Nos. 18-1638 through -1643

In the

United States Court of Appeals for the Federal Circuit

SAINT REGIS MOHAWK TRIBE AND ALLERGAN, INC.,

Appellants,

v.

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., AND AKORN, INC.,

Appellees.

Appeal from the Patent Trial and Appeal Board, Tina E. Hulse, Christopher G. Paulraj, and Sheridan K. Snedden, Administrative Patent Judges

BRIEF OF THE R STREET INSTITUTE AND THE ELECTRONIC FRONTIER FOUNDATION AS AMICI CURIAE IN SUPPORT OF APPELLEES

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CERTIFICATE OF INTEREST

Pursuant to Rules 29(a) and 47.4 of the Federal Circuit Rules of Practice, counsel certifies as follows:

(1) The full name of every party or amicus represented by me is **the R Street Institute and the Electronic Frontier Foundation**.

(2) The above-identified parties are the real parties in interest.

(3) The corporate disclosure statement of Rule 26.1 of the Federal Rules of Appellate Procedure is as follows: There is no parent corporation to or any corporation that owns 10% or more of stock in the above-identified parties.

(4) The names of all law firms and the partners and associates that have appeared for the party in the lower tribunal or are expected to appear for the party in this court, not including those who have entered or are expected to enter an appearance before this court, are: **None**.

(5) The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are: **None**.

Dated: May 14, 2018

<u>/s/ Charles Duan</u> Charles Duan

Counsel for amici curiae

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INTEREST OF AMICI CURIAE

The R Street Institute¹ is a non-profit, non-partisan public-policy research organization. R Street's mission is to engage in policy research and educational outreach that promotes free markets, as well as limited yet effective government, including properly calibrated legal and regulatory frameworks that support economic growth and individual liberty.

The Electronic Frontier Foundation is a nonprofit civil liberties organization that has worked for more than 25 years to protect consumer interests, innovation, and free expression in the digital world. EFF and its more than 35,000 dues-paying members have a strong interest in helping the courts ensure that intellectual property law furthers the public interest.

¹Pursuant to Federal Rule of Appellate Procedure 29(a), all parties received appropriate notice of and consented to the filing of this brief. Pursuant to Rule 29(c)(5), no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Amici curiae agree with Appellees and other supporting *amici* that the Patent Trial and Appeal Board correctly determined that sovereign immunity should not cause termination of inter partes review, at least because inter partes review is a public interest–oriented agency proceeding highly distinguishable from Article III court litigation in ways that render sovereign immunity inapplicable.² Rather than repeat those arguments, this brief presents larger considerations as to the advisability, as a matter of patent policy and public policy, of affirming the Board.

Because of the widespread impact on the patent system that this Court's decision could have, policy considerations should be at the forefront of this case. Allergan, the holder of several pharmaceutical patents, entered a patent assignment and licensing transaction with the Saint Regis Mohawk Tribe. The sole purpose of that transaction was to prevent inter partes review of several Allergan patents based on the Tribe's sovereign immunity. Other patent holders and tribes could easily replicate this sovereign immunity transaction, and there are strong incentives for others to take advantage of this method of circumventing inter partes review and other post-grant proceedings. As a result, there is no reason to believe that this case is a unique one-off situation; should this Court deem

²See also Brief of Public Knowledge and the Electronic Frontier Foundation as Amici Collegii in Opposition to the Motion to Terminate at 2–7, *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, Nos. IPR2017-01127 to -01132 (P.T.A.B. Nov. 30, 2017).

sovereign immunity transactions an effective loophole to escape inter partes review, it is likely that many, if not most, patentees will take advantage of that loophole.

Widespread evasion of inter partes review would lead to at least two serious harms. First, it would upset the basic balance of the patent system, with problematic fallout for all parties. Inter partes review was developed as the result of Congress weighing the tradeoffs between pre-grant examination and post-grant reconsideration of patents; in crafting the America Invents Act, Congress determined that it made policy and economic sense to correct erroneous patent grants after the fact, rather than to place the burden of accuracy entirely on pre-grant examination. If patent owners can easily avoid post-grant procedure, then pregrant examination would need to become far more stringent, rendering patents potentially more expensive and difficult to obtain. Sovereign immunity transactions for circumventing inter partes review could thus have unintended negative ramifications for patent applicants and the public.

Second, use of tribal transactions to avoid inter partes review negatively reflects on the reputation and integrity of the United States patent system as a whole. Allergan's transaction with the Tribe has been roundly criticized, and that criticism reveals a growing view that American patent law is not a driver of innovation but rather a game for lawyers to play. With intellectual property law's leading role in global policy today, it would be a step backwards to approve of a sovereign immunity stratagem that makes the patent system look illegitimate.

Certainly, inter partes review is not perfect; indeed, *amici* have called for improvements to the proceeding.³ But insofar as complaints about inter partes review are the sole policy justification offered by Allergan and the Tribe for their position, this case is the wrong vehicle for those complaints, and the policy concerns laid out above militate strongly against dismantling the proceeding entirely to answer those complaints. The decision of the Board should be affirmed.

³*See id.* at 13–15.

ARGUMENT

I. Use of Sovereign Immunity to Circumvent Inter Partes Review Will Likely Become Widespread if Approved Here

If Allergan is successful in using a tribe's sovereign immunity to avoid inter partes review, there is a strong likelihood that many—if not most or all—patent owners will employ the same tactic. Tribes are actively seeking to engage in patent transactions for the purpose of circumventing inter partes review, and history shows that patent litigants are more than willing to exploit loopholes in patent law to the fullest extent. Unless this Court affirms the Board, inter partes review will likely be rendered a virtual nullity, contrary to the plain expectations of Congress in designing the procedure.

Patent owners would face little difficulty in replicating Allergan's transaction with the Saint Regis Mohawk Tribe here. The terms of the agreement are largely public, so other patent owners could easily adapt them for other patents.⁴ And there are good reasons to believe that both patent owners and tribes will do so.

Historically, patent litigants have not been shy about using legal strategies to the fullest extent. The high profit potential of patents "creates enormous incentives" for attorneys to "find clever new ways of gaming the system."⁵

⁴*See* Appx2556; Appx2572.

⁵Adam Davidson, *Why Is Allergan Partnering with the St. Regis Mohawk Tribe?*, New Yorker (Nov. 13, 2017), *available online*. Locations of authorities available online are shown in the Table of Authorities.

For example, patent owners took full advantage of the later-overturned *Underwater Devices Inc. v. Morrison-Knudsen Co.* decision, which essentially mandated advice of counsel to overcome a charge of willfulness.⁶ Then-Professor Moore found that "willfulness claims are plaguing patent law," being alleged in 92.3% of patent cases, largely as a ploy to pierce attorney-client privilege to gain "significant insight into the infringer's substantive defenses."⁷ Similarly, only one year after *Forest Group, Inc. v. Bon Tool Co.* approved of any member of the public bringing *qui tam* false marking suits,⁸ analysts observed a "meteoric rise in false patent marking suits" as well as a spate of new firms established solely for the business of patent marking litigation.⁹ Given these precedents, it can be expected that patent owners will similarly not hesitate to take advantage of a sovereign immunity loophole for avoiding inter partes review.

Patent holders will likely find a receptive audience of tribes. The Saint Regis Mohawk Tribe itself has set up an Office of Technology Research and Patents, or

⁶See Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1389– 90 (Fed. Cir. 1983); Mark A. Lemley & Ragesh K. Tangri, Ending Patent Law's Willfulness Game, 18 BERKELEY TECH. L.J. 1085, 1099–108 (2003).

⁷Kimberly A. Moore, *Empirical Statistics on Willful Patent Infringement*, 14 FED. CIR. B.J. 227, 232–33 (2004).

⁸See Forest Group, Inc. v. Bon Tool Co., 590 F.3d 1295, 1304 (Fed. Cir. 2009).

⁹BRIAN T. YEH, CONG. RESEARCH SERV., REPORT NO. R41418, FALSE PATENT MARKING: LITIGATION AND LEGISLATION 2 (2010), available online; Nicholas W. Stephens, From Forest Group to the America Invents Act: False Marking Comes Full Circle, 97 IOWA L. REV. 1003, 1019 n.107 (2012); Justin E. Gray, False Marking— Settlement Update, GRAY ON CLAIMS (Aug. 9, 2011), available online.

"OTRAP," with the purpose of exploiting the "huge advantage for patents to be owned (through assignments) by entities that have sovereign immunity."¹⁰ Indeed, OTRAP has already engaged in at least one other patent transaction and says it "will be executing another soon."¹¹ When a reporter asked a lawyer for the Tribe whether he would consider other patent deals, the lawyer responded: "Yes. Can you put my phone number in your article?"¹²

Given the incentives for both tribes and patent owners to engage in sovereign immunity transactions and a straightforward blueprint for how to do so, there is little reason to believe that Appellants' situation will be a unique one-off if it is approved. Should the Board's decision be reversed, one would expect more tribes to set up OTRAPs, more patents to be placed into them, and the congressional scheme for reviewing patents to be largely, if not completely, circumvented.

II. EASY CIRCUMVENTION OF *INTER PARTES* REVIEW WILL UPEND THE CONGRESSIONAL BALANCE OF PATENT LAW, TO THE DETRIMENT OF ALL STAKEHOLDERS

Allowing patent owners to circumvent inter partes review at will is especially problematic because it upends a careful balance of resources between pre-grant

¹⁰Appx1910.

¹¹*Id.*; see Complaint for Patent Infringement at $\P\P$ 117–119, *SRC Labs, LLC v. Amazon Web Servs., Inc.*, No. 2:17-cv-547 (E.D. Va. Oct. 18, 2017) (noting assignment of SRC's patents to the Tribe).

¹²Meg Tirrell, Forget Casinos: This Native American Tribe Is Doing Business in Pharma Patents, CNBC (Sept. 8, 2017), available online.

examination and post-grant practice, an balance that Congress weighed and set in the America Invents Act.¹³ To upset this balance would harm the interests of all parties, including both technology-using firms and patent applicants.

The patent system requires filters, or screens, to weed out desirable patents from undesirable ones. Generally there are two categories of screens: pre-grant screens that reject improper applications before they are granted, and post-grant screens that retract patents granted incorrectly. Currently the Patent Act includes both pre-grant screening in the form of patent examination,¹⁴ and postgrant screening with procedures such as inter partes review.¹⁵

Pre-grant examination has proven insufficient as a screening mechanism. The U.S. Patent and Trademark Office receives over 600,000 patent applications a year, as it has every year since 2013.¹⁶ Examiners are severely hamstrung in conducting comprehensive examinations of these myriad applications. An examiner generally receives about 17 to 31 hours to review an application, an amount that 70% of examiners report as insufficient.¹⁷ Examiners often lack substantial experi-

¹³See America Invents Act, Pub. L. No. 112-29, sec. 6(a), 125 STAT. 284, 299 (2011).

¹⁴See 35 U.S.C. § 131.

¹⁵See 35 U.S.C. § 311.

¹⁶See U.S. Patent & Trademark Office, Performance & Accountability Report 169 tbl.2 (2017) [hereinafter USPTO PAR], available online.

¹⁷See U.S. Gov't Accountability Office, GAO-16-490, Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity 10, 26 (June 2016).

ence: Few have degrees beyond a bachelor's, and many leave the Office within five years.¹⁸ They lack access to the technical literature necessary for full examination.¹⁹ And the largely ex parte nature of patent examination prevents a rigorous, adversarial inquiry into patentability.²⁰ Underexamination leads to erroneous patent grants at a rate sufficiently high to be measured.²¹

Post-grant screening procedures such as inter partes review fill many of these gaps. They allocate greater time for consideration of individual patents, use more experienced adjudicators, and follow an adversarial process²² that is more likely to elicit the best prior art and the best arguments. Post-grant screening also allows the free market to determine which patents need reconsideration most.

¹⁹See Beth Simone Noveck, "Peer to Patent": Collective Intelligence, Open Review, and Patent Reform, 20 HARV. J.L. & ТЕСН. 123, 135 (2006).

²⁰See 35 U.S.C. § 122(c); NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 89 (Stephen A. Merrill et al. ed., 2004), *available online* (noting "significant concerns" with the USPTO's "impartiality" due to ex parte examination).

²¹See Shawn P. Miller, Where's the Innovation: An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents, 18 VA. J.L. & TECH. 1, 45 (2013) (estimating that 28% of issued patents would be invalidated as anticipated or obvious); see also Michael D. Frakes & Melissa F. Wasserman, Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment, 67 STAN. L. REV. 613, 652–53 (2015) (finding increased patent grant rates correlated with increased resource strain on the Office).

²²That the process is adversarial does not make it resemble a judicial proceeding. Agency rulemakings, for example, involve adversarial presentation of arguments but are certainly far removed from federal court procedure.

¹⁸See U.S. Gov't Accountability Office, GAO-16-479, Patent Office Should Strengthen Search Capabilities and Better Monitor Examiners' Work 28–29 (June 2016).

Few patents are litigated—perhaps 2% or less.²³ Allocating resources to pre-grant examination, then, may ultimately be wasteful for the vast majority of patents; allocating those same resources to post-grant procedures allows the market to determine which patents merit the costs of more careful scrutiny.²⁴

Given these considerations, it is a highly reasonable choice of tradeoffs to allow patents to issue after imperfect examination and then to allow for postgrant correction of errors after the fact. That is the choice Congress made.

Furthermore, Congress made a correct determination that other post-grant screening tools were inadequate for that task. Although patents can be "invalidated" in federal court, the public-good nature of patent invalidation reduces litigants' incentives to pursue invalidity theories in court.²⁵ Among other things,

²³See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. REV. 1495, 1501 & nn.24–27 (2001). That statistic is widely cited, but in fact is only an estimate. A more recent study identifies 11,236 litigated patents that were granted between 2005 and 2013. *See* Alan C. Marco & Richard D. Miller, *Patent Examination Quality and Litigation: Is There a Link?* 10 (U.S. Patent & Trademark Office, Economic Paper No. 2017-09, June 2017), *available online*. With about 4.5 million patents issued in that time frame, *see* USPTO PAR, *supra* note 16, at 169 tbl.2, that puts the litigated patents fraction at about a quarter of a percent.

²⁴See Stuart J.H. Graham et al., Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 74, 114 (Wesley M. Cohen & Stephen A. Merrill eds., 2003), available online.

²⁵See Joseph P. Farrell & Robert P. Merges, Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Review Might Help, 19 BERKELEY TECH. L.J. 943, 951–52 (2004); Megan M. La Belle, Patent Law as Public Law, 20 GEO. MASON L. REV. 41, 64–68 (2012). Technically, courts cannot invalidate patents; they have no statutory power to

noninfringement is often easier to prove in court than invalidity,²⁶ so a lowercost avenue to invalidation is necessary to provide incentives to pursue those legal theories. Factors such as these led Congress to conclude, in the America Invents Act, that ensuring the correctness of patent grants required "an effective and efficient alternative to often costly and protracted district court litigation."²⁷

Should sovereign immunity transactions effectively neuter the post-grant screening aspect of the statutory scheme, the remaining options for ensuring the correctness of patent grants are undesirable to inventors and patent applicants. On the one hand, the Office could give each application substantially more scrutiny, which would increase the backlog and pendency before the Office, forcing applicants to wait longer to receive patents. On the other hand, the Office might choose to use costs as a screening mechanism, raising fees to reduce incoming patent applications and to force applicants to signal which inventions are important enough to warrant stronger examination.²⁸ To do so would greatly disadvantage small-entity inventors and firms.

do so. *See United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 369 (1888) (discussing *Mowry v. Whitney*, 81 U.S. (14 Wall.) 434, 441 (1872)). A judgment of invalidity applies to the parties in litigation; it is only through the operation of collateral estoppel that this judgment applies more generally. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

²⁶See Roger Allan Ford, Patent Invaldity Versus Noninfringement, 99 CORNELL L. REV. 71, 102–03 (2013).

²⁷H.R. Rep. No. 112-98, at 45 (2011).

²⁸See Jonathan S. Masur, Costly Screens and Patent Examination, 2 J. LEGAL ANALYSIS 687 (2010).

To the extent that Allergan, the Tribe, and their supporters attempt to justify sovereign immunity transactions as a matter of policy, it is based on their perceptions that the congressional scheme is unfair in certain factors. That is largely a matter for Congress to decide; at a minimum, this Court should await a challenge appropriately tailored to whatever those particular unfairnesses may be. But to approve a transactional ploy that effectively eviscerates the intent of Congress would not only force this Court to usurp the function of the Article I branch of government, but also potentially trigger unexpected consequences that would ultimately harm the patent system.

III. SOVEREIGN IMMUNITY PATENT TRANSACTIONS WILL UNDERMINE THE INTEGRITY AND REPUTATION OF UNITED STATES PATENTS

In voicing "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed,"²⁹ Judge Bryson of this Court is far from alone. Commentary, both domestic and foreign, reveals grave doubt about the legitimacy of the sovereign immunity transaction at issue. To reverse the Board and to open the door to further exploitation of sovereign immunity would undercut not only the legitimacy of these patent transactions but the legitimacy of the patent system itself.

²⁹Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455, slip op. at 4 (E.D. Tex. Oct. 16, 2017).

Science and pharmaceutical experts have questioned the legitimacy of the transaction between Allergan and the Tribe. A former pharmaceutical researcher writing for a *Science* journal outlet said of the deal, "Awful, as far as I'm concerned"; he went on to say that "this absolutely cannot help but look like a slimy legal trick, an association the drug industry absolutely does not need any more of."³⁰ A drug industry analyst similarly found it "hard to imagine a better way to undercut" the already-maligned pharmaceutical industry.³¹ Two doctors, writing for *JAMA Internal Medicine*, called it a "legal maneuver that has left many rubbing their eyes," and went on to question whether the Restasis drug under patent was even a useful invention in the first place.³²

Financial analysts have condemned the transaction even more sharply. In looking for "words to describe the deal," a *Bloomberg* columnist wrote, "'Sleazy' comes to mind. Also: sneaky, unscrupulous and just plain wrong."³³ *Business Monitor International* called it a "bold move [that] will ultimately end in failure."³⁴

³⁰Derek Lowe, Allergan Pulls A Fast One, SCI. TRANSLATIONAL MED.: IN PIPELINE (Sept. 11, 2017), available online.

³¹Michael McCaughan, *United We Stand vs. Divide and Conquer: Pharma in the Age of Trump*, PINK SHEET PHARMA INTELLIGENCE (Jan. 8, 2018), *available online*.

³²Lisa M. Schwartz & Steven Woloshin, A Clear-eyed View of Restasis and Chronic Dry Eye Disease, 178 JAMA INTERNAL MED. 181, 181 (2018).

³³Joe Nocera, Allergan Patent Deal Isn't Just Unusual. It's Ugly, BLOOMBERG VIEW (Sept. 11, 2017), available online.

³⁴Allergan's Restasis Patent Gamble Looks Increasingly Unlikely To Succeed, Bus. MONITOR ONLINE, Oct. 24, 2017.

The *Washington Post* named it one of the "biggest turkey deals of 2017," on par with the Equifax data breach and Wells Fargo's account fraud scandal, saying that "Allergan has outdone itself in tackiness."³⁵

Most concerningly, foreign commentary reflects a growing sense that legal ploys such as Allergan's make the American patent system look like a joke. The *Financial Times* accused Allergan of "hypocrisy" after finding that the company itself had filed inter partes review petitions, noting also that the company's stock price had fallen 21% since the deal with the Tribe was announced.³⁶ The London-based *Economist* described that share price drop as "the heavy price [Allergan] is paying for its gambit."³⁷ Another London publication called the sovereign immunity transaction "one of the most breathtaking attempts at dodging competition" and a "dubious precedent that many will look to follow."³⁸ *Le Monde*, a French paper of record, described Allergan's use of sovereign immunity as a *tour*

³⁵Allan Sloan, *The Biggest Turkey Deals of 2017*, WASH. POST, Nov. 19, 2017, at G2, *available online*.

³⁶David Crow, *Pharma Industry Faces Hypocrisy Charge over Patents*, FIN. TIMES (Nov. 1, 2017), *available online*.

³⁷Allergan's Unusual Legal Tactic Attracts Political Scrutiny, THE ECONOMIST, Nov. 18, 2017, at 57, available online. It is unfortunately unlikely that Allergan's devaluation will dissuade other patent owners from undertaking sovereign immunity transactions, however: Once they become widespread, investors' willingness to punish those transactions will likely be too distributed to affect individual companies.

³⁸Allergan's Restasis Patent Scuffle: An Ugly Sight for Sore Eyes, PHARMAFOCUS, Oct. 2017, at 1, available online.

de passe-passe—a "sleight of hand."³⁹ The German *Frankfurter Allgemeine Zeitung* called it a "gimmick" (*Kniff*), in which Allergan "exploits" the Tribe's sovereign immunity, using a verb *ausnutzen* generally reserved for the shameless acts of a false friend.⁴⁰

The patent system should not be easily exploited by gimmicks or sleight of hand. Where clever lawyers attempt to use loopholes like sovereign immunity transactions to circumvent the clear design of Congress, they are no true friends of a patent system that ought to be held in high regard around the world. By affirming the Patent Trial and Appeal Board, this Court not only will reach a correct decision on the law, but also will preserve the integrity of American patents not as a contrivance for manipulation but as an engine of invention.

³⁹Chloé Hecketsweiler, Allergan passe un accord avec une tribu indienne pour protéger ses brevets [Allergan Signs an Agreement with an Indian Tribe to Protect Its Patents], LE MONDE (Sept. 19, 2017), available online.

⁴⁰Von Roland Lindner, Indianer als neue Patentwaffe [Indians as New Patent Weapon], FRANKFURTER ALLGEMEINE ZEITUNG, Sept. 14, 2017, available online; cf. Daniel Völz: Hat er Kristina Yantsen für die Karriere ausgenutzt? [Has He Exploited Kristina Yantsen for His Career?], GALA (May 4, 2018), available online (winner of German Bachelor, following breakup, describing herself as "betrayed, lied to and exploited" (betrogen, belogen und ausgenutzt); ausgenutzt is the past participle of ausnutzen).

CONCLUSION

For the foregoing reasons, the decision of the Patent Trial and Appeal Board should be affirmed.

Respectfully submitted,

Dated: May 14, 2018

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CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of the Federal Rules of Appellate Procedure and the Circuit Rules. The document contains **3,697** words, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f).

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Dated: May 14, 2018

/s/ Charles Duan Charles Duan Counsel for amici curiae

CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2018, I caused the foregoing **Brief of the R Street Institute and the Electronic Frontier Foundation as** *Amici Curiae* **in Support of Appellees** to be electronically filed with the Clerk of the Court using CM/ECF, which will automatically send email notification of such filing to all counsel of record.

Dated: May 14, 2018

/s/ Charles Duan Charles Duan Counsel for amici curiae