No. 09-1175

IN THE

Supreme Court of the United States

FERRING B.V., FERRING PHARMACEUTICALS, INC. AND AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC. AND LOUISIANA WHOLESALE DRUG CO., INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

1. The Biotechnology Industry Organization ("BIO") is a trade association representing over 1,100 companies, academic institutions, and biotechnology centers. BIO members are involved in research and development in healthcare, agricultural, environmental, and industrial products. The biotechnology industry currently has more than 370 products in clinical trials for treating more than 200 diseases. The vast majority of BIO members are small companies that have not yet brought a product to market or attained profitability.

The biotechnology industry is dependent on predictable and effective patent protection for the development of new technologies. Patents serve as the principal asset on which investors (such as venture capitalists) base decisions to invest in early-stage companies and fund research and development activities that will eventually bring new products to market. Predictability and transparency in the procurement and enforcement of patent rights provides the commercial certainty that is essential to support innovation in the biotechnology industry. BIO therefore wishes to promote the adoption and

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, their members, and their counsel, made any monetary contribution towards the preparation and submission of this brief. Petitioner Aventis Pharmaceuticals, Inc. is a member of both *amici curiae*, but has not authored the brief in whole or in part, nor contributed any money toward the brief's preparation and submission. Pursuant to Supreme Court Rule 37.2(a), *amici curiae* certify that counsel of record for both parties received timely notice of *amici curiae*'s intent to file this brief and have consented to its filing in letters on file with the Clerk's office.

application of standards for patent eligibility and enforcement that will ensure appropriate and consistent protection for the full range of inventions in the biotechnology sector.

2. The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. New medicines account for 40 percent of the lifespan increase between 1986 and 2000, see Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 5 Int'l J. of Health Care Fin. & Econ. 47, 68 (2005), and member companies are the source of a majority of all new medicines that have been discovered and marketed. In the last decade, PhRMA's members have invested more than $400 billion to develop new medicines, including an estimated $45.8 billion last year alone. See PhRMA, *Pharmaceutical Industry Profile 2010*, at 26 (2010) ("Industry Profile"), *available at* http://www.phrma.org/files/attachments/Profile_2010_FINAL.pdf.

The ability of the Federal Circuit to provide uniformity in the patent laws, an issue raised in this case, is significant to PhRMA members because of the critical role intellectual property plays in incentivizing pharmaceutical research and development. A 2007 study estimated that the average research and development costs of bringing a new drug to market was approximately $1.3 billion in 2005, including the costs for unsuccessful drugs. See DiMasi & Grabowski, *The Cost of Biopharmaceutical R&D: Is*

Biotech Different?, 28 Managerial & Decision Econ. 469, 477 (2007). Another study notes that it takes approximately sixteen years to bring a new chemical entity to market and that "only a fraction of drugs in the R&D 'pipeline' ever succeed in making it to market." See Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & Econ. 195, 196 & n.2 (2005). The patent laws reflect Congress's determination that the protections and corresponding incentives patents provide are essential to encouraging such costly, time-consuming, and high-risk research and development. With the creation of the Federal Circuit in 1982, Congress further recognized that uniformity and predictability in the patent laws is essential to meet these ends.

REASONS FOR GRANTING THE PETITION

The Second Circuit's decision strikes a serious blow to the uniformity and predictability of patent law that Congress sought to establish by giving the Federal Circuit exclusive jurisdiction over the vast majority of cases involving patent issues. As Congress understood well, stability in patent law is necessary to spur innovation by firms like those represented by *amici curiae*.

Consistent with Congress's intent, this Court made clear in *Christianson* v. *Colt Industries Operating Corp.*, 486 U.S. 800 (1988), that the Federal Circuit should hear virtually all appeals involving patent issues. The Court observed that the Federal Circuit has exclusive jurisdiction not only when "federal patent law creates the cause of action," but also whenever "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." *Id.* at 809. Exclusive Federal

Circuit jurisdiction over patent issues is defeated only if the claim raising a patent issue could also be supported by a non-patent theory sufficient to achieve the "overall success of [the] claim." *Id.* at 810.

Despite that instruction, the Second Circuit took jurisdiction here over an antitrust claim that raises substantial patent law issues. The court of appeals based this jurisdiction on the ground that respondents' claim included a non-patent theory, even though that theory concerned just a portion of the wrongful conduct for which relief was sought. The decision below conflicts both with *Christianson* and with decisions of the Federal Circuit and Seventh Circuit. Those conflicts, which are fully explained in the petition, are reason enough for this Court to intervene.

This Court's review is especially needed, however, because the potential for litigants to manipulate the Second Circuit's test is obvious and endless. Claims that raise substantial questions of patent law can be crafted to avoid Federal Circuit review through formalistic choices in pleading. As a result, the uniformity of patent law that Congress intended is placed in jeopardy. Since its creation in 1982, the Federal Circuit has adapted many areas of patent law, such as inequitable conduct, to changing practices and technology. In contrast, the patent law of the regional circuits is largely stuck in the late-1970s. Yet, those regional decisions remain good law, and, to the extent they vary from the Federal Circuit's decisions (which they not infrequently do), many litigants will be motivated to craft their pleadings to obtain review by regional circuits rather than the Federal Circuit.

This increased uncertainty and opportunity for forum shopping will undoubtedly dampen innovation.

Especially in industries like biotechnology and pharmaceuticals, which require enormous investments in research and development, stability in the rules of decision is critical. Before such investments are made, innovators must weigh the potential costs and benefits. Doubts about the law that will apply to patent applications and existing patents will create uncertainty regarding the potential patent benefits of their efforts. Consequently, firms will invest fewer resources, and fewer advancements will be made. This dynamic led Congress to create the Federal Circuit. Now this Court's action is required to restore Congress's scheme.

ARGUMENT

I. THE DECISION BELOW DEFINES FEDERAL CIRCUIT JURISDICTION IN CONFLICT WITH THIS COURT'S PRECEDENTS AND THE FEDERAL CIRCUIT.

The Second Circuit asserted jurisdiction over this case by applying a standard that cannot be squared with this Court's case law or the decisions of other circuits, including the Federal Circuit—Congress's preferred arbiter of patent issues. For the sake of much-needed stability and to vindicate the Federal Circuit's special role in shaping patent law, this Court should clarify the scope of the Federal Circuit's exclusive jurisdiction.

1. Although plaintiffs' cause of action in this case arises under the antitrust laws, substantial issues of patent law unquestionably dominate the basis for the relief set forth in the complaint. Plaintiffs asserted a *single count* of monopolization based on the following alleged misconduct: (1) the fraudulent procurement of U.S. Patent No. 5,407,398 ("the '398 patent"); (2) the improper listing of the '398 patent in the U.S.

Food and Drug Administration (FDA) publication known as the "Orange Book"; (3) the prosecution of sham patent infringement litigation against competitors to forestall FDA approval of generic drug products claimed to be covered by the '398 patent; and (4) the filing of a sham citizen petition to further delay final FDA approval of the generic drug products. Pet. App. 59a-60a. Indeed, plaintiffs characterized their claim as based on an "anticompetitive scheme in which the '398 patent is the linchpin." *Id.* at 15a. The district court dismissed the complaint for failure to plead facts sufficient to state a claim of fraud, and lack of standing to challenge the '398 patent under the patent laws and antitrust laws.

Plaintiffs appealed to the Second Circuit. Even though the case implicates substantial and important patent issues, the Second Circuit held that it, rather than the Federal Circuit, had jurisdiction over the appeal. The court of appeals proceeded to hold that plaintiffs had standing and that the complaint adequately pled fraud, and therefore remanded the case. Pet. App. 8a, 16a, 25a-26a, 33a. The Second Circuit's jurisdictional holding forms the basis of the instant petition.

That holding turned on the fact that plaintiffs' antitrust claim, based primarily on patent issues, also included a non-patent "theory," *i.e.*, the allegedly sham citizen petition filing, which the court below found was "an issue independent of patent law." Pet. App. 12a. Thus, even though the court of appeals recognized that plaintiffs' three other theories "turn on substantial questions of patent law," and that "appellate jurisdiction would lie exclusively with the Federal Circuit if the plaintiffs' success solely depended on one or more of these theories," the court

asserted jurisdiction because one of plaintiffs' theories could "support the claim without raising substantial questions of patent law." *Id.* at 11a, 15a-16a. The court reached this decision despite the fact that the non-patent theory could not provide plaintiffs with all the relief sought, given that the citizen-petition allegation would not justify awarding damages for the time periods covered by the other allegations. The Second Circuit dismissed this critical factor—*i.e.*, whether the non-patent theory could achieve the claim's overall success—as "lack[ing] jurisdictional significance." *Id.* at 15a.

2. The decision below conflicts with this Court's construction of the Federal Circuit's jurisdictional statute. Congress specified that whenever a district court's jurisdiction "was based, in whole or in part," on 28 U.S.C. § 1338(a), any appeal must be taken in the Federal Circuit. 28 U.S.C. § 1295(a). Section 1338(a), in turn, gives district courts broad jurisdiction over "any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). Taken together, these statutes reflect Congress's desire to empower the Federal Circuit as the authority over patent law, subject only to this Court's inherently limited supervision.

In *Christianson* v. *Colt Industries Operating Corp.*, 486 U.S. 800 (1988), this Court construed § 1338(a) to establish the governing test of Federal Circuit jurisdiction. In pertinent part, the Court explained that § 1338(a) includes cases in which "a well-pleaded complaint establishes" that "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 809. Thus, if any one of a plaintiff's claims pleaded in the complaint includes

even a single element that involves patent law, the Federal Circuit has jurisdiction.

The *Christianson* Court acknowledged that a "well-pleaded claim" could involve alternative theories, under any one of which the plaintiff would be "'entitled to the relief [the claim] seeks.'" *Id.* at 810. In that situation, Federal Circuit jurisdiction does not lie if one of the theories does not implicate patent law. *Id.* After all, if a theory allows the plaintiff to obtain the relief sought by the claim without resolution of a patent issue, there might be no patent issue for the Federal Circuit to review and thus no comparative advantage in having the appeal handled by that court.

To be sure, the distinction between a "claim" and "theory" can be difficult to draw. As shown below, the distinction has engendered conflict among the circuits, and the Second Circuit reached the wrong decision here by mistaking a theory for a claim. See *infra* 9-11.

Several guiding principles arise out of *Christianson*. First, the *Christianson* Court explained that a non-patent theory defeats Federal Circuit jurisdiction only if it is a sufficient basis for "the *overall success* of [the] claim." 486 U.S. at 810 (emphasis added). In this sense, if the operative facts underlying the claim implicate patent law issues, the non-patent theory does not defeat Federal Circuit jurisdiction if it arises from only a portion of those facts, since such a theory could not determine the claim's "'overall success.'" *Id.* Similarly, Federal Circuit jurisdiction remains if the non-patent theory cannot support all the "'relief [the claim] seeks.'" *Id.*

Applying that standard, the *Christianson* Court held that the Federal Circuit did not have exclusive

jurisdiction in that particular case because the plaintiffs could have supported the entirety of their antitrust claim with several theories having nothing to do with patent issues. *Id.* at 813. Tellingly, these were different *legal* theories pertaining to the same operative facts, as opposed to different *factual* scenarios combined under a single count. *E.g.*, *id.* (claim alleged that defendant's agreement with other businesses to boycott plaintiffs' business was wrongful both under a patent theory (that defendant's patent was invalid) and under a theory involving no patent issue (that defendant had authorized plaintiffs' use of technology)). This implies that Federal Circuit jurisdiction would remain if the non-patent "theory" were, in reality, a separate claim, based on different operative facts. Cf. *Keene Corp.* v. *United States*, 508 U.S. 200, 212 (1993) (construing the term "claim" in 28 U.S.C. § 1500 with relation to "operative facts" and "relief requested").

Second, *Christianson* instructed courts to guard against a plaintiff's attempt to manipulate jurisdiction through artful pleading. 486 U.S. at 809 n.3 ("a plaintiff may not defeat § 1338(a) jurisdiction by omitting to plead necessary federal patent-law questions"). This is consistent with this Court's broader jurisdiction case law, which has favored rules that apply to a pleading's substance, rather than its form. For example, in determining whether a case filed in state court may be removed, the federal court must look beyond plaintiff's styling of his claims and ask whether a "well-pleaded" complaint would provide a basis for federal jurisdiction. *E.g.*, *City of Chi.* v. *Int'l Coll. of Surgeons*, 522 U.S. 156, 164 (1997); *Franchise Tax Bd.* v. *Constr. Laborers Vacation Trust*, 463 U.S. 1, 22 (1983). Thus, while a

plaintiff may be "master of the complaint," by choosing which substantive legal claims to assert, a plaintiff cannot avoid the jurisdiction that governs those claims by crafty pleading.

The Second Circuit's decision plainly disregarded these principles. The "theory" on which the Second Circuit based its jurisdiction was an independent factual occurrence joined with other discrete factual events under a single antitrust count. Pet. App. 11a-16a. As noted, the "theory" alleged that petitioners unlawfully extended a monopoly by filing a sham citizen petition to delay FDA approval of a generic drug in 2004. *Id.* at 63a, 93a. But, that is not a theory capable of sustaining the claim's "overall success," as *Christianson* requires. 486 U.S. at 810. Respondents' claim sought a ruling declaring defendants' enforcement of the patent unlawful and treble damages for the period beginning in 2001. Pet. App. 63a, 93a. However, the non-patent "theory" regarding the citizen petition would not entitle respondents to relief against enforcement of the patents or for damages related to the period before 2004. Consequently, that theory could not entitle plaintiffs to the "'relief [the claim] seeks,'" and did not provide a non-patent basis for the claim's "overall success." 486 U.S. at 810.

This mismatch between the "theory" undergirding the Second Circuit's putative jurisdiction and the relief the overall claim seeks reveals that, in fact, respondents pleaded multiple antitrust claims, and simply styled them as multiple "theories" in a single antitrust count. Under *Christianson*, as well as this Court's other jurisdiction cases, the Second Circuit should have looked beyond the complaint's labels and examined its substance. See *id.* at 809 n.3. Viewed in the proper light, it is clear that respondents could

only obtain all the "relief [the claim] seeks" if the district court addressed the patent law issues raised in their antitrust claims, since those concerned conduct beginning in 2001 and encompassed far more than the citizen petition. Those patent-law issues, which included a *Walker Process* antitrust claim, are the type that Congress meant to fall within the Federal Circuit's review.

3. Just as problematic, the Second Circuit's jurisdictional test is utterly incompatible with the Federal Circuit's test for its own jurisdiction. The conflict flows primarily from the Second Circuit's misperception of the distinction between "claims" and "theories."

Unlike the Second Circuit, the Federal Circuit has drawn the distinction correctly. Thus, in *Davis* v. *Brouse McDowell, L.P.A.*, 596 F.3d 1355 (Fed. Cir. 2010), the plaintiff pleaded a single count of malpractice against her former patent attorney, but alleged two distinct factual events that provided bases for recovery. First, the plaintiff alleged that the attorney neglected to file international patent applications in a timely fashion. *Id.* at 1357-58. Second, the plaintiff alleged that the attorney was negligent in his preparation of U.S. patent applications. *Id.* at 1358-59. The plaintiff argued that the Federal Circuit lacked jurisdiction on the ground that the two events constituted alternative "theories," one of which (*i.e.*, the failure to file the international application) did not implicate U.S. patent law. *Id.* at 1360. The Federal Circuit rejected the argument, concluding that the complaint "presents multiple *claims*." *Id.* (emphasis added). The Federal Circuit explained that a "'claim' is broadly defined as the 'aggregate of operative facts giving rise to a right enforceable by a court.'" *Id.*

(quoting *Black's Law Dictionary* 264 (8th ed. 2004)). Because the complaint presented "at least two distinct claims," one of which raised an issue of U.S. patent law, the Federal Circuit exercised jurisdiction. *Id.* at 1360-62.

Had the Second Circuit applied the Federal Circuit's straightforward distinction between claims and theories, it would have properly declined to assert jurisdiction. Even though respondents contended that they alleged a single antitrust claim comprising multiple theories, those theories are actually distinct sets of "operative facts" that would give rise to varying rights to relief. Therefore, under the Federal Circuit's *Davis* decision, plaintiffs' complaint would be read as involving separate claims. Most of those "claims" require proof of substantial questions of patent law, such as whether petitioners committed fraud or inequitable conduct before the United States Patent and Trademark Office ("PTO"). See Pet. App. 59a. Under *Christianson*, those patent law issues should have been reviewed by the Federal Circuit. Instead, the Second Circuit simply accepted the plaintiffs' labeling of these events as different "theories," and retained jurisdiction. This divergence in results warrants this Court's resolution.

4. This Court's intervention is especially necessary because the disagreement over Federal Circuit jurisdiction is not limited to the Second and Federal Circuits. As the petition shows, the Second Circuit's decision conflicts also with Seventh Circuit decisions. Pet. 21-27.

Moreover, practitioners and scholars have long bemoaned the uncertainty that plagues Federal Circuit jurisdiction. As one of the leading patent law scholars noted nearly 40 years ago, whether "a case

arise[s] under the patent laws" is "one of the darkest corridors of the law of federal courts and federal jurisdiction." Chisum, *The Allocation of Jurisdiction Between State and Federal Courts in Patent Litigation*, 46 Wash. L. Rev. 633, 638-39 (1971) (emphasis omitted). Although this Court more recently addressed the effect of counter-claims on Federal Circuit jurisdiction, *Holmes Group, Inc.* v. *Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002), *Christianson* remains the Court's last word on what constitutes a non-patent theory sufficient to avoid Federal Circuit appellate review. See 15A Wright et al., *Federal Practice and Procedure* § 3903.1, at 169-70 (2d ed. 1992) (noting that, although *Christianson* gave some guidance, "questions of 'arising under' jurisprudence . . . continue to befog Federal Circuit jurisdiction"). As the decision below demonstrates, more illumination is needed from this Court to cut through that fog.

II. THE DECISION BELOW UNDERMINES MUCH-NEEDED STABILITY AND PREDICTABILITY IN PATENT LAW.

The Second Circuit's erroneous test poses a serious threat to the stability and predictability in patent law that Congress intended. Its rule will allow plaintiffs to avoid Federal Circuit jurisdiction through formalistic choices in their pleading. This will exacerbate the forum shopping in patent law that Congress hoped to curtail. And, would-be innovators will have to account for increased legal uncertainty when deciding whether to make the enormous investments that precede so many advancements today, especially in the biotechnology and pharmaceutical fields.

1. The Second Circuit's test casts a shadow over Congress's vision for the Federal Circuit. Congress

created the Federal Circuit to "provide nationwide uniformity in [the] patent law" and to "make the rules applied in patent litigation more predictable." H.R. Rep. No. 97-312, at 20 (1981). By channeling patent cases into a single appellate forum, Congress intended that the resulting uniformity of decisions would foster technological growth and industrial innovation, as well as eliminate often "unseemly" forum-shopping that previously characterized patent litigation. *Id.*

The Second Circuit's decision, however, materially erodes the Federal Circuit's jurisdiction over cases that involve substantial questions of patent law. The court of appeals wrested jurisdiction away from the Federal Circuit based on a non-patent "theory" that was clearly ancillary to respondents' *Walker Process* claim and that could not provide respondents with all the "relief [the claim] seeks."

Under the Second Circuit's test, plaintiffs in other cases can similarly engage in artful pleading to avoid Federal Circuit review of patent issues. Common and recurring patent issues such as inventorship, validity, infringement, and enforceability are often pleaded along with non-patent causes of action sounding in tort, fraud, contract law, antitrust law, and bankruptcy law. According to the decision below, a plaintiff can avoid Federal Circuit jurisdiction simply by joining with each patent claim some allegation of wrongdoing that does not raise a patent issue—even if that allegation could not support all the relief the plaintiff seeks, and even if the allegation is fairly insubstantial. By this approach, many claims that raise substantial patent questions can be shielded from Federal Circuit review.

The Second Circuit's test will undoubtedly lead to more patent issues being diverted from the Federal

Circuit. This increases the potential for conflicts in patent law, as well as major patent issues being decided by generalist courts of appeals. Further, the variation will invite litigants to file suit in a district court that offers opportunities to appeal to the forum they perceive as most favorable. In light of the broad availability of declaratory relief actions by putative patent infringers, see *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007), the risk of unseemly races to the courthouse and blatant forum shopping are particularly aggravated unless the Second Circuit's rule is reviewed and reversed. These are problems Congress meant for Federal Circuit jurisdiction to solve.

2. While Congress intended uniformity in all areas of the patent law, uniformity is especially important in *Walker Process* antitrust disputes, such as the instant case. A *Walker Process* claim alleges that a defendant obtained an unlawful monopoly by "knowingly and willfully misrepresenting facts" to the PTO in prosecuting a patent. *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). Although it arises under antitrust laws, a *Walker Process* claim inherently involves an inquiry into patent issues, such as the basis for the PTO's issuance of the patent and the materiality of the allegedly misrepresented facts. *E.g., Dippin' Dots, Inc.* v. *Mosey*, 476 F.3d 1337, 1346-47 (Fed. Cir. 2007). For that reason, *Walker Process* claims raise "issue[s] unique to the patent law." *Unitherm Food Sys., Inc.* v. *Swift-Eckrich, Inc.*, 375 F.3d 1341, 1357 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006). Indeed, patent issues were the "linchpin" of respondents' claims here. Pet. App. 15a. Nonetheless, the Second Circuit asserted jurisdiction based on a tangential, factually separate non-patent alle-

gation, largely ignoring the patent issues at the heart of the case.

The importance of the Federal Circuit's leading role in shaping *Walker Process* law is underscored by the potential for treble damages in *Walker Process* claims. The potential for such severe sanctions means that uncertainty in this area can chill technological growth and innovation. The Federal Circuit is best-situated to supervise a claim based on *Walker Process* with proper sensitivity to other patent doctrines that bear on incentives to innovate. But the decision below deprives the Federal Circuit of that role and serves as a blueprint for pleading that avoids Federal Circuit review. This Court's intervention is urgently needed to protect against these untoward consequences.

3. The law of inequitable conduct is another patent doctrine whose orderly development by the Federal Circuit would be disrupted by the decision below. Inequitable conduct is a claim that a patent, even if it is valid and infringed, is unenforceable because the patent holder misrepresented or concealed information from the PTO while obtaining the patent. See *Critikon Inc.* v. *Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997); 37 C.F.R. § 1.56. Inequitable conduct requires proof of materiality, a quintessential patent law issue concerning how the misrepresented or concealed information relates to the patent claims that the inventor was pursuing. See, *e.g.*, 37 C.F.R. § 1.56(b).

The Federal Circuit has recognized that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *Burlington Indus., Inc.* v. *Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). To combat this abuse, the Federal Circuit has rejected a gross negligence

standard for finding inequitable conduct and instead held that both deceptive intent and materiality must be shown in order to render a patent unenforceable. *Kingsdown Med. Consultants, Ltd.* v. *Hollister, Inc.*, 863 F.2d 867, 873-74 (Fed. Cir. 1988). And, more recently, the Federal Circuit clarified that both deceptive intent and materiality must be proven by clear and convincing evidence. See, *e.g.*, *Star Scientific Inc.* v. *R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed. Cir. 2008).

As a result, the Federal Circuit's strict inequitable conduct standards now differ markedly from those found in regional circuits. After the Federal Circuit's creation in 1982, most regional circuits had no opportunity to revisit their inequitable conduct doctrines, and so their less-exacting gross negligence tests persist. See, *e.g.*, *Digital Equip. Corp.* v. *Diamond*, 653 F.2d 701 (1st Cir. 1981); *True Temper Corp.* v. *CF&I Steel Corp.*, 601 F.2d 495 (10th Cir. 1979); *Int'l Tel. & Tel. Corp.* v. *Raychem Corp.*, 538 F.2d 453 (1st Cir. 1976)). Though decades old, these cases remain good law unless altered by the en banc court of appeals or by this Court, either of which is exceedingly rare, and litigants asserting inequitable conduct claims would undoubtedly prefer the benefit of those cases.

To date, the uncertainty created by these decisions has been kept in check by the regional circuits' limited opportunities to decide inequitable conduct issues. Under the Second Circuit's jurisdictional standard, however, the floodgates could break open. Litigants could cast claims of inequitable conduct as one "theory" in support of any number of non-patent causes of action sounding in fraud, rather than as a separate, independent "claim." Even though most inequitable conduct disputes necessarily turn on

substantial patent law issues (materiality requires an inquiry into claim construction, the scope and content of the prior art, and questions of potential invalidity based on, for example, anticipation and obviousness), such issues could be shielded from Federal Circuit review under the Second Circuit's erroneous rule.

Moreover, uncertainty in inequitable conduct law creates unpredictability in other aspects of patent litigation. For example, because the Federal Circuit's inequitable conduct standard includes a scienter element and sounds in fraud, the Federal Circuit requires plaintiffs to plead inequitable conduct claims with the particularity required by Federal Rule of Civil Procedure 9(b). See, *e.g.*, *Exergen Corp.* v. *Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc.* v. *Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). It is not clear, however, whether the regional circuits' different inequitable conduct standards require this same level of detailed factual pleading in a complaint. The possibility that less-detailed pleading suffices in those circuits creates additional incentive for litigants to forum shop. Patent enforceability should not be dependent on an accident of judicial venue.

Recognizing the need for clarity in these doctrines, the Federal Circuit recently granted rehearing en banc to provide guidance on the materiality standard in inequitable conduct, and its relationship to the doctrines of unclean hands and fraud. See *Therasense, Inc.* v. *Becton, Dickinson & Co.*, No. 2008-1511, 2010 WL 1655391 (Fed. Cir. Apr. 26, 2010) (per curiam). It is, therefore, particularly important that the Court reverse the decision below and prevent regional circuits from disrupting the Federal Circuit's

efforts to bring uniformity to these recurring patent law issues.

4. This Court should not underestimate the difficulties regional circuits would encounter in trying to apply their own antiquated patent law to current cases. By definition, patent cases deal with advancements in science and technology. As the court with almost exclusive jurisdiction over patent appeals since the early 1980s, the Federal Circuit has developed experience and expertise in the underlying sciences and the unique patent law issues raised by cutting-edge innovations.

By contrast, patent law in the regional circuits has largely remained frozen since the creation of the Federal Circuit. The Second Circuit decision here opens the door to important patent issues being decided by regional circuits that lack familiarity with rapidly advancing technology or the governing patent law. This will undermine the certainty Congress sought to establish by centralizing the development of patent law in the Federal Circuit. And, it will deprive practitioners and industry of the Federal Circuit's unique capability to adapt the law to technological advances. Perhaps no firms stand to lose more than biotechnology and pharmaceutical firms, which have played such an important role in this country's economic growth in the past 25 years and which will continue to play central roles in the country's economy for the foreseeable future.

To be sure, the regional circuits occasionally can decide patent issues. In *Holmes Group Inc.* v. *Vornado Air Circulation Systems Inc.*, 535 U.S. 826 (2002), this Court held that regional circuits have jurisdiction over patent issues raised in counterclaims, rather than in a well-pleaded complaint. But there is no dispute that Congress created the Federal

Circuit to bring a large measure of uniformity to patent law, and that goal has been largely achieved. Regional circuits have exercised *Vornado*-based appellate jurisdiction over patent counterclaims only infrequently. The decision below, however, threatens to break off a much larger piece of Federal Circuit jurisdiction. To prevent this unwarranted erosion of that court's exclusive grant of jurisdiction, this Court should grant review.

5. Because the decision below introduces substantial uncertainty into patent-law jurisdiction, it will needlessly increase the costs of patenting new innovations, and therefore deter the development of new, often life-saving, products.

In many industries—with biotechnology and pharmaceutical firms being chief among them—innovations result only because of enormous investments into research and development. As noted, on average, developing and securing regulatory approval for a new drug or biologic costs approximately $1.3 billion. See DiMasi & Grabowski, *supra*, at 477. In addition, the journey from research and development to regulatory approval averages approximately 16 years. See Giaccotto et al., *supra*, at 196 & n.2; see also Industry Profile at 27. During that time, the firm earns no return on its investment. And, the firm may never earn any return since just "very few drugs that enter development ever achieve final marketing approval." Industry Profile, at 27. Even with approval, just two in ten medicines ever produce revenues that match or exceed average R&D costs. See Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, Health Econ. (Aug. 2009), http://dx.doi.org/10.1002/hec.1538; see also Industry Profile at "Key Facts."

Given those realities, firms in these industries must undertake a careful cost-benefit analysis before embarking on a new line of research, and decisions are made years before any hope of actually creating a commercial product. For that reason, stability and predictability in the rules that govern potential litigation are absolutely essential. Congress realized this as it set up the Federal Circuit, intending it to develop a uniform, expertise-based body of patent law to guide innovation. By adopting a jurisdictional standard that makes it far more likely that a plaintiff could take a case to any circuit, particularly given the declaratory judgment device, the decision below will require innovators to keep tabs on differing laws across the regional circuits. Firms will have to factor in this uncertainty in their cost-benefit analysis, and consequently, discount the potential reward for years of hard work. This is precisely the result Congress sought to avoid. Only this Court can remedy the injury to Congress's intent created by the Second Circuit's wayward jurisdictional ruling in this case.

CONCLUSION

For these reasons, and those stated by petitioner, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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