State Bar of Michigan
Ipls Proceedings

2016-2017 Supreme Court Intellectual Property Review

By Christopher C. Smith and David C. Berry

Volume 28 • Issue 2 • 2017

In This Issue

The U.S. Supreme Court's October 2016 term was a blockbuster term for intellectual property issues. The Court decided five patent-related cases, as well as important copyright and trademark cases. The following is a concise review of the Court's IP decisions:

Patent: Court Restricts Venue in Patent Infringement Cases

TC Heartland LLC v. Kraft Foods Group Brands LLC
137 S.Ct. 1514 (May 22, 2017).

In the decision likely to have the most profound effect on patent litigation strategy, the Supreme Court rejected the prevailing interpretation of the patent venue statute, 28 U.S.C. § 1400(b), and held in an 8-0 decision that a domestic corporation defendant may be sued for patent infringement only in its state of incorporation or in a district where it allegedly "committed acts of infringement *and* has a regular and established place of business." The decision immediately causes a diversion of cases away from the U.S. District Court for the Eastern District of Texas and other jurisdictions favored by patent plaintiffs, to districts where defendants are incorporated or have an established presence.

Background

The decision resulted from a petition for a writ of mandamus filed by TC Heartland, a liquid sweetener manufacturer sued for patent infringement in the U.S. District Court for the District of Delaware, in its attempt to have the action against it transferred to a more favorable forum. The patent owner, Kraft Foods Group Brands LLC, a Delaware corporation, sued TC Heartland in the District of Delaware. The defendant moved to dismiss the action or transfer it to the U.S. District Court for the Southern District of Indiana, on the grounds that TC Heartland was an Indiana corporation with no presence in Delaware, other than the incidental sale of accused products. The district court denied the motion and the U.S. Court of Appeals for the Federal Circuit denied mandamus, relying on its controlling decision in *VE Holding Corp. v. Johnson Gas Appliance Co.,* 917 F.2d 1574 (Fed. Cir. 1990). That decision allowed infringement actions to be filed against corporations selling or distributing allegedly infringing products through nationwide channels of commerce in almost any judicial district. TC Heartland petitioned to the Supreme Court.

Continued on page 3

View from the Chair

The culmination of the Intellectual Property Law Section's programming for each year is the annual Intellectual Property Law Institute, which will take place at the Grand Hotel on Mackinac Island this year. For 43 years, the Section and the Institute of Continuing Legal Education have sponsored this outstanding event. In many ways, it reflects the objectives that the Section council seeks to achieve in all our activities: A high quality program, featuring distinguished national presenters, and providing both valuable updates on the most important IP topics, and also providing ample time to network with colleagues. We are especially pleased that Hon. Jimmie V. Reyna of the U.S. Court of Appeals for the Federal Circuit will be joining us on Mackinac this year. It promises to be another excellent summer event, and I hope you all can attend.

The Mackinac program is just one of the successful events that the Section council planned during 2016-2017. In September, the Section hosted a luncheon for Russ Slifer, the Deputy Director of the U.S. Patent and Trademark Office, in Detroit. The Section also co-sponsored a reception for members at the State Bar's annual meeting in Grand Rapids. Price Heveveld LLP generously supported the reception. Despite a morning snow storm, the Spring IP Seminar in East Lansing in March was well-attended, and those who braved the road conditions were treated to a craft brew tasting during a networking break. The Section supported World IP Day in May at the Henry Ford Museum, and volunteers from the Michigan Patent Pro Bono Project staffed a table to assist inventors with basic IP questions. Last week, the Section and the Michigan IP Inn of Court co-sponsored a reception at the Detroit Yacht Club to celebrate the 5th anniversary of the Midwest Regional U.S. Patent Office in Detroit. The event featured comments from the new Interim U.S. Patent and Trademark Office Director, Joseph Matal.

Our outstanding programs will continue through the end of 2017, with a new Fall seminar, "Basic Trademark and Patent Practice of Lawyers and Paralegals," to be held in Plymouth in October. You can find more details about that program in this issue of Proceedings, or on the ICLE website.

As I conclude my term on the council, I want to recognize the IP professionals who have volunteered their time and energies to make the Section's programs a success over the past several months. Four council members, Lisabeth Coakley, Kristin Murphy, Angela Caligiuri, and Matt Goska will be concluding their terms. Thanks to each of them for their contributions, especially to Kristin, who served on the council for six years! I also must recognize the excellent management skills of this year's Chair-elect, Hope Shovein, and Secretary/Treasurer, Kendra Mattison. I am confident that the Section's success will continue unabated under their able leadership. And finally, the entire council must recognize the groundwork of recent council officers, including Anna Budde, Adam Strauss, Karl Ondersma, and Kristen Spano, who helped to build the IP Law Section into such valuable resource for the Michigan IP law community.

Enjoy the rest of your summer, and I look forward to seeing you all at a future IP Law Section event.

—David C. Berry

Intellectual Property Law Section 2016-2017 Officers & Council

Chair
David Charles Berry, Southfield
P: (248) 358-4400
E: dberry@brookskushman.com

Chair-Elect
Hope V. Shovein, Southfield
P: (248) 358-4400
E:hshovein@brookskushman.com

Secretary-Treasurer
Kendra Sue Mattison
Auburn Hills
P: (248) 340-2170
E: kmattison@gmail.com

Term Ending: 2017
Angela Kathleen Caligiuri, Detroit

Lisabeth H. Coakley, Troy
E: coakley@hdp.com

Kristin L. Murphy, Southfield
E: kmurphy@brookskushman.com

Term Ending: 2018
Thomas J. Appledorn
Bloomfield Hills
E: tja@honigman.com

Kimberly A. Berger, Detroit
E: berger@millercanfield.com

Aaron J. Wong, Grand Rapids

Term Ending: 2019
E. Colin Cicotte, Troy
E: cicotte@reising.com

Matthew L. Goska, Grand Rapids
E: mgoska@wnj.com

Mary Margaret O'Donnell, Birmingham
mmo@bluefilamentlaw.com

Commissioner Liaison
Andrew Frederick Fink, III, Ann Arbor
E: andrew.fink@finkvalvolaw.com

ICLE
Jeffrey E. Kirkey, Ann Arbor
E: jkirkey@icle.org

© 2017 Intellectual Property Law Section State Bar of Michigan

Continued from page 1

Supreme Court Ruling

On appeal, TC Heartland challenged the Federal Circuit's interpretation of the patent venue statute, 28 U.S.C. § 1400(b), which states that infringement actions "may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." The Federal Court in *VE Holding had ruled that the general venue provision, 28 U.S.C.* § 1391, as amended in 1988, modified Section 1400(b) so that a corporation defendant "resides" in any district where it is subject to personal jurisdiction.

In a unanimous decision written by Associate Justice Clarence Thomas, the Court rejected the *VE Holding* analysis and held that a domestic corporation "resides" only in its state of incorporation. The Court limited its discussion to a traditional statutory construction analysis, and avoided commenting on the policy concerns raised by the parties and several amici curiae. The Court held that its interpretation of Section 1400(b) in *Fourco Glass Co. v. Transmirra Prods. Corp.,* 353 U.S. 222 (1957) was dispositive, and that Congress did not clearly indicate an intent to change that caselaw when it amended Section 1391. Furthermore, the Court noted that more recent amendments to Section 1391 in 2011 appeared to confirm that the Fourco decision remained good law because the general venue provision now includes a savings clause stating that it does not apply when "otherwise provided by law[.]"

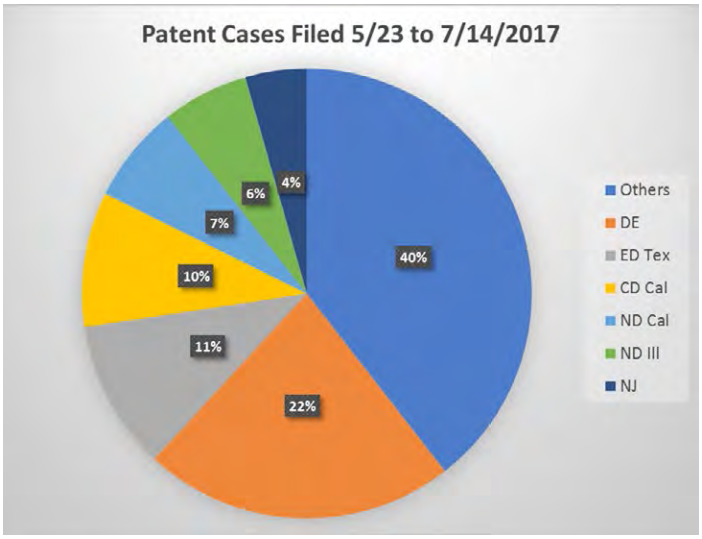
As a result, a patent owner has two venue options for defendants that are domestic corporations: (1) the defendant's state of incorporation, or (2) in a judicial district where the defendant allegedly has committed acts of infringement and has a regular and established place of business.

Practical Impact

The *TC Heartland d*ecision will have a significant and immediate impact on patent litigation practice and strategy. Under the prior *VE Holding* decision, patent owners opted to file infringement cases in favorable districts, with half of all patent infringement actions each year being filed in just two courts: the Eastern District of Texas and the District of Delaware. Critics have criticized this practice as "forum shopping," and have argued that subjecting defendants to litigation in inconvenient courts was unfair. Other critics have argued that the concentration of patent litigation in a handful of districts gave the limited number of federal judges in those districts a disproportionate influence over the interpretation and development of patent law.

The *TC Heartland* ruling has caused a substantial fraction of cases that otherwise would be filed in the Eastern District of Texas to be filed in other judicial districts. The precise redistribution of those cases will depend on the footprints of future defendant and the perceived tactical advantages and disadvantages of alternative jurisdictions. It is likely that many more cases will be filed in districts where corporate headquarters, manufacturing, and/or retail facilities are located. In addition, it is likely that defendants in cases currently pending in the Eastern District of Texas and other unfavorable fora will move to transfer venue, if the right to do so has not been waived.

For example, in 2016, 36.7 % of all patent cases were filed in the Eastern District of Texas, and 10.0 % were filed in District of Delaware. Lex Machina 2016 Patent Litigation Report. For the period immediately following the *TC Heartland* decision, only 11 % of cases were filed in the Eastern District of Texas. The volume of cases filed in Delaware more than doubled, to 22 %. The Central District of California (6.4 % to 10 %) and Northern District of California (4.1 % to 7 %) also saw significant increases in case filings. (Data from Docket Navigator).



The *TC Heartland* decision will cause patent owners to reassess their enforcement strategies, including evaluating the relative pros and cons of filing in districts outside Texas and Delaware. In some cases involving multiple defendants, plaintiffs will need to file separate actions in different courts, leading to possible coordinated multidistrict litigation. In addition, if patent owners adopt a strategy of filing infringement actions against retailers (which generally do have a presence in the Eastern District of Texas), manufacturers may be forced to defend those actions due to their contractual indemnification obligations. Although the decision raises numerous questions that can only be resolved by future cases, such as the appropriate venue rules for foreign corporation and limited liability

corporation defendants, the *TC Heartland* decision is sure to be a watershed event, which will shape patent litigation practice for many years.

Patent: Any Authorized Product Sale, Anywhere in the World, Exhausts Patent Rights

Impression Products, Inc. v. Lexmark Int'l, Inc.
137 S.Ct. 1523 (May 30, 2017)

The Supreme Court held that a patent owner's sale of a patented product exhausts its ability to bring infringement claims against the purchaser, or subsequent owners, of the product. In so holding, the Court rejected cases, such as *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (1992), which recognized contractual limitations on a purchaser's post-sale use or disposal of a product. In addition, the Court held that product sales in a foreign country trigger exhaustion, even when the product sold was not subject to patent protection in the place of sale. So, for example, if a U.S. patent owner sells a product covered by its U.S. patent in Germany, the product sold in Germany could be imported into the U.S. without infringing (the U.S. patent) because all rights of the patent owner would already have been exhausted by the sale in Germany. The decision is likely to expand the exhaustion doctrine as a hurdle to patent enforcement, and will likely cause patent owners to reevaluate their product sales and distribution strategies.

Background

The Court's decision is the latest in a long-running litigation between Lexmark International. Inc., a maker of computer printers, and Impression Products, Inc., which refurbishes and resells used printer toner cartridges. Lexmark sells toner cartridges both in the U.S. and in foreign markets. In the U.S., Lexmark sells cartridges in two configurations. First, Lexmark sells cartridges at full price with no restrictions on the purchaser's ability to refill and reuse the cartridges. Second, Lexmark sells its toner cartridges at a discount and the purchaser agrees to refrain from transferring spent cartridges to any person other than Lexmark (also called the Lexmark "Return Program"). All cartridge sales outside the U.S. were made without restriction on purchaser disposition of spent cartridges. In the litigation, Lexmark alleged that Impression infringed its patents by taking title to used toner cartridges, circumventing microchip technology intended to prevent refilling the cartridges, and reselling the refurbished cartridges in the United States (including importing cartridges from foreign markets).

Impression defended the infringement, arguing that the initial sales of Lexmark toner cartridges exhausted all patent rights, and thus the original purchasers and any downstream owners of the cartridges were free from infringement claims. The Federal Circuit held that patent exhaustion did not apply to either the domestic "Return Program" cartridges or the foreign-sale cartridges. *Impression Products, Inc. v. Lexmark Int'l, Inc.,* 816 F. 3d 721 (2016).

Supreme Court Ruling

In a decision written by Chief Justice John Roberts, the Supreme Court reversed the Federal Circuit and ruled that patent exhaustion applies both to "Return Program" cartridges and to cartridges sold outside the U.S.

First, in a discussion that strongly supported the right of a purchaser of a patented product to be free of lingering restriction on future use, the Court held that patent exhaustion occurs automatically whenever a patent owner sells a patented product. "When a patentee chooses to sell an item, that product 'is no longer within the limits of the monopoly' and instead becomes the 'private, individual property' of the purchaser, with the rights and benefits that come along with ownership." 137 S.Ct. at 1531, quoting *Bloomer v. McQuewan,* 14 How. 539 (1853). The Court noted that the principle of exhaustion had an "impressive historical pedigree[.]" "As Lord Coke put it in the 17th century, if an owner restricts the resale or use of an item after selling it, that restriction 'is voide, because . . . it is against Trade and Traffique, and bargaining and contracting betweene man and man.'" 137 S.Ct. at 1532, quoting 1 E. Coke, Institutes of the Laws of England §360, p. 223 (1628).

Further, the Court held that express restrictions on the purchaser's right to use the patented product do not prevent exhaustion. Those restrictions may be enforceable under contract principles, but they do not preserve the right to bring a patent infringement claim. Relying on prior decisions finding exhaustion, including *United States v. Univis Lens Co.*, 316 U. S. 241 (1942) and *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U. S. 617 (2008), the Court concluded that sales of cartridges under the "Return Program" resulted in exhaustion of Lexmark's patents:

> [W]e conclude that this well-settled line of precedent allows for only one answer: Lexmark cannot bring a patent infringement suit against Impression Products to enforce the single-use/no-resale provision accompanying its Return Program cartridges. Once sold, the Return Program cartridges passed outside of the patent monopoly, and whatever rights Lexmark retained are a matter of the contracts with its purchasers, not the patent law.

137 S.Ct. at 1533. Exhaustion will also occur when a product is sold by a licensee with authority to make the sale. "That licensee's sale is treated, for purposes of patent exhaustion, as if the patentee made the sale itself." *Id.* at 1535. The Court suggested, however, that a license of a patented product would not typically result in exhaustion, because title to the product did not pass to the licensee.

Second, the Court held that exhaustion applies to the sale of patented products outside the U.S., as well as domestic sales. It rejected the rationale adopted by the Federal Circuit that exhaustion should not apply to foreign sales because the seller is unable to command a premium price to compensate for a release of patent rights when the product sold is not covered by the patent. On this point, the Court looked to the contours of Copyright's first sale doctrine. *See Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U. S. 519 (2013). In the *Kirtsaeng* decision, one important factor supporting the Court's decision to apply the first sale doctrine to non-U.S. sales was "the fact that the first sale doctrine originated in 'the common law's refusal to permit restraints on the alienation of chattels.' That 'common-law doctrine makes no geographical distinctions.'" 137 S.Ct. at 1536. Applying a parallel reasoning, the Court ruled that patent exhaustion should apply to non-U.S. sales, citing the "'historic kinship between patent law and copyright law,' *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U. S. 417, 439 (1984), and the bond between the two leaves no room for a rift on the question of international exhaustion." *Id.* (quotations and citations omitted).

Thus, the Court further held:

> [a]llowing patent rights to stick remora-like to that item as it flows through the market would violate the principle against restraints on alienation. Exhaustion does not depend on whether the patentee receives a premium for selling in the United States, or the type of rights that buyers expect to receive. As a result, restrictions and location are irrelevant; what matters is the patentee's decision to make a sale.

137 S.Ct. at 1538. Associate Justice Ruth Bader Ginsburg dissented from the ruling on this issue, arguing that exhaustion, like the first sale doctrine, should be limited to U.S. sales.

Practical Significance

The *Impressions* decision is significant because it undercuts two leading Federal Circuit cases, which lower courts have relied upon to allow patent owners to sell products without losing the right to restrict post-sale activities. *See Jazz Photo Corp. v. International Trade Commission,* 264 F. 3d 1094 (2001) (holding that exhaustion does not apply to non-U.S. sales); and *Mallinckrodt, Inc. v. Medipart, Inc.,* 976 F. 2d 700 (1992)(upholding post-sale restrictions on product use). The decision will force patent owners to review their current sales and distribution strategies, including any arrangements with licensees. The decision raises several issues that will be litigated in future cases.

For example, although the Court indicated that licenses typically will not result in exhaustion, it remains unclear whether standard, mass market licenses, such as those used in the distribution of computer software, will trigger exhaustion issues. In addition, the Court noted that restrictions on post-sale activity may be enforced as a breach of contract. Patent owners may consider bringing claims for interference with contract against competitors who encourage customers to breach their contractual obligations by transferring products in violation of purchase terms.

Patent: Laches Is Not a Defense To Patent Infringement Damages Claim

SCA Hygiene Products Aktiebolg v. First Quality Baby Products, LLC
137 S.Ct. 954 (Mar. 21, 2017)

In *Petrella v. Metro-Goldwyn-Mayer, Inc.,* 134 S. Ct. (2014), the Supreme Court ruled that the equitable defense of laches is not available when a copyright owner brings a claim for damages under the Copyright Act within the Act's three-year statute of limitations period. The Court left unresolved whether laches is available in damage claims under the Patent Act. In a decision this term, the Court settled that open question: **Laches is not a defense to patent infringement damage claims filed within the six-year window set forth in 35 U.S.C. §286.**

Supreme Court Ruling

In an 7-1 decision written by Associate Justice Samuel Alito, the Court closely followed the reasoning of its earlier *Petrella* decision. It noted that laches is a common law equitable defense, which protects a defendant when the plaintiff's delay in commencing suit results in prejudice. If, however, a statute creating a cause of action also includes a specific limitations period, then Congress already has decided whether a claim is untimely. In those cases, courts are unable to bar an otherwise timely claim based on laches:

> The enactment of a statute of limitations necessarily reflects a congressional decision that the timeliness of covered claims is better judged on the basis of a generally hard and fast rule rather than the sort of case-specific judicial determination that occurs when a laches defense is asserted. Therefore, applying laches within a limitations period specified by Congress would give judges a "legislation overriding" role that is beyond the Judiciary's power. As we stressed in *Petrella,* "courts are not at liberty to jettison Congress' judgment on the timeliness of suit."

137 S.Ct. at 960 (citations omitted).

The Court ruled that although section 286 of the Patent Act is phrased differently than some other limitations provisions, it nonetheless reflects Congress' judgment on the time limit applicable to damages claims. Section 286 states that in

a patent infringement action, "[e]xcept as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action." 35 U.S.C. § 286. In effect, the provision allows a plaintiff to collect damages only for infringing conduct that occurred during a six-year window prior to suit. Thus, the Court noted that Section 286 cannot be distinguished from the Copyright Act's statute of limitation provision at issue in *Petrella.*

The Court also rejected the argument, adopted by the U.S. Court of Appeals for the Federal Circuit below, that laches is a defense codified in 35 U.S.C. § 282(b), which states that defenses in patent infringement cases include "[n]oninfringement, absence of liability for infringement or unenforceability." After a historical review of past patent decisions, the Court concluded that laches was not a widely-recognized defense to patent infringement actions seeking damages prior to passage of the current patent Act in 1952:

> We have closely examined the cases on which the Federal Circuit and First Quality rely, and we find that they are insufficient to support the suggested interpretation of the Patent Act. The most prominent feature of the relevant legal landscape at the time of enactment of the Patent Act was the well-established general rule, often repeated by this Court, that laches cannot be invoked to bar a claim for damages incurred within a limitations period specified by Congress.

137 S.Ct. at 963. Thus, the Court held that a claim for damages for patent infringement, brought within six years of the alleged infringing conduct, is not subject to the defense of laches.

Practical Significance

Although the *SCA Hygiene Products* decision eliminates laches as a defense against claims for patent infringement damages, it is unlikely to have a profound practical effect in most patent litigation matters. Defendants frequently allege laches as an affirmative defense, but it rarely impacts the case results. In addition, defendants will be able to raise other equitable arguments to oppose patent infringement claims. Although laches is unavailable, equitable estoppel remains a viable defense in some situations. For example, the Court noted that the "doctrine of equitable estoppel provides protection against some of the problems that First Quality highlights, namely, unscrupulous patentees inducing potential targets of infringement suits to invest in the production of arguably infringing products." Slip op. at 16. In addition, equitable factors akin to those arising in laches situations remain central to patent owner claims seeking injunctive relief. In considering whether to grant an injunction, a court must balance the equities favoring the plaintiff and defendant, and a trial court may consider an unreasonable delay in filing suit as a factor in determining appropriate injunctive relief. *See Petrella,* 134 S. Ct at 1978-79.

Patent: Suppliers Do Not Infringe Section 271(f)(1) By Exporting a Single Component Used to Fabricate Patented Device Outside U.S.

Life Technologies Corp. v. Promega Corp., 137 S.Ct. 734 (Feb. 22, 2017)

In this case, the Supreme Court ruled that 35 U.S.C. § 271(f)(1), a provision creating infringement liability when "all or a substantial part of the components" of an invention patented in the United States are exported for assembly outside the country, does not apply when an accused infringer exports only a single component. The Court based the result on a careful textual analysis of the statute. The Court's narrow decision leaves unresolved other important questions, including the number of exported components needed to trigger liability under the statute.

Background

The case arose from a patent license dispute between a patent owner, Promega Corporation, and a licensee, Life Technologies Corporation. Promega owned U.S. Patent No. RE 37,984, titled "Process for analyzing length polymorphisms in DNA regions," which included claims to a kit for carrying out DNA tests according to the invention. The kit consisted of at least five components, including a specific polymerase. Life Technologies was licensed to make and sell kits for the law enforcement market. It fabricated licensed kits in the United Kingdom using polymerase that it made in the United States and then exported abroad. Promega sued for infringement when Life Technologies exceeded the license by selling kits to other markets. The central issue in the case was whether Life Technologies was liable under Section 271(f)(1):

> Whoever without authority supplies or causes to be supplied in or from the United States *all or a substantial portion of the components of a patented invention,* where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(emphasis added). The district court granted judgment in favor of Life Technologies on the ground that a single component used in a test kit is not "all or a substantial portion of the components of a patented invention[.]". The Federal Circuit reversed, concluding that a "substantial" portion from Section 271(f)(1) means an "important" or "essential" portion, and in certain cir-

cumstances a single "main" component constitutes an "important" or "essential" portion of the patented invention. *Promega Corp. v. Life Technologies Corp.*, 773 F.3d 1338 (Fed. Cir. 2014).

Supreme Court Decision

In a 7-0 decision, the Supreme Court reversed and ruled that Section 271(f)(1) does not cover Life Technologies' export of polymerase. Chief Justice Roberts recused himself from the case. In the opinion, Associate Justice Sonia Sotomayor wrote that the text of the statute strongly indicates that "substantial" refers to the quantity of components exported by a defendant, not the qualitative importance of a component:

> [T]he phrase "substantial portion" is modified by "of the components of a patented invention." It is the supply of all or a substantial portion "of the components" of a patented invention that triggers liability for infringement. But if "substantial" has a qualitative meaning, then the more natural way to write the opening clause of the provision would be to not reference "the components" at all. Instead, the opening clause of §271(f)(1) could have triggered liability for the supply of "all or a substantial portion of . . . a patented invention, where [its] components are uncombined in whole or in part." A qualitative reading would render the phrase "of the components" unnecessary the first time it is used in §271(f)(1). Whenever possible, however, we should favor an interpretation that gives meaning to each statutory provision. *See Hibbs v. Winn,* 542 U.S. 88, 101 (2004). Only the quantitative approach does so here. *Thus, "substantial," in the context of §271(f)(1), is most reasonably read to connote a quantitative measure.*

137 S.Ct. at 740 (emphasis added). The Court rejected Promega's proposal that "substantial" could have both quantitative and qualitative aspects, noting that "the statute's structure provides little support for a qualitative interpretation of the term." *Id.* at 741.

The Court further held that Section 271(f)(1) requires more than a single component to be supplied. Again, the Court performed a textual analysis, emphasizing that "[t]he section is targeted toward the supply of all or a substantial portion 'of the components,' where 'such components' are uncombined, in a manner that actively induces the combination of 'such components' outside the United States. Text specifying a substantial portion of 'components,' plural, indicates that multiple components constitute the substantial portion." 137 S.Ct. at 741. Noting that Congress inserted Section 271(f) to fill a loophole recognized in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), which held that the creation of a complete kit of parts for assembling a patented device outside of the United States was not direct infringement under Section 271(a), the Court concluded that a quantitative interpretation was consistent with Congressional intent. The Court held that the requirement is also consistent with Section 271(f)(2), which creates liability for active inducement of infringement based on the exportation of a component that is specific to a claimed invention:

> Our ruling today comports with Congress' intent. A supplier may be liable under §271(f)(1) for supplying from the United States all or a substantial portion of the components (plural) of the invention, even when those components are combined abroad. The same is true even for a single component under §271(f)(2) if it is especially made or especially adapted for use in the invention and not a staple article or commodity. We are persuaded, however, that when as in this case a product is made abroad and all components but a single commodity article are supplied from abroad, this activity is outside the scope of the statute.

137 S.Ct. at 743.

Practical Significance

Although the *Life Technologies* decision makes it clear that U.S.-based suppliers do not face liability under Section 271(f)(1) for exporting a single component to be used to assemble a patented invention, it leaves unresolved several important issues. First, although a single component is not "substantial," the Court did not discuss the actual number of components needed for liability, or how to determine if exported materials are one or multiple "components." *See* Alito, J. Concurring Opinion ("today's opinion establishes that more than one component is necessary, but does not address *how much* more")(emphasis in original). Second, the Court did not consider whether Section 271(f) is limited to cases where a defendant causes another entity to practice the claimed invention, but does not apply when a defendant "exports" to itself. See 773 F.3d, at 1358–1360 (dissent by Chief Judge Prost). Finally, the Court did not shed any light on the requirements for liability under Section 271(f)(2), including the intent required to be liable for active inducement of infringement based on the exportation of one or more components.

Thus, although the *Life Technologies* decision provides some guidance to suppliers exporting components, careful analysis is warranted to assess potential liability for infringement based on other provisions of the Patent Act.

Design Patent: Court Limits Damages, Vacates Apple's $399 Million Award Against Samsung

Samsung Electronics Co. v. Apple, Inc.,
137 S.Ct. 429 (Dec. 6, 2016)

In a 8-0 ruling, the U.S. Supreme Court ruled that damages for infringement of design patents under 35 U.S.C. § 289 can be limited to the defendant's "total profits" from the article of manufacture that contains the patented design, which may only be one component of a commercial product, rather than the entire product. As a result, the Court vacated a $399 Million damage award against Samsung Electronics Co. in a lawsuit alleging infringement of design patents covering features of Apple, Inc.'s iPhone smartphones and sent the case back to the Federal Circuit for further analysis. The decision is likely to provide a platform for the Federal Circuit to limit available damages in design patent cases involving complex products, such as where an infringed patent covers design elements present only in individual components of the product.

Background

The Supreme Court decision is part of a far-reaching patent dispute between Apple and Samsung involving their respective smartphone and mobile device products. Apple owns the three design patents at issue in the case. Two of the patents cover a design for the exterior face of a mobile phone: U.S. Design Patent No. D618,677 and U.S. Design Patent No. D593,087. Apple's third design patent, U.S. Design Patent No. D604,305, covers the graphical user interface for a display screen. In April 2011, Apple sued Samsung for patent infringement in the U.S. District Court for the Northern District of California. A jury ruled for Apple on those claims and the district court awarded Apple $399 Million in damages, based on the total profit Samsung realized from sales of infringing devices.

At the Federal Circuit, Samsung argued that the award violated § 289, because the damages should have been based on profits from the components that infringed, not Samsung's entire products. The appeals court affirmed the district court, distinguishing prior cases awarding design patent damages for components by noting that the components in earlier cases were sold separately and considered separate products. "The facts at hand are different. The innards of Samsung›s smartphones were not sold separately from their shells as distinct articles of manufacture to ordinary purchasers." *Apple Inc. v. Samsung Elecs. Co.*, 786 F.3d 983 (Fed. Cir. 2015).

Supreme Court Ruling

In a unanimous decision written by Justice Sotomayor, the Supreme Court vacated the damage award. The central issue on appeal was whether an "article of manufacture" is necessarily an entire product sold to a consumer, or whether it can be a component of a product made from multiple parts. Section 289, governing damages in design patent cases, provides that:

> Whoever during the term of a patent for a design, without license of the owner, (1) applies the patented design, or any colorable imitation thereof, to any *article of manufacture* for the purpose of sale, or (2) sells or exposes for sale any *article of manufacture* to which such design or colorable imitation has been applied *shall be liable to the owner to the extent of his total profit*, but not less than $250, recoverable in any United States district court having jurisdiction of the parties.
>
> Nothing in this section shall prevent, lessen, or impeach any other remedy which an owner of an infringed patent has under the provisions of this title, but he shall not twice recover the profit made from the infringement.

35 U.S.C. § 289 (emphasis added). The Court noted that the term "article of manufacture" used in the statute is very broad:

> So understood, the term "article of manufacture" is broad enough to encompass both a product sold to a consumer as well as a component of that product. A component of a product, no less than the product itself, is a thing made by hand or machine. That a component may be integrated into a larger product, in other words, does not put it outside the category of articles of manufacture

137 S.Ct. at 435. The Court's broad definition was consistent with other Patent Act provisions using the term "manufacture" or "article of manufacture" and prior authority, which indicated that "[t]he broad term includes the parts of a machine considered separately from the machine itself." *Id.* (quotation omitted). As a result, contrary to the Federal Circuit's interpretation, "the term 'article of manufacture' is broad enough to embrace both a product sold to a consumer and a component of that product, whether sold separately or not." *Id.* at 436.

Since the district court and Federal Circuit required that Section 289 be applied to the entire Samsung products, the Court vacated the damage award. The Court, however, declined to identify a test for identifying the appropriate "article of manufacture" for a product made up of components, or to determine the relevant component for each of Apple's design patent found to infringe. Instead, it remanded for the Federal Circuit to "address any remaining issues on remand."

Practical Significance

The Court's decision is consistent with the broader trend of apportioning damages in utility patent cases to the particu-

lar patented technology found to infringe. Although Congress amended Section 289 in 1887 to overrule cases limiting damages to profits "due to" an infringed design, the Court focused on the phrase "article of manufacture," and said damages may be limited to articles of manufacture, which are mere components not separately sold to end users. While this decision does not affect design patent damages based on the patent owner's lost profits or a reasonable royalty, it is likely to limit the desirability of seeking the infringer's profits under 35 U.S.C. § 289 in some cases, primarily those involving designs on portions of products. The full impact of the decision will depend on how the Federal Circuit resolves the important unresolved issues on remand, including how to identify the appropriate "article of manufacture" for this analysis.

Clients with portfolios including design patents should monitor the developing law in this area and assess their current strategies. For example, patents covering the overall design of a product may have advantages over patents covering individual components of the product. Clients may decide that their portfolios should include a mix of design patents of different scope to maximize their ability to collect damages from infringing competitors. In addition, since a design patent's title establishes the "article," which embodies the protected design and may contribute to defining the scope of the patent, clients should avoid titles that may restrict the availability of infringement damages based on profits.

Trademarks: Court Strikes Down Lanham Act's Prohibition on Registration of Disparaging Marks

Matal v. Tam, 137 S.Ct. 1744 (June 19, 2017)

In this long-awaited decision, the Supreme Court ruled that a portion of Section 2(a) of the Lanham Act, 15 U.S.C. §1052(a), is unconstitutional as a violation of the First Amendment's protection of free speech. The decision was unanimous, although the justices differed on their rationales for the outcome. As a result of the decision, the U.S. Patent and Trademark Office may no longer refuse to register trademarks on the grounds that they "disparage . . . or bring . . . into contemp[t] or disrepute" any "persons, living or dead, institutions, beliefs, or national symbols." *Id.* The decision may trigger an increased number of registration applications for controversial trademarks, particularly those aggressively advancing political or social viewpoints. The decision also may signal that Section 2(a)'s restrictions on scandalous and immoral marks are potentially unconstitutional as well.

Background

Trademarks generally are created through commercial use under state law, but the Lanham Act provides a system of federal registration of marks. Registration potentially provides the trademark owners with significant benefits, including providing public notice of the mark and its use, conferring a presumption of validity and ownership, and offering the ability to attain "incontestable" status after five years.

Simon Shiao Tam filed an application to register the mark THE SLANTS for his band, which is made up of Asian-American musicians. Tam selected the mark, despite its reference to a disparaging term for persons of Asian descent, as an example of the well-established phenomenon of "reappropriation," in which members of minority groups "take ownership" of messages that once were slurs, and use them as badges of pride. The USPTO trademark examining attorney refused to register the mark on the grounds that a substantial number of persons would find the mark offensive and demeaning, and the Trademark Trial and Appeal Board affirmed the rejection. Tam appealed the rejection to the U.S. Court of Appeals for the Federal Circuit, which reversed the TTAB and held that the provision was unconstitutional viewpoint discrimination. *In re Tam*, 808 F.3d 1321 (Fed. Cir. 2015)(en banc). The USPTO appealed the Federal Circuit decision to the Supreme Court.

Supreme Court Decision

The Court unanimously affirmed the Federal Circuit and held that Section 2(a)'s prohibition on the registration of disparaging marks violated the First Amendment, although the decision was composed of two different opinions that arrived at the result using different paths. The Court addressed two major issues. First, it considered whether the federal trademark registration process is subject to the First Amendment. And second, if the First Amendment is applicable, it considered whether the prohibition on disparaging marks is subject to strict scrutiny as viewpoint discrimination, or a lesser scrutiny as commercial speech.

Trademark Registration Subject to First Amendment

On appeal, the USPTO proposed three theories supporting the position that the First Amendment did not apply to the trademark registration process. First, the government argued that the registration of trademark is government speech, not private speech, and thus not subject to the First Amendment. Second, it argued that trademark registration is a form of protected government subsidy based on viewpoint. Third, the USPTO proposed a new standard for review based on a so-called "government-program" doctrine.

In his opinion for the Court, joined by three other justices (Chief Justice Roberts and Justices Stephen Breyer and Thomas), Justice Alito ruled that USPTO's registration of trademarks is not government speech, and the other four justices participating in the appeal joined this portion of his opinion. Alito noted that unlike cases in which the government originated a message to achieve a policy objective, marks subject to registration are not created or edited by the government, and the grounds and procedures for rejection are narrowly defined by the Lanham Act.

In addition, Justice Alito noted a lack of evidence that the public regards trademark registration as a government message. He concluded, "In light of all this, it is far-fetched to suggest that the content of a registered mark is government speech." 137 S.Ct. at 1758. Alito distinguished the Court's recent decision in *Walker v. Texas Div., Sons of Confederate Veterans, Inc.*, 576 U. S. ___ (2015), which ruled that a state's approval of specialty vehicle license plates is government speech. Alito noted that *Walker* was based on the facts that states long have used license plates to convey messages, maintain strict direct control over the messages, and are closely identified with the plates (which states manufacture, design, and distribute). In contrast, registrants design and select trademarks, the government exercises limited control over trademark use, and the public generally does not consider a trademark registration to be a government message. Thus, Justice Alito concluded that none of the factors supporting Walker apply to trademark registration.

Justice Alito also rejected the other two theories proposed for shielding the trademark registrations. He noted that trademark registration is not a government subsidy. In fact, instead of the government making cash payments to registrants, trademark owners pay the government significant application fees. Justice Alito also rejected the government's proposed "government-program" doctrine, noting that it was based on cases involving collection on union dues, an issue far removed from the trademark registration process. Four justices (Kennedy, Ginsburg, Sotomayor, and Kagan) did not join the Court's opinion as to these two alternative theories.

Section 2(a) Prohibition on Disparaging Marks Is Unconstitutional

Next, Justice Alito held that Section 2(a)'s prohibition on disparaging marks was unlawful regardless of whether it was commercial speech. Applying the less restrictive commercial speech standard, Justice Alito noted that restrictions must serve "a substantial interest," and must be "narrowly drawn." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N. Y.*, 447 U. S. 557 (1980). Justice Alito ruled that Section 2(a) did not satisfy this requirement. Neither of the two substantial interests advanced as the basis for Section 2(a) -- preventing underrepresented groups from being bombarded with demeaning advertising and protecting an orderly flow of commerce – justified the restriction:

> A simple answer . . . is that the disparagement clause is not "narrowly drawn" to drive out trademarks that support invidious discrimination. The clause reaches any trademark that disparages any person, group, or institution. It applies to trademarks like the following: "Down with racists," "Down with sexists," "Down with homophobes." It is not an anti-discrimination clause; it is a happy-talk clause. In this way, it goes much further than is necessary to serve the interest asserted.

137 S.Ct. at 1764-65. Justice Alito also argued that Section 2(a) was overly broad because it protects "every person living or dead" and every institution from disparaging words, even though a disparaging comment about a deceased person is unlikely to upset the flow of commerce. *Id.* at 1765. Thus, Justice Alito concluded that Section 2(a)'s restriction on the registration of disparaging marks was unconstitutional.

Associate Justice Anthony Kennedy, joined by Justices Ginsburg, Sotomayor, and Elena Kagan, also concluded that Section 2(a) was unlawful, but used a different analysis. Justice Kennedy argued that the prohibition of disparaging marks was viewpoint discrimination subject to more rigorous scrutiny:

> In the instant case, the disparagement clause the Government now seeks to implement and enforce identifies the relevant subject as "persons, living or dead, institutions, beliefs, or national symbols." 15 U. S. C. §1052(a). Within that category, an applicant may register a positive or benign mark but not a derogatory one. The law thus reflects the Government's disapproval of a subset of messages it finds offensive. This is the essence of viewpoint discrimination.

Kennedy, concurring op., 137 S.Ct. at 1766. As viewpoint discrimination, Section 2(a) is presumptively unconstitutional. Further, Justice Kennedy concluded that the restriction could not be justified:

> The central purpose of trademark registration is to facilitate source identification. To serve that broad purpose, the Government has provided the benefits of federal registration to millions of marks identifying every type of product and cause. Registered trademarks do so by means of a wide diversity of words, symbols, and messages. Whether a mark is disparaging bears no plausible relation to that goal. While defining the purpose and scope of a federal program for these purposes can be complex, our cases are clear that viewpoint discrimination is not permitted where, as here, the Government expends funds to encourage a diversity of views from private speakers[.]

Id. at 1768-69 (quotation and citation omitted).

Thus, the Justices were unanimous in their agreement that Section 2(a)'s prohibition on the registration of disparaging marks was unlawful under the First Amendment. Four justices came to that result using the strict scrutiny applied to viewpoint discrimination, and four reached the same result using less-onerous limits applicable to restrictions on commercial speech.

Practical Significance

The Court's decision in *Tam* is unlikely to affect the trademark strategies of most commercial competitors, since few companies promote their products in the broad marketplace by adopting trademarks that customers view as offensive. The decision will have a direct impact on at least one high-profile mark, however, the mark associated with the NFL's Washington Redskins football team. The USPTO cancelled the REDSKINS mark for being disparaging in a case appealed to the U.S. Court of Appeals for the Fourth Circuit, but the appellants in that case have abandoned their appeal in light of the *Tam* decision. *See Pro-Football, Inc. v. Blackhorse*, No. 15-1874 (4th Cir Oct. 30, 2015). The Tam decision also is likely to increase trademark registrations filed for marks associated with political and social causes, or those directed to alternative markets. It is important to note that the decision only affects the federal registration of marks. Trademarks used and created under state law are generally enforceable under Section 43(a) of the Lanham Act, regardless of whether they are offensive. The Court's reasoning in Tam also may signal that the Lanham Act's prohibitions on scandalous and immoral marks violate the First Amendment, although the Court did not address those issues directly.

Copyright: Court Expands Protection of Pictorial, Graphic, and Sculptural Works Found in Useful Articles

Star Athletica LLC v. Varsity Brands, Inc.,
137 S.Ct. 1002 (March 22, 2017)

In this case, the Supreme Court established a standard for determining whether a design element incorporated into a useful article can be protected as a pictorial, graphic, or sculptural work under the Copyright Act. The Court ruled that a feature is eligible for copyright protection if it: "(1) can be perceived as a two- or three-dimensional work of art separate from the useful article and (2) would qualify as a protectable pictorial, graphic, or sculptural work—either on its own or fixed in some other tangible medium of expression—if it were imagined separately from the useful article into which it is incorporated." 137 S.Ct. at 1006. The decision supersedes varying tests developed by other courts to evaluate the copyrightability of features in useful articles, including tests that focused on concepts of "physical" and "conceptual" separability. The decision is likely to cause many companies producing functional products with significant design features, including those in the fashion industry, to consider copyright protection for their products.

Background

Varsity Brands, Inc. makes cheerleader uniforms. In addition to the functional aspects of those uniforms, such as the shape, cut, and physical dimensions of the garments themselves, the uniforms are embellished with stripes, chevrons, and other shapes. The arrangement of shapes and the colors used in the uniforms indicate that the wearer is affiliated with a particular team. Varsity obtained copyright registrations for several of its uniform designs, including those shown below:

Varsity filed suit against a competitor, Star Athletica LLC ("SA"), alleging that SA's uniforms infringed Varsity's copyrights. SA marketed cheerleader uniforms with stripes, chevrons and other design elements similar to those in Varsity's uniforms. SA argued that Varsity's designs were not protectable under the Copyright Act because the designs were purely functional, and could not be separated from for utilitarian cheerleader uniform. The U.S. District Court for the Western District of Tennessee agreed, ruling that the designs performed the function of identifying the garments as cheerleading uniforms, and were not separable from the garments. The U.S. Court of Appeals for the Sixth Circuit reversed, holding that the designs were separable from the functional garments because they were capable of existing independently, such as if they were applied to other garments or displayed as separate work of art. *Varsity Brands, Inc. v. Star Athletica LLC*, 799 F.3d 468 (6th Cir. 2015). Star appealed that ruling to the Supreme Court.

Design 074 Design 078 Design 0815

Supreme Court Ruling

In a 6-2 decision, the Supreme Court affirmed the court of appeals and ruled that Varsity's designs were protectable under the Copyright Act. Justice Thomas, writing for five justices, based the decision on the text of the Act, 17 U.S.C. § 102(a). Copyright protection extends to "pictorial, graphic, and sculptural works" that are fixed in a tangible medium of expression. 17 U.S.C. § 102(a)(5). If the work is incorporated into a useful article, the design is "considered a pictorial, graphical, or sculptural work only if, and only to the extent that, such design incorporates pictorial, graphic, or sculptural features that *can be identified separately from, and are capable of existing independently of, the utilitarian aspects of the article." Id.* (emphasis added).

The Court ruled that, under the Act, a pictorial, graphic, or sculptural feature in an otherwise useful article is eligible for copyright protection only if it both (1) "can be identified separately from," and (2) is "capable of existing independently of, the utilitarian aspects of the article."

As to the first requirement, the Court noted that "separate identification" exists when one is "able to look at the useful article and spot some two- or three- dimensional element that appears to have pictorial, graphic, or sculptural qualities." 137 S.Ct. at 1010. In order to satisfy the second "independent existence" requirement:

> [T]he feature must be able to exist as its own pictorial, graphic, or sculptural work as defined in §101 once it is imagined apart from the useful article. If the feature is not capable of existing as a pictorial, graphic, or sculptural work once separated from the useful article, then it was not a pictorial, graphic, or sculptural feature of that article, but rather one of its utilitarian aspects.

Id.. Under this test, the feature, when separated, "cannot itself be a useful article or an article that is normally a part of a useful article (which is itself considered a useful article)." *Id*. In addition, the Court also ruled that the same test applies to pictorial, graphic, or sculptural works that are two-dimensional and three-dimensional. *Id.* at 1009.

The Court's ruling overrules tests applied in some circuits, which focus on the concepts of physical and conceptual separability. *See, e.g., Brandir Int'l, Inc. v. Cascade Pacific Lumber Co.*, 834 F.2d 1142 (2d Cir. 1987). The Court noted that the Copyright Act:

> [M]ake[s] clear that copyright protection extends to pictorial, graphic, and sculptural works regardless of whether they were created as freestanding art or as features of useful articles. The ultimate separability question, then, is whether the feature for which copyright protection is claimed would have been eligible for copyright protection as a pictorial, graphic, or sculptural work had it originally been fixed in some tangible medium other than a useful article before being applied to a useful article.

137 S.Ct. at 1011.

Applying the test to Varsity's cheerleader designs, the Court ruled that, assuming the designs satisfied all other requirements for copyright protection – which the Court expressly did not consider – they were works protected by copyright:

> First, one can identify the decorations as features having pictorial, graphic, or sculptural qualities. Second, if the arrangement of colors, shapes, stripes, and chevrons on the surface of the cheerleading uniforms were separated from the uniform and applied in another medium—for example, on a painter's canvas—they would qualify as "two-dimensional . . . works of . . . art," §101. And imaginatively removing the surface decorations from the uniforms and applying them in another medium would not replicate the uniform itself. Indeed, respondents have applied the designs in this case to other media of expression—different types of clothing—without replicating the uniform. The decorations are therefore separable from the uniforms and eligible for copyright protection.

Id. at 1012.

Justice Ginsburg concurred in the result, but argued that the Court did not need reach the separability issue to decide the case. Since Varsity registered copyrights in its design consisting of two-dimensional shapes, stripes, and chevrons, and SA reproduced those designs on its uniforms, Justice Ginsburg concluded that the designs were "standalone" works and SA was potentially liable for infringement.

Justice Breyer, joined by Justice Kennedy, wrote a lengthy dissent. He argued that the designs in the Varsity uniforms were not separable because, if they existed in another medium, they would merely be a depiction of a cheerleader uniform. He expressed concern that, if applied too broadly, the majority opinion's test would roil the fashion industry, as companies sought to protect their designs under copyright, even though Congress has repeatedly failed to pass fashion design protection legislation.

Practical Significance

The Court's decision establishes a standard for protecting product design elements as copyrighted works, but lower courts may find the test difficult to apply in future cases. For example, fashion and clothing designs, which generally have not been protected by copyright, commonly contain design elements that may be envisioned as separate works. Thus, although an entire garment may not be copyrightable, copyright may protect the individual features. In addition, the decision suggests that a design feature may be protected by copyright even though it has some useful function. This may provide

pause to companies considering design patent protection, which has a limited 15-year term of protection as opposed to the much longer term for copyright protection. Also, companies in the fashion industry may consider filing copyright registrations on design elements as two-dimensional works in order to strengthen their positions against competitors.

The decision is likely to affect intellectual property strategies beyond the fashion industry. For example, the decision may accelerate the trend of "layering" intellectual property protection by applying patent, copyright, and trademark protection to different aspects of the same product. Companies must carefully evaluate the potential benefits of such a strategy.

Biologics: Court Interprets Provisions of Biologics Price Competition and Innovation Act

Sandoz Inc. v. Amgen Inc.,
137 S.Ct. 1664 (June 12, 2017)

On June 12, 2017, in its final patent-related decision of the October 2016 term, the U.S. Supreme Court issued a unanimous decision interpreting two disputed provisions in the Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262(l) (the "BPICA" or "Act").

Background

The BPICA governs U.S. Food and Drug Administration market approval of "biosimilars," or biologic products that are highly similar to a biologic product previously approved for commercial marketing. The Act provides a framework for biosimilar applicants to "piggyback" on the application filed by an original sponsor of an approved biologic, receiving approval if the applicant can establish that a proposed biosimilar is "highly similar" to the biologic with "no clinically meaningful differences" compared to the previously-approved product. The Act also creates mechanisms requiring an applicant to disclose detailed information concerning the proposed biosimilar, and for the sponsor of the approved biologic to assert claims for patent infringement against the applicant prior to the actual sale of the biosimilar.

In this case, Amgen Inc. obtained FDA approval to market a biologic, filgrastin, under the brand name Neupogen to stimulate a patient's production of white blood cells. Sandoz Inc. filed an application under the BPICA to market a corresponding biosimilar product. Disputes then emerged concerning the parties' obligations under the BPICA machinery. Ultimately, Amgen filed an action in federal district court alleging that Sandoz failed to disclose manufacturing information concerning its proposed biosimilar as required by § 262(l)(2)(A), and seeking an injunction under the BPICA and a California statute governing unfair trade practices. In addition, Amgen argued that Sandoz failed to provide notice of its intent to market the biosimilar at least 180 days before the first commercial marketing of the product as required by the BPICA, §262(l)(8)(A), because Sandoz provided its notice before receiving an FDA license to market the biosimilar.

Supreme Court Ruling

In a unanimous decision written by Justice Thomas, the Supreme Court reversed-in-part and affirmed-in-part the Federal Circuit. First, the Court ruled that a sponsor may not force the BPICA applicant to disclose application and manufacturing information under the Act through an injunction issued under the authority of federal law, because the BPICA provides specific, exclusive remedies that are inapplicable to such a failure. The Court noted that the BPICA only provides the biologic sponsor remedies for patent infringement, but an applicant's failure to provide technical information required under the Act is not itself an act of infringement. The Court ruled, however, that Amgen may qualify for injunctive relief under state law, including the California unfair competition statute, Cal. Bus. & Prof. Code Ann. §17205. The Court remanded for the Federal Circuit to consider whether Sandoz's failure to provide technical information under the BPICA was unlawful under state law and thus subject to state law remedies including an injunction.

Second, the Court held that a BPICA's notice provision, which requires the biosimilar applicant to provide notice to the biologic sponsor "not later than 180 days before the date of the first commercial marketing" of the approved biosimilar, allows the applicant to provide notice even before the FDA licenses such a sale. *See* 42 U.S.C. §262(l)(8)(A). Construing the statute narrowly, the Court reasoned that the Federal Circuit misread the statute in requiring the notice to occur both prior to commercial marketing and after FDA market approval of a biosimilar.

Justice Breyer filed a short concurring opinion inviting the FDA to promulgate regulations that potentially "would better serve the statute's objectives" than the Court's interpretation.

About the Authors

Christopher C. Smith *is a Shareholder and* ***David C. Berry*** *is Of Counsel at Brooks Kushman, P.C. www.brookskushman.com.*

In *Helsinn Healthcare*, the Federal Circuit Offers Guidance on the On-Sale Bar under the AIA

By Scott Siera, PhD and Eric Furman, PhD

The sale of a product prior to filing a patent application, or "on-sale bar," has long been a potential barrier to obtaining a patent in the United States. Especially in the biotechnology space, which can involve a long development cycle and regulatory approval cycle, pre-clinical manufacturing and testing activity has the potential to limit patent rights by triggering the on-sale bar.

The Leahy-Smith America Invents Act (AIA), enacted in 2013, dramatically changed the on-sale bar, but left some contours of this law open to interpretation. The Federal Circuit has just issued its first opinion on the "new" on-sale bar under the AIA in *Helsinn Healthcare, S.A. v. Teva Pharmaceuticals USA* (Fed. Cir. May 1, 2017). The Federal Circuit's opinion is a reminder that the on-sale bar is still a potential risk to patent applicants. However, by working together with IP counsel prior to sale of product, and judiciously entering agreements with other parties, innovators may now have more options to develop their business and marketing goals while protecting their IP.

Prior to the AIA, 35 U.S.C. §102 barred patentability when an invention was sold or offered for sale in the United States more than a year before a patent application was filed, regardless of whether the sale was known to the public. As amended under the AIA, the law now bars patentability for a sale anywhere in the world, but the invention must have been "on sale, or otherwise available to the public." Excerpts from the old and new versions of the law are shown below.

In *Helsinn Healthcare,* Helsinn entered an agreement with a third party marketing partner to distribute and sell the drug palonosetron nearly two years before Helsinn filed its patent application. The agreement specified the price, method of payment, and method of delivery, and was subsequently published in the marketing partner's 8-K filing with the SEC. The published sales agreement did not disclose all of the details that were claimed in Helsinn's patent, for example dosage levels of the drug. Nevertheless, the Federal Circuit held that Helsinn was barred from getting a patent because the sale itself was disclosed to the public, even though certain details of the invention were not:

> We conclude that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale.

As such, the court in *Helsinn Healthcare* found that the patents at issue were invalid due to the on-sale bar.

In dicta, the court alludes to some possible incentives for patent owners to maintain the secrecy of sales prior to filing a patent application. For example, secret sales had been a bar to patentability under the old law (*see, e.g., Woodland Trust v. Flowertree Nursery* 148 F.3d 1368 (Fed. Cir. 1998)). The Federal Circuit's ruling did not directly address secret sales (since Helsinn's sale had been disclosed to the public), but in dicta acknowledged statements from Congress that the AIA law was intended to eliminate the previous bar to patentability by secret sales ("[S]ubsection 102(a) was drafted in part to do away with precedent under current law that *private offers for sale*… may be deemed patent-defeating prior art" (emphasis in original)).

The court in *Helsinn Healthcare* did not directly address whether the date of the sale itself or the date of the public disclosure is the date that triggers the on-sale bar under the AIA (in *Helsinn Healthcare*, both the sale and the disclosure occurred more than a year before the patent application was

Pre-AIA on-sale bar **35 U.S.C. 102(b) (pre-AIA)**	**AIA on-sale bar** **35 U.S.C. 102(a)(1)**
the invention was patented or described in a printed publication in this or a foreign country or ***in public use or on sale in this country***, more than one year prior to the date of the application for patent in the United States	the claimed invention was patented, described in a printed publication, or in public use, ***on sale***, ***or otherwise available to the public*** before the effective filing date of the claimed invention

(emphases added)

filed). However, the court quoted floor statements from Congress implying that under the AIA, a sale would have to become public before the effective filing date in order to trigger the on-sale bar (Cong. Rec. 9782 (2011)(remarks of Sen. Smith)("…an action must make the patented subject matter 'available to the public' before the effective filing date.").

While the *Helsinn Healthcare* case does not guarantee that secret sales no longer trigger the on-sale bar, the Federal Circuit's reasoning alludes to additional incentives for patent owners to keep sales secret prior to filing a patent application.

About the Authors

Eric S. Furman, *PhD is a Senior Partner at Knobbe Martens LLP in San Diego, CA. He currently represents clients in the fields of genetically modified plants and organisms, stem cells, pharmaceuticals, vaccines, medical devices, dietary supplements, diagnostics, cleantech, and cosmetics. He has a practice that focuses on strategic patent counseling and procurement, freedom to operate analysis, counseling on infringement and invalidity issues, licensing, and due diligence studies as related to mergers and acquisitions.*

Scott Siera, PhD *is a Senior Associate at Knobbe Martens LLP in San Francisco, CA. He currently represents clients in the fields of antibodies, nucleic acids, molecular diagnostics, synthetic biology, and plant varieties. He has a practice that focuses on strategic patent counseling and procurement, freedom to operate analysis, counseling on infringement and invalidity issues, and licensing.*

Basic Trademark and Patent Practice for Lawyers and Paralegals

October 3, 2017, Inn at St. Johns, Plymouth

The perfect seminar for intellectual property lawyers and paralegals. Learn the nuts and bolts of IP law practice with practical advice from Michigan's top patent and trademark lawyers. Hear experienced practitioners' winning strategies and network with your colleagues.

For more information and to register visit http://www.icle.org

The Great Divide – Sorting Out Method Claims and Multiple Actors

By Colin Cicotte and Scott Hogan

Editor's Note: This article first appeared in IAM Yearbook 2017, published by Globe Business Media Group - IP Division. To view the issue in full, please go to *www.iam-media.com*.

Multiple-actor method claims lurk in patents, waiting to surprise patent owners that move to enforce their rights. Rather than simply identifying one entity that performs all of the steps of a claimed method and asserting infringement, patent owners could find themselves forced to establish the existence of a joint enterprise among multiple actors or otherwise to attribute performance of method steps to an entity that did not actually perform them. These method claims are also troubling to technology users that wish to perform only a portion of a claimed method, but fear that a patent owner will come knocking on their door when some other entity performs the remaining method steps. In the wake of the *en banc* decision of the Federal Circuit in *Akamai Technologies, Inc v Limelight Networks, Inc*, one actor's conduct can be attributed to another – even in the absence of a joint enterprise, an agency relationship or a contractual obligation governing that conduct. After a decade-long wrestling match in the U.S. federal courts in *Akamai*, the state of the law for multi-actor infringement of method claims seems less clear than ever.

Even in this shadow of uncertainty, the fact remains that the ease or difficulty of enforcing a method claim may largely depend on how carefully the drafting attorney limited the claim to acts attributable to one entity more than any other factor. Mindful claim drafting can remove much of the uncertainty associated with the enforcement of method claims and help patent owners to avoid the additional time, cost, and effort required to establish infringement.

Akamai v Limelight – a tale of four reversals

The uncertainty associated with multiple-actor method claims can be appreciated from the epic litigious journey of one humble method claim at issue in *Akamai*: the final claim of U.S. Patent 6,108,703. This journey began in a federal district court and continued all the way up to the Supreme Court, and then went part-way back. The answer as to whether this claim was infringed changed from yes to no, back to yes, back to no, and finally back to yes again. The defendant did not dispute that every step of the patented claim was performed. The question to be answered by the courts was whether any party could be held liable for patent infringement when no one entity actually performed every step of the claim.

The subject of the Akamai patent was a scheme of distribution and delivery of webpage content (*e.g.*, images and videos) among a number of physically separate computer file storage locations. The claimed method required the following steps:

- distributing objects across a network of servers;
- tagging embedded objects of a page (*e.g.*, a webpage) in a particular manner;
- resolving a client request for one of the embedded objects; and
- returning to the client an Internet Protocol address of a server where the requested object was hosted.

Limelight, Inc owned and operated a content delivery network (CDN) and provided a service to customers, allowing them to use the network to host webpage content remote to the customers' own servers. Akamai accused Limelight of infringing the patented method by providing this service. Limelight did not dispute that it performed three of the four steps, but denied infringing the claim based on the fact that Limelight did not perform the tagging step. Limelight's customers performed the tagging step, which generally involved modifying a customer-operated webpage to access the Limelight CDN when retrieving embedded objects. Akamai acknowledged that Limelight's customers were the actors actually performing the tagging step, but asserted that the actions of those customers should be attributed to Limelight as if Limelight itself had performed the tagging step, thereby making Limelight liable for patent infringement.

A jury found Limelight liable for infringement based on evidence that Limelight "directed or controlled" its customers' performance of the tagging step. The jury instruction explained the 'direct or control' requirement for attributing a different actor's conduct to the accused infringer using the rule set out by the Federal Circuit in *BMC Resources*. The jury applied this rule and relied on evidence that included:

- a service contract between Limelight and its customers;
- instructions provided to the customers for using the Limelight CDN; and

- the availability of Limelight customer service personnel to assist customers with the service.

The service contract included steps that must be taken by the customer to use the service, including performance of the tagging step, and the written instructions provided information on content tagging.

The district court vacated the jury decision, entering a judgment of non-infringement as a matter of law after the Federal Circuit issued its opinion in *Muniauction, Inc v Thomson Corp*, in which the owner of an auction website was not held liable for infringement of a method that required the step of placing a bid – a step performed by Muniauction's customers, who paid fees to Muniauction and who received bidding instructions from Muniauction. The judgment of non-infringement as a matter of law opinion reasoned that *Muniauction* required something more than a service contract between parties and instructions on using the service to establish conduct rising to the level of direction or control of another entity by the accused infringer.

On appeal, a Federal Circuit panel affirmed the judgment of non-infringement, holding "as a matter of Federal Circuit law that there can only be joint infringement when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps." The Federal Circuit reasoned that Limelight's customers were under no contractual obligation to perform the tagging step; rather, the customers performed the tagging step only under circumstances through which the customer wanted to use the service and on webpages identified by the customer – decisions controlled by the customer, not by the accused infringer.

Limelight's victory was short-lived. The Federal Circuit vacated the panel decision and reheard the case *en banc*, this time holding Limelight liable for patent infringement under 35 U.S. Code § 271(b) on a theory of inducement. The *en banc* court held that a defendant may be held liable for induced infringement of a method if the defendant performs some of the method steps and induces others to perform the remaining steps, also holding that no direct infringer is required for a party to be liable for induced infringement.

Soon after, Akamai's fortunes reversed when the Supreme Court stepped in and unanimously reversed the *en banc* decision. The court held that there can be no inducement without direct infringement and reminded the Federal Circuit of its own case law in *Muniauction* that requires a single entity to direct or control the performance of all steps of a method for there to be direct infringement. On remand, the Federal Circuit panel again affirmed the district court's judgment of non-infringement, holding that Limelight's customers did not perform the step of tagging as an agent of Limelight, as part of a joint enterprise with Limelight or under a contractual obligation to do so.

Just when it seemed that the dust had finally settled, the Federal Circuit issued a second *en banc* opinion – issued *per curiam* – again vacating the panel opinion and reinstating the jury's finding that Limelight directly infringed the patented method by attributing the actions of Limelight's customers to Limelight. The Supreme Court decided not to revisit the Federal Circuit's analysis the second time around. After a decade of patiently hoping for the law of divided infringement to be settled, patent owners and practitioners are left with what is arguably a less defined doctrine.

The more things change, the more they remain the same – or vice versa?

In the end, the original *Akamai* jury verdict was upheld and the Federal Circuit did not expressly overrule its precedents in *BMC Resources* or *Muniauction*. So did anything change? And if so, to what effect?

While the legal standard for attributing one actor's conduct to another in the context of a patented method claim remains unchanged, the type of conduct that rises to the level of directing or controlling another entity's actions appears to have broadened – albeit to an unknown extent; the effect is different for patent owners than for accused infringers. Now, according to the Federal Circuit, "Section 271(a) is not limited solely to principal-agent relationships, contractual arrangements, and joint enterprise, as the vacated panel decision held. Rather, to determine direct infringement, we consider whether all method steps can be attributed to a single entity." The Federal Circuit explained its legal framework for direct infringement by expanding its notion of vicarious liability. Specifically, in addition to the traditional agency and contractual relationships between actors, vicarious liability now also encompasses scenarios in which an accused infringer conditions participation in an activity or receipt of a benefit on performance of a step or steps of a patented method and establishes the manner or timing of that performance. These combined actions are sufficient to find that the accused infringer directed or controlled the acts of a third party.

The effect is that liability largely depends on the fact-based circumstances under which the method is performed. The Federal Circuit expressly invited litigants to test scenarios under which actions of one can be attributed to another, recognising that "[i]n the future, other factual scenarios may arise which warrant attributing others' performance of method steps to a single actor. Going forward, principles of attribution are to be considered in the context of the particular facts presented." The conditions of participation and the benefits received as part of a collectively performed patented method are open to interpretation, as is what constitutes the establishment of the manner or timing of the performance of its individual steps. The result is more uncertainty for both patent owners and those performing portions of patented methods.

Dispelling uncertainty

Prudent patent applicants can continue to take steps to avoid future problems and the uncertainty associated with divided infringement by pursuing method claims that are written to be performed by a single entity. This is not a new concept and was recognised by the *BMC Resources* court, which commented that "[a] patentee can usually structure a claim to capture infringement by a single party" – for example, by drafting its claims to focus on one entity. This prevents clever defendants from attempting to escape liability by asserting that some other entity performs one or more of the method steps and forcing the patent owner to present extensive fact-specific evidence of vicarious liability.

Patent practitioners or other claim drafters can implement this technique by first identifying the preferred actor that will perform the claimed method steps. This actor may be a person or entity, such as a business competitor of the patent applicant. Each method step can then be written from that actor's perspective and may include actions performed by the actor, by an apparatus controlled by the actor or at a location where the action is carried out. Also, claim passages can be written to avoid positively recited steps or actions where unnecessary, or where such steps are unlikely to be performed by the same actor as the other steps. As a real-world example, the relevant passage from the Akamai method claim discussed above could have easily been written differently to state:

> ***wherein,*** *for a given page normally served from the content provider domain,* ***~~tagging~~*** *at least some of the embedded objects of the page* ***are tagged*** *so that requests for the objects resolve to the domain instead of the content provider domain.*

In this example, the verb 'tagging' is omitted in favor of the adjective 'tagged', which is used to characterize the embedded objects. This simple change effectively eliminates a method step, resulting in a method claim in which all of the steps would be performed by the same actor – the CDN operator.

Even if patent owners find themselves with previously issued patents containing multiple actor claims without a path to amend these claims, the Federal Circuit has provided a lifeline with which they can assert direct infringement. However, a pre-litigation investigation may not conclusively determine whether a potential defendant conditioned participation or received a benefit on a third party's performance of a step, or whether the potential defendant established the manner or timing of that performance. These fact-intensive enquiries and proofs are sure to be time consuming, expensive, difficult, and uncertain.

Potential defendants that perform some, but not all, of the steps of a method claim have a much foggier path. While patent owners at least have some control over claim scope to help to avoid the complexities associated with divided infringement, defendants are left with more questions than answers. Potential defendants must determine whether their behavior towards another entity performing other method steps conditions participation in an activity or receipt of a benefit on that performance, and whether their own behavior establishes the manner or timing of that performance. Given the lack of identifiable pointers to what these various indicators of 'direct or control' mean, uncertainty reigns.

One subsequent district court case has found the latest *Akamai* test met when a doctor prescribes a treatment to a patient. In that case, administration of a medication to the patient was attributed to the doctor even though the patient self-administered the medication, because the doctor conditioned the benefit of the treatment on the patient's performance of taking the medication and established the manner or timing of taking the medication. Otherwise, despite the fact that *Akamai* was finally put to rest, potential defendants must continue to wait to better understand their position, as interpretation of the broader application of divided infringement unfolds in the coming years.

About the Authors

Colin Cicotte *and* ***Scott Hogan*** *are shareholders at Reising Ethington PC.*