The United States Supreme Court decided six very important patent cases in the 2016-17 term, Samsung Electronics Co., Ltd. v. Apple Inc., called the “design patent case of the century,” Life Technologies Corp. v. Promega Corp., an international supply chain patent case, SCA Hygiene Products v. First Quality Baby Products, LLC, where the doctrine of laches was not a defense in a patent infringement case, TC Heartland LLC v. Kraft Foods Group Brands LLC, which dealt with patent venue statute, Impression Products, Inc. v. Lexmark International, Inc., which held that the authorized first sale of a patented item exhausts the patent holder’s rights, and Sandoz Inc. v. Amgen Inc., which interpreted the Biologics Price Competition and Innovations Act. In each case, the Court of Appeals for the Federal Circuit was reversed, vacated, or both. Four of the cases were unanimous, and two had only one dissenter each, Justice Breyer and Justice Ginsburg, which sends a strong message from the Court in the area of patent law, as well as a strong message to the Court of Appeals for the Federal Circuit. This article reviews the six Supreme Court patent decisions and concludes with implications of this series of important cases.
SAMSUNG v. APPLE, LIFE TECHNOLOGIES v. PROMEGA, SCA HYGEINE PRODUCTS v. FIRST QUALITY BABY PRODUCTS, TC HEARTLAND v. KRAFT, IMPRESSION PRODUCTS v. LEXMARK, and Sandoz v. Amgen: The U.S. Supreme Court Decides Six Patent Cases in 2016-17

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SUE ANN GANSE

I. INTRODUCTION

Congress has the power “[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”

The United States Supreme Court decided six very important patent cases in the 2016-17 term, Samsung Electronics Co., Ltd. v. Apple Inc., Life Technologies Corp. v. Promega Corp., SCA Hygiene Products v. First Quality Baby Products, LLC, TC Heartland LLC v. Kraft Foods Group Brands LLC, Impression Products, Inc. v. Lexmark International, Inc., and Sandoz Inc. v. Amgen Inc. In each case, the Court of Appeals for the Federal Circuit became reversed, vacated, or both. Four of the cases were unanimous, and two had only one dissenter each, Justice Breyer and Justice Ginsburg, which sends a strong message from the Court in the area of patent law, as well as a strong message to the Court of Appeals for the Federal Circuit.

In Samsung v. Apple, on December 6, 2016, the Supreme Court held unanimously that the “article of manufacture” for design patent infringement damages cases could be a component of a product, and not just the entire end product. In this case, the entire profits from Samsung’s smartphones found infringing upon Apple’s design patents were initially awarded, but the Supreme Court reversed the decision of the
Court of Appeals for the Federal Circuit, and remanded, leaving the test to be used on remand for a later day, since it wasn’t before the Court because the parties hadn’t briefed the issue. This very important case has been called the “design patent case of the century,” and is also the first design patent damages case in over a century.

In *Life Technologies v. Promega*, the Supreme Court on February 22, 2017 held seven to zero with a concurrence in part, that in the international supply chain, supplying a “substantial portion” of a patented invention from the United States, which could give rise to infringement under the Patent Act, is a quantitative assessment, and requires more than one component supplied from the U.S., reversing the decision of the Federal Circuit and remanding.

In *SCA Hygiene Products v. First Quality Baby Products, LLC*, the Supreme Court on March 21, 2017 held seven to one that the doctrine of laches had no availability as a defense to a patent infringement case during the six-year patent statute of limitations, vacating the en banc decision of the Court of Appeals for the Federal Circuit and remanding the case. Justice Breyer dissented.

In *TC Heartland v. Kraft Foods Brand Group*, the Supreme Court on May 22, 2017 held eight to zero that a corporation resides only in its state of incorporation for purposes of the specific patent venue statute, reversing and remanding the Court of Appeals for the Federal Circuit. This case restricts the jurisdiction in which patent infringement cases may be filed, and although this case did not involve a patent non-practicing entity or patent troll, nor did it even mention the term, curtailed the forums in which patent trolls or any patent infringement plaintiff may bring suit, thus is a very important decision during this term.

In *Impression Products, Inc. v. Lexmark Int’l*, another very important patent case, the Supreme Court held eight to zero that an authorized first sale of a patented product in the United States exhausts the patent holder’s right in that product, and seven to one with Justice Ginsburg dissenting that patent exhaustion applies to the first sale of a patented product outside the United States. Again, the Court of Appeals for the Federal Circuit became reversed and remanded. The patent holder may use contract restrictions with the purchaser, but may not use a patent

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9. Id. at 436.
10. Id.
12. In 1886, the Supreme court decided *Dobson v. Dornan* on U.S. design patents D10,778, D10,870, and D11,034 on carpet designs. 118 U.S. 10 (1886). The prior year, the Court decided *Dobson v. Hartford Carpet Co.*, which awarded six cents in damages on U.S. Pat. D6,832, also on carpets. 114 U.S. 439 (1886). The Patent Act was changed subsequent to these cases.
17. Id. at 967.
21. Id.
infringement case against a company such as Impression Products who refurbished and resold Lexmark toner cartridges.22

In *Sandoz Inc. v. Amgen Inc.*,23 the full Court unanimously, with one concurrence, interpreted the Biologics Price Competition and Innovation Act, holding that a biological biosimilar applicant not participating in the first step of the Act does not subject the applicant to an injunction, and the applicant may give the reference product manufacturer the required 180-day notice of commercial marketing under the Act before the FDA licensure of the biosimilar product. The Court both vacated and reversed the Court of Appeals for the Federal Circuit, and remanded.24

The six patent decisions of 2016-17 tied the record-setting six patent decisions by the Court in 2014,25 but in the recent term, the Court of Appeals became reversed, vacated, or both every time.26 The theme of the Supreme Court in the six patent decisions in 2016-17, if there is a theme, is that the Court of Appeals for the Federal

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22 *Id.* Impression Products did not have the contract with Lexmark, the purchaser did, which makes the contract solution more difficult.


24 *Id.*


Circuit should be attentive to Supreme Court precedence\textsuperscript{27} and statutory language.\textsuperscript{28} Each case is essential to intellectual property law and practice, and this article reviews and analyzes the six Supreme Court patent decisions of 2016-17. This article concludes with implications from this term of patent cases.

II. SAMSUNG ELECTRONICS CO., LTD. v. APPLE INC.

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.\textsuperscript{29}

But, what is that “article of manufacture” from this section of the Patent Act for computing design patent infringement damages? Is it the entire end product, as the Court of Appeals for the Federal Circuit held,\textsuperscript{30} or may it be a component of the end product? The Supreme Court on December 6, 2016 in Samsung v. Apple held that the “article of manufacture” of the Patent Act,\textsuperscript{31} above, not necessarily constituted the end product, a smartphone, but could be a component of the end product.\textsuperscript{32} The Court of Appeals for the Federal Circuit ruled to the contrary. The Supreme Court thus unanimously reversed the Court of Appeals for the Federal Circuit and remanded.\textsuperscript{33}

Apple Inc. became incorporated in 1977 in California,\textsuperscript{34} and “designs, manufactures, and markets mobile communication and media devices and personal computers,” and sells software and sells these and other products and services.\textsuperscript{35} Samsung Electronics Co., Ltd. became incorporated in South Korea in 1969, and has three business divisions: consumer electronics, information technology and mobile devices, and device solutions.\textsuperscript{36} In the first quarter of 2017, Samsung stood as the world’s top smartphone manufacturer, with a 20.7% market share, and Apple followed with a 13.7% market share, both down from the first quarter of 2016.\textsuperscript{37}

\textsuperscript{27} See SCA Hygiene, infra notes 121-155, TC Heartland, infra notes 156-190 and accompanying text, and Impression Products, infra notes 191-250 and accompanying text.
\textsuperscript{28} See Sandoz, infra notes 251-309 and accompanying text.
\textsuperscript{31} 35 U.S.C. § 289.
\textsuperscript{33} Id. at 436.
In 2007, Apple released its iPhone smartphone, which had numerous design and utility patents. Samsung released smartphones which resembled Apple's iPhone. On April 15, 2011, Apple filed a patent infringement lawsuit alleging that Samsung smartphones including the Galaxy S 4G infringed some of Apple’s design and utility patents. Specifically, Apple’s complaint and amended complaint alleged that design patents1 including U.S. Patent Number D593,087 (the ‘087 patent)2 for “a rectangular front face with rounded corners and a raised rim,”3 and U.S. Patent Number D618,677 (the ‘677 patent)4 for “a black rectangular front face with rounded corners,”5 both at issue in the appeal which reached the U.S. Supreme Court, for the ornamental design of an electronic device, were infringed, among others. Apple requested a preliminary injunction against Samsung’s devices which allegedly infringed, but the district court denied the motion for the preliminary injunction. The Court of Appeals for the Federal Circuit in 2012 affirmed the denial of the requested preliminary injunction for products embodying the two design patents at issue in the Supreme Court case.

After trial on August 24, 2012, the jury returned a verdict largely in Apple’s favor on infringement of design and utility patents as well as trade dress dilution, and

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[2] Id.
[7] U.S. Patent No. D618,677 (June 29, 2010) available at https://www.google.com/patents/USD618677?dq=us+d618,677&hl=en&sa=X&ved=0ahUKEwiio0KOsKXgR6rUAhUNySYKHf5dBSgQ6AEIKDAA.
[11] Apple Inc. v. Samsung Electronics Co., Ltd., 678 F.3d 1314, 1333 (Fed. Cir. 2012). The denial of the preliminary injunction on the ‘381 utility patent was also affirmed on May 14, 2012, but the denial of the preliminary injunction on the ‘889 patent was vacated and remanded. Id. On June 26, 2012, the district court preliminarily enjoined Samsung from making, using, offering to sell, or selling in the U.S. Samsung’s Galaxy Tab 10.1 tablet computer or any other product which embodied any design contained in the ‘889 patent. Apple, Inc. v. Samsung Electronics Co., Ltd., No. 11-CV-01846-LHK, 2012 U.S. Dist. LEXIS 88436 at *24 (N.D. Cal. June 26, 2012). When the jury determined that the ‘889 design patent was not infringed, the district court lifted this preliminary injunction. Id. at *51.
 awarded over $1 billion in damages.\textsuperscript{49} At issue in the Supreme Court opinion, specifically, found infringement of the '677 patent, the '087 patent, and U.S. patent No. D604,305 (the '305 patent)\textsuperscript{50} on a “grid of 16 colorful icons on a black screen.”\textsuperscript{51} Samsung, however, received a judgment as a matter of law because Apple's damages numbers relied on improper notice dates.\textsuperscript{52} The district court struck approximately $410 million of the damages,\textsuperscript{53} and set a limited retrial on damages.\textsuperscript{54} On November 21, 2013, a jury after a six day trial awarded Apple approximately $290 million for the struck damages for patent infringement,\textsuperscript{55} which, when added to the non-struck damages, left damages of about $930 million,\textsuperscript{56} and $399 million by the time the case reached the Supreme Court.\textsuperscript{57}

After the initial trial, Apple requested a permanent injunction.\textsuperscript{58} Applying the four-factor test set by the Supreme Court in eBay,\textsuperscript{59} the district court denied the permanent injunction.\textsuperscript{60} The Court of Appeals for the Federal Circuit affirmed for the design patents and trade dress in question, but vacated and remanded on the utility patents at issue.\textsuperscript{61} On remand, the permanent injunction received, again, denial.\textsuperscript{62}


\textsuperscript{50} U.S. Patent No. D604,305 (Nov. 17, 2009) available at https://www.google.com/patents/USD604305?dq=D604,305&hl=en&sa=X&ved=0ahUKEwjW2u6oj6rUAhWIwiYKHVwhALMQ6AEIKDAA, on a graphical user interface for a display screen or portion thereof.


\textsuperscript{52} Apple, Inc. v. Samsung Electronics Co., Ltd., No. 11-CV-01846-LHK, 2014 U.S. Dist. LEXIS 17204 at *42 (N.D. Cal. Feb. 7, 2014). Since Apple did not provide sufficient evidence to recalculate damages due to proper notice dates, $410 million was knocked off the first award. Id. at *42-43.

\textsuperscript{53} Id. at *55.

\textsuperscript{54} Id. at *36; “A jury may not award lost profits in a patent case in the absence of ‘sound economic proof.’” Id. at *25. Thus, the district court granted Samsung’s Emergency Motion to Enforce the Nov. 7, 2013 order, as well as the April 29, 2013 order. Id. at *28.

\textsuperscript{55} Id. at *42. Nearly $114 of this became lost profits due to patent infringement of one of Apple’s patents. Id. at *48. Over $34 million was for reasonable royalties. Id. at *55. Just over $142 million was for infringement of the '305 and '677 patents. Id. at *63-64.

\textsuperscript{56} Id. at *56.

\textsuperscript{57} Samsung Elecs. Co. v. Apple Inc., 137 S. Ct. at 433.


\textsuperscript{62} Apple Inc. v. Samsung Electronics Co., Ltd., No. 11-CV-01846-LHK, 2014 U.S. Dist. LEXIS 29721 at *123 (N.D. Cal. March 6, 2014). The district court concluded that “it would be inequitable to enjoin Samsung’s products from U.S. markets. Id. at *122.
On Samsung’s appeal of the validity of the utility patents, the design patent infringements, the damages, and whether the trade dress is protectable, the Court of Appeals ruled in favor of Apple on the first three, but agreed with Samsung on the trade dress issue. Specifically, Samsung argued that the district court erred in allowing the entire profits on allegedly infringing Samsung smartphones as damages; Samsung argued that damages should be apportioned, and the profits awarded should relate only to the infringing “article of manufacture,” and not the entire smartphone. The Court of Appeals for the Federal Circuit, however, did not agree with Samsung; the entire smartphone is the “article of manufacture,” since “consumers could not separately purchase components of the smartphone,” and thus Samsung’s entire profits related to infringing smartphone sales should go to Apple. Samsung received grant for a writ of certiorari at the U.S. Supreme Court on the issue of when a design patent is applied to a component of a product, should profits be limited only to the component?

The U.S. Supreme Court on December 6, 2016 unanimously held that the “article of manufacture” for computing design patent infringement damages, could be a component of a product and isn’t necessarily always the entire end product, reversing the Court of Appeals for the Federal Circuit. Writing for the entire Court, Justice Sotomayor stated that ascertaining design patent infringement damages under the Patent Act is a two-step process. First, the court must determine what constitutes the article of manufacture which infringes on the design patent. Second, the court must determine the total profit attributable to that article of manufacture. The only question resolved by the Court revolved around whether, in a multicomponent product, the “article of manufacture” is always the end product, or whether it may be a component of the product. According to the Court, an “article of manufacture” could be the final product or a component thereof, “whether sold separately or not.” Thus, the court of appeals erred by narrowly interpreting “article of manufacture” design patent infringement damages to cover only damages on the end product, and not damages on a component.

The Supreme Court declined to develop a test to determine the relevant “article of manufacture” for the first step of the two-step process to determine design patent infringement damages as the issue had no briefing, leaving this for the Court of

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63 Apple Inc., 786 F.3d at 1005.
64 Id. at 1001-02.
65 Id. at 1005.
66 Samsung Elecs. Co., 137 S. Ct. at 432
67 Apple Inc., 786 F.3d at 1002.
72 Id. In a single component product, the article of manufacture is always the end product.
73 Id. at 436. “The Patent Office and the courts have understood § 171 to permit a design patent for a design extending to only a component of a multicomponent product.” Id. at 435. Further, the Supreme Court has used the term “manufacture” to include the production of articles from raw materials by giving them new forms or properties. Id., citing Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).
Appeals for the Federal Circuit on remand. This may set the stage for this case to return to the Supreme Court on the issue of the appropriate test to determine this key issue.

III. LIFE TECHNOLOGIES CORP. v. PROMEGA CORP.

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 a 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.

Does the “substantial portion” of this subsection of the Patent Act have a quantitative or a qualitative meaning? The Court of Appeals for the Federal Circuit in Promega Corp. v. Life Technologies Corp. gave the phrase a qualitative meaning, holding that one component could qualify for infringement. The decision of the Court of Appeals for the Federal Circuit became, again, unanimously reversed and remanded seven to zero by the Supreme Court in Life Technologies Corporation v. Promega Corporation, wherein the Court gave the phrase a quantitative meaning, so that supplying a single component from the United States does not confer infringement under this subsection. Justice Sotomayor, again writing for the Court, stated that the term “substantial portion” has a quantitative and not qualitative meaning, and “does not cover the supply of a single component of a multicomponent invention.”

Promega Corporation originated in 1978 in Madison Wisconsin and holds “intellectual property rights and licenses in several key areas” including short tandem repeat (STR) for human identification. Life Technology Corporation manufactured genetic testing kits which contain components “for carrying out a multiplex amplification of STR loci from DNA samples” for law enforcement for identification.

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75 Id.
77 773 F.3d 1338 (Fed. Cir. 2014).
79 137 S. Ct. 734, 197 L. Ed. 2d 33 (2017).
80 Id. at 743.
83 Promega Corp. v. Life Technologies Corp., 773 F.3d 1338, 1344 (Fed. Cir. 2014).
“and by clinical and research institutions for purposes such as analyzing cancer cells.”

These kits contain five components, one of which Life Technology manufactured in the U.S. and then shipped to the United Kingdom, where the kits were assembled and sold worldwide.

Promega owned four patents and held the exclusive license of a fifth, the “Tautz” patent, which became cross-licensed in 2006 for “Forensics and Human Identity Applications” to a company later acquired by Life Technologies. In 2010, Promega sued Life Technologies for infringement of claims of all five patents, alleging that Life Technologies sold testing kits incorporating the technologies, beyond the scope of the 2006 cross license. Life Technologies answered that the license covered all applications, plus counterclaimed that claims of Promega’s patents were invalid. The district court orally ruled that the cross-license was for live forensic law enforcement purposes only, and all other sales were infringing. At trial, a jury found in Promega’s favor and awarded $52 million in damages. The district court judge, however, granted Life Technologies’ judgment as a matter of law, because Promega failed to prove infringement.

Under the Patent Act, infringement may be found if one supplies from the United States “all or a substantial portion of the components of a patented invention,” which are uncombined in whole or part, to actively induce the combination of these components outside the United States in a way which would infringe, had this occurred in the United States. The issue grappled with by the district court, which became ruled the same way by the Supreme Court, is whether a single component shipped out of the United States suffices. The district court looked to the next subsection of the Patent Act, which also includes similar wording, “where such component is uncombined in whole or in part,” and the district court concluded that Promega did not prove that Life Technologies’ accused products contained a “substantial portion” of components from the United States, when only one component came from the United States.

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84 Id.
85 Id.
86 U.S. Pat. RE37984, on a Process for analyzing length polymorphisms in DNA regions, called the Tautz patent after one of the inventors, Diethard Tautz, available at http://www.google.com/patents/USRE37984. This patent expired in 2015, and all subsequent appeals involved only prior infringement.
87 Promega, 773 F.3d at 1344.
88 Id.
89 Id.
91 Id. at *6.
94 Id. at *18.
96 Promega Corp. v. Life Technologies Corp., No. 10-cv-281-bbc, 2012 U.S. Dist. LEXIS 190681 at *23 (W.D. Wis. Sept. 13, 2012). Promega also failed on its infringement claim under 35 U.S.C. § 271(a), the whoever makes, uses, offers to sell, or sells any patented invention within the United States or imports into the United States any patented invention is an infringer section, because Promega did not provide evidence on this point. Id. at *30-31.
Promega appealed the judgment as a matter of law, and Life Technologies appealed the oral ruling that the cross-license didn’t cover all its products, plus that asserted claims of Promega’s four patents were found not invalid.\textsuperscript{97} On appeal, the Court of Appeals for the Federal Circuit found the patent claims in question invalid, but also reversed Life Technologies’ judgment as a matter of law on the infringement issue and remanded; the oral ruling upheld the cross license, however.\textsuperscript{98} Addressing the issue before the Supreme Court concerning infringement by supplying from the United States a substantial portion of the components, the appeals court disagreed with the district court that a single component can never constitute a substantial portion of the components of the patented invention.\textsuperscript{99}

Judge Prost dissented in part, and agreed with the district court the Life Technologies should not be liable for infringing by supplying the one component of the kit from the United States,\textsuperscript{100} but not for the reason of the district court,\textsuperscript{101} and later the Supreme Court.\textsuperscript{102} Judge Prost didn’t reach the single component infringement issue, but rather that the Patent Act subsection\textsuperscript{103} requires inducement of another to infringe, and Life Technologies could not be liable for that, since it only induced its own subsidiary, and not another. Judge Prost, thus, would have held that no infringement liability occurred from Life Technologies supplying from the United States because one cannot induce oneself to infringe.\textsuperscript{104}

The U.S. Supreme Court granted the writ of certiorari\textsuperscript{105} on the sole issue of “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.”\textsuperscript{106} On February 22, 2017, the Supreme Court unanimously held that the Federal Circuit did err, because a single supplied component is not a substantial portion of the components, reversing and remanding.\textsuperscript{107}

Justice Sotomayor, again writing for the Court, stated her opinion, “this case concerns the intersection of international supply chains and federal patent law.”\textsuperscript{108} The Court had to determine whether “substantial portion” constituted qualitative as the Federal Circuit and Promega believed, or quantitative, as Life Technologies

\begin{thebibliography}{99}
\item Promega Corp. v. Life Technologies Corp., 773 F.3d 1338, 1341 (Fed. Cir. 2014).
\item Id.
\item Id. at 1356. See generally, Michael Sanzo, Exporting Components of Patented Products: A Unique Way to Infringe, 18 N.C. J. L. & TECH. ON. 322 (2017).
\item Promega, 773 F.3d at 1358.
\item Life Techs. Corp., 137 S. Ct. at 739.
\item See generally Promega Corp. v. Life Technologies Corp., 773 F.3d at 1344-58.
\item Life Technologies Corp. v. Promega Corp., 136 S. Ct. 2505 (2016).
\item Life Techs. Corp., 137 S. Ct. at 739.
\end{thebibliography}
argued. Starting with the Patent Act itself, “substantial” is not defined, and the dictionary meaning could go either way. Looking at the context of the subsection, “substantial” has a quantitative meaning, as it modifies “of the components of a patented invention,” and is a workable definition.

The Court then had to decide if a single component could be a “substantial component,” and examining again the text of the Patent Act, the Court decided that “components” could not be a single component. Congress meant “components” to be plural, and “component to be singular.

Not joined by Justices Alito and Thomas in this portion only, the Court looked to legislative history and concluded that their decision “comports with Congress’ intent.” Justice Alito’s concurrence further stated that any number of components greater than one is not necessarily sufficient, only that more than one is required.

This is an important opinion by the Supreme Court, both for what it states, and what it does not. Specifically, the Court did not “consider how to identify the ‘components’ of a patent or whether and how that inquiry relates to the element of a patent claim.” Further, the Court left open the issue of “how close to ‘all’ of the components ‘a substantial portion’ must be.” Finally, no mention in the opinion occurred for the presumption against extraterritoriality, although it was brought up at oral argument. Again, these issues may be left for a later day.

109 Id.
110 Id.
112 Life Techs. Corp., 137 S. Ct. at 740. While Promega does not agree with the quantitative definition, it also proposed a case specific approach, which the Court did not adopt, because it would compound complexity.
113 Id. at 741.
114 Id. Looking at the next subsection, 35 U.S.C. § 271(0)(2), this refers to “any component,” in the singular sense.
115 Id. at 742. The Court discussed its holding in Microsoft Corp. v. AT&T Corp., 550 U.S. 437 (2007), which didn’t involve the number of components, but rather whether there was a component. See generally, Sue Mota, MedImmune, Microsoft, and KSR: The U.S. Supreme Court in 2007 Tips the Balance In Favor of Innovation in Patent Cases, and Thrise Reverses the Federal Circuit, 11 MARQ. INTELL. PROP. L. REV. 181 (2007).
116 Life Techs. Corp., 137 S. Ct. at 742-43. Congress enacted this subsection after the Court’s decision in Deepsouth Packing Co. v. Laitram Corp., 206 U.S. 518 (1972). The Court concluded that a single component is outside the scope of the subsection.
117 Id. at 743.
118 Id.
119 Id. at 742.
IV. SCA HYGIENE PRODUCTS V. FIRST QUALITY BABY PRODUCTS, LLC

Except 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.\(^{121}\)

Is laches a defense against infringement falling under the “except as otherwise provided” clause above, during the six-year statute of limitation? The Court of Appeals for the Federal Circuit said yes en banc in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC.*\(^{122}\) The United States Supreme Court, however, on March 21, 2017 vacated and remanded, seven to one, holding that laches may not be used as a defense during the six-year patent statute of limitations.\(^{123}\)

SCA Hygiene Products (hereinafter SCA) is a “leading global hygiene and forest products company” founded in 1929 and headquartered in Stockholm, Sweden.\(^{124}\) First Quality Baby Products, LLC, founded in New York in 20018, is a subsidiary of First Quality Enterprises, and produces and markets baby care products.\(^{125}\) First Quality Enterprises is a private corporation founded in New York in 1998.\(^{126}\) The parties each offer a broad range of products, and compete in the toddler and adult disposable diaper markets.

SCA is the original assignee of U.S. Patent No. 6,375,646 (the ‘646 patent) issued in the U.S. in 2002 on a disposable absorbent pants-type diaper.\(^{127}\) SCA’s legal counsel sent the President of First Quality Enterprises a letter in 2003 which stated in part, “we suggest that you study” the ‘646 patent. “If you are of the opinion that the First Quality Prevail All Nites absorbent pants-type diaper does not infringe any of the claims of this patent, please provide us with an explanation as to why you believe your products do not infringe.” Further, if First Quality believed that infringement occurred, they needed to give assurances that the infringement would cease, and a request a response in less than a month.\(^{128}\) On the requested reply-by date, First Quality’s legal counsel responded in part that, “as you suggested, we studied” the ‘646 patent, and believed that a prior patent invalidated SCA’s patent, and further stated, “as you know, an invalid patent cannot be infringed,” and directed all further correspondence to the legal counsel.\(^{129}\)

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\(^{121}\) 35 U.S.C. § 286.

\(^{122}\) 807 F.3d 1311 (Fed. Cir. 2015).


\(^{128}\) SCA Hygiene Prod. Aktiebolag, 137 S. Ct. at 957-58.

\(^{129}\) *Id.* Four months later, in 2004, SCA sent another letter to First Quality alleging that another SCA patent was infringed. First Quality replied that this patent’s claims were not infringed, and repeated that correspondence should go to First Quality’s legal counsel.
In 2004, SCA requested an ex parte reexamination of the '646 at the U.S. Patent Office, concerning the patent which First Quality previously claimed to the '646 patent and thus invalidated it. In 2007, the U.S. Patent Office issued a reexamination certificate that not only confirmed the validity of all the '646 patent claims, but also added dependent claims.\footnote{Id. SCA did not notify First Quality of this, nor did it tell First Quality that SCA intended to file suit.}

In 2010, SCA filed this patent infringement suit, alleging that some of First Quality Baby Products’ pants-type disposable diapers infringe on claims of SCA’s ‘646 patent. First Quality counterclaimed alleging non-infringement and patent invalidity.\footnote{Markman\textsuperscript{132} hearing was held. First Quality then moved for summary judgment, arguing that SCA’s allegations were barred by laches and equitable estoppel.\footnote{Since SCA knew of its patent infringement claims against First Quality in 2003 when they sent first letter, the district court granted First Quality’s motion for summary judgment.\footnote{SCA appealed, and in 2014 a panel of the Court of Appeals for the Federal Circuit affirmed on the laches issue.\footnote{In 2014, however, the U.S. Supreme Court decided the copyright case \textit{Petrella v. Metro-Goldwyn-Mayer},\footnote{SCA Hygiene Prod. Aktiebolag, 137 S. Ct. at 960. First Quality also moved for partial summary judgment of non-infringement, among other things.} that laches may not be used as a defense during a copyright’s three-year statute of limitations. The appeals court \textit{en banc} held six to five that laches remains a defense in patent appeals cases.\footnote{The dissent would have applied Petrella in this patent case, and laches would not have been a defense during the six years patent statute of limitations.\footnote{SCA requested certiorari on the issue of whether or to what extent a defense of laches applies during the six-year patent statute of limitations, and granted the writ of certiorari in 2016.\footnote{On March 21, 2017, the \textit{en banc} decision of the Court of Appeals for the Federal Circuit vacated and remanded the case, seven to one at the Supreme Court, with Justice Breyer dissenting.\footnote{Writing for the majority, Justice Alito}}}}}}\footnote{SCA did not notify First Quality of this, nor did it tell First Quality that SCA intended to file suit.}


\textit{Id.} at 1342.
stated that the Court’s reasoning in the *Petrella*\textsuperscript{141} copyright case that laches does not apply during the three year copyright statute of limitations\textsuperscript{142} applies here, during the six year patent statute of limitations.\textsuperscript{143} While statutes of limitations and laches both protect against untimely claims, statutes of limitations are Congressionally set, and should override judicial decisions made on a case-by-case basis.\textsuperscript{144} “Laches is a gap-filling doctrine, and where there is a statute of limitations, there is no gap to fill.”\textsuperscript{145}

Looking to the Patent Act statute of limitations section,\textsuperscript{146} the copyright logic works in this patent case, according to the majority.\textsuperscript{147} The Federal Circuit read the Patent Act phrase “except as otherwise provided by law”\textsuperscript{148} to include a section of the Patent Act listing defenses, but not laches.\textsuperscript{149} The appeals court cited cases decided before the enactment of the Patent Act of 1952 to support this contention.\textsuperscript{150} “After surveying the pre-1952 case law, we are not convinced that Congress . . . departed from the general rule regarding the application of laches to damages suffered within the time for filing suit set out in a statute of limitations.”\textsuperscript{151} Thus, laches may not be applied within the statute of limitations period.\textsuperscript{152}

Justice Breyer, while agreeing that consistency between copyright and patent law by applying *Petrella*\textsuperscript{153} is the majority’s strongest argument, nonetheless dissented.\textsuperscript{154} Justice Breyer believes that *Petrella* came to the wrong decision, and started the Court in the wrong direction, and would have upheld the *en banc* decision.\textsuperscript{155}

V. TC HEARTLAND LLC v. KRAFT FOODS GROUP BRANDS LLC

Any civil action for patent infringement 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.\textsuperscript{156}

\textsuperscript{141}Petrella v. Metro-Goldwyn-Mayer, 188 L. Ed. 2d 979 (2014).
\textsuperscript{142}17 U.S.C. § 507(b).
\textsuperscript{143}SCA Hygiene Prod. Aktiebolag, 137 S. Ct. at 959.
\textsuperscript{144}Id. at 960, citing Petrella, 188 L. Ed. at 986.
\textsuperscript{145}Id.
\textsuperscript{146}35 U.S.C. § 286.
\textsuperscript{147}SCA Hygiene Prod. Aktiebolag, 137 S. Ct. at 960.
\textsuperscript{148}35 U.S.C. § 286.
\textsuperscript{149}35 U.S.C. § 282(b)(1) (2017), which states that, “the following shall be defenses involving the validity or infringement of a patent and shall be pleaded: (1) noninfringement, absence of liability for infringement or unenforceability.”
\textsuperscript{150}SCA Hygiene Prod. Aktiebolag, 137 S. Ct. at 963-64.
\textsuperscript{151}Id. at 966. The Court separately reviewed pre-1938 equity cases, pre-1938 law cases, and cases after the merger of law and equity in 1938 and before 1952. The pre-1938 cases provide “minimal support,” and the evidence after 1938 is “scant” to support this contention. *Id.* at *23. Other arguments made by First Quality “do not require extended discussion.”
\textsuperscript{152}Id. at 967.
\textsuperscript{154}SCA Hygiene Prod. Aktiebolag, 137 S. Ct. at 971.
\textsuperscript{155}Id. at 973.
\textsuperscript{156}28 U.S.C. § 1400(b).
Where is the residence of a corporation, in terms of this section on where a patent action may be brought? The U.S. Supreme Court on May 22, 2017 unanimously held, eight to zero,¹⁵⁷ in TC Heartland LLC v. Kraft Foods Group Brands LLC that a corporation resides only in its state of incorporation under this statute section, which is not amended by another provision,¹⁵⁸ reversing and remanding the Court of Appeals for the Federal Circuit.¹⁵⁹

Kraft Foods Group (hereinafter, Kraft) is “one of the largest consumer packaged food and beverage companies in North America and worldwide,” and initially incorporated in Delaware in 1980, with its principal place of business in Illinois.¹⁶⁰ TC Heartland, hereinafter Heartland, is “a global leader in the production of liquid water enhancers and is headquartered in, and produces product in, Indiana,¹¹ and is a competitor of Kraft in the flavored drink mix market.¹⁶² In 2014, Kraft sued Heartland in district court in Delaware,¹⁶³ alleging infringement of three of Kraft’s patents which generally relate to packages and containers for shelf-stable flavored liquid beverage concentrates.¹⁶⁴


¹⁶² TC Heartland LLC, 137 S. Ct. at 1517.


Defendant Heartland moved to dismiss for lack of personal jurisdiction because Heartland did not reside in Delaware, and Heartland did not have an established place of business in Delaware, and Heartland requested a transfer of venue to a district court in Indiana; the district court in Delaware denied the motion to dismiss. Heartland’s unsuccessful arguments at the district court level also included that only 2% of its product shipped into Delaware, and that the Delaware district court should not address the out of state alleged infringement. The district court observed that if this novel jurisdiction theory that 98% of its sales were not in Delaware were adopted by the court, it would result in “sweeping changes to the way patent litigation proceeds in the United States.” Heartland also argued that venue in a patent case is only in the defendant’s state of incorporation, or where the defendant has committed acts of infringement and has a regular place of business, citing 28 U.S.C. § 1400(b), and that amendments by Congress in 2011 changed patent venue, and thus Delaware is not the appropriate venue for this litigation. The district court disagreed, and also thus denied transfer of the case.

Heartland then requested that the Court of Appeals for the Federal Circuit issue a writ of mandamus to the Delaware district court to dismiss or transfer Kraft’s patent infringement case. The appeals court denied the request in 2016. Calling a writ of mandamus an “extraordinary remedy appropriate only in exceptional circumstances,” the Federal Circuit followed its own precedent, thus in this author’s opinion inviting reversal, and denied the writ.

On December 14, 2016, the U.S. Supreme Court granted Heartland’s petition for a writ of certiorari, on the issue of whether 28 U.S.C. § 1400(b) is the sole and exclusive patent jurisdiction statute, unencumbered by 28 U.S.C. § 1391(c). On May 22, 2017, the Supreme Court unanimously reversed the Court of Appeals for the Federal Circuit and remanded.

Writing for the Court, Justice Thomas started with the specific patent venue statute, 28 U.S.C. § 1400(b), which states, as above, that the proper district is where

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Id. at *3-4.

Id. at *21.


Kraft Foods Group Brands, LLC v. TC Heartland, LLC, 821 F.3d 1338 (Fed. Cir. 2016).

Id. at 1341.


Id. at 1516.
the defendant resides, and instead could be where the defendant has allegedly committed infringing acts and has a regular established place of business. Justice Scalia then addressed, under this statute, the district where a domestic corporation resides. The Supreme Court in 1957 in *Fourco Glass Co. v. Transmirra Products Corp.* held that a domestic corporation resides only in its state of incorporation. The Court in *Fourco* rejected the argument that the specific patent venue statute is modified by the general corporate residence statute section. The former specific section has not been modified since *Fourco*, but the latter general section has been subsequently modified twice. The Court concluded that these modifications of the general statute do not affect the specific patent venue statute as interpreted in *Fourco*, and thus the ruling stands, that a domestic corporation resides only in the incorporation state. The appeals court reversed, holding that the amendments of the general statute did also amend the specific patent venue statute as interpreted in *Fourco*.

In reaching this conclusion, Justice Thomas reviewed the predecessor of the 1948 specific patent venue statute, as well as subsequent to its enactment, leading up to *Fourco*, which stated that Congress intended 28 U.S.C. § 1400(b) to be “complete, independent and alone controlling in its sphere.” When Congress amended the general statute in 1988 and again in 2011, Congress did not alter the specific patent venue statute. Addressing the issue of whether Congress changed the specific section when modifying the general, Justice Thomas cited the late Justice Scalia and Garner’s book, which states, “A clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted in the same statute or even in an affiliated statute.”

Justice Thomas started the opinion framing the issue as where a patent infringement lawsuit should be brought, against a domestic corporation. Whether *Heartland* is or is not a corporation for purposes of this section is left for remand. The Court did not address the issue of what is the proper district for non-corporations, nor the issue of the appropriate district for foreign corporations, and again, is left for another case.

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VI. IMPRESSION PRODUCTS, INC. v. LEXMARK INT’L., INC.

Except as otherwise provided in this title, whoever makes, uses, offers to sell, or sells any patented invention, in the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.191

But, once that first sale is made, does the patent holder have rights which continue under patent law, or are those rights exhausted? The U.S. Supreme Court on May 30, 2017 ruled eight to zero that the patent holder’s rights are exhausted under patent law with the first sale in the U.S., and seven to one, with Justice Ginsburg dissenting, that this first sale exhausts a patent holder’s right in international first sales in Impression Products, Inc. v. Lexmark International, Inc.192

Lexmark International, Inc. (hereinafter Lexmark) is a publicly traded company founded in 1991, and is headquartered in Lexington, Kentucky.193 Lexmark has become a “leading developer, manufacturer and supplier of printing, imaging,” and other devices such as printer toner cartridges.194 Lexmark holds a number of patents on its printer cartridges.195 Impression Products, Inc. (hereinafter Impression Products) founded in 1979, and since the early 1990’s, “bought used printer cartridges, refurnished them, and resold them.”196 Lexmark’s printer cartridges were sold domestically and abroad. All of the domestic, and some of the foreign, printer cartridge sales included a printer cartridge single use/no resale user agreement under which the user, who was told they were buying the cartridge at a discount, agreed to a single use and only return the cartridge to Lexmark and not have it refilled elsewhere.197 Impression Products obtained, refilled, and sold in the U.S. Lexmark printer cartridges, and also obtained Lexmark cartridges abroad and imported them into the U.S.198

Lexmark sued Impression Products199 for patent infringement under 35 U.S.C. § 271.200 The district court held that Lexmark’s patent infringement claims were

192 137 S. Ct. 1523, 198 L. Ed. 2d 1 (2017).
195 Lexmark Int’l., Inc. v. Impression Products, Inc., 816 F. 3d. 721, 727 (Fed. Cir. 2016). Impression Products did not dispute the validity or enforceability of Lexmark’s patents. Id. at 729.
197 Lexmark Int’l., Inc., 816 F. 3d. at 727. Lexmark sells directly to end users, and to resellers.
198 Id.
199 Id. at 728. Lexmark also sued others, but at the time of litigation, Impression Products was the only company left as a defendant.
200 Id. Lexmark sued under 35 U.S.C. § 271(a) for direct patent infringement, and under 35 U.S.C. § 271(c) for contributory infringement, for the few cartridges which only the end user infringes.
barred by the patent doctrine of exhaustion, and “must be dismissed.” The district court reviewed the first patent exhaustion case decided by the Supreme Court in 1853, *Bloomer v. McQuewan*, which held that when the patented item comes into the hands of the purchaser, it is no longer subject to the patent monopoly, and is the purchaser’s personal property, not protected by federal law, but by state law. In 2008, the Supreme Court decided *Quanta Computer, Inc. v. LG Electronics, Inc.*, which stated that “the authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control post sale use of the article.” Consequently, the sale of the printer cartridges by Lexmark to consumers “took the cartridges outside the scope of the patent monopoly” and Lexmark couldn’t use patent law to hold First Impression liable. The district court stated that this is consistent with *Quanta*, and to hold otherwise would be confusing for consumers, granted Impression Products’ motion to dismiss, and Lexmark’s patent infringement claims against Impression Products on the domestic return printer cartridges were dismissed.

The Court of Appeals for the Federal Circuit heard the appeal en banc, to consider whether two decisions of the appeals court remained valid in light of subsequent Supreme Court decisions. On both issues, the domestic sales as well as the international sales, the Court of Appeals started its analysis with its own precedents, which in hindsight, wasn’t the best starting point. According to Chief Justice Roberts, writing for the Court, the Federal Circuit “got off on the wrong foot.” The Court of Appeals for the Federal Circuit reconfirmed its 1992 decision in *Mallinckrodt, Inc. v. Medipart, Inc.* even in light of the Supreme Court’s 2008 decision in *Quanta*. The appeals court also reconfirmed its 2001 decision in *Jazz Photo Corp. v. International Trade Commission* in light of the Supreme Court’s 2013
The copyright decision in *Kirtsaeng v. John Wiley & Sons, Inc.* "Mallinckdrodt has been the governing case law since 1992 and has been reiterated in subsequent precedent," according to the Federal Circuit, and the majority saw no reason not to apply it to allow Lexmark to use legal restrictions on downstream use of the printer cartridges. For the sales abroad, the appeals court concluded, as it did in *Jazz Photos*, that U.S. rights are not waived in foreign sales. *Kirtsaeng* does not apply, according to the Federal Circuit, because patent cases have their own considerations. A restriction such as Lexmark placed does not exhaust downstream uses by the purchaser, and thus the Federal Circuit upheld the district court’s ruling of non-exhaustion on the international sales, and reversed the district court’s ruling of exhaustion on U.S. sales.

Judge Dyk, joined by Judge Hughes, dissented. Concerning *Mallinckdrodt*, Judge Dyk stated, “we exceed our role as a subordinate court by declining to follow the explicit domestic exhaustion rule announced by the Supreme Court,” and would overrule *Mallinckdrodt*. Further, concerning *Kirtsaeng* and other Supreme Court precedent, “The majority’s justifications for refusing to follow Supreme Court authority establishing the exhaustion rule misconceive our role as a subordinate court,” and would have overruled *Jazz Photos*’ blanket ban on international patent exhaustion.

The U.S. Supreme Court granted the writ of certiorari on December 2, 2016 on the two issues of domestic and international patent exhaustion, in light of *Kirtsaeng*. and on May 30, 2017, the Supreme Court reversed eight to zero holding that Lexmark exhausted its patent rights on U.S. sales, and reversed seven to one with Justice Ginsburg dissenting, that Lexmark exhausted its patent rights on international sales, and remanded.

Chief Justice Roberts, writing for the majority, started with the domestic sales, and concluded that Lexmark exhausted its patent rights in these cartridges the...
moment it sold them. While the contracts with end purchasers may be legal under contract law, they may not be used by Lexmark to retain patent rights, according to all eight voting members of the Court. According to the Court, for over 160 years since the Court’s ruling in *Bloomer v. McQuewan*, the doctrine of patent exhaustion has automatically limited the exclusive right of the patent holder to sell that particular item, and granted a personal property right to the owner. This “venerable principle” was “dismissively viewed” by the majority of the Federal Circuit, according to the Court. Chief Justice Roberts then gave a very practical example of a shop that restores and sells used cars; the “smooth flow of commerce would sputter if companies that made the thousands of parts which go into a vehicle could keep their patent rights after the first sale.” The Court examined its precedent including *Quanta* and stated that the long line of precedent “allows for only one answer.” Lexmark may not sue Impression Products under patent infringement law, but may turn to contract law. The Court summarized, “patent exhaustion is uniform and automatic. Once a patentee decides to sell—whether on its own or through a licensee—that sale exhausts its patent rights, regardless of any post-sale restrictions the patentee purports to impose, either directly or through a license.” Thus, the Court of Appeals for the Federal Circuit reversed the domestic sales issue by all eight voting members of the Court.

Moving to the international sales, seven of the Court’s voting members agreed that “an authorized sale outside the United States, just as one within the United States, exhausts all rights under the Patent Act.” The majority examined the first sale under copyright law and the Court’s copyright precedent in *Kirtsaeng v. John Wiley & Sons, Inc.* Interestingly, the Court turned to its own precedent under copyright law twice this term, in *Lexmark*, and previously in *SCA Hygiene Products v. First Quality Baby Products*. Just as the first sale doctrine was straightforward in international sales of copyrighted goods, “applying patent exhaustion to foreign sales is just as straightforward.” The Court distinguished its prior international patent exhaustion decision in 1890, *Boesch v. Graff*, because the patentees in *Graff* didn’t

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228 Id. at *12.
229 Id.
230 55 U.S. 539 (1853).
232 Id. at *13.
233 Id.
236 Id.
237 Id.
238 Id. at *17.
243 133 U.S. 697 (1890).
exhausted their patent rights because they hadn’t sold them. The Court rejected a middle approach suggested by the United States as amicus, that patent rights are exhausted unless reserved,\textsuperscript{244} because “restrictions and location are irrelevant.”\textsuperscript{245} Thus, reversing the Federal Circuit on both issues.\textsuperscript{246}

Justice Ginsburg dissented on the second international issue, because a U.S. patent does not confer rights abroad.\textsuperscript{247} Justice Ginsburg also dissented in Kirtsaeng on the issue of international first sale under copyright law.\textsuperscript{248}

This decision is bound to cause numerous changes in the global and domestic supply chain across many sectors. Companies will have to adjust to avoid refurbishing, re-importation, and arbitrage involving their products. Chief Justice Roberts pointed out that Lexmark’s contracts were with the direct-sale customers, not with Impression Products,\textsuperscript{249} and further, that these contracts may be valid and enforceable.\textsuperscript{250} One possible solution for the many companies grappling with this issue post-Lexmark is to be sure to have such restrictions in all contracts, and enforce them with the other parties to the contract. Of course, this is a much more difficult enforcement issue due to the many end-users, rather than dealing directly with a company such as Impression Products, who now is not reachable under patent exhaustion, and further doesn’t have a contract with a patent holder such as Lexmark.

VII. SANDOZ INC. v. AMGEN INC.

It shall be an act of infringement to submit -

(C)(i) with respect to a patent which is identified in . . . an application seeking approval of a biologic product, or (ii) if the applicant . . . fails to provide the application and information required, . . . if the purpose for such submission is to gain approval under such act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent, or the use of which is claimed in a patent before the expiration of such patent.\textsuperscript{251}

The U.S. Supreme Court on June 12, 2017, held nine to zero in Sandoz Inc. v. Amgen Inc., the only patent case decided this term with a full Court, that a biological biosimilar applicant may not be forced by injunction to comply with the procedure of giving the reference product manufacturer twenty day notice of the biosimilar FDA application spelled out in the Biologics Price Competition and Innovation Act (BPCIA),

\textsuperscript{245} Id. at *20.
\textsuperscript{246} Id.
\textsuperscript{247} Id.
\textsuperscript{248} Id. at *21.
\textsuperscript{250} Id. at *12.
and that under the BPCIA, the biological biosimilar applicant may give the reference product sponsor the required 180 day notice of commercial marketing, before the biosimilar producer gets the FDA license.\textsuperscript{252} The Court of Appeals for the Federal Circuit vacated, reversed, and remanded the case.\textsuperscript{253}

Amgen, one of the world’s leading biotechnology companies,\textsuperscript{254} originated in California in 1980, and went public in 1983.\textsuperscript{255} In 1991, the FDA approved Amgen’s drug, Filgrastim,\textsuperscript{256} a bone marrow stimulant which can help the body make white blood cells, which Amgen sold under the brand name Neupogen. Sandoz, a division of Novartis, is “a global leader in generic and biosimilar medicines.”\textsuperscript{257}

Congress passed the complex Biologics Price Competition and Innovation Act (BPCIA) as part of the Patient Privacy and Affordable Care Act, signing the Act into law in March of 2010.\textsuperscript{258} A biologic is a “type of drug derived from natural, biological sources such as animals or microorganisms.”\textsuperscript{259} The BPCIA gives producers of biologic products\textsuperscript{260} which are biosimilar\textsuperscript{261} to the reference product already on the market with an FDA license, an abbreviated pathway to approval,\textsuperscript{262} and also gives ways and times in that process to resolve patent disputes.\textsuperscript{263} The biosimilar applicant may not apply until four years after the FDA has licensed the original reference product sponsor, and the FDA may not approve a biologic biosimilar application until twelve years after the approval of reference product sponsor’s license.\textsuperscript{264} Within twenty days of being notified by the FDA that the application for a biosimilar product has been received, the biosimilar producer “shall” provide the reference product’s sponsor with the application and other material provided.\textsuperscript{265} This notice within twenty days triggers an “artificial” act of infringement (because a traditional act of infringement hasn’t yet occurred),\textsuperscript{266} for which there are remedies of damages and injunctive relief.\textsuperscript{267} Within sixty days of this notice, the reference product sponsor is to give a list of patents which

\textsuperscript{253} Id.
\textsuperscript{254} Amgen, About, http://www.amgen.com/about/ (last visited June 18, 2017).
\textsuperscript{256} Id.
\textsuperscript{258} BPCIA, Title VII, Subtitle A, PPACA, which amends 42 U.S.C. § 262.
\textsuperscript{260} 42 U.S.C. § 262(i)(1) defines biologic product as a virus, therapeutic serum, toxin, antitoxin, blood, blood derivative or component, among others, applicable to the prevention, treatment, or cure of a disease of humans.
\textsuperscript{261} 42 U.S.C. § 262(i)(2) defines biosimilarity as highly similar to the reference product with only minor differences in clinically inactive components, and no clinically meaningful differences in the biosimilar product from the reference product in safety, purity, and potency.
\textsuperscript{262} 42 U.S.C. § 262(k).
\textsuperscript{263} 35 U.S.C. § 271(e).
\textsuperscript{264} 42 U.S.C. § 262(K)(7)(A), (B) (2017).
\textsuperscript{265} 42 U.S.C. § (l)(2).
\textsuperscript{266} 35 U.S.C. § 271(e)(2)(c)(i), (ii).
\textsuperscript{267} 35 U.S.C. § 271(e)(4).
may be infringed, and also a list of which patents, if any, the sponsor would license. Then, the applicant has sixty days to respond, giving any other patents which the applicant deems relevant, discussing why the applicant believes it might not infringe, and responding to the licensure issue. Then the sponsor has sixty days to respond back about validity, enforceability, and infringement of each patent. The parties then proceed to the first stage of litigation, on the patents they both agree to litigate, or if they don’t agree, the patents in a simultaneous list exchange. This is the first stage of patent litigation.

The second stage of patent litigation involves patents not litigated in the first phase, and neither party may sue the other for a declaration of infringement, validity, or enforcement of any non-litigated patent prior to the date that notice of commercial marketing is received. This notice of commercial marketing is to be given by the biosimilar producer no later than 180 days before the first commercial marketing of the biosimilar product. But, if the biosimilar producer does not engage in this so-called patent dance, then the reference product sponsor, but not the biosimilar producer, may bring an action for declaration of infringement, validity, or enforcement of any patent without waiting for notice of commercial marketing. If the biosimilar producer does engage in the patent dance, then after the notice of first commercial marketing and before the first commercial marketing, the reference product sponsor may request a preliminary injunction against the biosimilar producer on the validity, enforcement, and infringement of any involved patent.

On July 7, 2014, Sandoz got notice that the FDA accepted its application to make Filagrasitain. The next day, Sandoz mailed Amgen a letter offering conditional access to the application, and stating that it anticipated FDA approval in first or second quarter 2015, and it would start marketing immediately upon approval. On July 25, 2014, Amgen received a second letter, announcing intention to not follow the procedural “dance,” or allow the full access and subsequent back-and-forth; Amgen should sue for patent infringement to obtain information.

Not surprisingly, on October 24, 2014, Amgen sued Sandoz for patent infringement for claims of U.S. Patent No. 6,162,427 (the ‘427 patent), as well as under California unfair competition law, and requested a preliminary injunction. Sandoz counterclaimed, including alleging both non-infringement and invalidity of the

276 Id.
277 U.S. Patent No. 6,126,427 relates to the combination of G-CSF with a chemotherapeutic agent for stem cell mobilization.
279 Id. at *4.
‘427 patent, and requested declaratory judgment that its conduct was permissible and within the BPCIA.\textsuperscript{281}

In its analysis, the district court analyzed the BPCIA process and the failure to provide Amgen all required documentation within 20 days; the district court observed that the “shall” language of the statute “does not imply it is mandatory in all contexts.”\textsuperscript{282} If Sandoz had complied, it would have enjoyed a “temporary safe harbor from litigation,”\textsuperscript{283} but, “perhaps confident in its limited exposure to liability and eager to resolve patent disputes so as to not delay market entry,”\textsuperscript{284} and this decision by Sandoz was permissible, according to the district court.\textsuperscript{285} It was also permissible for Sandoz to give its 180-day notice prior to FDA approval.\textsuperscript{286} Thus, Sandoz did not violate the BPCIA, according to the district court, and further, Amgen’s claims against Sandoz under California state law were also dismissed with prejudice.\textsuperscript{287} The Court dismissed Amgen’s motions for partial summary judgment or, in the alternative, partial judgment on the pleadings, as well as its request for preliminary injunction.\textsuperscript{288}

The decision was, of course, appealed, and in the first appellate decision\textsuperscript{289} on the BPCIA, the Court of Appeals for the Federal Circuit in 2015 ruled that Sandoz did not violate the BPCIA by not initially giving Amgen access to their FDA application and relevant information.\textsuperscript{290} The appeals court, however, did reverse the district court on the issue of when notice of commercial marketing may be given, which is only after FDA approval, according to the appeals court.\textsuperscript{291} Since Sandoz gave Amgen another notice of commercial marketing when the FDA approved Sandoz’s application on March 6, 2015,\textsuperscript{292} this is the notice which counts under the BPCIA, according to the appeals court, and Sandoz would be allowed to market its biosimilar 180 days after that, on September 2, 2015.\textsuperscript{293} Amgen’s injunction pending appeal denied by the district court but reversed and granted by the appeals court extended to September 2, 2015.\textsuperscript{294} The Federal Circuit affirmed the dismissal of the California state claims.\textsuperscript{295}

The U.S. Supreme Court granted the writs of certiorari on the two issues under the BPCIA of whether the “shall” language requires the biosimilar applicant to provide

\begin{footnotesize}
\begin{itemize}
\item[281] Id.
\item[282] Id. at *17.
\item[283] Id.
\item[284] Amgen Inc., at *20-21.
\item[285] Id. at *21.
\item[286] Id. at *25.
\item[287] Id. at *28.
\item[288] Id. at *33-34.
\item[290] Amgen, 794 F.3d at 1356.
\item[291] Id. at 1358.
\item[292] Id. at 1353.
\item[293] Id. at 1360.
\item[294] Id. at 1362.
\item[295] Amgen, at 1360. Judge Newman dissented in part, on the issue of not requiring Sandoz to follow the BPCIA procedure. Id. at 1366. Judge Chen dissented in part, on the issue of the injunction pending appeal, and would dissolve the injunction. Id. at 1371.
\end{itemize}
\end{footnotesize}
the application and relevant notice within twenty days to the reference product sponsor, and whether the 180-day commercial marketing notice may be given before FDA approval.\(^{296}\)

On June 12, 2017, the full Supreme Court unanimously held that failure to give the twenty day notice under the BPCIA by the applicant is not enforceable by injunction, and the 180-day notice may be given before FDA approval, both vacating and reversing the Court of Appeals for the Federal Circuit and remanding.\(^{297}\) Again writing for the Court, Justice Thomas stated that the Court agreed with the Federal Circuit that an injunction is not available to enforce the “patent dance,”\(^{298}\) but for a different reason than the appeals court gave.\(^{299}\) The Supreme Court concluded that Sandoz’s failure to disclose the required information within twenty days of its FDA application is not an artificial act of infringement, which could be remedied by an injunction.\(^{300}\) The remedy for an applicant such as Sandoz which fails to give the required information is that the reference product sponsor may bring an action for declaration of infringement,\(^{301}\) not an injunction. The action for declaration of infringement excludes all other remedies, according to the Court.\(^{302}\) Congress did include an injunction in the BPCIA for breach of confidentiality in the process,\(^{303}\) so the Court concluded that Congress, if they desired, could also have included an injunction as a remedy for an applicant who fails to engage in the initial BPCIA process.\(^{304}\) So, according to the Court, the appeals court correctly denied the injunction, but for the wrong reason. On remand, the Federal Circuit considered whether Sandoz’s action constituted illegality under state law and then determine if the BPCIA preempted state law, or just assume that California law provided remedy and consider the preemption issue.\(^{305}\)

Turning to the issue of the timing of the 180-day notice of commercial market, the Supreme Court held that the 180-day notice did not have to be given only after FDA licensure of the biosimilar biologic product, reversing the Court of Appeals for the Federal Circuit which held that this notice could only come after FDA licensure.\(^{306}\) While the licensure must exist before the first commercial marketing, licensure isn’t required before giving the notice.\(^{307}\) Thus, the Federal Circuit’s incorrectly decided to

\(^{300}\) Id. at *22.
\(^{305}\) Id. at *28-29.
\(^{306}\) Id. at *29.
\(^{307}\) Id.
keep the injunction until 180 days after licensure, according to the Court, which vacated, reversed, and remanded.\footnote{Id. at \#33.}

Justice Breyer briefly concurred, calling the Court’s ruling a “reasonable interpretation,” but also invited the FDA, when they gained more experience with the BPCIA, to modify this interpretation.\footnote{Id. at \#33.}

Thus, the Court interpreted the first stage of the BPCIA process so as to not require the biosimilar biologic applicant to engage in the “patent dance,” but suffer the consequence of a patent infringement lawsuit, as per the statute, if they didn’t. In the second stage, the commercial marketing notice may be given immediately upon application, under the BPCIA, and the applicant does not need to wait 180 days after licensure if the notice is given before then.\footnote{Sandoz Inc. v. Amgen Inc., Nos. 15-1039 and 1195, 2017 U.S. LEXIS 3723 (U.S. June 12, 2017).}

Both of these rulings are reasonable and consistent with the statutory language, in this author’s opinion.

VIII. CONCLUSION

The U.S. Supreme Court in the 2016-17 term decided six patent cases,\footnote{Supra notes 2-7.} a tie for a record-setting term of the Court, and each case reversed or vacated, or both, the Court of Appeals for the Federal Circuit, four unanimously, and two with one dissenter. This sends a strong message to the Federal Circuit, to review and adhere to Supreme Court precedent, which should be the starting point in the analysis, and not the appeals court’s own precedent. Each case is important and adds to patent jurisprudence, and has long-reaching implications.

To summarize, in Samsung Electronics Co., Ltd. v. Apple Inc.\footnote{Samsung Electronics Co., Ltd. v. Apple Inc., No. 15-777, 2016 U.S. LEXIS 7419 (U.S. Dec. 6, 2016).} the Supreme Court unanimously held that the proper “article of manufacture” for ascertaining design patent infringement damages may be a component of an end product, whether sold separately or not, and not the entire end product, reversing the Court of Appeals for the Federal Circuit. This is the legally appropriate decision, in this author’s opinion, as a “manufacture” for patent purposes may include a component of a final product.\footnote{Id. at \#12-13.} This outcome makes practical sense as well, as the article of manufacture may be only a very small portion of the end product, leaving an unfair result if only the minor component is infringed, and holding otherwise could widen the door for patent assertion entities which could claim that a design patent they own is infringed by a very small component of an end product with very large sales. Since the Court didn’t give a test to ascertain the relevant article of manufacture because the issue wasn’t properly before them, this protracted design patent litigation could end up at the U.S. Supreme Court again.

In Life Technologies v. Promega, the Court held seven to zero that supplying “a substantial portion of the components” of a patented invention from the United States

\footnote{Id. at \#33.}
requires a quantitative and not a qualitative analysis, and means more than one component is supplied, reversing the Court of Appeals for the Federal Circuit and remanding. The Court did not mention extraterritoriality, nor did it give a test on how to identify “components,” nor how close to all the “substantial portion” must be, since these last two issues were not before the Court.

In *SCA Hygiene Products v. First Quality Baby Products, LLC*, the Court held seven to one, with Justice Breyer dissenting, that the defense of laches does not apply during the six-year patent statute of limitations, vacating the *en banc* decision of the Court of Appeals for the Federal Circuit and remanding. This is consistent with the Court’s 2014 holding in *Petrella v. Metro-Goldwyn-Mayer*, under which the copyright defense of laches did not apply during the copyright three-year statute of limitations.

In *TC Heartland v. Kraft Foods Group*, the Court held eight to zero that a corporation resides only in its state of incorporation for purposes of the specific patent venue statute, reversing the Court of Appeals for the Federal Circuit and remanding. The term “patent troll” was not actually used in this case, since Kraft is obviously not a patent troll, nor was the term used by the Court at all in 2017, as it was by the late Justice Scalia in the dissent in *Commil USA, LLC v. Cisco Systems, Inc.* in 2015. But *TC Heartland v. Kraft Foods Group* will have the effect of limiting jurisdiction in patent infringement litigation against domestic corporations, and thus will have the practical result of reigning in the ability of patent trolls to file suit in favorable jurisdictions. So, this is an extremely important patent ruling this term, curtailing patent infringement plaintiffs’ ability to select friendly forums.

In *Impression Products, Inc. v. Lexmark Int’l, Inc.*, the Court on May 30, 2017 held eight to zero that the first domestic sale of a patented good exhausts the patent holder’s rights under patent law, and seven to one that the first international sale does the same, reversing the Court of Appeals for the Federal Circuit. This is a very important decision in the global and international supply chain. This case will have the practical effect of having many companies across many sectors dealing with the problem of arbitrage and international re-importation. After *Lexmark*, valid contracts may continue to be used with users restricting what they may do with the products, but patent exhaustion will be a complete defense after the first domestic or international sale.

In *Sandoz, Inc. v. Amgen, Inc.*, the Court unanimously held on June 12, 2017 that an injunction is not the statutory remedy under the BPCIA for a biosimilar biologic

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319 Id.
applicant who does not comply with the preliminary stage of fully notifying the reference product sponsor within 20 days of the application, and further, the second notice of commercial marketing may be given by the applicant to the reference product sponsor before licensure.\textsuperscript{322} In Sandoz, the Court of Appeals for the Federal Circuit became both reversed and vacated, and the case remanded. In this author’s opinion, this result is fully consistent with the statutory language of the BPCIA.

The year 2017, like prior years, was not a good year for patent assertion entities at the United States Supreme Court. The Court in 2017 struck a blow against patent trolls in Kraft by limiting the jurisdiction in which patent infringement cases may be brought against domestic corporations.\textsuperscript{323} The Court applied copyright precedent in the patent setting in two cases, SCA Hygiene\textsuperscript{324} and Impression Products.\textsuperscript{325} In Apple, patent infringement damages are not necessarily the total damages of the final product, when only one component infringes.\textsuperscript{326} The Court applied common sense interpretation to the BPCIA in Sandoz.\textsuperscript{327} The Court properly did not reach beyond issues before it, leaving some issues to potentially reach the Court again, but in every case, reversed or vacated the Court of Appeals for the Federal Circuit, six times unanimously and twice with only one dissenter, which perhaps is the big story from the Court this term.

\textsuperscript{323} Supra notes 156-190 and accompanying text.
\textsuperscript{324} Supra notes 121-155 and accompanying text.
\textsuperscript{325} Supra notes 191-250 and accompanying text.
\textsuperscript{326} Supra notes 29-75 and accompanying text.
\textsuperscript{327} Supra notes 251-309 and accompanying text.