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Overqualified and Underrepresented: Gender Inequality in Pharmaceutical Patent Law*

S. Sean Tu†

Paul R. Gugliuzza‡

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Pharmaceutical patents represent some of the most valuable intellectual property assets in the world: they can be worth billions of dollars if courts uphold their validity and find them infringed. But, if invalidated, generic drug manufacturers can get to market earlier, generating billions of dollars of revenue for themselves and creating enormous savings for consumers. Accordingly, drug patents are the product of careful, high-cost prosecution and are associated with high-stakes, bet-the-company litigation.

But women lawyers are noticeably absent from pharmaceutical patent practice. This article reports an original empirical study finding that women comprise only one-third of the top pharmaceutical patent litigators and only one-quarter of lawyers who prosecute litigated pharmaceutical patents – numbers far below the share of women in the legal profession overall. The usual

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explanation for any lack of representation in patent practice is the “pipeline” problem – that is, an insufficient number of women in the technical fields underlying patent law. But our study finds little support for any pipeline problem. Indeed, recent studies indicate that more women law students have scientific undergraduate and graduate degrees than their male counterparts.

Interestingly, the gender gap among pharmaceutical patent lawyers does not carry over to public sector work. The U.S. Patent and Trademark Office is the one place where our study finds anything close to parity: 42.3% of pharmaceutical patent examiners are women and 57.7% are men. This finding adds to a nascent literature documenting vast disparities in gender representation in the private versus public sectors, both in patent law and in law practice more generally.

It also suggests that the lack of women doing patent law in private practice in the pharmaceutical field probably is not due to any pipeline problem; instead, it likely stems from structural inequalities that permeate the highest levels of corporate law firms. Those firms, as well as their pharmaceutical company clients, all say that diversity is important. But, as our study shows, there is a disconnect between rhetoric and reality. Fully solving structural inequality in law practice is a formidable task, but this article sketches a few ways in which firms and their clients could help create a patent bar that is more diverse and inclusive.

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INTRODUCTION

Pharmaceutical patents are among the most valuable intellectual property assets in the world.¹ Obtaining and enforcing drug patents is a big business and is an area where clients expect their law firms to have high billable hours. This is because drug companies earn billions of dollars a year on each blockbuster drug, so a decision on whether or not a profitable product is protected by

1. See Arti K. Rai, Saurabh Vishnubhakat, Jorge Lemus & Erik Hovenkamp, *Post-Grant Adjudication of Drug Patents: Agency and/or Court?*, 37 BERKELEY TECH. L.J. (forthcoming) (manuscript at 3), <https://ssrn.com/abstract=3865804> (“[F]ew areas of technology can match [the biopharmaceutical industry]. Particularly . . . for small-molecule drugs . . . a billion-dollar drug monopoly may be protected from competition by a relatively small number of patents.”).

a patent has huge ramifications.² For example, Eli Lilly laid off a large chunk of its sales staff when its antidepressant Cymbalta went off patent at the end of 2013.³ And Merck cut almost a third of its workforce after the loss of patent protection on its asthma medication Singulair.⁴ Indeed, the entire cost of a patent litigation can amount to just a single day's worth of sales.⁵

The litigation stakes are high. Winning a pharmaceutical patent case can result in billion-dollar verdicts for the brand manufacturer or years of additional market exclusivity.⁶ For example, in 2013, Pfizer won a \$2.15 billion patent infringement judgment against generic drug makers Teva and Sun,⁷ one of the largest patent damage awards in U.S. history.⁸ But a loss by the brand manufacturer can

2. For critical commentary on drug prices and industry profits, see generally *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition: Hearing Before the S. Comm. on the Judiciary*, 116th Cong. (2019); *Examining the Actions of Drug Companies in Raising Prescription Drug Prices: Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. (2019); Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860-63 (2016) (noting that patents are the primary reason for high drug prices and blaming manufacturers for using "product life-cycle management" to extend the life of patents); I-MAK, AMERICA'S OVERSPEND: HOW THE PHARMACEUTICAL PATENT PROBLEM IS FUELING HIGH DRUG PRICES, (Oct. 2017), <https://www.i-mak.org/wp-content/uploads/2020/10/Excess-Costs-Briefing-Paper-FINAL-2017-10-24-with-cover-rev.compressed.pdf>. But see Johnathan Darrow, *Debunking the "Evergreening" Patents Myth*, HARV. L. REC., Dec. 8, 2010, at 6 (discussing how the lag time between filing a patent application and Food and Drug Administration (FDA) approval can dramatically shorten periods of market exclusivity).

3. *Lilly's Sales-Force Restructuring to Affect 1,600-Plus*, INDIANAPOLIS BUS. J. (May 6, 2013), <https://www.ijb.com/articles/41201-lilly-s-sales-force-restructuring-to-affect-1-600-plus>.

4. Tracy Staton, *10 Largest U.S. Patent Losses*, FIERCE PHARMA (Oct. 24, 2011, 8:35 PM), <https://www.fiercepharma.com/special-report/merck-10-largest-u-s-patent-losses>.

5. AbbVie's Humira, for instance, had \$20 billion in sales in 2021 – or \$550 million per day. *Leading Drugs Worldwide Based on Projected 2021 Sales*, STATISTA, <https://www.statista.com/statistics/973523/top-drugs-by-year-on-year-sales-increase>.

6. See Aaron Stiefel, *10 Years Later – Impact of eBay on Patent Injunctions in the Life Sciences*, ARNOLD & PORTER (June 21, 2016), https://www.arnoldporter.com/en/perspectives/publications/2016/06/2016_06_21_10_years_later_impact_of_ebay_13037.

7. *Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 671 (D. Del. 2012).

8. Indeed, three of the top five largest patent damage awards in U.S. history were in pharmaceutical cases. See *Top 10 Largest Patent Infringement Awards*, GREYB, <https://www.greyb.com/largest-patent-infringement-awards>. The other two were *Gilead Sciences, Inc. v. Merck & Co.*, 888 F.3d 1231 (Fed. Cir. 2018), in which a jury awarded \$2.54 billion but the patents were later found invalid by the Federal Circuit, and *Centocor Orth Biotech v. Abbott Laboratories*, 636 F.3d 1341 (Fed. Cir. 2011), in which the Federal Circuit reversed a \$1.67 billion damages award.

allow generic companies to get to market early, earn their own share of profits, and save consumers billions of dollars.⁹

Procuring a drug patent at the U.S. Patent & Trademark Office (USPTO) in the first place is a similarly high-stakes endeavor because drug patents are *ex ante* known to be valuable.¹⁰ Drafting a pharmaceutical patent often requires post-graduate education as well as years of experience in patent drafting.¹¹ Though much has been written about the breadth, vagueness, and questionable validity of many of the software- and computer-related patents asserted by so-called patent trolls,¹² drug patents are much different.¹³ Because they are crucial to market success, companies put much effort into careful prosecution to ensure the patents withstand any later challenge to their validity.¹⁴

Because pharmaceutical patent practice is among the most high-stakes and complex types of commercial law practice, it provides an important context in which to examine the demographics of the legal profession. In the empirical study presented in this Article, we consider questions about gender equality – or, more accurately, the

9. See *Generic Drugs and Low-Cost Prescriptions*, FED. TRADE COMM'N, <https://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions> (noting that generic drugs cost 20 to 70% less than their branded counterparts).

10. For summaries of the patent prosecution process, see S. Sean Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, 38 CARDOZO ARTS & ENT. L.J. 391, 395–99 (2020); Naira Rezende Simmons, *Putting Yourself in the Shoes of a Patent Examiner: Overview of the United States Patent and Trademark Office (USPTO) Patent Examiner Production (Count) System*, 17 J. MARSHALL REV. INTELL. PROP. L. 32, 33 (2017).

11. See *infra* Section II.A.

12. See, e.g., Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2126 (2013); Paul R. Gugliuzza, *Patent Trolls and Preemption*, 101 VA. L. REV. 1579, 1580 (2015). Patent trolls, or, less pejoratively, non-practicing entities (NPEs), do not sell any products or provide any services; they exist for the sole purpose of enforcing patents. For an analysis of the heterogeneity among patentees typically tagged with the NPE moniker, see Christopher A. Cotropia et al., *Unpacking Patent Assertion Entities (PAEs)*, 99 MINN. L. REV. 649, 654 (2014).

13. See generally Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1675 (2003) (discussing the different characteristics of innovation—and patentability and infringement—across various technological sectors).

14. See Dani Kass, *Patent Specification Concerns Make IPRs Tricky for Drug Cos.*, LAW360 (Jan. 28, 2022, 8:46 PM), <https://www.law360.com/ip/articles/1458065/patent-specification-concerns-make-iprs-tricky-for-drug-cos> (“Drug patents tend to hold high value for their companies, which means taking out a singular patent may have more of an impact than it would in the technology world. Companies also work harder to make sure drug patents are bulletproof from the outset. . . . ‘There’s a lot of effort put into these. Excellent counsel. Excellent disclosures. Excellent considerations of everything put into the claims.’”).

lack thereof—in pharmaceutical patent examination, prosecution, and litigation. This study builds on other recent work documenting gender inequality in patent law practice.¹⁵ And it adds to a growing literature examining why—after decades of formal equality under the law—women are still markedly underrepresented in the corporate world.¹⁶

One oft-mentioned explanation (or, perhaps, “justification”) for the dearth of women in patent practice is that women tend not to have the science and technology backgrounds that are essential to work in the field.¹⁷ The pharmaceutical sector is an interesting context in which to examine this supposed “pipeline” problem because the evidence suggests that it should be relatively minor—as data we have collected indicates, today, women obtain a majority of the biological science undergraduate and graduate degrees issued in the United States, as well as a majority of chemistry undergraduate degrees and 40–45% of chemistry graduate degrees.¹⁸

This study first reviews the backgrounds of every examiner at the USPTO involved in an abbreviated new drug application (ANDA) patent from 2005 through 2021. It then reviews every pharmaceutical patent involved in infringement litigation between 2009 and 2021 that terminated in a final decision on the merits undertaken by lawyers hailing from the top five law firms representing brand pharmaceutical companies and the top five law firms representing generic pharmaceutical companies. We proceed to review the practitioners associated with those specific patents: (1) the patent prosecutors who helped the brand pharmaceutical

15. Paul R. Gugliuzza & Rachel Rebouché, *Gender Inequality in Patent Litigation*, 100 N.C. L. REV. 1683 (2022).

16. See, e.g., NAOMI CAHN, JUNE CARBONE & NANCY LEVIT, *SHAFTED: WHY WOMEN LOSE IN A WINNER-TAKE-ALL WORLD* (forthcoming), https://www.law.northwestern.edu/research-faculty/events/colloquium/law-gender/documents/2021_sp_cahn_shafted_introduction.pdf; Naomi Cahn, June Carbone & Nancy Levit, *Gender and the Tournament: Reinventing Antidiscrimination Law in an Age of Inequality*, 96 TEX. L. REV. 425, 471 (2018); Jennifer L. Berdahl et al., *Work as a Masculinity Contest*, 74 J. SOC. ISSUES 422, 423 (2018); see also Claire Cain Miller, *Women Did Everything Right. Then Work Got ‘Greedy,’* N.Y. TIMES (Apr. 26, 2019), <https://www.nytimes.com/2019/04/26/upshot/women-long-hours-greedy-professions.html>.

17. See John Murph, *Minority in IP: Navigating a Lonely Road*, WASH. LAW., Mar.–Apr. 2022, at 26 (discussing the “glaring racial and gender disparities in STEM (science, technology, engineering, and mathematics) related to the professional fields.”).

18. See *infra* Section I.B.1.

companies obtain the patents and (2) the patent litigators who represented both the brand and generic pharmaceutical companies who litigated the cases to a final decision on validity.

We find that women are noticeably absent from both pharmaceutical patent prosecution and litigation. Specifically, of the 217 patent prosecutors in our dataset who worked on pharmaceutical patents that were eventually litigated to a final decision on the merits by one of the select firms, 75.1% are men and only 24.9% are women.¹⁹ Likewise, of the 333 patent litigators in our dataset who litigated pharmaceutical patents on the merits from one of the select firms, 62.5% are men and only 37.5% are women.²⁰

These gaps are surprising because studies also find that women are *overrepresented* in many of the undergraduate and graduate school fields associated with the pharmaceutical industry.²¹ Furthermore, women represent a majority of law students who have the scientific educational backgrounds that can be helpful when litigating or prosecuting drug patents.²² Indeed, the (comparatively few) female patent prosecutors and litigators who appear in our dataset tend to have higher levels of education overall as compared to their male counterparts.²³

Our study finds that the only place where we see anything close to parity between women and men in the pharmaceutical patent area is among examiners at the USPTO, where women represent 42.3% of the examiners in the most relevant technology center and men represent 57.7%.²⁴ This finding in particular adds to an emerging literature showing that gender inequality—though it remains prevalent throughout the legal profession²⁵—is less pronounced in government legal work than in the private sector, particularly in the field of pharmaceutical patent law.²⁶

19. See *infra* Section IV.A.2.

20. See *infra* Section IV.B.

21. See *infra* Section I.B.1.

22. See *infra* Section I.B.2.

23. See *infra* Section IV.C.

24. See *infra* Section IV.A.1.

25. See *Women in the Profession*, AM. BAR ASS'N, <https://www.americanbar.org/groups/diversity/women>.

26. Gugliuzza & Rebouché, *supra* note 15, 1713 fig. 13 (showing that women working for the government argued approximately the same number of cases as men at the Federal Circuit), 1718 fig. 18 (showing that women conducted approximately 50% of the oral arguments by the USPTO Solicitor's Office at the Federal Circuit).

The remainder of this Article proceeds as follows. In Part I, we outline the problem of gender inequality in the legal profession, examine the role of education in patent practice, and provide statistics on the gender composition of the pool of people with undergraduate and graduate degrees in the fields that are relevant to pharmaceutical patent law. In Part II, we review the legal requirements to become a patent agent or patent attorney, describe the field of patent law practice, and summarize the process of pharmaceutical patent litigation. In Part III, we describe the novel datasets we created for this study. In Part IV, we discuss our results on the participation of women in patent law practice, analyzing whether there is a gender disparity among examiners at the USPTO as well as among lawyers who assist clients prosecuting pharmaceutical patents. Additionally, we examine the participation of women who litigate drug patents, both on the brand and generic sides, at top law firms. Finally, in Part V, we sketch some possible solutions to the gender inequality in patent law that our study documents.

I. WOMEN IN SCIENCE AND THE “PIPELINE” PROBLEM

Today, women are well represented in the sciences at the undergraduate and graduate levels as well as in the work force. In fact, in life sciences and health-related jobs, women represent 48% and 74% of the workforce, respectively.²⁷ Additionally, in the biological and life sciences, the average annual salary for women actually exceeds that of men: \$68,000 for women and \$65,000 for men.²⁸ This is especially striking because women make an average of 84% of their male counterparts’ salaries across all professions.²⁹

27. Richard Fry et al., *STEM Jobs See Uneven Progress in Increasing Gender, Racial and Ethnic Diversity*, PEW RSCH. CTR. (Apr. 1, 2021) <https://www.pewresearch.org/science/2021/04/01/stem-jobs-see-uneven-progress-in-increasing-gender-racial-and-ethnic-diversity>.

28. See *Women, Minorities, and Persons with Disabilities in Science and Engineering*, NAT’L SCI. FOUND. (2019), <https://www.nsf.gov/statistics/wmpd> [hereinafter *2019 NSF Study*].

29. *Id.* (\$76,000 median salary for women versus \$90,000 median salary for men). The U.S. Census Bureau has recently shown that women still make approximately 18–20% less than men at the median. Thomas B. Foster, Marta Murray-Close, Liana Landivar & Mark deWolf, *An Evaluation of the Gender Wage Gap Using Linked Survey and Administrative Data* 8 fig. 1 (U.S. Census Bureau, Working Paper No. CES-20-34, 2020). Among the other sciences relevant to pharmaceutical patents, the data in the physical sciences (which includes chemistry) shows greater inequality, with average annual salaries of \$60,000 for women and \$78,000 for men. *Id.*

Women's parity in representation and salary in some fields of science, however, does not translate to the legal profession.³⁰ Women's representation began increasing in the legal profession in the 1970s, but the United States has lagged well behind other countries.³¹ While women made up 50% of the legal profession in countries like Romania and Poland by the mid-2000s, they had reached only the 30% mark in the United States by that point.³²

Today, women comprise nearly half of all associates in private law practice (and over half of all summer associates).³³ Yet only about 38% of attorneys at the largest U.S. law firms are women, and 23% of law firm equity partners are women.³⁴ Furthermore, although women start at relatively equal levels of pay, the wage gap quickly increases when women are promoted to non-equity as well as equity partners. Though some studies find that women lawyers work more hours on average than men, women are still represented in top positions far below their rate of representation in the legal profession overall.³⁵

In the remainder of this Part, we dig more deeply into the data on gender representation in patent law in the pharmaceutical field, first discussing the supposed "pipeline" problem, then presenting evidence debunking that explanation for gender inequality in patent practice in the pharmaceutical field, and finally linking our evidence to data on women in the legal profession more broadly.

30. See JOYCE STERLING & LINDA CHANOW, IN THEIR OWN WORDS: EXPERIENCED WOMEN LAWYERS EXPLAIN WHY THEY ARE LEAVING THEIR LAW FIRMS AND THE PROFESSION, AM. BAR ASS'N (2021), <https://www.americanbar.org/content/dam/aba/administrative/women/intheirownwords-f-4-19-21-final.pdf>.

31. Ethan Michelson, *Women in the Legal Profession, 1970–2010: A Study of the Global Supply of Lawyers*, 20 IND. J. GLOB. L. STUD. 1071, 1075 (2013).

32. *Id.* at 1083.

33. James Leipold, NALP UPDATE: THE LEGAL EMPLOYMENT MARKET 6, 9 (2022) (on file with authors) (reporting that 48.2% of associates are women).

34. Jacqueline Bell, *Law360's Glass Ceiling Report: What You Need to Know*, LAW360 (Sept. 13, 2021, 3:03 PM), <https://www.law360.com/appellate/articles/1418221/law360-s-glass-ceiling-report-what-you-need-to-know>.

35. Gabe Friedman, *Harvard Study: Women Lawyers Work More Than Men*, BLOOMBERG LAW (May 12, 2015), <https://news.bloomberglaw.com/business-and-practice/harvard-study-women-lawyers-work-more-than-men> (discussing a time series study of Harvard Law School graduates).

A. Patent Law's Pipeline Problem

Previous studies have shown that women are generally underrepresented in the patent system.³⁶ Women not only lack representation as inventors,³⁷ there is also a lack of gender diversity among the lawyers who prosecute patents. Women comprise only 17% of the attorneys registered to practice at the USPTO.³⁸ Further, women account for only 12% of total attorney appearances in the important new post-issuance proceedings at the USPTO's Patent Trial and Appeal Board (PTAB), which began operating in 2012.³⁹

36. Gugliuzza & Rebouché, *supra* note 15; Annette I. Kahler, *Examining Exclusion in Woman-Inventor Patenting: A Comparison of Educational Trends and Patent Data in the Era of Computer Engineer Barbie*, 19 AM. U. J. GENDER SOC. POL'Y & L. 773 (2011); Saurabh Vishnubhakat, *Gender Diversity in the Patent Bar*, 14 J. MARSHALL REV. INTELL. PROP. L. 67 (2014); Mary T. Hannon, *The Patent Bar Gender Gap: Expanding the Eligibility Requirements to Foster Inclusion and Innovation in the U.S. Patent System*, 10 IP THEORY 1 (2020).

37. Until recently, after urging by Congress, the USPTO had not collected demographic information on patentees. A recent study by the USPTO used statistical analysis to analyze historical rates of patents granted by gender and found that women represented only 12% of named inventors. U.S. PAT. & TRADEMARK OFF., PROGRESS AND POTENTIAL: A PROFILE OF WOMEN INVENTORS ON U.S. PATENTS 4 (Feb. 2019), https://www.uspto.gov/sites/default/files/documents/20190502_PPAC_Progress-and-Potential.pdf [hereinafter PROGRESS AND POTENTIAL]. The USPTO found that in 1980 only 7% of patents had at least one woman listed as an inventor; this figure increased to 21% by 2016. *Id.* at 3. Another study found that over the nearly 40-year period between 1976 and 2013, the rate of women patenting increased from 2.7% to 10.8%. Cassidy Sugimoto, Chaoqun Ni, Jevin West & Vincent Larivière, *The Academic Advantage: Gender Disparities in Patenting*, 10 PLOS ONE 1 (2015). Furthermore, these patenting rates are similar for every country represented in USPTO patent applications. *Id.* fig. 1. Interestingly, women inventors are concentrated around certain technologies. Specifically, women are most represented in biotechnology (25% invention rate), pharmaceuticals (23% invention rate), and organic fine chemistry (21% invention rate). *Id.* Correspondingly, the female share of patent inventors is highest among chemical and pharmaceutical companies. PROGRESS AND POTENTIAL, *supra*, at 10 (showing that the three companies with the highest rates of women inventorship are all chemical and pharmaceutical companies: Procter and Gamble (24%), Bristol-Myers Squibb (24%) and Abbott Laboratories (21%)). This rate, however, still seems low considering that women represent nearly 50% of biological and life scientists.

38. Vishnubhakat, *supra* note 36, at 79.

39. PTAB BAR ASS'N, WOMEN AT THE PTAB: POST-GRANT PROCEEDINGS 3 (2021), https://www.ptabbar.org/docs/2021_PTAB_Bar_Report_on_Women_at_the_PTAB.pdf. In 2012, the USPTO, through the PTAB, started a new form of post-issuance proceedings. The new proceedings are designed mainly to give parties in patent infringement suits a quicker and cheaper route to challenge the validity of the patents they are accused of infringing. The proceedings have been enormously popular—the USPTO has received over 10,000 petitions for review in the first eight years of their existence. J. Jonas Anderson & Paul R. Gugliuzza, *Federal Judge Seeks Patent Cases*, 71 DUKE L.J. 419, 460 (2021). For a detailed overview of the new procedures, see Rochelle Cooper Dreyfuss, *Giving the Federal Circuit a Run for Its Money: Challenging Patents in the PTAB*, 91 NOTRE DAME L. REV. 235, 242–49 (2015).

Many commentators have described the root cause of patent law's lack of gender diversity as a pipeline problem.⁴⁰ Specifically, the upstream lack of women with science, technology, engineering, and mathematics (STEM) degrees creates the downstream problem of fewer women with STEM-related jobs, including the practice of patent law.

As we discuss in more detail below,⁴¹ being a member of the patent bar is required to assist clients with prosecuting patents before the USPTO, and, generally speaking, one cannot participate patent prosecution without a science degree or equivalent training.⁴² Additionally, one cannot become a patent examiner without a science degree. Finally, while lawyers can litigate patents without a science degree, it is often helpful to have a science degree to understand the technology at issue during litigation.

Because of these educational prerequisites, proponents of the pipeline argument contend that the diversity problem could be fixed simply by increasing the rate at which women graduate in STEM fields.⁴³ This would increase the upstream supply of women with STEM degrees, and we would then see more women becoming patent attorneys downstream. Equality would be reached as older male lawyers age into retirement and are replaced by a cohort of lawyers who have near gender parity. The problem would, in other words, fix itself if given the time; there would

40. See, e.g., Elaine Spector & LaTia Brand, *Diversity in Patent Law: A Data Analysis of Diversity in the Patent Practice by Technology Background and Region*, AM. BAR ASS'N (Sept. 16, 2020), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/september-october/diversity-patent-law-data-analysis-diversity-patent-practice-technology-background-region (“[P]atent law requires a hard science degree. As such, the pipeline with respect to diverse candidates entering a STEM field needs to be addressed.”); Emily Collins, *Gender Inequality – How Many Patent Offices Does It Take to Fix a Leaky Pipeline?*, KILBURN & STRODE (Mar. 6, 2020), <https://www.kilburnstrode.com/knowledge/in-house/gender-inequality>; Esther H. Lim, *Breaking Down Barriers*, INTELL. PROP. MAG. (Mar. 27, 2020), <https://www.finnegan.com/en/insights/articles/CDMR-breaking-down-barriers.html> (“Targeted outreach to high school and undergraduate students about STEM, and careers in IP, will help fill the pipeline of future women and diverse attorneys.”). For a general discussion of the pipeline problem, see CAROLINA ACADEMIC PRESS, *THE EDUCATION PIPELINE TO THE PROFESSIONS: PROGRAMS THAT WORK TO INCREASE DIVERSITY* (Sarah E. Redfield ed., 2012).

41. See *infra* Section II.A.

42. For a scholarly critique of the requirements imposed for admission to the patent bar, see William Hubbard, *Razing the Patent Bar*, 59 ARIZ. L. REV. 383 (2017).

43. See the sources quoted *supra* note 40.

be no need to further scrutinize the issue of discrimination in professional life.

But phrasing the matter as a pipeline problem oversimplifies the issue. As the empirical study presented below makes plain, simply increasing the number of women in the United States with scientific degrees will not solve the gender diversity problem in patent law in the pharmaceutical field because women are *already* heavily represented in the sciences relevant to pharmaceutical patent practice—and they have been for a while.

Accordingly, the problem goes deeper than the supply chain. The patent field, as well as private sector law firms generally, need to address embedded structural barriers and systematic biases before gender equality is achieved. As we describe later in the Article,⁴⁴ it will be necessary for law firms, clients, and courts to take active steps to achieve these goals because the problem will not solve itself by simply educating women in STEM fields.

B. Women Science Majors at Undergraduate, Graduate, and Law Schools

Education is a springboard to both STEM jobs as well as legal jobs that require a scientific background. According to a recent survey, today, women in the United States earn a majority of all undergraduate and advanced college degrees (58%) and also represent a majority of all STEM college degrees (53%).⁴⁵ In this section, we show that, when it comes to the sciences most relevant to pharmaceutical patent practice, women are well-represented—indeed, arguably overrepresented—at the undergraduate and graduate levels and among law students in the United States. Accordingly, the pharmaceutical patent sector provides an excellent context in which to assess whether any pipeline problem could really be solved if more women simply graduated with the relevant degrees.

1. Undergraduate and Graduate Degrees

A 2019 study conducted by the National Science Foundation (NSF) found that, over the past decade, women attending U.S.

44. See *infra* Part V.

45. See Fry et al., *supra* note 27.

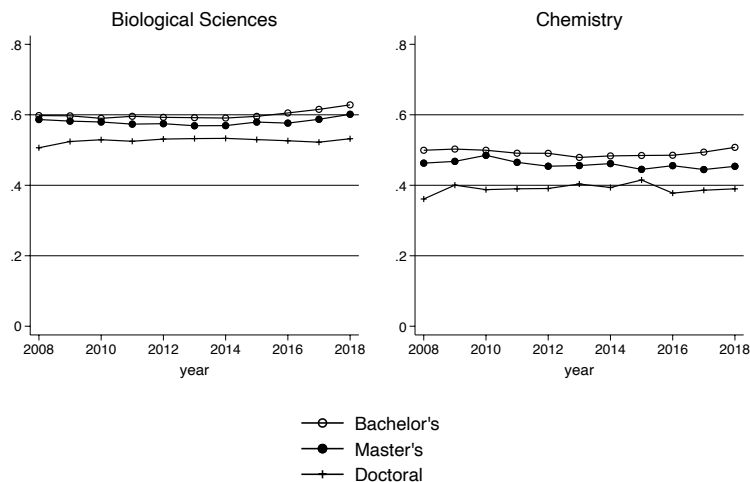
universities have been awarded a majority of the degrees in biological sciences at all degree levels—bachelor’s, master’s, and doctorate.⁴⁶ Likewise, women have received a majority of bachelor’s degrees in chemistry. Though men still receive a majority of graduate degrees in chemistry, the numbers are close. That is to say, women are arguably *overrepresented* in the fields of study that are most associated with pharmaceutical drug patents.

Specifically, 49,262 (60%) and 78,568 (63%) of biological sciences bachelor’s degrees were awarded to women in 2008 and 2018, respectively. Similarly, 5,611 (59%) and 10,358 (60%) of master’s degrees in biological sciences were awarded to women in 2008 and 2018, respectively. Finally, 3,707 (51%) and 4,308 (53%) of doctorate degrees in biological sciences were awarded to women in 2008 and 2018, respectively.

Likewise, 5,909 (50.0%) and 7,588 (50.8%) of chemistry bachelor’s degrees were awarded to women in 2008 and 2018, respectively. Though men still received a majority of graduate degrees in chemistry, the proportions are relatively close: 1,116 (45.4%) and 1,035 (46.3%) of master’s degrees in chemistry were awarded to women in 2008 and 2018, respectively. And 901 (36.1%) and 1,193 (39.0%) of doctorate degrees in chemistry were awarded to women in 2008 and 2018, respectively.

46. 2019 NSF study, *supra* note 28.

Figure 1: Percentage of Women with Degrees in Biological Sciences or Chemistry



2. Law Schools

Over half of law students in the United States today are women;⁴⁷ that number has been over 40% since the 1980s and has increased in the decades since to gender parity.⁴⁸ However, given the topic of this Article, one might wonder the extent to which women with *science degrees* are attending law school. To address this question, we collected data from the Law School Admissions Counsel (LSAC), which is the organization through which most candidates apply to law school.⁴⁹

LSAC's data on undergraduate majors is self-reported and is sorted by year. Dual degrees are counted as two separate degrees.

47. See Elizabeth Olson, *Women Make Up Majority of U.S. Law Students for First Time*, N.Y. TIMES (Dec. 16, 2016), <https://www.nytimes.com/2016/12/16/business/dealbook/women-majority-of-us-law-students-first-time.html>.

48. Janet Taber et al., *Gender, Legal Education, and the Legal Profession: An Empirical Study of Stanford Law Students and Graduates*, 40 STAN. L. REV. 1209, 1209 (1988) (providing general statistics on gender representation in law schools and the legal profession); see also LSAC, *Current Volume Summaries by Region, Race/Ethnicity, Gender Identity & LSAT Score*, <https://www.lsac.org/data-research/data/current-volume-summaries-region-raceethnicity-gender-identity-lsat-score> (LSAC 2008 application data showing applicant ratios of 40,486 (49%) women and 41,687 (51%) men; LSAC 2018 application data showing applicant ratios of 32,488 (54%) women and 27,508 (46%) men).

49. LSAC kindly provided us with applicant and matriculant undergraduate major data.

Applicants who apply in multiple years are included in all years (these duplicates are not removed). Most relevant for our purpose, LSAC aggregates majors into “health professions” and “natural sciences” categories. From 2001–2020 there were a total of 4,703 (63.0%) women and 2,728 (36.6%) men in the health professions and 19,741 (46.4%) women and 22,629 (53.2%) men with degrees in natural sciences who matriculated to law schools.⁵⁰ The proportions of applicants with health professions and natural science degrees were largely the same.⁵¹

Overall, only a small minority of law students have backgrounds in the sciences. For example, in 2020, approximately 3,689 students with natural science majors⁵² applied to law school—less than 5% of the total applicant pool. Although the undergraduate GPAs for natural science majors are about equivalent to other majors, the LSAT scores for natural science majors are significantly higher than other majors.⁵³

Figure 2 shows the percentage of women who attended law schools from 2001–2020 with undergraduate degrees in either health or natural sciences.⁵⁴

50. Numbers do not add up to 100% because some applicants do not indicate their sex as part of the LSAC application.

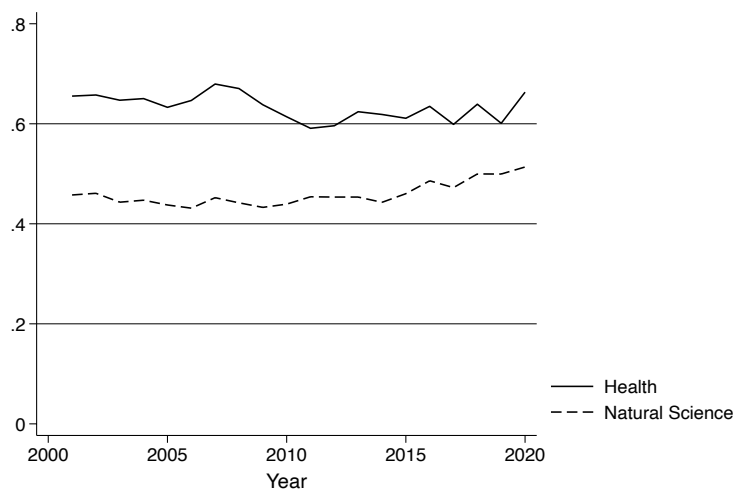
51. From 2001–20 there were 10,414 (63.7%) women and 5,862 (35.8%) men with health professions degrees. Additionally, from 2001–20 there were 39,918 (45.7%) women and 37,665 (53.9%) men with natural science degrees who applied to law schools.

52. Natural sciences include majors such as: biology, chemistry, biochemistry zoology, and biophysics among others—all of which would make a student eligible for admission to the patent bar. *See infra* Section II.A.

53. The mean and median GPA scores for natural science majors are 3.29 and 3.34, respectively. The mean and median GPA scores for all majors are 3.31 and 3.38, respectively. The mean and median LSAT scores for natural science majors are 157.99 and 158.40, respectively. The mean and median LSAT scores for all majors are 154.62 and 154.67, respectively.

54. Health professions include majors such as: health (kinesiology), health care administration, nursing, premedical (medicine), dietetics/nutritional science, speech pathology/audiology, pharmacy, radiology, animal sciences, physical therapy, dentistry, and occupational therapy. Although most health professions majors are not classified under Category A for patent bar eligibility, most health professions majors would likely qualify under Category B. *See infra* Section II.A.

Figure 2: Percentage of Women Law Students with Degrees in Natural Sciences or Health



Despite few law students with scientific backgrounds, the data above makes plain that women are very close to equally represented among law students who have majors associated with pharmaceutical patent practice. Accordingly, we would expect to see women represented at parity or even slightly higher than men in an area of law practice, like patent law, associated with those very degrees. However, as our empirical study shows, this is not the case.

C. Women in the Legal Job Market

Today, women and men enter the legal profession in equal numbers and initially make roughly the same amount, billing the same number of hours, at approximately the same billing rates.⁵⁵ However, a gap develops as women move from associates to non-equity and equity partners. Although women bill the same number

55. DESTINY PEERY, NATIONAL ASSOCIATION OF WOMEN LAWYERS 2019 SURVEY REPORT ON THE PROMOTION AND RETENTION OF WOMEN IN LAW FIRMS (2019) [hereinafter 2019 NAWL STUDY].

of hours, they are paid less, and their billing rates are significantly lower than similarly situated male partners.

Women are also largely absent in the upper echelon of law firm leadership. Specifically, according to a 2019 survey conducted by the National Association of Women Lawyers (NAWL), 47% of associates are women, but only 30% of non-equity partners and only about 20% of equity partners are women.⁵⁶ The gap increases when looking at women of color. Specifically, less than 4% of partners are women of color, even though they comprise 15% of all associates.⁵⁷

Similar to the overall wage gap, the NAWL survey found that the average male law firm associate makes \$12,272 more than the average female associate.⁵⁸ At the associate level, women make 94% of their male counterparts.⁵⁹ Compensation, however, greatly diverges at the partner level. The average non-equity female partner makes only 89% as much as a non-equity male partner (non-equity male partners make \$40,566 more per year than female non-equity partners).⁶⁰ At the equity level, male partners make, on average, \$109,491 more than female partners.⁶¹ Female equity partners make only 88% as much as the average male equity partner.⁶²

Interestingly, at least according to the NAWL survey, there is no substantial difference in the billable hours recorded by men and women “at different levels and in different roles.”⁶³ Furthermore, the survey indicates that associate billing rates start out relatively

56. Elaine Spector & LaTia Brand, *Diversity in Patent Law: A Data Analysis of Diversity in the Patent Practice by Technology Background and Region*, 13 *LANDSLIDE*, Sept.–Oct. 2020, at 1, https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2020-21/september-october/diversity-patent-law-data-analysis-diversity-patent-practice-technology-background-region.

57. DESTINY PEERY, PAULETTE BROWN & EILEEN LETTIS, *LEFT OUT AND LEFT BEHIND: THE HURDLES, HASSLES, AND HEARTACHES OF ACHIEVING LONG-TERM LEGAL CAREERS FOR WOMEN OF COLOR* at v (2018).

58. 2019 NAWL STUDY, *supra* note 55, at 4.

59. *Id.* (showing that the mean male associate makes \$204,082 versus the mean female associate, who makes \$191,810).

60. *Id.* at 5.

61. *Id.* at 6.

62. *Id.*

63. *Id.* at 4.

similar but diverge when they reach the partner level.⁶⁴ Male non-equity partners bill at an hourly rate about 5.5% higher than female non-equity partners.⁶⁵

Overall, these studies show that women enter private law practice in numbers roughly equal to men. However, women are not promoted or paid at a rate equal to men, and the wage disparities grow as associates move up the ladder to partner. We show next how these inequalities are replicated in the field of pharmaceutical patent law.

II. PATENT PROSECUTION AND LITIGATION

Patent prosecution and patent litigation are specialized fields of law practice. In this Part of the Article, we describe the educational and licensing requirements required to practice at the USPTO and to litigate patent cases in federal court. We also describe the existing literature on the demographics of patent lawyers and summarize the basic processes of pharmaceutical patent prosecution and litigation.

A. Requirements for Patent Prosecutors and Patent Litigators

Patent prosecution is the process by which a patent agent or patent attorney helps an inventor get a patent by “prosecuting” the patent application at the USPTO. Passing the patent bar is required to prosecute patents, and there are educational requirements to sit for the patent bar exam.⁶⁶ One need not be a lawyer to take the patent bar; a non-lawyer who passes the patent bar is admitted as a patent agent.

To qualify to take the patent bar, a candidate needs to show “the required scientific and technical training.”⁶⁷ The most common way of meeting the requisite scientific and technical qualification is to be classified as satisfying the requirements for “Category A” by the USPTO. Category A can be met by having a bachelor’s, master’s, or

64. *Id.* (showing that at the associate level men bill at an average of \$441 per hour while women bill \$425 per hour).

65. *Id.* at 5.

66. See U.S. PAT. & TRADEMARK OFF., GENERAL REQUIREMENTS BULLETIN FOR ADMISSION TO THE EXAMINATION FOR REGISTRATION TO PRACTICE IN PATENT CASES BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE 3–8 (2021). Under certain circumstances, former patent examiners can waive the examination requirement.

67. *Id.* at 3.

doctoral degree in a recognized technical subject from an accredited U.S. college or university or an equivalent bachelor's degree from a foreign university.⁶⁸ Category A fields of study include biology, computer science, chemistry, physics, and engineering. However, not all fields are created equal.⁶⁹ For example, not all computer software degrees qualify as Category A; some computer software degrees require additional accreditation.⁷⁰

The patent bar exam tests an applicant's knowledge of patent laws, rules, and procedures as set out in the *Manual of Patent Examination Procedure*. Only upon passing the examination does the applicant receive a USPTO registration number, which allows the patent practitioner to represent others before the USPTO in patent matters.

During the patent application process, on the other side of the negotiating table from the prosecutor are patent examiners. Patent examiners represent the USPTO and review the patent application to make sure that all requirements for patentability are met. In general, a patent must recite eligible subject matter,⁷¹ be novel⁷² and nonobvious,⁷³ and describe the invention in an appropriate level of detail.⁷⁴ Patent examiners and patent agents or attorneys work together to help inventors obtain a patent. The requirements to be a patent examiner are a minimum of a bachelor's degree in engineering or science and to be a U.S. citizen.⁷⁵ Patent examiners do not need to pass the patent bar, but they undergo a four-month

68. *See id.*

69. *Id.*

70. *See id.* The USPTO states that "acceptable Computer Science degrees must be accredited by the Computer Science Accreditation Commission (CSAC) of the Computing Science Accreditation Board (CSAB), or by the Computing Accreditation Commission (CAC) of the Accreditation Board for Engineering and Technology (ABET), on or before the date the degree was awarded."

71. 35 U.S.C. § 101.

72. *Id.* § 102.

73. *Id.* § 103.

74. *Id.* § 112. For more on the requirements of patentability, see S. Sean Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, 38 CARDOZO ARTS & ENT. L.J. 391 (2020) and S. Sean Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, 2021 MICH. ST. L. REV. 411 (2021).

75. U.S. PAT. & TRADEMARK OFF., AMERICA'S INNOVATION AGENCY (2021), <https://www.uspto.gov/sites/default/files/documents/USPTOPatentExaminerInfographicAPPLYNOW1.pdf>.

residency at the Patent Training Academy before joining their permanent division.⁷⁶

In contrast to patent prosecution, patent litigation is the process by which an attorney either sues someone for patent infringement or defends a client from a patent infringement suit. Patent litigators can represent clients in various legal matters and thus must have a law degree. They must also be licensed to practice within the federal courts in the relevant state.⁷⁷ Most states require a juris doctor (J.D.) from a law school accredited by the American Bar Association before being able to sit for the state bar, which is usually a requirement to practice within the federal courts of that state. While it is certainly advantageous for patent litigators to have a scientific degree or a technical background, it is not required or necessary. Indeed, many partners in law firms litigating patent cases do not have a science background.⁷⁸

B. Women in Patent Prosecution

Women are poorly represented among patent prosecutors. One study reviewed 47,228 registered patent practitioners and found that women made up only 21.8% of prosecutors.⁷⁹ Of those women, 75.6% were registered patent attorneys and 24.4% were patent agents.⁸⁰ In contrast, 85.7% and 14.3% of the male patent practitioners

76. *Work-Based Learning for World-Class Patent Examiners*, U.S. DEP'T OF COM., <https://www.commerce.gov/americanworker/work-based-learning-world-class-patent-examiners> (last visited Jan. 1, 2022).

77. The federal courts have exclusive jurisdiction over cases “arising under” federal patent law. See 28 U.S.C. § 1338(a). For a more detailed discussion of what, precisely, it means for a case to arise under patent law, see Paul R. Gugliuzza, *Rising Confusion About “Arising Under” Jurisdiction in Patent Cases*, 69 EMORY L.J. 459, 477–99 (2019).

78. Legal commentators have observed that the notion that careers in patent law are only for those with backgrounds in the hard sciences is increasingly wrong. See generally Lee Petherbridge & David L. Schwartz, *The End of an Epithet? An Exploration of the Use of Legal Scholarship in Intellectual Property Decisions*, 50 HOUS. L. REV. 523, 552–53 (2012) (“Those who teach patent law are aware that to this day there exist the remnants of a culture that preferred attorneys with technical backgrounds to other attorneys Today that view seems archaic”). Indeed, as one of us has shown in prior work, patent cases today are often handled by the most prominent generalist litigators in the country, including well-known appellate advocates such as Paul Clement, Carter Phillips, and Seth Waxman. Paul R. Gugliuzza, *The Supreme Court Bar at the Bar of Patents*, 95 NOTRE DAME L. REV. 1233 (2020); Paul R. Gugliuzza, *Elite Patent Law*, 104 IOWA L. REV. 2481 (2019).

79. Spector & Brand, *supra* note 56, at 2 fig. 4.

80. *Id.*

were registered attorneys and agents, respectively.⁸¹ Though the gender gap among practitioners at the USPTO remains wide, it is closing. In 1950, there were almost no female patent agents or attorneys, but that number has gradually increased, with the biggest gains made in 1997 and 2011.⁸²

Similar to what we see outside of law practice, although women are generally poorly represented in most technological fields, women are better represented in biotechnology and chemistry patent prosecution.⁸³ Specifically, women patent practitioners represent 41.4% and 31.7% of the inventors seeking patents in the biotechnology and chemical fields, respectively.⁸⁴ These numbers are in stark comparison to the lack of women representing inventors seeking patents in computer science (14.8%), electrical (11.4%), and mechanical (11.1%) fields.⁸⁵

C. Women in Patent Litigation

Little empirical work has been done on the presence or absence of women in patent litigation. The work that has been done suggests that women are largely absent, at least when it comes to work in the private sector. In a prior study, one of us (Gugliuzza) showed that women argue far fewer patent cases at the U.S. Court of Appeals for the Federal Circuit (which has exclusive jurisdiction over all patent appeals nationwide)⁸⁶ than their male counterparts, with women arguing only 12.6% of cases from 2010 through 2019.⁸⁷ Women were better represented in pharmaceutical patent litigation at the Federal Circuit compared to other technology areas, presenting 16.4% of arguments in those cases as compared to only 12.0% in non-pharmaceutical cases.⁸⁸

Interestingly, gender inequality largely disappeared when the analysis was limited to attorneys litigating patent cases on behalf of

81. *Id.*

82. *Id.* at 3 fig. 5.

83. *Id.* at 4 fig. 9.

84. *Id.*

85. *Id.*

86. 28 U.S.C. § 1295(a)(1). For more on the Federal Circuit's jurisdiction, see Paul R. Gugliuzza, *Rethinking Federal Circuit Jurisdiction*, 100 GEO. L.J. 1437, 1458–61 (2012).

87. Gugliuzza & Rebouché, *supra* note 15, at 1709 fig. 9.

88. *Id.* at 1726–27 figs. 20–21.

the federal government.⁸⁹ From 2010 through 2019, the USPTO Office of the Solicitor was represented by women in about half of the cases in which it presented oral argument at the Federal Circuit.⁹⁰ (The Office of the Solicitor serves as the USPTO's legal counsel on matters of intellectual property law.⁹¹ For the purpose of this Article, the Solicitor's Office's most significant responsibility is defending the USPTO's decisions in patent examination or in post-issuance review of patent validity when those decisions are challenged in court.)⁹²

Additionally, women make up almost a third of judges at the PTAB—an important administrative tribunal within the USPTO.⁹³ Moreover, five of the Federal Circuit's twelve active judges are women,⁹⁴ and, among the court's recent appointees, the women tend to have more pre-appointment experience in patent law than their male counterparts.

D. Requirements for Abbreviated New Drug Application (ANDA) Litigation

Before discussing our empirical study of gender inequality in pharmaceutical patent practice, some background on the unique aspects of pharmaceutical patent litigation will be useful.

Branded pharmaceutical companies list patents covering their products in the Food and Drug Administration's (FDA's) "Orange Book."⁹⁵ A generic company that wishes to sell a product covered

89. *Id.* at 1713 fig. 13.

90. *Id.* at 1718–1719 figs. 18–19 (also showing that in 2013, 2014, and 2018 women represented the majority of Federal Circuit oral arguments by the USPTO Solicitor's Office).

91. See *Office of the General Counsel*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/about-us/organizational-offices/office-general-counsel> (last visited Sept. 2, 2022).

92. See *Office of the Solicitor*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/about-us/organizational-offices/office-general-counsel/office-solicitor> (last visited Sept. 2, 2022).

93. Amy Semet, *A Data-Driven Analysis of the Patent Trial and Appeal Board's First Decade* (unpublished manuscript) (on file with authors). The PTAB hears appeals from rejections of patent applications and also conducts the new post-issuance proceedings created by the America Invents Act, which began operation in 2012. See *supra* note 39.

94. Gugliuzza & Rebouché, *supra* note 15, at 1707 fig. 7.

95. The "Orange Book" (formally, the *Approved Drug Products with Therapeutic Equivalence Evaluations*) is a list of drugs and pharmaceuticals that the FDA has approved as both safe and effective. The Orange Book also includes the patent numbers associated with each product and the calculated expiration dates of those patents. See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm> (last visited Sept. 24, 2022).

by a patent listed in the Orange Book has numerous options. Most pertinent to this article, the relevant statutes provide incentives for generic companies to challenge patents through what is called a “paragraph IV” certification, under which the generic firm argues that the branded firm’s Orange Book patents are either invalid or not infringed by the generic product.⁹⁶ In response to the paragraph IV certification, the branded company may sue the generic company for infringement.⁹⁷

ANDA litigation—so named for the “abbreviated” new drug application a generic company files with the FDA—is one of the most complex types of litigation because it combines drug regulatory practice with patent law, biology, and chemistry. Many practitioners in this area have both a science degree and a law degree. Additionally, many practitioners have a deep knowledge of FDA law and procedure. However, the only formal requirement to litigate in this area is the ability to practice in front of a federal court, which usually requires only a law degree and admission to a state bar.⁹⁸

III. DATASETS AND METHODOLOGY

To examine gender representation in the important and high-stakes area of pharmaceutical patent law practice, we built three original datasets. The datasets contain demographic information about (1) all patent *examiners* working at the USPTO who examined all ANDA patents since 2005, (2) all lawyers who *prosecuted* ANDA patents that were litigated to a final judgment on validity by lawyers from a group of top law firms from 2009 through 2021, and (3) all lawyers who *litigated* those same patents.

We built the first dataset using information obtained from a Freedom of Information Act (FOIA) request filed with the USPTO. To construct the second and third datasets, we compiled a list of both litigated cases as well as litigated patents from 2009 through 2021. We examined all ANDA cases that were terminated from

96. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). For a more complete description of the ANDA litigation process, see Kenneth LAURENCE DORSNEY, *ANDA LITIGATION: STRATEGIES AND TACTICS FOR PHARMACEUTICAL PATENT LITIGATORS* (3d ed. 2020); S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 97 WASH. L. REV. (forthcoming 2022).

97. 35 U.S.C. § 271(e).

98. See *supra* Section II.A.

January 1, 2009 through December 31, 2021.⁹⁹ To focus more closely on cases that were *actually litigated*, we included in our analysis only those cases that concluded with a final judgment based on the validity provisions of the Patent Act: 35 U.S.C. §§ 101 (subject matter or utility), 102 (novelty), 103 (nonobviousness), and 112 (written description, enablement, definiteness, and, prior to the adoption of the American Invents Act, best mode).¹⁰⁰ Our dataset included 243 federal district court cases concerning a total of 379 patents. We further restricted the dataset to only those cases involving the most active brand and generic lawyers, reducing the number of cases to 169.¹⁰¹ Sixty of those cases (and 143 patents) contained a finding of invalidity and 109 cases (and 236 patents) contained a finding of no invalidity.

One limitation of our prosecutor and litigator datasets is that they include only patents that were litigated to a final judgment by lawyers from the most active law firms in the field. We chose to focus on those patents because they represent some of the most important patents for brand pharmaceutical firms—they are the patents generic companies are willing to spend the full cost of litigation on in an effort to invalidate. The patents litigated to a final judgment are also contained within the cases that required the most work by litigators because many of them went to trial.

99. During this time frame, there were 4,162 ANDA cases terminated. Most of those cases (over half) were terminated due to express settlements between the parties, and another 1,127 cases were terminated due to consent judgments, which are akin to settlements.

100. Out of the over 4,000 cases that were terminated from 2009 through 2021, 335 cases ended in a judgment of some sort on either validity, infringement, or another issue. Out of those 335 cases, in 243 cases, courts decided the validity of the patent. While a patent is presumed valid, a court can find a patent invalid if a party proves by clear and convincing evidence that one of the statutory sections of the Patent Act is not satisfied, as, for example, if there was prior art that rendered the invention anticipated or obvious, if the subject matter of the patent was not something that can be patented to begin with, or if certain requirements regarding the write-up of the patent are not met. See generally Paul R. Gugliuzza, *Patent Law's Deference Paradox*, 106 MINN. L. REV. 1397, 1406–08 (2022), for more discussion of patent law's validity requirements. We used the database service LexMachina to compile our list of cases. Cases coded by LexMachina as "ANDA" cases are included in the dataset. It is possible that there may be some additional ANDA cases that were not coded by LexMachina as ANDA cases. Also, by "final judgment," we include cases coded by LexMachina as being resolved in favor of the patentee or accused infringer on a motion for judgment on the pleadings, a summary judgment motion, at a jury or bench trial, or through judgment as a matter of law. At least half of the cases coded as being resolved in the patentee's or claimant's favor were done so on consent judgments. These are not included in the analysis because they are akin to settlements in most cases. See *supra* note 99.

101. See *infra* note 124 for a discussion of the law firms we included in our analysis.

Because those litigated patents are important and sufficiently valuable that both brand and generic companies would pay to litigate them to judgment, it is crucial to understand who is *prosecuting* those patents on the applicant side and who is reviewing those patents on the examiner side.

A. Patent Examination

As explained above, there are two sides during patent prosecution: (1) the USPTO patent examiner, who represents the public interest, and (2) the inventor, represented by a patent attorney or agent. We assembled a list of all patent examiners in the biotechnology sciences and organic chemistry to assess the representation of women as patent examiners. We then compiled a separate list of the patent lawyers at top law firms who worked as representatives of the inventors during the prosecution of patents that were eventually litigated to a final decision on validity.

After determining the names of examiners, we coded them for gender using the Social Security Administration's list of top female and male names for the years 1901–2000.¹⁰² Names on this list are considered common and gender identifying, which accords with methodologies previously used in the literature.¹⁰³ For uncommon or ambiguous names, we reviewed information such as law firm websites and LinkedIn on each individual person to see how that person identified their gender.¹⁰⁴

As detailed in section III.A.1 below, in analyzing examiners, we looked at all examiners who issued an ANDA-based patent from 2005 through 2021, regardless of whether or not that patent was later involved in litigation. As for the lawyers who represented inventors during the prosecution process, we limited the analysis to only those patents that were later resolved on

102. See Joshua Comenetz, *Frequently Occurring Surnames in the 2010 Census*, U.S. CENSUS BUREAU (Oct. 2016), <https://www2.census.gov/topics/genealogy/2010surnames/surnames.pdf>. A similar process was used to account for gender for patent prosecutors and litigators.

103. See, e.g., W. Michael Schuster, R. Evan Davis, Kourtenay Schley & Julie Ravenscraft, *An Empirical Study of Patent Grant Rates as a Function of Race and Gender*, 57 AM. BUS. L.J. 1 (2020).

104. We note that the male/female binary approach we have taken in this study does not account for the myriad ways in which gender identity manifests. Though we are sensitive to this issue, it bears emphasizing that this study often determined gender identity by consulting biographical materials prepared by the practitioners themselves.

validity grounds in federal court patent proceedings by lawyers from top law firms.¹⁰⁵

1. *Pharmaceutical Patent Examiners*

To assess gender representation on the USPTO side of pharmaceutical patent prosecution, we obtained the names and highest education levels for every patent examiner from 2005 to 2021 who worked in Technology Center 1600 from our FOIA request. Technology Center 1600¹⁰⁶ represents inventions that cover “Biotechnology and Organic Chemistry,” and almost all Orange Book patents come from it.¹⁰⁷ Unlike our prosecutor and litigation datasets, which focused on patents that were eventually litigated by lawyers from the most active firms in the field, this dataset is broader and reflects all examiners who issued pharmaceutical patents, even if they were never litigated in court.

105. Most challenges of patents are brought in the federal district courts. Patents can also be challenged through an administrative process. As discussed *supra* note 39, any third party can contest the validity of a patent through a proceeding at the PTAB. Challenges at the PTAB are more limited than at the district court. For instance, *inter partes* review—the most popular new proceeding—can only consider questions of novelty under § 102 and nonobviousness under § 103 and can be based only on prior art references that are “patents” or “printed publications.” 35 U.S.C. § 311(b). Patent validity can also be challenged through proceedings at the International Trade Commission (ITC) when a party seeks an exclusion order to prevent potentially infringing products from being imported into the United States. See 19 U.S.C. § 1337; see also Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529, 534 (2009) (providing an overview of patent proceedings at the ITC). Though those other proceedings are important, our study focuses exclusively on litigated patents that are challenged before the federal district courts because gender inequality at the PTAB is already well-documented, see *supra* note 93, and because the small number of patent proceedings filed at the ITC each year (between 50 and 100, give or take, see Section 337 Statistics: Number of New, Completed, and Active Investigations by Fiscal Year (Updated Quarterly), U.S. INT’L TRADE COMM’N (July 19, 2022), https://www.usitc.gov/intellectual_property/337_statistics_number_new_completed_and_active.htm) pales in comparison to the roughly 4,000 patent cases filed in the district courts each year. DOCKET NAVIGATOR, 2021 PATENT LITIGATION YEAR IN REVIEW 7 (2022), <https://brochure.docketnavigator.com/2021-year-in-review>.

106. The USPTO’s corps of roughly 8,000 examiners is divided into nine “technology centers,” which represent broad technology types, such as “biotechnology and organic chemistry” and “computer networking.” Those technology centers are further divided into “art units,” which represent narrower categories such as “immunology” and “cryptography and security.” See *Patent Technology Centers Management*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management>.

107. Tu & Lemley, *supra* note 96, at 1678.

This dataset includes 388 unique patent examiners.¹⁰⁸ We coded for gender (using the methodology described above), General Schedule (GS) level,¹⁰⁹ art unit (the specific type of art category within the USPTO technology center),¹¹⁰ hire date, separation date, and highest graduate degree. From the separation and hire date we were able to calculate the average patent examiner tenure.¹¹¹ For those examiners who are currently working at the USPTO, we used a separation date of December 31, 2021.¹¹² We obtained most of this information directly from the FOIA request; however, there was information missing for about 15% of the examiners, so we looked at LinkedIn, law firm websites, obituaries, and other online sources to obtain the relevant information.¹¹³ When we were unable to find the information online, we imputed the median value in our analysis.¹¹⁴

108. Many examiners work in several art units within the same technology center. Accordingly, we removed any duplicate examiners so that the dataset includes only “unique” examiners.

109. The General Schedule (GS) pay scale is the federal government pay scale used to determine the salaries of over 70% of federal civilian employees. *See General Schedule (GS) Payscale Table for 2021*, FEDERALPAY <https://www.federalpay.org/gs/2021> (last visited Sept. 24, 2022). Examiners typically start at GS-7, or -9 depending on education level and experience and can advance through GS-15. There are ten steps within each GS grade. For example, in 2021, GS-7 step 1 made an annual base salary of \$43,683 while a GS-15 step 10 made \$166,502. These salaries are also adjusted for localities and designed to reflect the varying cost-of-living across different areas of the country. *See id.*

110. *See supra* note 106.

111. A few examiners left the agency and then rejoined it years later so their cumulative tenure was calculated.

112. December 31, 2021 was chosen because that was the current date when coding the information.

113. In addition, in a few cases, some of the data given by the USPTO in the FOIA request was erroneous. For instance, an examiner might have a master’s, Ph.D., or law degree that was not listed. It is also possible that some of the examiners may have obtained a law degree or an advanced degree after departing the agency that was not accounted for in the data. However, any degree obtained *after* an examiner’s tenure at the USPTO ended would be irrelevant for the purpose of our study.

114. Failure to account for missing data could affect the analysis because it could be the case that the missingness is correlated to some variable of interest. It is common in statistics to impute the median value when there is missingness in the data. In this case, for the roughly 15% of examiners for which we were missing information even after a thorough online search, we assumed that they have an ANDA-based bachelor’s degree, and do not have a master’s, Ph.D., or law degree.

2. *Pharmaceutical Patent Prosecutors for ANDA Litigated Patents*

To assess who assisted inventors in prosecuting patents at the USPTO, we isolated every patent from our dataset that was litigated to a final judgment on validity by lawyers from select firms and determined the names and registration numbers for the “working” patent attorney or agent—that is, the prosecutor who signed the majority of the Office Action responses. We obtained these names from the patent prosecution history on the USPTO’s Patent Application Information Retrieval (PAIR) system.¹¹⁵ We reviewed each Office Action¹¹⁶ and recorded the working attorney or agent who signed off on each Office Action response.

This dataset includes the 217 patent prosecutors who helped inventors obtain every Orange Book patent that underwent litigation in the district courts to a final validity decision from January 2009 through December 2021 by lawyers from select firms.¹¹⁷ Many patent prosecutors were involved in multiple cases.¹¹⁸ We coded for educational background (bachelor’s, master’s, doctorate, and law

115. See *Check the Filing Status of Your Patent Application*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/apply/checking-application-status/check-filing-status-your-patent-application> (last visited Sept. 24, 2022).

116. An Office Action is written correspondence from the patent examiner to the applicant stating grounds for rejecting the application. An Office Action requires a response from the applicant to each ground of objection for prosecution of the application to continue. *Responding to Office Actions*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/maintain/responding-office-actions> (last visited Sept. 24, 2022).

117. For a small number of prosecutors, where the Office Actions were unavailable, we looked to the Attorney tab on PAIR, and if one clear attorney was listed, we included that person. In most cases, we were not able to find any information about that person online, so we could only ascribe a gender to them based on their name. We were not able to get additional demographic information on fifty-three of the prosecutors, or about 25% of the prosecutors involved in the litigated patents in our dataset. Of those fifty-three, we were not able to get any information at all on thirty-one prosecutors (not even name or gender). This is a significant limitation of our dataset, since it could be that the demographic profile of prosecutors involved in litigation in the early years of the study particularly involving patents issued before 2000 (whose file histories tend to be inaccessible online) may differ systematically from patents issued in recent years. To the extent any data was missing, we imputed the median value, which would be a male prosecutor, who attended law school, and who majored in an ANDA-related science without an advanced scientific degree. Given the time frame of the patents with unavailable prosecution histories, it is likely that most prosecutors were male, so we doubt the missing information affects our results much.

118. While the median prosecutor was involved in two cases, 25% of prosecutors were involved in prosecuting at least three litigated patents. The highest number of prosecuted patents for a given prosecutor in the database was ten.

degree),¹¹⁹ USPTO registration number, registration status (patent agent or patent attorney), and date of registration as a patent attorney and/or patent agent.¹²⁰ We also determined if the prosecutor was a registered patent agent or a registered patent attorney (i.e., if they had a law degree).

B. Patent Litigation

There are thousands of litigators involved in ANDA litigation, and many cases involve multiple firms representing different parties. For example, it is not uncommon for both the brand name pharmaceutical company and its licensee, if it has one, to be separately represented. Moreover, multiple generic drug companies may be attacking the validity of a single patent, with each having its own lawyers and law firms. As such, to analyze the demographic characteristics of *all* litigators involved in *all* ANDA cases would be a monumental task. To make our dataset more manageable, we limited our study to litigation involving only the most active firms that litigated ANDA cases to a final judgment on validity between January 1, 2009, and December 31, 2021.

In recent years, many law firms have formed practice groups focusing on life sciences, ANDA litigation, and Federal Circuit appellate litigation.¹²¹ This is especially true since most ANDA litigation is geographically centralized in New Jersey and Delaware.¹²² Moreover, the highest ranks of patent litigation is an exclusive club: previous studies have shown that only a handful of lawyers have presented a large proportion of Federal Circuit patent arguments over the past decade.¹²³ Accordingly, because much of this type of litigation relies on repeat players, we chose to focus on lawyers from the most active firms instead of doing a random sample of all litigators. We defined active as the top five firms

119. As with information concerning examiners, educational and professional information was recorded from various websites such as LinkedIn or more commonly a law firm website with biographical information.

120. Registration information was obtained directly from the Office Action response. Registration status and current city and state were obtained from the USPTO's Office of Enrollment and Discipline's "find a patent practitioner" website. *Find a Patent Practitioner*, U.S. PAT. & TRADEMARK OFF., <https://oedci.uspto.gov/OEDCI/practitionerSearchEntry> (last visited Sept. 24, 2022).

121. Paul R. Gugliuzza, *Pluralism on Appeal*, 100 GEO. L.J. ONLINE 36, 42 (2012).

122. Tu & Lemley, *supra* note 96, at 1690.

123. Gugliuzza & Rebouché, *supra* note 15, at 1721–22.

representing brand pharmaceutical companies and the top five firms representing generic pharmaceutical companies, based on number of ANDA cases litigated to a final judgment on validity during the time period in question.¹²⁴ We then determined the names of the lawyers from each of the indicated firms.¹²⁵ This dataset includes 333 total litigators involved in 169 cases. Many of these litigators are repeat players. The median litigator was involved in five cases, with one litigator being involved in over sixty cases.¹²⁶

We then gathered additional information for each litigator, including: (1) PTO registration number (if any), (2) gender, (3) undergraduate major,¹²⁷ (4) master's degree, (5) Ph.D., and (6) law school attended. The data was also segmented by whether the

124. The top five plaintiff's firms representing brand pharmaceutical companies in resolving disputes on the merits during the indicated time frame were: (1) Morris, Nichols, Arsht & Tunnell; (2) Venable; (3) McCarter & English; (4) Finnegan, Henderson, Farabow, Garrett & Dunner; and (5) Covington & Burling. The top five defense firms representing generic pharmaceutical companies were: (1) Phillips, Goldman, McLaughlin & Hall; (2) Winston & Strawn; (3) Young, Conaway, Stargatt & Taylor; (4) Richards, Layton & Finger; and (5) Potter Anderson & Corroon.

125. To ensure that we did not include lawyers who were not active litigators, in order to be included a lawyer must have litigated at least ten cases as of the termination date of the case in question. As with the examination and prosecution data, if any data was missing, we imputed the median value.

126. Each case can involve multiple patents that are resolved in different ways. In patent litigation, parties challenge certain claims for validity, and the court may make its determination about claims at different times. For example, the court could find on summary judgment that some claims are not invalid, then later find at a bench trial that different claims on that same patent are invalid. As such, each litigated case can have multiple outcomes if it involves multiple patents. To simplify things for our empirical analysis, we came up with a single measure of validity for each case. Many cases have a clear outcome with the court holding all patents invalid or all not invalid. Where there was a split outcome and the case involved multiple patents, we assigned the invalidity score to be based on the outcome for the majority of the patents. If only one patent was involved, and there was a split verdict among the claims, we assigned the case as invalid. Our analysis only considers the litigated judgment, so if there were settlements or consent judgments among disputed patents, they were not considered in the analysis to assign a validity value.

127. We were interested in whether the person had majored in an ANDA subject matter. Thus, we also coded for "ANDA major" defined as a major in: Biology, Biochemistry, Bioengineering, Bio-environmental Engineering, Biomedical Engineering, Biomedical Science, Chemistry, Chemical Engineering, Polymer Science, Genetics, Immunology, Molecular Biochemistry, Molecular Biology, Molecular Genetics, Microbiology, Neuroscience, Toxicology, Pharmacy, and Veterinary Medicine. We were not able to obtain undergraduate science major for many of the litigators as law firm websites and the like only stated that the person had a bachelor of science degree. To the extent such information was not available, we assumed that the person did not have an ANDA-related degree.

lawyer represented the brand or generic pharmaceutical company and if the patents were ultimately found invalid or not invalid.¹²⁸

C. Limitations

To be clear, our analysis does not cover a representative sample of all ANDA prosecutors nor even all ANDA prosecutors who have their patents later litigated in court. It is also not representative of all ANDA litigators. Rather, our analysis is narrowly tailored only to prosecutors who later have their patents litigated to a final validity conclusion by a lawyer from one of the most active law firms in ANDA litigation. There are roughly 4,000 patent infringement suits filed in the United States every year involving tens of thousands of patents.¹²⁹ It would be a monumental undertaking to analyze the demographic profile of every prosecutor or litigator of every patent asserted in ANDA litigation. Our analysis thus focuses solely on patents litigated by the law firms that appear most frequently in the district courts and on the patents that reach a final judicial decision on validity. We think this is a critical subset of cases and lawyers because they represent the most hotly contested and highest-stakes pharmaceutical patent disputes and thus provide important insight into what the upper-echelon of pharmaceutical patent practice looks like.

It could be that these firms are not representative of law firms in general or patent firms in particular. Because the law firms in our dataset tend to be large, they may differ in their propensity to only have senior partners sign Office Action responses or appear on court filings. Junior lawyers may work on matters, yet not have their name attached, and as such they would not be included in our data. Still, the point of our study is to assess gender equality (or the lack thereof) at the *highest levels* of patent law practice, so, to the extent women are working on these matters but do not have their names associated with them, that would actually prove our point.

128. This dataset includes only ANDA litigated patents. Accordingly, plaintiffs' lawyers are defined as a brand pharmaceutical company who brought an ANDA infringement case against a generic drug company under 35 U.S.C. § 271(e)(2). Defense lawyers were defined as generic companies who most often bring paragraph IV challenges in an attempt to argue non-infringement or to invalidate the brand company's patents. See *supra* Section II.D.

129. See Gene Quinn, *Patent Litigation in the United States, 1980 to 2020*, IPWATCHDOG (Nov. 4, 2021), <https://www.ipwatchdog.com/2021/11/04/patent-litigation-in-the-united-states-1980-to-2020/id=139510>.

Our study does not nor was it designed to offer insights into disparities for *all* ANDA-related patent litigation. Although we would hypothesize that there is some disparity—and our data suggests that there is, in fact, substantial disparity—how wide or narrow that disparity is in other ANDA-related litigation is not something our study was designed to test.

Another limitation is that litigators at smaller law firms do not appear in our data. It could be that they differ from the big firms where gender inequality is long-standing and well-documented.¹³⁰ Also, since we determined the top firms based on whether their cases were litigated to a final judgment, our analysis necessarily would exclude firms where settlement is popular. It could be, for example, that a law firm that settles more often differs in its demographics. Again, however, cases that end in settlement are less relevant to our research interest into gender inequality at the *highest levels* of patent practice. Cases with high settlement rates—such as the low-value cases brought en masse by so-called patent trolls—are not considered the most elite field of patent law practice.¹³¹

Mindful of these limitations, we believe our datasets capture crucial insights about the demographics of pharmaceutical patent law practice. The patents covered by our dataset—which were ultimately litigated to a final judgment by the most active patent law firms in the country—are some of the most important patents to both brand and generic pharmaceutical firms, as evidenced by the fact that both sides were unwilling to settle and required a final court ruling. Additionally, the litigations captured in our dataset are among the most labor intensive and include many hours associated with discovery, motions, trial, and appeal. These litigations require litigators to engage in complex litigation strategy, motion practice, brief writing, and oral advocacy. Accordingly, the sample of litigations and patents covered by our dataset represent some of the most high-stakes cases and valuable intellectual property rights that exist. These are precisely the types

130. See *supra* Section I.C.

131. See David L. Schwartz, *The Rise of Contingent Fee Representation in Patent Litigation*, 64 ALA. L. REV. 335, 369–70 (2012) (“At the ‘bottom’ of the patent contingent market are very small patent contingent firms. . . . The patents are enforced against an entire industry, or alternatively against a slew of defendants in a single lawsuit. They litigate these cases very sparingly, attempting to avoid motion practice and substantial discovery.”).

of high-level matters on which we might be most concerned to find significant gender disparities.¹³²

1. Patent Prosecution

There are a few additional limitations specific to how we analyzed prosecutors. First, our dataset focused on patents that had a prosecution history that was available on public PAIR. Electronic copies of the patent prosecution histories are generally only available for patents with a filing date from 2000 to present. Accordingly, most patents that were filed before 2000 were not included in our dataset,¹³³ but we do not believe this limitation affects our results much.¹³⁴

A second limitation for patent prosecution coding, which we alluded to above, is that the person who signs off on the Office Action response may not always be the “working” attorney or agent. Specifically, junior associates may write the Office Action response, but the senior partner may review and sign the response. Unfortunately, our study cannot capture these events simply because if the “working” associate does not sign the response, there is no way of knowing who did the majority of the work. Accordingly, while there may be an undercount of female involvement in prosecution work, we assume that the most involved practitioner was the one who “signed” the Office Action response.¹³⁵

132. For analyses of gender inequality at the highest levels of corporate work more generally, see Naomi Cahn, June Carbone & Nancy Levit, *Discrimination by Design*, 51 ARIZ. ST. L.J. 1, 7 (2019); June Carbone, Naomi Cahn, & Nancy Levit, *Women, Rule-Breaking, and the Triple Bind*, 87 GEO. WASH. L. REV. 1105, 1109 (2019).

133. There may be other prosecutors for patents that were filed after 2000 that were not included because there was not a file history noted in PAIR. For any patents missing prosecutors, we also looked at the “Attorney Information” tab on PAIR to see if we could gain additional information about the fifty or so patents that were missing matching prosecutor information. In most cases, only a law firm or the pharmaceutical company’s in-house legal team was listed, thus preventing us from obtaining further information on which lawyer prosecuted the patent.

134. See *supra* note 117.

135. In ten cases, two lawyers were listed on the signature block of the Office Action response. To gauge which lawyer should be included in the database, we looked at which of the two (or in one case three) actually signed the Office Action, even if they signed for someone else. Where there was still a discrepancy, we reviewed multiple Office Actions if they were available to come up with the lawyer who seemed to be most involved during the prosecution of the patent.

2. Patent Litigation

Similar to the patent prosecution dataset, if a litigator does not enter an appearance or sign a legal brief, then they will not be captured by our dataset. Thus, if any litigator did work but was not recorded on any Public Access to Court Electronic Records (PACER) document, then they are unaccounted for in our dataset.¹³⁶ This could be a limitation since there may be a wide disparity among law firms in whether junior (and more female) attorneys are recorded in PACER as being a part of the case. But, again, if women are being undercounted in this fashion, that reinforces our point—women are disproportionately unrepresented at the highest levels of pharmaceutical patent litigation practice.

To be clear, we do not intend and cannot make conclusions about whether there is gender disparity among *all* patent litigators for *all* ANDA litigation pending before the federal courts. Many ANDA cases do not involve lawyers from one of the ten firms we studied.¹³⁷ Rather, our analysis focuses on the more targeted issue of whether there is gender disparity concerning the litigation of patent cases to a conclusion by lawyers coming from the busiest ANDA litigation law firms.

IV. RESULTS

To recap: our study focuses on gender inequality in the pharmaceutical patenting area. Our data is segmented into patent prosecution and patent litigation, with patent prosecution data further segmented into patent examiners and patent prosecutors. The patent examiner data includes all patent examiners from the USPTO's Technology Center 1600, the administrative unit within the USPTO from which most pharmaceutical patents issue.¹³⁸ The patent prosecutor and patent litigator data focus only on those patents that were litigated to a final judgment on validity by the

136. In addition, our analysis is necessarily limited by the information that LexMachina captures from PACER, so if there was an error here and there then the lawyer would not be accounted for.

137. All told, our database involving the ten most litigated brand and generic pharmaceutical companies accounts for about two-thirds (68%) of terminated ANDA cases during the time frame under study that was litigated to a final judgment involving validity. The remaining third of litigation do not involve the ten law firms involved in our study.

138. *See supra* note 106.

most active firms in the field. Finally, the patent litigators are subdivided into plaintiffs' lawyers (i.e., generally lawyers representing branded companies) and defendants' lawyers (i.e., generally lawyers representing generic companies). We also coded for whether the relevant patents were found invalid or not invalid.

A. Pharmaceutical Patent Prosecution

There are two sides to patent prosecution. First, there are patent agents and attorneys who help inventors obtain patents for their invention. Second, there are the patent examiners who represent the USPTO and ensure that applications meet the relevant patentability requirements. We examine gender representation on each side.

1. Pharmaceutical Patent Examiners

Figure 3 shows the gender makeup for the 388 pharmaceutical patent examiners in Technology Center 1600 at the USPTO employed from 2005 through 2021. As will become clear shortly, the gender makeup of the USPTO examiner corps is surprisingly balanced when compared to the prosecutors who practice before it.¹³⁹ Women represent 42.3% of the patent examiners in our dataset and men represent 57.7%.

139. See *infra* Section IV.A.2.

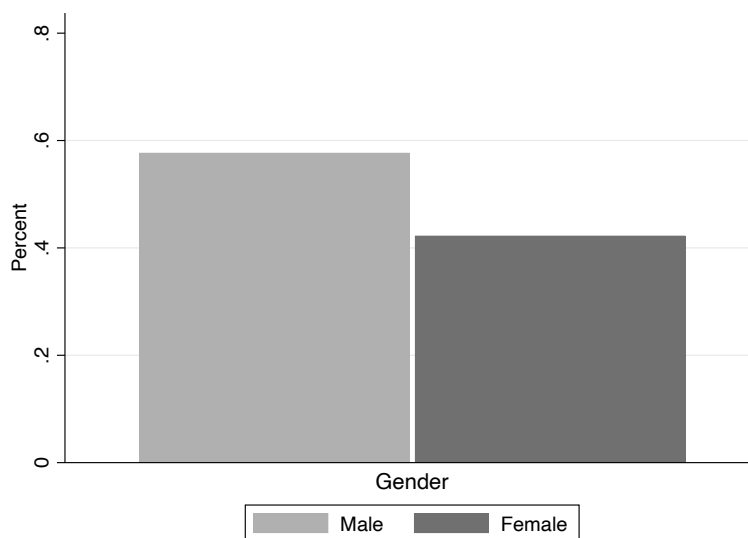
Figure 3: Patent Examiner Percentages, by Gender

Table 1 and *Figure 4* below show that the patent examiners in our dataset do not vary by gender in terms of educational backgrounds, average promotional level, and experience at the USPTO. Women are near equal to men in their proclivity to have an educational background in an ANDA field; 95.1% of women have ANDA backgrounds compared to 93.3% of men. There are also approximately the same number of women and men who have either a master's degree or a doctorate in an ANDA-related field.¹⁴⁰ Although slightly more men (76.9%) than women (73.2%) have an advanced science degree in an ANDA field, these differences are not statistically significant.¹⁴¹ There is also not a gender disparity with respect to whether patent examiners have a law degree, at

140. Data was gathered on the entire relevant population. To illuminate the data further, analysis was done using chi-squared tests, which measure the likelihood that the observed difference between the genders' frequencies is due simply to chance. The standard confidence level of 95% is used unless otherwise stated. In other words, if a result is significant at the $p=0.05$ level, there is a 5% chance of an incorrect inference.

141. By contrast, men have higher rates of obtaining a doctorate in an ANDA-related field, a difference that is statistically significant. This pattern is the same regardless of whether or not the advanced degree is in an ANDA-field. The majority of examiners with advanced degrees have an advanced science degree in an ANDA-related field. For many doctoral programs, if a student enters into the Ph.D. program but fails the qualification examination, he or she usually exits with a master's degree.

least measured as of the time they were working at the USPTO and thus accounted for in our data.¹⁴²

Not only are patent examiner educational levels approximately the same, but the tenure and pay grades are also very similar, regardless of gender. Although the difference in the doctorate rate between females and males is statistically significant, such disparity is less relevant for patent examiners because the tenure and pay grades are also very similar regardless of gender. *Table 1* shows that the highest promotional level, as measured by General Schedule (GS) level,¹⁴³ and the length of time on the job are approximately the same for both women and men. Indeed, women measure slightly higher on both metrics.

Table 1: Patent Examiner Education/Professional Background Percentages, by Gender

	ANDA	Master's	Ph.D.	Advanced	J.D.	Average GS ¹⁴⁴	Average Tenure (days)
Male	93.3	22.8	55.4***	76.9	10.3	11.9	2993
Female	95.1	28.7	44.5***	73.2	11.6	12.0	3183

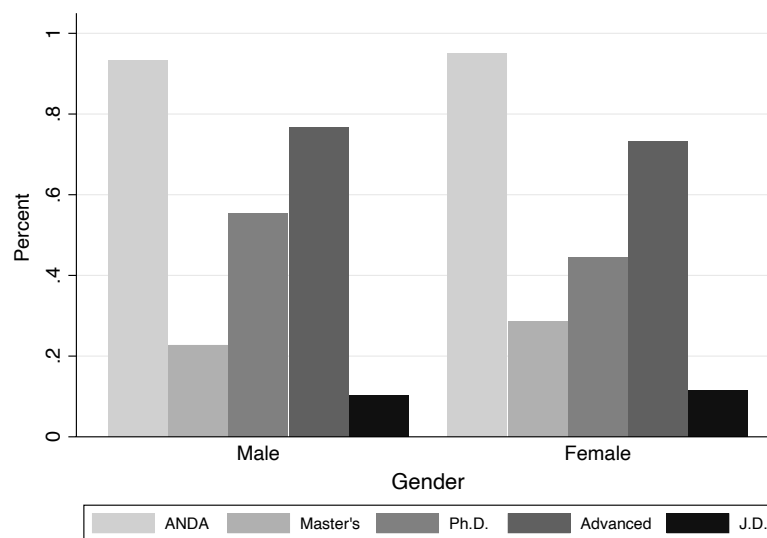
* 90% confidence, ** 95% confidence, *** 99% confidence. N=388.

Figure 4: Patent Examiner Percentages, by Gender and

142. The information we obtained from the USPTO allows us to only assess whether an examiner had a law degree as of the date they were employed by the agency. A cursory look at the profiles of some of the examiners after leaving the agency reveals that many examiners subsequently obtained law degrees after leaving the agency. These later-obtained law degrees are not reflected in our data, which is appropriate because this study focuses only on examiner education at the time examiners were employed at the USPTO (and not the education that the examiner may have received after the examiner left the USPTO).

143. *See supra* note 109.

144. Some people had left the agency and came back or were reflected multiple times in the data when they changed GS levels. The highest GS level was used for this analysis.

Educational/Professional Background

Overall, our data suggest that, with government jobs in the patent prosecution field, there seems to be general equality between the genders in qualifications, hiring, tenure, and pay. Specifically, many examiners have a degree in an ANDA-related science. Those with equal educational backgrounds are treated similarly when it comes to tenure and pay. In contrast, as we show below, there is a large gender disparity in private practice.¹⁴⁵

2. Pharmaceutical Patent Prosecutors

Unlike with examiners at the USPTO, there is a much larger gender disparity when it comes to private practice that applies to both prosecutors and, as we show in section IV.B, litigators.¹⁴⁶ *Figure 5* shows that, of the 217 patent prosecutors in our dataset from the most active firms who worked on litigated pharmaceutical patents that terminated in a final judgment on validity, 75.1% are men and only 24.9% are women, a nearly fifty-percentage-point

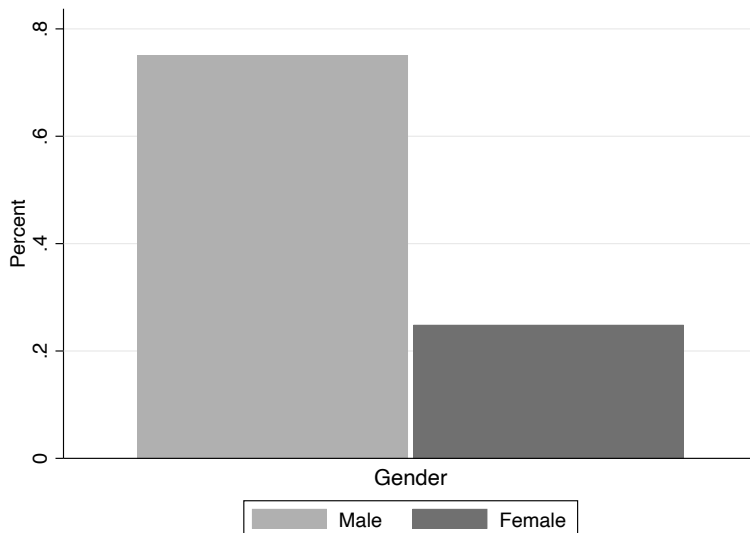
145. *See infra* Section IV.A.2.

146. *See infra* Section IV.B.

disparity that is far disproportionate to the share of women in the legal profession and in American law schools.¹⁴⁷

Figure 5: Patent Prosecutor Percentages, by Gender

Crucially, Table 2 and Figure 6 below show that the education



levels of women in patent prosecution are similar to those of men, refuting the notion that a pipeline problem is impeding women's participation in patent prosecution. The women and men in our dataset have similar backgrounds in ANDA-related training, with 59.3% of women having an ANDA-based degree compared to 58.3% of men. Similarly, women have advanced degrees in a near equal proportion to men (35.2% versus 35.0%). Further, while men have more master's degrees (16.0% versus 14.8%), a larger percentage of women (24.1%) than men (22.1%) have doctorates, although neither difference is statistically significant.

Additionally, regardless of gender, most of these patent prosecutors are patent attorneys, not patent agents. While women

147. See *supra* Section I.B. Most of the demographic information, such as educational and professional information, was compiled using only the names of the 186 prosecutors for which we could obtain a name. Statistics were computed based on the 217 prosecutors by imputing the median to those with missing values.

are slightly more likely to be agents, the difference is only significant at 90% confidence. Specifically, 96.9% of men and 90.7% of women prosecutors are also registered patent attorneys.¹⁴⁸ This high rate of prosecutor-lawyers is consistent with previous studies that have shown that 76% of women and 86% of male prosecutors are registered patent attorneys.¹⁴⁹

All in all, the data show that women and men have virtually indistinguishable educational and professional backgrounds, making the near fifty-percentage point discrepancy in their overall representation among the patent prosecution bar perplexing.

Table 2: Patent Prosecutor Percentages, by Gender and Educational/Professional Background

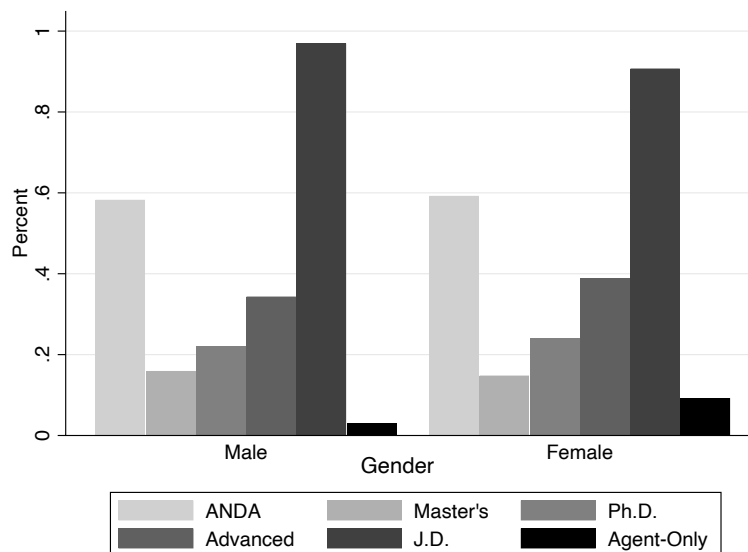
	ANDA	Master's	Ph.D.	Advanced	J.D.	Agent-Only
Male	58.3	16.0	22.1	35.0	96.9	3.1*
Female	59.3	14.8	24.1	35.2	90.7	9.3*

* 90% confidence, ** 95% confidence, *** 99% confidence. N= 217.

148. The few patent prosecutors who were not coded as going to law school have very low registration numbers (representing that they passed the patent bar before 1970). For many of these patent prosecutors, we were unable to determine if they attended law school because they have long retired and do not have websites describing their educational background. In more recent times, there are some patent prosecutors who worked as patent agents at law firms.

149. All of the prosecutors have USPTO registration numbers. This is not surprising because to prosecute patents in front of the USPTO requires licensure by the USPTO. Spector & Brand, *supra* note 56, at 4 fig. 4, shows that 21.8% of all USPTO registered attorneys and agents are women. 75.6% of those women are patent attorneys and 24.4% are agents. Men make up 78.2% of all USPTO registered attorneys and agents. 85.7% of those men are registered as attorneys and 14.3% are registered as agents.

Figure 6: Patent Prosecutor Percentages, by Gender and Educational/Professional Background



Interestingly, however, women prosecutors are more likely than men to have their patents invalidated in court. Women have their patents invalidated 50.5% of the time, while only 32.7% of patents prosecuted by men are invalidated, a difference that is statistically significant at the 95% confidence level. Of course, there are many factors that impact whether or not a patent is declared invalid, such as the complexity of the patent, the wordiness of the claims, and the date of the patent, among others.¹⁵⁰ The gender disparity we document does not control for any of those factors so, while it is interesting to note, we cannot claim it has any causal significance.

B. Pharmaceutical Patent Litigation

Similar to patent prosecutors working in private practice, there is a large gender disparity among patent litigators in private practice. *Figure 7* below shows that, of the 333 patent lawyers who litigated pharmaceutical patents in our dataset, 62.5% are men and

150. See Colleen V. Chien, *Predicting Patent Litigation*, 90 TEX. L. REV. 283, 287 (2011).

only 37.5% are women. This nearly 30% gender disparity is not as large as it is among prosecutors, but it still is disproportionate to the share of female lawyers overall and the share of female law students with scientific backgrounds. These data are also consistent with prior articles showing that, while women are largely absent from patent litigation across all areas of technology, there is greater representation of women when it comes to litigation in the pharmaceutical industry.¹⁵¹ One of us, for example, has shown that the litigants who had more than 20% of their Federal Circuit oral arguments presented by female attorneys were disproportionately companies in the pharmaceutical industry.¹⁵²

Figure 7: Patent Litigator Percentages, by Gender

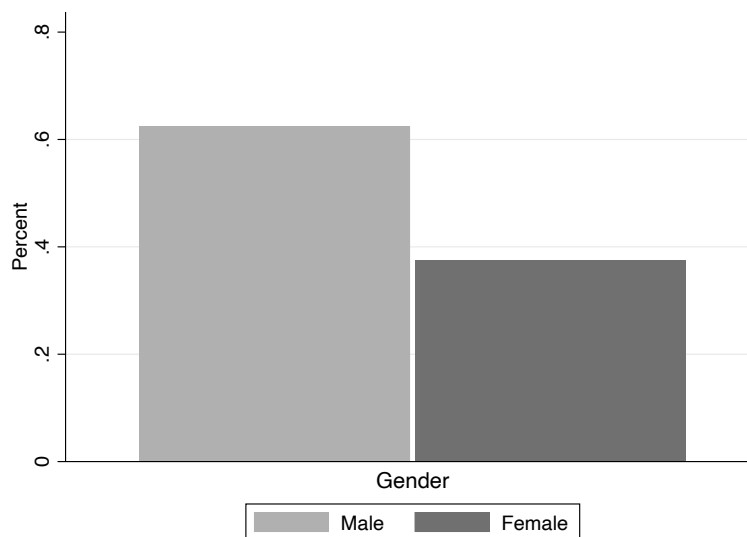


Table 3 below shows that the education and experience levels of women in patent litigation is similar to that of men, again refuting

151. Gugliuzza & Rebouché, *supra* note 15, at 1726 fig. 20 (16.4% of Federal Circuit arguments were presented by women in pharmaceutical cases as compared to 12.0% in non-pharmaceutical cases).

152. *Id.* at 1724 tbl. 1 (showing that Mylan, Apotex, Watson, and Sandoz all had a greater than 20% of their arguments presented by women attorneys).

the pipeline argument in the pharmaceutical field. Although not statistically significant, as shown in *Table 3* and *Figure 8*, the women patent litigators in our dataset tend to have *higher* education levels than the male litigators in our dataset. Specifically, women have a higher percentage of bachelor's, master's, and doctorate degrees.¹⁵³ Fewer female litigators, however, are members of the patent bar (38.4% versus 42.3%), but that difference is not statistically significant.

These data contradict the idea that litigators need to be admitted to the patent bar or need science degrees to litigate patents. Overall, according to our database, only 61.3% of ANDA litigators have bachelor of science degrees, 48.1% have degrees in ANDA-related fields,¹⁵⁴ and 40.8% are registered patent attorneys.¹⁵⁵ Yet, though the differences are not statistically significant, women litigators in our dataset actually score higher in science degrees (64.0% versus 59.6%), ANDA-related degrees (55.2% versus 46.6%), master's degrees (12.0% versus 10.6%), and doctorates (13.6% versus 10.1%).

Table 3: Patent Litigator Percentages, by Gender and Educational/Professional Background

	B.S.¹⁵⁶	ANDA	Master's	Ph.D.	Advanced	Registered
Male	59.6	46.6	10.6	10.1	17.8	42.3
Female	64.0	55.2	12.0	13.6	23.2	38.4

* 90% confidence, ** 95% confidence, *** 99% confidence.

153. These figures are reported by each individual person, with each person in the database as a unique observation.

154. The list of ANDA degrees are defined in *supra* note 127.

155. These numbers are derived from our dataset of cases litigated to a judgment on the validity of a patent and involving large law firms. Where data is missing, we made some assumptions about whether or not someone has a science or ANDA-based degree. Many lawyers simply list that they have a bachelor of arts or bachelor of science degree, without indicating their specific major. Where the major was not listed, we assumed it was in a non-ANDA-related topic. This may undercount the true number of ANDA-majors, but we have no reason to believe that this undercount would disproportionately affect women versus men. Further, if a lawyer's information simply stated he or she had a bachelor's degree, we assumed he or she did not have a science degree. This was not always true, as some colleges (particularly liberal arts colleges) only award bachelor of arts degrees, yet students still major in fields such as chemistry or biology. Again, to the extent this assumption was wrong, we have no reason to believe it disproportionately affects women over men or vice versa.

156. This represents a bachelor of science, regardless of whether it is in an ANDA-related field.

Figure 8: Patent Litigator Percentages, by Gender and Educational/Professional Background

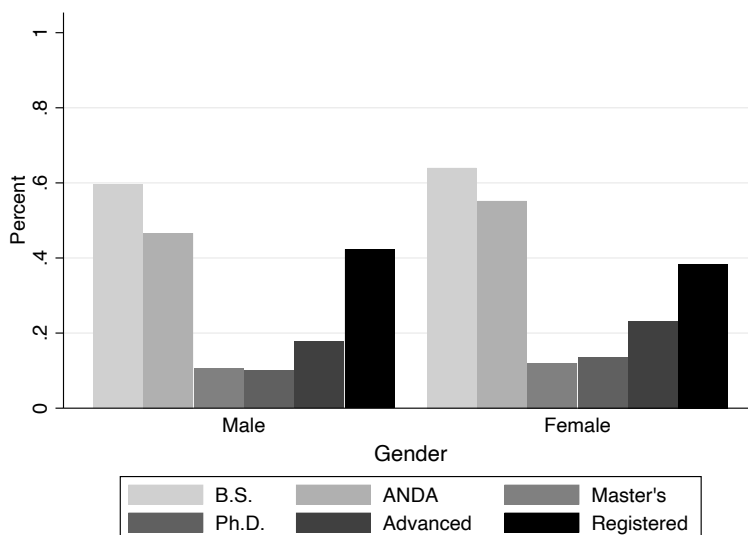


Table 4 and Figure 9 below look at case-lawyer-gender pairs as the unit of analysis to discern whether the male-female ratio changes when the data is segmented by brand or generic lawyers or when segmented by invalid or not invalid judgments.¹⁵⁷ To be sure, use of the case-lawyer-gender pair may overstate some law firms and lawyers in the database. For example, firms representing branded pharmaceutical companies (such as Finnegan and Covington & Burling) often have large teams working on their cases, while many of the law firms representing generic companies have smaller teams. Moreover, there are more repeat players especially among the law firms representing generic companies, with the same lawyers representing generics over and over again.

Still, as shown on Table 4 and Figure 9, there is a statistically significant difference at the 95% confidence level concerning gender differences with respect to representation of brands versus generics. Females disproportionately represent generic companies

157. In total, there are 1,402 observations of case-lawyer-gender pair, with no duplicates removed. The ratios are approximately the same when the analysis includes unique names only.

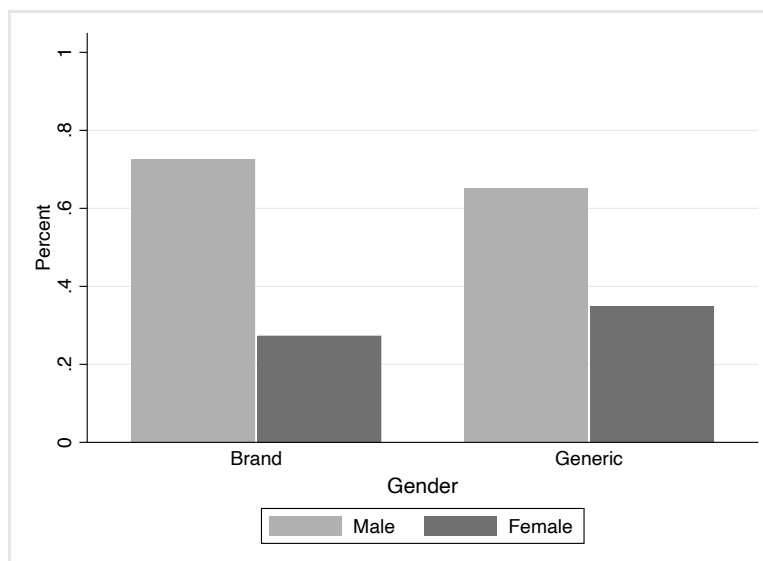
(34.8%) compared to brands (27.4%), while men have a higher rate of representing brands (72.6%) versus generics (65.2%). This suggests that there is a greater proportion of women at some of the smaller firms that generally represent generics than at the largest, most prestigious firms that tend to represent branded companies – further evidence of the acute absence of women at the highest levels of private law practice.

Table 4: Patent Litigator Percentages, by Gender, and Whether Represent Brand/Generic Pharmaceutical Company, and Validity Outcome

	Brand	Generic
Overall		
Male	72.6**	65.2**
Female	27.4**	34.8**
Invalid		
Male	73.3	71.8
Female	26.7	28.2
Not Invalid		
Male	72.3***	61.9***
Female	27.7***	38.1***

* 90% confidence, ** 95% confidence, *** 99% confidence.

Figure 9: Patent Litigator Percentages, by Gender, and Whether Represent Brand/Generic Pharmaceutical Company



C. Education and Pharmaceutical Patent Litigation

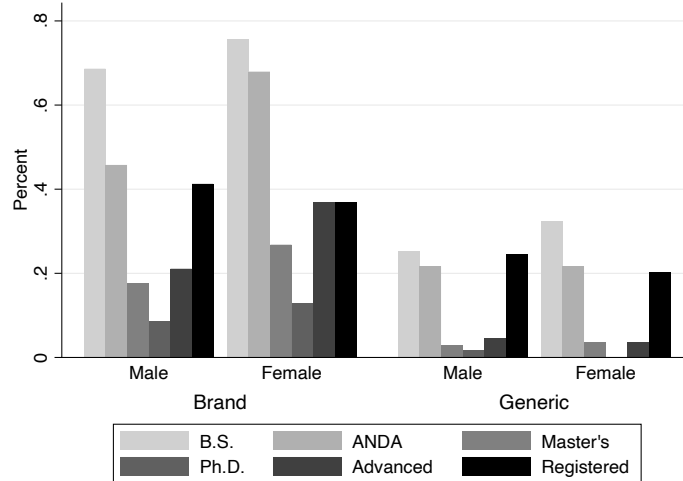
Table 5 and Figure 10 below break down the data by the educational qualifications of the 333 lawyer-gender pairs by type of litigant. For example, as shown in Figure 10, it is apparent that lawyers representing generics have lower educational qualifications, in terms of degrees. Overall, lawyers representing generic pharmaceutical companies have a lower percentage of science or advanced degrees as well as represent a lower percentage of USPTO registered patent attorneys compared to lawyers representing brand pharmaceutical companies, a difference that is statistically significant at 99% confidence.

Table 5: Patent Litigator Percentages, by Gender, Educational/Professional Background, and Whether Represent Brand/Generic Pharmaceutical Company

	B.S.	ANDA	Master's	Ph.D.	Advanced	Registered
Overall¹⁵⁸						
Brand	75.9***	62.0***	13.4*	16.2***	25.5***	49.5***
Generic	34.2***	27.4***	6.8*	2.6***	9.4***	24.8***
Brand: Overall						
Male	73.5	56.6**	13.2	13.2	22.1	50.0
Female	80.0	71.3**	13.8	21.3	31.3	48.8
Generic: Overall						
Male	33.3	27.8	5.6	4.2	9.7	27.8
Female	35.6	26.7	8.9	0.0	8.9	20.0

* 90% confidence, ** 95% confidence, *** 99% confidence.

Figure 10: Patent Litigator Percentages, by Gender, Educational/Professional Background, and Whether Represent Brand/Generic Pharmaceutical Company



158. These figures are generally the same if the data is further broken down by whether the patent in the case-lawyer-gender pair is ruled invalid or not invalid. This data reinforces the fact that brand pharmaceutical companies are generally represented by lawyers with greater education.

Further, women who represent brands typically have higher levels of education than men who do. Limited to lawyers representing brand pharmaceutical companies, female lawyers disproportionately have an ANDA-related degree (71.3%) compared to men (56.6%), a difference that is statistically significant at the 95% confidence level. There are virtually no differences between the genders for lawyers representing generics. In fact, the data show that most litigators for generic pharmaceutical companies do not have a science degree. In contrast, *Table 5* and *Figure 10* show that the most scientifically educated patent litigators represent the brand companies. Yet, despite the fact that female litigators are better educated than men, men still are disproportionately represented at firms representing brand companies. This finding of women appearing to have superior qualifications accords with literature suggesting that, to succeed in high-stakes corporate environments, women are disproportionately required to “prove themselves over and over again.”¹⁵⁹

Table 6 below compares how diverse teams fare with respect to validity outcomes. About 81.1% of cases involved at least one female litigator. In order to determine whether a team was diverse, we calculated the ratio of female lawyers to total lawyers on the case. The median was 0.29, meaning that over half of the teams in ANDA cases have less than a third of the lawyers on the team who are female. We then constructed a dichotomous variable with “1” indicating that the litigation team has a higher female-to-male membership ratio than the median litigation team in our dataset.¹⁶⁰ With a dichotomous variable, we could then compare invalidation rates based on whether or not the team was diverse.

We similarly constructed a dichotomous measure based on advanced degrees, with a value of “1” for groups that had above the mean value of 14.5% for an advanced degree. This gave us a way to measure whether more educated teams (defined by having

159. See, e.g., Joan C. Williams, *The Five Biases Pushing Women Out of STEM*, HARV. BUS. REV. (Mar. 24, 2015), <https://hbr.org/2015/03/the-5-biases-pushing-women-out-of-stem>.

160. These ratios are of course approximate. Moreover, we only selected lawyers from the most active law firms, so it could be the case that a lawsuit involving many different firms have a different ratio than what we assign to each case. Nonetheless, we think that the ratio of female lawyers to total lawyers at the large firms gives at least some measure of how diverse the team representing the client was.

an advanced degree) have different outcomes on validity to a statistically significant degree.

Table 6 below presents the data based on the two dichotomous variables regarding team diversity and education, comparing invalidation rates between brands and generics. Invalidation rates do not markedly differ based on whether the team is more diverse or more educated. Though not significant (barely), diverse teams with more women have lower rates of invalidation, a “winning” outcome for the brand pharmaceutical companies. With respect to education, teams composed of those with more than the mean for an advanced degree fare no better or worse with respect to outcomes.

Table 6: Patent Litigation Outcome Percentages, Whether Diverse/Not Diverse, and Whether More Educated/Less Educated

	Diverse	Not Diverse	Educ	Less Educ
Overall				
Invalid	31.0	40.2	34.8	36.3
Not Invalid	69.0	59.8	65.2	63.8
Brand				
Invalid	29.3	38.5	33.3	25.8
Not Invalid	70.7	61.5	66.7	74.2
Generic				
Invalid	32.6	43.3	37.9	42.9
Not Invalid	67.4	56.7	62.1	57.1

* 90% confidence, ** 95% confidence, *** 99% confidence.

V. TOWARDS WOMEN’S INCLUSION IN PATENT LAW

This study expands the scope of previous studies¹⁶¹ and finds that women rarely litigate pharmaceutical patents for private sector clients in the federal district courts. Additionally, women do not prosecute pharmaceutical patents for private sector clients at rates comparable to their male counterparts.

These data are particularly interesting because, unlike in many areas of science, women are well-represented in biological, chemistry, and health care related fields.¹⁶² Additionally, women

161. *E.g.*, Gugliuzza & Rebouché, *supra* note 15.

162. See OFF. OF THE CHIEF ECONOMIST, U.S. PAT. & TRADEMARK OFF., PROGRESS AND POTENTIAL: 2020 UPDATE ON U.S. WOMEN INVENTOR-PATENTEEES 7 (2020), <https://www.uspto.gov/ip-policy/economic-research/publications/reports/progress-potential> [hereinafter 2020 UPDATE].

who have science backgrounds are equally represented among students attending law school. Our data thus call into question the idea that simply increasing the number of women in the sciences will bring about gender equality in the pharmaceutical field. There *already are* a lot of women in pharmaceutical-related scientific fields, but they do not make it to the highest levels of pharmaceutical patent law practice.

Interestingly, this gender disparity is not found in many government jobs related to patent law. Specifically, patent examiners working at the USPTO within the pharmaceutical art units see something close to gender parity.¹⁶³ This finding is consistent with prior scholarship observing proportionately greater gender equality in patent-related jobs in the public sector, whether as PTAB judges, Federal Circuit judges, or lawyers at the USPTO Solicitor's Office.¹⁶⁴

Patent litigation and patent prosecution in the pharmaceutical sector are two of the most lucrative areas of practice.¹⁶⁵ Obtaining patents in the pharmaceutical sector can represent billions of dollars of revenue for pharmaceutical firms and millions of dollars in revenue for the law firms that represent them.¹⁶⁶ Also similar to other lucrative and prestigious areas of law, women are underrepresented.¹⁶⁷ This is most likely because most law firm partners are male and—consciously or not—resist surrendering control over these high-value clients. To incentivize greater gender parity, firms could begin to tie compensation directly to diversity and inclusion goals.¹⁶⁸ Shy of that, however, reform will likely have to come outside of the law firm community.

163. See *supra* Section IV.A.1.

164. See Gugliuzza & Rebouché, *supra* note 15, at 1713 fig. 13; Semet, *supra* note 93.

165. See generally *Most Lucrative Areas of Law 2021: Top 7*, BSCHOLARLY, <https://bscholarly.com/most-lucrative-areas-of-law> (listing intellectual property law among the highest paying areas of law) (last visited Oct. 15, 2021).

166. See Chandra Mohan, S.B. Puranik, Prasanna Sagar, Swamy Sreenivasa & Madhu Rao, *Patents – An Important Tool for Pharmaceutical Industry*, 2 RES. & REV.: J. PHARM. & NANOTECHNOLOGY 12 (2014).

167. See, e.g., Afra Afsharipous, *Women and M&A*, 12 UC IRVINE L. REV. (forthcoming 2022) (showing that women are underrepresented in mergers and acquisitions transactions).

168. See, e.g., Iain Carlos, *DEI Is Now a Factor in Executive Pay. But There's One Big Disconnect*, BUS. J. (July 29, 2021), <https://www.bizjournals.com/bizjournals/news/2021/07/29/dei-is-not-in-long-term-incentive-programs.html>.

In this final Part of the Article, we sketch ways in which Congress and the USPTO could further gender equality in patent law practice, discuss steps law firms and their clients could take to the same end, and assess whether some steps the USPTO has recently taken have succeeded in nudging patent practice toward gender parity.

A. Congressional and USPTO Solutions

Both Congress and the USPTO are aware of the lack of gender and racial diversity in the patent bar and are exploring several approaches to address the issue. Over the past few years, both the House and Senate have held hearings on so-called “lost Einsteins” who are not included in the patent law system.¹⁶⁹ The USPTO recently took on the charge of creating a new database linking up historical data to code each patent with the inventor’s gender to spur research in the field.¹⁷⁰

Congress is currently considering the Unleashing American Innovators Act to address the diversity gap.¹⁷¹ This Act would establish additional USPTO satellite offices in locations where there are underrepresented demographic groups. These offices will target the Southeastern region¹⁷² of the United States to “increase participation in the patent system by women, people of color, veterans, individual inventors, [and] members of any other demographic, geographic, or economic group that . . . [is] underrepresented in patent filings.”¹⁷³ Furthermore, the Act attempts to bolster the patent pro bono program¹⁷⁴ and create a pre-prosecution patentability assessment program.¹⁷⁵ Each of these programs endeavor to help low-income inventors in disadvantaged

169. See, e.g., House Judiciary Committee, *Lost Einsteins: Lack of Diversity in Patent Inventorship and the Impact on America’s Innovation Economy* (Mar. 27, 2019), <https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1802>; House Small Business Committee, *Enhancing Patent Diversity for America’s Inventors* (Jan. 15, 2020), <https://www.congress.gov/event/116th-congress/house-event/LC65529/text?s=1&r=24>.

170. See 2020 UPDATE, *supra* note 162.

171. Unleashing American Innovators Act of 2021, S.B. 2773, 117th Cong.

172. The Southeastern region of the United States is defined as Virginia, North Carolina, South Carolina, Georgia, Florida, Tennessee, Alabama, Mississippi, Louisiana, and Arkansas. *Id.* § 2(4).

173. *Id.* § 3(c)(2).

174. *Id.* § 5.

175. *Id.* § 6.

geographic locations gain better access and help them understand the patent system.

The USPTO has also responded to a lack of diversity by changing the requirements for admission to the patent bar. In 2021, the USPTO changed the “technical and scientific qualifications” necessary to take the patent bar exam.¹⁷⁶ These changes expanded eligibility for the patent bar exam to a wider range of degrees and were made, in part, as a response to the low gender diversity in the patent bar.¹⁷⁷

Specifically, the USPTO made three changes to the patent bar eligibility requirements: (1) expanding the list of “Category A” bachelor’s degrees that are accepted as meeting requisite technical and scientific requirements, (2) expanding “Category A” to include master’s and doctoral degrees, and (3) revising the coursework requirements of “Category B” to be more flexible with the inclusion of biology courses.¹⁷⁸ Category A degrees now include bioengineering, biological science, environmental engineering, genetic engineering, genetics, and neuroscience, which are all areas of science that are highly populated with women. Furthermore, the additional qualifying biology courses under Category B tend to be heavily populated by women.¹⁷⁹ Finally, inclusion of advanced degrees helps women by allowing women with scientific graduate degrees but non-scientific bachelor’s degrees to take the exam. Previously, for example, a woman with a bachelor’s degree in English and a doctorate in Biology would not qualify under Category A. Inclusion of graduate degrees into Category A fixes this problem.

The USPTO has also created a program to help foster development of legal skills through experience. This new USPTO initiative is called the Legal Experience and Advancement Program

176. See Administrative Updates to the General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases Before the United States Patent and Trademark Office, 86 Fed. Reg. 52652 (proposed Sept. 22, 2021).

177. Courtenay C. Brinkerhoff, *Will Revised Patent Bar Qualifications Address Low Gender Diversity?*, NAT’L L. REV. (Mar. 22, 2021), <https://www.natlawreview.com/article/will-revised-patent-bar-qualifications-address-low-gender-diversity>.

178. See U.S. PAT. & TRADEMARK OFF., *supra* note 66, at 3–7 (showing the different scientific and technical requirements necessary for Category A, B, and C classifications to take the patent bar).

179. See *supra* Figure 1 (showing that more women than men receive biological science and chemistry degrees at the bachelor’s, master’s, and doctoral level).

(LEAP).¹⁸⁰ The LEAP program allows the PTAB to grant up to 15 minutes of additional argument time to parties that choose to participate. The only requirement is that the arguing patent agent or attorney must have three or fewer substantive oral arguments in any federal tribunal.¹⁸¹

It is not clear that opportunities for less-experienced lawyers will necessarily translate to opportunities for women or, for that matter, people of color. But the fact that the USPTO is aware of the need to spread patent work among a more diverse array of lawyers is a step in the right direction.

B. Corporations and Law Firms

Corporations and firms have spent decades paying lip service to gender equality, yet significant progress has not been made.¹⁸² Commentators have shown how law firms implemented diversity initiatives to win subsequent discrimination litigation.¹⁸³ However, these same law firms have little incentive to ensure that the strategies they adopt “make actual and tangible improvements in the demographic diversity and inclusiveness of their organizations.”¹⁸⁴

Most major law firms have made commitments to diversity, but our data on patent practice suggests that those commitments have not made a significant difference in some of those firms’ most high-stakes matters. The literature on diversity in the legal profession often laments that law firms are quick to tout the value of inclusion but then engage in strategies that are superficial at best and treat people as tokens at worst.¹⁸⁵ Women regularly report being required “to go ‘above and beyond’ to get the same

180. *Legal Experience and Advancement Program (Leap)*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/ptab/leap> (last visited Sept. 2, 2022).

181. *See id.* (noting that, as of November 18, 2021, the USPTO removed the requirement that practitioners needed to have seven or fewer years of experience to qualify for LEAP).

182. *See* Veronica R. Martinez & Gina-Gail S. Fletcher, *Equality Metrics*, 130 YALE L.J. F. 869, 885–88 (2021) (showing that firms may be implementing diversity efforts that have empirically proven to be ineffective but are rewarded for doing so).

183. *Id.* at 888.

184. *Id.*

185. *See, e.g.*, DESTINY PEERY, PAULETTE BROWN & EILEEN LETTS, AM. BAR ASS’N COMM’N ON WOMEN IN THE LEGAL PROFESSION, LEFT OUT AND LEFT BEHIND: THE HURDLES, HASSLES, AND HEARTACHES OF ACHIEVING LONG-TERM LEGAL CAREERS FOR WOMEN OF COLOR at viii (2020) (“[Women of color] felt that they were often treated as tokens and trotted out to clients only when it would help the firm look good but not necessarily in ways that helped them further their own careers.”).

recognition and respect as their colleagues[.]” that they face pressure to act feminine and to do undervalued administrative work, and that they are treated worse than their male colleagues after taking time off to have children.¹⁸⁶ To enact sustained change, firms’ most powerful lawyers must be willing, at times, to use their high-profile roles for the career advancement of lawyers who do not look like them. The problem, of course, is that such a strategy depends on the will of powerful actors.

To move beyond the status quo, the expectations of and incentives for those in power must change. For instance, some large corporations have begun tying annual executive compensation to explicit, objective diversity and inclusion goals.¹⁸⁷ Law firms could take similar steps. And some have by, for example, eliminating “origination credits,” which reward powerbrokers with an essentially indefinite stream of commission-like income from key clients.¹⁸⁸ In that vein, a recent report by the American Bar Association and the Minority Corporate Counsel Association on “bias interrupters” provides a clear roadmap, complete with objective metrics and techniques for furthering diversity in law firm work assignment and compensation systems.¹⁸⁹

Moreover, clients who hire law firms should wield their economic power to require women to hold positions of responsibility when it comes to the client’s case.¹⁹⁰ Some clients have started to exercise that power of the purse, withholding legal spending from firms that do not meet diversity and inclusion requirements, requiring teams to consist of a specified percentage of women and people of color, and giving bonuses to firms when their legal teams meet diversity goals.¹⁹¹ The general counsel of

186. JOAN C. WILLIAMS ET AL., AM. BAR ASS’N COMM’N ON WOMEN IN THE PROFESSION & MINORITY CORP. COUNSEL ASS’N, YOU CAN’T CHANGE WHAT YOU CAN’T SEE: INTERRUPTING RACIAL & GENDER BIAS IN THE LEGAL PROFESSION 7–8 (2018), <https://www.mcca.com/wp-content/uploads/2018/09/You-Cant-Change-What-You-Cant-See-Executive-Summary.pdf>.

187. See Carlos, *supra* note 168.

188. See Irene Liu, Robin Preble & Megan Redmond, *Strategies to Help Close IP Law’s Long-Standing Gender Gap*, LAW360 (Apr. 19, 2022, 5:12 PM), <https://www.law360.com/ip/articles/1483932>.

189. WILLIAMS ET AL., *supra* note 186, at 18–21, 25–28.

190. See STEPHANIE A. SCHARF & ROBERTA D. LIEBENBERG, AM. BAR ASS’N, FIRST CHAIRS AT TRIAL: MORE WOMEN NEED A SEAT AT THE TABLE 16 (2015).

191. Lynn S. Scott, *Moving the Needle – We Can’t Give Up*, LAW PRAC. TODAY (May 14, 2019), <https://www.lawpracticetoday.org/article/moving-needle-cant-give>.

Coca-Cola, for example, was recently in the news for requiring the company's law firms "to give a portion of work to Black attorneys specifically and withholding a nonrefundable 30% of fees from those that fail to meet diverse staffing metrics."¹⁹²

To effect meaningful change, clients must be willing to make good on their promise to make engagement decisions based on whether firms meet benchmarks of diversity. Law firms have reported being "frustrated by clients who asked for detailed information on diversity and then failed to follow up or to reward firms that had performed well."¹⁹³

C. Lessons from the USPTO

A final place we might look for reform ideas is the USPTO—not so much its regulatory positions (discussed in section V.A above), but how the agency works on the ground. As our empirical study makes clear, patent examiners at the USPTO are comprised roughly equally of men and women. Additionally, their promotion and tenure schedules are about equal. Accordingly, the private sector might enhance diversity by doing some of what the USPTO is already doing. Important strategies might include: telework, flexible schedules, and parental leave, among others.

1. Telework and Flexible Schedules

Since 1997, the USPTO has allowed some of its employees a telework option.¹⁹⁴ In 2012, the USPTO launched its Telework Enhancement Act Pilot Program (TEAPP), which allowed USPTO employees to work "throughout the country and waive government paid costs for required travel back to headquarters."¹⁹⁵ This program has led to increased productivity and higher retention

192. Ruiqi Chen, *Coke GC Tired of 'Good Intentions,' Wants Firm Diversity Now*, BLOOMBERGLAW (Jan. 28, 2021), <https://news.bloomberglaw.com/business-and-practice/coke-gc-tired-of-good-intentions-wants-law-firm-diversity-now>.

193. DEBORAH L. RHODE, *THE TROUBLE WITH LAWYERS* 80 (2015).

194. See U.S. PAT. & TRADEMARK OFF., 2018 TELEWORK ANNUAL REPORT, https://www.uspto.gov/sites/default/files/documents/Telework_Annual_Report_2018%20508%20Compliant.pdf [hereinafter 2018 TELEWORK ANNUAL REPORT].

195. U.S. PAT. & TRADEMARK OFF., TELEWORK ENHANCEMENT ACT PILOT PROGRAM 1 (TEAPP), <https://www.uspto.gov/sites/default/files/documents/TEAPP%202020%20Fact%20Sheet.pdf>.

rates as well as increased employee morale.¹⁹⁶ In 2018, there were 11,093 teleworkers and 8,824 of them were patent teleworkers.¹⁹⁷

The USPTO also allows its examiners to have flexible schedules. Flextime schedules allow for employees to arrive as early as 5:30 am or as late as 11:30 am.¹⁹⁸ Furthermore, the flexible schedule allows for a “4/10 plan” that allows an employee to work 10 hours a day for only four days a week.¹⁹⁹ Another work option is the “5/4/9 plan” which allows for eight nine-hour days, plus one eight-hour day with one day off during each pay period.²⁰⁰

Since many women are the primary care providers for their family, the ability to work from home is an advantage that cannot be understated. Countless studies confirm that women remain much more likely to take time away from their careers to engage in dependent care than men.²⁰¹ And decades of scholarship have documented the costs to people who take on care of relatives and dependents²⁰² as well as how the value and importance of that care

196. *Id.*

197. See 2018 TELEWORK ANNUAL REPORT, *supra* note 194, at 6 (showing the 11,093 teleworkers represent 94.20% of the positions that are telework eligible and that the 8,824 patent teleworkers represent 94.01% of patent positions that are telework eligible).

198. *Work-life balance*, U.S. PAT. & TRADEMARK OFF, <https://www.uspto.gov/jobs/why-choose-us/work-life-balance> (last visited Sept. 2, 2022).

199. *Id.*

200. *Id.*

201. Both men and women report dissatisfaction with long hours that mean less time with family. But a recent study of legal careers fifteen years after law school graduation found that “[a]lthough men’s incomes remain high relative to the women, their satisfaction with the family has declined steadily . . . while women’s satisfaction with the family has remained higher and roughly constant.” The study thus concludes on the somewhat dispiriting note that “[i]t seems that the non-traditional roles for men are becoming even less attractive.” Kenneth G. Dau-Schmidt & Kaushik Mukhopadhyaya, *Men and Women of the Bar: A Second Look at the Impact of Gender on Legal Careers* 86 (June 15, 2022) (unpublished manuscript), <https://ssrn.com/abstract=3745044>.

202. A long line of feminist and family law scholarship has identified the means by which care work is excluded from the market. This exclusion rests on gendered expectations of what labor family members should provide as acts of altruism and gendered expectations of parents, partners, and children. See, e.g., Patricia Smith, *Family Responsibility and the Nature of Obligation*, in *KINDRED MATTERS: RETHINKING THE PHILOSOPHY OF THE FAMILY* 44–46 (Diana Tietjens Meyers, Kenneth Kipnis & Cornelius F. Murphy, Jr. eds. 1993). These expectations, many have observed, affirm the societal resistance to mixing economic exchange and intimacy. See, e.g., ARLIE HOCHSCHILD, *THE OUTSOURCED SELF: INTIMATE LIFE IN MARKET TIMES* 22 (2012); Jill Hasday, *Intimacy and Economic Exchange*, 119 *HARV. L. REV.* 491, 492 (2005).

is perpetually discounted.²⁰³ Teleworking combined with a flexible work schedule results in removing significant structural barriers for caregivers, who are overwhelmingly women. These options help women to advance their careers while also allowing them to act as the primary caregiver.

This benefit may be more widely adopted since the COVID-19 pandemic has allowed many workers to reap the benefits of telework. The USPTO telework model is likely to be adopted by many private firms, which will allow many primary caregivers to work full-time jobs while also taking care of their families.²⁰⁴

Yet the promise of connection and work through online platforms could also reinforce inequalities that already exist. Since the pandemic began, women have exited the labor force at much higher rates than men.²⁰⁵ Women, and especially women of color, have been acutely burdened by the closure of schools, daycares, and elder care facilities.²⁰⁶ The result could be that those without caretaking responsibilities remain best positioned to take advantage of new opportunities. Likewise, it is far from clear how more flexible working arrangements will affect career advancement. Though firms may have stated policies that allow

203. See, e.g., Katharine Silbaugh, *Commodification and Women's Household Labor*, 9 YALE J. L. & FEMINISM 81, 82 (1997); MARGARET BRINIG, FROM CONTRACT TO COVENANT: BEYOND THE LAW AND ECONOMICS OF THE FAMILY 22 (2000); MARTHA ALBERTSON FINEMAN, THE AUTONOMY MYTH: A THEORY OF DEPENDENCY 22 (2004); Naomi Schoenbaum, *The Law of Intimate Work*, 90 WASH. L. REV. 1167, 1168 (2015); Meredith Harbach, *Childcare, Vulnerability, and Resilience*, 37 YALE L. & POL'Y REV. 459, 460 (2019).

204. See Chiara Criscuolo, Peter Gal, Timo Leidecker, Francesco Losma & Giuseppe Nicoletti, *Telework After COVID-19: Survey Evidence from Managers and Works on Implications for Productivity and Well-Being*, OECD GLOB. F. ON PRODUCTIVITY, <https://oecdecoscope.blog/2021/07/28/telework-after-covid-19-survey-evidence-from-managers-and-workers-on-implications-for-productivity-and-well-being/?print=pdf>.

205. Kathryn A. Edwards, *Women Are Leaving the Labor Force in Record Numbers*, RAND BLOG (Nov. 24, 2020), <https://www.rand.org/blog/2020/11/women-are-leaving-the-labor-force-in-record-numbers.html>. But see Xiumei Dong, *COVID-19 Hasn't Forced an Exodus of Women from BigLaw*, LAW360 (Feb. 25, 2021, 11:35 AM), <https://www.law360.com/pulse/articles/1358490/covid-19-hasn-t-forced-an-exodus-of-women-from-biglaw> (reporting that about 40% of attorneys leaving the 200 largest law firms in 2020 were women, "a percentage that is consistent with results from the past three years").

206. Claire Cain Miller, *When Schools Closed, Americans Turned to Their Usual Backup Plan: Mothers*, N.Y. TIMES (Nov. 17, 2020), <https://www.nytimes.com/2020/11/17/upshot/schools-closing-mothers-leaving-jobs.html>; Steven Brown, *How COVID-19 Is Affecting Black and Latino Families' Employment and Financial Well-Being*, URB. INST. (May 6, 2020), <https://www.urban.org/urban-wire/how-covid-19-affecting-black-and-latino-families-employment-and-financial-well-being>.

flexibility, those who can be physically present in the office the most might reap the greatest professional rewards.²⁰⁷

2. Parental Leave

The USPTO has a relatively generous parental leave program for their non-probationary employees. This program gives a parent up to six months of leave after a baby is born or adopted.²⁰⁸ This leave can be used in combination with sick leave, annual leave, compensatory time, and leave without pay. Leave time can be used continuously or intermittently.

Additionally, under the Family Medical Leave Act (FMLA), an employee with at least one year of federal government service can take up to twelve weeks of leave without pay. Accordingly, an employee could take a continuous nine-month leave of absence after the birth or adoption of a child.²⁰⁹ Finally, an employee can earn up to 160 hours of compensatory time before the baby is born that may be used after the baby is born.²¹⁰

Of course, most large law firms also offer leave, flexible hours, or part-time status for new parents. But accommodation of care arrangements will only go so far if the benchmarks of how one succeeds in the long term do not change.²¹¹ Many of the accommodations

207. For a general discussion of the challenges and possibilities of remote working arrangements at law firms, see Manar Morales, *5 Steps For Law Firms Rethinking Flexible Work Post-COVID*, LAW360 (May 14, 2021), <https://www.law360.com/articles/1383234/5-steps-for-law-firms-rethinking-flexible-work-post-covid>.

208. *POPA Help Guide for Maternity/Paternity Issues, Non-Probationary Employees*, U.S. PAT. & TRADEMARK OFF., http://popa.org/static/media/uploads/uploads/POPA_HELP_GUIDE_FOR_MAT_PAT_NONPROB_01152015.pdf (last visited Sept. 2, 2022).

209. This would include six months under the USPTO maternity/paternity policy and twelve weeks under FMLA. *Id.*

210. Up to 160 hours may be carried over from bi-week to bi-week. Additionally, an employee can continue to earn and use additional hours of maternity/paternity compensatory time after the baby is born or placed for adoption for the first six months after the birth or placement. This program allows the employee to use compensatory time instead of leave without pay. *Id.*

211. Indeed, a more trenchant critique of current reform strategies, such as efforts to facilitate a “work-life balance,” is that they do little to upend the markets (or the neo-liberal impulse to help those markets expand without limit) that thrive on and exploit unpaid dependency work. See Nancy Fraser, *Between Marketization and Social Protection: Resolving the Feminist Ambivalence*, in *FORTUNES OF FEMINISM: FROM STATE-MANAGED CAPITALISM TO NEOLIBERAL CRISIS* 227–42 (2013); see also Nancy Fraser, *Contradictions of Capital and Care*, 100 *NEW LEFT REV.* 1, 1 (2016) (“[The crisis of care,] often linked to ideas of ‘time poverty,’ ‘family-

intended to create flexibility operate, in practice, as *penalties* that have detrimental impacts on women's career advancement.²¹² Women might fare better if there were greater state and private investments in dependent care and paid family leave, to name two often-proposed reforms.²¹³

CONCLUSION

It is worth noting that the gendered nature of patents and what is patented may affect who is interested in the subject. The legal definition of what is patentable is not objective, is socially constructed, and, therefore, is "open to change."²¹⁴ As one scholar put it, "we need to stop talking about [women in STEM] and instead focus on why women need to be in STEM in order to partake" in the patent system.²¹⁵ The "gendered" nature of the laws and regulations governing the patent system could certainly affect women's interest in entering patent law.²¹⁶

work balance,' and 'social depletion,' . . . refers to the pressures from several directions that are currently squeezing a key set of social capacities: those available for birthing and raising children, caring for friends and family members, maintaining households and broader communities, and sustaining connections more generally. Historically, these processes of 'social reproduction' have been cast as women's work. . . . Without it there could be no culture, no economy, no political organization. No society that systematically undermines social reproduction can endure for long. Today, however, a new form of capitalist society is doing just that. The result is a major crisis, not simply of care, but of social reproduction in this broader sense.") (internal grammar altered).

212. DEEPALI BAGATI, CATALYST REPORT, WOMEN OF COLOR IN U.S. LAW FIRMS 3 (2009) ("Women lawyers perceived existing flexibility options within law firms as detrimental to their careers.").

213. The assumption of care as an altruistic service relieves the state from responsibility to provide stronger support for families. In this regard, theorizing on vulnerability, led by Martha Fineman, is instructive. Vulnerability analysis "provides a means of interrogating the institutional practices that produce the identities and inequalities in the first place." Martha Fineman, *The Vulnerable Subject: Anchoring Equality in the Human Condition*, 20 YALE J.L. & FEM. 1, 16 (2008). By describing the inevitable and universal condition of human vulnerability—the "risks of harm, injury and misfortune that are constant, complex, particular, and out of our control"—Fineman argues for state action that allows people, and institutions, to build resilience to those risks. *Id.* at 266–69, 272.

214. JENNIFER C. LAI, PATENT LAW AND WOMEN: TACKLING GENDER BIAS IN KNOWLEDGE GOVERNANCE 194 (2021).

215. *Id.*

216. There is a rich literature critiquing patent law doctrine from a feminist perspective. For a sample, see Malla Pollack, *Towards a Feminist Theory of the Public Domain, or Rejecting the Gendered Scope of the United States Copyrightable and Patentable Subject Matter*, 12 WM. & MARY J. WOMEN & L. 603 (2006); Dan L. Burk, *Do Patents Have Gender?*, 19 AM. U. J. GENDER,

Moreover, although there are more women entering STEM, there is great inequity in who those women are “in terms of their racial, ethnic, cultural and social backgrounds.”²¹⁷ Giving women the opportunity to succeed as well as removing embedded structural barriers will be necessary to achieve gender equality in patent law. This study helps refute the pipeline argument at least with respect to the pharmaceutical field. Simply increasing the number of women who graduate with science degrees will likely not increase the number of patent prosecutors or patent litigators in the private sector in the pharmaceutical field.

To significantly improve gender diversity in the legal workplace, law firm clients must demand more from their legal counsel. Clients will likely have to drive this change because law firms seem unwilling or unable to achieve those results alone. Solutions may include programs that reduce legal fees for services provided by firms that do not meet diversity goals or simply changing law firms that refuse to commit to diversity and equity. Alternatively, clients could award bonuses to firms who meet diversity goals and provide opportunities to their minority members. In short, tying law firm profitability explicitly to the achievement of diversity and inclusion²¹⁸ may be the best way to incentivize greater diversity at the patent bar.

SOC. POL'Y & L. 881 (2011). For feminist critiques in other areas of intellectual property law, see, e.g., Ann Bartow, *Likelihood of Confusion*, 41 SAN DIEGO L. REV. 721, 816-17 (2004); Carys Craig, *Reconstructing the Author-Self: Some Feminist Lessons for Copyright Law*, 15 AM. U. J. GENDER, SOC. POL'Y & L. 207, 207 (2007).

217. LAI, *supra* note 214, at 196.

218. *See supra* note 191.