IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., ET AL.,

Respondents.

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

BRIEF OF NATURAL RESOURCES DEFENSE COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Does Article III's grant of jurisdiction of "all Cases ... arising under ... the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable, or not infringed?

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INTEREST OF AMICUS CURIAE

The Natural Resources Defense Council, Inc. (NRDC) submits this brief as amicus curiae in support of the petitioner because affirmance of the Federal Circuit's decision would distort Article III's case-or-controversy requirement in ways that could have damaging effects on the justiciability of a broad range of cases not involving patents, including environmental litigation to which NRDC is often a party.¹

NRDC is a nonprofit environmental membership organization founded in 1970. NRDC's purposes include protection of human health and the environment. NRDC's staff of lawyers, scientists, and other environmental professionals work to protect the planet's wildlife and wild places and to ensure safe and healthy communities for NRDC's more than one-half million members and their families.

NRDC's efforts to protect the environment often involve litigation. NRDC regularly seeks judicial review of governmental actions damaging to the environment, and it intervenes in cases where industry challenges government regulations and policies that protect the environment. See, e.g., Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984) (NRDC as plaintiff); Orff v. United States, 125 S. Ct. 2606 (2005) (NRDC as intervenor). NRDC also sues polluters directly in cases where federal or state law affords a right of action. See, e.g., Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., 484 U.S. 49 (1987); NRDC v. Southwest Marine, Inc., 236 F.3d 985 (9th Cir. 2000).

Article III justiciability issues, particularly standing and ripeness, are often critically important in these cases. Indeed,

¹ Letters of consent to the filing of this brief from all parties have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party. No person or entity other than amicus curiae, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

many of this Court's leading standing decisions have arisen from environmental litigation. See, e.g., Sierra Club v. Morton, 405 U.S. 727 (1972); United States v. SCRAP, 412 U.S. 669 (1973); Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59 (1978); Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871 (1990); Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992); Bennett v. Spear, 520 U.S. 154 (1997); Steel Co. v. Citizens for a Better Env't, 523 U.S. 83 (1998); Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., 528 U.S. 167 (2000).

Although this case involves patent validity and not environmental issues, it implicates NRDC's interests because Article III's requirements apply to all cases, regardless of subject matter. A decision in a patent case that ignores or alters the criteria this Court has set forth for determining when an Article III case or controversy exists may affect all cases, including environmental litigation. NRDC is therefore keenly interested in the proper application of Article III's case-or-controversy requirement in this case.

SUMMARY OF ARGUMENT

The Federal Circuit held in this case that there is no Article III case or controversy when a patent licensee sues a patent owner for a declaration of patent invalidity without first breaching the license agreement. In such a case, the court held, the licensee is "under no threat or apprehension of suit" and hence lacks "standing to bring a declaratory challenge." *MedImmune, Inc. v. Genentech, Inc.*, Nos. 04-1300, -1384, slip op. 9 (Fed. Cir. Oct. 18, 2005). In so holding, the lower court followed its previous decisions in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), and *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), which similarly held that a licensee must breach its license agreement to create a justiciable case or controversy over the validity of the underlying patent.

Remarkably, in none of these opinions did the Federal Circuit so much as cite any of this Court's many recent precedents defining when a plaintiff has standing to present a federal court with a case or controversy within the meaning of Article III. Those decisions establish that a plaintiff has standing, and that there is a justiciable case or controversy under Article III, when three elements are present: (1) the plaintiff has suffered or is likely to suffer a legally cognizable injury ("injury in fact"); (2) there is a fairly traceable causal relationship between the defendant's challenged conduct and the injury ("causation"); and (3) the relief sought from the defendant will likely redress the injury ("redressability"). See, e.g., Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 771 (2000).

Each of these elements, ignored by the Federal Circuit, is present here: The plaintiff has suffered a present and ongoing *injury* in having to pay money to the defendant to avoid a lawsuit for infringement; that injury was *caused by* the defendant's challenged conduct of obtaining an allegedly invalid patent; and a favorable decision on validity would likely *redress* the injury by relieving the plaintiff of the ongoing need to pay royalties to the defendant. Whatever obstacles there may be to the maintenance of this lawsuit, the absence of an Article III case or controversy is not one of them.

Moreover, the Federal Circuit's view that the existence of a case or controversy is negated by the plaintiff's choice of taking a costly action (paying royalties) to avoid an even more serious injury (being sued for damages for infringement, or possibly even treble damages and fees for willful infringement) could have far-reaching, negative consequences. Plaintiffs often choose a lesser form of injury over a greater one. For example, a plaintiff in an environmental case may choose to stop swimming in a river to avoid being harmed by pollutants, or a corporate plaintiff challenging a federal regulation may choose to bear the costs of complying with it rather than violate it and risk an enforcement action. The injury in such a case is no less real, and a case or controversy no less present, than in a case where the defendant has

no choice about how the injury will be suffered. Indeed, cases involving plaintiffs faced with the immediate dilemma of incurring costs of avoidance (or compliance) or suffering a direct injury are generally viewed as the *easiest* cases for justiciability purposes in that they readily satisfy not only Article III standing and ripeness requirements but also the additional prudential requirements of the ripeness doctrine. *See, e.g., Abbott Labs. v. Gardner*, 387 U.S. 136, 152-154 (1967).

Whether MedImmune's claim of patent invalidity is a justiciable case or controversy depends not on legal doctrines and policies exclusive to patent cases, but on the constitutional principles this Court has developed to implement the requirements of Article III, which are applicable to all federal judicial proceedings. Those principles, fairly applied, require the Court to reverse the Federal Circuit's holding that there is no Article III case or controversy here.

ARGUMENT

I. This Court Has Established That the Requisites of an Article III Case or Controversy Are Injury in Fact, Causation, and Redressability.

Article III, section 2 extends the judicial power of the United States only to "cases" and "controversies." The Declaratory Judgment Act, 28 U.S.C. § 2201, which MedImmune has invoked in this case, similarly empowers federal courts to provide declaratory remedies only in "case[s] of actual controversy within [their] jurisdiction," a phrase that incorporates the same limitations as the constitutional provision. See, e.g., Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 239-240 (1937); Ashwander v. TVA, 297 U.S. 288, 325 (1936).

The case-or-controversy requirement embodies a number of "doctrines that cluster about Article III—not only standing but mootness, ripeness, political question, and the like," *Allen v. Wright*, 468 U.S. 737, 750 (1984) (citation omitted), all designed to limit courts to their "proper—and properly lim-

ited—role ... in a democratic society." Warth v. Seldin, 422 U.S. 490, 498 (1975). Among the critical functions served by the case-or-controversy requirement is limiting intervention by the courts to disputes that are sufficiently "concrete" (as opposed to merely "abstract") to entitle the parties to judicial resolution. Allen, 468 U.S. at 750-52.

Of the doctrines devised by the courts to achieve this objective, standing "is perhaps the most important." Id. at 750. Over the past quarter century, this Court has repeatedly addressed the requirements of standing and refined them into a now-familiar litany: "[T]he 'case' or 'controversy' provision of Article III" requires, as an "irreducible constitutional minimum' ... (1) that the plaintiff have suffered an 'injury in fact'—an invasion of a judicially cognizable interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) that there be a causal connection between the injury and the conduct complained of—the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court; and (3) that it be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." Bennett v. Spear, 520 U.S. at 167. The Court has emphasized over and over that the three critical elements of injury in fact, causation, and redressability are the sine qua non of standing under Article III. See, e.g., McConnell v. FEC, 540 U.S. 93, 225 (2003); Stevens, 529 U.S. at 771; Laidlaw, 528 U.S. at 180-81; Lujan v. Defenders of Wildlife, 504 U.S. at 560-61; Lewis v. Cont'l Bank Corp., 494 U.S. 472, 477 (1990); Valley Forge Christian College v. Americans United for Separation of Church and State, 454 U.S. 464, 472 (1982).²

² The other two principal elements of the case-or-controversy requirement, ripeness and mootness, which are not at issue here, address the interaction of the standing requirements with matters of timing, but do not add new elements to the basic building blocks of a case or controversy.

(Footnote continued)

II. The Federal Circuit's Holding That MedImmune's Claim Presents No Case or Controversy Cannot Be Squared with this Court's Article III Case Law.

Although it held that MedImmune's claims do not present an Article III case or controversy, the Federal Circuit did not attempt to analyze whether those claims satisfied the "irreducible constitutional minimum" requirements of standing (*Bennett*, 520 U.S. at 162) as set forth in this Court's decisions. Indeed, neither in the opinion below nor in its predecessors, *Gen-Probe*, 359 F.3d 1376, and *MedImmune v. Centocor*, 409 F.3d 1376, did the Federal Circuit even relate its Article III holding to this Court's many recent precedents defining the bounds of the case-or-controversy requirement.³

A straightforward application of this Court's precedents to MedImmune's claims demonstrates that there is a case or controversy here. MedImmune claims that, to avoid liability for infringing Genentech's patent, it has paid substantial royalties to Genentech. The monetary losses MedImmune has thus sustained constitute the quintessential injury in fact; it is uncontroversial that "[p]ecuniary injury is a sufficient basis for standing." *Fair v. EPA*, 795 F.2d 851, 853 (9th Cir.

The constitutional dimension of ripeness, for example, is satisfied at least where the plaintiff's injury is imminent enough to confer standing, *see NTEU v. United States*, 101 F.3d 1423, 1427-28 (D.C. Cir. 1996), and the mootness doctrine demands *less* concreteness than is necessary for standing at the commencement of litigation. *See Laidlaw*, 528 U.S. at 190-92.

³ There is no doubt that the Federal Circuit's holdings rested on Article III. Although the term "standing" is also used to refer to prudential, non-constitutional limits on justiciability, and sometimes to denote whether a plaintiff has satisfied the requirements necessary to bring a particular cause of action (for example, "antitrust standing"), each of the Federal Circuit's opinions expressly stated that what was lacking, in the court's view, was an Article III case or controversy. *See MedImmune v. Genentech*, slip op. at 5; *MedImmune v. Centocor*, 409 F.3d at 1378-79, 1382; *Gen-Probe*, 359 F.3d at 1379. This Court, in turn, granted certiorari solely to determine the scope of "Article III's grant of jurisdiction."

1986). See, e.g., Bacchus Imports, Ltd. v. Dias, 468 U.S. 263, 267 (1984); Gen. Motors Corp. v. Tracy, 519 U.S. 278, 286 (1997); Barlow v. Collins, 397 U.S. 159, 163-64 (1970). The injury satisfies the causation element of standing because it is "fairly traceable" to Genentech's procurement of an allegedly invalid patent and its efforts to license or enforce the patent. Absent the patent, MedImmune would not have to pay Genentech royalties for the use of the invention. And the injury is redressable through the relief MedImmune seeks, for it is at least likely that a declaration that the patent is invalid will effectively relieve MedImmune from the obligation to pay royalties by providing it a defense against an effort by Genentech to enforce the license agreement. See Lear, Inc. v. Adkins, 395 U.S. 653 (1969).

That the application of this Court's Article III precedents leads to this result should come as no surprise, because this Court long ago held that the payment of royalties to avoid infringement of an allegedly invalid patent creates a case or controversy. In Altvater v. Freeman, 319 U.S. 359, 365 (1943), this Court held that "the requirements of case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim." Indeed, this passage from Altvater anticipates all the elements of this Court's later-articulated standing analysis and demonstrates how each one is satisfied: (1) injury ("payment is made"); (2) causation (payment is "demanded as of right" and is "involuntary or coercive"); and (3) redressability (there is a right to "recover the sums paid or to challenge the legality of the claim").

III. The Federal Circuit's Reasoning, If Applied in Other Settings, Would Radically Alter Conventional Justiciability Analysis.

The Federal Circuit nonetheless held that there is no case or controversy here simply because the plaintiff is "under no threat or apprehension of suit." *MedImmune v. Genentech*, slip op. 9. This statement is perplexing, and, from the standpoint of this Court's Article III jurisprudence, a non sequitur. Whether a plaintiff has Article III standing to bring a declaratory judgment action depends on whether it has suffered injury, caused by another's allegedly wrongful conduct, that can be redressed by a declaratory judgment, not on whether the *defendant* has a cause of action against the *plaintiff*.

Moreover, to the extent the Federal Circuit's analysis suggests that making payments or taking other volitional actions to avoid a more serious injury (here, being sued for infringement) does not constitute an injury, the court's holding is flatly inconsistent with conventional standing principles that are routinely applied in other types of cases.

For example, the injury in fact suffered by plaintiffs in environmental cases often consists of actions they choose to take to minimize their exposure to health threats posed by environmental contamination. In this Court's decision in Laidlaw, the injury on which this Court's recognition of the plaintiff's standing rested was that the plaintiff organization had members who had curtailed their use of the North Tyger River because of the defendant's discharge of pollutants into it. That is, the organization's members had chosen not to fish or swim in the river, to canoe on it, or to hike, camp, or picnic near it, in order to avoid exposure to noxious and hazardous pollutants. 528 U.S. at 181-83. Similarly, lower courts regularly recognize that environmental plaintiffs who have stopped engaging in recreational activities in polluted areas have suffered injuries sufficient to support standing. See, e.g., American Canoe Ass'n, Inc. v. City of Louisa Water & Sewer Comm'n, 389 F.3d 536 (6th Cir. 2004), American Canoe Ass'n v. Murphy Farms, Inc., 326 F.3d 505 (4th Cir. 2003); Piney Run Pres. Ass'n v. County Comm'rs, 268 F.3d 255 (4th Cir. 2001); Ecological Rights Found. v. Pacific Lumber Co., 230 F.3d 1141 (9th Cir. 2000), Friends of the Earth, Inc. v. Gaston Copper Recycling Corp., 204 F.3d 149 (4th Cir. 2000). If the Federal Circuit were to prevail in its view that such avoidance injuries do not suffice to create a case or controversy, plaintiffs in such cases could not gain access to court without eating contaminated fish or swimming in sewage.

Similarly, plaintiffs in First Amendment cases suffer injury in fact not only when the government takes action against them for engaging in protected speech, but also when they change their behavior to avoid a genuine threat of such direct consequences. Thus, this Court found a justiciable controversy in Steffel v. Thompson, 415 U.S. 452 (1974), where the plaintiff alleged that he had decided to stop distributing handbills at a shopping mall in order to avoid prosecution. As the Court explained, "it is not necessary that petitioner first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights." Id. at 459. And the Court held in Meese v. Keene, 481 U.S. 465, 472-73 (1987), that a plaintiff suffered injury in fact when he chose not to show films branded as propaganda by the government in order to avoid the reputational injuries that would follow if he were associated with such propaganda.

Lower courts also regularly hold that plaintiffs who change their conduct in order to avoid a realistic threat of sanctions have standing to raise First Amendment challenges to the laws that pose the threat. *E.g., Eldred v. Reno*, 239 F.3d 372, 375 (D.C. Cir. 2001) (plaintiffs had standing to challenge copyright statute because they were injured by *compliance* with its restrictions on exploitation of copyrighted works), *aff'd sub nom. Eldred v. Ashcroft*, 537 U.S. 186 (2003); *see also Brister v. Faulkner*, 214 F.3d 675, 679-81 (5th Cir. 2000); *Wilson v. State Bar*, 132 F.3d 1422, 1428 (11th Cir. 1998); *Jacobs v. Florida Bar*, 50 F.3d 901, 904-05 (11th Cir. 1995); *Int'l Soc'y for Krishna Consciousness v. Eaves*, 601 F.2d 809, 817-19 (5th Cir. 1979). As the First Circuit has put it, a threat of sanctions if a plaintiff exercises

First Amendment rights "poses a classic dilemma for an affected party: either to engage in the expressive activity, thus courting prosecution, or to succumb to the threat, thus forgoing free expression. Either injury is justiciable." *New Hampshire Right to Life Political Action Comm. v. Gardner*, 99 F.3d 8, 14 (1st Cir. 1996). The Federal Circuit's justiciability analysis is difficult, if not impossible, to square with this firmly established precedent.

The Federal Circuit's view would be equally devastating to corporate plaintiffs seeking to challenge government regulations that they claim go too far. Plaintiffs in such cases typically are not required to take the risk of violating a regulation in order to challenge it. Rather, they rely on costs of compliance (similar to the costs MedImmune has incurred to comply with its license terms) to establish their injury for standing purposes. See, e.g., City of Waukesha v. EPA, 320 F.3d 228, 234 (D.C. Cir. 2003) ("The administrative record shows that the City of Waukesha would face substantial costs if it was required to comply with the [challenged] regulations. This is sufficient for injury-in-fact."); Cellco P'ship v. FCC, 357 F.3d 88, 100 (D.C. Cir. 2004) ("As an entity continuously burdened by the costs of complying ... with what it contends are 'unnecessary' regulations ..., Verizon Wireless' injuries are concrete and actual, traceable to the Commission's alleged failure to meet the statutory deadline, and redressable by a ruling adopting Verizon Wireless' interpretation [of the statute]."); Ass'n of Am. R.Rs. v. Department of Transp., 38 F.3d 582, 585-86 (D.C. Cir. 1994) (cost of compliance with two sets of regulations sufficient to support standing). Under the Federal Circuit's view of standing, industry plaintiffs in these and similar cases would have to violate applicable regulations and put themselves at risk of being sued (or possibly even criminally prosecuted) by the government before they could present the courts with a justiciable controversy.

That would constitute a significant reversal of ordinary notions of justiciability in administrative law cases. Indeed, cases where a plaintiff faces the dilemma of either taking costly measures to comply with a regulation or violating it and facing an enforcement action are generally considered the easiest from the standpoint of justiciability, because they most readily satisfy not only the constitutional case-orcontroversy requirement, but also prudential limitations on ripeness. See, e.g., Abbott Labs., 387 U.S. at 152-154 (holding a controversy was ripe where the plaintiff either had to incur compliance costs or risk prosecution); Nat'l Ass'n of Home Builders v. United States Army Corps of Eng'rs, 417 F.3d 1272, 1284 (D.C. Cir. 2005) (holding a claim justiciable where the plaintiffs were required "either [to] modify their projects to conform to [required] thresholds and conditions ... or refrain from building until they can secure individual permits"); Ciba-Geigy Corp. v. EPA, 801 F.2d 430 (D.C. Cir. 1986) (holding a claim justiciable where "[t]he Company's only alternative to costly compliance with EPA's regulatory directive would be to run the risk of serious civil and criminal penalties"). By ruling that there is no case or controversy in precisely analogous circumstances, the Federal Circuit has turned ordinary justiciability principles upside down.

IV. This Case Does Not Turn on Legal Principles or Policies Unique to Patent Litigation.

Article III applies equally to all cases in the federal courts, and its basic requirements generally do not vary with the subject matter of the case. The Federal Circuit held not that patent cases require prudential limitations on standing or that there is no right of action in cases such as this one, but that this case involves no Article III case or controversy. That holding—which is the only one before this Court—turns on "general principles of law with which [this Court is] familiar," not on "the peculiarities of patent litigation." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 103 (1993) (Scalia, J., concurring in part and in the judgment). In *Cardi-*

nal Chemical, for example, the majority applied general Article III principles to hold that an appellate ruling of noninfringement does not moot the issue of patent validity if there was a live controversy over validity in the trial court. The Court then went on to consider policies specific to patent litigation in determining whether there was a valid nonconstitutional basis for the Federal Circuit's practice of vacating declaratory judgments on validity when it held that a patent was not infringed. See 508 U.S. at 96-103.

In this case, the question on which the Court granted certiorari is limited to the constitutional issue, so there is no reason to proceed further once that issue is resolved. The Federal Circuit's apparent view that permitting suits in the circumstances here is not sound policy because it leads to some "inequity" or "imbalance" between patent owners and licensees (*MedImmune v. Genentech*, slip op. 7), even if it were convincing, is irrelevant to the issue before the Court. That issue is no more and no less than whether such disputes present an Article III case or controversy.⁴

The Federal Circuit seems to have gone astray by confusing the case-or-controversy issue with the question whether a licensee has a *right of action* in these circumstances. That could well be a more difficult question, and one to which policies and legal principles specific to patent cases would be relevant. Whatever the answer to that question might be, its resolution, unlike the resolution of the case-or-controversy issue, would not have the potential to distort time-honored,

⁴ The Federal Circuit's view that it is somehow inequitable to permit a challenge to a patent without requiring the challenger to infringe it is, in any event, hard to square with the fact that one of the principal purposes of the Declaratory Judgment Act was to relieve parties of the "in terrorem choice" between engaging in conduct that may subject them to suit or giving in to the threat posed by a patent owner or other potential plaintiff who seeks to coerce them into complying with its wishes. See Cardinal Chem. Co., 508 U.S. at 95-96.

generally applicable Article III principles and settled policies regarding the justiciability of a wide range of cases involving federal statutes and regulations outside the patent field.

The cause-of-action question might be difficult in part because the Declaratory Judgment Act, 28 U.S.C. § 2201, has been held not to create new causes of action, but only to provide a form of relief that may be granted in otherwise cognizable cases. See Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667 (1950). The form of relief made available by the Act often permits a suit to be initiated by the party who would normally be the defendant in a coercive action, but according to the Skelly doctrine it does not alter the elements of the underlying cause of action that must be set forth in a well-pleaded complaint, nor does it transform defenses into elements of affirmative causes of action. See id. Because patent invalidity is primarily a defense (either to a claim of patent infringement under 35 U.S.C. § 281, which presents a federal question, or to a contractual claim of breach of a license agreement, which does not, see Milprint, Inc. v. Curwood, Inc., 562 F.2d 418 (7th Cir. 1977)), it is conceivable that there would be no cause of action for a declaratory judgment of invalidity when the patent owner would have no cause of action for infringement or breach of a license agreement. Of course, a party seeking to argue that there would be no cause of action in such circumstances would have to account for this Court's statement in Cardinal Chemical that "a party seeking a declaratory judgment of invalidity presents a claim independent of the patentee's charge of infringement." 508 U.S. at 96.

Whether there is a cause of action (an issue on which we take no position here) is, however, a question wholly distinct from the antecedent question whether there is an Article III case or controversy. *See Steel Co.*, 523 U.S. at 89 ("[T]he absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the courts' statutory or constitutional power to adjudicate the case."); *see*

also Arbaugh v. Y & H Corp., 126 S. Ct. 1235, 1242-44 & n.10 (2006). Only the latter question is presented by this case, and the Federal Circuit's answer to that question cannot be squared with this Court's consistent and longstanding construction of the requirements of Article III.

CONCLUSION

For the foregoing reasons, the judgment of the Federal Circuit should be reversed.

Respectfully submitted,
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