



SPECIAL REPORT

2020 IP LAW YEAR IN REVIEW

PATENTS

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**McDermott
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EXECUTIVE SUMMARY

In 2020, the US Supreme Court and Court of Appeals for the Federal Circuit continued to refine key aspects of intellectual property law on issues that will have an impact on litigation, patent prosecution and business strategy. This *Special Report* discusses some of the most important decisions.

The Federal Circuit issued several panel decisions clarifying the bounds of patent-eligible subject matter in the area of life sciences and computer technology. In the life sciences space, the court found several patents satisfied the conditions for patent eligibility. For example, the Federal Circuit found patent-eligible claims directed to preparing a fraction of cell-free DNA enriched in fetal DNA, claims directed to a method of operating a flow cytometry apparatus with a number of detectors to analyze at least two populations of particles in the same sample to be patent eligible, and claims directed to a method of treating type 2 diabetes mellitus using a DPP-IV inhibitor. In the area of computer technology, the court clarified that claims directed to an improvement to computer networks were patent eligible, but that claims directed to applying longstanding commercial practices to generic computer components remain ineligible. Given the uncertainty of patent eligibility law, questions surrounding life sciences and computer-related technology will continue to be raised in cases.

The Supreme Court issued one decision in 2020, in which it found that the Patent Trial and Appeal Board's application of the time bar for filing a petition for *inter partes review* (IPR) is not appealable. The Federal Circuit issued two *en banc* decisions, including one decision confirming discussing the use of the phrase "consisting essentially of" in patent claims and patent eligibility of mechanical inventions.

Following on the heels of the Supreme Court's 2017 *TC Heartland v. Kraft Foods* decision addressing patent venue, the Federal Circuit addressed patent venue in Hatch-Waxman litigation. The court explained that for the purposes of determining venue, infringement occurs only in judicial districts where actions related to the submission of an abbreviated new drug application (ANDA) occur, and not in all locations where future distribution of the generic products specified in the ANDA is contemplated. This ruling may have far-reaching consequences, including the ability for ANDA defendants to effectively control venue for litigation.

§ 101 DECISIONS IN 2020

In 2020, the Federal Circuit continued delineating patent-eligible subject matter from patent-ineligible subject matter. Subject matter eligibility under the two-step *Alice/Mayo* framework requires determining (1) whether the claims are directed to a “patent-ineligible concept,” such as an abstract idea, a law of nature or natural phenomenon, and if so, (2) whether the claim elements “transform the nature of the claim” into a patent-eligible application. The Federal Circuit this year also shed light into the weight of the USPTO’s 2019 Revised Patent Subject Matter Eligibility Guidance. In *In re: Christopher John Rudy*, 19-2301 (Fed. Cir. 2020) (*IP Update, May 2020*), the Federal Circuit explained that neither the guidance nor its October Supplement are binding on the court’s patent eligibility analysis. Questions surrounding subject matter eligibility remain, but the Supreme Court did not hear § 101 cases in 2020.

PATENT-ELIGIBLE SUBJECT MATTER

LIFE SCIENCES

The Federal Circuit reversed several district court decisions of § 101 patent-ineligibility for method claims in the life sciences. In *Boehringer Ingelheim Pharms., Inc. v. Mylan Pharms., Inc.*, 19-1172 (Fed. Cir. Mar. 16, 2020), the Federal Circuit explained that a claim directed to a “particular method of treatment,” such as a “method of treating type 2 diabetes mellitus using a DPP-IV inhibitor” is patent-eligible subject matter.

In March, the Federal Circuit in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 19-1419 (Fed. Cir. Mar. 17, 2020) (*IP Update, Apr. 2020*) decided that “method of preparation” claims, unlike patent-ineligible

diagnostic or patent-ineligible method of treatment claims, are patent eligible. The Federal Circuit decided that Illumina’s claims directed to methods of preparing a fraction of cell-free DNA enriched in fetal DNA was patent-eligible subject matter. This method solved an identified problem of separating the small amount of fetal DNA from the vast amount of maternal DNA in the mother’s blood based on a 500 base-pair threshold. Then in *August*, the Federal Circuit issued a modified opinion, explaining that the claims are directed to the exploitation of a natural phenomenon as a method to prepare a mixture enriched in fetal DNA by separation from maternal DNA according to a threshold size of a human engineered parameter.

Then in *XY, LLC v. Trans Ova Genetics, LC*, 19-1789 (Fed. Cir. July 31, 2020) (*IP Update, Aug. 2020*), the Federal Circuit found claims directed to a method of operating a flow cytometry apparatus with a number of detectors to analyze at least two populations of particles in the same sample to be patent eligible. These claims relating to technology for sex selection of non-human mammals via a method of sorting particles using flow cytometry technology to classify and sort particles into at least two populations are an improved method.

MEDICAL DEVICES

The Federal Circuit also reversed district court opinions of patent-ineligibility in the medical device field. In *CardioNet, LLC v. InfoBionic, Inc.*, 19-1149 (Fed. Cir. Apr. 17, 2020) (*IP Update, Apr. 2020*), the Federal Circuit decided that claims directed to an improved cardiac monitoring device are not abstract but are patent-eligible subject matter. These claims are directed to using electrodes on an individual’s skin to measure electrical signals from the heart and determining variability in the heart rate to detect and distinguish atrial fibrillation and atrial flutter from other forms of cardiac arrhythmias. The claims focus on a “specific means or method that improves”

cardiac monitoring technology. They are not “directed to a result or effect that itself is the abstract idea” and they do not merely invoke generic process and machinery. The Federal Circuit also pointed to the patent specification that explains the technical advantages offered by the system, including the higher accuracy in detecting the occurrence the cardiac arrhythmias and allowing for reliable and immediate treatment of the medical conditions by avoiding false positives and negatives.

Another case in the field of medical devices addressed § 101 issues found in the printed matter doctrine. In *C R Bard Inc. v. AngioDynamics, Inc.*, 19-1756, -1934 (Fed. Cir. Nov. 10, 2020) (*IP Update, Nov. 2020*), the Federal Circuit found that claims relating to printed matter that fulfill a specific need for easy vascular access during imaging are patent eligible because the claims are not “directed solely to non-functional printed matter” and have an inventive concept. Printed matter is information claimed for its communicative context, and it is patentable if it creates a new functionality in the claimed device or causes a specific action in the claimed process. These claims are directed at identifying a power-injectable vascular access port and a method of performing a power-injection procedure. The radiographic marker on the invention, in the form of letters, symbols, patterns or characters, makes the claimed port particularly useful because it would allow the implanted device to be readily and reliably identified via X-ray.

COMPUTER TECHNOLOGY

In the realm of computer-based technologies, the Federal Circuit found improvements to a function or solutions to problems in the field patent-eligible subject matter. For example, in April, the Federal Circuit in *Uniloc USA, Inc. v. LG Electronics USA, Inc.*, 19-1835 (Fed. Cir. Apr. 30, 2020) (*IP Update, May 2020*), decided that claims changing the normal operation of a communication system to overcome a problem specifically arising in computer networks are

patent eligible. Conventional systems with primary and secondary stations experienced long delays in sending data. These claims improve on the conventional communication system to enable a rapid response time between primary and secondary stations. The Federal Circuit explained that in the cases involving software innovations, the first step of the patent-eligibility analysis could depend on if a claim’s focus is “on specific asserted improvements in computer capabilities,” and that claims “directed to improvements to the functionality of a computer or network platform itself” are routinely found eligible. These claims are directed to an improvement of computer functionality, specifically enabling the primary station to simultaneously send inquiry messages and poll secondary stations. This reduced delays present in conventional systems, which is more than merely combining or manipulating data.

The Federal Circuit found patent-eligible claims in *Packet Intelligence LLC v. Netscout Systems, Inc.*, 19-2041 (Fed. Cir. July 14, 2020) (*IP Update, July 2020*) for claims providing a technical solution to a technical problem directed to collection, comparison and classification of information. More specifically, these claims are directed to a system and method to monitor packets exchanged over a computer network. The problem in the art was that prior art monitors could not identify disjointed connection flows as belonging to the same conversational flow. The Federal Circuit explained that the claim solves a challenge unique to computer networks, identifying disjointed connection flows in a network environment so that the different connection flows can associate with each other and with an underlying application or protocol.

PATENT-INELIGIBLE SUBJECT MATTER

Having discussed patent eligibility, the discussion turns to the other side—patent ineligibility. The Federal Circuit found multiple computer technology-based claims patent ineligible, summarized below via

the *Alice/Mayo* steps. In view for 2021 are the *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 18-1763 (Fed. Cir. July 31, 2020) (*IP Update*, Aug. 2020) method claims relating to manufacturing driveline propeller shafts, where the Federal Circuit, in a modified opinion, decided that one claim may be patent eligible due to a “positioning” limitation and remanded but held the others ineligible.

Customedia Techs., LLC v. Dish Network Corp., 18-2239 (Fed. Cir. Mar. 6, 2020) (*IP Update*, Mar. 2020)

- Claims were directed to data management and processing systems for storing advertising data, describing a remote account-transaction server and local host data management system and audio/video processor recorder-player.
- Step 1: This was an abstract idea of using a computer to deliver targeted advertising to a user, improving a user’s experience while using a computer application but not improving the function of the computer itself. The computer was merely a tool.
- Step 2: The patent specification acknowledged that the claimed storage device could merely be any storage device for audio/video information or digital or analog signal receiver and/or transmitter capable of accepting a signal. Aside from the abstract idea of delivering targeted advertising, claims recited only generic computer components.

Elec. Commc’n Techs., LLC v. ShoppersChoice.com, LLC, 19-1587 (Fed. Cir. May 14, 2020) (*IP Update*, May 2020)

- Claims were directed to a system allowing a user to select authentication information to be included with a future delivery notification and indicate the notification as legitimate, reciting computer components and a program code associated to six functions.

- Step 1: Two functions, monitoring the location of the package and notifying a party in advance of its arrival, were already existing business methods. Other functions, like including authentication information, such as a phone number or partial credit card number, were longstanding commercial practice and abstract, amounting to nothing more than gathering, storing and transmitting information.
- Step 2: Claims applied longstanding commercial practice using generic computer components and technology. The Federal Circuit stated that the claim “merely invoke[d] well-understood, routine, conventional components and activity to apply the abstract idea.”

Ericsson Inc. v. TCL Commc’n Tech. Holdings Ltd., 18-2003 (Fed. Cir. Apr. 14, 2020) (*IP Update*, Apr. 2020)

- Claims were directed to a method and system for limiting and controlling access to resources in a telecommunications system, specifically an access controller to access software services comprising an interception module, a decision entity and security access manager.
- Step 1: The claims were directed to the “bare” abstract idea of controlling access or limiting permission to resources by receiving a request, then determining if the request for access should be granted. The Federal Circuit explained that the access controller, security access manager, decision entity and interception module elements were the same.
- Step 2: The allegedly novel aspects that were argued as fulfilling this analysis step were “wholly missing” from the claims. The Federal Circuit explained that even though these aspects were described in the specification, the aspects could not be imported into the claims.

Simio, LLC v. Flexsim Software Products, Inc., 20-1171 (Fed. Cir. Dec. 29, 2020) (*IP Update*, Jan. 2021)

- Claims were directed to a computer-based system, using graphics instead of programming to create object-oriented simulations.
- Step 1: The claims' focus was on an abstract idea of using graphics instead of programming to create object-oriented simulations. Agreeing with a district court's "thoughtful" opinion, the Federal Circuit decided the claims were directed to a "decades old computer programming practice[.]" merely improving a user's experience while using a computer application without an improvement in computer functionality.
- Step 2: Even a new idea may be abstract. The idea of using graphics instead of programming to create object-oriented simulation may be a new idea but it was still abstract. The executable-process limitation was conventional or known in object-oriented programming.

2020 AT THE SUPREME COURT

At the beginning of 2020 the Supreme Court appeared poised to take on multiple patent cases, but a series of *cert* denials resulted in only one decision from the High Court in 2020. The Supreme Court avoided entering the Section 101 debate by denying *certiorari* for a number relevant patent cases including *Athena Diagnostics Inc. v. Mayo Collaborative Services, LLC*, No. 19-430 (2020) (*IP Update*, Vol. 22, No. 2) and *Chamberlain Group, Inc. v. One World Techs., Inc.*, No. 19-1299 (2019) (*IP Update*, Jan. 2020). The Court also denied *cert* in various cases relating to whether the America Invents Act (AIA) violates the Takings Clause of the Fifth Amendment, including *Collabo Innovations v. Sony Corp.* No. 19-601 (2019) (*IP Law Year in Review – 2019*).

The only patent decision to come from the Supreme Court in 2020 was *Thryv, Inc. v. Click-to-Call Techs., LP*, 590 US ___ (2020), in which the Court held that 35 USC §314(d) precludes judicial review of the Patent Trial and Appeals Board's (PTAB) application of §315(b)'s one-year time bar. The Court largely reiterated its reasoning in *Cuozzo Speed Techs., LLC v. Lee*, 579 US ___ (2016) (*IP Update*, Vol. 19, No. 7) stating that because the § 315(b) time bar is "closely tied to the application and interpretation of statutes related to" the institution determination, a party may not appeal the PTAB's application of the one-year time bar of § 315(b). In a lengthy dissent, Justice Neil Gorsuch argued that § 314(d)'s prohibition on appeal applied only to the subsections "under this section" of § 314, as explicitly stated in the text of the statute, especially given the strong presumption in favor of judicial review.

ARTHREX DECISION

The US Supreme Court is scheduled to hear arguments in March in *US v. Arthrex Inc*, No. 19-1434 on the constitutionality of the PTAB, a forum that has become a central piece of US patent litigation since its formation by the AIA in 2012. The Supreme Court is reviewing the 2019 decision of the US Court of Appeals for the Federal Circuit finding the appointment of Administrative Patent Judges (APJs) unconstitutional under the Appointments Clause because of a lack of adequate oversight and resolving the issue by making it easier to remove APJs. The case can potentially have far-reaching implications on the future of the PTAB and the thousands of decisions it has rendered over the past decade.

Through the AIA, Congress sought to create in the PTAB a cost-effective and efficient alternative to federal district court patent litigation. The PTAB has since become a staple of patent litigation, with more than 12,000 petitions filed since the PTAB's formation. Although institution rates have fallen in recent years, more than half of all petitions are still instituted, and happenings at the PTAB can have

significant effects on parallel litigations in other forums, like district court or the International Trade Commission (ITC). For example, district courts have been influenced by claim constructions in PTAB proceedings, even where petitions have been denied, and the ITC has suspended enforcement of remedial orders pending appeal of PTAB decisions of unpatentability, relying on the PTAB's lead role in assessing patent validity.

In 2019, the Federal Circuit ruled in *Arthrex Inc. v. Smith & Nephew, Inc.*, 18-2140 (Fed. Cir. Oct. 31, 2019) that the appointment of APJs to the PTAB was unconstitutional. It found APJs acted as principal officers and their appointment without Senate approval violated the Appointments Clause of the Constitution, which mandates that principal officers be appointed by the president with the advice and consent of the Senate. APJs, in contrast, are appointed by the Secretary of Commerce. Despite this finding, the Federal Circuit declined to invalidate decisions made by unconstitutionally appointed APJs. Instead, the Federal Circuit cured the defect by severing the portion of the AIA that provided for-cause removal protections to APJs, thus making them inferior officers whose appointments do not require Senate approval. As inferior officers, APJs could continue in their duties without violating the Appointments Clause.

As a result of the *Arthrex* decision, the Federal Circuit vacated more than 100 PTAB decisions where the parties preserved an Appointment Clause challenge on appeal and remanded those decisions back to the PTAB for proceedings before newly designated APJ panels. Only cases predating the *Arthrex* decision were affected. After denial for rehearing *en banc* at the Federal Circuit, the chief APJ issued an order to avoid burdening the US Patent and Trademark Office, holding all remanded cases under *Arthrex* in administrative abeyance until the Supreme Court acted on a petition for certiorari. Those cases remain pending.

Last October, the Supreme Court granted *certiorari* for three petitions filed separately by the US Government and Smith & Nephew and Arthrex,

which have been consolidated for briefing and oral argument. The Supreme Court granted *certiorari* on two issues: (1) whether, for purposes of the Appointments Clause, APJs are principal officers who must be appointed by the President with the Senate's advice and consent, or inferior officers whose appointment Congress has permissibly vested in a department head; and (2) whether, if APJs are principal officers, the Federal Circuit properly cured any Appointments Clause defect by severing the removal protections provided to APJs.

The US Government and Smith & Nephew are appealing the principal officers finding, arguing the Federal Circuit was wrong and that the APJs were properly appointed. Arthrex is appealing the Federal Circuit's remedy, asserting the Federal Circuit's solution did not go far enough and that the current system must be overhauled and fixed by Congress. Amicus briefs have also been filed advocating an array of views and possible remedies.

There are a range of possible outcomes at the Supreme Court of varying consequence. The narrowest impact would be if the Supreme Court finds no violations of the Appointments Clause, which would essentially reset to a pre-*Arthrex* landscape with business continuing as usual. The Supreme Court could also affirm the Federal Circuit on both the principal officers finding and the statutory fix, which would also likely have a limited impact, mainly affecting cases currently held in abeyance and awaiting review by newly designated APJ panels. A more open-ended outcome could result if the Supreme Court agrees with the principal officers' finding but determines the remedy to be inadequate. The Supreme Court could attempt to craft a remedy of limited impact or order a more sweeping solution, including, as Arthrex advocates, finding the fix properly resides with Congress. This could potentially throw thousands of PTAB decisions into jeopardy and, if requiring a solution by a Congress already busy with a number of other issues, including an ongoing national pandemic, create uncertainty indefinitely.

EN BANC AT THE FEDERAL CIRCUIT – TWO CONTENTIOUS DENIALS

HZNP Fin. Ltd. v. Actavis Labs. UT, Inc., 17-2049
(Fed. Cir. Feb. 25, 2020) (*IP Update*, Mar. 2020)
(rehearing *en banc* denied)

In its first high-profile denial of the year, the full court upheld a 2019 panel decision 8–4, finding a claim using the transitional phrase “consisting essentially of” to be indefinite because of inconsistencies in the manner in which the patent specification explained the meaning of “better drying time” in connection with use of the claimed formulation. When “consisting essentially of” precedes a list of ingredients in a composition, the claim not only includes the items in the list but is also open to additional unlisted ingredients that do not materially affect the basic and novel properties of the invention. In this case, the original panel found that such properties of the invention were listed but not defined with reasonable certainty to allow a person of ordinary skill in the art to discern the scope of the properties. Specifically, the property of “better drying time” was indefinite because the methods for determining it as outlined in the specification (including the appropriate timeframe to evaluate), did not show consistent results.

Judge Alan D. Lourie dissented in both the panel and *en banc* decisions, and was joined by Judges Newman, O'Malley and Stoll in arguing that the majority misconstrued the transition “consisting essentially of” in finding the phrase “better drying time” to be indefinite since that phrase is not recited in the claim at issue. He reasoned that “it is the language of the claims that must not be indefinite, not the understanding or clarity of an advantage of the invention.” He further warned that the denial of *en banc* review is not based on “sound precedent,” and worried that the holding “could have unintended potential effects well beyond this particular case.”

HZNP’s petition for *certiorari* with the Supreme Court was denied in November 2020.

American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 18-1763 (Fed. Cir. Oct. 3, 2019) (*IP Update*, Aug. 2020) (rehearing *en banc* denied)

Highlighting internal disagreement regarding patent eligibility under § 101, a divided Federal Circuit panel issued a series of opinions revising and reissuing a previous opinion (*IP Update*, Vol. 22, No. 11) on § 101 patent eligibility for a mechanical invention and, in an even split, denied a petition for *en banc* review. The court found two of three patent claims ineligible for being merely directly to an application of Hooke’s law. It reversed as to a third claim, finding that the claim had an additional limitation such that it was not a mere application of the natural law. Judge Kimberly A. Moore maintained her dissent from the initial panel opinion, arguing that the majority was announcing a new patentability test: the “Nothing More” test. She argued that the decision created a new test for instances when claims are directed to a natural law even though no natural law is specifically recited in the claims.

The reissued decision, particularly the 6–6 decision to deny a rehearing *en banc*, highlights the Federal Circuit’s division on patent eligibility. The judges denying the *en banc* petition apparently viewed the panel’s decision as a simple application of prior precedent, while the dissenting judges appeared to view the panel’s decision as announcing a new patentability test in which a claim can be directed to a law of nature even if the law is not recited in the patent claims or specification. This even split shows uncertainty regarding the scope of § 101. With such contrasting views among the judges, patent owners and inventors must continue to navigate an uncertain § 101 landscape until more clarity is provided by the Courts or Congress.

American Axle filed a petition for *certiorari* with the Supreme Court. It also sought a stay from the Federal Circuit, which was denied. (*IP Update*, Nov. 2020).

THE FEDERAL CIRCUIT LIMITS VENUE FOR HATCH- WAXMAN LITIGATION

For the first time since *TC Heartland v. Kraft Foods*, 16-105 (Fed. Cir. Apr. 29, 2016) changed the venue landscape for patent cases, the Federal Circuit addressed the question of where infringement occurs in a Hatch-Waxman litigation. *Valeant Pharms. N.A. LLC v. Mylan Pharms. Inc.* 19-2402 (Fed. Cir. Nov. 5, 2020). Specifically, in *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals, Inc.*, the Court held that for the purposes of determining venue, infringement occurs only in judicial districts where actions related to the submission of an ANDA occur, and not in all locations where future distribution of the generic products specified in the ANDA is contemplated.

Hatch-Waxman litigation presents a unique issue with respect to venue. In *TC Heartland*, the Supreme Court held that venue is only appropriate in judicial districts where a defendant corporation (i) is incorporated or (ii) has committed *acts of infringement* and established place of business. Acts of infringement are different in Hatch-Waxman litigation than in traditional patent litigation. Under the Hatch-Waxman Act, it is an act of infringement to submit an ANDA for a drug claimed in a patent or the use of which is claimed in a patent ... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Thus, the submission of an ANDA is an act of infringement, even though no infringing drug product been commercially manufactured, used and/or sold.

In *Valeant*, the Federal Circuit rejected Valeant's argument that for venue purposes, acts of infringement should include all judicial districts where a generic product specified in an ANDA is likely to be distributed. Focusing on the plain language of statute,

the court found that in Hatch-Waxman cases, venue is proper *only* in judicial districts that are sufficiently related to the ANDA submission—*i.e.*, districts where acts occurred that would suffice to categorize the actor as a submitter of the ANDA. The Federal Circuit therefore affirmed the district court's finding that venue was not proper in the District of New Jersey because Mylan had not submitted its ANDA in that district.

Acknowledging the impact of its decision-limiting venue in Hatch Waxman cases, the Court noted that in circumstances with multiple ANDA filers on a single drug product, "branded drug companies may be required to file and maintain largely identical suits in multiple districts." In view of the *Valeant* decision, courts may see a shift in the filing and litigation strategy by branded companies. For example, branded companies may:

File and maintain lawsuits against each generic company separately in individual districts. While potentially making it more difficult for generic companies to coordinate their efforts, this strategy increases the time and expense required to resolve the litigation and may result in inconsistent rulings, *e.g.*, claim construction and summary judgment, across district courts.

Seek consolidation into a multidistrict litigation (MDL) for pre-trial proceedings. When lawsuits are filed in multiple judicial districts, a party may request that the Judicial Panel on Multidistrict Litigation (JPML) consolidate the lawsuits into an MDL pursuant to 28 USC § 1407. This strategy might mitigate concerns regarding increased time and expense, as well as the risk of inconsistent rulings, but parties have very little control over forum and choice of law that the JPML selects. Generally, the JPML considers (i) the location of documents and witnesses; (ii) the number of related cases pending in the judicial district; (iii) the expertise and resources of the judicial district; and (iv) the experience of the MDL judge. *See, e.g., In re Yahoo! Inc. Customer Data Sec. Breach Litig.*, 223 F. Supp. 3d 1353, 1355 (JPML 2016). But ultimately the JPML can assign the MDL

to a district judge in any of the 94 judicial districts, even one where none of the cases in the MDL was initiated. And the MDL judge applies the federal and procedural law as interpreted in that circuit. *See In re Temporomandibular Joint (TMG) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996).

File a single lawsuit against all parties in the District of Maryland. Interestingly, the court suggested that the District of Maryland, where the Food and Drug Administration (FDA) is located and receives the ANDA, might satisfy the test for venue, but it did not definitively rule on the issue. However, the District of Maryland has limited experience with

Hatch-Waxman litigation and, of the nine cases filed within the last five years, no plaintiffs have won on the merits. *LexMachina, District of Maryland – Patent/ANDA Analytics December 2020*.

Valeant’s petition for rehearing *en banc* was recently denied on January 26, 2021. The court’s opinion, as it stands, means that venue will be foreclosed where the defendant’s only connection is through future distribution of the generic drug. The full implications of this important decision on Hatch-Waxman litigation strategy, and whether any of these potential strategies may be adopted, remain to be seen.

2021 OUTLOOK

The Supreme Court is set to hear at least two patent cases and one copyright case this term. In *The United States of America v. Arthrex, Inc.*, the Court will consider whether PTAB judges are unconstitutionally appointed and the other addressing whether assignor estoppel and in *Minerva Surgical, Inc. v. Hologic, Inc., et al.*, the Court will consider whether the doctrine of assignor estoppel bars an assignor from asserting invalidity of an assigned patent in district court. A decision is also expected in *Google LLC v. Oracle America, Inc.* on the issue of copyright ownership of application programming interfaces used in computer technology. We also expect to see many patent trials occurring toward the middle and end of 2021. The COVID-19 pandemic has created a backlog of cases that were set to be tried and parties are likely to face pressure from Court to narrow the issues to be tried. Judge Alan Albright has also made headlines and has attracted case to the filed in the US District Court for the Western District of Texas. We expect even more cases to be filed this year.

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