Before the U.S. Patent and Trademark Office

In the Matter of Request for Comments on Patent Eligibility Jurisprudence Study

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Comments of

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The U.S. Patent and Trademark Office (USPTO) has requested public comments on "the current state of patent eligibility jurisprudence in the United States, and how the current jurisprudence has impacted investment and innovation."

We write as academics who have conducted empirical studies of the U.S. patent system. We have no relevant or material financial interests that relate to the research described in these comments. Rather, our interest is in seeing patent law develop in a way that improves social welfare, including by encouraging innovation and long-run productivity growth.

Many have argued—largely based on anecdotes or descriptive data—that recent changes in patent eligibility caselaw have either increased or decreased innovation. Here, in comments drawn in part from Ouellette and Williams (2020), we argue that neither view is supported by the available empirical evidence. Answering the question of whether limits on patent eligibility increase or decrease innovation requires specifying a counterfactual of how innovation would have evolved in the absence of these caselaw changes. Anecdotes and descriptive data are unable to provide such a counterfactual, and related empirical studies that do develop a rigorous counterfactual framework do not purport to answer the broad policy question of whether limits on patent eligibility increase or decrease innovation.

I. It is unclear whether limits on patent eligibility increase or decrease innovation.

A. Whether stronger patents increase or decrease research investments is theoretically ambiguous.

Theoretical models of patents originally focused on one central trade-off: society tolerates the cost of higher prices for patented products or processes in the short term (during the life of the patent) in exchange for these higher prices increasing the incentives for inventors to

develop new technologies (see e.g. Nordhaus 1969). These types of theoretical models generate the intuitive prediction that stronger—that is, longer or broader—patent terms will induce additional research investments. However, work by Suzanne Scotchmer and others considered the more realistic case where patents not only affect incentives for the development of an initial invention, but also affect subsequent innovation. In markets where innovation is cumulative—in the sense that inventions are themselves inputs into later follow-on discoveries—it is theoretically ambiguous whether stronger patents will increase or decrease innovation (see e.g. Scotchmer 2004).

B. Empirical evidence has not resolved whether patents increase research investments.

This theoretical ambiguity naturally suggests turning to empirical evidence for guidance. But unfortunately, the available evidence linking patents and research investments is mixed.

On one hand, Boldrin and Levine (2013) argue that there is no empirical evidence that patents increase innovation. Their 2008 book *Against Intellectual Monopoly* exposits a series of (largely historical) case studies suggesting that—to the contrary—patents tend to discourage research investments and innovation. Along similar lines, Petra Moser has argued that historical evidence from World's Fair exhibitions—for example, evidence that many award-winning innovations came from countries without patent laws—suggests that patents may discourage research investments (Moser 2005; Moser 2013).

On the other hand, Moscona (2021) presents causal evidence that the introduction of patent protection for plant biotechnology in the United States increased the development of novel plant varieties in affected crops and induced a variety of other benefits, including increased crop yields and agricultural land values. Less directly, Budish, Roin, and Williams (2015) provide evidence consistent with—although not conclusively in favor of—a strong positive relationship between patent terms and research investments in the context of cancer drug development. Haber (2016) takes a much stronger position in this direction, arguing that "the weight of the evidence supports the claim of a positive causal relationship between the strength of patent rights and innovation."

This mixed evidence could reflect differing effects of patents across industries. However, given the very small number of studies offering a rigorous causal test of how patents affect research investments, two of us have previously argued (Ouellette 2015; Williams 2017) that we currently lack sufficient evidence to inform the question of whether strengthening the patent system—through longer or stronger patents—would increase research investments and innovation, much less whether this benefit is large enough to outweigh patents' costs.

C. Because it is unclear how patents affect research investments, it is thus also unclear whether patent eligibility limits improve social welfare.

Despite this theoretical and empirical uncertainty, legal and policy decisions are nonetheless moving ahead.

On one hand, critics of the "patent troll" industry—who suggest that a raft of "weak" patents are hindering innovation—were largely pleased with the recent U.S. Supreme Court rulings (*Bilski v. Kappos*, *Mayo v. Prometheus*, *Association for Molecular Pathology v. Myriad Genetics*, and *Alice v. CLS Bank*) that imposed sharp limits on inventors' abilities to patent certain technologies (particularly software, medical diagnostics, and human genes) where patents have been argued to be problematic. The Supreme Court has described its restricted patent eligibility rules as an empirical judgment that allowing patents in ineligible categories "might tend to impede innovation more than it would tend to promote it" (*Alice*, 573 U.S. at 216). Although these cases have been applied in many areas of technology, the overwhelming majority of patentable subject matter cases have involved software and information technology—areas in which arguably frivolous patent litigation has caused particular concern (Lemley and Zyontz 2021).

On the other hand, advocates of the view that patents are critical to innovation were largely pleased with a 2019 bill proposed by Senators Tillis (R-NC) and Coons (D-DE) that sought to abrogate these Supreme Court decisions and reinstate firms' abilities to patent these types of technologies. These critics of the *Alice*/*Mayo* approach contend that reduced patent protection as well as unpredictability around the current legal definition of patent eligibility will negatively impact incentives to innovate, especially in areas such as medical diagnostics. After a lack of consensus from IP stakeholders stalled progress on the 2019 bill, Senators Tillis and Coons—joined by Senators Hirono (D-HI) and Cotton (R-AR)—have requested the USPTO to undertake the present study.

Choosing a side in this patent eligibility debate essentially requires taking a stand on whether patent protection in a given field of technology is good or bad for society. If patent protection is socially beneficial, patentable subject matter reforms like the Tillis–Coons legislation make sense; if patent protection is—at least in some markets—imposing social costs that outweigh their social benefits, then the Supreme Court's recent patent eligibility decisions make more sense. Yet as argued above, neither theory nor empirical evidence offers clear answers to this question. Ongoing academic research has started to generate empirical evidence on the practical implications of these recent Supreme Court decisions in specific fields, but as we describe in the following section, much more work is needed to inform future reform efforts in this area.

II. Current evidence does not demonstrate whether the *Alice*/*Mayo* framework is good or bad for social welfare in contested fields.

Debates over patentable subject matter have primarily involved two fields of innovation: the biotech/life sciences industry and the software/information technology industry. We consider each of these industries in turn. In both cases, it is unclear whether the new *Alice*/*Mayo* limits on patent eligibility have increased or decreased research investments and innovation, much less whether they have improved social welfare.

A. It is unclear whether patent eligibility limits increase or decrease innovation in biomedical markets.

Critics of the recent patentable subject matter restrictions argue that these rules stifle research and innovation by eliminating incentives to develop life-saving medical technologies. Supporters of the new *Alice*/*Mayo* test argue that patent protection in this market serves only to create hurdles that scientists and firms must navigate, raising the costs of research—and, downstream, prices associated with new technologies—without stimulating new investment. We argue that neither stance is supported by existing empirical work, and in our view, the available evidence fails to support any conclusion that the *Alice*/*Mayo* regime has either spurred or hindered biomedical innovation.

Evidence that can shed light on these questions needs to go beyond observed changes in research investments and technology development under new patentability rules. Rather, to draw a rigorous causal inference about the effect of *Alice*/*Mayo*, these observed changes must be benchmarked against a "counterfactual" scenario: what would investments have looked like *had there been no policy change*? That is, we are interested in the effect of *Alice*/*Mayo* on, for example, diagnostic technology investments relative to a world without *Alice*/*Mayo*, not the total change in diagnostic technology investments since *Alice*/*Mayo*. Of course, we never observe true counterfactuals. Instead, legal changes are sometimes implemented in a way that allows us to identify "plausible counterfactuals" using carefully designed research methodologies, from which we can disentangle the effects of patentability restrictions from other trends in the economy.

To understand how this sort of "natural experiment" might arise, consider a contrived hypothetical example. Say—counter to fact—that the Supreme Court ruled that discoveries related to cancers starting with odd-numbered letters (A, C, etc.—corresponding to e.g. acute lymphoblastic leukemia and cervical cancer) were patent-eligible, whereas discoveries related to cancers starting with even-numbered letters (B, D, etc.—corresponding to e.g. bladder cancer and ductal carcinoma in situ) were not. One might guess that, prior to this ruling, cancers starting with odd-numbered letters and cancers starting with even-numbered letters would have attracted similar amounts of scientific research funding: all else equal, we expect cancer research investments to be more driven by factors like

market size and scientific opportunity, rather than by whether the disease's first letter is even or odd. In this case, odd-numbered letter cancers can offer a reasonable counterfactual for how research investments on even-numbered letter cancers would have evolved in the absence of the court ruling.

Unfortunately, real-world markets have not yet offered opportunities to make this kind of comparison. In particular, patentability boundaries apply to entire technology classes, complicating efforts to identify comparable "treatment" and "control" groups. For example, in recent cases the Federal Circuit has generally held diagnostic claims unpatentable, whereas therapeutic claims are patent-eligible (see *Illumina v. Ariosa Diagnostics*, 967 F.3d 1319, 1325 (Fed. Cir. 2020)). But given the different scientific and regulatory requirements, there is no reason to expect diagnostics and therapeutics to have attracted similar research investments prior to these cases. Therapeutic investments thus cannot offer a reasonable counterfactual for how diagnostic investments would have evolved in the absence of recent limits on patent eligibility.

Against this background, let us now review the evidence cited by various sources arguing that the *Alice*/*Mayo* regime has either spurred or hindered biomedical innovation.

On one hand, some industry practitioners and academics have argued that biomedical research investments have declined as a result of *Mayo* and related decisions (e.g. Kilbride, U.S. Chamber of Commerce, 2019 testimony). For example, Taylor (2019) reports results from a survey of venture capital and private equity investors and argues that they "overwhelmingly indicated that the elimination of patents would either somewhat decrease or strongly decrease their firms' investments in the biotechnology (77%), medical device (79%), and pharmaceutical industries (73%)." Advocates for the pharmaceutical industry have cited historical investments in natural products—including the blockbuster cancer drug Taxol and the antibiotic penicillin—that they argue may not have occurred without the guarantee of patent protection (e.g. Derzko, Pharmaceutical Research & Manufacturers of America, 2019 testimony; Knowles, Knowles Intellectual Property Strategies, 2019 testimony; Sauer, Biotechnology Innovation Organization, 2019 testimony). One industry practitioner has noted examples of projects involving natural products—including cytotoxin research for tissue sarcoma and snake venom for multiple sclerosis—that experienced funding difficulties in the wake of changes in patent eligibility rules (Lefstin, Menell and Taylor 2018, p. 584).

Such survey data and anecdotes are valuable insofar as they provide practitioner perspectives on the patent system. However, survey data and anecdotes are unable to provide a counterfactual, and thus cannot support a causal conclusion about how *Alice*/*Mayo* has affected research investments. For example, historical investments into medicines derived from natural sources were made at a time when such inventions were eligible for patent protection, but that fact is insufficient to demonstrate that patent

protection was necessary for their development. Furthermore, patent protection is still available on a number of aspects of therapeutics derived from natural sources. More comprehensive analysis of projects that were discontinued due to patent eligibility concerns would provide a promising avenue for future empirical work.

On the other hand, defenders argue that the *Alice*/*Mayo* test has removed barriers to follow-on innovation, and thus increased research investments. These arguments frequently cite two empirical papers authored by one of us: Williams (2010) documents causal evidence that one non-patent form of intellectual property on human genes deterred follow-on innovation; Sampat and Williams (2019) document causal evidence that human gene patents do not appear to induce a similar chilling effect on follow-on innovation. These studies have been misinterpreted in the ongoing patent eligibility debate in two ways.

First, consider Ruane (ACLU, 2019 testimony), who argues that gene patents have a "chilling effect" on innovation, citing a report from the HHS Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) (2010) and Williams (2010). The SACGHS report presents eight detailed case studies that may not be representative. As explained above, Williams (2010) together with Sampat and Williams (2019) fail to support the view that gene patents have hindered follow-on innovation.

Second, consider Duan (R Street Institute, 2019 testimony), who asserts that if—as Sampat and Williams (2019) argue—gene patents have no impact on follow-on innovation, then *Alice*/*Mayo* does not impact this innovation ecosystem. This conclusion does not logically follow. Intellectual property rights on human genes may or may not have provided incentives for private investment in e.g. gene sequencing (as in the case of the private firm Celera's sequencing of the human genome); Sampat and Williams tackle the narrower question of whether—once discovered—patent rights on existing human genes affect follow-on innovation. Without measuring the possible incentive effects patents have on initial inventions, Duan's conclusion that *Alice*/*Mayo* will not impact innovation cannot be supported.

In summary, although arguments raised by critics and defenders of the *Alice*/*Mayo* framework propose a number of fruitful avenues for future empirical inquiry, the existing stock of evidence is inconclusive to support either position.

B. It is unclear whether patent eligibility limits increase or decrease innovation in software markets.

The other primary field of contestation over patent eligibility rules has been the software industry. Since *Alice* was decided in 2014, 90% of judicial decisions on patent eligibility have involved software and information technology, compared with 9% in biotech/life science and 1% in other industries (Lemley and Zyontz 2021). Critics of the *Alice*/*Mayo* test

argue that these rulings have undermined investment in the software industry, while supporters argue that the change in doctrine actually has increased investment by protecting innovative firms from the high costs of litigation pursued by patent-assertion entities (PAEs). As in the biomedical market, we argue that neither stance is supported by existing empirical work.

Determining the net effect of *Alice*/*Mayo* on software research investments is challenging for the same reason as in the biomedical industry: the new patentability restrictions apply across all fields of software innovation, making it difficult to construct any plausible counterfactual of what research investments would have looked like in the absence of this change. This is particularly true because the change in doctrine has occurred across numerous cases, spanning from at least the Federal Circuit's 2008 decision in *Bilski* to the Supreme Court's 2014 decision in *Alice*, making it difficult to pinpoint the timing of any changes in investments.

Thus, although supporters of current doctrine note that R&D investments in the software and internet industries have increased since *Alice* (e.g. USPTO 2017, p.26; Mohr, Software and Information Industry Association, 2019 testimony), these trends over time are difficult to link to any clear counterfactual of what R&D investment trends would have been in the absence of the *Alice*/*Mayo* changes. Similarly, although critics of current doctrine point to increased difficulty obtaining patent protection for software and information technology innovations (e.g. Kesan and Wang 2020; Kappos, Cravath, Swaine, and Moore LLP, 2019 testimony), firms have many non-patent alternatives for appropriating returns on their R&D investments, including trade secrecy.

Many of the arguments about the effect of *Alice* on the software industry have focused on PAEs—also known as non-practicing entities (NPEs) or patent trolls—that generate profits solely through patent licensing and litigation (see e.g. USPTO 2017, pp.25-26; Moss, Electronic Frontier Foundation, 2019 testimony). A number of researchers have documented evidence consistent with PAEs being problematic. For example, Feng and Jaravel (2020) find that PAEs primarily purchase and litigate patents issued by "lenient" USPTO examiners, which are more likely to be found invalid; Cohen, Gurun, and Kominers (2019) characterize firms targeted by PAEs and conclude that PAE litigation is opportunistic rather than value-creating. More generally, many software industry representatives support the *Alice*/*Mayo* regime because it allows firms to save litigation resources by providing a shortcut to invalidate low-quality patents in early-stage proceedings (see Gugliuzza 2019).

On the other hand, the above studies do not purport to provide an overall welfare analysis, and PAEs may have some beneficial effects. For example, Maurer and Haber (2018) argue that PAEs improve the functioning of patent markets by developing or purchasing patents that they then license to operating companies. Similarly, Haber and Levine (2014) argue

that PAEs increase the efficiency of technology markets and that the rise in patent litigation over the past few decades is not the result of strategic behavior by PAEs but rather reflects courts establishing the boundaries of patent rights for new, innovative technologies. Providing a shortcut to invalidate patents in early-stage proceedings creates a risk that courts will erroneously invalidate socially beneficial patents without an adequate factual record. To the best of our knowledge, no research teams have made a clear case that allowing PAEs to operate is either welfare-increasing or welfare-reducing.

In summary, as with biomedical markets, software markets have not yet offered opportunities to construct a clean experiment for assessing how innovation changed because of the *Alice*/*Mayo* decisions.

III. Policy experiments could inform the question of how patent eligibility limits shape research investments.

Our argument that the available evidence neither supports nor refutes the *Alice*/*Mayo* framework leaves a clear question: what should guide policy decisions at times when evidence is not available? To this question, we have two responses.

First, uncertainty is not an excuse for inaction. The USPTO, Congress, and other institutions focused on increasing innovation should look for opportunities to support research that can deepen the evidence base in this area. The USPTO, for example, could issue a call for proposed prospective randomized studies designed to produce rigorous empirical evidence on these questions. Such collaborative randomized trials are frequently conducted for other U.S. government agencies such as the Centers for Medicare and Medicaid Services (CMS), and could fruitfully be applied to this patentable subject matter debate as well as other key innovation policy questions. Ho and Ouellette (2020) illustrate how patent examination can be studied through a randomized field experiment, and Ouellette (2015) and Chien (2019) provide additional examples of how randomization can be used to improve evidence-based policymaking in patent law. Many academic teams would welcome the opportunity to collaborate with innovation agencies on piloting and rigorously evaluating the most promising policy interventions.

Second, we would emphasize the value of creating certainty for market participants. The *Myriad* ruling is a good example. While reasonable individuals may agree or disagree with the decision, the ruling that cDNA (complementary DNA) is patentable whereas gDNA (genomic DNA) is not is at least a clear rule around which markets can adjust—although the Supreme Court did not make clear how to apply this rule to other natural products. Ideally, *Myriad* would have been based on empirical analyses suggesting that the social cost-benefit analysis for patents on cDNA is more favorable than for patents on gDNA. But even if policymakers do not offer such a justification, the distinction between patentable and unpatentable subject matter ought to at least be clear to market participants. The *Alice*

ruling, in contrast, unfortunately delineates much less clearly which types of technologies are affected versus unaffected. The boundary between unpatentable abstract ideas and patent eligible subject matter remains uncertain and contested, as illustrated by the Federal Circuit's 6–6 denial of rehearing en banc in *American Axle v. Neapco Holdings*, 966 F.3d 1347 (Fed. Cir. 2020), with no fewer than five separate opinions from the twelve judges. Efforts to clarify the boundaries of past rulings would be valuable.

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