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 FOR AMICUS CURIAE ROCHE MOLECULAR SYSTEMS, INC. IN SUPPORT OF RESPONDENTS AND URGING AFFIRMANCE

KEVIN A. MARKS
MICHAEL D. LISI
ROCHE MOLECULAR SYSTEMS, INC.
4300 Hacienda Drive
Pleasanton, CA 94588

KEVIN E. Noon
Counsel of Re
ARON V. GIN, I
McDonnell Bo

KEVIN E. NOONAN, PH.D.

Counsel of Record

JEREMY E. NOE

AARON V. GIN, PH.D.

McDonnell Boehnen

Hulbert & Berghoff LLP

300 South Wacker Drive

Chicago, IL 60606

(312) 913-0001

noonan@mbhb.com

Counsel for Amicus Curiae

TABLE OF CONTENTS

			Page
TABL	E O	F CONTENTS	i
TABL	E O	F CITED AUTHORITIES	iii
INTE	RES	ST OF AMICUS CURIAE	1
SUMI	MAF	RY OF ARGUMENT	2
ARGU	JME	ENT	4
I.	IN	ESERVINGTHE LACHES DEFENSE PATENT INFRINGEMENT ACTIONS EQUITABLE AND FAIR	4
	A.	Laches limits litigation risk for good- faith manufacturers, who bear a substantial burden in ascertaining whether a patentee has a legitimate patent infringement claim	6
	В.	Laches protects immense investments made by manufacturers in regulated industries	8
	С.	Laches prevents unreasonable delays while knowing patent owners "lie in wait"	10

$Table\ of\ Contents$

	Page
D. Removing the laches defense constituted lead to unintended results to can stifle growth, unjustly endilatory patentees, and eliminalife-saving drugs and medical deverties from the marketplace	that rich nate vices
E. Preserving laches as a defense patent infringement strikes right balance between protection diligent patent owners and good-manufacturers	the ting faith
II. ABSENT THE DEFENSE OF LACH PATENT TROLLS AND OTH DILATORY PATENTEES CANTHWA CONGRESS'S INTENT THAT T 35 U.S.C. § 156 TERM RESTORAT UNIQUE TO PATENT LAW OPERA AS A VALUE-MAXIMIZI INCENTIVE TO ENCOURA CONTINUED DEVELOPME OF NEW PHARMACEUTICALS	ER ART THE ION ATE NG GE NT
CONCLUSION	18

TABLE OF CITED AUTHORITIES

Page
Cases
A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992)
Advanced Hydraulics, Inc. v. Eaton Corp., 415 F. Supp. 283 (N.D. Ill. 1976)4
Angiotech Pharm. Inc. v. Lee, No. 1:15-CV-1673, 2016 WL 3248352 (E.D. Va. June 8, 2016)
CardSoft v. Verifone, Inc., 769 F.3d 1114 (Fed. Cir. 2014)
Carhart v. Carhart-Halaska Int'l, LLC, 788 F.3d 687 (7th Cir. 2015)
Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920 (2015)
eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006)
Gen. Elec. Co. v. Hoechst Celanese Corp., 740 F. Supp. 305 (D. Del. 1990)12
Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F.2d 392 (Fed. Cir. 1990)

$Cited\ Authorities$

Page
Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923 (2016)10
Hoechst Aktiengesellschaft v. Quigg, 724 F. Supp. 398 (E.D. Va. 1989), rev'd, 917 F.2d 522 (Fed. Cir. 1990)
In re Packard, 751 F.3d 1307 (Fed. Cir. 2014), cert. denied sub nom. Packard v. Lee, 135 S. Ct. 2310 (2015)10
Medinol Ltd. v. Cordis Corp., 15 F. Supp. 3d 389 (S.D.N.Y. 2014)
Petrella v. Metro-Goldwyn-Mayer, Inc., 134 S. Ct. 1962 (2014)
SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC, 807 F.3d 1311 (Fed. Cir. 2015), cert. granted, 136 S. Ct. 1824 (2016)
Stryker Corp. v. Zimmer, Inc., 741 F. Supp. 509 (D.N.J. 1990)
Statutes
21 U.S.C. § 301 <i>et seq.</i>
35 U.S.C. § 156

$Cited\ Authorities$

Pa	ıge
35 U.S.C. § 2824,	16
Sup. Ct. R. 37.3(a)	.1
Sup. Ct. R. 37.6	.1
Other Authorities	
H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 (1984)	17
John C. Low, Finding the Right Tool for the Job: Adequate Protection for Research Tool Patents in A Global Market?, 27 Hous. J. Int'l L. 345 (2005)	8-9
Mark A. Lemley, <i>The Economics of Improvement in Intellectual Property Law</i> , 75 Tex. L. Rev. 989 (1997)	7
Michael J. McKeon, <i>The Patent Marking and Notice Statute: A Question of "Fact" or "Act"?</i> , 9 Harv. J.L. & Tech. 429 (1996)	.7
Natasha N. Aljalian, The Role of Patent Scope in Biopharmaceutical Patents, 11 B.U. J. Sci. & Tech. L. 1 (2005)	9

INTEREST OF AMICUS CURIAE¹

Roche Molecular Systems, Inc., is an affiliate of F. Hoffmann-La Roche Ltd. ("Roche"), the world's largest biopharmaceutical company and one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. For more than 100 years, Roche has been a pioneer in the discovery and development of novel healthcare solutions, including leading biopharmaceuticals, cancer medicines and in vitro diagnostics (IVD) systems. Twenty-four medicines developed by Roche are included in the World Health Organization's "Model Lists of Essential Medicines," among them life-saving antibiotics, antimalarial drugs and chemotherapeutic agents. Roche's broad line of oncology, virology, microbiology and blood screening tests are used by researchers, hospitals, laboratories and blood banks around the world.

As both a patent holder and licensee of patented biopharmaceutical and diagnostic technologies, Roche has a uniquely balanced perspective on the issues raised in this litigation. Roche invests billions of dollars annually in research and development for its pharmaceutical and diagnostic technologies. Patent protection is necessary

^{1.} Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amicus curiae* or its counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for Petitioners in this case has filed a letter pursuant to Supreme Court Rule 37.3(a) reflecting consent to the filing of *amicus curiae* briefs in support of either party. Counsel of Record for Respondents consented in writing to the filing of this brief.

not only to prevent free-riding on Roche's substantial investments, but also to incentivize innovation in areas that hold the greatest promise for improving treatment and facilitating diagnostic decisions. Roche recognizes, however, that an environment that fosters innovation requires more than just patent protection. It also requires rules and norms that facilitate early disclosure and dissemination of patented technologies, as well as fairness in how these rules and norms are established and followed by those in the pharmaceutical industry. The traditional principle of laches, that patent rights be asserted in a timely fashion so that the market is not lulled into relying on a patentee's inaction, is just such a rule. The questions presented in this case are therefore of great significance to Roche and to the biotechnology industry as a whole.

SUMMARY OF ARGUMENT

The case before the Court raises the question of whether the laches defense is available to bar claims for damages under the Patent Act, in light of this Court's decision in *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 134 S. Ct. 1962 (2014). The Federal Circuit recognized the availability of laches as a defense to damages claims in unreasonably-delayed patent infringement actions in *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028-1032 (Fed. Cir. 1992). *Amicus* respectfully submits that the defense of laches serves an important purpose in balancing the equities between a manufacturer, acting in a good-faith belief that her activities did not infringe a patentee's monopoly, and a diligent patent owner seeking to enforce her patent.

Compared to allegations of copyright infringement where independent creation is a defense, it is often much harder for a good-faith manufacturer to ascertain whether a patentee can claim with any justice that a new product infringes its patent, and whether such a claim could be successfully litigated against the manufacturer. Indeed, the ultimate risk to accused infringers is often only fully understood after claim construction at trial.

Laches is particularly important in fields subject to complex regulatory schemes. Such regulatory processes significantly add to the expense of the research, development, and patenting of innovative therapies and medicines. A good-faith manufacturer that, at enormous cost, develops a product and markets it for years without action from a knowing patentee should be able to reasonably conclude that, after a certain period of time, it no longer faces the risk of an infringement claim.

Courts have effectively utilized the laches defense to punish patent-troll abuses embodied in unreasonable delays in bringing suit. *Amicus* warns that removing the laches defense may undo such efforts and could lead to unexpected results that could stifle growth, unjustly enrich dilatory patentees, and eliminate life-saving drugs and medical devices from the marketplace. Furthermore, without the defense of laches, patent trolls will be unrestrained from bypassing Congress's intent when it created the Patent Term Restoration provision under 35 U.S.C. § 156.

Regardless of how this Court chooses to reach its decision, it is clear that preserving laches as an equitable defense to patent infringement maintains the correct balance of equities by protecting good-faith manufacturers, and the public at large, without causing undue prejudice to diligent patent owners.

ARGUMENT

I. PRESERVING THE LACHES DEFENSE IN PATENT INFRINGEMENT ACTIONS IS EQUITABLE AND FAIR

As a matter of policy and in the interests of fairness, those who are granted a monopoly under the patent system have an obligation to enforce their rights in a timely manner. See, e.g., Advanced Hydraulics, Inc. v. Eaton Corp., 415 F. Supp. 283, 286 (N.D. Ill. 1976). Accordingly, under the equitable doctrine of laches, a court may bar a plaintiff's recovery in instances where an accused infringer is unfairly disadvantaged due to an inexcusable delay by a patentee in providing notice or bringing suit. Id.

The laches defense has been codified in the Patent Act as an equitable defense to patent infringement under 35 U.S.C. § 282. Where laches can be established, a court in its sound discretion can bar a patentee's claim for damages for activities prior to suit. See Aukerman, 960 F.2d at 1028.

In order to invoke laches, a defendant bears the burden to prove two elements. First, that the patentee delayed filing suit for an unreasonable and inexcusable length of time, as measured from the time she knew or reasonably should have known of her claim against the defendant. *Id.* at 1032. Second, any such delay must have operated to the accused infringer's prejudice or injury. *Id.*

The case before the Court raises the question of whether the Federal Circuit correctly held that the laches defense is available to bar claims for damages under the Patent Act in light of this Court's decision in *Petrella*. Resp't Br. i. *Amicus* urges this Court to affirm the Federal Circuit's ruling and retain laches as a defense that may be applied, on a discretionary basis, to bar damages for patent infringement, for at least the reasons enumerated herein.

Amicus believes that laches serves an important purpose in balancing the equities between a manufacturer acting in a good-faith belief that her activities did not infringe a patentee's monopoly and a diligent patent owner seeking to enforce her patent. For example, manufacturers, some who receive notice letters on a daily basis, can have difficulty in ascertaining whether allegations of patent infringement are legitimate. Against such a backdrop, laches provides a temporal limitation on the universe of litigation risks that businesses face.

These risks are exacerbated for companies in highly regulated industries, such as the pharmaceutical and medical device industries, that invest enormous amounts of time and money not only in developing a product but in moving the product through often complex regulatory processes. For these companies, laches operates to help protect their million- or billion-dollar investments directed to bringing safe and effective medicines and medical devices to the marketplace. Laches also fosters diligence by patent owners in identifying potential infringers and providing notice which, when ineffective, can result in a lawsuit; such diligence incentives can reduce inefficiencies in developing non-infringing alternatives. Perhaps most

importantly laches may be effective in deterring patent assertion entities (otherwise known as "patent trolls") from lying in wait for an unsuspecting manufacturer and then, after an unreasonably long waiting period calculated to permit products to mature and potential damages to accumulate, filing a patent infringement lawsuit where the troll's damages are maximized. This scenario also carries the possibility and frequently the distinct likelihood that products upon which doctors and the public have come to rely for improved medical care will be banished from the marketplace.

Removing laches as a defense in patent infringement cases would lead to harsh and unintended results, including harming innovation, unjustly enriching dilatory patent owners, and shelving life-saving drugs and medical devices. Accordingly, *amicus* believes that preserving laches as an equitable defense to patent infringement strikes the correct balance by protecting good-faith manufacturers without adversely affecting diligent patent owners.

A. Laches limits litigation risk for good-faith manufacturers, who bear a substantial burden in ascertaining whether a patentee has a legitimate patent infringement claim

Compared to allegations of copyright infringement, it is often much harder for a good-faith manufacturer to ascertain whether a patentee can claim with any justice that a new product infringes its patent, and whether such a claim could be successfully litigated against the

manufacturer.² SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC, 807 F.3d 1311, 1330 (Fed. Cir. 2015), cert. granted, 136 S. Ct. 1824 (2016) ("[B]usinesses receive demand letters every day—many of which assert unmeritorious claims—and it is often impractical for companies to determine which claims have merit."). Furthermore, the extent of damages liability for patent infringement can be quite uncertain, not least because a patent's infringement scope is dependent on claim construction, a concept unique to patent litigation, and therefore cannot be calculated with any certainty until litigation is underway. See CardSoft v. Verifone, Inc., 769 F.3d 1114, 1117 (Fed. Cir. 2014) ("Claim construction is a legal statement of the scope of the patent right.") (internal quotation marks omitted). Unlike in copyright, independent creation is not a defense to patent infringement, and "[a]n innocent infringer [who] performs infringing acts unaware of the infringement" may still face liability. Michael J. McKeon, The Patent Marking and Notice Statute: A Question of "Fact" or "Act"?, 9 Harv. J.L. & Tech. 429, 437 (1996).

In view of these very different realities in patent and copyright law, a manufacturer can spend many years and vast sums of money on research, development, regulatory

^{2.} See Mark A. Lemley, The Economics of Improvement in Intellectual Property Law, 75 Tex. L. Rev. 989, 1014 (1997) ("Anyone who makes, uses, or sells a product within the claims of a patent infringes that patent, whether or not they copied the idea from the patent owner, and indeed whether or not they were even aware that the patented technology existed. By contrast, a copyright protects its owner only against those who have actually taken the plaintiff's work. Independent development of the work is a complete defense.") (citations omitted).

approval, due diligence, and marketing for a new product honestly believing she does not infringe. Laches operates to limit litigation risks faced by manufacturers by barring claims of infringement that arise after an unreasonable period of delay and where that delay causes prejudice to the accused infringer. Sound policy dictates that a good-faith manufacturer that develops a product and is permitted by a dilatory patentee to market it for years without action should be able to rest easy that, after a certain period of time, it no longer faces the risk of a patent infringement lawsuit.

B. Laches protects immense investments made by manufacturers in regulated industries

Laches is particularly important in fields subject to significant regulatory oversight. The biopharmaceutical and medical diagnostics fields, in which *amicus* is a global leader, are governed by complex regulatory schemes, including, but not only, FDA approval, that significantly increase the time and expense of research, development, patenting and bringing to market innovative therapies and medicines.³ John C. Low, *Finding the Right Tool for the Job: Adequate Protection for Research Tool Patents in A*

^{3.} See Angiotech Pharm. Inc. v. Lee, No. 1:15-CV-1673, 2016 WL 3248352, at *2 (E.D. Va. June 8, 2016) ("[I]nventors may well not have sufficient incentive to expend the resources necessary to develop new drugs and medical devices, as patents claiming medical innovations subject to FDA review may have an effective life of less than the standard twenty years owing to the time consumed by the FDA review and approval process."); Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224, 1225 (E.D. Va. 1989), aff'd, 894 F.2d 392 (Fed. Cir. 1990) ("[P]rocedures often require years to complete, thereby diminishing the commercial rights provided by the patent.").

Global Market?, 27 Hous. J. Int'l L. 345, 358 (2005) ("59 percent of [biotech companies] cited difficult, antiquated, and expensive regulatory and approval processes as major barriers to further progress and competitiveness."); see also Natasha N. Aljalian, The Role of Patent Scope in Biopharmaceutical Patents, 11 B.U. J. Sci. & Tech. L. 1, 22 n.87, 42 (2005) ("Biopharmaceutical research and development is a lengthy, expensive and risky process. . . . It is said it takes more than a decade and capital in the several hundred millions of dollars to commercialize one drug."). Additionally, for highly-regulated industries, it is often much harder for alleged infringers to switch to a non-infringing alternative because of the required regulatory approval for redesigned products or drugs.

For at least these reasons, a reasonable time limitation on patent infringement damages, as is provided by the laches doctrine, helps protect the enormous investments of time and money involved in bringing a regulated product to the marketplace. Unless and until Congress indicates that there should be another avenue leading to such protection, laches is the only equitable, balanced way to ensure that a patentee is not permitted to tactically delay suit to the detriment of a good-faith biopharmaceutical or medical diagnostics entity serving a strong public interest in its business pursuits. Indeed, such a good-faith entity, that undertakes a substantial research and development effort, expends significant time and investment to seek and obtain approval of a new drug or treatment through multiple clinical trials, launching the product, and generating a successful market for it, should not be unduly subject to a late-patentee's attempt to reap an unearned windfall while at the same time threatening the public with the loss of beneficial medicines or medical devices.

C. Laches prevents unreasonable delays while knowing patent owners "lie in wait"

Without the laches defense, a calculating patentee would be allowed to wait until a regulated medical device or product comes to full maturity in the marketplace and then be able to pounce when the product is at its peak value, seeking six years—perhaps the best six years worth of damages. Courts, including this Court, have recognized with disfavor the deleterious effects of such troll-like behavior from patentees. See, e.g., Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1930 (2015) ("The Court is well aware that an 'industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.' Some companies may use patents as a sword to go after defendants for money, even when their claims are *frivolous*.") (emphasis added) (citation omitted); Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923, 1935 (2016) ("Trolls, in the patois of the patent community, are entities that hold patents for the primary purpose of enforcing them against alleged infringers, often exacting outsized licensing fees on threat of litigation"); Carhart v. Carhart-Halaska Int'l, LLC, 788 F.3d 687, 691 (7th Cir. 2015) ("The commonest example of a law troll is the patent troll, who acquires by purchase or application to the Patent and Trademark Office a patent that he uses not to protect an invention but to obtain a license fee from, or legal judgment against, an alleged infringer."); In re Packard, 751 F.3d 1307, 1324-25 (Fed. Cir. 2014), cert. denied sub nom. Packard v. Lee, 135 S. Ct. 2310 (2015) ("There are good reasons why unnecessary incoherence and ambiguity in claim constructions should be disapproved . . . [as] they waste scarce judicial resources on claim construction cases that should never have been necessary to litigate, supporting and encouraging the kinds of litigation that have made 'patent trolls' dirty words."). Avoiding such outcomes is critical to the proper performance of the patent system, even without the added factor that the patentee has used stealth and delay to enhance her position for collecting damages or extracting undue recompense by the threat of obtaining an injunction that would do away with a beneficial medical product or device from the market.

Amicus believes that such patent assertion abuses are deterred by laches, which could be, and in fact has been, applied to reduce dilatory action by patent assertion entities. Under the current laches jurisprudence in the lower courts, laches has been used to inhibit troll-like behavior provided there is evidence for: 1) delay in filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant; and 2) prejudice or injury of the defendant due to the plaintiff's delay.

An evidentiary showing of a failure to notify or bring suit identifies those patentees who have intentionally waited until the opportunity is a "ripe plum to be picked." See Stryker Corp. v. Zimmer, Inc., 741 F. Supp. 509, 514 (D.N.J. 1990) (motion for partial summary judgment based on laches granted) ("A patentee who, with knowledge of the alleged infringing activity, does nothing over a period of years other than mislead a purported infringer...lying in wait until... it has become 'commercially and economically worthwhile' to do something, has engaged in affirmatively misleading silence of the worst order and should not be insulated merely because, for whatever reason, it did not

articulate a threat or assert a right but, rather, chose to mislead from day one."). Evidence tending to show large increases in possible damages during a period of plaintiff inaction also have helped support a conclusion that a patentee has unreasonable delayed filing an infringement lawsuit. See, e.g., Gen. Elec. Co. v. Hoechst Celanese Corp., 740 F. Supp. 305 (D. Del. 1990) (barring recovery under laches where evidence demonstrated plaintiff knew of defendants' alleged infringement for 9 years prior to bringing of action, during which time defendants' sales of infringing product rose from less than \$150,000 to near \$8,000,000 per year).

Unreasonable dilatory behavior by a patentee can be used to provide evidence showing economic prejudice at least based on the enormous amount of resources needed to change course to a non-infringing alternative at a later date. In the case of a regulated product, the entity subject to a delayed suit may find it difficult to switch because of the additional time, effort, and cost required to obtain approval of the redesigned product. Under such circumstances, courts have found that economic prejudice may be established under a laches defense where a delay in bringing suit prevents the development of a non-infringing product. See, e.g., Medinol Ltd. v. Cordis Corp., 15 F. Supp. 3d 389, 408 (S.D.N.Y. 2014) (barring recovery under laches where patent owner delayed in bringing suit against competitor who had developed alternative products in response to prior accusations of infringement).

As these examples illustrate, laches provides a defense for good-faith manufacturers in cases where patent assertion entities knowingly delay infringement suits until the situation is most financially favorable for them and unfavorable to not just the manufacturer, but more importantly unfavorable to the public.

D. Removing the laches defense could lead to unintended results that can stifle growth, unjustly enrich dilatory patentees, and eliminate life-saving drugs and medical devices from the marketplace

This Court could decide to eliminate or narrow the longstanding application of the laches doctrine under the Patent Act (although "a major departure from the long tradition of equity practice should not be lightly implied").⁴ Amicus cautions that such a decision would be extremely problematic because patent assertion entities could then, without any limit on when suit could be filed, choose a time that is most profitable for their own interests. Such a distorted patent enforcement regime would result in unjust enrichment of these dilatory patentees (while working no prejudice on conscientious patentees), to the detriment of good-faith manufacturers and businesses.

Removing or limiting the laches defense becomes even more dubious when the clinical impact of health-enhancing and potentially life-saving products is considered. If a drug or medical device is having a positive impact on patients or helps doctors performing diagnosis and treatment, it is societally dysfunctional to allow a dilatory patentee who has slept on her monopoly to step in and prevent this beneficial use. Court-mandated modification or wholesale withdrawal of an allegedly infringing product

^{4.} See SCA Hygiene, 807 F.3d at 1333 (quoting eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 388 (2006)).

from the marketplace in these situations is a draconian and foolhardy remedy that fails to take into account the practical impact on patients who may need these products to survive. In considering the equities of the laches defense, *amicus* urges the Court to address whether it is equitable to allow a dilatory patentee, who has watched and waited quietly from the sidelines for years, to cause beneficial medicines and medical devices to be removed from the marketplace—medicines and devices that the public has come to rely upon during the calculated period of delay—as would be the case should the laches defense no longer be available.

Apart from the potentially ruinous effects on both manufacturers and the public at large, limiting or eliminating the laches defense in these cases can be expected to greatly stifle innovation. Companies will be less inclined to undertake the risks of research and development knowing an infringement allegation may spring up at any time, even if the product has been marketed for years without a hint that it may infringe. Investors will be less inclined to financially support innovative and ground-breaking businesses, electing instead to back the conservative status quo. The natural consequence of increased risk and resulting lower investment will be stagnant business growth and a meager appetite for novel products and processes by the companies otherwise in the best position to take those risks and make those investments in ground-breaking medical innovation.

E. Preserving laches as a defense for patent infringement strikes the right balance between protecting diligent patent owners and goodfaith manufacturers

Amicus believes that preserving the laches defense maintains an equitable middle ground between good-faith business enterprises and diligent patentees who timely assert their patent rights. Although a court can apply the laches defense to bar patent damages outright, even an unreasonably delaying patentee is not without her own protections under the doctrine.

For example, the accused infringer who asserts laches must operate in good faith. If not, a patentee may be able to prevent the infringer from relying on the laches defense using proof that the accused infringer was itself guilty of misdeeds towards the patentee. See, e.g., Aukerman, 960 F.2d at 1038. Furthermore, evidence that goes to either of the two laches prongs may be rebutted by the patentee. For example, a considerable investment during a delay period cannot be a result of the delay if it was "a deliberate business decision to ignore [a] warning, and to proceed as if nothing had occurred." Medinol, 15 F. Supp. 3d at 408.

And the laches defense remains as an equitable remedy to be applied within the sound judgment of the trial court in light of all the circumstances. See Aukerman, 960 F.2d at 1036. Laches is not established by undue delay and prejudice per se. Those factors merely lay the foundation for the exercise of a trial court's discretion. Id.

 $^{5. \;}$ This result flows from the maxim, "He who seeks equity must do equity."

Where there is evidence of other factors that would make it inequitable to recognize the defense (despite undue delay and prejudice), a court can assess the strength of the totality of the evidence and, in appropriate circumstances, deny application of the laches defense. *Id. Amicus* asserts that these considerations show that laches in the patent infringement context is a fair and equitable doctrine that serves an important role to reduce dilatory abuses in the Federal Courts.

II. ABSENT THE DEFENSE OF LACHES, PATENT TROLLS AND OTHER DILATORY PATENTEES CAN THWART CONGRESS'S INTENT THAT THE 35 U.S.C. § 156 TERM RESTORATION UNIQUE TO PATENT LAW OPERATE AS A VALUE-MAXIMIZING INCENTIVE TO ENCOURAGE CONTINUED DEVELOPMENT OF NEW PHARMACEUTICALS

In declining to extend *Petrella* to patent law, the Federal Circuit noted that fundamental statutory distinctions between copyright and patent law indicated that Congress did not intend to treat copyright and patent infringement suits as equals. *See SCA Hygiene*, 807 F.3d at 1329. Specifically, the Federal Circuit observed that 1) copyright law contained no express equivalent of patent law's 35 U.S.C. § 282 codification of laches as a defense to infringement; and 2) statutory provisions governing copyright infringement require proof that a defendant has access to a copyrighted work, whereas patent statutes treat infringement as a strict liability offense.

^{6.} SCA Hygiene, 807 F.3d at 1321.

^{7.} Id. at 1330.

The Patent Term Restoration provision under 35 U.S.C. § 156 (which has no counterpart in copyright law), however, provides yet another example of a statutory distinction that counsels against broad application of this Court's *Petrella* decision to patent law. The concept of patent restoration was codified in 1984 as part of the socalled Hatch-Waxman Act, which was designed to strike a balance between promoting generic competition and promoting continued development of new pharmaceuticals by restoring some of the patent term that had been lost during the regulatory review process. See Hoechst Aktiengesellschaft v. Quigg, 917 F.2d 522, 528 (Fed. Cir. 1990) (citing H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 5-6 (1984)); see also Hoechst Aktiengesellschaft v. Quigg, 724 F. Supp. 398, 399 (E.D. Va. 1989), rev'd, 917 F.2d 522 (Fed. Cir. 1990). Because patents claiming medical innovations subject to FDA review may have an effective life of less than the statutory twenty-year term calculated from a patent's earliest filing date, owing to the time consumed by the FDA review and approval process, Title II of the Hatch-Waxman Act provides that if the product and the patent meet certain statutory criteria, the PTO shall extend the term of the patent to make up for the time lost during regulatory review. See, e.g., Angiotech, 2016 WL 3248352, at *2 (citing 35 U.S.C. § 156).

The important policy concern addressed in 35 U.S.C. § 156 is to maximize the value of the exclusivity period for FDA-regulated innovations, thereby providing inventors sufficient incentive to expend the resources necessary to develop new drugs and medical devices. See id.; see also Glaxo, 706 F.Supp. at 1225 ("Because the patent owner

^{8. 21} U.S.C. § 301 et seq.

cannot market the claimed product commercially without FDA approval, several years of the patent monopoly can be entirely unprofitable."). Absent the defense of laches, patent trolls and other patentees can thwart Congress's intent to confer maximum exclusivity and opportunity to recoup the often enormous investments required to usher drugs through the FDA approval process and into the market by the dilatory litigation tactics discussed herein. Specifically, without laches a patent troll or other patentee could lie in wait, delaying an infringement suit until an innovator builds up a successful market, and then pounce when the product is at its peak value and strategically seek the best six-year period for their damages to be calculated. Application of the laches defense properly stymies tactical use of such dilatory behavior.

CONCLUSION

The Federal Circuit's recognition of laches as a bar to damages for patent infringement should be affirmed.

Respectfully Submitted,

KEVIN A. MARKS MICHAEL D. LISI ROCHE MOLECULAR SYSTEMS, INC. JEREMY E. NOE 4300 Hacienda Drive

Pleasanton, CA 94588

Counsel of Record AARON V. GIN, PH.D. McDonnell Boehnen HULBERT & BERGHOFF LLP

KEVIN E. NOONAN, PH.D.

300 South Wacker Drive Chicago, IL 60606 (312) 913-0001 noonan@mbhb.com

Counsel for Amicus Curiae