No. 15-927

IN THE

Supreme Court of the United States

SCA HYGIENE PRODUCTS AKTIEBOLAG
AND SCA PERSONAL CARE, INC.,

Petitioners,

v.

FIRST QUALITY BABY PRODUCTS, LLC,
FIRST QUALITY HYGIENIC, INC.,
FIRST QUALITY PRODUCTS, INC., AND
FIRST QUALITY RETAIL SERVICES, LLC,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF COOK MEDICAL LLC AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae Cook Medical LLC ("Cook Medical") is a global leader in the medical device industry, providing groundbreaking, lifesaving technologies for the medical field. Most recently, Cook Medical and others in the industry have become favored targets of patent assertion entities ("PAEs") that acquire and assert medical device patents issued many years ago. PAEs often seek to use a medical device company's product investments and the potential damages that accrue during the delay in filing suit as a weapon for making enormous settlement demands or demanding higher licensing fees. Cook Medical believes its experience in dealing with stale – and unfounded – claims by PAEs may be useful to the Court in addressing the laches questions under consideration.

In one such case, Cook Medical is the respondent in *Endotach LLC v. Cook Medical LLC*, No. 16-127, pending in this Court ("*Endotach Supreme Court Appeal*").[2] Most pertinent here, the district court in the *Endotach Supreme Court Appeal* granted summary judgment in favor of Cook Medical on its laches defense with respect to the two patents asserted by Endotach LLC ("Endotach") against Cook Medical. *Endotach LLC v. Cook Medical Inc.*, No. 13-01135, Dkt. No. 229, slip op. at 42–43 (S.D. Ind. Jan. 27, 2015)

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[1] No counsel for any party authored this brief in whole or in part and no person other than *amicus curiae*, its members, and its counsel made a monetary contribution intended to fund this brief's preparation or submission. Petitioners have filed a blanket consent with the Court. Counsel for Respondents has consented to the filing of this *amicus* brief, and their consent letter is on file with the Clerk's office.

[2] Cook Medical LLC is the surviving entity following conversion of Cook Medical Incorporated to Cook Medical LLC.

("*Endotach District Court Litigation*").[3] Endotach appealed the district court's decision to the Federal Circuit Court of Appeals. Pertinent here, the Federal Circuit affirmed the district court's decision on laches. *Endotach LLC v. Cook Medical LLC*, No. 2015-1357, Dkt. No. 64 (Fed. Cir. May 6, 2016) ("*Endotach Federal Circuit Appeal*"). Endotach LLC appealed to this Court the Federal Circuit's order in the *Endotach Federal Circuit Appeal*. Petition for a Writ of Certioari, *Endotach LLC v. Cook Medical LLC*, No. 16-127 (July 25, 2016). This Court's decision here may affect the outcome of the *Endotach Supreme Court Appeal*.

SUMMARY OF ARGUMENT

The laches defense serves an essential role in protecting defendants in patent infringement cases from suffering economic and evidentiary prejudice caused by a patentee's unreasonable delay in bringing suit. This Court has recognized the importance of the laches defense in patent cases noting: "[c]ourts of equity, it has often been said, will not assist one who has slept upon his rights, and shows no excuse for his laches in asserting them." *Lane & Bodley Co. v. Locke*,

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[3] The two asserted patents are U.S. Patent No. 5,122,154 (the "'154 patent") and U.S. Patent No. 5,593,417 (the "'417 patent"). They sometimes are referred to collectively as the "Rhodes Patents" after the named inventor, Dr. Valentine J. Rhodes. The '154 patent issued on June 16, 1992 and expired on August 15, 2010. The '417 patent issued on January 14, 1997 and expired on November 27, 2015. On May 6, 2016, the Federal Circuit affirmed a finding by the Patent Trial and Appeal Board that all asserted claims of the '417 patent were unpatentable. *Endotach LLC v. Medtronic, Inc.*, 639 F. App'x 644, 645 (Fed. Cir. 2016); *see also Medtronic, Inc. v. Marital Deduction Trust*, IPR2014-00100, Paper 46 at 29, 2015 WL 1384339, at *18 (P.T.A.B. Mar. 24, 2015).

150 U.S. 193, 200-01 (1893). Laches should remain a viable defense in patent cases, and the Federal Circuit's en banc decision in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products LLC*, 807 F.3d 1311 (Fed. Cir. 2015) affirming, in part, the Federal Circuit's decision in *A.C. Aukerman Co. v. R.L. Chaides Construction Co.*, 960 F.2d 1020 (Fed. Cir. 1992) (en banc) should be upheld.

Amicus curiae's experience presents a real-world application of the laches defense in patent cases that exemplifies the criticality of the defense. Medical device companies, such as Cook Medical, expend substantial time and monetary investments in research and development of new devices, gaining premarket approval from the United States Food & Drug Administration ("FDA"), and maintaining compliance with the FDA's postmarket regulations. When a patentee sleeps on its rights, the laches defense protects medical device companies from suffering economic prejudice caused by the delay.

The laches defense also protects a defendant from suffering evidentiary prejudice caused by the patentee's delay that prevents a defendant from presenting a full and fair defense in patent cases. In stark contrast to copyright cases, extrinsic evidence serves a pivotal role in patent cases. When a patentee delays filing suit, the risks of lost extrinsic evidence, witness unavailability including death and fading memories increase to the detriment of a defendant. The elimination of the laches defense would unfairly inure to the benefit of the dilatory patentee and create an unacceptable uncertainty in the marketplace that deters innovation.

INTRODUCTION

Bill Cook founded the first of the Cook Medical family of companies in Bloomington, Indiana in 1963. Initially producing wire guides, needles, and catheters, the Cook Medical family of companies today makes 16,000 products. Its world headquarters in Bloomington is home to nearly 2,500 employees.

The required approval of medical devices by the FDA is a long, rigorous, and costly process, as the district court in the *Endotach District Court Litigation* recognized for the Cook Medical Zenith Products[4] at issue in that case:

> Cook has spent many millions of dollars to develop the Accused Products, including biocompatibility, bench, graft permeability and animal testing; finite element analysis; clinical trials; preparing clinical data for the [FDA]; presenting to the FDA circulatory device panel and ultimately achieving FDA premarket approval. . . . From 2003 to 2013, Cook invested hundreds of millions of dollars in marketing and sales of the Accused Products as well as hundreds of millions of dollars in royalties. . . . During that period of time, sales of the Accused Products ha[ve] increased.

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[4] One of Cook Medical's product lines consists of endovascular stent-grafts marketed under the name "Zenith" and used for treating aortic aneurysms ("Zenith Products"). The Zenith Products have been showcased at major scientific meetings and used at tradeshows to demonstrate the use and advantages of stent-graft procedures. The first of the Zenith Products was implanted in a patient in Australia in 1993. Cook Medical received regulatory approval for the Zenith Product line in Europe in 2000 and in the United States in 2003.

(*Endotach District Court Litigation*, Dkt. No. 229, slip op. at 25.)

Laches should remain a defense to claims of patent infringement occurring within the six-year damages period established by 35 U.S.C. § 286. The defense of laches protects the enormous investments that medical device companies and others are required to make in order to sell their FDA-regulated products when, through no fault of their own, the companies are forced to defend against stale claims of patent infringement. *See Aukerman*, 960 F.2d at 1033. Laches also shields against unjust deprivations that may result from an inability to present full and fair defenses because the passage of time has led to lost records, faded memories, and the deaths of potential witnesses. *Id.*

Cook Medical agrees with Respondents, First Quality Baby Products, LLC, First Quality Hygienic, Inc., First Quality Products, Inc., and First Quality Retail Services, LLC ("First Quality"), that laches should remain a defense in patent cases. *See* Resp. Br. 16-33. First Quality has convincingly explained why the Court's decision in *Petrella v. Metro-Goldwyn-Mayer*, 134 S. Ct. 1962 (2014), does not affect the availability of laches in patent cases and why the Federal Circuit's decision in *SCA Hygiene* should be upheld. *See id.* at 36-49. Cook Medical also agrees with First Quality that the presumption of prejudice after six years of delay should be retained. *See id.* at 51-53.

Cook Medical will not repeat First Quality's arguments here. Instead, Cook Medical will focus on real-world experiences from the medical device industry to illustrate why the laches defense has been, and why it must remain, a central tenet of patent law.

ARGUMENT

I. THE LACHES DEFENSE PROTECTS THE MEDICAL DEVICE INDUSTRY FROM SUFFERING UNJUST ECONOMIC PREJUDICE.

The FDA regulates the U.S. sale of medical device products (including diagnostic tests) and monitors the safety of all regulated medical products. *FDA's Role in Regulating Medical Devices*, FDA, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/ucm204884.htm (last visited Sept. 15, 2016). Before any but the lowest risk medical devices can be legally sold in the United States, the person or company desiring to sell the device must seek and obtain marketing authorization from the FDA. FDA clearance or approval of medical devices occurs through one of two primary regulatory pathways: the 510(k) process, *see* 21 U.S.C. § 360(k), or the Premarket Approval ("PMA") process, *see id.* § 360e,[5] depending on the level of potential risk associated with use of the device.

[5] The FDA uses the PMA process to evaluate the safety and effectiveness of medical devices that "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury." *Premarket Approval (PMA)*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm2007514.htm (last visited Sept. 15, 2016). For medical devices for which a PMA is not required, the FDA uses the 510(k) process to evaluate whether the proposed medical device is substantially equivalent to a legally marketed device. *Premarket Notification 510(k)*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last visited Sept. 15, 2016).

JOSH MAKOWER et al., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION 12-13 (2010). The 510(k) process is less expensive and less time-consuming than the PMA process. JUDITH A. JOHNSON, FDA REGULATION OF MEDICAL DEVICES (CRS REPORT NO. R42130) Summary (Cong. Res. Serv. 2012), *available at* https://www.fas.org/sgp/crs/misc/R42130.pdf. To gain approval, the applicant must present evidence that the device is reasonably safe and effective for a particular use. MAKOWER, 14.[6]

According to a 2010 survey of over 200 medical technology companies, the average cost to bring even a 510(k) medical device from concept to FDA clearance was approximately $31 million. *Id*. at 28. Of that total, $24 million was spent on "FDA dependent and/or related activities." *Id*. Bringing a PMA device from concept to approval carried an average cost of $94 million, "with $75 million spent on stages linked to the FDA." *Id*.

As part of the approval process, the FDA may request clinical data. This request often requires that a company seek permission to perform clinical trials through an investigational device exemption ("IDE"). *Id.* at 12. According to the 2010 survey, every month that a company spends seeking an IDE costs an additional $400,000 for 510(k) products and over $750,000 for PMA products. *Id*. at 28. On average, this additional process takes ten to fifteen months and costs millions of dollars. *Id*. at 29–30, Figs. 8, 11.

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[6] This Court has acknowledged that the PMA process is "rigorous" and requires the submission of "detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

Medical device development costs also may include "proof of concept (for example, bench testing and animal testing), clinical unit development, . . . safety and feasibility studies (for example, small-group human trials), [and] pivotal trials." PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: BALANCING PATIENT SAFETY AND INNOVATION, 20 (Theresa Wizemann ed., 2010). When a company's overhead is included, navigating devices from concept to clearance or approval may cost as much as $73 million for 510(k) products and $136 million for PMA products. *Id*.

In addition to premarket approval, the FDA requires compliance with postmarket regulations on "labeling and advertising, manufacturing, postmarketing surveillance, device tracking [when so ordered by the FDA for a specific product], and adverse event reporting." JOHNSON, 13. These postmarket regulations demand even further investments of time and money that may not be recovered for years and/or until a product's third or fourth generation. *See* Wizemann, 20.

In the *Endotach District Court Litigation*, several of the Zenith Products targeted for claims of patent infringement had been sold in the United States since 2003, but Endotach did not attempt to sue Cook Medical until 2012. During the 10-year period of delay, Cook Medical spent millions of dollars in development, clinical testing, and acquiring FDA approvals for the product line, as well as investing hundreds of millions of dollars in related marketing and sales and in royalties, all as sales of Zenith

Products increased. (*See Endotach District Court Litigation*, Dkt. No. 229, slip op. at 25.)

The district court in the *Endotach District Court Litigation* recognized the economic prejudice that Cook Medical suffered as a result of Endotach's delay:

> There is also no question of material fact that Cook was prejudiced by the delay in being sued for infringement of the Rhodes patents. Here, over the nearly ten year delay, Cook invested large sums of money in development, promoting, and marketing its endovascular product line and, if it had been sued in a timely manner, could have altered its business strategy. There is no dispute that Cook has increased its market presence during the delay period. Further, although there is evidence that another Cook entity, Cook Group, Inc., had knowledge of at least the '154 patent, there is no indication that the entity sued in this case had been put on notice that it might be sued for infringement at any time. For these reasons, there is no material question of fact that Cook suffered economic prejudice because of the delay.

(*Id.* at 36.)

The Federal Circuit in *SCA Hygiene* also recognized this distinction in patent cases as compared to copyright cases stating:

> In patent law, however, the calculus is different [from copyright law]. For example, in the medical device industry, a company may independently develop an invention and spend enormous sums of money to usher

> the resultant product through regulatory approval and marketing, only to have a patentee emerge six years later to seek the most profitable six years of revenues.

SCA Hygiene, 807 F.3d at 1330.

Laches rightly discourages patentees from waiting silently and watching damages accrue. *Aukerman*, 960 F.2d at 1033. Given the significant investments that are required for the development and regulated sale of medical devices, early notice of possible infringement is crucial.

As noted above, PAEs have started to acquire medical device patents issued many years ago and are asserting those patents against the medical device industry. As part of their strategy, PAEs use the targeted company's product investments and the potential accruing damages during the delay in filing suit to try to extract higher royalties. When PAEs and others unreasonably and inexcusably delay asserting a claim, medical device companies such as Cook Medical rely upon the laches defense to counter this strategy and to protect their good-faith investments and product growth.

While non-infringement and invalidity defenses often carry the day in defending against these cases, the laches defense is an important arrow in the targeted company's quiver. The laches defense preserves a medical device company's significant investments – buildings, factories, employees, machines, and products – and may short-circuit extensive and expensive discovery on non-infringement and invalidity, and thereby also preserving judicial resources. *See, e.g, Lautzenhiser Techs., LLC v. Sunrise Med. HHG, Inc.*, 752 F. Supp. 2d 988, 1004 (S.D. Ind. 2010)

(finding economic prejudice where defendants spent tens of millions of dollars in product development, research and development, marketing, and sales of the accused products); *Integrated Cards, L.L.C. v. McKillip Indus., Inc.*, No. 06 C 2071, 2009 WL 4043425, at *6 (N.D. Ill. Nov. 19, 2009) (finding economic prejudice where during the delay the accused infringer spent over one million dollars in several new machines to produce the accused products).

While a patentee delays, the original medical device brought to market often expands into an entire product line introduced product by product over time. The medical device company's investment also likely has increased considerably through government-imposed regulations and required testing.

These delays and these costs should not inure to the benefit of an inattentive or a calculating patent owner, all to the detriment of a medical device manufacturer working to help save lives, be it Cook Medical or another. The Federal Circuit should be affirmed, so that laches may continue to offer the medical device industry the protection and certainty necessary to continue investment in this vital industry.

II. THE RISK OF SUBSTANTIAL EVIDENTIARY PREJUDICE IN PATENT CASES SUPPORTS THE LACHES DEFENSE.

Extrinsic evidence is critical in patent cases, including the ability to cross-examine and corroborate extrinsic evidence in support of a defendant's invalidity and noninfringement defenses. When a patentee delays and sits on its rights, a defendant's ability to present a full and fair defense through the use of

extrinsic evidence is compromised and the defendant may suffer evidentiary prejudice.

In patent cases, to rebut a charge of patent infringement, a defendant may assert invalidity defenses pursuant to 35 U.S.C. §§ 101, 102, 103 and 112 and non-infringement defenses. 35 U.S.C. § 282(b). An invalidity defense must be proved by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). To rebut an invalidity defense based on prior art under pre-AIA[7] 35 U.S.C. §§ 102 & 103, a patentee may attempt to antedate its patent by showing through extrinsic evidence that the named inventor was the first to invent, i.e. first to conceive the invention and diligently reduce it to practice. *Brown v. Barbacid*, 436 F.3d 1376, 1378-79 (Fed. Cir. 2006). *See also* pre-AIA 35 U.S.C. § 102(g). In response, a defendant will, in turn, need to antedate its prior art through extrinsic evidence to show an earlier conception and reduction to practice.

Also, to rebut an invalidity defense based on prior art under pre-AIA and post-AIA 35 U.S.C. §§ 102 & 103, a patentee will assert that the prior art does not disclose certain elements of the claimed invention. In response, a defendant may use extrinsic evidence, including the author or inventor of the prior art and the testimony of expert witnesses, to support the prior art's disclosure.

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[7] The America Invents Act (AIA) modified 35 U.S.C. §§ 102 & 103, including the removal of 35 U.S.C. § 102(g), and applies to United States patent applications filed on or after March 16, 2013. *See* Leahy-Smith America Invents Act, Pub. L. 112–29, §§ 3(b)(1), 3(c) & 3(n)(1), 125 Stat. 285-287, 293 (2011). United States patent applications filed before March 16, 2013 are subject to pre-AIA 35 U.S.C. §§ 102 & 103. *See id.* at § 3(n)(2), 125 Stat. 293.

Extrinsic evidence may include an inventor's testimony, which must be corroborated, testimony of other fact and expert witnesses, laboratory notebooks, or other written documentation. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). When a patentee delays filing suit, the risks of documents being lost, memories fading, and the death of witnesses increase, and a defendant's ability to prove its invalidity defenses is jeopardized. *See Thomas v. Echostar Satellite LLC*, No. 05-494, 2006 WL 3751319, at *4 (W.D.N.C. Dec. 19, 2006) (finding the absence of testimonial and documentary evidence inhibited the defendant's ability to present a full and fair defense).

This type of evidentiary prejudice was present in the *Endotach District Court Litigation.* In finding that laches applied, the district court found that Cook Medical suffered evidentiary prejudice as a result of Endotach's 10-year delay:

> The undisputed facts further evidence that Cook has suffered evidentiary prejudice because of the delay as well. Endotach relies heavily upon the testimony of Brenda, Cuffari, Stein, and Dungan, to evidence that Dr. Lee's disclosure and patent are not prior art to the '154 patent. However, the testimony of those witnesses shows that their memories of the events in the question have faded and that valuable documentary evidence has been lost because of intervening events or because the witnesses simply cannot remember what happened to their own or Dr. Rhodes' [,the deceased sole inventor of the patents-in-suit,] files. Dkt. No. 174 at 17 (Dungan's testimony regarding a discussion of a "Chinese finger cuff"); Dkt. No. 153-1 at 48 (Cuffari testimony

> regarding drawings on napkins and any records being destroyed in a 2005 flood), 48-49 (Brenda's testimony regarding Dr. Rhodes' files and drawings), 49-50 (Stein's testimony that he did not recall anything about the drawings he turned over of the alleged inventions or about Dr. Rhodes' efforts to license the patents), 50 (Dungan testimony regarding first draft of the '154 patent application). Many of the documents referenced were readily available when Cook first brought the Accused Products to market and for several years thereafter.
>
> Even though the missing documents and faulty memories is enough standing alone to indicate evidentiary prejudice, there are other evidentiary issues. Cook's expert relies, in part, upon an article by Dr. Alexander Balko ("Dr. Balko" and the "Balko article"), and a corresponding patent, U.S. Patent No. 4,512,338 ("Balko '338 patent"), for its invalidity defense. Dkt. No. 153-1 at 51. Endotach, like Dr. Rhodes during prosecution of the '154 patent, disputes the breadth of these Balko disclosures. *Id.* However, Dr. Balko died on September 16, 2008. *Id.* Again, had Cook been sued closer in time to the introduction of the accused devices, Dr. Balko would have been available to testify. Although an inventor's testimony is not always the most reliable indicator of claim scope, his testimony would have been relevant.

(*Endotach District Court Litigation*, Dkt. No. 229, slip op. at 36-37.) *See also Odetics, Inc. v. Storage Tech.*

Corp., 919 F. Supp. 911, 922-23 (E.D. Va. 1996) (finding evidentiary prejudice, in part, where documents related to defendant's 35 U.S.C. § 102(g) invalidity defense were "lost or destroyed as a consequence of the delay"), *vacated on other grounds*, 116 F.3d 1497 (Fed. Cir. 1997).

To prove infringement, a patentee may rely upon extrinsic evidence, including written documentation, to show an accused device or product infringes its patent. 35 U.S.C. § 271. To rebut a charge of patent infringement, a defendant may also rely upon extrinsic evidence to show that its accused device does not infringe the asserted patent. 35 U.S.C. § 282(b)(1). Due to the passage of time from the patentee's delay, a defendant's ability to present a full and fair defense of noninfringement is compromised by the lack of available extrinsic evidence. In the *Endotach District Court Litigation*, this is an additional reason why the district court found that Cook Medical suffered evidentiary prejudice:

> Endotach's '417 patent infringement analysis relies, in part, on the Greenberg study. Dkt. No. 174 at 28-29. But, Dr. Greenburg died on December 7, 2013. Dkt. No. 153-1 at 51. If Endotach or its predecessors had sued on the Rhodes patents sooner, Dr. Greenberg would have been available to testify. Taking the impact of all of these pieces of evidence together, there is no material question of fact that Endotach has been prejudiced by the patent holders' delay in filing suit.

(*Endotach District Court Litigation*, Dkt. No. 229, slip op. at 37.) Endotach's delay unfairly prejudiced Cook Medical's ability to support its invalidity and noninfringement defenses as a result of the death of

witnesses, faded memories, and the loss of documentary evidence.

In contrast, the Court in *Petrella* dismissed the risk of evidentiary prejudice as a basis for upholding a laches defense in copyright cases because "[t]he registration mechanism . . . reduces the need for extrinsic evidence", "[k]ey evidence in the litigation . . . will be the certificate, the original work, and the allegedly infringing work", and "the adjudication will often turn on the factfinder's direct comparison of the original and the infringing works, *i.e.*, on the factfinder's 'good eyes and common sense' in comparing the two works' 'total concept and overall feel'." 134 S. Ct. at 1977 (internal citation omitted). This holding does not hold true in patent cases.

In patent cases, a defendant's use of extrinsic evidence is prevalent and necessary to defend against a charge of patent infringement. A patentee's delay in filing suit results in a substantial risk of evidentiary prejudice to a defendant including the defendant's inability to rely upon extrinsic evidence to rebut the patentee's patent infringement claims. Laches in patent cases equitably protects a defendant from suffering such evidentiary prejudice.

CONCLUSION

Amicus curiae urges this Court to affirm the Federal Circuit's *en banc* decision in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products LLC*, 807 F.3d 1311 (Fed. Cir. 2015). Given the differences between patent law and copyright law, this Court's decision in *Petrella v. Metro-Goldwyn-Mayer*, 134 S. Ct. 1962 (2014), does not affect the availability of the much-needed laches defense in patent cases.

Respectfully submitted,

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