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A Newsletter from the Intellectual Property Practice Group

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The Year in Intellectual Property

Look Back and Look Forward 2018-2019

Last year was an active year in intellectual property. There were many notable developments in 2018 by the Supreme Court and Federal Circuit. These courts issued key rulings involving *Inter Partes* Reviews of the validity of patents, damages for foreign profits, validity and prior art, the licensing and assertion of standard essential patents and FRAND, trademark protections for disparaging, immoral and scandalous marks, patent eligibility, obviousness-type double-patenting, copyright protection for software, and venue.

As we look ahead to 2019, jurisprudence in these areas will continue to develop as the lower courts react to these key rulings. In addition, in 2019, the USPTO issued new guidance on subject matter patent eligibility. A detailed discussion of all of these developments follows.

Supreme Court Denies Constitutional Challenge to AIA Reviews

The Supreme Court resolved the first existential challenge AIA reviews in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC et al.*, 138 S. Ct. 1365 (2018). The Leahy-Smith America Invents Act in 2012 (AIA) created a new system for expedited patent validity challenge to be decided by three Administrative Law Judges at the Patent Trial and Appeal Board (PTAB), without a jury. The system has been popular and very successful for challengers. The former Chief Judge of the Federal Circuit has called PTAB panels overseeing this system a "death squad" for patents. (https://aippi.org/no-show/the-hon-randall-r-rader-on-the-future-of-the-patent-system/). Certainly, the availability of AIA reviews of issued patents was the biggest and most controversial change to the U.S. patent system in a generation.

Oil States had won a patent litigation against its competitor Greene's Energy. However, a challenge to the patents was conducted concurrently before the PTAB, who a few months later found the patents-in-suit invalid, nullifying the district court's determination (and demonstrating the power of the AIA review system). Oil States challenged the PTAB ruling, arguing that patents were private rights and that the PTAB procedures instituted under the AIA usurped their right to a jury trial under Article III of the Constitution and the Seventh Amendment. The Federal Circuit affirmed the PTAB decision.

In a majority (7-2) decision written by Justice Thomas, the Supreme Court affirmed that the PTAB procedures did not violate the Constitution. Justice Thomas held that "the decision to grant a patent is a matter involving public rights—specifically, the grant of a public franchise. *Inter partes* review is simply a reconsideration of that grant, and Congress has permissibly reserved the PTO's authority to conduct that reconsideration. Thus, the PTO can do so without violating Article III."

While additional challenges to the constitutionality of the AIA review system have been brought (*e.g.*, due process, etc.), it looks like the AIA review system will continue its crucial role in our patent system for the foreseeable future.

Notably, however, the newly appointed U.S.P.T.O. director, Andrei Iancu, is in favor of tightening the AIA review system because he believes the "patent opposition procedures continue to create uncertainty for rights holders." (https://www.uspto.gov/about-us/news-updates/remarks-director-andrei-iancu-us-chamber-commerce-patent-policy-conference). Director Iancu has already taken steps to:

1. Change the claim construction standard away from the "broadest reasonable construction" to the potentially narrower claim construction standards applied in court (https://www.federalregister.gov/documents/2018/05/09/2018-09821/changes-to-the-claim-construction-standard-for-interpreting-claims-in-trial-proceedings-before-the);
2. Change the procedures for amending claims to make it easier for patentees (https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-10th-annual-patent-law-policy-conference); and
3. Have more input into the precedential effect of PTAB opinions on procedural matters (*Id.*).

Supreme Court Allows Damages for Foreign Profits

In *WesternGeco, LLC v. ION Geophysical Corp.* (No. 16-1011), the Supreme Court addressed the question of whether a U.S. patent holder can recover damages for a defendant's conduct abroad based on extraterritorial application of the U.S. patent statutes. Or at least that's what most people expected the Court to address following briefing and oral argument. Writing for a majority of seven, however, Justice Thomas found it unnecessary to even reach the question of when U.S. patent statutes could apply to conduct abroad because he concluded, the defendant's infringing conduct (as defined by U.S. patent law) occurred in the United States.

WesternGeco owns four patents relating to a system for surveying the ocean floor. ION Geophysical developed a competing system but, to avoid infringing WesternGeco's patents, it manufactured the components for its system in the U.S. and then shipped them abroad for assembly. WesternGeco sued for patent infringement, and a jury found ION liable for $93.4 million in WesternGeco's lost profits. ION moved to set aside these damages, arguing that WesternGeco could not recover lost profits on foreign sales because the U.S. patent statute cannot apply extraterritorially to ION's conduct abroad. The district court disagreed but, on appeal, the Federal Circuit vacated the damages award,

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concluding that the patent act did not allow patent owners to recover for lost foreign sales. The Supreme Court granted certiorari.

Before the Supreme Court, the parties' briefs and arguments focused (as had the lower courts) on the question of whether the patent act could apply extraterritorially to allow recovery of foreign profits. As the Court has discussed in numerous opinions in the last few years, it is a general rule of statutory interpretation that federal statutes should be presumed to apply only within the territorial jurisdiction of the United States. That presumption, however, can be rebutted by clear evidence that Congress intended the statute to apply abroad. Thus, the parties debated whether this presumption should apply at all in this context and, if so, whether the presumption had been rebutted.

Justice Thomas' majority opinion avoided all of these questions, however, instead deciding the case based on another aspect of the extraterritoriality doctrine: Whether the case involves an extraterritorial (as opposed to domestic) application of the patent statute. That issue turns on the statute's "focus": Is it seeking to regulate conduct in the United States or protect interests here? Or is the relevant conduct something occurring abroad? While this can often be a difficult question, Justice Thomas found it relatively easy in this case given how the Patent Act defines "infringement." Specifically, one of the acts defined to constitute "infringement" of a U.S. patent is *supplying* certain components of a patented combination from the U.S. with the intent that they be combined outside the U.S. in a way that would have infringed the patent if the combination had occurred in the U.S. (to 35 U.S.C. § 271(f)(2)). Thus, the *conduct* regulated by the Patent Act–its focus–was supplying components from the United States, exactly what it was that ION was found liable for doing. And the *damages* that foreseeably flowed from that conduct included the sales ION was able to make in foreign countries due to its infringement. Thus, as noted in a footnote, the question of whether these foreign profits could be recovered was not a question of extraterritoriality, only one of causation.

Supreme Court Nixes Partial Institutions and Requires IPRs to Finally Resolve Patentability of All Challenged Claims

In order to successfully institute an *Inter Partes* Review (IPR), a petitioner must convince the Patent Trial and Appeal Board (PTAB) that it has a "reasonable likelihood" of prevailing on at least one of the challenged patent claims. Previously, the PTAB interpreted the relevant statute as permitting "partial institution" of only the subset of the challenged claims where that standard was met. In some instances, this meant a petitioner could successfully challenge some claims through an IPR, only to then resort to action in the courts to eliminate the remaining uninstituted claims, effectively bearing the burden of both the IPR and subsequent litigation.

The Supreme Court eliminated that paradigm in *SAS Institute v. Iancu*, holding, in a 5-4 ruling that as a matter of statutory interpretation, once an IPR is instituted, the PTAB must finally resolve the patentability of **all** challenged claims, regardless of whether the "reasonable likelihood" standard was met universally.

Certain challengers will no doubt rejoice that they get the shot they want before the PTAB, while patentees will walk away with more finality if they win the IPR, the challenger will face higher estoppel burdens in then pursuing litigation. This new all-or-none dynamic will likely increase settlement pressures as it raises stakes for both parties.

Supreme Court Confirms AIA Doesn't Change 'On Sale Bar' and That 'Secret' Sales Remain Prior Art

In *Helsinn Healthcare v. Teva Pharmaceuticals USA*, a unanimous Supreme Court affirmed a Federal Circuit decision invalidating the patent for Helsinn's nausea drug Aloxi based on U.S. patent law's "on sale" bar. The Court affirmed the Federal Circuit's longstanding interpretation of the "on sale" bar, holding that "Congress did not alter the meaning of 'on sale' when it enacted the AIA." The focus of this case was whether so-called "secret" (private) sales continue to qualify as prior art after the enaction of the AIA which revised Section 102.

During development of the drug, Helsinn entered into a license agreement and a supply and purchase agreement with another pharmaceutical company, MGI Pharma, in which MGI agreed to distribute the drug if it was approved by the FDA. These agreements included dosage information for Helsinn's invention, but required MGI to keep this information confidential. Helsinn and MGI announced their deal publicly, but the press releases and other

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announcements did not disclose the specific dosage formulations covered by the agreements. Two years later Helsinn filed a patent application covering two doses of palonosetron, which led to further patents for other doses down the road. Years later, Teva Pharmaceuticals sought FDA approval to market a generic palonosetron product at one of Helsinn's dosage levels. Helsinn sued, alleging that this product infringed its patent.

Since 1836, U.S. patent laws have provided that an invention cannot be patented if it was "on sale" before the effective date of the patent application. Teva argued that this rule made Helsinn's patent invalid because it had sold confidential information about the drug to MGI two years before it filed for its patent. Helsinn countered that the drug was not "on sale," because this was a "secret" sale to MGI and not a sale of the product to the general public. Notably, the Federal Circuit has long held that patents can be invalidated based on pre-application secret sales like this one. But Helsinn argued that the most recent iteration of the U.S. patent laws, the Leahy-Smith America Invents Act (AIA), changed this rule, by amending on-sale bar statute to preclude the granting of a patent for an invention that was "in public use, on sale, *or otherwise available to the public*" before the effective filing date of the application. Those six italicized words, which were added in the AIA, Helsinn argued and the district court in this case had held, required that any sale be a *public* one in order for the on-sale bar to apply. The district court's decision was not without some support: since 2011, practitioners have wondered whether this new language modified the scope of the rule. But the Federal Circuit disagreed with the district court, upholding its prior decisions that the on-sale bar applies even to secret sales. The Supreme Court granted certiorari and, writing for a unanimous Court, Justice Thomas affirmed. Although the Supreme Court had never expressly addressed secret sales like the one in this case, Federal Circuit decisions going back long before the 2011 AIA had made "explicit what was implicit" in the Supreme Court's own precedent: that secret sales also make an invention unpatentable. Prior to 2011, "on sale" had a settled meaning, one that included secret sales and not just sales to the general public. Retaining the same "on sale" language in the AIA and adding the phrase "or otherwise available to the public" was not "enough of a change" to conclude that Congress intended to repudiate this precedent by limiting the on sale bar to public sales.

The *Helsinn* ruling underscores the importance of filing patent applications as soon as possible. Applicant should be aware that confidential licenses, even prior to a product being publicly on sale, can give rise to invalidation under the on sale bar.

Courts and Regulators Continue To Grapple with FRAND

In recent years, a handful of courts have assessed whether parties' offers in licensing negotiations involving standard essential patents ("SEPs") complied with their obligation to license SEPs at a fair reasonable and non-discriminatory ("FRAND") rate. In some cases, courts have actually directed the parties to license their SEPs at a particular FRAND rate. These cases include: *Unwired Planet Int'l Ltd. v. Huawei Techs.* (UK High Court of Justice, Chancery Division, Patents Court May 4, 2017) ("Unwired Planet"); *TCL Comm. Tech. Holdings, Ltd. v. Telefonaktiebolaget LM Ericsson,* No. SACV 14-341 JVS (C.D. Cal. Nov. 8, 2017) ("TCL"); *Saint Lawrence Comm'ns vs. Vodafone* (Regional Court Dusseldorf March 31, 2016) ("Saint Lawrence"); and *Sisvel v. Haier* (Higher Regional Court Dusseldorf March 30, 2017) ("Sisvel").

These cases have employed a range of approaches in valuing patents. In TCL, the court applied a "top-down" methodology, whereby it set the maximum aggregate FRAND royalty for all licensors for each standard. It apportioned Ericsson's royalty share based on Ericsson's share of unexpired declared SEPs for each of 2G, 3G and 4G (i.e., "patent counting"). In *Unwired Planet,* which involved some of the same Ericsson patents at issue in *TCL* that Ericsson had sold to the plaintiff, the court conducted a comparable licensing analysis to calculate FRAND rates. The *Saint Lawrence* and *Sisvel* likewise assessed FRAND compliance based on comparison to other licenses.

The Shenzhen Intermediate People's Court also weighed in recently with its landmark decision in *Huawei v. Samsung* (华为诉三星专利侵权案一审判决总结), 2016 Yue 03 Min Chu No. 816 & 840, at 3.1(a) (Shenzhen Intermediate People's Ct.) ("*Huawei v. Samsung*"). There, the court calculated a top-down figure, starting with an aggregate royalty, for the value of Huawei's SEPs. It found that Samsung had similar portfolio strength, yet offered to license its technology at three times the price that Huawei offered. The court concluded that Huawei's lower rate offers were

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FRAND, while Samsung's higher offer was non-FRAND. The court employed a fault-based approach in granting an injunction against Samsung's infringement of Huawei's SEPs. The Court found Samsung to have negotiated in bad faith by, among other things, failing to timely respond to or engage with Huawei's offers and failing to make its own offers, justifying an injunction.

The *Huawei v. Samsung* decision is noteworthy as a recent example where a court in a high-profile litigation issued an injunction against Samsung after valuing both Samsung and Huawei's SEPs. But last year it included several other important developments concerning the availability of injunctive relief. In *Unwired Planet,* the court of first instance found that Huawei had infringed Unwired Planet's patents and issued an injunction against Huawei until it entered a license. The decision was recently affirmed on appeal by the U.K. Court of Appeal. *Unwired Planet Int'l v. Huawei Techs.* [2018] EWCA (Civ) 2344. The U.K. Court of Appeal explained that "SEP owners . . . are entitled to an appropriate reward for carrying out their research and development activities and for engaging with the standardisation process, and they must be able to prevent technology users from free-riding on their innovations. It is therefore important that implementers engage constructively in any FRAND negotiation and, where necessary, agree to submit to the outcome of an appropriate FRAND determination". *Id.* at [54]

Here in the United States, the Department of Justice's Antitrust Division has weighed in repeatedly on the need to ensure that injunctions are available to SEP-holders in order to appropriately incentivize important innovation. In December 2018, for example, Assistant Attorney General Makan Delrahim announced that the Antitrust Division had withdrawn its assent to the 2013 Joint "Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments." He explained that the 2013 Statement's language that an injunction "may harm competition and consumers" could cause "confusion" because "injunctions against infringement *do* serve the public interest in maintaining a patent system that incentivizes and rewards successful inventors." *Id.* He said, "[a]ny discussion regarding injunctive relief should include the recognition that in addition to patent holders being able to engage in patent 'hold up,' patent implementers are also able to engage in 'hold out' once the innovators have already sunk their investment into developing a valuable technology." Makan Delrahim, Dep't of Just.: "Telegraph Road: Incentivizing Innovation at the Intersection of Patent and Antitrust Law" (Dec. 7 2018), *available at* https://www.justice.gov/opa/speech/file/1117686/download. He further explained that "no special set of rules" applies when evaluating injunctions for SEPs because the Supreme Court's ruling in *eBay v. MercExchange* concerning availability of injunctions for patent infringement "already strikes a careful balance that optimizes the incentives to innovate." *Id.* Further guidance from the Antitrust Division is expected on this topic so stay tuned.

Another topic of recent attention has been whether FRAND requires that the royalty base be limited to the "smallest saleable patent practicing unit" ("SSPPU"). In January of 2019, Chief Judge Gilstrap of the Eastern District of Texas, in *HTC Corp. v. Telefonaktiebolaget LM Ericsson*, 2019 WL 126980 (E.D. Tex.) addressed the issue in the context of the globally influential ETSI IPR policy that guides the cellular industry. The court, applying French contract law to the ETSI Patent Policy, held that as a matter of law it did not. The court noted that ETSI FRAND commitment "is embodied in ETSI's Intellectual Property Rights ('IPR') policy and forms a contract between [the innovator] and ETSI, in which standards-implementers are third-party beneficiaries (citing Taffet, Richard & Harris, Phil, *Standards and Intellectual Property Rights policies, in* Patents and Standards)). *Id.* at *1. The court also explained that "[s]everal independent sources confirm that the prevailing industry standard or approach has been to base FRAND licenses on the end-user device . . . ." *HTC Corp. et al. v. Telefonaktiebolaget LM Ericsson et al.,* 6:18-cv-00243-JRG, 2019 WL 126980, at *5(E.D. Tex. Jan. 7, 2019) (approvingly citing Kjelland, Kurt, Brooks, Roger G., & Zhang, Xiaolin, *FRAND Licensing of Standard Essential Patents, in* Patents and Standards Practice, Policy, and Enforcement 11-8 (Michael L. Drapkin et al. eds., *Bloomberg Law* Book Division 2018)) Thus, the ETSI IRP policy neither *requires nor precludes* a license with a royalty based on SSPPU." (p. 12).

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Examination of Disparaging, Immoral and Scandalous Marks In Wake of Holding That Ban on These Marks Was Unconstitutional

We saw more action on the trademark front in 2018 as well. In the Supreme Court's 2017 decision in *Matal v. Tam* 137 S. Ct. 1744 (June 19, 2017), the Supreme Court held that the Lanham Act's Section 2(a) prohibition against registration of marks that are deemed to disparage or bring into disrepute persons living or dead, institutions, beliefs, or national symbols violated the First Amendment.

In that case, Simon Shiao Tam's application for federal registration of the name of his band, "The Slants" was refused under Section 2(a) of the Lanham Act ("Trademark Act") on the basis that the designation was disparaging to Asian Americans. Following a series of appeals, the U.S. Supreme Court granted certiorari and unanimously affirmed the decision by the Court of Appeals holding that Section 2(a)'s ban on disparaging marks was a violation of the Constitutional guarantees of the right to freedom of speech under the First Amendment.

As a result of the Supreme Court's Tam decision, the Patent and Trademark Office modified Section 1203 of the *Trademark Manual of Examining Procedure*, the manual used by Examiners in examining applications for federal registration, as follows:

> No trademark by which the goods of the applicant may be distinguished from the goods of others shall be refused registration on the principal register on account of its nature unless it–
>
> **(a)** Consists of or comprises immoral, deceptive, or scandalous matter; or matter which may falsely suggest a connection with persons, living or dead, institutions, beliefs, or national symbols; or a geographical indication which, when used on or in connection with wines or spirits, identifies a place other than the origin of the goods and is first used on or in connection with wines or spirits by the applicant on or after one year after the date on which the WTO Agreement (as defined in section 3501(9) of Title 19) enters into force with respect to the United States.

Soon thereafter, a series of appeals following a Section 2(a) refusal of registration by the Patent and Trademark Office, the *In re Brunetti* case, a case dealing with a refusal of registration of "FUCT" as being immoral or scandalous within contemplation of Section 2(a)'s prohibition against registration of immoral or scandalous marks, landed in the Court of Appeals for the Federal Circuit.

Not surprisingly, as in *Tam,* the Court of Appeals for the Federal Circuit reversed the U.S. Patent and Trademark Office Trademark Trial and Appeal Board's decision affirming the Patent and Trademark Office Examining Attorney's refusal. *In re Brunetti,* 2015-1109 (Fed. Cir. Dec 15, 2017). The Court did not find a lack of evidence that the term "FUCT" comprises immoral or scandalous matter. Rather, the Court found that Section 2(a)'s prohibition against registration of immoral or scandalous matter, like marks considered to be disparaging, constitutes an unconstitutional restriction on free speech in violation of the First Amendment.

While one might have thought that the Supreme Court's decision in *Tam* would provide sufficient guidance for an immoral/scandalous mark, the government, on September 7, 2018, filed a Petition for a Writ of Certiorari, arguing that *Tam* did not control the decision in the *Brunetti* case.

The government's Petition raises the following issues:

- Whether trademark registration qualifies as a "government subsidy" or as "commercial speech," both of which could impact the level of constitutional scrutiny that should be applied to the Lanham Act.
- That *Tam* is not controlling because it was decided on viewpoint grounds, whereas vulgar or obscene expression is viewpoint-neutral.
- That Section 2(a) does not restrict speech because trademark rights inure through use, and owners of unregistered marks have protections and remedies under the Lanham Act such that the inability to register a mark does not prevent the owner from using the mark, with the result that Section 2(a) is not a restriction on speech.
- That although the First Amendment does not permit government restrictions on speech, it also does not confer an affirmative right to government assistance in speaking.
- That Congress intended to allow use of immoral or scandalous mark, but did not intend to use government funds to provide the statutory benefits of registration for such marks.
- That the Federal Circuit erred in using analysis that draws parallels between trademarks and copy-

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rights, and in not applying the so-called "government subsidy" line of cases.

- That the government offered legitimate justifications for the prohibition against immoral or scandalous marks sufficient to address whatever level of constitutional scrutiny the Supreme Court might apply.
- Finally, the government argues that because the Court of Appeals for the Federal Circuit's decision invalidated Section 2(a) on its face, the U.S. Patent and Trademark Office can no longer issue a scandalous refusal under Section 2(a), and there would be "no meaningful likelihood that any further dispute concerning the constitutionality of the scandalous-marks provision will again be presented for judicial resolution," leaving the constitutionality issue essentially unanswered.

On January 4, 2019, the Supreme Court granted the U.S. Patent and Trademark Office's Writ of Certiorari.

Stay tuned for a future IP Year End Review discussing the ultimate outcome of the *Brunetti* case.

What Can Be Appealed From an *Inter Partes* Review?

What aspects of an *Inter Partes* Review decision are appealable was also clarified in 2018. In *Wi-Fi One, LLC v. Broadcom Corp.*, No. 2015-1944 (Fed. Cir. 2018), the Federal Circuit, sitting *en banc,* considered what can be appealed from an *Inter Partes* Review (IPR) decision.

Under the AIA (formally known as the Leahy-Smith America Invents Act), patent validity may be challenged at the U.S. Patent and Trademark Office (USPTO), using an administrative trial before a panel of three judges at the Patent Trial and Appeal Board (PTAB).

One frequent criticism of PTAB trials is what can be appealed from the administrative decisions by the PTAB. Under 35 U.S.C. § 315(b), if an IPR petition is initially filed more than one year after the date on which the petitioner or real party in interest is served with a complaint for infringement, the IPR "may not be instituted." Further, 35 U.S.C. § 314(d) states that decisions of "whether to institute an *inter partes* review under this section shall be final and nonappealable."

In *Wi-Fi*, the Federal Circuit held that a PTAB decision determining that an IPR position is time-barred under 35 USC § 315(b) is indeed appealable and subject to review by Article I courts. This overturned the ruling in *Achates Ref. Publg., Inc. v. Apple Inc.*, 803 F.3d 652 (Fed. Cir. 2015) that a decision to institute an IPR was final and non-appealable from the PTAB.

Wi-Fi distinguishes from *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016), which interpreted the provision under 35 U.S.C. § 314(d) to preclude appeal in instances where "questions that are closely tied to the application and interpretation of statutes related to" a decision to institute, such as whether a reasonable likelihood of success is present. In *Wi-Fi*, the Court held that constitutional questions, or those instances where the decision is less closely related to the other statutes, in this case a time bar, are subject to appeal.

In the majority, Judge Reyna argued that there is a "strong presumption" favoring the judicial review of agency actions, unless there is a "clear and convincing indication" that Congress intended to prohibit review. Here, the Court found no "clear and convincing indication that Congress intended to block judicial review of time-bar decisions. Instead, Judge Reyna interpreted the "final and nonappealable" limits imposed by 314(d), as limited to "under this section," to be confined only to Section 314, and not to time-bar decisions in 315(b).

The Federal Circuit declined to definitively rule on whether any determinations under Sections 311-314 are final and nonappealable, instead focusing only on Section 315.

While this case ever so slightly chips away at the breadth of the PTAB's power, the strength of the post-grant process and the PTAB is clear.

Federal Circuit Clarifies Extent to Which Courts Can Resolve Section 101 Defenses on a Motion to Dismiss or Summary Judgment

In February 2018, the Federal Circuit issued a controversial and potentially far-reaching decision that impacts on the ease with which summary judgment proceedings can be used to invalidate patent claims under 35 U.S.C. §101, because they only cover abstract ideas without more. Prior to that time, a significant number of software-based patents were invalidated under Section 101, either at the pleading stage or on summary judgment. In *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018), a panel opinion penned by Judge Moore, the Federal Circuit indicated, as it had done previously, that the §101 patent eligibility inquiry may turn on issues of fact.

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Mr. Berkheimer's patent included claims that related to digital processing and archiving of files. The invention was described as eliminating redundant storage of common text and graphical elements and permitting a one-to-many editing process in which a change to one element would carry over to all archived documents. Certain of the method claims explicitly recited these features. In the district court, HP successfully obtained summary judgment of invalidity based on §101, and Mr. Berkheimer appealed.

In reviewing the lower court's summary judgment decision of §101 invalidity, the Federal Circuit agreed that the claims in question were found to be directed to an abstract idea and met the first step of the Supreme Court's *Alice* test (*Alice Corporation v. CLS Bank International* (34 S. Ct. 2347 (2014)). However, the Federal Circuit took issue with the district court's further conclusion that the claims also did not contain an inventive concept under the second step of the *Alice* test sufficient to avoid invalidity on summary judgment. In particular, the district court had concluded that the claims only described "steps that employ only 'well-understood, routine, and conventional' computer functions" that were claimed "at a relatively high level of generality." Mr. Berkheimer, the inventor, had argued that the claimed combinations, including removal of redundancies and a one-many editing feature, improved computer functionality and were therefore patentable. Significantly, the Federal Circuit stated that:

> Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination. Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.

The Federal Circuit, agreeing with the inventor's argument, concluded that these issues raised sufficient underlying questions of fact to overcome summary judgment.

In response to this decision, the U.S.P.T.O. issued a memorandum in April, 2018 seeking to clarify its examination guidelines for 101 issues to address potential factual issues; and defendants seeking summary adjudication of patents under §101 have recognized that they have to be more actively focused on convincing a court that the claims raise no genuine issues of fact. In October of last year, HP petitioned the Supreme Court to address the fundamental issue of whether §101 patent eligibility should be decided as a question of law based on the scope of the claims or as a question of fact for the jury to decide based on the state of the art at the time of the patent.

Federal Circuit Continues to Restrict the Patentability of Medical Diagnostic Inventions

In a 2-1 panel decision rendered in February 2019 (*Athena Diagnostics Inc. v. Mayo Collaborative Services*, Fed. Cir., No. 2017-2508, Feb. 6, 2019), the Federal Circuit continued to narrowly restrict the patent eligibility under 35 U.S.C. §101 of methods for performing medical diagnostics, agreeing with the district court that the claims at issue impermissibly covered a law of nature.

Here, Athena had asserted its patent against Mayo. The claims covered methods for diagnosing if a patient had myasthenia gravis ("MG"), a debilitating neurological disorder, by detecting whether a patient produced antibodies to a particular protein known as "MuSK." Although it was previously known that 80% of patients with MG produced antibodies to another substance, Athena had discovered that the remaining 20% could be diagnosed by determining if they developed antibodies to MuSK.

Based on this discovery, the asserted claims of Athena's patent covered methods for diagnosing whether a patient had MG by, for example, attaching a radioactive marker (such as radioactive iodine) to the MuSK protein in a sample of the patient's bodily fluid (to which any MuSK antibodies that might be produced would bind), separating such antibody/MuSK complexes from the fluid, and monitoring for the presence of the radioactive label to determine their presence which would indicate that the patient was suffering from MG.

The district court, in considering Mayo's Rule 12(b)(6) motion to dismiss, applied the Supreme Court's test for patent eligibility set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. 66 (2012) and *Alice Corp. v. CLS Bank International,* 573 U.S. 208 (2014). The court focused on the fact that the interaction of MuSK with MuSK antibodies, i.e., Athena's discovery, occurred naturally and found the claims to be invalid under § 101 because they covered a law of nature. Athena appealed this result.

In its *de novo* review of the district court's decision, the Federal Circuit

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relied heavily on the patent's specification, which acknowledged that attaching a radioactive label to a protein and separating any resultant radioactive complexes to perform a radioimmunoassay were all steps known in the art. Relying on the Supreme Court's prior *Mayo* decision, the Federal Circuit reiterated that adding "conventional steps, specified at a high level of generality" to a law of nature did not make a claim to the law of nature patentable.

Ultimately holding against Athena, the Federal Circuit distinguished its prior decision in *CellzDirect (Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.,* 827 F. 3d 1042 (Fed. Cir. 2016)) because the claims in that case were not simply directed to detection of a natural law. Citing to its prior decisions in *Cleveland Clinic (Cleveland Clinic Found. v. True Heath Diagnostics LLC,* (859 F. 3d 1352)) and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.,* 788 F. 3d 1371 (Fed. Cir. 2015)), the Federal Circuit held that claims that only recite routine, well-known steps to detect a naturally existing correlation, regardless of their specificity, are still only directed to a law of nature and therefore not eligible for patent protection under Section 101.

It is noteworthy that Judge Newman penned a vigorous dissent, stating that the Federal Circuit's decisions on the patent-ineligibility of diagnostic methods were inconsistent and that her colleagues' rulings created disincentives to the development of new diagnostic methods. Judge Newman characterized the claims at issue as not simply claiming a law of nature, but rather a reaction sequence that was part of a new diagnostic procedure. Judge Newman further argued that in a Section 101 analysis it was improper to parse claim steps into whether they are conventional or not, since these issues are better left to the separate anticipation/obviousness inquiries required under 35 U.S.C. Sections 102 or 103.

In referring to Judge Newman's dissent in footnote 4 of the majority opinion, Judges Lourie and Stoll acknowledged, somewhat apologetically, that "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts," but in their view the Supreme Court's prior *Mayo* decision and other precedent left no room for a different result.

It remains to be seen whether and when the Supreme Court will decide to clarify this important area of patent law.

USPTO Issues New 2019 Guidance for Determining Subject Matter Eligibility

The United States Patent and Trademark Office has issued various guidelines over the past years aimed at aligning its examination procedures with the many Court decisions concerning what is and is not patent-eligible subject matter. The latest guidance ("2019 Revised Patent Subject Matter Eligibility Guidance") was ushered in with the start of the New Year and is intended to change how examiners deal with claims that implicate the so-called three "judicial exceptions" to what otherwise is broad patentable subject matter under 35 U.S.C.§101 (i.e., laws of nature, natural phenomena, and abstract ideas). Particularly, this latest guidance seeks to clarify how U.S.P.T.O examiners should apply the U.S. Supreme Court's two-step *Alice/Mayo* framework in an effort to reduce uncertainty regarding the patent eligibility of abstract ideas – an issue that frequently arises when seeking to patent software-based inventions.

This 2019 Revised Guidance clarifies prior U.S.P.T.O guidance for determining if a claim recites an "abstract idea" by specifically identifying the following three subject matter categories as potentially falling under the "abstract ideas" exception to patentability: (1) mathematical concepts – including mathematical relationships, formulas or equations, or calculations; (2) certain methods of organizing human activity; and (3) mental processes. This replaces the more nebulous prior guidance issued by the U.S.P.T.O. for identifying what subject matter falls within the ambit of an "abstract idea." If an Examiner believes that an idea outside these three categories is abstract, they must get approval from the Director in their technology area before issuing a patent eligibility rejection.

The 2019 Revised Guidance indicates that, with rare exception, only if a claim recites subject matter that falls within one of these three specific categories, must it be further evaluated (under step two of *Alice*) to determine if the claim is "directed to" an abstract idea (making the claim ineligible for patent protection) or if the claim as a whole integrates the recited abstract idea into a specific practical application (in which case the claim is eligible for protection).

It remains to be seen whether these Revised Guidelines will result in more clarity and consistency in how the U.S.P.T.O deals with this complex area of patent law that is so important to protecting the growing numbers of computer-based inventions at the heart of many new technologies.

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The Aftermath of *TC Heartland*: Foreign Companies Can Be Sued Anywhere

Following the Supreme Court's landmark patent venue decision in *TC Heartland LLC v. Kraft Foods Group Brands LLC,* 137 S. Ct. 1514, 1521 (2017), which limited the places where domestic companies can be sued for patent infringement, the Federal Circuit has refused to put similar limits on where foreign companies can be sued for patent infringement.

In *In Re: HTC Corporation,* No. 2018-130, Slip. Op. (Fed. Cir. May 9, 2018), the Federal Circuit explained that *TC Heartland* did not change the law as to the appropriate venue for patent infringement cases against foreign corporations, which under Supreme Court precedent may be sued in any judicial district in the United States. In that case, HTC Corporation ("HTC Corp."), a Taiwanese company, petitioned the Federal Circuit for a writ of mandamus to dismiss a patent suit brought against it in the District of Delaware for improper venue. The plaintiffs had filed the suit against both HTC Corporation and its U.S.-based subsidiary, HTC America, Inc. Both HTC America and HTC Corp. filed motions to dismiss for improper venue under Rule 12(b)(3). The district court found venue improper as to HTC America (which resided in the State of Washington and had no place of business in Delaware). However, as to HTC Corp., a foreign corporation, the district court found that venue in Delaware was proper. The Court reasoned that under 28 U.S.C. § 1391(c)(3), "a defendant not resident in the United States may be sued in any judicial district." In *Re: HTC Corp.* at 11. The Federal Circuit specifically rejected the arguments that Section 1391(c)(3) does not apply in patent cases. It explained that "the patent venue statute was not intended to supplant the longstanding rule that the venue laws do not protect alien defendants," an issue addressed by the Supreme Court in its 1972 opinion in *Brunette Machine Works v. Kockum Industries,* 92 S.Ct. 1936 (1972) holding that a foreign corporation can be sued in any judicial district. *Id.*

Thus, while the impact of *TC Heartland* has been felt greatly as to domestic companies, it has not created any precedent for foreign companies to avoid being sued for patent infringement throughout the U.S. While the full implications of the ruling remain to be seen, this decision may incentivize patent owners to sue foreign parents, rather than a U.S. subsidiary, if the foreign parent is making or selling the infringing products in the United States so that they can bring suit in preferred districts.

Impact of Obviousness-Type Double Patenting Considerations on Patent Portfolio Management for Life Sciences Patents

In December 2018, the Federal Circuit issued two decisions clarifying the application of the obviousness-type double patenting doctrine in *Novartis AG v. Ezra Ventures LLC1*, 2018 WL 6423564 (Fed. Cir. Dec. 7 2018) and *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.* 2018 WL 6423451 (Fed. Cir. Dec. 7. 2018). In both cases, the Federal Circuit declined to extend the reasoning of *Gilead Sciences Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), which held that a later-filed, earlier expiring patent can be used as a double patenting reference to invalidate an earlier-filed but later expiring patent.

Novartis v. Ezra

In *Ezra*, the Federal Circuit rejected an obviousness-type double patenting attack based on a grant of a patent term extension ("PTE") under 35 U.S.C. § 156. The court held that a PTE in and of itself does not create an obviousness-type double patenting issue, "so long as the extended patent is otherwise valid without the extension." *Ezra,* 2018 WL 6423564, at *6.

Novartis owned two patents, U.S. Patent No. 5,604,229 ("the '229 Patent") and U.S. Patent No. 6,004,565 ("the '565 Patent"), covering its multiple sclerosis drug Gilenya®. Novartis was granted five years of PTE on the '229 Patent. The '565 Patent expired on September 23, 2017. The '229 Patent, including its PTE period, expired on February 18, 2019, without which it would have expired on February 18, 2014. Ezra filed an Abbreviated New Drug Application ("ANDA") related to a generic version of Gilenya® and Novartis filed suit, asserting the '229 Patent. Ezra attacked the validity of the '229 Patent, arguing that the '229 Patent was invalid for obviousness-type double patenting over the '565 Patent and that the PTE period of the '229 Patent was an improper extension of the term of the earlier-expiring '565 Patent thus violating the PTE statute. The district court rejected both these arguments, and the Federal Circuit affirmed.

On the double patenting issue, the Federal Circuit held that, although the PTE Novartis obtained on the '229 Patent caused the '229 Patent to expire after the '565 Patent, the '565

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Patent was not a proper obviousness-type double patenting reference for the '229 Patent. The Court relied on *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*,482 F.3d 1317 (Fed. Cir. 2007) in which the Federal Circuit upheld the validity of a PTE granted to a patent that had been terminally disclaimed during prosecution to overcome an obviousness-type double patenting rejection. It held that under *Merck*, a terminally disclaimed patent with PTE "necessarily will expire after the patent to which it had been subject to an obviousness-type double patenting rejection." *Ezra*, 2018 WL 6423564, at *5. Thus, it held that "if a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE." *Id.*

In so doing, the Federal Circuit rejected Ezra's argument that the PTE on the '229 Patent violated 35 U.S.C. § 156(c)(4), which states that "in no event [may] more than one patent be extended … for the same regulatory review period for any product." It held that Novartis had complied with the legal requirements of § 156 by selecting one patent to receive PTE. The Court held that patentees have the flexibility to choose which of the patents covering a product should receive PTE regardless of whether the selection of a patent for PTE extends the term of any other patent.

Novartis v. Breckenridge

In *Breckenridge*, the Federal Circuit rejected an obviousness-type double patenting attack on a pre-Uraguary Round Agreements Act ("URAA") patent, which used a post-URAA patent as the purportedly invalidating reference. Novartis owns U.S. Patent No. 5,665,772 ("the '772 Patent"), which claims the compound everolimus, and 6,440,990 ("the '990 Patent"), which claims methods of treatment using everolimus and specific compositions comprising everolimus. The '772 Patent was filed prior to the effective date of the URAA, entitling it to a term of 17 years from issuance. Accordingly, its original expiration date was September 9, 2014, before application of a five-year PTE period that extended the term to September 9, 2019. The '990 Patent was filed after the effective date of the URAA and therefore had a term of 20 years from the earliest effective filing date (making its expiration date September 23, 2013). Thus, even though the '990 Patent was both filed after and issued after the '772 Patent, it expired before the '772 Patent.

Novartis sued Breckenridge and two other generic challengers for infringement of the '772 Patent after it sought FDA approval to market generic versions of Zortress® and Afinitor®, both of which use everolimus as the active ingredient. Relying on the Federal Circuit's decision in *Gilead*, the district court found that the '990 Patent was a proper double patenting reference against the '772 Patent.

The Federal Circuit reversed, concluding that the District Court improperly relied on *Gilead* which was limited to instances in which both patents at issue are post-URAA patents unlike the case at hand involving the use of a *post*-URAA patent as a double patenting reference against a *pre*-URAA patent. In so ruling, the Federal Circuit found it significant that the '772 Patent's expiration after the '990 Patent was a result of an intervening change in patent term law. It concluded that the later-filed, later-issued, post-URAA '990 Patent was not a proper double patenting reference for the earlier-filed, earlier-issued, pre-URAA '772 patent. It found this result was consistent with Congress' intent to allow patent owners, who had filed patent applications before the URAA transition date, to enjoy the longest possible patent term available under either pre-URAA or post-URAA patent term law.

For life sciences patents, where a PTE is often critical to extend the life of a patent and often added on top of any extensions due to a patent term adjustment ("PTA"), patent portfolio managers and patent practitioners must be cognizant of the risks of having a PTA-extended patent invalidated for obviousness-type double patenting versus the loss of a PTA term from filing a terminal disclaimer in order to safeguard a term added by a PTE. Unlike a PTE, which is not impacted by a terminal disclaimer, a PTA can be disclaimed.

The Federal Circuit Holds That Patent-Holder's Tribal Immunity Does Not Apply as Defense to IPR Proceedings

In July of 2018, the Federal Circuit held that tribal sovereign immunity does not apply in *Inter Partes* Review ("IPR") proceedings. In so doing, the Federal Circuit rejected a highly controversial attempt by Allergan PLC to shield its patents for its dry eye medication, Restasis, from review at the PTAB.

In 2017, Allergan transferred ownership of a patent relating to its Restasis product to the Saint Regis Mohawk Tribe ("the Tribe") and then had them licensed back to it. In the pending IPR proceedings, the Tribe asserted tribal

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sovereign immunity for the Restasis patents. The PTAB denied the Tribe's motion to terminate the IPRs and the Tribe appealed. The Federal Circuit affirmed the PTAB's denial of sovereign immunity. *Saint Regis Mohawk Tribe et. al. v. Mylan Pharmaceutical Inc. et al.*, 896 F.3d 1322 (Fed Cir. 2018). In reaching its decision, the Federal Circuit was careful not to mention the political and policy considerations which surrounded the Tribe's attempts to circumvent review of its patents and instead focused on whether IPRs were more similar to a civil lawsuit where tribal immunity would apply, as opposed to traditional agency actions where the immunity generally does not apply.

The Federal Circuit relied on the Supreme Court's analysis in *Fed. Maritime Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743 (2002) ("*FMC*"), which held that tribal sovereign immunity does not apply. In *FMC*, the Court looked to whether the adjudications at issue were "the type of proceedings from which the Framers would have thought the States possessed immunity when they agreed to enter the Union." *Id.* at 5-6. Relying on *FMC*, the Federal Circuit noted that "[g]enerally, immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action." *Saint Regis Mohawk Tribe*, 896 F.3d 1325. It further stated that "[i]n doing so, the [*FMC*] Court recognized a distinction between adjudicative proceedings brought against a state by a private party and agency-initiated enforcement proceedings." *Id.* at 1326. It observed that "IPR is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government." *Id.* The Federal Circuit concluded that "IPR is more like an agency enforcement action than a civil suit brought by a private party" and thus "tribal immunity is not implicated." *Id* at 1327.

After the Federal Circuit denied rehearing, Allergan filed a cert. petition in January 2019 to the U.S. Supreme Court to appeal the Federal Circuit's decision. Therefore, this battle may not yet be over. We will keep you updated on further developments.

Copyright Protection and Software: How Far Can a Fair Use Defense Protect You?

The Federal Circuit issued a landmark fair use ruling in March 2018 in *Oracle America, Inc. v. Google LLC*, 886 F. 3d 1117 (Fed. Cir. 2018), finding that Google's copying of a small portion of Oracle's code to interface with Java was not fair use. Oracle's predecessor, Sun Microsystems, developed the Java programming language and the associated platform, which is software used to write and run programs in the Java programming language. *Id.* at 1186. Oracle owned copyrights in the platform. *Id.* The platform includes, among other things, an application programming interface, or "API," which allows programmers to interface with prewritten code within the platform to perform specified functions. *Id.* In developing its Android platform for mobile devices, Google copied and used the Java platform APIs. *Id.* at 1187. In an earlier decision, the Federal Circuit had ruled that the APIs are entitled to copyright protection. *Id.* at 1188. On remand, a jury found that Google's use of the APIs constituted fair use. *Id.* On appeal, the Federal Circuit ruled that as a matter of law Google's use of the APIs could not constitute fair use. The Court's conclusion was premised on its analysis of the four fair use factors.

As to the first factor, concerning "the purpose and character of the use, including whether such use is of a commercial nature," the Court concluded that Google's use of the APIs in its Android platform was commercial use that heavily weighed against fair use. *Id.* at 1197-98. The Court dismissed Google's argument that its use could have been found to be noncommercial based on Google not charging for use of its Android platform. *Id.* at 1197. The Court reasoned that "although Google maintains that its revenue flows from advertisements, not from Android, commerciality does not depend on how Google earns its money." *Id.* The court also ruled that Google's use was not transformative as a matter of law, focusing on the facts that the APIs serve the same purposes in the Android platform uses as the Java platform and Google had not made any alteration to the APIs. *Id.* at 1199. The Court rejected Google's argument that its use should be considered transformative because Google wrote its own code implementing the APIs, and used only a fraction of the total APIs, holding that despite Google adding its own implementing code for the APIs, Google was "merely copying the material and moving it from one platform to another." *Id.* The popularity of the Android platform on smartphones did not render Google's use transformative, particularly because smartphones already used the Java platform before Android was introduced. *Id.* at 1201.

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As to the second factor, concerning the nature of the copyrighted work, the Court noted that although the APIs involve some level of creativity, "reasonable jurors could have concluded that functional considerations were both substantial and important." On that basis, the Court ruled that this factor favored a finding of fair use, but had "less significance to the overall analysis." *Id.* at 1204.

The third factor involves the amount and substantiality of the portion used in the context of the copyrighted work. *Id.* at 1205-06. The Federal Circuit stressed the parties' stipulation that only 170 lines of Java code are required to write in the Java language, yet Google's use of the APIs required copying 11,500 lines of code. *Id.* at 1206. The Federal Circuited noted that Google was not claiming that its use of the Java APIs was based on interoperability, and that Google instead sought "to capitalize on the fact that software developers were already trained and experienced in using the Java API packages at issue." *Id.* The Court reasoned that even if Google had copied only a very small fraction of the total Java platform code, "no reasonable jury could conclude that what was copied was qualitatively insignificant, particularly when the material copied was important to the creation of the Android platform." *Id.* at 1207. The Court thus held that this factor was at best neutral and arguably weighed against fair use. *Id.*

The fourth fair use factor focuses on the effect of the use on the potential market for the copyrighted work. *Id.* at 1207-08. The Federal Circuit agreed with Oracle that the evidence of actual and potential harm stemming from Google's copying was overwhelming. *Id.* at 1208. The Court cited evidence that showed that Android competed directly with Java in the market for mobile devices. *Id.* The Court noted that the record contained substantial evidence that Android was used as a substitute for Java and harmed Oracle in the process. *Id.* The Federal Circuit held that this factor weighed heavily against a finding of fair use.

Balancing these factors, the Court ruled "that allowing Google to commercially exploit Oracle's work will not advance the purposes of copyright in this case." *Id.* at 1210. The Court stressed that although copying of computer code could be fair use in an appropriate case, "[t]here is nothing fair about taking a copyrighted work verbatim and using it for the same purpose and function as the original in a competing platform." *Id.*

Google is now seeking review of this decision with the Supreme Court. Its Petition for Certiorari, which has not yet been taken up by the Court, raises several interesting questions about the role of copyright in protecting software, namely:

1. Whether copyright protection extends to a software interface.
2. Whether, as the jury found, petitioner's use of a software interface in the context of creating a new computer program constitutes fair use.