

# 2019 PATENTLY-O PATENT LAW JOURNAL

## Piloting Applicant-Initiated 101 Deferral Through A Randomized Controlled Trial<sup>1</sup>

Colleen V. Chien<sup>2</sup>

*“The journey of a thousand miles begins with a single step.” - Lao Tzu*

In response to frustration with the Supreme Court’s patentable subject matter (PSM) jurisprudence, courts have issued clarifying decisions and the USPTO has issued guidance regarding how to apply Section 101.<sup>3</sup> Stakeholders have continued to press for legislative attention and have started to receive it, most recently from closed-door roundtables being held by Senators Coons and Tillis.<sup>4</sup>

In this short essay, I underscore the importance of rigorously measuring the impact of these interventions and propose a complementary approach that aims to conserve agency and applicant resources even while policymakers

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<sup>1</sup> Cite as Colleen Chien, *Piloting Applicant-Initiated 101 Deferral Through A Randomized Controlled Trial*, 2019 Patently-O Patent Law Journal 1.

This essay is the second in a series of pieces about insights developed based on USPTO data (the first piece, *Decoding Patentable Subject Matter* by Jiun Ying Wu and Colleen V. Chien, is available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3267742](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3267742) and summarized in *The Impact of 101 on Patent Prosecution*, Colleen V. Chien, PatentlyO, October 21, 2018, at <https://patentlyo.com/patent/2018/10/impact-patent-prosecution.html>. A draft of the longer law review article from which this particular piece draws (Colleen Chien, *Policy Pilots: Experimentation in the Administration of the Law*, Iowa L. Rev. *forthcoming*), written for the 2018 Iowa Law Review Symposium on the Administrative State, is available at <https://ssrn.com/abstract=3300167>.

<sup>2</sup> Thanks to Santa Clara Law University students Jiu-Ying Wu, Nicholas Halkowski, Marvin Mercado, and Saumya Sinha and to William Gvoth, Peter Glaser, and Rocky Bernsden of Harrity LLP for assistance with data, and to Jenna Clark, Rohit Nainpally, Bill Sundstrom, Jennifer Johnson, Hans Sauer, and Jonathan Probell for their comments on earlier drafts. All errors are mine.

<sup>3</sup> Described at USPTO, *Subject Matter Eligibility*, <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility> (providing a list of published guidance, the latest of which took effect 1/7/2019, hereinafter “January 2019 Guidelines”)

<sup>4</sup> Ryan Davis, *Sens. Set Meeting To Talk Revamp Of Patent Eligibility Law*, Law360 - The Newswire for Business Lawyers (2018). <https://www.law360.com/articles/1108393/sens-set-meeting-to-talk-revamp-of-patent-eligibility-law>

work to clarify the law. As to the first point, as discussed previously<sup>5</sup> and below (see Figs. 1A & 1B), *Mayo* and *Alice* have been followed by the elevated prevalence of PSM rejections (overall and pre-abandonment) and PSM *ex parte* decisions among software and medical diagnostics applications.<sup>6</sup> Office actions including a 101 subject matter rejection rose from 25% pre-*Alice*, to a steady state of 75% as of the last USPTO release (in 2017) among software applications and 7% pre-*Mayo* to about 50% among medical diagnostic applications (Fig. 1A), though only to 15% among all applications. The rate of *ex parte* decisions addressing 101 has also shot up, from less than 10% to over 80% in 2018 in medical diagnostic and software technology areas, and to 26% overall.<sup>7</sup> If the aim is to restore certainty to pre-*Alice* and *Mayo* levels, then one would expect to see these rates decline with effective interventions. The USPTO has previously made data available to track office action metrics, but the last update was in 2017. As in the first post, I urge the USPTO to release updated data so that the impact of any policy intervention - new guidelines, new decisions, or 101 deferral - can be gauged using these metrics.

The second idea, a complementary approach to 101 guidance, builds on the idea of deferring 101 subject matter until other rejections are dealt with. Though 101 usually comes first, the new guidelines explicitly state that there is no “mandate that the patentability requirements be analyzed in any particular order.”<sup>8</sup> My proposal builds on the initial suggestion of Professors Robert Merges and Dennis Crouch<sup>9</sup> that 101 be considered only when “absolutely necessary”<sup>10</sup> but with some important modifications. I propose that deferral be applicant’s option, not mandatory, and the USPTO should, as it has done previously,<sup>11</sup> initially roll out the policy as a pilot pilot with

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<sup>5</sup> Chien (Oct. 2018) *supra* note 1.

<sup>6</sup> See Chien and Wu, *supra* note 1, for definitions.

<sup>7</sup> Based on a text search of decisions posted to the USPTO PTAB database including “101 and (bilski or benson or alice or mayo or diehr or nuijten or ariosa or enfish or smartgene),” accuracy of which, based on manual inspection of 142 cases, correctly identified 138 of them. Excludes IPR/CBM, Interference cases. The bulk of the appeals in the combined analysis of TC36BM and MedDx analysis are TC36BM cases.

<sup>8</sup> Jan 2019 101 Guidelines, *supra* note 3 at 26.

<sup>9</sup> Dennis Crouch & Robert P. Merges, *Operating Efficiently Post-Bilski By Ordering Patent Doctrine Decision-Making*, 25 Berkeley Tech. L.J. 1673 (2010).

<sup>10</sup> *Id.*

<sup>11</sup> See 77 FR 30197, 30198, *Changes in Requirements for Specimens and for Affidavits or Declarations of Continued Use or Excusable Nonuse in Trademark Cases* (describing pilot program in which the USPTO randomly chose 500 trademark registrants to participate in a pilot that required the selected owners to submit proof of use. The test was used to seed a roundtable discussion that supported establishment of a permanent program similar to the pilot, which in turn was used to support a final rule.

randomization, to ensure that deferral is having the desired impact of reducing uncertainty according, e.g. to the metrics outlined above.

### Experimenting with Ordering

The case for deferring 101 builds on the insight that rarely is patentable subject matter the single dispositive issue.<sup>12</sup> As shown below in Fig. 2, the share of office actions just prior to abandonment that only raise 101 issues is less than 2%. Even among business method (TC36BM) and medical diagnostic applications, the share is less than 15%. (Fig. 2) At the same time, 101 has become highly controversial - from rarely being appealed, 101 subject matter rejections are now increasingly the subject of *ex parte* appeal decisions.<sup>13</sup> (Fig. 1B) Deciding non-101 grounds first could avoid difficult subject matter discussions. The USPTO's new guidelines implement this logic to a degree, shifting focus towards 112 and away from 101.

The idea of deferral is precedented. As Crouch and Merges point out, the Supreme Court doctrine of avoidance allows the Court to “resolve[] cases on non-constitutional grounds whenever possible,”<sup>14</sup> to conserve court resources and legitimacy. The Deferred Action for Childhood Arrivals (DACA) Program, in effect, was put in place during the Obama Administration to delay the deportation of young undocumented immigrants while awaiting Congressional immigration reform.<sup>15</sup> Other federal agencies have also used deferral, for example, in the mid to late 2000s, when the application of immigration law to same-sex couples in some cases risked the undesirable outcome of family separation.<sup>16</sup> To avoid this harsh consequence, Department of Homeland Security prosecutors administratively closed some cases, immigration judges granted continuances for unusually long periods, and US Customs and Immigration enforcement officials granted requests for deferred action.<sup>17</sup> That is to say, they avoided the law by deferring its application.

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<sup>12</sup> Though 101 may tip the balance in cases where other rejections are pending.

<sup>13</sup> Even though 101 patentable subject matter issues appear in a quarter of 2018 appeals decisions, this share is still dwarfed compared to the share of decisions that mention, for example, “102” (, “103”, or “112” issues though note that these numbers are inflated because they do not include case specific limitations that can weed out false positives based on incidental mentions (such as “ 10/282102”)

<sup>14</sup> Crouch & Merges, *supra* note 9, at 1681–82.

<sup>15</sup> Described in Joseph Landau, *Bureaucratic Administration: Experimentation and Immigration Law*, 65 Duke L. J. 1173, 1180 (2016).

<sup>16</sup> Described *Id.*, at 1202-1204.

<sup>17</sup> *Id.* (also describing similar approaches for preventing the separation of military families and effecting gender asylum).

The USPTO could create a way for applicants to signal their desire to defer and hopefully avoid PSM issues, on the theory that cases could in many cases resolve, through allowance or abandonment, through resolution of less controversial, non-101 grounds.<sup>18</sup> But because 101 deferral could also be counterproductive, prolonging prosecution and withholding information that the applicant would have otherwise relied upon, I propose making 101 deferral optional, at applicant's discretion. This would preserve the benefits of compact prosecution and the freedom of prosecutors to select a slow or fast track for each application. Although some may worry that applicants will game play and deliberately delay with this option, it's unclear that 101-deferral would provide substantially greater opportunities to delay than existing continuation practice.

### *The Advantages of Experimentation*

Trying out applicant-initiated 101 deferral through a rigorous pilot has several advantages. First, unlike changing the law or its application which requires all to adjust, only applicants dissatisfied with the status quo would see a change. Applicants that don't have a problem with 101, which could well be the vast majority of them - 85% of office actions don't even include a PSM rejection, I've reported previously<sup>19</sup> - and those that examine their applications wouldn't need to alter their ways.

Second, implementing 101 deferral as a pilot with randomization, like the USPTO did when it conducted the post-trademark registration proof-of-use pilot, will support effective policy-making through evaluation, iteration, and refinement. In that pilot, the USPTO randomly selected 500 registrations to participate in the initial program to assess the accuracy and integrity of the trademark register.<sup>20</sup> Though companies selected to participate in the pilot had to comply with additional regulatory requirements, randomization ensured that the pilot's findings were representative and its burdens, fairly distributed.<sup>21</sup> The results of the test and related USPTO reports, outreach and

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<sup>18</sup> For example, if an invention is incurably anticipated, obvious or unsupported, the case will have been resolved without considering subject matter. Likewise, if the claims have been reformulated responsive to non-101 rejections and mooted any subject matter defects in the process, PSM will not factor into the application's outcome.

<sup>19</sup> Chien (Oct. 2018), *supra* note 1.

<sup>20</sup> Described in 77 FR 30197, *supra* note 11.

<sup>21</sup> 77 FR 30197, 30198 *supra* note 11 (explaining that randomness in the pilot was necessary to "ensure that the resulting assessment is *not skewed* by consideration of registrations with

deliberations were used to expand and make the program permanent.<sup>22</sup> A 101 deferral pilot could take a similar route. I explore design (intent-to-treat), ethical (through consent) and methodological (power, randomization, etc.) concerns and details below.

Finally, my proposal preserves the benefits of the status quo, including the little-discussed incentive prosecutors now have to add details to their patent applications and claims, a good thing. In work with students<sup>23</sup> that I presented at the Federal Trade Commission's recent hearings, building on an earlier analysis in IP Watchdog<sup>24</sup> by Will Gvoth, Rocky Bernsden, and Peter Glaser from Harrity & Harrity LLP, we observed that there has been a "flight to quality" among patent complaints and applications. Applying a differences-in-differences approach, we observed that specification length and counts of words and unique words in first claims have grown among software applications relative to others following *Alice*. (Figure 3A-C) Deferring 101 would preserve this previously unexplored, largely positive aspect of the "Mayo-Alice effect" on software patent drafting. If 101 were eviscerated by Congress, so too could the incentive to be more concrete in describing and claiming inventions.

### Implementing 101 Deferral through a Randomized Control Trial

Due to their rise in the wake of *Mayo* and *Alice*, 101 shares among appeals and last office actions pre-abandonment, as explored previously and below) present strong candidates for evaluation. From the baseline, then, we would expect to see declines in the proportion of 101 in appeals and office actions, and possibly a shorter pendency, among treated (101-deferred) as compared to control (101-not deferred) cases.

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particular criteria, and that implementation of the rules *does not create an unfair burden on specific types of trademark owners*").

<sup>22</sup> Department of Commerce, *Changes in Requirements for Affidavits or Declarations of Use, Continued Use, or Excusable Nonuse in Trademark Cases*, Federal Register 82 (2017) . <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-00317.pdf>

<sup>23</sup> Chien et al. *Flight from Quantity... Flight to Quality? A Differences in Differences Analysis of Patent Applications and Complaints Following Patent Reform?* (October 2018), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3320907](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3320907)

<sup>24</sup> Peter Glaser & William Gvoth, *Changes in Patent Language to Ensure Eligibility Under Alice*, IPWatchdog.com, Patents & Patent Law (2017), <http://www.ipwatchdog.com/2017/12/06/changes-patent-language-ensure-eligibility-alice/id=90721/>.

The USPTO could begin a pilot by offering applications in high impact art units that have a PSM rejection on the first office action a chance to defer.<sup>25</sup> Using an intent-to-treat design, the agency could then randomly grant deferral to half of participants,<sup>26</sup> using a process like rolling a die, picking out of a hat, or some other non-game-able criteria. All who wanted to defer 101 would participate, but by giving half of the group the right to do so and denying it to the other, the outcomes of otherwise identical groups could be compared.

The idea of offering deferral to some but not all applicants may seem unfair. But by their nature, policy pilots, for example the first action interview pilot program, which was initially available only to certain art units,<sup>27</sup> test out a policy on some and withhold it from others. In addition, the opt-in process should make clear that participants will receive a chance, not guarantee of deferral, minimizing any risk of unwanted surprise. Because the proposal implements 101 deferral as optional, not mandatory, an opt-in would not compromise external validity (the extent to which findings can be generalized beyond the test group).

To ensure that the results of a pilot yield statistically precise results requires sufficient “power” - that is, a large enough group of applications to detect differences in the treated group and control group, which ideally would be at least as large as the treated group. The minimum number of applications in which 101 was deferred would depend on the size and nature of the impact of the pilot program. There is always random variation between applications that can make it difficult to tell how effective an experimental treatment actually is. The larger the expected effect of any policy, the easier it is to find

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<sup>25</sup> In another “examiner-initiated” version of the treatment, examiners would, in randomly selected cases, forbear from applying 101 patentable subject matter in the first office action, or from making subject matter rejections until all other bases for rejection had been exhausted. Due to the desire to minimize the risk of introducing needless delays into cases, I do not favor this implementation. However, it would require a smaller sample size because it would not require compensating for uptake. What could be inferred would also be different - while the examiner-initiated version of the treatment would provide information about the impact of the treatment; rolling out the treatment at the initiative of the applicant would reveal the popularity of the concept, and also the impact of the treatment among “early adopters” which may differ from the general population in significant ways.

<sup>26</sup> Although one might be tempted to insert randomization earlier in the process, for example at the offer stage, this could introduce significant selection bias because those likely to take the offer are unlike those who decline the offer differ in important ways.

<sup>27</sup> USPTO, *Full First Action Interview Pilot Program* (June 7, 2011) available at <https://www.uspto.gov/web/offices/com/sol/og/2011/week23/TOC.htm#ref11> (announcement “expanding the Enhanced First Action Interview Pilot Program to all utility art areas.”)

that effect, and so fewer cases are required. For example, to reliably detect a difference in proportions of 20 percentage points, for example from a 80% last office action pre-abandonment rate of 101 rejections to a 60% rate would require only about 200 applications receiving deferral,<sup>28</sup> whereas to reliably detect a difference of 10 percentage points, for example, from a 25% PSM appeals rate to a 15% rate would require closer to 600-700 101-deferred cases.<sup>29</sup> Either way, rates of 101 rejections and appeals would be compared between the control and deferral groups using a chi-squared test. To detect statistically relevant differences in resolution time (as opposed to a difference in proportions), would require some estimation of the magnitude of the anticipated change, e.g. whether it was expected to be small, medium, or large. To detect a difference of as little as 4 months (on the basis of a 36-month current time to resolution estimate) would require about 1100 treated cases. Time to dispensation would be compared between the control and 101-deferred groups using a t-test.

Whatever the target number of total applications in the pilot, more applications will be required to compensate for imperfect compliance and attrition (e.g. someone dropping out early). As of early 2017, the USPTO sent approximately 300 MedDx and 2500 software and business (“36BM”) office actions per month,<sup>30</sup> some subset of which were first office actions. At an estimated prevalence of 101 rejections of 30%-40%,<sup>31</sup> a trial would involve applications filed over multiple months. Expanding the pilot to include other technology centers would result in more applications over the same period of time, but the expected difference in outcome metrics might be smaller, in turn requiring a larger sample size.

### Conclusion

If successful, the treatment would result in the diminished presence of 101 subject matter issues within *ex parte* appeals and rejections and, potentially, resolution time, e.g. closer to pre-*Mayo* or *Alice* levels. However, applicant and

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<sup>28</sup> Based on a power analysis in SAS 9.4 conducted to determine how many cases would be needed to detect differences of 3% to 30% at an alpha level of 0.05, resulting in a respective range of 84 to 7526 cases with 80% power. The code for replication is provided at <https://sites.google.com/view/colleenchien/about>

<sup>29</sup> Id.

<sup>30</sup> Author’s analysis - see “101 subject matter rejection analysis,” Detail 16-2017-01 sheet. Further, if the treatment applied only to “first office actions,” more time would be needed to achieve sufficient power.

<sup>31</sup> Author’s analysis.

prosecutor satisfaction with the process, changes made to what gets filed, timelines, and such factors would also be worth tracking. The conservation of USPTO resources and political capital, though harder to measure, also comprise desired outcomes.

How might such a test dovetail with other inventions, like updates to examiner guidance? Starting a trial to test “101 deferral” at a slightly different time than the guideline update would be consistent with standard experimental design. If the USPTO were to implement add 101-deferral onto another policy it was rolling out (e.g. guidance) , it could efficiently do so by specifying four groups: a pure control (“untreated”) group, one that received just the guidance, one that received just “101 deferral,” and one that received both treatments.<sup>32</sup> Assuming that examiners are trained in 101 guidance sequentially, it’s likely that all four cohorts would exist naturally anyway. Known as “factorial design,” this approach to experiments is used routinely when multiple interventions are being tested.

It should be noted that while deferring subject matter considerations would require be new for the USPTO, the practice is old. By bifurcating search and examination, the European Patent Office and the majority of the world, in effect vet novelty and nonobviousness issues first, and defer subject matter and other questions to the second phase of examination.<sup>33</sup> Why not give it a try here too? Your reactions and suggestions are welcome [here](#)<sup>34</sup> and will be shared with policymakers.

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<sup>32</sup> Using a factorial experimental design, described e.g. at Alan Montgomery, Tim Peters and Paul Little, *Design, Analysis and Presentation of Factorial Randomised Controlled Trials*, 3 BMC medical research methodology (2003), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC305359/>

<sup>33</sup> Colleen V. Chien, *Comparative Patent Quality*, 50 Arizona State Law Journal 68 (2018).

<sup>34</sup> SurveyMonkey, 101 Deferral Survey at <https://www.surveymonkey.com/r/D75KWXR>



**Figures:**

Figure 1A: Share of Office Actions Including a 101 Subject Matter Rejection

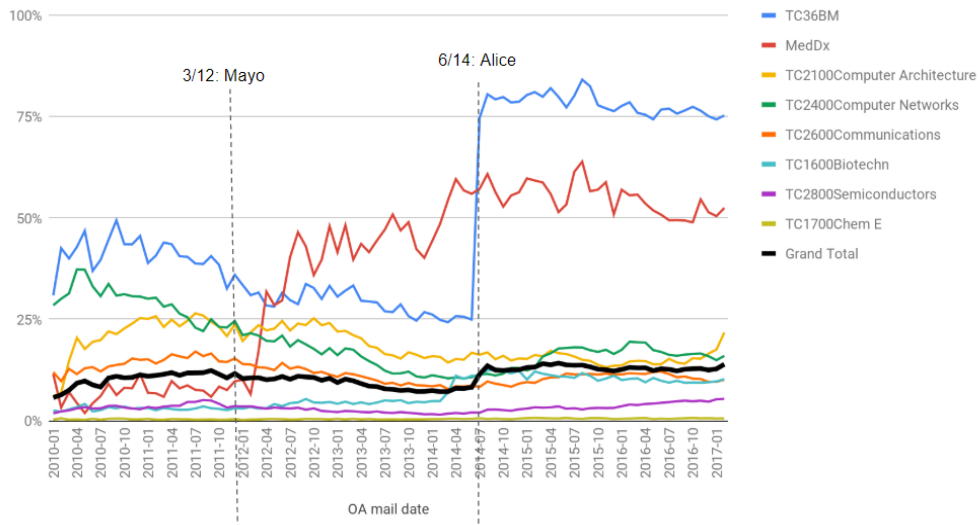
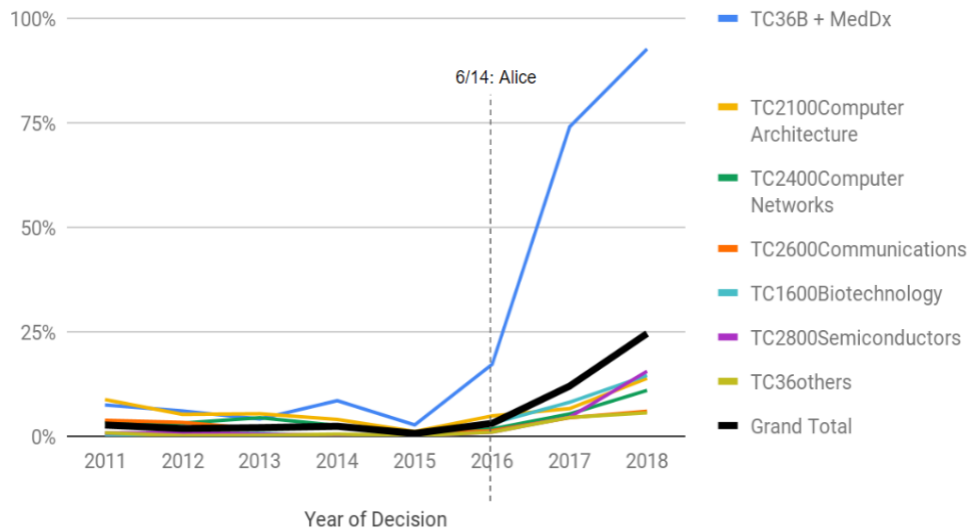


Fig 1B: Ex Parte Appeals Decisions Addressing 101 Subject Matter



\*Based on text search of decisions including "101 and (bilski or benson or alice or mayo or diehr or nuijten or ariosa or enfish or smartgene)," accuracy of which, based on manual inspection of 142 cases, correctly identified 138 of them. Excludes IPR/CBM, Interference cases.

Fig. 2: Share of Pre-Abandonment Office Actions Containing Only a 101 Rejection

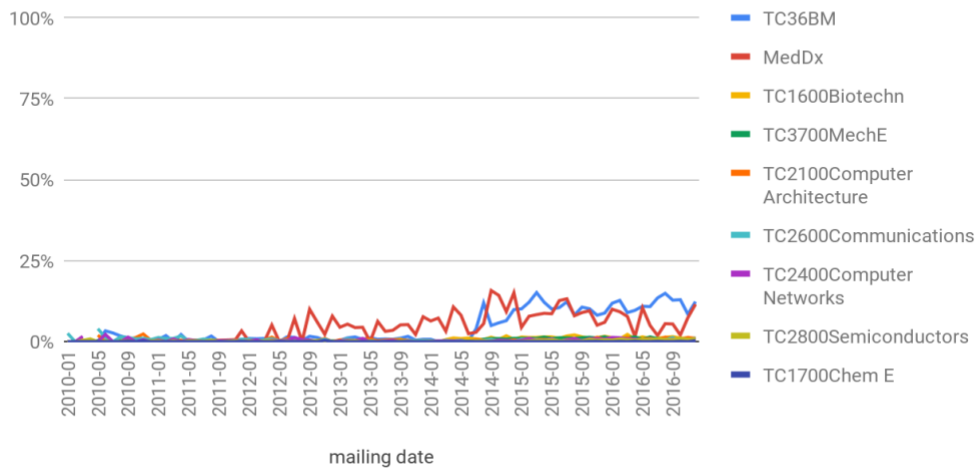
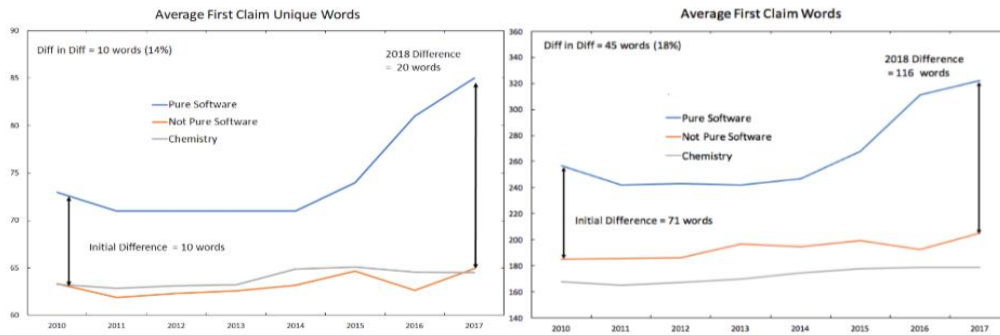
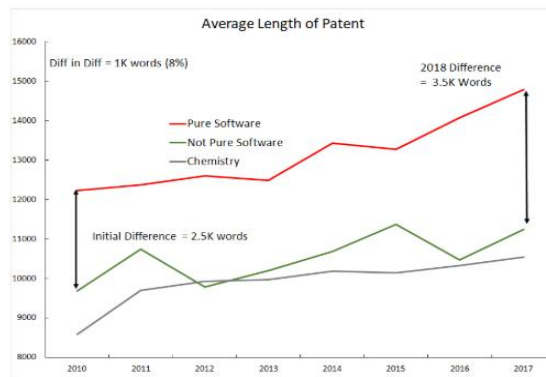


Figure 3A & 3B: Software First Claim Characteristics Before and After Alice (DiffNDiff)



From Chien et al., *Flight from Quantity, Flight to Quality?*, Originally presented to the FTC Roundtable on Intellectual Property and Innovation, Oct 23, 2018.

Figure 3C: Software Specification Length Before and After Alice (DiffNDiff)



From Chien et al., *Flight from Quantity, Flight to Quality?*, Originally presented to the FTC Roundtable on Intellectual Property and Innovation, Oct 23, 2018.

(Full presentation available at Chien et al., *supra* note 23)