

INTELLECTUAL PROPERTY 2016 YEAR IN REVIEW

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The Year in Intellectual Property: A Look Back at 2016 & A Look Ahead to 2017

Last year was an active year in intellectual property law. There were many notable developments in 2016 by a busy United States Supreme Court and the Federal Circuit. The Supreme Court and Federal Circuit issued key rulings involving patent damages, patent eligibility, venue, laches, claim construction, extraterritoriality, attorneys' fees, the nominative fair use doctrine, and patent office procedures. As we look ahead in 2017, the jurisprudence in these areas will develop as the lower courts react to these key rulings and the Supreme Court issues decisions on important matters such as patent venue and laches. As discussed in greater detail below, whether you are a plaintiff or defendant in intellectual property matters, you will need to be cognizant of the impact of these decisions.

2016 YEAR IN REVIEW

Enhanced Damages for Patent Infringement and Use of Opinions of Counsel

In June 2016, the U.S. Supreme Court handed down a decision in *Halo Electronics v. Pulse Electronics* (14-1513), in which it addressed the Federal Circuit's test for determining whether enhanced damages should be awarded for patent infringement under 25 U.S.C. § 284. The Court held that judges have broad discretion to award enhanced damages for patent infringement, concluding that the prior Federal Circuit test was "unduly rigid, and impermissibly encumbers the statutory grant of discretion to the district courts." Specifically, the Court rejected the prior *Seagate* test, which required clear and convincing evidence of both objective recklessness on the part of the infringer as well as subjective knowledge of the risk of infringement.

While acknowledging that the *Seagate* test reflects, in many respects, a sound recognition that enhanced damages are generally appropriate under section 284 only in "egregious cases," the Court faulted the test allowing a showing of "objective recklessness" at the time of litigation to absolve the accused infringer regardless of what they thought when they realized the patent was relevant to their products. The Supreme Court also relaxed the evidentiary burden for proving willful infringement from clear and convincing evidence to a preponderance of the evidence.

The prior *Seagate* test made the ability of the alleged infringer to put forth a reasonable (even though unsuccessful) defense at the time of trial, an effective shield to enhanced damages. *Halo*, by contrast, emphasizes that the legal inquiry for culpability must be measured at the time the alleged infringer became aware of

the assertion of infringement. This places renewed importance on the practice of getting an opinion of counsel, which can be used to show that the alleged infringer acted reasonably.

It remains to be seen how the lower courts and Federal Circuit will apply the more flexible standards set forth by the Supreme Court for finding willfulness and how they will decide whether to enhance the fee awards. Since the Supreme Court puts more emphasis on what defenses existed when an alleged infringer was confronted with a patent, companies may want to consider their policies concerning replying to infringement letters and whether an opinion from outside patent counsel may be necessary. In particular, under *Halo*, companies will need to consider that where there was a pre-suit assertion of infringement, an opinion of counsel can be used as good evidence to show that a defendant's behavior was not willful or careless.

Damages for Design Patent Infringement

In December 2016, in a unanimous decision in *Samsung Electronics Co. Ltd. et al. v. Apple Inc.*, slip op. No. 15-777, the U.S. Supreme Court overturned a \$400 million jury award to Apple for Samsung's infringement of certain Apple design patents relating to smartphones. This Supreme Court decision is significant because it addresses the proper measure of damages for infringement of a design patent.

In 2015, the Federal Circuit (*Apple Inc. v. Samsung Electronics Co., Ltd.*, 786 F.3d 983 (Fed. Cir. 2015)) had affirmed this jury award based on its interpretation of the relevant statute which states, in pertinent part, that

whoever "sells any article of manufacture" to which an infringing design has been applied "shall be liable to the owner to the extent of his total profit..." (see, 35 U.S.C. § 289, emphasis added).

Samsung had unsuccessfully argued that under this statute, damages should have been limited to only the profit attributed to the infringement, or alternatively to the profit on the infringing "article of manufacture," i.e., the component that is the subject of the design patent, such as the screen or case of a smartphone, rather than the entire smartphone.

The Supreme Court agreed with Samsung, holding that in the case of a multi-component end product, the relevant "article of manufacture" could only be a component of that end product, whether or not that component is sold separately from the end product. Significantly, however, the Court declined to give further guidance on what that component would be in the context of the disputed design patents, leaving it to the Federal Circuit to resolve such issues on remand.

While this decision opens the door to reducing damages awarded for design patent infringement, litigants, damages experts and the lower courts are sure to raise many further questions as to how to apply the Supreme Court's guidance to disputes involving design patents. This decision also shows that both patentees and accused infringers need to carefully consider damage valuation as part of their litigation or licensing strategy, including in the context of design patents.

All eyes will be on the Federal Circuit this year when it revisits this high profile case and rules on what kind of damages you can get in a design patent case.

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Attorneys' Fees

The Court also took up the issue of judicial discretion over monetary awards in *Kirtsaeng v. John Wiley & Sons, Inc.* (No. 15-375), clarifying the standard for attorney's fee awards in copyright cases. Section 505 of the Copyright Act provides that a court "may ... award a reasonable attorney's fee to the prevailing party." Specifically, the Court held that while the objective reasonableness of the losing party's position is the most important factor a district court judge should consider in determining whether to award fees under section 505, it is not "the controlling one."

As a number of circuit courts have held, "[a]lthough objective reasonableness carries significant weight, courts must view all the circumstances of a case on their own terms, in light of the Copyright Act's essential goals. In certain jurisdictions this may constitute attorney advertising goals." For example, a party pressing a reasonable legal position may have engaged in unreasonable litigation conduct. Thus, as in *Halo, Kirtsaeng* held that a more flexible test for fee awards should be applied.

Claim Construction Standard in IPRs

In June 2016, in *Cuozzo Speed Technologies v. Lee*, the Court addressed whether the "broadest reasonable construction" standard used during *inter partes* review (IPR) and post-grant review (PGR) proceedings to challenge patent validity before the Patent Trial Appeal Board (PTAB) was the correct claim construction standard, or whether the PTAB must instead use the same (potentially narrower) claim construction standard used by district courts.

The difference in claim construction standards used by the PTAB and district courts had been a source of much debate. Applying the "broadest reasonable interpretation" standard, the PTAB has been invalidating a large percentage of the patents that it has evaluated, leading patent-holders to criticize the standard and the fact that there were different standards in two different forums that evaluate the validity of patents.

The Supreme Court resolved this debate by unanimously affirming the Federal Circuit, holding that the Patent and Trademark Office (PTO), which promulgated the "broadest reasonable interpretation" standard for Intellectual Property Rights (IPRs), had the authority to issue such a regulation. The Court deferred to the PTO's choice of the standard because Congress gave the PTO discretion to design the IPR process. This standard is one reason that militates in favor of challenging patent validity in an IPR proceeding, where possible.

Timing for Filing Continuation Applications

In *Immersion Corp. v. HTC Corp.*, 2015-1574, the Federal Circuit confirmed the United States Patent and Trademark Office's position, beginning in 1961 (MPEP §211.01(b)), of permitting continuations to be filed on the same day as the parent issues. This became an issue because the continuation statute (35 U.S.C. §120) only says that a continuation must be "filed before the patenting or abandonment of or termination of proceedings" of the parent. Thus, there is no way to clearly prove compliance with the statute for continuations filed the day the parent issues are filed.

The Federal Circuit took the position that, for the "before the patenting" condition to be met, the continuing application may be "filed before the patenting" of the earlier application when "both legal acts, filing and patenting, occur on the same day." Thus, it held that the requirement is met if they are filed the same day. In doing so, the Federal Circuit reversed a lower court ruling that a filing on the same day is not before the patent issues. By maintaining the status quo and not disturbing long standing PTO practice, the Federal Circuit sought to avoid disruption and provide stability for patentees.

Nominative Fair Use Doctrine

In May 2016, the Second Circuit issued an opinion on trademark law's nominative fair use doctrine disagreeing with other circuit courts, including the Ninth Circuit, which had developed the doctrine, and adopted a different approach to the doctrine which was in place for decades.

In 1992, the U.S. Court of Appeals for the Ninth Circuit had identified "nominative use" as a distinct concept in trademark law in *New Kids on the Block v. News America Publishing, Inc.*, 971 F.2d 302 (9th Cir. 1992). Under this ruling, the term "nominative use" described instances when another company's trademark could be used as a non-infringing fair use and limited that use to situations when the trademark was used only to describe the thing, rather than identify the source or suggest sponsorship or endorsement.

In *International Information Systems Security Certification Consortium Inc. v. Security University LLC*, the Second Circuit first considered the nominative fair use test adopted by the Ninth Circuit in *New Kids on*

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the Block. According to the Second Circuit, the nominative fair use defense in the Ninth Circuit is not an affirmative defense because it does not protect a defendant from liability if there is a likelihood of confusion. As a result, the Second Circuit held that the nominative fair use defense was not available if the use is likely to cause consumer confusion. It emphasized that the district courts are required to consider each of the likelihood of confusion factors, known as the *Polaroid* factors under *Polaroid Corp. v. Polarad Electronics Corp.*, 287 F.2d 492 (2d Cir. 1961), when considering whether a use, nominative or not, is confusing. Thus, although the Second Circuit agreed with the Ninth Circuit that nominative fair use is not available as an affirmative defense when confusion is likely, it disagreed with the Ninth Circuit adopting a separate nominative fair use test to replace the likelihood of confusion analysis.

The appellee in *International Information Systems* has requested the U.S. Supreme Court to review the Second Circuit decision and address the Circuit split. If the Supreme Court grants *certiorari*, it could bring uniformity to the application of the doctrine.

Patent Venue

In December 2016, in *TC Heartland LLC v. Kraft Food Brands Group LLC*, the Supreme Court granted *certiorari* to address patent venue laws and to decide whether new and more stringent limitations should be imposed on where patent lawsuits can be filed.

By way of background, venue in patent cases is governed by 28 U.S.C. § 1400(b), which provides that venue is appropriate either: (1) “in the judicial district where the defendant resides,” or (2) “where the defendant has committed acts of infringement and has a regular and established place of business.” Section 1400 does not define the term “resides” or explain how it should be applied to corporate defendants, thereby leaving it to the courts to deduce Congress’s intent. The Federal Circuit has held that patent suits can be filed in any district where the defendant makes sales.

While *TC Heartland*’s arguments are couched in statutory interpretation and analysis of legal precedent, policy concerns are also at the forefront in this debate. *TC Heartland* argues that the Federal Circuit’s position has led to extensive forum shopping by patentees which needs to be addressed. The Supreme Court’s ruling will determine whether a defendant’s residence or where it has committed an act of infringement and has an established place of business should be the choice of venue. It could also affect whether popular jurisdictions for patentees, such as the Eastern District of Texas, will still be viable when a defendant does not actually reside there. On the other hand, Delaware, where a substantial number of businesses are incorporated, could see an increase in patent cases.

Continued Guidance on Patent Eligibility

After the Supreme Court’s decision in *Alice Corp. v. CLS Bank* (2014) that abstract ideas implemented using a computer are not patent-eligible under Section 101 of the Patent Act, many courts invalidated computer-related patents.

In 2016, the Federal Circuit attempted to provide more clarity on the parameters of Section 101 and patent eligibility for computer-related patents. Beginning with the May 2016 decision in *Enfish v. Microsoft*, the Federal Circuit issued its first decision finding software patent claims directed to an innovative logical model for a computer database to be patent eligible. *Enfish* was followed by several other Federal Circuit decisions finding software and internet patent claims to be patent eligible. See e.g., *McRO, Inc. dba Planet Blue v. Bandai Namco Games America, Inc.* 120 USPQ2d 1091 (Fed. Cir. 2016) and *BASCOM Global Internet Services v. AT & T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016). However, at the same time the Court also affirmed many patent ineligibility decisions. Moreover, while several decisions have attempted to clarify *Alice*, none of them have significantly reinterpreted the *Alice* ruling.

In the life sciences space, following *Alice*, the Federal Circuit held in *Sequenom v. Ariosa*, 788 F.3d 1371 (Fed. Cir. 2015) that the discovery of a test for detecting fetal genetic conditions in early pregnancy that avoided dangerous, invasive techniques that are potentially harmful to both the mother and the fetus was “a significant contribution to the medical field,” but that did not matter insofar as patent eligibility is concerned. In June 2016, the Supreme Court denied *Sequenom*’s *certiorari* petition

which presented the sole question: Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

In July 2016, the Federal Circuit found in *Rapid Litigation Management v. CellzDirect* that the claimed methods for cryopreserving liver cells for use in “testing, diagnostic, and treating purposes” to be patent eligible and not directed to a judicial exception. The Federal Circuit focused on the fact that the claims in *CellzDirect* were directed to a process for achieving an outcome (cryopreservation of the cells) as opposed to an observation or detection.

Thus, defendants will still seek to invalidate patents under *Alice*, but now patentees have the benefit of some more jurisprudence, such as *Enfish* and *Cellzdirect*, to give credence to their arguments. 2017 will likely lead to more jurisprudence on these issues and perhaps a clearer path forward.

Extraterritoriality of Patent Laws

On June 27, 2016, the Supreme Court granted *certiorari* in *Life Technologies Corp. v. Promega Corporation* and heard arguments in December 2016 on the scope of 35 U.S.C. § 271(f)(1). Section 271(f)(1) makes it an act of infringement to supply from the U.S. “all or a substantial portion of the components” of a patented invention so as to actively induce the combination of the components outside of the U.S. The *Life Technologies* case continues the Court’s

trend of examining the extraterritorial scope of U.S. patent laws.

Life Technologies supplied an enzyme from the U.S. to its UK subsidiary, which then incorporated the enzyme into a diagnostic kit abroad, and was sold worldwide. At trial, the jury found infringement and awarded \$52 million in damages to *Promega*. However, in his ruling on post-trial motions, the Judge reversed, holding that the “substantial portion” language of section 271(f)(1) required that multiple components were shipped abroad. The Federal Circuit reversed, holding that the “substantial portion” language referred to importance rather than quantity and could be met by a single component, here the enzyme.

The question that the Supreme Court will address is “whether the Federal Circuit erred in holding that supplying a single commodity component of a multi-component invention from the United States is an infringing act under 35 U.S.C. § 271(f)(1), exposing the manufacturer to liability for all worldwide sales.” Whether the Supreme Court will provide clear guidance on this issue or remand to the Federal Circuit to design a test remains to be seen.

Patent Exhaustion

In December 2016, the Supreme Court granted *certiorari* in *Impression Products, Inc. v. Lexmark International, Inc.* This case address two significant issues pertaining to the patent exhaustion doctrine: (1) whether a “conditional sale” that transfers title to the patented item while specifying post-sale restrictions on the article’s use or resale avoids application of the patent exhaustion doctrine and therefore permits the enforcement of such post-sale restrictions

through the patent law’s infringement remedy; and (2) whether, in light of the Supreme Court’s holding in *Kirtsaeng*, the exhaustion doctrine applies to authorized sales of a patented article that take place outside of the United States.

The Supreme Court’s ruling will impact a wide range of industries. If the Court reverses the Federal Circuit’s holding that patent exhaustion does not apply to a conditional sale or to sales abroad, it is likely to impact on many contractual relationships and lead to complications in enforcing patents.

Availability of Laches as a Defense

In the *SCA Hygiene v. First Quality* case, the Supreme Court will address the availability of laches as a defense to the award of past damages for patent infringement. *Certiorari* was granted in May 2016 and arguments heard in September 2016. Currently, the equitable doctrine of laches is available as a defense to limit damages for past infringement that would otherwise be available under the Patent Act’s six-year statutory limitations period for past damages, 35 U.S.C §286. As such, laches encourages a patent owner to exercise its patent rights promptly upon learning of infringement, rather than waiting to sue until the defendant is prejudiced, for example, by having expended substantial resources in developing a potentially infringing product. If laches is no longer available as a defense, patent owners will be able to hold off bringing suit until there are significant past damages available within the six-year statutory period, without concern that delay in bringing suit will potentially reduce their ability to collect past damages.

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Biosimilars and Interpretation of the BPCIA

In January 2017, the U.S. Supreme Court agreed to review some of the patent dispute resolution provisions of the Biologics Price Competition and Innovation Act (BPCIA) that could determine how soon firms can sell biosimilars. The BPCIA creates an abbreviated approval pathway for biosimilar medicines and prescribes defined procedures for a biosimilar applicant to challenge innovator patents, a process often referred to as the “patent dance.” The Court granted *certiorari* in the dispute between Amgen Inc. and Novartis’s subsidiary Sandoz involving Sandoz’s biosimilar Zarxio, the first biosimilar approved under the BPCIA. The Federal Circuit decided that the biosimilar patent dance provisions are optional, but pre-marketing notice always is required.

There are two issues before the Supreme Court. First, Sandoz’s February 2016 petition for *certiorari* asked the Court to decide whether biosimilar applicants have to wait for approval to give pre-marketing notice. In particular, the question before the Court is: Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating 42 U.S.C. § 262(l)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper.

Second, Amgen’s March 2016 conditional-cross petition for *certiorari* asked the Court to decide whether

biosimilar applicants have to join in the patent dance. In particular, the question before the Court is: Is an Applicant required by 42 U.S.C. § 262(l)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant “shall provide,” and, where an Applicant fails to provide that required information, is the Sponsor’s sole recourse to commence a declaratory-judgment action under 42 U.S.C. § 262(l)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)?

The Solicitor General of the United States filed an amicus brief that sided with Sandoz on both issues. In particular, the Solicitor General thinks the Federal Circuit correctly held that the information exchange provisions of 42 USC § 262(l)(2)(A) are optional, but does not agree that the pre-marketing notice required by 21 USC § 262(l)(8)(A) cannot be given until the biosimilar product has been approved by the FDA.

The Supreme Court is likely to hear oral arguments in April, with a decision expected before July. The outcome is important because it will affect how quickly lower-cost biosimilars get to market. Only four biosimilars have the U.S. Food and Drug Administration’s approval, but only two, Zarxio and Pfizer Inc.’s Inflectra, have entered the U.S. market so far.

We will keep you updated as the law on these various topics develops in 2017.