No. 19-414

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

MARK A. BARRY, M.D.,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MOTION FOR LEAVE TO FILE AND BRIEF OF THE R STREET INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION

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MOTION FOR LEAVE TO FILE

The R Street Institute moves pursuant to Supreme Court Rule 37.2(b) to file a brief as *amicus curiae* in support of this petition for certiorari. Petitioner Medtronic, Inc. consents to the filing; Respondent does not consent but will not oppose this motion. Both parties received notice of intention to file this brief at least 10 days prior to the due date of this brief.

Movant is a nonprofit public interest organization that produces research in the fields of technology and intellectual property policy. The nature of Movant's interest (explained in detail in the Interest of *Amicus* section of the brief) is to engage in policy research and educational outreach on issues including intellectual property law. Previous briefs of Movant have been relied upon and cited in opinions of this Court and the courts of appeals.

The petition for certiorari presents two questions of great national importance relating to the validity of patents filed after technology has been in use for an extended period. The purpose of the present brief is to demonstrate the broad importance of resolving these questions, especially to ongoing public policy concerns over high drug prices and access to medical treatments, which the present case directly implicates.

Accordingly, the tendered brief offers useful information about the larger effect of the questions presented and the importance of granting certiorari to review that rule, which will assist this Court in evaluating whether the petition merits review on a writ of certiorari. The motion for leave to file the brief should be granted.

Respectfully submitted,
Charles Duan
Counsel for Movant

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INTEREST OF *AMICUS CURIAE*

The R Street Institute[1] is a nonprofit, nonpartisan 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.

[1]This brief is being tendered with a motion for leave to file this brief. Pursuant to Rule 37.6, 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 *amicus*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The petition for a writ of certiorari should be granted because the questions presented are of exceptional importance to the national interest. Aside from upsetting the balance of the patent system itself, the new rules of patent law applied by the Federal Circuit in this case enable the possibility of unduly extended patent terms on drugs and other medical treatments, thereby exacerbating the national crisis of unbridled health care costs.

In reaching its decisions in this case, the Federal Circuit applied two rules of patent law that, as Petitioner explains, are inconsistent with this Court's decisions and those of the other circuit courts. Both questions arise under the statutory bars of 35 U.S.C. § 102, which prohibit the patenting of inventions placed on sale or in public use more than a year prior to the filing of a patent application. The appeals court first held that an invention is not "ready for patenting," for purposes of invoking the statutory bars, unless it meets an "intended purpose" proffered by the patent holder, even where that purpose is stated nowhere in the patent text. Second, it considered the "experimental use" exception to the statutory bars, and held that the patent owner bears no burden of persuasion as to whether a use was experimental, such that nothing more than uncorroborated inventor testimony could suffice to overcome the § 102 bar.

Both of these rules of patent law are ripe for exploitation by patent owners and applicants, particularly in the medical and pharmaceutical industries, who hope to obtain extended patent terms beyond the congressionally prescribed 20-year period. The Federal Circuit's narrowing of the § 102 statutory bars in this case could allow drug and medical device developers to delay applying for

patents until even after regulatory approval, contrary both to the express statutory scheme and the policies of the patent system. Yet by doing so, the patent owners who avail themselves of these strategies stand to earn unjustified profits amounting to millions or billions of dollars, at the expense of American health care consumers.

These opportunities to exploit the patent system could not come at a worse time. Americans are in the midst of a widely-recognized crisis of rising health care costs, with elected officials across the political spectrum agreeing that prescription drug prices need to be reined in. Yet despite these ongoing and widespread concerns, history shows that the pharmaceutical industry has made repeated efforts to extend the length of patent protection through patent tactics, keeping prices high at the public's expense. That the Federal Circuit has opened the door to exploitation of the health care system through patent strategy is thus a matter of pressing national concern, warranting a grant of certiorari.

ARGUMENT

I. The Federal Circuit's Erroneous Rules Will Exacerbate an Already Problematic Situation of Medical Treatment Costs

The questions presented are of exceptional importance warranting a grant of certiorari, because they directly implicate one of the most pressing national crises of our time: the skyrocketing costs of health care. The pharmaceutical industry and others in the medical field have repeatedly demonstrated their willingness to exploit rules of patent law that allow for effective extensions of patent term beyond limits contemplated by Congress, generating large private profits for themselves but exacerbating the problem of the public costs of health care.

A. The United States Is Currently Suffering a Crisis of High Drug Prices, in Large Part Due to Pharmaceutical Patents

There is little question that the high cost of medical care is among the most pressing problems facing the American polity today. A Kaiser Family Foundation survey finds that 8 in 10 Americans call the price of prescription drugs "unreasonable," a result supported by the fact that many of the most popular drugs saw price increases of 3 to 9 times the rate of inflation—"15.7% for Lyrica, a pain medication, 15.3% for Revlimid, a cancer medication, and 13.2% for Humira Pen, for rheumatoid arthritis" between 2016 and 2017. Ashley Kirzinger et al., *KFF Health Tracking Poll—February 2019: Prescription Drugs*, Henry J. Kaiser Fam. Found. (Mar. 1,

2019), *available online*;[2] Juliette Cubanski & Tricia Neuman, *Assessing Drug Price Increases in Medicare Part D and the Implications of Inflation Limits*, Henry J. Kaiser Fam. Found. 2 (Oct. 2019), *available online*. An overwhelming majority—80% of Americans surveyed—ranks lowering prescription drug prices as "extremely important." Rachel Roubein & David Brown, *Politico–Harvard Poll: New Congress Should Fight Hate Crimes, Tackle Drug Prices*, Politico (Jan. 3, 2019), *available online*. The White House and key leaders in both the House and the Senate have all made lowering drug prices a national priority. *See* Abby Goodnough, *Pelosi's Drug Plan Would Let U.S. Negotiate Prices of 250 Medications*, N.Y. Times, Sept. 19, 2019, A18, *available online*.

Pharmaceutical patents are widely understood to be a key contributor to these high costs, because such patents prevent entry of competitive generics that impose market discipline on drug prices. The U.S. Food and Drug Administration finds that the presence of just two generic manufacturers of a drug cuts prices in half; six or more and prices drop by over 74%. *See* Ctr. for Drug Evaluation & Research, *Generic Competition and Drug Prices*, U.S. Food & Drug Admin. (Nov. 20, 2017), *available online*.

The savings are not just monetary: The Association for Accessible Medicines finds that patients are 62% less likely to abandon treatment by generic medicines *vis à vis* prescription drugs, and abandonment of prescription treatment in the United States is estimated to cause, annually, about 10% of hospitalizations and 125,000 deaths. *See* Ass'n for Accessible Meds., *Ensuring the Future*

[2]Locations of authorities available online are shown in the Table of Authorities.

of Accessible Medicines in the U.S. 5 (2018), *available online*; Meera Viswanathan et al., *Interventions to Improve Adherence to Self-Administered Medications for Chronic Diseases in the United States*, 157 Annals Internal Med. 785, 785 (2012).

Because patents, being market exclusivities on products such as drugs, prevent competitive generic entry, they prevent realization of the above benefits and thus keep prices of medical treatments high. Commentators report that "the average markup for patented drugs is nearly 400%" and that "introducing generic competition can cause prices to fall to as little as 6% of the patent-protected price." Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 284–85 (2016) (citing FDA and other studies); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. Econ. Mgmt. Strategy 75, 83–84 & tbl.2 (1997) (finding that generic drug prices drop to below 50% of the patent-based price within 3 years of patent expiration).

This is emphatically not to say that patents on pharmaceuticals or other technologies are inherently problematic; the incentive value of patents for promoting research and commercialization is no doubt at its apex in the medical field. But the massive public costs of health care in America demand vigilance for misalignments in interpretations of the patent laws that could exacerbate this policy crisis of national scope.

B. Drugmakers Are Demonstrably Willing to Exploit Any Available Avenues to Extend the Term of Patent Protection

Despite the public harms thus discussed, the medical and pharmaceutical industries have strong pecuniary interests in exploiting any weaknesses in the patent system to extend their patent terms as far out as possible. Indeed, history shows those industries' repeated willingness to take advantage of such loopholes in multiple areas of patent law.

The extension of a pharmaceutical patent by even just a short period can represent an alarming cost to Americans but a major profit stream for drugmakers. Patented drugs can be billion-dollar markets for companies holding the exclusivities, and industry shows no disinclination to increase prices to maximize those exclusive markets. *See* Inst. for Clinical & Econ. Review, *Unsupported Price Increase Report: 2019 Assessment* ES2 (Oct. 8, 2019), *available online* (finding $5.1 billion in price increases "unsupported by new clinical evidence"). Consider, for example, that a month's supply of Pfizer's cholesterol-lowering drug atorvastatin (Lipitor) cost about $165 while under patent and $15 after the patent expired. *See* W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 Notre Dame L. Rev. 1611, 1622 & n.67 (2017). Extending the patent on Lipitor would have represented a wealth transfer from American consumers to Pfizer of about $41 million *per day*.[3]

[3]That number is computed as follows: The U.S. Census Bureau estimates the population of Americans aged 40 and over at 147 million in 2012. The Centers for Disease Control and Prevention reports that 27.9% of that population used a cholesterol-lowering medication, and 20.2% of them used atorvastatin. *See* Qiuping Gu et al., Nat'l

The medical treatment industries thus face powerful incentives to seek out ways to extend their patent protection terms by by building massive estates of patents: AbbVie, for example, has a "formidable wall" of over 100 patents that extend protection over Humira by two decades past the original patent on the biologic compound. *See* Peter Loftus & Denise Roland, *By Adding Patents, Drugmaker Keeps Cheaper Humira Copies Out of U.S.*, Wall St. J. (Oct. 16, 2018), *available online*. Pharmaceutical firms also seek to take advantage of the doctrines of patentability to obtain effective patent term extensions. In practices variously known as "evergreening," "product hopping," and "patent thicketing," drug companies will obtain patents on minor modifications to known drug compounds, often years after the initial patent applications were filed. A "brand name company," for example, may attempt "switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantages." Gregory H. Jones et al., *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 Blood 1398, 1399–400 (2016). The most common strategy for evergreening is for a pharmaceutical company to obtain patents on methods of using a drug, such as forms of delivery or dosage amounts: "a slightly different tablet or

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Ctr. for Health Statistics, Ctrs. for Disease Control & Prevention, *NCHS Data Brief No. 177, Prescription Cholesterol-Lowering Medication Use in Adults Aged 40 and Over: United States, 2003–2012*, at 1–2 (Dec. 2014), *available online*. Thus, 8.29 million Americans used atorvastatin in 2012. The difference between the on-patent and off-patent daily cost is $5 ($150 per month divided by 30 days), leading to a nationwide cost of $41.45 million per day.

capsule does or a slow-release formulation," for example. *Id.* at 1399.

In other areas of patent law, this Court has repeatedly rejected rules that would improperly extend the length of patent protection. Most recently, this Court encountered an attempt to extend patent term in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 139 S. Ct. 628 (2019). There, the owner of a patent on a chemotherapy nausea treatment sought an interpretation of the on-sale bar under § 102 that would allow for patents to be filed after the one-year grace period following the first sale of the patented drug, so long as the sale was "secret." *See id.* at 630–31. This Court unanimously rejected that interpretation based on the plain text of § 102, but what is important about *Helsinn* is the justification for the patent owner's late filing: Helsinn and *amici* from the biopharmaceutical industry asserted that delayed filing was necessary to enable firms to form "business and development partnerships" to commercialize newly developed medicinal molecules. *E.g.*, Brief of the Biotechnology Innovation Organization as *Amicus Curiae* at 22, *Helsinn*, 139 S. Ct. 628 (Aug. 30, 2018) (No. 17-1229); *see* Brief for the Petitioner at 48–49, *Helsinn*, 139 S. Ct. 628 (Aug. 23, 2018) (No. 17-1229). Yet by congressional design, inventors are expected to do the work of commercializing inventions *during* the patent term, not before it. *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 271–72 (1977) (discussing patent law incentives to file prior to commercialization). The immense industry effort to turn this Court away from a plain-text interpretive result demonstrates the immense financial incentive of extended patent terms.

Even this Court's recent clarifications of patent-eligible subject matter have come to be exploited to extend the term of medical treatment patents. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* held unpatentable the discovery of a natural correlation between a diagnostic test and adjustment of administration of a drug. *See* 566 U.S. 66, 87 (2012). Were it otherwise, it should be fairly obvious that patents on those correlations would be a prime target for evergreening, since drugmakers could identify correlations years after patenting the original drug and obtain further later-expiring patents. And indeed, pharmaceutical patent owners have repeatedly tried to skirt around *Mayo*, in some cases successfully, in order to broaden and preserve their patent monopolies over drugs and medical treatments. *See, e.g.*, *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1120–21 (Fed. Cir. 2018) (disputing under 35 U.S.C. § 101 a method-of-use patent that would extend patent protection by 11 years), *petition for cert. filed sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc.*, No. 18-817 (U.S. petition filed Dec. 27, 2018); *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349 (D. Mass. 2015) (rejecting under *Mayo* a patent directed to a "correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer").

As the present case demonstrates, the pharmaceutical and medical treatment industries are willing to push the patent laws to their limits to extend patent protection as long as possible, contrary to the statutory design of the patent laws and the § 102 bars in particular. That pushing of the boundaries injures the public interest both

in a balanced patent system and in affordable health care. It is a matter of exceptional importance for this Court to ensure that the patent laws are correctly interpreted to avoid such exploitation.

II. The Statutory Bars of § 102 Are Intended to Prevent Improper Extensions of Patent Term

By design, the Patent Act balances the interests of patent protection against the aforementioned harm to the public of excessively long patents. It does so specifically through the on-sale and public-use bars on patenting under § 102.

Patent term is determined based on the date on which the patent application was filed. *See* § 154(a)(2). Thus, a later-filed patent will be a later-expiring one, enabling the holder of that patent to reap profits at the tail end of the patent term for a longer period of time. To be sure, the later-filed patent's enforcement period will start later, but nothing prevents filing for two or more patents, one early and one late, effectively providing a longer total term of patent protection than the Patent Act contemplates.

The statutory bars under § 102 are intended to curb this possibility by requiring patent applications to be filed early. Specifically, § 102 provides that where an invention is "in public use, on sale, or otherwise available to the public," the inventor has at most one year to file for patent protection. § 102(a)(1); *see* § 102(b)(1).

It has long been recognized that these statutory one-year limits reflect congressional intent to place limits on effective patent term. As early as 1829, this Court explained an inventor was not permitted to "for a long pe-

riod of years retain the monopoly, and make, and sell his invention publicly," only later seeking a patent on the invention; to allow for such behavior "would materially retard the progress of science and the useful arts." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829). Congress soon after codified the holding of *Pennock*. *See* Patent Act of 1836, ch. 357, § 6, 5 Stat. 117.

Subsequently, courts have reiterated concern about undue extensions of patent term in applying the statutory bars. *Elizabeth v. Pavement Co.* explained that "an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law." 97 U.S. 126, 137 (1878). An inventor who, "for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress." *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1859).

More recent decisions have identified concern about undue patent extension as the explicit purpose behind § 102. In *Pfaff v. Wells Electronics, Inc.*, this Court explained that the statutory bars serve the purpose of "confining the duration of the monopoly to the statutory term." 525 U.S. 55, 64 (1998) (citing *Frantz Mfg. Co. v. Phenix Mfg. Co.*, 457 F.2d 314, 320 (7th Cir. 1972)). Judge Learned Hand similarly wrote, in the seminal case *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, that the statutory bars ensure that an inventor "does not thereby extend the period of his monopoly." 153 F.2d 516, 520 (2d Cir. 1946).

The recognized purpose of the statutory bars is to prevent undue extensions of the patent term beyond that provided by Congress. That purpose is essential where

extended patent term can impose substantial costs on important sectors of the economy, such as American consumers of health care.

III. Left Uncorrected, the Federal Circuit's Rules Will Enable Unwarranted Extensions of Patent Term

The Federal Circuit's two determinations in this case, namely the definition of "ready for patenting" and the scope of experimental use, are also ripe for exploitation by patent owners hoping to extend their patents and extract unwarranted monopoly rents from American health care consumers. As explained below, those patent owners have many ways to do so, indicating the salience of this case to national health care costs.

A. The "Intended Purpose" Requirement Enables Extended Drug Patents Contrary to Congressional Intent

The Federal Circuit first held that in order for an invention to be "ready for patenting" such that it triggers the one-year time bar under § 102, the invention must meet not just the objective elements of the patent claims but also a subjective "intended purpose" potentially manufactured by the inventor during litigation. If allowed to stand, this novel intended-purpose element would easily facilitate extensions of patent term.

The "intended purpose" rule would essentially upend the congressional scheme for patents in the context of drug development. To avoid triggering the on-sale and public use bar, a pharmaceutical company can claim that all possible benefits of a new compound have not been

elucidated in the early stages of testing, and that further forward-looking studies are required to determine whether a drug works for the "intended purpose," in particular the studies required for the years-long premarket approval process by the U.S. Food and Drug Administration. According to the Federal Circuit, this subjective intended purpose does not have to be listed anywhere in the patent. A company could also argue that follow-up time is required to determine that the drug creates the desired effect, despite shorter-term clinical evidence confirming the benefits. Finally, a company could also rely on its own "after-the-fact testimony" to claim that a wide variety of early testing was experimental. Creative exploitation of the "intended purpose" rule could thus enable a drug patent applicant to obtain more than the five-year additional term that Congress intended.

Besides being contrary to the Patent Act generally by enabling drugmakers to obtain patents years after commercial exploitation, the above tactic dismantles a very specific drug patent statutory scheme. Under the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch–Waxman Act, the lengthy pendency of FDA approval is expected to run during the term of patents on the drug, and Congress provides a credit for that pendency in the form of "patent term extension" applied to the drug patent. Pub. L. No. 98-417, § 201(a), 98 Stat. 1585 (1984) (codified as amended at 35 U.S.C. § 156(a)). Yet Congress did not provide for full recapture of the regulatory process time: Recognizing that the patent term is always supposed to account for a portion of time spent on bringing inventions to market, Hatch–Waxman extends the patent by only 50% of the testing period of the drug, and the extension

is subject to further caps and limitations. *See* 35 U.S.C. § 156(c)(2); *see also* § 156(c)(3) (14-year total patent term limit); § 156(g)(6)(A) (5-year maximum extension).

If a drugmaker can delay patenting until after the testing process on the theory that the drug only satisfied an "intended purpose" and was thus only "ready for patenting" after approval, then the drugmaker would receive a patent with an effective 100% extension of term—double what Hatch–Waxman provides, and disregarding the other caps in § 156. That is a plain circumvention of a statutory scheme that already provides "wide berth for the use of patented drugs related to the federal regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). There was no need for the Federal Circuit to have opened a new loophole in this regard, and this Court should grant certiorari to close it.

B. Shifting the Burden of Proof for Experimental Use Will Prevent Invalidation of Improperly Filed Medical Treatment Patents

Second, the Federal Circuit held that where an inventor argues that the § 102 time bar is not triggered because an inventor's use was experimental, the inventor does not bear the burden of persuasion and can prove experimental use on uncorroborated testimony alone. Left uncorrected, this rule is again ripe for exploitation to the end of extending patent terms.

For one thing, the nature of drug development means that experimental use could become a powerful shield for protecting improper patents. Pharmaceutical companies may designate information as confidential or a trade secret when they submit it to the FDA, protecting it from

disclosure. 21 C.F.R. § 20.61(c). Thus, it may be difficult for defendants to gain access to the information needed to prove that the use was not experimental. Since the patent owner has access to the relevant testing information, relieving the patent owner of the burden of persuasion on experimental use could obscure a legitimate invalidity defense.

The experimental use rule could also enable medical treatment developers to engage in pre-patent commercialization activity, contrary to the intent of the patent system. Generally, the experimental use exception to the § 102 bars permits experimentation on the merits of an invention, but not experimentation on the marketability of the invention, since the latter is a use of the invention "for a profit" rather than "a *bona fide* effort to bring his invention to perfection." *See Pfaff*, 525 U.S. at 64–65 (quoting *Elizabeth*, 97 U.S. at 137). With drug patents, for example, randomized control tests for safety and efficacy cleanly fall on the merits-based experimentation side of the line. But in the context of health care treatments such as medical devices, where placebos cannot be administered, trial recipients are generally people who would otherwise have bought the device from the treatment developer, meaning that the line between merits testing and market testing is blurry. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 682 (1990) (Kennedy, J., dissenting). To the extent that those inventors can avail themselves of the Federal Circuit's experimental use rule, they likely would overgeneralize the merits-based experimental use to be as long as necessary until they can confidently conclude that the treatment will or will not be profitable.

Besides putting developers of those technologies in a privileged class with respect to the patent system, a rule

that enables patent applicants to hold out experimental use through the commercialization phase of market testing impinges on the basic patent bargain. Patents are intended to encourage public disclosure of inventions, regardless of whether they turn out to be of commercial value in the short term, because the incremental nature of innovation means that even unsuccessful ideas can be sources of knowledge. *See* Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539, 590–91 (2009). This is especially important for the development of medical devices, where a characteristic feature of the field is the incremental nature of innovation. *See* Michael Drummond et al., *Economic Evaluation of Medical Devices*, Oxford Res. Encyclopedia: Econ. & Fin. (Mar. 28, 2018), *available online*. If the experimental use doctrine gave insufficient incentives to file for patents and thus to disclose new technologies until the inventor deemed them profitable, then in many cases inventors would fail to reveal inventions to the public to retain the future possibility of incremental improvement until profitability for themselves. The result would thus be a failure of the patent laws, under the Federal Circuit's reading, to "promote the progress of science and useful arts." U.S. Const. art. I, § 8, cl. 8.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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October 2019