Fixing Alice

The US courts and patent office have spent years trying to solve issues created by *Alice*, but is it working? **Michael Jacobs** and **Barbara Barath** assess

Nearly five years after the Supreme Court's *Alice* decision led to a spike in patent eligibility challenges under 35 USC § 101, Federal Circuit Judge Jay Plager wrote that "the law ... renders it near impossible to know with any certainty whether [an] invention is or is not patent eligible."[1]

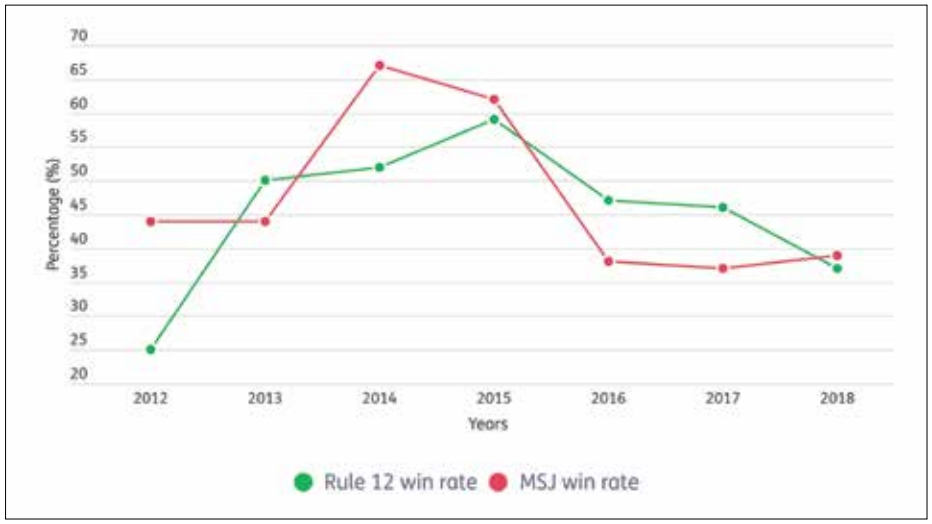
In the last year, Congress, the Federal Circuit, and the United States Patent and Trademark Office (USPTO) have pushed to expand the scope of eligibility and make pleading-stage eligibility challenges more difficult.

Alice led to a spike in Section 101 challenges

In *Alice Corp v CLS Bank International*,[2] the Supreme Court set forth a framework that seemed to make patent eligibility challenges to software patents easier. Under *Alice*, a court must determine: (1) whether challenged claims are directed to a patent-ineligible concept (eg, laws of nature, natural phenomena, and abstract ideas) and (2) if so, whether an "inventive concept" transforms the nature of the claims into a patentable application of that concept.

At first blush *Alice's* impact on challenger win rates appears limited (figure 1[3]). Pleading-stage motion win rates (Rule 12 win rate) increased from 25% in 2012 to 50% in 2013, even before *Alice* issued. Rule 12 refers to motions to dismiss (under Federal Rule of Procedure 12(b)(6)) and motions for judgment on the pleading (under Federal Rule of Procedure 12(c)). The win rates are the number of times that the party challenging patent validity got a complete win (as opposed to a loss or partial win). After peaking at 59% in 2015, win rates have declined to 37%, below pre-*Alice* levels. While summary judgment (MSJ) win rates increased from 44% in 2012 to 67% in 2014, they have now dipped below pre-*Alice* levels to just under 40%.

Figure 1: Impact of *Alice* on challenger win rates
Source: Docket Navigator



As illustrated in figure 2, however, the number of pleading-stage eligibility challenges – and thus the number of patents invalidated – increased significantly after *Alice* (figure 2).

In the last year, the Federal Circuit, Congress, and the USPTO chipped away at *Alice*.

The Federal Circuit and USPTO confirmed that pharmaceutical patents claiming the application of natural relationships can be patent-eligible. *Alice* and its predecessors foreclosed identifying any "inventive concept" in the discovery of natural relationships.[4] Accordingly, courts repeatedly held ineligible even groundbreaking discoveries in the pharmaceutical industry – including those that revolutionised prenatal care,[5] and heart

Figure 2: Impact of *Alice* on pleading stage eligibility challenges
Source: Docket Navigator

disease diagnosis.[6] Such decisions raised the ire of biopharmaceutical industry groups.

On 13 April 2018, the Federal Circuit's decision in *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals*[7] created a safe haven for certain pharmaceutical patents. The patent at issue related to a method of treating schizophrenia patients and recognised a natural relationship (between an individual's ability to metabolise a drug with the proper dosage for that individual). The court held that the patent nevertheless was valid because, unlike the patent in *Mayo*, it actually "claimed an application of that relationship" and was directed to "a method of treating patients based on this relationship."[8]

This decision prompted the USPTO to issue a guidance to its examining corps confirming that "[m]ethod of treatment claims (which apply natural relationships as opposed to being 'directed to' them)" are not implicated by *Mayo* "because they 'confine their reach to particular applications'".[9]

The Federal Circuit's decision along with the USPTO's guidance are likely to provide some relief to the biopharmaceutical industry.

Congress proposed new eligibility standards

Last year, several intellectual property groups proposed legislation to clarify eligibility standards. For example, the Intellectual Property Law Association of Chicago ("IPLAC") proposed a single exception to subject matter eligibility, "If and only if the claimed invention as a whole exists in nature independently of and prior to any human activity, or exists solely in the human mind."[10]

In June 2018, Representatives Thomas Massie, R-Ky, and Marcy Kaptur, D-Ohio, introduced a bill – called the "Restoring America's Leadership in Innovation Act" – adopting IPLAC's proposal. The bill states its intention to "effectively abrogate" *Alice* and "ensure that life sciences discoveries, computer software, and similar inventions and discoveries are patentable, and that those patents are enforceable."[11]

"The Restoring America's Leadership in Innovation Act and the USPTO's new guidance both reflect a desire to increase patent protection after the surge in eligibility challenges post-*Alice*."

USPTO adopts new guidance on how to apply Alice step one

While the wheels of change turned in Congress, the USPTO issued new guidance for eligibility determinations by its examiners.

The January 2019 *Revised patent subject matter eligibility guidance* synthesises "abstract ideas" as falling into three categories: (1) mathematical concepts, (2) certain methods of organising human interactions, and (3) mental processes. The guidance also sets forth a revised procedure to determine whether a claim is "directed to" a judicial exception under *Alice* step one. An examiner must determine whether (1) a claim recites a judicial exception (ie, law of nature, natural phenomenon, or abstract idea) and (2) if it "integrates the exception into a practical application."[12] Only when a claim recites a judicial exception and fails to integrate the exception into a practical application, is the claim "directed to" a judicial exception, requiring analysis under *Alice* step two. The Restoring America's Leadership in Innovation Act and the USPTO's new guidance both reflect a desire to increase patent protection after the surge in eligibility challenges post-*Alice*.

Federal Circuit makes Alice step two harder?

In a pair of cases early this year, the Federal Circuit potentially made early-stage eligibility challenges more difficult.

In *Berkheimer*, the court held that "whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact."[13] The court also cautioned that disclosure in the prior art does not mean something is well-understood, routine, or conventional under *Alice* step two.[14]

But the court left open the door to early resolution of patent eligibility:

- First, the court confirmed that patent eligibility can be "resolved on motions to dismiss or summary judgment."[15]
- Secondly, the court highlighted an avenue for arguing that no issues of fact remain. Claims must "capture" any purported improvements.[16] Where the claims failed to capture purported inventive concepts, the court found that there was no factual dispute.

Despite these concessions to early resolution, the Federal Circuit reaffirmed its growing concern with pleading-stage challenges in *Aatrix*. There, it found that patent eligibility can be determined at the pleading stage "only when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law."[17]

Berkheimer and *Aatrix* immediately affected patent examination standards. The USPTO responded in August 2018 with new guidance that makes it harder to reject an application as invalid under Section 101. The guidance permits an examiner to conclude that an element represents well-understood, routine, conventional activity only when he "can readily conclude that the element is widely prevalent or in common use in the relevant industry" and can cite express statements in the specification/prosecution, court decisions, or a publication to support that conclusion.[18]

An examiner can take official notice of the conventional nature of an element only when he is certain of that nature based upon his personal knowledge. This guidance likely will make it easier for patentees to defeat eligibility challenges before the USPTO.

But *Berkheimer*'s and *Aatrix*'s impact on litigation has yet to be seen. As shown in figure 3, district courts continued last year to invalidate patents at near-2017 rates.[19] While pleading-stage win rates declined slightly, win rates for motions for summary judgment (MSJ) actually increased. Of the approximately 120 orders that issued since *Aatrix,* approximately 40 were granted in their entirety. Of the approximately 55 that were denied in their entirety, only around 20 were denied as a result of factual disputes relating to *Alice* step two.

District courts continued to grant eligibility challenges where:

- The specification makes clear that the claimed methods or components were well-known;[20]
- The claims do not capture the alleged inventive concept; or[21]
- The asserted inventive concept is the abstract idea or law of nature itself.[22]

The Federal Circuit also recently rejected a patent owner's assertions – that the claimed methods were "novel" and "improve the technology used in electronic communications" – as "not factual in nature, but conclusory legal assertions which the district court was not bound to accept as true."[23]

In fact, the Supreme Court may review *Berkheimer* and decide "[w]hether patent eligibility is a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of the art at the time of the patent."[24] It likely will be several months before the court makes a *cert* decision.

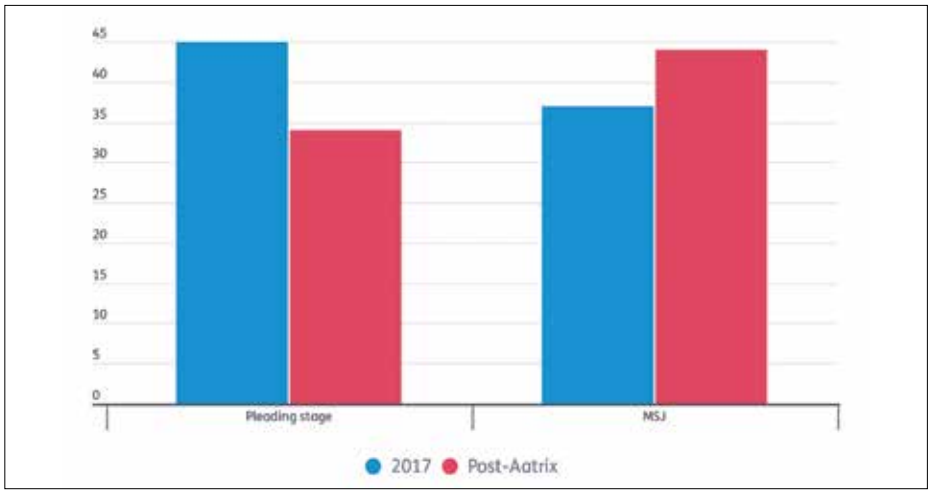
Summary

With the Federal Circuit, USPTO, and Congress apparently intent on strengthening patent protection and the Supreme Court poised to weigh in on eligibility standards again, *Alice*'s heyday may be coming to an end. But, at least for now, courts appear to be finding no dispute of fact about *Alice* step two and invalidating patents at pre-*Aatrix* levels.

Footnotes

1. *Interval Licensing LLC v AOL, Inc,* 896 F.3d 1335, 1348 (Fed Cir 2018).
2. 573 US 208 (2014).
3. This data is from Docket Navigator; Legal Issue "35 USC 101" (2012 to December 2018). Data in this article understates win rates because partial grants and denials were considered a win for the patent holder.
4. See, eg, *Mayo Collaborative Services v Prometheus Laboratories, Inc,* 566 US 66 (2012) (method for determining correct Crohn's disease medication dosage patent-ineligible).
5. *Ariosa Diagnostics, Inc v Sequenom, Inc,* 788 F.3d 1371 (Fed Cir 2015).
6. *Cleveland Clinic Foundation v True Health Diagnostics LLC*, 859 F.3d 1352 (Fed Cir 2017).
7. 887 F.3d 1117 (Fed Cir 2018).
8. Id at 1135-36.
9. https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.pdf
10. https://patentdocs.typepad.com/files/2018-04-19-ilpac-letter.pdf
11. HR 6264 (Sec 7(b)(3)).
12. https://federalregister.gov/d/2018-28282
13. *Berkheimer v HP Inc*, 881 F.3d 1360, 1367-68 (Fed Cir 2018) (reversing summary judgment of ineligibility).
14. Id at 1369.
15. Id at 1368.
16. Id at 1370.
17. *Aatrix Software, Inc v Green Shades Software, Inc*, 882 F.3d 1121, 1125 (Fed Cir 2018) (reversing grant of motion to dismiss).
18. Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v HP, Inc*), available at https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.pdf
19. This data is from Docket Navigator; Legal Issue "35 USC 101" (14 Feb 2018 to Dec 2018).
20. See, eg, *Hyper Search, LLC v Facebook, Inc*, Case No. 17-cv-1387 (D Del, 17 Dec 2018).
21. See, eg, *Valmont Industries, Inc v Lindsay Corporation and Lindsay Sales & Services, LLC*, Case No. 15-42-LPS (D Del, 14 Nov 2018).
22. See, eg, *Consumer 2.0, Inc d/b/a Rentey v Tenant Turner, Inc*, Case No. 2:18-cv-355 (E D Va, 1 Nov 2018).
23. *Glasswall Sols Ltd v Clearswift Ltd*, No. 2018-1407, 2018 WL 6720014, at *2 (Fed Cir 20 Dec 2018); see also *Umbanet Inc v Epsilon Data Mgmt, LLC*, No. 2017-2556, 2018 WL 6444523 (Fed Cir, 10 Dec 2018) (Rule 36 affirmance of motion to dismiss grant despite patentee's argument that lower court improperly ignored factual allegations).
24. https://www.supremecourt.gov/DocketPDF/18/18-415/65216/20180928162630738_36823%20pdf%20Hong%20l%20br.pdf

Figure 3: District court litigation win rates after *Aatrix Software, Inc v Green Shades Software* in 2018. Motion for summary judgment (MSJ)
Source: Docket Navigator



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