

**Authorship and Inventorship: An analysis of publishing and patenting norms and their consequences at American universities**

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## Introduction

Norms governing academic science are different from those governing patent law. Yet the two spheres are increasingly in contact, and sometimes conflict, as many academics patent their scientific discoveries. Under U.S. law, patents can be invalidated for omitting inventors. Such omissions can arise from discrepancies between the criteria for authorship and that for inventorship, but they can also arise from illegitimate exclusion of actual inventors. Junior scientists are more likely to be excluded, both by conventional wisdom as well as data-driven analyses.<sup>1</sup> A few junior scientists have brought their grievances to court, some with more success than others.<sup>2</sup> Recent and ongoing lawsuits between students and their superiors underscore the persisting incongruence between publishing and patenting norms particularly with respect to seniority.<sup>3</sup> Even if they are included as inventors, junior scientists have faced discrimination in the patenting process.<sup>4</sup> Given the reputational and monetary costs, research universities have an incentive to reconcile the publishing and patenting spheres of academic science.

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<sup>1</sup> Lissoni, F. et al. "Inventorship and authorship as attribution rights: An enquiry into the economics of scientific credit." *Journal of Economic Behavior and Organization* 95, (2013): 46-49; Haeussler, C., Sauermaun, H., "Credit where credit is due? The impact of project contributions and social factors on authorship and inventorship." *Research Policy* 42(3), 2013: 688-703.

<sup>2</sup> For an example of success, see *Chou v. University of Chicago*, 2000 WL 222638 (N.D Ill. 2000) and the discussion on it later in the thesis. For an example of failure, see *Stern v. The Trustees of the University of Columbia in New York City*, 01-CV-10086 (S.D.N.Y. Feb 17, 2005). For other past cases, see Smith, G. Kenneth. "Faculty and Graduate Student Generated Inventions: Is University Ownership a Legal Certainty?" *Va. JL & Tech.* 1 (1997): 4-7.

<sup>3</sup> For a recently decided case, see *Hor v. Chu*, No. 11-1540 (Fed. Cir. Nov. 14, 2012). For an ongoing case, see *Scilimenti v. Leland Stanford Junior University et al*, filed on September 22, 2008 to the California Southern District Court.

<sup>4</sup> For an example, see the discussion on streptomycin, Albert Schatz, Selman Waksman, and Rutgers University in a later chapter. Although Schatz was named an inventor, he did not receive the corresponding treatment with regards to royalties and international patents. His lawsuit and the publicity it generated led Rutgers University to settle generously with him in private. More recently, a former graduate student of chemistry at Harvard University Mark Charest sued his professor Andrew Myers for fraud, breach of contract concerning antibiotic synthesis royalties. Filed on June 28, 2013 to the Massachusetts District Court, the case has received media attention.

How can universities improve management of authors and inventors in the life sciences?

To inform university policy and practice on authorship and inventorship, I seek to better understand the publishing and patenting norms in academia. Specifically, this thesis addresses the following questions: To what extent do conceptions of inventorship and authorship overlap formally, and to what extent do seniority, gender, and collaboration within and across institutions affect an author's likelihood of being named as an inventor? To what extent do disputes over invention impose costs, monetary and reputational, for the universities involved, and what can they do to prevent and mitigate those costs?

I approach the first of these questions in Chapter 1 by comparing the formal criteria for inventorship from the United States Patent and Trademark Office (USPTO) and authorship from the International Committee of Medical Journal Editors (ICMJE) and other sources. While inventorship and authorship share many formal requirements, they are by no means synonyms. Authors can legitimately be dropped from the corresponding patent, for example, if they contribute only to the interpretation and analysis of data but not to the design and conception of the patented invention.

Chapter 2 presents a logistic regression that uses patent-paper pair data and shows that more junior authors as well as authors working in larger groups and across more institutions are less likely to be named as inventors. While much has been written about the role of seniority in credit assignment in academic science, the empirical evidence also calls our attention to the growth in scientific collaboration and the difficulties that having more authors and potential inventors may pose for technology transfer offices in the future.

Chapter 3 consists of three case studies in which junior scientists experienced differential treatment either in the initial naming or subsequent stages of university patenting activities. The

first concerns recombinant DNA technology developed by biochemists and geneticists at Stanford University and the University of California, San Francisco in the early 1970s. Although the inventorship disputes were never brought to court, junior authors who were omitted from the patent—John Morrow and Robert Helling—expressed their dissent through other avenues and attempted to attain inventorship. The discrepancy resulted in prolonged patent examination, associated legal fees, and a less profitable licensing scheme for the universities involved.

Another prominent case in the biomedical sciences is the discovery of streptomycin, a powerful antibiotic, by Selman Waksman and his graduate student Albert Schatz. Listed as an inventor, Schatz was not treated as Waksman's equal in decisions concerning the patent. Questionable behavior on the part of the professor further generated negative publicity when Schatz sued. The dispute, about which Peter Pringle wrote a book, *Experiment Eleven*, in 2012, tarnished the reputation of Rutgers University, and resulted in monetary payments to Schatz. The last case, the only one decided in court, pertains to herpes vaccines developed by Joanne Chou and her mentor Alex Roizman at the University of Chicago in the late 1990s. Excluded from inventorship, Chou successfully sued Roizman and the University for breach of fiduciary duty, among other claims, and became entitled to 25% of the royalties.

The concluding chapter synthesizes evidence from the qualitative case studies and quantitative regression analysis on the roles of seniority, gender, and collaboration in discrepancies between authorship and inventorship at and their costs to American research universities. Broadly, I conclude that universities might best protect themselves by increasing transparency and accountability in laboratories, and offers examples of possible action by universities and academic journals to facilitate that change.

## Chapter 1: Authorship and Inventorship—Criteria and Literature Review

As patenting in the biomedical sciences become more common in academia, the process governing the transfer of scientific credit from publications to patents has become increasingly consequential. Many have noticed the discrepancy between the number of coauthors on publications and that of coinventors on the corresponding patents; Philippe Ducor, a Swiss professor and practitioner of intellectual property law in the life sciences, argues that there should be no discrepancy given the authorship guidelines of the International Council of Medical Journal Editors (ICMJE) and the inventorship criteria from United States Patent and Trademark Office (USPTO). He concludes that they “use essentially the same principles and terminology: both are based on substantial contributions to conception and design.”<sup>5</sup> Through a sample of forty patent-paper pairs in a field of molecular biology, he found the average number of authors to be ten and that of inventors to be three.<sup>6</sup> He suggests several potential causes, including salami science<sup>7</sup>, coauthorship inflation, dilution of responsibility for content, and gift authorship. Even though the exclusion of some coauthors on a patent would be valid under these scenarios, he notes that any discrepancy nonetheless “creates the presumption that one or more inventors were omitted and constitutes a legal hazard on both the validity and the value of the patent.”<sup>8</sup> Both the issues of authorship assignment and the transfer from that to inventorship are therefore relevant to the owners of these patents, namely the research universities in our study.

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<sup>5</sup> Ducor, Philippe. "Intellectual property: coauthorship and coinventorship." *Science* 289, no. 5481 (2000): 873-875.

<sup>6</sup> 14 article-patent pairs in which the first, the last, or authors in both positions on the paper were not mentioned as inventors on the corresponding patent. *Method*: manual search of databases for paper-patent pairs whose main disclosure were (genetic/amino acid sequence for) proteins in a field in molecular biology. *Results*: Out of 40 article-patent pairs, the last author was named as inventor in 37 cases, whereas the first author was named in 26 cases. 38 had more authors than inventors, 2 had as many inventors as authors, and none listed more inventors than authors. The average number of authors was 10 and the average number of inventors was 3.

<sup>7</sup> Salami-slicing refers to “the practice of fragmenting single coherent bodies of research into as many publications as possible.” See “The cost of salami slicing,” Editorial, *Nature Materials* 4, (2005): 1.

<sup>8</sup> Ducor, “Coauthorship and Coinventorship.” (2000).

There has been a wealth of information and publications on academic authorship, clarifying its purpose in science as well as warning against unethical practices.<sup>9</sup> In theory, authorship, as recognition for scientific priority, is meant to spur the growth of science.<sup>10</sup> Practically, however, authorship is the currency through which academic researchers earn funding, prestige, and tenure.<sup>11</sup> Evident from the motto, “publish or perish,” scientists face considerable pressure to publish, which plausibly leads to creative and unethical solutions. Merton suggests that the incentive is further augmented because recognition and esteem are the “sole property right of the scientist in his discoveries,” a result of the institutional norm of communism and humility.<sup>12</sup> Career pressures and the reward system of science combined have contributed to the rise of problematic practices in authorship assignment.<sup>13</sup>

“Salami-slicing” is one of them. The term refers to the “the practice of fragmenting single coherent bodies of research into as many publications as possible,” or in other words, shortening the least publishable unit (LPU) to inflate publication counts.<sup>14</sup> In as early as 1981, William J.

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<sup>9</sup> For the purpose of authorship in science, see Robert K. Merton, “Priorities in Scientific Discovery: A Chapter in the Sociology of Science.” *American Sociological Review*, Vol. 22, No. 6 (Dec., 1957), pp. 635-659; Kevin Strange, “Authorship: why not just toss a coin?” *American Journal of Physiology Cell Physiology* 295(3), 2008: 567-575; Biagioli, Mario, and Peter Galison, eds. *Scientific authorship: Credit and intellectual property in science*. Routledge, 2014. Published in many prominent journals, warnings against unethical practices take the form of editorials, of which the following form a small collection: Luther Friedy, “Publication ethics and scientific misconduct: the role of authors,” *Journal of Orthodontics* 35, (2008): 1-4; “The cost of salami slicing,” *Nature Materials* 4, (2005): 1; Titus, Sandra L., James A. Wells, and Lawrence J. Rhoades. “Repairing research integrity.” *Nature* 453, no. 7198 (2008): 980-982; Alberts, Bruce, “Promoting Scientific Standards,” *Science* 327, (2010): 12. Alberts and Kenneth Shine also called for “high ethical standards” in the journal nearly two decades ago: B. Alberts, K. Shine, *Science* 266, (1994): 1660.

<sup>10</sup> For more on the role of authorship in science, see Robert K. Merton, “Priorities in Scientific Discovery” and “The normative structure of science.” *The sociology of science: Theoretical and empirical investigations* 267, (1973).

<sup>11</sup> Louis, Karen Seashore, Janet M. Holdsworth, Melissa S. Anderson, and Eric G. Campbell. “Everyday ethics in research: Translating authorship guidelines into practice in the bench sciences.” *The Journal of Higher Education* 79, no. 1 (2008): 88-112.

<sup>12</sup> For institutional norm of communism, see Merton, “Normative Structure of Science.” For institutional norm of humility, see Merton, “Priority in the Sciences.”

<sup>13</sup> Diane Bennett and David Taylor, “Unethical Practices in authorship of scientific papers,” *Emergency Medicine* (2003) 15, 263-270; “The cost of salami slicing,” *Nature Materials* 4, 1 (2005).

<sup>14</sup> “The cost of salami slicing,” *Nature Materials* 4, 1 (2005).

Broad noted the problem as well as that of publishing the same data several times.<sup>15</sup> There are many perils associated with “salami-slicing,” among them the financial burden of maintaining a large number of journals; the time referees waste on reviewing articles that make little original contribution; loss of meaningful comparisons of data due to slicing; over-representation of the same patient series in medical literature to name a few prominent concerns.<sup>16</sup>

Another issue broadly written about by academics and journal editors alike is that of “gift” and “ghost” authorship. The former pertains to individuals who are named as authors without meeting the criteria, and the latter to those who are not named as authors while satisfying the requirements. Neither assignment abides by the formal authorship requirements of the ICMJE, yet both occur frequently in high impact journals that adopt those criteria. Corroborating past studies, Wislar et al. estimated the prevalence of articles with a gift or ghost author or both in six respected medical journals at 21%.<sup>17</sup> Since there is no way for reviewers to know the specific contributions of the authors given the current disclosure format, scholars have found widespread non-compliance of ICMJE or other journal-specific authorship criteria. Bates et al. found that 60% of 72 articles in the *Annals of Internal Medicine* and 21% of 107 articles in the *British Medical Journal* have at least one author that does not meet the first ICJME criterion.<sup>18</sup>

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<sup>15</sup> Board, William J. “The Publishing Game.” (1981).

<sup>16</sup> “The cost of salami slicing,” *Nature Materials* 4, 1 (2005); William J. Dupps and J. Bradley Randleman, “The Perils of the Least Publishable Unit,” *Journal of Refractive Surgery* 28, 9 (2012): 601-602.

<sup>17</sup> Wislar, Joseph S., Annette Flanagin, Phil B. Fontanarosa, and Catherine D. DeAngelis. “Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey.” *BMJ: British Medical Journal* 343 (2011). For past studies, see Mowatt, Graham, Liz Shirran, Jeremy M. Grimshaw, Drummond Rennie, Annette Flanagin, Veronica Yank, Graeme MacLennan, Peter C. Gøtzsche, and Lisa A. Bero. “Prevalence of honorary and ghost authorship in Cochrane reviews.” *Jama* 287, no. 21 (2002): 2769-2771; Flanagin, Annette, Lisa A. Carey, Phil B. Fontanarosa, Stephanie G. Phillips, Brian P. Pace, George D. Lundberg, and Drummond Rennie. “Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals.” *Jama* 280, no. 3 (1998): 222-224.

<sup>18</sup>Bates, Tamara, Ante Anić, Matko Marušić, and Ana Marušić. “Authorship criteria and disclosure of contributions: comparison of 3 general medical journals with different author contribution forms.” *Jama* 292, no. 1 (2004): 86-88.

Similar results were found in the *Journal of Radiology*, *The Lancet*, and the *Dutch Medical Journal*.<sup>19</sup>

Under the above scenarios, some coauthors should indeed be excluded as an inventor, because they would likely not meet the criteria specified in patent law, namely that one was involved in the conception of the invention and contributed to at least one claim.<sup>20</sup> Even if all authors satisfy the ICMJE requirements, there are legitimate reasons for discrepancy between number of coauthors and that of coinventors. One is that conception is not required of authors by the ICMJE criteria, which consist of the following:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.<sup>21</sup>

In other words, if the researcher contributes substantially to “the acquisition, analysis, or interpretation of data for the work,” he can be a legitimate author by the ICMJE criteria without conceiving any part. Those contributions alone, however, would not qualify the researcher for inventorship on the corresponding patent.

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<sup>19</sup> Hwang, S. S., et al., “Researcher contributions and fulfillment of ICMJE authorship criteria: analysis of author contribution lists in research articles with multiple authors.” *Radiology* 22 (2003): 16-23.

<sup>20</sup> Patents, 35 U.S.C. § 116.

<sup>21</sup> ICMJE, 2007. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. International Committee of Medical Journal Editors, [http://www.icmje.org/roles\\_a.html](http://www.icmje.org/roles_a.html)

Another reason is that conception becomes plausibly harder to define when researchers collaborate in larger teams. According to the Scientific Citation Index (originally produced by the Institute for Scientific Information, which is now known as Thomas Reuters), the average number of authors per paper was 1.67 in 1960, 2.58 in 1980, 3.18 in 1990, and most recently 4.83 in 2010.<sup>22</sup> Similar statistics have been published by the National Library of Medicine on PubMed/MEDLINE publications: The average number of authors has steadily risen from 1.90 for pre-1975 articles to 5.03 for those published between 2010 and 2012 (See Figure 1). Moreover, the maximum number of authors on a given paper was 39 for the former timeframe and 3,172 for the latter.<sup>23</sup> There have been different reasons suggested for this rise in the number of co-authors, such as the spread of gratuitous authorship, other unethical practices, as well as the increased desirability of collaboration given the need for more specialized knowledge.<sup>24</sup> The implication remains, however, that accurately defining each person's contribution and achieving consensus are more difficult when research involves teams of tens, hundreds, or even thousands. These difficulties are magnified when assigning inventorship, which involves legal responsibility and monetary rewards absent from conventional authorship.

Some reasons for the discrepancy between the number of coauthors and coinventors pertain to the *process* of translating academic work into patents. First, universities often leave inventorship assignment to the principal investigator in a given laboratory.<sup>25</sup> Accustomed to the

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<sup>22</sup> Board, "The Publishing Game," 1981; Paul Jump, "The expanding universe of scientific authorship," *Times Higher Education*, July 8, 2010.

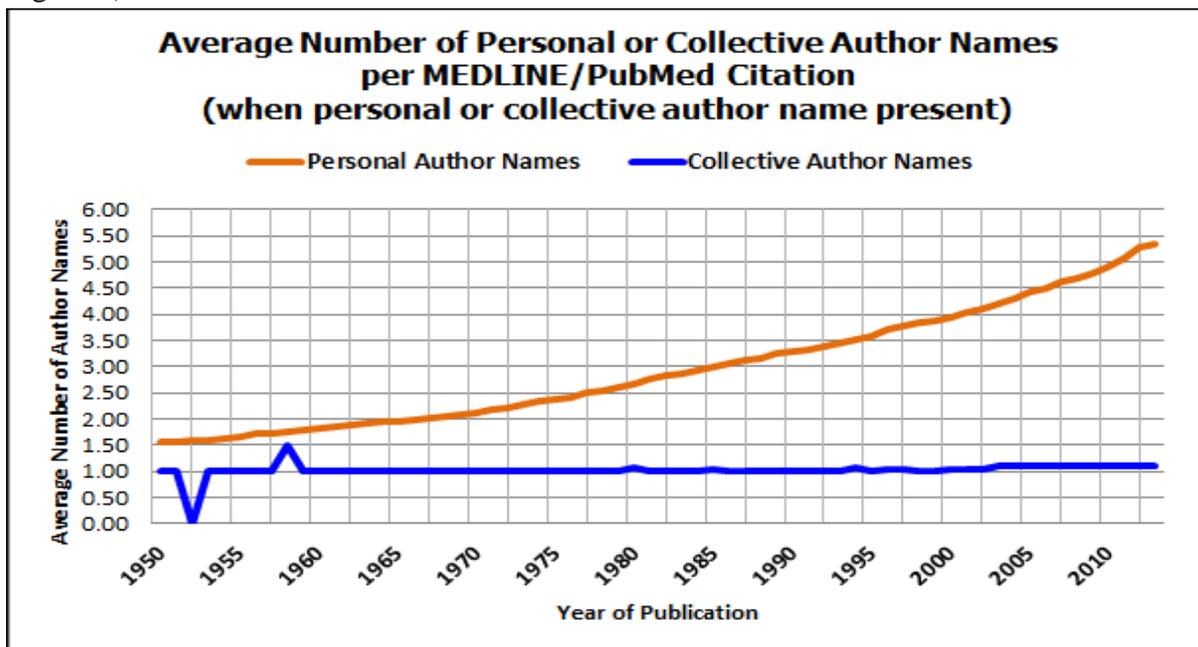
<sup>23</sup> "Number of Authors per MEDLINE®/PubMed® Citation," *National Library of Medicine*, National Institutes of Health, <http://www.nlm.nih.gov/bsd/authors1.html>

<sup>24</sup> Gans, Joshua S. and Murray, Fiona, Credit History: The Changing Nature of Scientific Credit (October 9, 2013). Rotman School of Management Working Paper No. 2338038; de Solla Price, Derek J., and Donald Beaver. "Collaboration in an invisible college." *American psychologist* 21, no. 11 (1966): 1011; Jones, Anne Hudson. "Changing traditions of authorship." *Ethical issues in biomedical publication* (2000): 3-29.

<sup>25</sup> Fasse, W. F., "The Muddy Metaphysics of Joint Inventorship: Cleaning Up after the 1984 Amendments to 35 U.S.C. § 116." *Harvard Journal of Law and Technology* 5, (1992): 73-74; Colyvas, J.A., "From divergent meanings

conventions of academia, these individuals might act according to them without fully understanding the legal definition of an inventor. Secondly, patent examiners do not rigorously check the inventors named by the applying institution or individuals.<sup>26</sup> Signed declarations are sufficient, and if not challenged in court, most inventorship attribution retains its original form without scrutiny. Combined, these procedural norms further promote discrepancies in authorship and inventorship assignment, as the former increases the likelihood of incorrect assignment and the latter decreases the incentive on the applicants' part to rigorously review and apply the formal criteria for inventorship.

Figure 1 | Personal Author Counts from 1975-2013



Note: The data presented were extracted from the 2014 Statistical Reports on MEDLINE®/PubMed® Baseline Data, which include detailed statistics on all data elements in the baseline database. The baseline contains all completed records in PubMed at the end of the NLM 2013 production year, which occurred in mid-November, after the global updating for the new year of MeSH (Medical Subject Headings). Publication Year 2013 is not yet complete and a few hundred citations with Publication Year 2014 are included. The baseline files exclude PubMed records identified as "in process" or "as supplied by publisher" (approx. 4% of the total). Note that very few citations from 1966-2000 contain collective author data. Source: "Number of Authors per MEDLINE®/PubMed® Citation," *National Library of Medicine*, National Institutes of Health, <http://www.nlm.nih.gov/bsd/authors1.html>

to common practices: the early institutionalization of technology transfer in the life sciences at Stanford University." *Research Policy* 36, (2007): 91-109.

<sup>26</sup> Lissoni et al. "Inventorship and authorship as attribution rights." (2013).

Several scholars have explored the economics of the discrepancy of interest. Through a sample of 680 Italian patent-publication pairs (related sets of patents and publications), economists Francesco Lissoni, Fabio Montobbio, and Lorenzo Zirulia have shown that the first and last authors are less likely to be excluded from the patent.<sup>27</sup> Though not formalized, the first authors are generally the main researchers on the project, and the last the senior mentor and head of the laboratory.<sup>28</sup> More precisely, Lissoni et al. found that the probability of exclusion declines with seniority and increases for women.<sup>29</sup> Other researchers have observed similar trends with regards to seniority but not gender in the German and British life sciences.<sup>30</sup> Research showing that American scientists comply with the ICMJE criteria more than their international counterparts provides another rationale for investigating possible cross-national differences.<sup>31</sup> Beyond the lack of an existing analysis on inventorship assignment trends in American universities, the preeminence and productivity of the American science community motivate my attempt to fill the void with regression modeling.

Several plausible explanations have been put forth for the lower likelihood of being named as an inventor among junior researchers. It could be that junior researchers contribute solely to the “reduction to practice” and not the “conception” component of inventorship. Others have suggested that junior researchers value inventorship less, as opposed to authorship, the

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<sup>27</sup> Lissoni et al. “Inventorship and authorship as attribution rights.” (2013).

<sup>28</sup> Teja Tschardt et al. “Author Sequence and Credit for Contributions in Multiauthored Publications.” *PLoS Biol.* 5, (2007). Published online 2007 January 16.

<sup>29</sup> Lissoni et al. “Inventorship and authorship as attribution rights.” (2013).

<sup>30</sup> Haeussler, C., Sauermann, H., “Credit where credit is due?” (2013).

<sup>31</sup> Hwang, S. S., et al., “Researcher contributions and fulfillment of ICMJE authorship criteria.” (2003); Hoen WP, Walvoort HC, Overbeke AJ. What are the factors determining authorship and the order of the authors’ names? A study among authors of the *Nederlands Tijdschrift voor Geneeskunde* (Dutch Journal of Medicine). *JAMA* 280, (1998): 217-218; Yank V, Rennie D. “Disclosure of researcher contributions: a study of original research articles in *The Lancet*.” *Ann Intern Med* 130, (1999): 661-670.

traditional currency for advancing their careers.<sup>32</sup> Still some attribute the phenomenon to “the Matthew Effect,” which American sociologist Robert K. Merton describes as “the accruing of greater increments of recognition for particular scientific contributions to scientists of considerable repute and the withholding of such recognition from scientists who have not yet made their mark.”<sup>33</sup> Although Merton’s discussion focuses on the common forms of recognition at the time, namely authorship, memberships in various Academies, and prestigious awards such as the Nobel Prize, the concept readily applies to inventorship.

To explain trends in gender, some have hypothesized that women value inventorship less holding all else constant, while others have suggested differences in access to industry contacts and perception of the time commitment demanded by commercial activity.<sup>34</sup> Using a Cox regression model<sup>35</sup> on data of faculty who earned their doctorates between 1967 and 1995 in diverse disciplines in the United States, Ding et al. estimated that female life scientists patent at a rate that is only 0.40 times that of their male counterparts, controlling for productivity, social

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<sup>32</sup> Stephan, P.E., and Levin, S. *Striking the Mother Lode in Science: The Importance of Age, Place and Time*. Oxford University Press, New York: 1992. Audretsch, D.B., and Stephan, P.E., “Knowledge spillovers in biotechnology: sources and incentives.” *Journal of Evolutionary Economics* 9, (1999): 97-107.

<sup>33</sup> Merton, Robert K., “The Matthew Effect in Science: The reward and communication systems of science are considered.” *Science* 159(3810): 58. January 5, 1968.

<sup>34</sup> Azoulay, Pierre, Waverly Ding, and Toby Stuart. “The determinants of faculty patenting behavior: Demographics or opportunities?” *Journal of Economic Behavior & Organization* 63, no. 4 (2007): 599-623; Ding, Waverly W., Fiona Murray, and Toby E. Stuart. “Gender differences in patenting in the academic life sciences.” *Science* 313, no. 5787 (2006): 665-667; Murray, Fiona, and Leigh Graham. “Buying science and selling science: gender differences in the market for commercial science.” *Industrial and Corporate Change* 16, no. 4 (2007): 657-689; Whittington, Kjersten Bunker, and Laurel Smith-Doerr. “Women Inventors in Context Disparities in Patenting across Academia and Industry.” *Gender & Society* 22, no. 2 (2008): 194-218.

<sup>35</sup> Cox regression, a proportional hazard model, belongs to class of survival models that relate the time that elapses before an event occurs to different covariates. The coefficient for a given covariate then pertains to the impact of a unit increase in that covariate on the hazard rate of the event occurring. In the context of Ding et al., the event is patenting and the covariates include gender, and the coefficient 0.40 means that being female decreases the rate of patenting by a factor of 0.40. The Cox regression model estimates pertain to rates of patenting, whereas the model in Lissoni et al. and the next chapter in this thesis measures the probability of being named an inventor conditional on being named an author.

network, scientific field, and employer characteristics.<sup>36</sup> After concluding that there is no notable gender difference in the scholarly influence of research, as measured by journal impact factor (JIF), the authors outlined two possible explanations based on interviews: Women have fewer contacts in industry but more concerns that pursuing commercial opportunities might hinder their university careers.<sup>37</sup> On the other hand, women seem to enjoy more encouragement from their coauthors and institutional advisors to consider patenting as part of their research undertaking. Furthermore, other studies have found that gender gaps in disclosure and patenting activity have narrowed, even converged, in recent years.<sup>38</sup> These analyses are not directly comparable with that employed in Lissoni et al. and the next chapter, but they provide valuable context to the findings reported later.<sup>39</sup>

While many have suggested solutions to the problems with authorship,<sup>40</sup> and some journals have adopted them,<sup>41</sup> less has been proposed for universities and their technology transfer offices. From their standpoint, discrepancy between the number of coauthors and coinventors increases the vulnerability of their patent portfolio and decreases its monetary value. And since much of the discrepancy stems from vagueness surrounding authorship assignment, universities can solve parts of the problem by adopting strategies similar to journals, by requiring employees to track and disclose their contributions to publications and patents systematically. Through regression modeling, I investigate patterns in inventorship assignment in American

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<sup>36</sup> Ding, Waverly W., Fiona Murray, and Toby E. Stuart. "Gender differences in patenting in the academic life sciences." (2006).

<sup>37</sup> Ibid.

<sup>38</sup> Ibid.; Thursby, Jerry G., and Marie C. Thursby. "Gender patterns of research and licensing activity of science and engineering faculty." *The Journal of Technology Transfer* 30, no. 4 (2005): 343-353.

<sup>39</sup> See footnote 35.

<sup>40</sup> Sebastian Frische, "It is time for full disclosure of author contributions." *Science* 489, 475 (27 September 2012); Vicens, Quentin, and Philip E. Bourne. "Ten simple rules for a successful collaboration." *PLoS computational biology* 3, no. 3 (2007): e44.

<sup>41</sup> The *Proceedings of the National Academies of Sciences* require coauthors to publish their contributions to the work as a footnote in the paper. *Nature* journals encourage authors to do so.

research universities. Then, through case studies in the biomedical sciences, I demonstrate some implications, particularly the reputational and monetary costs, of patent-publication disputes for academic institutions. Concluding, I explore their alternatives not only for preventing illegitimate discrepancy between coauthors and coinventors but also for protecting themselves with valid processes when a discrepancy is legitimate. Adherence to authorship and inventorship criteria can strengthen patents and also more fairly reward contributions to patented inventions arising in research universities.

## Chapter 2: Factors in Inventorship Attribution

### Background

Discrepancies between authorship and inventorship are widespread, prompting many to opine about the causes, consequences, and occasionally solutions to the phenomenon.<sup>42</sup> While some discrepancies stem from legitimate differences between authorship and inventorship criteria, others arise from academic norms concerning gender and seniority, difficulties reaching consensus and defining contributions among many collaborators, as well as various unethical practices such as gratuitous authorship.<sup>43</sup> Past research using patent-paper pairs (PPP) in Italian, British, and German science has found consistently that junior authors are less likely to be named inventors, but female scientists seem only disadvantaged in Italy.<sup>44</sup> The objective of this analysis is not only to characterize seniority and gender trends in the United States through American PPPs, but also to investigate the effects of collaboration in light of the increased need for more specialized knowledge in modern science.<sup>45</sup>

### Data

We use PPP data from Stern and Murray 2005, which were constructed from 340 research articles published between 1997 and 1999 in *Nature Biotechnology*.<sup>46</sup> To estimate the effects of gender, seniority, and collaboration at American universities, we include PPPs whose

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<sup>42</sup> See footnotes 5, 9, 11, and 39.

<sup>43</sup> See footnote 23.

<sup>44</sup> See footnotes 1 and 18.

<sup>45</sup> See footnote 23.

<sup>46</sup> Murray, Fiona, and Scott Stern. "Do formal intellectual property rights hinder the free flow of scientific knowledge? An empirical test of the anti-commons hypothesis." *Journal of Economic Behavior & Organization* 63, no. 4 (2007): 648-687. The authors detail the process of constructing the PPP dataset there. I thank them for sharing their dataset with me, without which this analysis would not have been feasible.

patent had at least one American and academic assignee. Seventy-five PPPs and 392 authors qualified.

To measure the impact of collaborating within and across institutions, we use the number of authors and institutions. The average number of authors is 6.554, with a minimum of one and a maximum of seventeen. The average number of institutions is 2.052, with a minimum of one and a maximum of five. Given theories on the burden of knowledge, these statistics would be much larger for more recent articles, further magnifying the effects we identify in our analysis.

For gender, three authors are randomly assigned as either female or male, since neither their names nor a thorough internet search yields any useful information. The results are not sensitive to their gender assignment for all possible permutations. The sample is predominantly male, with only 69 individuals or 21.2% being female. As gender roles evolve over the last decade, and women account for more than 40% of full time faculty at American universities (compared to around 35% in 2000), the composition of inventors might have also changed.<sup>47</sup>

Seniority is measured in both absolute and relative terms. For the former, we record the year of completing the doctoral thesis and/or medical school. Twenty-eight authors have neither a Ph.D. nor a M.D. degree. Forty-one have both, and sixty-six authors cannot be identified through ProQuest dissertation database, U.S. News doctor database, or internet search using the name and institution provided on the publication. For six authors who are known to have a doctorate or medical degree whose date could not be easily ascertained (e.g. ProQuest does not include dissertations completed outside of the U.S., U.K., and Ireland), we substitute the year of

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<sup>47</sup> John W. Curtis, *Persistent Inequity: Gender and Academic Employment*, special report prepared for Equal Pay Day, April 11, 2011. The statistics cited are from Figure 2, "Percentage Distribution of Full-Time Faculty by Gender, 1974-75 to 2010-11," using data from the Faculty Compensation Survey by the American Association of University Professors. Ding, Waverly W., Fiona Murray, and Toby E. Stuart. "Gender differences in patenting in the academic life sciences." (2006).

the author's earliest PubMed citation.<sup>48</sup> Results are not sensitive to the inclusion of these observations. The final number of authors is 325.

As in Lissoni et al., we also measure author  $i$ 's seniority relative to the other authors using the following equation:

$$\text{RELATIVE SENIORITY}_{ij} = t_i - t_j$$

where  $t_i$  is the year of author  $i$ 's first advanced degree and  $t_j$  is that of the most senior author's first advanced degree. Although the absolute measure of seniority is comparable across the authors in our dataset because the papers were all published within two years of each other, the relative measure captures the context of each PPP in which authorship and inventorship were decided.

In line with previous studies, we also include indicator variables for being the first or last author. Given academic norms concerning authorship order, these variables serve as proxies for rough estimates of seniority and provide a framework for checking the robustness of results regarding absolute and relative seniority. In addition, we include indicator variables for not having a Ph.D., an M.D., and neither. These variables provide an estimate of the extensive marginal effect of having an advanced degree. There are many plausible confounding factors beyond academic rank and seniority that can decrease the likelihood of an author without an advanced degree being named as an inventor. For example, those without an advanced degree might be truly lacking in creativity and aptitude for conception required for an inventor. Rather than academic rank, their intellectual inclinations can be the primary driver behind their being

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<sup>48</sup>The six observations have reasonable values for other explanatory variables. Low leverage values suggest that they are not outliers among other authors. Results robust to their inclusion provide further evidence that the substitution does not bias the analysis.

omitted from the patent. Nonetheless, these variables provide a framework for quantifying the impact of not having an advanced degree, a condition that applies to a non-negligible fraction of research personnel such as technicians and research assistants in many universities.

## Methods

We use a logistic regression model to estimate the effect of each covariate on the probability of an author being named an inventor. The specifications follow the same form as the equation below, which contains only covariates used in the preferred specification:

$$y_i = \alpha + \beta Female_i + \gamma RSeniority_i + \delta FAuthor_i + \lambda NumAuthor_i + \epsilon_i$$

where  $y_i$  is the binary outcome for whether the author was named an inventor,  $Female_i$  an indicator for author  $i$  being female,  $RSeniority_i$  the relative seniority of author  $i$ ,  $FAuthor_i$  an indicator for author  $i$  being the first author, and  $NumAuthor_i$  the number of authors on the author  $i$ 's publication.  $\beta$ ,  $\gamma$ ,  $\delta$ , and  $\lambda$  are the coefficients of interest as estimates for the effects of gender, seniority, and collaboration on an author's probability of being named an inventor.

We assess the characteristics of the authors (Table 1). We also examine the relationship between the covariates. Given moderate correlation between the number of authors and institutions ( $\rho=0.40$ ), the final model only includes the former, because it is more statistically significant. Furthermore, we regress likelihood of being named the first or last authors on absolute and relative measures of seniority. The results indicate that seniority predicts first and last authors well (Table 2). In order to avoid inflated standard errors often caused by correlated covariates, the final model includes only a subset of seniority-related variables. Lastly, we explore interaction terms but none of them appear to be statistically significant. Selected specifications adjusting for different combinations of covariates are reported below (Table 3).

Table 1 | Characteristics of Authors Sample.

<b>Sample (N=325)</b>	
<b>Named Inventor (%)</b>	49.5%
<b>Female (%)</b>	21.2%
<b>Ph.D. (%)</b>	76.9%
<b>Ph.D. Year</b>	
<b>Min.</b>	1953
<b>1<sup>st</sup> Quartile</b>	1980
<b>Mean</b>	1986
<b>3<sup>rd</sup> Quartile</b>	1994
<b>Max</b>	2007
<b>M.D. (%)</b>	27.1%
<b>M.D. Year</b>	
<b>Min.</b>	1960
<b>1<sup>st</sup> Quartile</b>	1981
<b>Mean</b>	1986
<b>3<sup>rd</sup> Quartile</b>	1993
<b>Max</b>	2005
<b>Relative Seniority</b>	
<b>Min.</b>	-30
<b>1<sup>st</sup> Quartile</b>	0
<b>Mean</b>	10.44
<b>3<sup>rd</sup> Quartile</b>	18
<b>Max</b>	41
<b>No Advanced Degree (%)</b>	8.62%
<b>First Authors</b>	21.2%
<b>Last Authors</b>	22.8%*
<b>Number of Authors</b>	
<b>Min.</b>	1
<b>1<sup>st</sup> Quartile</b>	4
<b>Mean</b>	6.554
<b>3<sup>rd</sup> Quartile</b>	8
<b>Max</b>	17
<b>Number of Institutions</b>	
<b>Min.</b>	1
<b>1<sup>st</sup> Quartile</b>	1
<b>Mean</b>	2
<b>3<sup>rd</sup> Quartile</b>	3
<b>Max</b>	5

Notes: \*The percentage of first and last authors are not the same because 6 first authors and 1 last author were omitted from the sample due to missing values.

All analyses are performed with R and

the results are reported with their standard errors in parentheses and p-values denoted by asterisks.

Table 2 | Probability of being named first or last authors by individual covariates

	<b>First Author</b>	<b>Last Author</b>
<b>Ph.D. Year</b>	0.09459*** (0.02004)	-0.07134*** (0.01518)
<b>M.D. Year</b>	0.07659* (0.03080)	-0.07768** (0.02786)
<b>Relative Seniority</b>	0.05318*** (0.01370)	-0.12200*** (0.02091)

Notes: Standard errors are reported beneath the coefficients in parentheses.

\* p-value < 0.05

\*\* p-value < 0.01

\*\*\* p-value < 0.001

Table 3 | Probability of being named as an inventor: Logistic regression results

	Dependent variable: Probability of being named an inventor									
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Female	-0.08240 (0.32189)	0.02245 (0.31385)	0.24989 (0.35576)	<b>-0.09319</b> <b>(0.32535)</b>	0.46833 (0.52433)	-0.11709 (0.34679)	0.56577 (0.70301)	0.23913 (0.35459)	0.01234 (0.30391)	0.03149 (0.30909)
No Ph.D.										-1.78131*** (0.36784)
Ph.D. Year					-0.02758* (0.01476)	-0.01928 (0.01360)				
No M.D.							-0.06274* (0.02730)			
M.D. Year										
Earliest Advanced Degree								-0.01003 (0.01523)		
Relative Seniority	-0.03622** (0.01276)	-0.04063** (0.01241)	-0.01953 (0.01490)	<b>-0.04345**</b> <b>(0.01360)</b>						
No Advanced Degree										-1.96448*** (0.57283)
First Author										
Last Author										
Number of Authors	-0.19910*** (0.04389)									
Number of Institutions		-0.23086* (0.10942)								
Ph.D. Year*										0.05982 (0.03927)
Female										

Note: The dependent variable in all specifications is the probability of an author being named as an inventor on the corresponding patent. Covariates are listed to the left, and specifications listed at the top. Different specifications contain different combinations of covariates. The coefficients for those included are reported with standard errors in parentheses beneath. A blank space indicates that the covariate is not included in the specification. For example, in the preferred model (bolded), effects associated with being female and a first author are presented alongside those associated with relative seniority and the number of authors.

- p-value < 0.10
- \* p-value < 0.05
- \*\* p-value < 0.01
- \*\*\* p-value < 0.001

## Results

In none of the specifications is gender a significant predictor of the likelihood of an author's being named as an inventor. Being female is not consistently associated with either an increase or a decrease of that likelihood, which underscores the insignificance of gender as a predictor. On the contrary, collaboration appears to be a significant factor in inventorship attribution. In all specifications including only one of the collaboration covariates, an increase in the number of authors and institutions is associated with a statistically significant decrease in the author's likelihood of being named an inventor. With greater variation, the number of authors often has a larger and more significant effect than the number of institutions. Since the two are correlated, when they are both included, only the number of authors is statistically significant, masking the effect of the number of institutions in unreported results.

Indicator variables concerning advanced degrees are statistically significant. Specification 10 shows that not having a Ph.D. is associated with a decrease in the likelihood of being named as an inventor by a factor of 0.1684174 (95% Confidence Interval: 0.07931923, 0.3376534) holding all else constant. Similarly, not having a M.D. is associated with a decrease by a factor of 0.4655 (95% CI: 0.23588102, 0.8824146). The effect could be smaller because many who do not have an M.D. have a Ph.D., whereas those without a doctorate are less likely to have a medical degree. Specification 9 shows that all else equal, having neither degrees is associated with a decrease by a factor of 0.1402 (95% CI: 0.03922332, 0.3914629). Authors without advanced degrees are extremely unlikely to be named as an inventor when many of their coauthors have either or both degrees. These authors, likely technicians and research assistants, can be underrepresented in the sample if they are less likely to be named authors as well.

Absolute seniority is not a consistently significant predictor. Holding all else constant, absolute seniority of Ph.D.'s is somewhat significant in specification 5, which includes an interaction term with gender. The interaction allows more flexibility for modeling the effects of absolute seniority in the event that they are different between male and female scientists. Although the interaction itself is not statistically significant, unreported plots and the improved performance of the model overall suggests that gender might have an effect on the relationship between absolute seniority of Ph.D.'s and their likelihood of being named as an inventor. On the other hand, absolute seniority of M.D.'s is a statistically significant predictor (specification 6). Holding all else constant, attaining an M.D. each year later is associated with a decrease in the likelihood of being named as an inventor by a factor of 0.9392 (95% CI: 0.0871, 0.9886). In unreported results, models including the absolute seniority of Ph.D.'s and M.D.'s, the minimum of the two, or both measures, do not yield significant coefficients on those covariates. A possible reason is that the model cannot distinguish between which degree and the associated date is influential on the inventorship attribution process. Depending on the context of the research group i.e. a group of predominantly M.D.'s or Ph.D.'s, those with both degrees might have different chances of being named as an inventor.

Relative seniority is a consistently significant predictor. Our preferred model is specified in the fourth column. It differs from specification 3 in that it does not include the indicator for being the last author. Given the strong association between last authorship and relative seniority demonstrated earlier, the effect of the relative seniority of authors is dominated by that of their being last authors in specification 3. Since first authorship is associated with more junior authors, countervailing the effects of relative seniority, the model is more flexible

than one without first authorship. The choice to use the number of authors rather than that of institutions is based on the statistical significance of the predictors as discussed earlier.

In our preferred model, the baseline individual, a male non-first author on a paper with six (the median) authors who attained an advanced degree the same year as the most senior author, has a 63.1815% chance of being named as an inventor. Attaining the first advanced degree a year later than the most senior author is associated with a decrease in that likelihood by a factor of 0.9575 (95% CI: 0.9317, 0.9828) holding all else constant. Similarly, having one more author is associated with a decrease by a factor of 0.9822 (95% CI: 0.7622, 0.9090). On the other hand, being the first author is associated with an increase by a factor of 1.7526 (95% CI: 0.9317, 3.3599) holding all else constant. Being female does not have a significant impact.

## **Discussion**

Our regression analysis addresses the impact of gender, collaboration, and seniority on inventorship attribution at American research universities. Given the observational nature of our data, none of the results imply causality. Nonetheless, the associations provide insight into how technology transfer offices at American universities might decrease the number of illegitimate discrepancies between authorship and inventorship and the attending vulnerability of those patents in their portfolio.

Our analysis suggests that female scientists are not disadvantaged in inventorship attribution at American universities, and their technology transfer offices should instead target trends in seniority and collaboration. One limitation is the timeframe of our dataset. As gender dynamics have changed in American society in the past decade and a half, they may have also changed in laboratories and research universities. If gender equality has increased over this

period, the insignificance of being female in our results would have been an overestimate and further reassures that women today are not systematically disadvantaged in inventorship attribution. Another possible scenario involves more uncertainty. Increasing gender equality might have increased the number of women in science. The very equality that resulted in their being authors would plausibly decrease the effect of gender. However, that equality might also change the personality profiles of female scientists at American universities. In other words, In other words, the insignificance in our results may have stemmed from other qualities of the female researchers that have led them to enter and thrive in science in less equitable times. The persisting gender inequality in inventorship attribution might then become more evident as the female fraction becomes larger and more diverse.

Collaboration within and across institutions may be of strong interest to the technology transfer offices at American universities. Both the number of authors and that of institutions listed on an article were strong predictors for an author being named as an inventor. The negative effect of having more authors or institutions implies that the number of authors are increasing while the number of inventors remain relatively stable. The strong positive effects of being named as a first or last author suggest that those authors are the staple of two to three inventors on most patents. This is consistent with Philippe Ducor's findings in a smaller dataset.<sup>49</sup> Given the increasing desirability to collaborate, and the rising number of authors and institutions on any given research paper, technology transfer officers cannot ignore the trend and continue to name or allow the naming of the first and last authors as the sole inventors.

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<sup>49</sup> Ducor, "Coauthorship and Coinventorship," (2000).

With regards to seniority, junior scientists are disadvantaged, particularly if their colleagues are much more senior. This is consistent with other studies of the kind.<sup>50</sup> It is important to note that this association is not causal, and that there are many plausible confounding factors that would render senior researchers legitimately more likely to be named as an inventor. For example, one might argue that more senior scientists are on average more likely to contribute to the conception and design of the experiment than their more junior counterparts on average, as they have more resources, experience, and a more directorial role in the laboratory. Although we cannot identify the causal effect of seniority, qualitative accounts in the following chapters demonstrate that junior scientists have been prejudiced against for their academic rank.

There are several limitations to our estimates on seniority. If seniority effects have weakened since a decade ago, we may have overestimated the impact of seniority on inventorship assignment. However, we might have underestimated the impact considering the distribution of the authors omitted due to missing values. Only eleven of them were inventors, six of them first authors, and only one a last author. Given the strong relationship between authorship order and seniority, the omitted authors are likely to be more junior and the omissions may have biased the results slightly. A similar analysis on a more recent set of PPPs will reduce both problems. Not only will information on current authors be easier to ascertain, but the data themselves would reflect a more recent reality.

## **Conclusion**

American universities should focus on the impact of seniority and collaboration on inventorship attribution. At least in the universities (as opposed to industry), American science

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<sup>50</sup> Lissoni et al. "Inventorship and authorship as attribution rights." (2013).

does not seem to suffer from strong gender inequality, contrary to the findings in Lissoni et al. Our findings with regards to seniority are consistent with those in earlier studies and sociological norms in academic science. A less-studied effect is that of collaboration, approximated in terms of the number of author and institutions on a publication. These simple measures indicate strong and clear effects of collaboration on inventorship attribution. In light of the rising level of collaboration among scientists, it might be worthwhile to develop more complete proxies for collaboration and conduct the analysis on a more recent dataset to determine longitudinal trends. In sum, the results of our study underscore the need to investigate effects of collaboration, and develop guidelines to facilitate patent-friendly collaboration in the future.

## Chapter 3: Historical Accounts of Author-Inventor Discrepancies

### Case Study 1: Recombinant DNA

Recombinant DNA (rDNA) shifted the paradigm of basic and applied research in the biomedical sciences. It enabled scientists to combine DNA fragments from different species and reproduce the product in large quantities. After collaborators from Stanford University and the University of California – San Francisco (UCSF) published their paper<sup>51</sup> confirming the faithful replication of DNA from *Xenopus laevis* – a eukaryotic organism in the family of African clawed frogs – in the bacterium *Escherichia coli*, the universities jointly filed a patent application with a subset of the authors as inventors.<sup>52</sup> Given the demand for rDNA technology, Stanford and UCSF arguably could have pursued a more aggressive licensing scheme and generated more royalties. Yet due to widespread dissatisfaction among faculty and graduate students at the Stanford biochemistry department, who had pioneered rDNA research in the late 1960s,<sup>53</sup> and discrepancy between authors and inventors, Stanford instead marketed non-exclusive and relatively low-price licenses to discourage companies from challenging the patent. The discrepancy, in the case of rDNA technology, was not only one about accurately attributing credit but also one of significant monetary costs, considering that the patent made around \$254 million for the universities even under the weakened scheme.<sup>54</sup>

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<sup>51</sup> Morrow, John F., Stanley N. Cohen, Annie CY Chang, Herbert W. Boyer, Howard M. Goodman, and Robert B. Helling. "Replication and Transcription of Eukaryotic DNA in *Escherichia coli*." *Proceedings of the National Academy of Sciences* 71, no. 5 (1974): 1743-1747.

<sup>52</sup> Cohen, Stanley, and Herbert Boyer. Process for Producing Biologically Functional Molecular Chimeras. US Patent 4,237,224, filed January 4, 1979, and issued December 2, 1980. File Wrapper.

<sup>53</sup> Doogab Yi, "Cancer, Viruses, and Mass Migration: Paul Berg's Venture into Eukaryotic Biology and the Advent of Recombinant DNA Research and Technology, 1967 – 1980," *Journal of the History of Biology* 41, (2008): 589-636. Also see Paul Berg and Arthur Kornberg's biographies: Errol Friedberg. *The recombinant DNA controversy revisited: a biography of Paul Berg*. (Singapore: World Scientific Publishing Company, 2014); Arthur Kornberg, *For the Love of Enzymes* (Cambridge, MA: Harvard University Press, 1989).

<sup>54</sup> Feldman MP, A Colaianni and C Liu, "Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program." In *Intellectual Property Management in Health and Agricultural*

Two scientists at the Stanford biochemistry department independently conceived of rDNA technology in the late 1960s. In 1965, Paul Berg, who won the 1980 Nobel Prize for his contribution to recombinant DNA, attended a seminar by his Stanford colleague Dale Kaiser and learned that some mammalian cell viruses such as polyoma and SV40 integrate into the genomes of host mammalian cells—just as other viruses that infect bacteria do.<sup>55</sup> In a subsequent grant application to the American Cancer Society (ACS) in 1970, Berg proposed the construction of so-called “trivalent” recombinants containing the entire SV40 genome, the promoter region of bacteriophage lambda DV, and the *gal* operon in *E. coli*.<sup>56</sup> He planned to insert this new recombinant into *E. coli* to produce large quantities of SV40 for cancer research. He also planned to insert the recombinant into mammalian cells to see whether they would replicate or express the *gal* operon. The first of its kind, Berg’s pursuit positioned him and his lab at the forefront of rDNA technology.

The other researcher was Peter Lobban, a graduate student in Kaiser’s group. In 1969, he also attended a departmental seminar, this time by fellow graduate student Thomas Broker. Presenting on an enzyme called terminal transferase, Broker mentioned near the end of his talk that it might be able to add nucleotides to the ends of DNA molecules. Upon hearing this, Lobban said to himself, “Bingo!”<sup>57</sup> On November 6 that year, Lobban proposed a method for

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*Innovation: A Handbook of Best Practices*, eds. A Krattiger, RT Mahoney, L Nelsen, et al. (MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. 2007). Available online at [www.ipHandbook.org](http://www.ipHandbook.org).

<sup>55</sup> Friedberg. *The recombinant DNA controversy revisited*. (2014); Yi. *The Recombinant University*. (Forthcoming).

<sup>56</sup> Paul Berg, ACS Grant, 1970, p.5. SUA SC 358, Box 16, Folder: ACS Grant, quoted in Doogab Yi, “Cancer, Viruses, and Mass Migration: Paul Berg’s Venture into Eukaryotic Biology and the Advent of Recombinant DNA Research and Technology, 1967 – 1980,” *Journal of the History of Biology*, 41(2008), 610.

<sup>57</sup> Peter Lobban, interview on file with author. At the time, Lobban was looking for a topic for his third Ph.D. exam, which the biochemistry department required of its graduate students. Berg describes it in the following manner in *A Stanford Professor’s Career*: “Normally, these Ph.D. propositions are exercises in which people present an idea. They’re supposed to demonstrate a capacity for being creative in generating a new idea, devising an experimental way of testing their idea, and then they continue on their thesis, whatever that is. Most often, the proposal and thesis are totally unrelated.”

joining DNA molecules using terminal transferase and five other enzymes. He wrote, “the eventual goal...[is] to produce a collection of transductants synthesizing the products of genes of higher organisms.”<sup>58</sup> By then, Lobban had started a thesis project to search for what is now known as integrase. Yet “so struck by the novelty of his idea,” Berg recalled, Lobban’s thesis committee permitted him to switch projects.<sup>59</sup> As a second-year graduate student in 1969, Lobban foresaw the potential to clone and express eukaryotic genes in prokaryotes.

Lobban and Berg worked on the technique concurrently, approaching it from different angles. Berg needed it to construct the trivalent molecule, which would in turn enable him to study cancer viruses and their behavior. Lobban, on the other hand, focused on the method rather than its applications. Even though Lobban had discussed insulin and immunoglobulin genes with Kaiser, he had joined two bacteriophage P22 molecules instead, despite their comparative lack of exciting medical prospects.<sup>60</sup> This was a perplexing choice to Berg, but Lobban used P22 because it was easy to grow and its DNA had blunt ends and so would not automatically re-anneal. We had “a different mindset,” Lobban explained as the difference between him and Berg; “by temperament I’m at least as much an engineer as a scientist. And engineers do model systems...then they look for ways to apply it that are more useful. Paul wasn’t an engineer at all, he’s a scientist.”<sup>61</sup> In the spring of 1972, both groups were able to create their desired recombinant: Lobban synthesized nucleotides at the 5’ ends of bacteriophage P22 monomers to construct circular dimers, and David Jackson, a postdoctoral fellow in Berg’s laboratory, produced the bacteriophage  $\lambda$ dvgal-SV40 trivalent recombinants (See Figure 1).

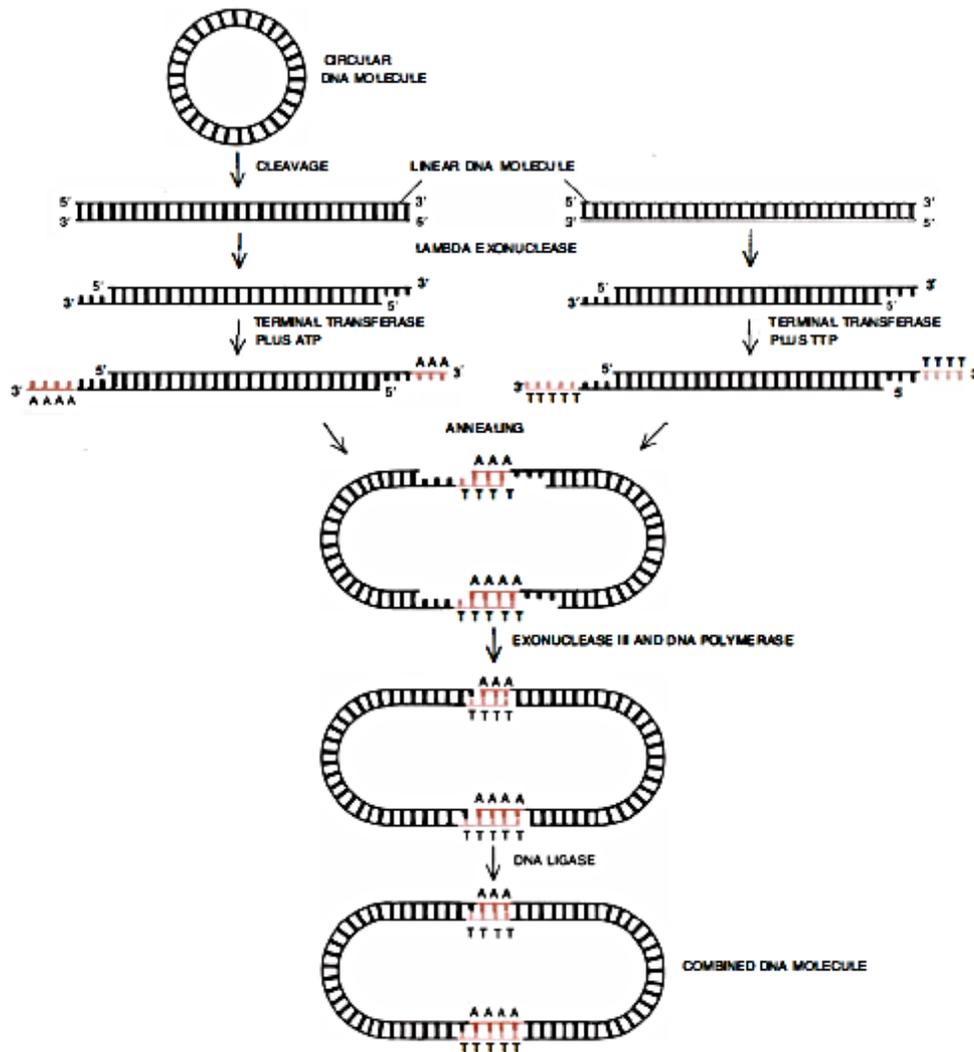
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<sup>58</sup> Peter Lobban, “The Generation of Transducing Phate *In Vitro*,” Third PhD exam, November 6, 1969, 15, courtesy of Paul Berg.

<sup>59</sup> Berg, *A Stanford Professor’s Career*, 3, 103.

<sup>60</sup> Peter Lobban, Letter to Kornberg, September 15, 1986, courtesy of Paul Berg.

<sup>61</sup> Peter Lobban, interview on file with author.



**Figure 1 | Constructing a Recombinant with Terminal Transferase**

The mainstream narrative of the origins and conception of rDNA technology, on the other hand, has focused mostly on Cohen and Boyer's meeting at the Japan-United States Joint Conference on Bacterial Plasmids in Honolulu in November 1972. Cohen was interested in combining his plasmid expertise with Boyer's in restriction enzyme EcoR1 for cloning. The Cohen-Boyer meeting at a local deli afterwards is commonly known as the spawning ground of genetic engineering, so much so that the announcement of their Lemelson-MIT award, dubbed

the “Oscar for Inventors,” opens with the following scene: “Over hot pastrami and corned beef sandwiches, Herbert Boyer and Stanley Cohen opened the door to genetic engineering and laid the foundations for gene therapy and the biotechnology industry.”<sup>62</sup> Another celebrated microbiologist Stanley Falkow was present at the meal, and titled his recollection “I’ll have the chopped liver please, or how I learned to love the clone.”<sup>63</sup>

Following the Conference in Honolulu, Cohen and Boyer collaborated on the first demonstration of recombinant DNA cloning in 1973.<sup>64</sup> Cohen and his technician, Annie Chang, proceeded to clone DNA from *Staphylococcus aureus*, the same time John Morrow, a graduate student in Berg’s group, was covertly collaborating with them to clone *Xenopus* DNA.<sup>65</sup> The *Staph.* paper became the basis for the ‘224 patent, but the *Xenopus* experiment made it “clear that you could put any DNA into *E. coli*. And, that’s when the whole thing exploded.”<sup>66</sup> In a *New York Times* article covering the Chang experiment, Cohen said, “the same ability to create what

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<sup>62</sup> “Winner’s Circle: Herbert Boyer and Stanley Cohen,” Lemelson-MIT Program: Celebrating Invention and Innovation, accessed June 27, 2012, <http://web.mit.edu/invent/a-winners/a-boyercohen.html>. Funded by the Lemelson Foundation, the Lemelson-MIT Prize is an annual, \$500,000 prize for “mid-career inventors who have developed a patented product or process of significant value to society, which has been adopted for practical use, or has a high probability of being adopted...the prize is designed to spur inventive careers and provide role models for future generations of inventors.”

<sup>63</sup> Stanley Falkow. “Ill Have the Chopped Liver Please, or How I Learned to Love the Clone.” *Am Soc Microbiol News* 67(2001): 555-559; Stanley Falkow. “The Fortunate Professor.” *Annual Review of Microbiology* 62(2008): 1-18.

<sup>64</sup> Cohen et al. “Construction of biologically functional bacterial plasmids in vitro.” *PNAS* 70(11) 1973: 3240-4.

<sup>65</sup> Of this incident, Morrow recalled: “I first learned of the *Staphylococcus aureus-E. coli* chimeric DNAs verbally from Stan[ley] Cohen at his laboratory AFTER the success of the *Xenopus* frog-*E. coli* cloning was clear, but not submitted for publication. This was long after the June, 1973 Gordon Conference. Stan Cohen said he and Annie Chang needed to complete the *Staph. aureus* paper immediately, because it would not be of general interest after the *Xenopus-E. coli* paper was published. I still remember it, because I was surprised by this parallel effort that Stanley Cohen and Annie Chang were working on. Our joint *Xenopus-E. coli* project had higher priority in my eyes, and I viewed the *Staph. aureus-E. coli* work as an interfering matter that might allow another group to achieve priority. Stan Cohen did not agree with me and he did not allow Annie Chang to spend more effort on the *Xenopus* project, as I requested” (Correspondence with the author, March 2010, in Yi, *The Recombinant University*. Forthcoming.). Annie Chang and Stanley N. Cohen. “Genome construction between bacterial species *in vitro*: replication and expression of *Staphylococcus* plasmid genes in *E. coli*.” *PNAS* 71 (1974): 1030-1034.

<sup>66</sup> Paul Berg, interview by Sally Smith Hughes, 1997, Program in the History of the Biosciences and Biotechnology, *A Stanford Professor’s Career in Biochemistry, Science Politics, and the Biotechnology Industry* (California: The Regents of the University of California: 2000), 117, accessed June 12, 2012, <http://content.cdlib.org/>.

amounts to new species of bacteria could lead to colonies of *E. coli*, equipped with the gene-carrying plasmids, growing large supplies of insulin for diabetics, who now depend on supplies obtained from beef and pork pancreases.”<sup>67</sup> Indeed, the social consequences of rDNA technology proved to be enormous, but not all were happy about the focus on this trio of Cohen-Boyer papers.

Aside from Berg and Lobban, another critical scientist not on the *Xenopus* or *Staphylococcus* paper was Janet Mertz, who joined Berg’s group in December 1970 to study mammalian virus SV40. In the spring of 1972, Mertz discovered that EcoR1 created cohesive ends at its cleavage sites. She was charged with identifying potentially useful variants of the SV40 virus, and more specifically with determining whether linear SV40 DNA was infectious. After repeatedly observing infectious activity in cut SV40 molecules, Mertz hypothesized that EcoR1-cleaved sites had cohesive ends and could thus be joined to create circular infectious DNA.<sup>68</sup> Over the night of April 22, 1972, Mertz determined with electron microscopy that the SV40 linear molecules had indeed circularized. She then worked with Ronald Davis, an assistant professor in the department, in May and early June to construct SV40- $\lambda$ dvgal 120 recombinants using her method.<sup>69</sup> The discovery was critical to the advent of rDNA, as Cohen and Boyer used it to recombine plasmid DNA, and subsequently clone them for the first time.<sup>70</sup>

In retrospect, Mertz wishes that her mentors and department had filed a patent application in 1972, when she had made the EcoR1 discovery, because “then the Stanford bio-chemistry

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<sup>67</sup> Victor McElheny. "Animal Gene Shifted to Bacteria, Aid Seen to Medicine and Farm," *New York Times*, May 20, 1974, 61. 46.

<sup>68</sup> Janet Mertz, interview on file with author.

<sup>69</sup> Janet Mertz and Ronald Davis, "Cleavage of DNA by R<sub>1</sub> Restriction Endonuclease Generates Cohesive Ends," *PNAS* 69, no. 11 (1972): 3374.

<sup>70</sup> Berg, Paul, David Baltimore, Herbert W. Boyer, Stanley N. Cohen, Ronald W. Davis, David S. Hogness, Daniel Nathans et al. "Potential biohazards of recombinant DNA molecules." *Science* 185, no. 4148 (1974): 303.

department was responsible for the development of all of the ideas, all of the methods because we did all of them before Cohen even had his first idea about making a recombinant DNA clone.”<sup>71</sup> Berg and Lobban had conceived of the technology in the late 1960s; Lobban and Jackson had developed the terminal transferase method in early 1972, after which Mertz made her EcoR1 discovery; and others in the Kaiser lab had developed the calcium chloride precipitation method for inserting DNA molecules into *E. coli* long before. Moreover, Lobban had adapted the method for phage and Mertz for viral and plasmid DNA which they shared with Cohen.<sup>72</sup> Morrow felt that “every one of the claims of the patent had been demonstrated by Mertz and Davis except...claim number 12 because they did not clone,”<sup>73</sup> and could not clone due to the self-imposed rDNA moratorium on oncogenic viruses they were working with at the time. So essential to the advent of rDNA technology, communalism and collaboration in Stanford’s biochemistry department were ironically a source of contention in attributing inventorship.

As case law and the official interpretation of USPTO dictate that inventors “must contribute to conception” and that “reduction to practice, *per se*, is irrelevant...insofar as defining an inventor is concerned,” Lobban and Berg had strong claims to inventorship.<sup>74</sup> For instance, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, defines conception as “the formation in

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<sup>71</sup> Mertz, interview on file with author.

<sup>72</sup> Ibid. Her statement that Cohen was learning techniques from Lobban and Mertz is corroborated by Lobban and Morrow in their interviews with the author in 2012, but also by Berg and Kornberg in their oral histories with Sally Smith Hughes in 1997.

<sup>73</sup> Morrow, interview on file with author.

<sup>74</sup> “The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor. ... Insofar as defining an inventor is concerned, reduction to practice, *per se*, is irrelevant [except for simultaneous conception and reduction to practice, *Fiers v. Revel*, 984 F.2d 1164, 1168, 25 USPQ2d 1601, 1604-05 (Fed. Cir. 1993)]. One must contribute to the conception to be an inventor.” *In re Hardee*, 223 USPQ 1122, 1123 (Comm’r Pat. 1984). Excerpt from “35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent,” USPTO, <http://www.uspto.gov/web/offices/pac/mpep/s2137.html>. Accessed February 3, 2014.

the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”<sup>75</sup> Through his research proposal in 1969, Lobban had demonstrated a definite and permanent idea of rDNA technology. Berg’s ACS grant proposal was an early documentation of his independent conception. Even Falkow, an eyewitness of the Honolulu meeting, emphasized the important but practical contribution Cohen and Boyer made to rDNA technology:

The idea of joining distinct DNA species had been at the cutting edge of molecular biology and was, in fact, the focus of Berg’s group, as well as those of Kaiser and Lobban, but [the meeting produced] a direct way to do the experiment...Cohen and Boyer did not receive the Nobel Prize for their contribution...However, in my view, [they] performed the most clear-cut gene splicing experiments and the most convincing. They reduced it to practice.<sup>76</sup>

In a recent interview, Lobban revealed, “if I’d known then what I know now I certainly would have had no trouble in joining an effort to try to show that the patent was invalid... simply because the claims have to do with the things that [biochemistry people] conceptualized. And we conceptualized them before Stan Cohen did.” After Mertz’s “sticky-end” discovery, in particular, one could argue that genetic engineering and cloning involved less conception than reduction to practice.

Neither were the authors of the trio of papers all satisfied with the attribution of credit over rDNA technology. Morrow, a graduate student in Berg’s group, proposed the experiment on eukaryotic DNA, contributed the most figures, and subsequently was first author on the resulting paper. When he learned of what became the Cohen-Boyer patent application, he felt excluded from his rightful inventorship. Even though he did not think that he had a role equal to Cohen and Boyer, he felt that he “played an original role in proposing the project and going through what was needed to demonstrate that we had steadily and faithfully replicated these *Xenopus*

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<sup>75</sup> *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986).

<sup>76</sup> Falkow, “I’ll Have the Chopped Liver Please,” 558-559.

DNA sequences in *E. coli*.”<sup>77</sup> Robert Helling, a visiting researcher at Boyer’s laboratory, refused to waive his inventorship. He “felt that [he] was part and parcel of the whole thing, and [did] not want to sign a letter saying that [he] was just another laboratory worker.”<sup>78</sup> Annie Chang, Cohen’s technician, was the only one who signed the waiver.

Although to no avail, Helling and his home institution, the University of Michigan, pushed for his inventorship claim, partially because there was a financial gain at stake. On the other hand, Morrow had become an assistant professor at Johns Hopkins by the time he learned about the patent application in 1978. Despite his conviction that he contributed significantly to claim 11 on the patent (see Appendix I), which if true would qualify him for co-inventorship under American patent law (which does not require co-inventors to contribute the same amount or to the entire invention but only to at least one claim),<sup>79</sup> Johns Hopkins would not legally represent him in defense of his claim, since he had not completed the relevant work at Johns Hopkins and the University did not stand to gain monetarily. “I had nearly no money,” Morrow added, “so it would’ve been quite a challenge for me, practically speaking, to have established my rights, even if I had excellent claims.”<sup>80</sup>

The discrepancy led to many monetary costs for Stanford in way of a prolonged legal battle with patent examiner Alvin Tanenholtz to approve the claims. It took six years before the examiner accepted that Cohen and Boyer provided the “major inspiration and direction” for the experiments described in the *Staph.* and *Xenopus* papers.<sup>81</sup> Tanenholtz initially rejected all claims in the ‘224 patent on the grounds of missing inventors because “the inventive entity of the

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<sup>77</sup> Morrow, interview on file with author.

<sup>78</sup> David Dickson, “Inventorship dispute stalls DNA patent application,” *Nature* 284, no.3 (April 1980), 388.

<sup>79</sup> Patents, 35 U.S.C. § 116.

<sup>80</sup> Morrow, interview on file with author.

<sup>81</sup> *Ibid.*

instant application is different from the authors of the references, Cohen et al (1973), Chang et al (1974), and Morrow et al (1974).”<sup>82</sup> In response, Rowland distinguished between co-authors and co-inventors, arguing that Cohen and Boyer directed the rest of the co-authors on the referenced articles. He also alluded to scientific norms, arguing that, “senior authors normally publish contemporaneously with co-workers and graduate students,” and denied “any basis for suggesting that Annie Chang, Professor Cohen’s student, is in fact a co-inventor, rather than a co-author.”<sup>83</sup> In a communal environment, where junior researchers collaborated with established professors and received first authorship on different occasions, as was in the case here, the distinction between co-authorship and co-inventorship was difficult to define and defend.

On October 4, 1979, Tanenholtz issued a final rejection of all claims over “the inventive entity,” rejecting all of Rowland’s justifications for listing Cohen and Boyer as sole inventors. He further insisted that the references could only be removed through “a disclaiming affidavit or declaration by the other authors.” Rowland recalled,

...when the case was originally filed, under the rule of *In re Katz* I believe, I sent letters to all of the other authors of the three articles asking them to waive any inventorship interest. Of the nine inquiries, one agreed and the others either did not respond or sent unkind letters about the inventors and Stanford’s filing of the application. One professor claimed joint inventorship. I did not pursue this avenue any further, but chose to swear back of the references.<sup>84</sup>

Without disclaimers, Rowland filed a Declaration by Cohen and Boyer “that work was done by them or under their supervision antedating all the articles of which they are co-authors and demonstrating a reduction to practice of the subject invention.” The Declaration focused

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<sup>82</sup> Office Action, A. E. Tanenholtz, July 18, 1979, in US Patent 4,237,224, file wrapper.

<sup>83</sup> Response, Bertram I. Rowland, October 1, 1979, in ‘224 file wrapper.

<sup>84</sup> Bertrand Rowland. “Cloning and the Cohen-Boyer Patent.”  
<http://www.law.gwu.edu/Academics/FocusAreas/IP/Pages/Cloning.aspx>

primarily on Cohen, et al. (1973). Tanenholtz finally conceded in a telephone interview with Rowland on March 14, 1980, and approved claims 1 to 13 and 16.<sup>85</sup>

The discrepancy between authors and inventors rendered the patent vulnerable to challenges and invalidation under U.S. law.<sup>86</sup> This vulnerability in turn constrained Stanford's licensing programs. Stanford licensed rDNA technology broadly and at low cost not solely to widely distribute the technology and contribute to the subsequent development of commercial biotechnology, but also to keep costs low and licensing terms reasonable to reduce the incentive to challenge to the patent.<sup>87</sup> Reimers recalled, "I got one letter from an alumnus: '... Why are you charging such a low royalty?' ... Well, [the patent] was a bit flaky... whether we could get the broad claims."<sup>88</sup> Helling pointed out Stanford's practical reasoning in a letter to *Nature* in 1997:

[The Stanford licensing] policy was set carefully so as to generate the largest possible return without causing the patent to be contested. Companies wishing to use the technology weighed the cost of royalties against the cost of a suit and eventually all decided it was cheaper to pay royalties.... If the patent had been contested, there is a significant probability that it would have been ruled invalid.<sup>89</sup>

Had the patent been invalidated on inventorship grounds, Stanford would have sustained considerable legal costs (UCSF did not share these costs) and attained no royalties. Reimers therefore made a conscious decision to charge little for a technology that arguably had a relatively inelastic demand in the biomedical establishment.<sup>90</sup>

Beyond the justice in correctly assigning credit and the monetary costs associated, the discrepancy could also have had a macroeconomic cost to the research establishment. Then and now, Berg and many others felt that credit was not appropriately attributed. Reimers remembered

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<sup>85</sup> US Patent 4,237,224. File wrapper.

<sup>86</sup> Patents, 35 USC § 102.

<sup>87</sup> Ducor, Philippe. "Are patents and research arch compatible?" *Nature* 387 (1997): 13-14.

<sup>88</sup> Reimers, *Stanford's Office of Technology Licensing*, vii.

<sup>89</sup> Helling, Robert B. "Patents and royalties." *Nature* 387, no. 6633 (1997): 546-546.

<sup>90</sup> Reimers, *Stanford's Office of Technology Licensing*, vii.

that “Paul Berg wanted to meet with me, and he was quite upset that I had filed on this case, very upset. Then he noted the work that he and his student—Janet Mertz—had done earlier.”<sup>91</sup> In 2010, Berg and Mertz characterized “[Cohen and Boyer’s] claims to commercial ownership of the techniques for cloning all possible DNAs, in all possible vectors, joined in all possible ways, in all possible organisms [as] dubious, presumptuous, and hubristic.”<sup>92</sup> They are currently drafting a response to Cohen’s recent recollection, in which they felt the author deliberately excluded their contributions and those of others in the biochemistry department.<sup>93</sup> Given the communal spirit of the department, which welcomed Cohen despite his official appointment being in the Department of Medicine in the early 1970s, the discrepancy and subsequent disputes have also incurred a cost in collaborative potential.

## **Case Study 2: Streptomycin**

The streptomycin case differs from the recombinant DNA case in that the junior scientist, a postdoctoral researcher Albert Schatz, was named as a coinventor on the Streptomycin patent with his doctoral adviser, postdoctoral mentor, and Nobel Laureate Selman Waksman.<sup>94</sup> The discrepancy no longer lied in inventorship assignment but in their differential treatment as coinventors. Yet this case also underscores the importance of accurate assignment because treating Schatz more as a coauthor and Waksman as both that and an inventor cost Rutgers University greatly in monetary and reputational terms. Denied royalties and kept in secrecy regarding the patent for many years, Schatz sued Waksman in 1949 and achieved a private

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<sup>91</sup> Ibid., 12.

<sup>92</sup> Berg, Paul, and Janet E. Mertz. "Personal reflections on the origins and emergence of recombinant DNA technology." *Genetics* 184, no. 1 (2010): 9-17. The quotation came from pp. 15.

<sup>93</sup> Cohen, Stanley N. "DNA cloning: A personal view after 40 years." *Proceedings of the National Academy of Sciences* 110, no. 39 (2013): 15521-15529. As of December 2013, Berg and Mertz plan to write a response to leaven this “personal view.”

<sup>94</sup> Waksman, Selman A, and Albert Schatz. Streptomycin and Process of Preparation. US Patent 2449866 A, filed February 9, 1945, and issued September 21, 1948.

settlement in December 1950, receiving a lump sum of \$125,000 and 3% of the royalties in the remaining years of the patent.<sup>95</sup> With newspaper articles in from the *New York Times* and *The Guardian* to scholarly ones in *Nature* highlighting the contributions of Schatz<sup>96</sup>, as well as books written in favor of the junior scientist,<sup>97</sup> the streptomycin controversy has imposed great reputational costs on Waksman and Rutgers University as well. This cost is augmented because the deception and scandal surrounding the University and Waksman's conduct created more of a "hate campaign" easily relatable to the masses than a more technical debate on scientific priority, which some argue tips in Waksman's favor.<sup>98</sup> The discrepancy in the treatment of coinventors can be costly to research universities.

On August 23, 1943, Schatz isolated two strains of a gray-green actinomycete named *Streptomyces griseus*. After experiments arranged by Waksman at Mayo Clinic in Minnesota, one of the strains became known as streptomycin, the wonder drug that cured tuberculosis. In 1944, Schatz, Waksman, and another graduate student Elizabeth Bugie jointly published the discovery of streptomycin, with Schatz as the first author.<sup>99</sup> The next year, Schatz and Waksman were made co-inventors for the antibiotic, while Bugie was excluded for no known reasons.<sup>100</sup>

After the USPTO granted the patent, Rutgers set up a new trust, the Rutgers Research and

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<sup>95</sup> "Dr. Schatz Wins 3% of Royalty; Named Co-Finder of Streptomycin; Key Figures in Streptomycin Discovery Suit". *New York Times*. 30 December 1950. Retrieved 8 February 2014; Lawrence, Peter A. "Rank injustice." *Nature* 415, no. 6874 (2002): 835-836.

<sup>96</sup> Veronique Mistiaen. "Time, and the great healer." *The Guardian*. 1 November 2002. Retrieved 8 February 2014; Peter Pringle. "Notebooks Shed Light on an Antibiotic's Contested Discovery." *New York Times*. 11 June 2012. Retrieved 12 July 2012.

<sup>97</sup> Peter Pringle. *Experiment Eleven*. (New York, New York: Walker & Company, 2012); Frank Ryan. *Tuberculosis: The Greatest Story Never Told*. (Bromsgrove, Worcester: Swift Publishers, 1992). Milton Wainwright, *Miracle Cure: The Story of Penicillin and the Golden Age of Antibiotics* (Oxford: Basil Blackwell, 1990).

<sup>98</sup> William Kingston. "Streptomycin, Schatz v. Waksman, and the Balance of Credit for Discovery." *Journal of the History of MEDICINE and Allied Sciences* 59.3 (2004): 441-462.

<sup>99</sup> Schatz, Albert, Elizabeth Bugie, and Selman A. Waksman. "Streptomycin, a Substance Exhibiting Antibiotic Activity Against Gram-Positive and Gram-Negative Bacteria." *Experimental Biology and Medicine* 55, no. 1 (1944): 66-69.

<sup>100</sup> Waksman, Selman A, and Albert Schatz. Streptomycin and Process of Preparation. US Patent 2449866 A.

Endowment Foundation (RREF), and offered Waksman a percentage of the royalties in exchange for rights to “all improvements and future inventions.”<sup>101</sup> In the end, Waksman emerged not only as the beneficiary for 20% of the royalties but also as the manager of the patents. Without disclosing these ties to the Foundation, Waksman persuaded Schatz to assign his rights to the ‘866 patent to the Foundation, and would continue to do so for foreign patents on the drug for several years.<sup>102</sup> In the period leading up to May 1946, when Schatz left Rutgers for a position at the New York Department of Health, Waksman had ceased describing Schatz as the discoverer or even the co-discoverer of streptomycin, but merely as his assistant.<sup>103</sup> In addition, Waksman had Schatz sign a letter typed by his secretary, advised by Russell Watson, the Foundation lawyer in anticipation of the “Schatz claim” on streptomycin, including a passage clearly relegating Schatz to the rank of an assistant.<sup>104</sup>

In 1949, Schatz sued his former professor and the university, when he found out that he was a co-inventor only in name and that Waksman had been receiving payments covertly from the Rutgers Foundation. Like Morrow, he had a tight budget, but unlike Morrow, Schatz had the fortune of a wily uncle who found him a lawyer willing to take the case on a contingency fee basis, so that he did not have to pay unless he won. Schatz claimed that he was “under pressure amounting to blackmail” to assign his patent rights to the Foundation;<sup>105</sup> he recalled hesitating to sign on May 3, 1946, and that Waksman threatened to take his name off the patent application and “kill job chances” with his influence.<sup>106</sup> If these claims were true, they show the uneven

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<sup>101</sup> Pringle. *Experiment Eleven*. 78-79.

<sup>102</sup> Ibid.

<sup>103</sup> Waksman, Selman A. "The story of antibiotics." *Chemistry* 19, no. 8 (1945): 1-10.

<sup>104</sup> Kingston, ““Streptomycin, Schatz v. Waksman.” (2004); Russell Watson to A.S. Johnson, December 30, 1947, REFF; Albert Schatz to Selman Waksman, May 21, 1946, SAW, box 14, 4, in Pringle, 84-85.

<sup>105</sup> Selman Waksman. *My Life with the Microbes*. (New York, NY: Smino and Schuster, 1954).

<sup>106</sup> Pringle, 79.

power balance between professors and their students. This dynamic according to Schatz, was also the reason he signed the letter before he left: “I signed because I needed letters of recommendation from him when I applied for jobs.”<sup>107</sup> To avoid negative publicity, Rutgers reached a generous settlement with Schatz, and Waksman sent \$500 dollar checks to all of his twenty-four former assistants “to present a more generous picture and protect Waksman from further litigation.”<sup>108</sup>

Despite the monetary efforts on the part of the university and Waksman, the negative publicity nonetheless followed. Newspapers took Schatz’s sides, with headlines such as “He Finally Gets Credit” and “Dr. Schatz is modest in victory.”<sup>109</sup> A former assistant found the general consensus on Waksman was that he “was a shrewd codger and you cleared away some of his manure pile to expose the true contents of the man.”<sup>110</sup> Even Russell Watson, the Foundation lawyer who believed it would have won in court but succumbed to the Trustees’ fear of unfavorable publicity,<sup>111</sup> was pessimistic: he wrote personally to Waksman that the newspaper accounts “were grievously injurious to the University and to you, in less degree to the University than to you. How long this public impression will persist is uncertain.”<sup>112</sup> The impression persisted and in many ways has been renewed in recent years. Milton Wainwright “attempted to redress an historical imbalance in favour of Albert Schatz” in his book *Miracle Cure* in 2001.<sup>113</sup>

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<sup>107</sup> Albert Schatz to Peter Lawrence and Veronique Mistiaen, undated 2002, in Pringle, 84.

<sup>108</sup> Doris Jones to Albert Schatz, January 11, 1951, in Pringle, 169.

<sup>109</sup> “He Finally Gets Credit,” Editor’s Opinion. *Newark Star-Lodger*. December 30, 1950; Max Wienir. “Dr. Schatz Is Modest in Victory: Scientist Quips About Streptomycin Suit.” *The Newark Sunday*. December 31, 1950; “Dr. Schatz Wins 3% of Royalty.” *New York Times*. 1950. For a detailed listing of newspaper articles on the streptomycin case, see “About Albert Schatz.” About Albert Schatz.

<http://www.albertschatzphd.com/?cat=about&subcat=newspapers> (accessed April 16, 2014).

<sup>110</sup> Doris Jones to Albert Schatz, January 11, 1951, MW, in Pringle, 169.

<sup>111</sup> Letter dated 5 February 1951 from the university’s attorney, Russell E. Watson, to Arthur F. Vanderbilt, Waksman papers.

<sup>112</sup> Pringle, 168.

<sup>113</sup> Wainwright. *Miracle Cure*. 2001.

The next year, *Nature* published an article that used the streptomycin case to support its claim that “the misallocation of credit is endemic in science” and concluding that “Waksman created the myth that he alone deserved the credit.”<sup>114</sup> The publication of *Experiment Eleven* in 2012 further shows ongoing interest in the debate. Furthermore, many popular science channels, including *Scientific American*, has framed Schatz as one of the most notable omissions from the Nobel Prize.<sup>115</sup>

The lack of standardized protocol with regards to the relationship between inventors and the university contributed to the monetary and reputational costs sustained by Rutgers through Schatz’s litigation and the controversy that followed. The Foundation operated in a nearly ad hoc fashion, not only prejudicing against junior inventors but also allowing Waksman to wield his influence and seniority in legal and PR affairs. In particular, Waksman attempted to circumvent Schatz’s rights as an inventor with tactics that reflected badly upon his character as well as his institution. Had Schatz been excluded from inventorship, as fellow graduate student Bugie was, the streptomycin case would not be much different than that of rDNA, and Rutgers could have maintained that Schatz was merely a “pair of hands.” Instead, they faced a hard place between two rocks: removing his inventorship or compensating him both implied past remises. Regardless of whether Schatz’s inventorship was correctly awarded, Waksman had abused his power and employed strategies that would be difficult to explain away if they surfaced.

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<sup>114</sup> Lawrence. "Rank injustice." (2002).

<sup>115</sup> “No Nobel For You: Top 10 Nobel Snubs.” *Scientific American*. 2008. Accessed February 9, 2014. <http://www.scientificamerican.com/slideshow/10-nobel-snubs>. For the websites that list Schatz as a winner, see [www.garynull.com/Issues/Fluoride/FluorideVoices.htm](http://www.garynull.com/Issues/Fluoride/FluorideVoices.htm), [www.shirleys-wellness-cafe.com/fluoride.htm](http://www.shirleys-wellness-cafe.com/fluoride.htm), and [www.apfn.org/apfn/poison.htm](http://www.apfn.org/apfn/poison.htm). All accessed 27 January 2004, in Kingston, ““Streptomycin, Schatz v. Waksman.” (2004).

One such strategy was the claim of missing notebooks. In May 1946, Waksman claimed that a member of Schatz's family broke into the laboratory and carried off Schatz's notebooks that contained the critical streptomycin experiments. He went as far as to install locks on the laboratories, even though he knew that the notebooks, Schatz's and his own, were with the technology transfer officers at the University and Merck. As part of the lawsuit, he further suggested that Schatz had removed crucial pages in the notebook as an attempt to damage his credibility in court. In 2010, a librarian at Rutgers found the notebook in Waksman's papers. A page was indeed cut out, but it was toward the end of the streptomycin experiment, and the previous pages had demonstrated Schatz's discovery decidedly. Furthermore, Waksman's correspondence with his lawyers show that they knew the page was "insignificant" but deliberately leveraged the claim to instill doubt anyway.<sup>116</sup>

The moral pitfalls of Waksman by no means imply that Schatz was owed scientific credit, as many have been eager to suggest, especially about the Nobel Prize. Rather, they are calls for standardized protocols for translating authorship to inventorship, so as not to give unqualified graduate students incentives and standing to litigate. The freedom with which Waksman acted reminds research universities to adhere to their assignment decisions irrespective of traditional professor-student dynamics in academia. The discrepancy between authorship and inventorship was nominal in the rDNA case, whereas it lies in the practical treatment of the named inventors here. The histories show that either type of discrepancy can incur high monetary and reputational costs for research universities.

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<sup>116</sup> Pringle. "Notebooks Shed Light on an Antibiotic's Contested Discovery." *New York Times*.

Even the judging proceedings behind the 1952 Nobel Prize of Medicine represent a strong case for improving authorship documentation in academia, not only in light of new forms of credit such as inventorship but also with regards to the oldest and most prestigious in the institution of science. In 1952, the only year Schatz was nominated, by a Yugoslav professor of medicine, Einar Hammerson, a professor of chemistry at the Karolinska Institutet was charged with recommending the final recipients for Nobel to be awarded for streptomycin. By one of many idiosyncratic rules of the Prize, Hammerson could not read materials aside from scholarly articles. He did not read the patent applications, lab notebooks, or Schatz's thesis to conclude that he was only an assistant of inferior rank – “medarbetare” in Swedish – in the discovery of streptomycin. Some argue that the result was just because Schatz's discovery did not require new insights but repetitive testing with known techniques.<sup>117</sup> What undermines the credibility of this system is not the validity of the final decision but that Hammerson made factual mistakes in his deductive endeavor.<sup>118</sup> Without descriptions of the actual contributions of each author, one can imagine how difficult it would be to choose one, two, or three of them for the coveted prize. Those – including prestigious research universities - irate at so-called Nobel snubs - especially of their faculty - can reduce future frustration by advocating for more detailed and accurate authorship documentation in scholarly journals.

### **Case Study 3: Herpes Vaccine**

Neither the rDNA nor the streptomycin course was decided in court. A more recent dispute between a postdoctoral student at the University of Chicago, Joany Chou, and her supervisor Bernard Roizman was decided in favour of the junior research in 2001. Chou co-

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<sup>117</sup> Kingston, “Streptomycin, Schatz v. Waksman.” (2004).

<sup>118</sup> Einar Hammerston, “Betränkande Angående, Elizabeth Bugie, Karl Folkers, Albert Schatz, Selman Abraham Waksman, och Oscar Wintersteiner,” Nobel Archives, August 21, 1952, 10 AS personal archive, in Pringle, 178.

discovered a vaccine for the herpes virus and co-authored a paper with Roizman on the topic. Excluded from inventorship, she sued for correction. Furthermore, she sued successfully for fraudulent concealment on the part of her professor. The ruling is relevant to research universities and their technology transfer offices because the court established a legal precedent that such institutions were liable for the actions of their faculty, who in turn had a fiduciary duty to their students. In light of the ruling, to minimize legal costs and reputational backlash, universities have incentives to better police illegitimate discrepancies between authorship and inventorship assignments, and to ensure that tenured faculty do not abuse their seniority and influence in the translation from paper to patent.

In February 1991, Chou approached Roizman about patenting her discoveries relating to the herpes simplex virus and its use in an avirulent vaccine. Although Roizman advised her against it, he filed a patent as the sole inventor of the work around the same time. In 1996, Chou became suspicious when Roizman requested that she resign. She soon discovered that the patent he had filed had been granted, and that he was receiving substantial royalty payments from the University of Chicago, to which the patent was assigned. As a result, she sued Roizman, the University of Chicago, and the company that had licensed the technology, Aviron. The District Court in Illinois concluded that Chou did not have standing to challenge the inventorship, because her inventorship rights, even if she had them, would have been assigned to the University of Chicago by her employment contract.<sup>119</sup> On appeal, the Federal Circuit concluded that “an expectation of ownership of a patent is not a prerequisite for a putative inventor to possess standing to sue to correct inventorship under Section 256.”<sup>120</sup>

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<sup>119</sup> Chou v. University of Chicago, 2000 WL 222638 (N.D Ill. 2000).

<sup>120</sup> Chou v. University of Chicago. 254 F. 3d 1347 (Fed. Cir. 2001), pp.11.

Several rulings are relevant to research universities and their technology transfer offices. The Federal Circuit found Roizman guilty of fraudulent concealment and breach of fiduciary duty “given the disparity of their experience and roles, and Roizman’s responsibility to make patenting decisions regarding Chou’s inventions.”<sup>121</sup> The University of Chicago was held liable for both actions “under the doctrine of respondeat superior.”<sup>122</sup> Research universities therefore have a legal stake in ensuring accurate credit attribution, not only on patents but also on scholarly articles. After the court defined the legal relationship between professors and students, and the relationship between universities and their employees, research universities have the responsibility to interfere when faculty abuse traditional hierarchy to enlarge their credit. The court also discouraged universities from abusing that hierarchy, as it found the University guilty of breaching its express contract to Chou because “counsel for the University and Roizman reviewed her laboratory notebooks on April 20, 1999...decided that [she] was an inventor...[but never sent] the paperwork to correct inventorship.”<sup>123</sup>

The Federal Circuit decision was both “a major victory for student researchers”<sup>124</sup> and a wakeup call to research universities. Having long left credit attribution to professors, respecting the unique norms governing basic science, the universities are now legally liable for illegitimate discrepancies between authorship and inventorship. Although the share of royalties to which Chou became entitled did not diminish the University’s revenues but Roizman’s, the University sustained monetary costs for the litigation process. Other tangible costs include potential damages the courts may grant to student researchers, who may be more inclined to voice their

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<sup>121</sup> Ibid., 17.

<sup>122</sup> Ibid., 16, 18.

<sup>123</sup> Ibid., p. 20.

<sup>124</sup> Grimshaw, Kyle. "A Victory for the Student Researcher: Chou v. University of Chicago." *Duke Law & Technology Review* 1, no. 1 (2001): 1-7.

grievances now that Chou's case had set a favorable precedent. Beyond legal and associated monetary costs, discrepancies between authorship and inventorship, especially in the context of professors and students, whose helpless situation is so embraced by the popular press, can impose significant reputational costs to research universities and their faculty. If not for the inherent justice in accurate credit attribution, research universities have been given many other incentives to better police authorship and inventorship practice in light of *University of Chicago vs. Chou*.

## Conclusion

Discrepancies between inventors on patents and authors on their corresponding papers can impose significant monetary and reputational costs on research universities. The case studies provide qualitative evidence for such costs. The regression analysis corroborates some of the findings from the case studies. My analysis points toward a way forward for American universities to reduce conflict, reward authorship and inventorship, and better manage faculty and student contributions in the commercialization of their work. Universities can protect themselves by being aware of and acting on the differences and similarities between authorship and inventorship.

Both the case studies and the regression analysis suggest that junior researchers are disadvantaged in the technology transfer process from papers to patents. Results from the regression corroborate the conclusion that being female does not significantly affect an author's likelihood of being named as an inventor. The most concerning trend is increasing scientific collaboration. Given a growing number of authors on each paper and the prevalence of collaboration among scientists, technology transfer offices might consider implementing electronic laboratory notebooks among other measures to improve accountability in the publishing and patenting processes both at their universities and beyond. A more complex knowledge production process involving more players plausibly requires a more systematic monitoring process.

The three case studies present examples of costs that the discrepancies can impose on universities. Even though the vulnerabilities of Stanford's rDNA patents were never brought to court, the prolonged legal battle with examiner Tanenholtz and the weakened licensing scheme imposed significant monetary costs on Stanford University. In the streptomycin case, the senior

scientist, Selman Waksman, was heavily involved in the patenting process, occasionally in ways that would reflect badly upon him. When the junior scientist, Albert Schatz—perhaps bolder and luckier than his counterparts Robert Helling and John Morrow at Stanford—brought his accusations to court, they posed a large public relations problem for the relatively smaller, much less prestigious Rutgers University. In the end, the solution involved significant monetary compensation from the university to the student. The only case to have been decided in court, *University of Chicago vs. Chou* not only imposed reputation and monetary cost on the University but also showed that research universities have a legal responsibility to ensure their faculty employees carry out their fiduciary duty to their students.

The case studies also suggest that junior scientists are more frequently lost in the translation from paper to patent (that is, were listed as authors but not as inventors). This is corroborated and further generalized by my regression analysis. Receiving an advanced degree each year later than the most senior author is associated with a decrease in the author's likelihood of being named an inventor by a factor of 0.9575. Neither the regression coefficients nor the case studies alone provides convincing evidence that the lack of relative seniority *causes* the junior scientists to be excluded. It seems plausible, however, that given the case study on streptomycin, some junior scientists have been excluded precisely because they are junior. Since it would be impractical to track every interaction of every scientist, there is no simple method for distinguishing legitimate exclusion from illegitimate exploitation. American universities might better prevent the illegitimate cases and associated costs by educating students and their mentors about their duties to each other and the criteria for appropriately attributing authorship and inventorship in their publishing and patenting endeavors.

Unlike seniority, gender is not a significant predictor of discrepancies between authors and inventors. Mertz emphatically dismissed the possibility that she was disadvantaged by her gender.<sup>125</sup> More recently, Chou did not seem inhibited by her gender when she won her case against her mentor Roizman and the University of Chicago. Both episodes and the PPP data suggest that women were not discriminated against on the basis of gender. This conclusion applies to women who have published in academic science, for they may be plausibly different in relevant ways than those who have not pursued science or succeeded, particularly in the time frames of our case studies and data. Assuming that the profile of women in science does not change, the current emphasis on gender equality bodes well for gender to become an even less significant factor determining authorship and inventorship.

The PPP analysis alerts us to discrepancies and associated costs that growing collaboration might pose for the technology transfer offices at research universities. While the number of authors skyrockets in science, the number of coinventors remains relatively stable. Whether increasing levels of collaboration arise from the burden of knowledge, demands of technology, or other causes, the phenomenon needs to be addressed at research institutions so as to avoid prolonging patent examinations and weakening patent portfolios as well as to lower the chances of incurring the reputational and monetary costs of resolving conflicts in court. First, universities need to better understand the landscape of academic collaboration. This may entail developing more accurate measures of collaboration for more recent PPP datasets to confirm the relationships inferred from crude proxies such as the number of institutions and authors. Then, universities can better assess how they can best adapt their programs to minimize discrepancies,

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<sup>125</sup> Interview on file with author.

perhaps by naming more inventors, working with journals and scientists to mitigate unnecessary growth in the number of coauthors, or both.

In practice, universities might best protect themselves by increasing transparency and accountability in managing authorship and inventorship. Technology transfer offices in universities can encourage the use of electronic lab notebooks and keeping detailed records. Had Schatz's notebooks been archived by Rutgers' licensing office, the scandal surrounding the "eleventh experiment" may not have occurred. The *U Chicago vs. Chou* verdict further demonstrated the importance of using the information in lab notebooks, as the University was guilty of breach of duty for never mailing Chou the paperwork to correct inventorship after determining that she was indeed an inventor, according to her lab notebooks. To facilitate greater transparency and accountability across institutions, universities might consider forming networks with other academic institutions to securely share information such as that in electronic notebooks. Journals can help reduce discrepancies between the authors and inventors. By requiring authors to specify their individual contributions, journals can not only ensure adherence to authorship guidelines but also provide useful information to technology transfer officers, particularly when authors collaborate across institutions. Technology transfer offices can also deal with inventorship with particular attention to the rights and interests of junior faculty and staff who contribute to inventions, by asking for explicit reasons that authors on papers are not included as inventors on patents. In sum, American universities should educate faculty and students on appropriate conduct in publishing and patenting, adapt existing practices at the technology transfer office to growing collaboration and growth of research teams, and foster an environment of accountability and transparency to reduce the monetary costs and reputational harms associated with failing to properly include inventors on patents.

## **Appendix I: The Cohen-Boyer Patent Claims 1980**

**Title:** Process for producing biologically functional molecular chimeras

**Inventors:** Stanley Cohen and Herbert Boyer

**Patent Number:** 4237224

**Filing Date:** January 4, 1979

**Issued Date:** December 2, 1980

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### **Claims:**

1. A method for replicating a biologically functional DNA, which comprises:
  - transforming under transforming conditions compatible unicellular organisms with biologically functional DNA to form transformants; said biologically functional DNA prepared in vitro by the method of:
    - (a) cleaving a viral or circular plasmid DNA compatible with said unicellular organism to provide a first linear segment having an intact replicon and termini of a predetermined character;
    - (b) combining said first linear segment with a second linear DNA segment, having at least one intact gene and foreign to said unicellular organism and having termini ligatable to said termini of said first linear segment, wherein at least one of said first and second linear DNA segments has a gene for a phenotypical trait, under joining conditions where the termini of said first and second segments join to provide a functional DNA capable of replication and transcription in said unicellular organism;
  - growing said unicellular organisms under appropriate nutrient conditions; and
  - isolating said transformants from parent unicellular organisms by means of said phenotypical trait imparted by said biologically functional DNA.

2. A method according to claim 1, wherein said unicellular organisms are bacteria.
3. A method according to claim 2, wherein said transformation is carried out in the presence of calcium chloride.
4. A method according to claim 3, wherein said phenotypical trait is resistance to growth inhibiting substance, and said growth is carried out in the presence of a sufficient amount of said growth inhibiting substance to inhibit the growth of parent unicellular organisms, but insufficient to inhibit the growth of transformants.
5. A method according to claim 1, wherein said unicellular organism is E. coli.
6. A method according to claim 1, wherein said predetermined termini are staggered and cohesive.
7. A method according to claim 6, wherein said joining conditions includes enzymatic ligation.
8. A method according to claim 6, wherein said cohesive ends are formed by staggered cleavage of said viral or circular plasmid DNA and a source of said second segment with a restriction enzyme.
9. A method according to claim 6 wherein said cohesive termini are formed by addition of nucleotides.
10. A method according to claim 1, wherein said predetermined termini are blunt end and said joining conditions include enzymatic ligation.
11. A method for replicating a biologically functional DNA comprising a replicon compatible with a host unicellular organism joined to a gene derived from a source which does not exchange genetic information with said host organism, said method comprising:
  - isolating said biologically functional DNA from transformants prepared in accordance with claim 1;
  - transforming unicellular microorganisms with which said replicon is compatible with said isolated DNA to provide second transformants; and
  - growing said second transformants under appropriate nutrient conditions to replicate said biologically functional DNA.
12. A method for producing a protein foreign to a unicellular organism by means of expression of a gene by said unicellular organism, wherein said gene is derived from a source which does not exchange genetic information with said organism, said method comprising:
  - growing transformants prepared in accordance with any of claims 1 and 11 under appropriate nutrient conditions, whereby said organism expresses said foreign gene and produces said protein.

13. A method according to claim 12, wherein said protein is an enzyme.

14. A method according to claim 11, wherein said method is repeated substituting said biologically functional DNA from transformants prepared in accordance with claim 1 with second or subsequent transformants to produce additional transformants.