at 2250, n57 (listing articles where scholars argued that increased patenting might stymic research).

<sup>&</sup>lt;sup>146</sup> Need sources here.

<sup>&</sup>lt;sup>147</sup> Strandburg, *supra* note \_\_\_\_, at 2239. <sup>148</sup> See *id.* at 2250 (finding that "it appears that patents are simply not being enforced against research use," and that "[t]here is a norm of ignoring patents for research tool use, consistent with academic preferences for research tool sharing"). See also \_\_\_\_\_ ("there is a long history of shared biological materials, such as plant germplasm or genetic stocks, and for the most part this has been done freely and often without any form of a legal agreement").

<sup>&</sup>lt;sup>149</sup> Alan B. Bennett, Wendy D. Streitz, & Rafael A. Gacel, Specific Issues with Material Transfer Agreements, Chapter 7.3, p. 697 in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (eds. A Krattiger, RT Mahoney, L Nelson, et al) (2007), available at www.ipHandbook.org.

<sup>&</sup>lt;sup>150</sup> *Id*.

<sup>&</sup>lt;sup>151</sup> Id. (explaining "there appear to be more significant difficulties with sharing of research materials, particularly across the industry-academic boundary"). <sup>152</sup> Strandburg's norm sharing model here.

The two barriers focused on in this Article are the changing norms of sharing, the so-called ethos of sharing or open science, and the increasingly complex interactions between universities, and between universities and industry partners. These interactions often result in the transfer of materials. In the past, there may have been an open and free sharing environment, but now scholars have noticed that technology transfer offices almost always require a material transfer agreement (MTA). The MTA is so frequently used that it dominates much of the time of university technology transfer office.

The Council on Governmental Relations (COGR), an association comprised of "leading research-intensive universities," finds that the "attempt to balance [the conflicting missions] [] has triggered the increase care and rigor in the negotiation of material transfer agreement terms. The unfortunate consequence of this increase attention is the delay in the material exchanges that is so frustrating to investigators."<sup>153</sup>

The difference in missions between universities and industry entities are even noticeable in how complaints about the transfer of materials are voiced. "Unlike academic researchers, who report scientific competition and sharing costs as the major impediments to sharing materials, industry researchers report protecting commercial value and inability to obtain desired licensing terms (probably also related to commercial competitiveness) as by far the most important reasons not to share."<sup>154</sup> The following section will discuss the role of contract law generally in academic science focusing on the MTA.

# B. The Increased Role of Contract Law

While much focus in academic science is on patent law and obtaining patents, many more contracts are entered into in academic science than patents applied for in academic science. Beyond the common licensing agreements between the industry users of academic science, there is daily use in the academy of MTAs. And while there is heavy use, there is not a widely accepted standardized agreement. I do not propose to provide that here, but rather to point out the particularly tricky areas of the MTA that causes misunderstandings and delay in negotiations. Once these areas are addressed, there is room for policy suggestions on how to move beyond and more efficiently transfer materials, research tools, and data.

#### i. The Material Transfer Agreement

After the Bayh-Dole Act was passed and biomedicine boomed, scientists became increasingly vocal that the progress of their research was slowed down because of lengthy MTA negotiations. The largest research universities often execute and manage several thousand MTAs per year, while smaller private institutions manage

<sup>&</sup>lt;sup>153</sup> *Id.* (the report goes on to explain however that "[t]he fortunate consequences are less easy to appreciate, because they manifest themselves as an absence of downstream problems"). <sup>154</sup> *Id.* 

several hundred.<sup>155</sup> Collectively, the academy spends millions of dollars every year processing MTAs.<sup>156</sup>

MTAs slow down research, cost a lot of money, and there are studies finding that perhaps because of this cost and lengthy negotiation process, scientists frequently ignore or deny other scientists' request for materials. An empirical study published in 2002 study found that over the course of three years, 47% of geneticists who had asked other faculty members for access to data or materials regarding already published research were denied.<sup>157</sup> This is a significant increase from the previously reported number in the mid-1990s, which was just over 34%.<sup>158</sup> The authors of the study posit that "it may be that material transfer agreements have become so complex and so demanding that they inhibit sharing."<sup>159</sup>

The MTAs that are talked about as providing delays in research are not simple agreements covering just the transfer of basic research materials or tools. Those are easy and generally do not need more than an hour to look over and send to the parties to execute. Instead, the MTAs that are of concern are complicated agreements that may call for a cash payment, a reach-through royalty on the sales of any developed product, a reach-through equity share of any company developed from technology developed using the transfer materials, a grant-back provision allowing the university an option to license any technology arising through the use of the materials, a provision prohibiting the sharing of the materials with other universities or private firms, and even prepublication editorial review of any research results.<sup>160</sup>

Although the materials requested by university researchers from industry suppliers frequently or at least somewhat frequently contain these burdensome terms of transfer according to an AUTM report on MTAs published in 2011,<sup>161</sup> upfront fees are rare and generally never more than \$1000.<sup>162</sup> MTAs may also include indemnification terms and prohibition on the use of research findings in future work without express permission of the original grantor of the material.<sup>163</sup>

As a response to the criticism of the increasingly complicated MTA, the National Institutes of Health (NIH) and universities joined together in 1995 to develop a standard material transfer agreement for the transfer of biological materials (e.g., plasmids, compounds, antibodies, peptides, etc). This standard agreement is called the

<sup>&</sup>lt;sup>155</sup> www.vanderbilt.edu/cttc//cttc/sites/cttc.co/files/public/page/mtashare-ppt-website.pdf. Across the world, "hundreds of thousands of MTAs are processed annually." *Id*.

<sup>&</sup>lt;sup>156</sup> Id.

<sup>&</sup>lt;sup>157</sup> Eric G. Campbell et al, *Data Withholding in Academic Genetics: Data From a National Survey*, 287 JAMA 473, 478 (2002).

<sup>&</sup>lt;sup>158</sup> Id.

 $<sup>^{159}</sup>$  *Id.* at 479.

<sup>&</sup>lt;sup>160</sup> Rai & Eisenberg, *supra* note \_\_\_\_\_, at 294-95. *See also* http://www.ucop.edu/ott/faculty/overacad.html (explaining that MTAs have problematic terms that "restrict academic freedom," "assert excessive rights of ownership," and "ask for inappropriate indemnification by the university."

https://www.autm.net/AM/Template.cfm?Section=Documents&Template=/CM/ContentDisplay.cfm&ContentID=5761

<sup>&</sup>lt;sup>162</sup> Strandburg, citing another source. Find again.

<sup>&</sup>lt;sup>163</sup> http://www.ucop.edu/ott/faculty/overacad.html

"Uniform Biological Material Transfer Agreement," or UBMTA, and there are just over 500 universities and colleges that are signatories.<sup>164</sup>

The UBMTA is the most widely recognized pre-negotiated, standardized MTA. The terms and conditions that were agreed upon are relatively simple and short. Most notably, ownership of the material stays with the provider, although if any substances are created that contain or incorporate the material that results in a modification of the material, the recipient retains that ownership ("except that, the Provider retains ownership rights to the material included therein"). If the modification is a result of collaboration, the UBMTA simply instructs the two parties that "joint ownership may be negotiated." If, however, the Recipient wants to use or license the material or modification for commercial purposes, it must "negotiate in good faith" with the Provider for this separate right.

Moreover, under the UBMTA, the Recipient of the materials agrees to only use it "for teaching and academic research purposes" and only in the Recipient Scientist's lab. The Recipient may not transfer the material anyone else without written permission. If the Recipient wants to use the material in clinical trials or for other diagnostic purposes involving human subjects, the Recipient has to get prior written consent of the Provider.

And, finally, among other things, the UBMTA contains a standard warranty disclaimer, a clause whereby the Recipient assumes all liability for damages arising out "from its use, storage or disposal of the Material," and an attribution clause in all publications using the material.

When two universities or other non-profits transfer biological materials and both are signatories to the UBMTA, all they have to do is execute the two-page "UBMTA Implementing Letter." This Letter serves to record materials or tools transferred between universities, and the only place in the two-pages that might vary (besides the parties to the Letter of course) is if there is or is not a "transmittal fee" for the materials. This is not mandatory, but if the parties choose to include one, than the recipient can "reimburse the PROVIDER for preparation and distribution costs." The opening paragraph, and only substantive prose of the contract (see appendix A for the entire 2 page contract) is as follows:

### **UBMTA** Implementing Letter

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") March 8, 1995, and to certify that the recipient (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The recipient organization's Authorized Official also will sign this letter if the recipient scientist is not authorized to certify on behalf of the recipient organization. The recipient scientist (and the Authorized Official of Recipient, if necessary) should sign both copies of this letter and return one signed copy to the provider. The provider scientist will forward the

<sup>&</sup>lt;sup>164</sup> http://www.autm.net/Master\_UBMTA\_Signatories.htm

material to the recipient scientist upon receipt of the signed copy from the recipient organization.

Yet if the material transfer involves support from industry, and many do, the UBMTA is generally inappropriate because it was pre-negotiated without the third party's involvement. The 2011 AUTM Report on MTAs ("MTA Report") found that out of the survey respondents (83) reporting on academic-to-academic transfers (understood to be the least difficult kind of transfer), "only 31 percent reported frequently receiving the uniform biological material transfer agreement as the proposed agreement."<sup>165</sup> Conversely, 61 percent reported frequently using their own template agreement.<sup>166</sup>

The NIH itself provides standardized options for academic-to-academic transfers, as well as those involving industry partners. Those that receive funding from the NIH are strongly encouraged to use the NIH forms, but the MTA Report showed that only 15 percent of survey respondents frequently use the NIH Simple Letter Agreement.<sup>167</sup>

The NIH describes its Simple Letter of Agreement (SLA) as one that may be "[u]sed to transfer vectors, plasmids, compounds, antibodies, peptides, etc,"<sup>168</sup> and, accordingly, covers the same materials that the UBMTA does. But it is different than the UBMTA in that it is not just used for recording purposes. Instead, the SLA has specific representations that the recipient makes when using this agreement, most notably, that the material transferred "will be used for teaching or not-for-profit research purposes only," that the material "will not be further distributed to others without the Provider's written consent," and that the recipient "agrees to acknowledge the source of the Material in any publications reporting use of it."<sup>169</sup>

The SLA also expressly disclaims on the Provider's behalf that any representations or warranties come with the Material, and that the "Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider."<sup>170</sup>

The NIH provides similar templates to use for the transfer of human materials, the Human Materials – Material Transfer Agreement (HM-MTA), and for organisms such as mice and flies, the Material Transfer Agreement for the Transfer of Organisms ("MTA-TO"). Both the HM-MTA and the MTA-TO are only for the transfer to academic institutions or not-for-profit organizations.

As stated above, despite the readily available standardized MTAs, the UBMTA and NIH Simple Letter Agreement, institutions frequently use their own agreements. This is likely for several reasons, but mainly because the underlying grant that

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https://www.autm.net/AM/Template.cfm?Section=Documents&Template=/CM/ContentDisplay.cfm&ContentID=5761, at 11.

<sup>&</sup>lt;sup>166</sup> *Id*. at 16.

<sup>&</sup>lt;sup>167</sup> *Id*.

<sup>&</sup>lt;sup>168</sup> https://ttc.nci.nih.gov/forms/mta.php.

 $<sup>^{169}</sup>$  *Id*.

 $<sup>^{170}</sup>$  *Id*.

supported the creation of the material, tool, or dataset to be transferred has strings attached to any future transfers. And certainly, if the grant is from an industry partner, there will be transfer restrictions regardless of its use, whether it is for upstream or downstream transfer.

# ii. Contracting at Technology Transfer Offices

These next sections will look at individual universities, both private and public, large and small, to get a small sampling of university specific template agreements. University technology office staff understands that "academic investigators often find MTAs burdensome," but they are steadfast in that MTAs must be used to help protect their institution's interests.<sup>171</sup> "This protection is important to the university, investigators and laboratory personnel, and seeking this protection is driving the increased number of MTAs."<sup>172</sup> Many universities execute hundreds of MTAs per year, taking an incredible amount of resources and time. The following discussion will highlight a few specific MTA practices at universities across the nation. These practices will be compared and contrasted to the UBMTA to fully understand what universities often need that the UBMTA does not provide.

The Technology Transfer System of the University of California ("UC") has existed in some capacity for over forty years, and is quite expansive. The UC Technology Transfer System is made up of, and responsibility is shared, by the UC's Office of the President, 10 UC campus technology offices, and the Lawrence Berkeley National Laboratory.<sup>173</sup> Accordingly, technology transfer at UC is "in-house" and not a separate entity. Like the missions of universities back in the 1930s and 1940s, UC focuses on the public's access to any resulting innovation, stating that "[o]ne significant aspect of the University of California's public service mission is to ensure that the results of its research are made available for public use and benefit."<sup>174</sup>

The UC Technology Transfer Program publishes annual Technology Commercialization Reports, with the 2013 Report detailing number of inventor disclosures (1,727), the number of new license agreements executed (427), and new companies launched (71).<sup>175</sup> The 2013 Report also shows that in 2013 UC filed 1,832 patent applications, was issued 395 patents, and had 2,328 active licenses.<sup>176</sup> And, finally, the 2013 Report shows that its royalty and fee income was \$106 million.<sup>177</sup>

The UC Technology Transfer Program has 12 technology transfer offices, with a staggering number of personal that are focused on MTA analyzed and negotiating. In the UC-Davis Office alone, for example, there are two staff members who are "Senior MTA Analyst[s]," and two more that are "MTA Analyst[s]."<sup>178</sup> There is one more spot

<sup>&</sup>lt;sup>171</sup> James Henderson, Commentary: Counterpoint: MTAs as a Practical Necessity, 22 NATURE BIOTECHNOLOGY, 722, 722 (2007) (available at www.nature.com/nbt/journal/v25/n7/full/nbt0707-

<sup>722.</sup>html). <sup>172</sup> *Id*. <sup>173</sup> www.ucop.edu/innovation-alliances-services/\_files/ott/genresources/documents/IASRptFY13.pdf <sup>174</sup> http://www.ucop.edu/ott/genresources/ttprog.html

<sup>&</sup>lt;sup>175</sup> www.ucop.edu/innovation-alliances-services/ files/ott/genresources/documents/IASRptFY13.pdf <sup>176</sup> Id.

 $<sup>^{177}</sup>$  Id.

<sup>178</sup> research.ucdavis.edu/a/cu/contact-ia

listed on the website for an MTA Analyst that is currently "In Recruitment."<sup>179</sup> This is in addition to each science-heavy college, such as the College of Biological Sciences and College of Engineering, having their own designated Intellectual Property Officer.<sup>180</sup>

The practice of UC system is that prior to "proprietary or valuable material changes hands," a material transfer agreement should be executed between the sponsor and receiving party.<sup>181</sup> Each technology transfer office is tasked to help its respective faculty members and researchers negotiate and execute these agreements.<sup>182</sup> There is a standard procedure in place at each individual UC technology transfer office. This procedure is not consistent as to the precise intake forms from campus to campus, although generally it is consistent in that the faculty member, depending on whether it is an outgoing material transfer or an incoming material transfer, fills out a transfer form and submits it to the office for its review.

These forms, for example, both the UC-Davis and the UC-Irvine incoming material forms, require contact information and names for the Principal Investigator (the faculty member or researcher in charge of the project), the UC Primary Contact other than the Principal Investigator, the Outside Organization, and finally the Outside Organization's MTA Negotiator and/ or Legal or Administrative Contact. In this first part of the UC MTA information gathering forms, they UC-campus specific forms look very similar to the UBMTA (the main purpose seems to gather the proper recordation information). This continues as the forms have fill-in slots for the date the materials will be needed and for what period of time, as well as a general description of the material being requested. These forms also notably ask whether derivatives or modifications of the material will be made, and inquire the extent of possible third party interaction with the material. This includes whether third party material will be added to this incoming material, whether there is third party funding for this material, and what interest there is by the principal investigator at this outside organization, if any.<sup>183</sup>

From these intake forms, the respective UC technology transfer office has the basic information and just needs to likely add a few provisions. In the UC-Irvine MTA Agreement covering outgoing biological materials, presumably used in instances when the receiving institution is not an implementing member of the UBMTA or when there is a third party interest at stake and so the UBMTA form is not an option, UC-Irvine states that the following conditions must be agreed to prior to the transfer of the materials:

<sup>&</sup>lt;sup>179</sup> Id.

<sup>&</sup>lt;sup>180</sup> Id.

<sup>&</sup>lt;sup>181</sup> See, e.g., ota.uci.edu/industry-resources/research-materials.html

 $<sup>^{182}</sup>$  Id.

<sup>&</sup>lt;sup>183</sup> UC-Irvine specifically asks: "Do you plan to use third party materials that were brought into UCI in your research the Material(s)?" and "Do you have a financial interest in the outside institution (income, consulting, gift, stock ownership or management position)?" The UC-Davis form similarly asks "If you will use the Material with other material provided by a third party  $[\ldots][,]$  If you will provide Material that uses or incorporates material provided by a third party  $[\ldots][,]$  "Do you or your spouse, domestic partner or dependent children have a financial interest in the Outside Organization?"

[T]he Biological Materials will be used only in scientific research;

[T]he Biological Materials will be used with caution and prudence in any experimental work and that the Biological Materials will not be used on any human subjects;

Recipient Institution will bear all risk to Recipient Investigator and to others resulting from use of the Biological Materials;

Recipient Institution will defend, indemnify and hold harmless The Regents for all claims, losses and expenses resulting from your use of the Biological Materials;

Recipient Investigator and Institution will not allow the Biological Materials to be transferred to any other party or use them for commercial purposes without the express written consent of The Regents;

Recipient Investigator and Institution will not allow the Biological Materials to be transferred to any other party or use them for commercial purposes without the express written consent of The Regents;

The University of California will be acknowledged in any publications resulting from your work with the Biological Materials and the UCI Investigator will be given credit in such publications, as scientifically appropriate; and

Recipient Investigator will inform the UCI Investigator of experimental results obtained from using the Biological Materials.

Finally, the UC-Irvine standardized MTA adds in the typical disclaimer of any express or implied warranties, and, further, a sentence adding that "The Regents makes no representation and provides no warranty that the use of the material will not infringe any patent or other proprietary right." The remainder of the agreement is a clause stating that there is no license be granted or implied in the MTA, and then finally signature lines.

A smaller public institution than the system of the University of California, but that nevertheless has a very active technology transfer practice is Georgia Technology Institute ("Georgia Tech"). At Georgia Tech, the Georgia Tech Research Corporation (GTRC), set up as a state-chartered 501(c)(3) not-for-profit corporation, serves, similar to the WARF, as the governing body that protects and manages all intellectual property created at Georgia Tech.<sup>184</sup> The GTRC was created not long after WARF on April 13, 1937.<sup>185</sup>

The GTRC and the WARF are just two of roughly 100 separate entities connected to state institutions that either completely own or perhaps just license intellectual property of those respective state institutions.<sup>186</sup> The GTRC does a variety of business and contracting activities for Georgia Tech, but it is the Office of Industry

<sup>&</sup>lt;sup>184</sup> www.gtrc.gatech.edu.

<sup>&</sup>lt;sup>185</sup> www.gtrc.gatech.edu/about-us/

<sup>&</sup>lt;sup>186</sup> See *id*. The website also explains that "[t]hese foundations are organized primarily to permit their host universities to operate research programs by minimizing the impact of restrictive state contracting and financial procedures."

Engagement within the GTRC that "is responsible for the protection, licensing, and management of Georgia Tech's intellectual property portfolio.<sup>187</sup>

In 2012, the Office of Industry Engagement reported that it spent \$730 million on research expenditures, had 407 invention disclosures filed, received 79 new U.S. patents, executed 89 new licenses and/or license options (bringing the total active licenses to 620), and facilitated the formation of 12 new startups.<sup>188</sup> Despite the different organization structure from UC. Georgia Tech employs a similar process for when faculty or researchers want to send or receive materials to support research. There is an Outgoing Material Transfer initiation form and an Incoming Material Transfer initiation form.<sup>189</sup>

The questions on the Incoming Initiation Form again focus on third-party involvement, asking "[w]ill the Material be used with any materials you have received or will receive from any other institution, corporation, or business entity" and "[w]ill the Material be used in collaboration with any non-GIT parties"?<sup>190</sup> The Georgia Tech Incoming form does get a bit more detailed, however, specifically wanting to know if the Material being received by the Georgia Tech researcher is human embryonic stem cells or recombinant DNA, both biological materials that are infamously covered by university patents. Curiously, it also asks whether the Provider requires a MTA, and, if not, the Principle Investigator is able to skip a number of questions and, accordingly, provide very little detail to the Georgia Tech Office of Industry Engagement.

The Outgoing Initiation Form asks whether the Material being sent from Georgia Tech is "associated with an invention already disclosed to the Office of Innovation and Translational Research."<sup>191</sup> The Outgoing Form also asks the third party question, and adds: "[a]re there other reasons why you believe an MTA is necessary?"

Private institutions also must deal with the hundreds of MTAs per year. Most of them handle them very similarly to UC and Georgia Tech, for example, Emory<sup>192</sup> and Columbia.<sup>193</sup> Dartmouth is slightly different in that it publically posts its standardized agreements for all to see prior to the transfer, as opposed to just an initiation or intake form.<sup>194</sup> Dartmouth has three separate Outgoing MTAs: MTA to Nonprofit Institutions, to Industry, and to Industry with a Fee. The MTA with Nonprofit Institutions looks similar to the UBMTA, and covers biological materials. Ownership stays with Dartmouth, Dartmouth gives no warranties, and the Recipient must defend, indemnify and hold Dartmouth "harmless form any loss, claim, damage or liability, which may arise from Recipient's use, storage and disposal. ... "195

<sup>&</sup>lt;sup>187</sup> www.gtrc.gatech.edu/related-offices

<sup>&</sup>lt;sup>188</sup> industry.gatech.edu/about/impact/

<sup>&</sup>lt;sup>189</sup> Id.

<sup>&</sup>lt;sup>190</sup> Incoming MTA. GIT.

<sup>&</sup>lt;sup>191</sup> Outgoing Initiation Form

<sup>&</sup>lt;sup>192</sup> See http://ott.emory.edu/about/statistics/mta.html (explaining that Emory executed roughly 700 MTAs last year). Attach form link.

<sup>&</sup>lt;sup>193</sup> See techventures.columbia.edu/inventors/forms-agreements (using the common Incoming and Outgoing forms to help expedite the information sharing process and get the MTA drafted and executed quickly).

<sup>&</sup>lt;sup>194</sup> See www.dartmouth.edu/~tto/mtas.html <sup>195</sup> *Id*.

The Outgoing MTA to Industry and to Industry with Fee also covers "Biological Material" and both have the same warranty disclaimer. The other provisions are much more carefully, and perhaps warily, drafted. The MTAs state that the Biological Material is "not to be given or made available to any other person (other than those scientists working in collaboration with you), firm, or corporation, but [is] to remain under your immediate and direct control." The next paragraph explains that the Biological Material, or any part of it, is not to be use "in or for the production of products for sale, unless XYZ also agrees that prior to any commercialization of any provide appropriate compensation to Dartmouth in accordance with license or other agreement negotiated in good faith between Dartmouth and XYZ."

The MTAs also make clear that Dartmouth is to retain and/or obtain specific rights, namely, that sharing the Biological Material with "XYZ" does not prohibit Dartmouth from sharing the Biological Material with any other commercial or non-commercial entities. Moreover, that XYZ agrees that if it publishes any results of its research that it must appropriately acknowledge Dartmouth's contribution, "as scientifically appropriate."

The MTA for Industry with Fee is substantially identical to a transfer without any fee, but has a one-time payment fee ("the Biological Material is provided to you for a one-time license free of \$5000 for internal research and /or evaluation purposes only").

Another private university is emerging as a particular leader in the MTA field. Vanderbilt launched "MTAShare" this past spring, an automated and scale-able system that both processes and manages Vanderbilt-specific MTAs.<sup>196</sup> MTAShare uses the standardized UBMTA and the NIH Implementing Letter, and also has a tracking system to help Vanderbilt track its many outgoing and incoming MTAs. Although it is just available for Vanderbilt transfers currently, Vanderbilt is actively lobbying more institutions to use MTAShare. With MTAShare, Vanderbilt believes that the MTA transaction time will be reduced, which will result in saved money and less researcher frustration.<sup>197</sup>

This particular system is a great start, but it is limited in its adaptability and widespread use. The largest impediment is that the UBMTA and NIH standardized forms may be widespread, they are not often used as demonstrated by the recent AUTM MTA report. These standardized MTAs do not have the ability to tailor terms in accordance to the type of collaboration that is being fostered or at least enabled by the MTA.

# IV. BUILDING A SANDBOX FOR MATERIAL TRANSFERS

Even though there have been efforts by the NIH, AUTM, and others in recent years to simplify and to encourage the use of specific terms, the use of MTAs continues to grow in number and complexity. Industry partners question if it is worth their time to

<sup>&</sup>lt;sup>196</sup> www.vanderbilt/edu/cttc//cttc/sites/cttc.co/files/public/page/mtashare-ppt-website.pdf
<sup>197</sup> Id.

exchange materials, most notably research tools, to academic institutions.<sup>198</sup> And as mentioned above, academic institutions are denying or ignoring MTAs to other academic institutions in record numbers.

Although there are several factors as to why research tools, material, and data are no longer shared as consistently or freely, such as tighter budgets and the limited availability of the number of tools and materials under the restricted budgets, there is much support from both scholars and practitioners that the growing complexity and demands of MTAs are making it harder to share. With the increased pressure on academic scientists to play a greater role in the back-end process and academic institutions learning the potential value of its faculty output, there is tighter control than ever on the informal sharing of materials, tools, and data. This tighter control is manifested by no longer informally sharing tools and materials, but, rather, having an MTA for nearly every transfer.

That said, not every MTA is hard to negotiate or move forward quickly. When academic institutions are transferring routine materials, such as laboratory mice, a one page (either UBMTA or SLA, for example) is used. The academic institutions are merely recording the transfer, and perhaps documenting that there is a small fee the receiving academic institution will pay to cover the cost of the mice.

On the other hand, with valuable research tools as to cost of the tool and potential for the tool to help create new intellectual property, or materials, there is often a long negotiation process. A team from UC-Davis estimated in 2007 that "10%-25% of MTAs received from industry for incoming materials [] were never executed because the terms compromised fundamental academic principles or created legal obligations that the university cannot fulfill."<sup>199</sup> There are other times when the MTA might end up being executed after three, six, or longer months of negotiation, but at that time the grant has expired or there is a better resource that was developed during the negotiation time that makes the present research futile.<sup>200</sup> Other accounts from universities include prolonged MTA negotiations that cause a six-month or longer delay that ultimately ends up halting research and then missing the deadlines for the corresponding grant

When the negotiation process slows down, it is likely because of one of the three following reasons: differing views regarding ownership or access to any potential IP resulting from the use of the transferred materials, indemnification (e.g., from third party claims or accidents in the laboratory), and the right to publish results from experiments or data collected using the transferred materials. The following sections will address each of those three points of tension when transferring materials, most notably when it involves an industry partner and academic institution. The discussion will focus on why these particular aspects are often deal-breakers for academic institutions, and will propose alternative solutions that will enable both parties to move forward and transfer the materials. Ultimately, sharing materials, tools, and data with

 <sup>&</sup>lt;sup>198</sup> Professor Eisenberg explains that companies are questioning the worth of exchanging research materials with academic institutions. (CHECK). *Bargaining over the Transfer of Research Tools: Is This Market Failing or Emerging*? In Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society (eds. Dreyfull, Zimmerman, & First). Oxford Univ. Press: New York. Pp. 223-49.
 <sup>199</sup> Handbook of Best Practices, *supra* note \_\_\_\_\_, at 699.

<sup>&</sup>lt;sup>200</sup> Wendy D. Streitz & Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, p. 1 (available at http://www.ncbi.nim.nih.gov/pmc/articles/PMC523866/.

other commercial and noncommercial scientists is creating more synergistic innovative activity.

[Please contact me for the remainder of the draft if interested. Thank you for not further posting this or circulating this early draft].