No. 12-182

In the Supreme Court of the United States

HUGH E. MONTGOMERY, ET AL., PETITIONERS

v.

DAVID J. KAPPOS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, UNITED STATES PATENT AND TRADEMARK OFFICE

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

BRIEF FOR THE RESPONDENT IN OPPOSITION

DONALD B. VERRILLI, JR.
Solicitor General
Counsel of Record
STUART F. DELERY
Acting Assistant Attorney General
SCOTT R. MCINTOSH
JEFFREY CLAIR
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

Whether petitioners' claimed method of using ramipril to treat or prevent stroke was anticipated by a research study that was designed to test ramipril's effectiveness for those purposes.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Statute:

Miscellaneous: Page

In the Supreme Court of the United States

No. 12-182

HUGH E. MONTGOMERY ET AL., PETITIONERS

v.

DAVID J. KAPPOS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, UNITED STATES PATENT AND TRADEMARK OFFICE

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

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-24a) is reported at 677 F.3d 1375. The opinion of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (PTO) (Pet. App. 33a-58a), and the Board's opinion on rehearing (Pet. App. 25a-32a), are unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 2012. The petition for a writ of certiorari was filed on August 6, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Section 102 of the Patent Act provides that an invention must be "novel" to qualify for patent protection. 35 U.S.C. 102. As relevant here, Section 102(b) states that "[a] person shall be entitled to a patent unless * * * the invention was patented or described in a printed publication in this or a foreign country * * * more than one year prior to the date of the application for patent in the United States." 35 U.S.C. 102(b). The novelty requirement ensures that the patent system encourages the invention of new and useful products, while permitting "ideas in the public domain [to] remain there for the free use of the public." *Aronson* v. *Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979); see also *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 481 (1974).

Under Section 102, an invention is not novel, and thus does not qualify for patent protection, if it is "anticipated" by a reference in the prior art. A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention and "enables" one of skill in the art to practice an embodiment of the claimed invention without undue experimentation. *American Calcar, Inc.* v. *American Honda Motor Co., Inc.*, 651 F.3d 1318, 1341 (Fed. Cir. 2011); *Lewmar Marine, Inc.* v. *Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988). Even if the prior art reference does not expressly disclose a feature of the claimed invention, it may nonetheless anticipate the invention if the missing element is necessarily present or "inherent" in the anticipating reference. *Verizon Servs. Corp.* v. *Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010); see generally 2 *Moy's Walker on Patents* §§ 8.23-8.24 (4th ed. 2012).

2. Petitioners applied for a patent pertaining to a method of treating stroke with a class of drugs known as renin-angiotensin system (RAS) inhibitors, including the drug ramipril. Since the 1980s, RAS inhibitors have been used to treat high blood pressure—a "known risk factor for stroke"—but they were not generally used to treat or prevent stroke. Pet. App. 2a-4a. In 2005, petitioners filed a patent application (the '824 application) for a method of using ramipril or a subclass of other RAS inhibitors to treat or prevent stroke. *Id.* at 2a-3a. Specifically, the application claimed a "method for the treatment or prevention of stroke or its recurrence, wherein said method comprises administering, to a patient diagnosed as in need of such treatment or prevention," the subclass of RAS inhibitors that included ramipril. *Id.* at 3a.

3. a. The patent examiner rejected these claims as anticipated by each of four prior art references denoted as the Acute Infarction Ramipril Efficacy Study (AIRE), Frampton, Gohlke, and the Heart Outcomes Prevention Evaluation Study (HOPE). Pet. App. 3a-4a. The examiner concluded that each of these studies described the administration of ramipril to patients at risk of stroke and thus anticipated petitioners' patent claims. *Ibid.*

b. Petitioners filed an administrative appeal before the Board of Patent Appeals and Interferences (Board). The Board affirmed the examiner's conclusion that each of the four prior art references anticipated petitioner's claimed method of administering ramipril to patients at risk of stroke. Pet App. 33a-58a. As relevant here, the Board explained that the HOPE reference is a proposal for a large, randomized human clinical trial to determine the efficacy of using ramipril to reduce the risk of vari-

ous cardiovascular conditions, including stroke. *Id.* at 47a. The HOPE reference explained that, as of its publication, the patients in the trial had already been treated with ramipril, but the results of the trial had not yet been obtained. *Ibid.*

The Board concluded that the HOPE reference disclosed the administration of ramipril in a clinical trial to "patients diagnosed as in need of prevention of stroke," Pet. App. 49a, and that the HOPE study informed persons of ordinary skill in the art how to use ramipril "to treat patients * * * with previous stroke," *id.* at 48a. The Board rejected petitioners' argument that the HOPE study could not anticipate the '824 application because practitioners in the field would not have learned from the HOPE reference itself whether ramipril was in fact effective in treating stroke. *Ibid.* Because HOPE's method "would necessarily result in the treatment or prevention of stroke," the Board explained, Federal Circuit precedent held that "anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." *Id.* at 49a.

c. Petitioners sought rehearing, and the Board reaffirmed its determination that petitioners' claimed method was anticipated by each of the four prior art references at issue. Pet. App. 25a-32a.

4. a. The court of appeals affirmed. Pet. App. 1a-24a. The court concluded that petitioners' claims were anticipated by the HOPE study, and it therefore did not consider whether the claims were also anticipated by the other three references. *Id.* at 10a.

The court of appeals explained that determining whether claims are anticipated involves first construing the claims at issue, which is a question of law, and then

comparing the claims to the prior art, which is a question of fact. Pet. App. 9a. The court therefore applied a substantial-evidence standard in reviewing the Board's analysis of whether the HOPE study contained all of the elements of the claims at issue. *Ibid.*

Construing petitioners' claims, the court of appeals explained that the key elements of petitioners' method were (1) the administration of ramipril to a patient diagnosed as in need of stroke treatment or prevention (2) "where such administration is 'for the treatment of stroke or its recurrence.'" Pet. App. 10a. The court expressed doubt that the second element of petitioners' claims required that ramipril be effective in treating stroke, but it assumed for purposes of its decision that the claims did include an efficacy requirement. *Id.* at 11a-12a.

The court next upheld, as supported by substantial evidence, the Board's conclusion that the HOPE study inherently anticipated the '824 application. Pet. App. 12a-17a. The court explained that the HOPE study expressly disclosed the first element of petitioners' claims because it disclosed the administration of ramipril to patients at high risk of adverse cardiovascular events such as stroke. *Id.* at 10a. Although the HOPE study did not expressly disclose the second element of petitioners' claims because the study did not expressly state that ramipril would be effective in treating stroke, the court held that the HOPE study inherently disclosed ramipril's efficacy.

The court of appeals explained that a prior art reference inherently anticipates if a claim limitation inevitably results from the steps disclosed in the prior reference. Pet. App. 9a. The court found that the HOPE study satisfied that standard. The court agreed with the

Board's conclusion that "HOPE reveals the actual administration of ramipril for treatment or prevention of stroke." *Id.* at 14a. Patients in the HOPE study were at risk of stroke and were administered therapeutic doses of ramipril sufficient to treat hypertension, which "is a risk factor for stroke," thus inevitably reducing the risk of stroke. *Id.* at 14a n.12.

Because the court of appeals understood the HOPE study to involve the actual administration of ramipril to patients, the court rejected petitioners' contention that the HOPE study "does not disclose actual performance of the method" of treatment and therefore could not anticipate petitioners' claims. Pet. App. 14a. The court explained, however, that even if the HOPE study "merely proposed the administration of ramipril for treatment," it would still inherently anticipate petitioners' claims. *Ibid.* The court acknowledged that a prior reference's mere "invitation to investigate" a method of treatment does not amount to an inherent disclosure of the method's efficacy. *Id.* at 15a. The court observed, however, that the HOPE study was "far from an abstract theory" because it was at "an advanced stage of testing designed to secure regulatory approval," and it was based on "substantial evidence that ramipril improved cardiovascular health, including by treating stroke risk factors." *Ibid.* The court further explained that the PTO considered the initiation of "human clinical trials for a therapeutic product or process" to be "reasonably predictive of having the asserted therapeutic utility." *Id.* at 16a (quoting PTO, *Manual of Patent Examining Procedure* § 2107.03 (8th ed. rev. 6, Sept. 2007)). The court therefore concluded that "[i]n all relevant respects, HOPE is identical to the patent itself." *Ibid.*

The court of appeals also rejected petitioners' argument that the HOPE study could not anticipate the '824 application because the HOPE authors and others skilled in the art had not verified at the time that the administration of ramipril was effective in treating stroke. Pet. App. 13a-14a. The court explained that "newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Id.* at 13a (quoting *Bristol-Myers Squibb Co.* v. *Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001)).

Judge Lourie dissented. Pet. App. 18a-24a. He would have held that the HOPE study did not inherently disclose ramipril's efficacy. In his view, there was "no evidence in the record to prove that HOPE discloses administration sufficient to inevitably treat or prevent stroke." *Id.* at 23a.

ARGUMENT

Petitioners contend (Pet. 14-25) that the court of appeals erred in holding that the HOPE study anticipated the '824 application. Petitioners assert that persons of ordinary skill in the art—physicians and other health professionals—would not have known based on the HOPE study that prescribing ramipril for stroke prevention would be effective. Petitioners further argue that the court of appeals' ruling conflicts with this Court's decision in *Tilghman* v. *Proctor*, 102 U.S. 707 (1881). The court of appeals' decision is correct, and it does not conflict with *Tilghman* or with any other decision of this Court or the Federal Circuit. Further review is not warranted.

1. a. Petitioners contend (Pet. 2-7, 15-23) that prior art cannot inherently anticipate a subsequent invention unless the inherent feature of the prior art was recog-

nized at the time by persons of skill in the art. It is well-established, however, that a claimed invention may be inherently anticipated by an earlier invention that uses the same method as the claimed invention, even if the claimed invention is the first to recognize certain inherent results or characteristics of the earlier disclosure. "[T]he application of an old process to a new and analogous purpose does not involve invention, even if the new result had not before been contemplated." *Ansonia Brass & Copper Co.* v. *Elec. Supply Co.*, 144 U.S. 11, 18 (1892).

In *Ansonia Brass*, the Court held that a claim to a method of using paint to insulate wires in order to make them incombustible was anticipated by a process that used paint to insulate wires in a materially similar manner, even though the inventor of the earlier process was not seeking, and did not recognize, the incombustibility that resulted from the method. 144 U.S. at 17-18. The Court explained that prior art had disclosed to the public the invention at issue—the method of using paint to insulate wires—even though it had not explained that the method rendered the wires incombustible. *Ibid.*; see *Pennsylvania R.R. Co.* v. *Locomotive Engine Safety Truck Co.*, 110 U.S. 490, 494 (1884) ("[T]he application of an old process or machine to a similar or analogous subject, with no change in the manner of application, and no result substantially distinct in its nature, will not sustain a patent, even if the new form of result has not before been contemplated."). Consistent with that holding, the Court has continued to recognize that "[w]here there has been use of an article * * * more than a new advantage of the product must be discovered in order to claim invention." *General Elec. Co.* v. *Jewel Incandescent Lamp Co.*, 326 U.S. 242, 249 (1945); accord *Radio*

Corp. of Am. v. *Radio Eng'g Labs., Inc.*, 293 U.S. 1, 14 (1934); *Lovell Mfg. Co.* v. *Cary*, 147 U.S. 623, 637 (1893).

Petitioners' reliance (Pet. 14-15) on *Tilghman* is misplaced. The Court in *Tilghman* addressed the distinct situation where the result produced by the allegedly anticipatory process was only accidental or fortuitous, rather than necessarily present. Tilghman had invented a process for separating fats into fatty acids and glycerine in order to manufacture candles. The Court held that Tilghman's process, which had no precise analogue in the prior art, was not anticipated by an existing process for using tallow to lubricate a steam engine, even though the steam-engine process may have had the incidental consequence of separating fatty acids from glycerine. 102 U.S. at 710-711. The Court emphasized that it was unclear whether the prior art process in fact produced the fatty acids that were the intended result of Tilghman's invention, and that in any event, any fatty acid formation was purely the accidental and "unwitting[]" byproduct of the process. *Id.* at 711. Because the later inventor did not simply recognize a result or useful characteristic of an existing process, but instead designed a new process that achieved a result that was only an unintended byproduct of the prior art, the Court held that Tilghman's candle-making process was not anticipated by the prior art. *Id.* at 711-712; see *Eibel Process Co.* v. *Minnesota & Ont. Paper Co.*, 261 U.S. 45, 66 (1923) ("accidental results, not intended and not appreciated, do not constitute anticipation").

The *Tilghman* Court also explained that because the prior art produced at most an "accidental phenomenon," "[t]hose engaged in the art of making candles * * * certainly never derived the least hint" from the steam-engine process "in regard to any practicable process for

manufacturing such acids." 102 U.S. at 711. Contrary to petitioners' argument (Pet. 4-5), that statement does not suggest that prior art cannot anticipate a subsequent claim if the efficacy of the prior art was not previously recognized. Rather, in view of the Court's emphasis on the steam-engine byproduct's happenstance nature, and the Court's subsequent reaffirmation of the principle that recognizing the result of an existing process does not constitute invention, see *Ansonia Brass*, 144 U.S. at 18, the *Tilghman* Court's statement is best understood as pertaining only to situations in which the result of the allegedly anticipatory process is purely an accidental byproduct. See *Schering Corp.* v. *Geneva Pharms.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003) (reading *Tilghman* to hold that accidental, fortuitous consequences do not anticipate subsequent inventions). Similarly, the other decisions on which petitioners rely (Pet. 15-18) also concern fortuitous consequences. See *Eibel Process*, 261 U.S. at 66; *American Original Corp.* v. *Jenkins Food Corp.*, 696 F.2d 1053, 1059 (4th Cir. 1982); *Dewey & Almy Chem. Co.* v. *Mimex Co.*, 124 F.2d 986, 990 (2d Cir. 1942) (Hand, J.); *Edison Elec. Light Co.* v. *Novelty Incandescent Lamp Co.*, 167 F. 977 (3d Cir.), cert. denied, 215 U.S. 596 (1909).

Here, by contrast, the treatment or prevention of stroke through use of ramipril was scarcely an "accidental" (*Tilghman*, 102 U.S. at 711) or fortuitous consequence of the method described in the HOPE study. The HOPE study was "designed to secure regulatory approval" by verifying the hypothesis that ramipril is effective for those purposes. Pet. App. 15a. The study involved "administration of ramipril to stroke-prone patients, *id.* at 13a, in dosages sufficient to ameliorate hypertension, *id.* at 14a n.12. To be sure, the purpose of

the HOPE study (unlike the purpose of petitioners' claimed method of treatment) was to evaluate ramipril's efficacy rather than to improve the medical conditions of the subjects who participated in the study. But the two purposes are closely linked, and the natural effect of administering the drug in the course of the study was to "treat[] or ameliorate[] [the subjects'] hypertension." *Ibid.*

b. The Federal Circuit has long held that when an existing process necessarily produced a particular result, and the claimed invention differs from the prior art only in its recognition of the utility or efficacy of that result, the claimed invention may be anticipated. See *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969). That is so even though persons of ordinary skill in the art did not recognize a particular utility or efficacy of the prior art. See *Rasmusson* v. *SmithKline Beecham Corp.*, 413 F.3d 1318, 1325-1326 (Fed. Cir. 2005) (holding that where the claimed invention disclosed for the first time the utility of a prior art process, the fact that the prior art did not disclose utility was not in itself sufficient to defeat a claim of anticipation) (collecting cases); see also *Ansonia Brass*, 144 U.S. at 18.

Petitioners argue (Pet. 15) that when persons of skill in the art do not appreciate the utility of an existing process, that process does not "enable" practitioners to use the invention, and therefore the process cannot anticipate a later invention that recognizes the utility of the pre-existing process. But although a prior art reference must be an "enabling disclosure" in order to anticipate a claimed invention, *Schering*, 339 F.3d at 1380, that standard does not require the prior art reference to disclose the result or utility that the subsequent inventor discovers. See *Hafner*, 410 F.2d at 1405 ("a disclosure

lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process"); see also *Rasmusson*, 413 F.3d at 1325-1326. Thus, even if persons of ordinary skill in the art would not have recognized the efficacy or utility of a previously existing process, the prior art process may anticipate a claimed invention whose only innovation is its recognition of the utility of the pre-existing process.

2. The court of appeals correctly applied the doctrine of inherent anticipation to the facts of this case, and its decision does not conflict with *Tilghman*. The court's factbound conclusions do not warrant this Court's review.

a. The court of appeals first determined that, although the HOPE study does not expressly disclose ramipril's efficacy in treating and preventing stroke, substantial evidence supported the Board's conclusion that "efficacy is inherent in carrying out the claim steps." Pet. App. 12a. Consistent with *Tilghman*, the court correctly recognized that "a result is only inherent if it inevitably flows from the prior art disclosure." *Ibid.* Applying that principle to the facts of this case, the court rejected petitioners' argument that because the HOPE reference is a design for a clinical study to test the use of ramipril to treat stroke and other conditions, the study could not inherently disclose that ramipril was in fact effective in treating stroke. The court explained that while not every research proposal is sufficiently concrete to involve an inherent disclosure of efficacy, *id.* at 15a, the HOPE study was more than a mere proposal for further investigation, because it disclosed a method

of administering ramipril to stroke-prone patients "in an amount sufficient for treatment or prevention" of stroke, *id.* at 14a & n.12.

The court of appeals observed that, when the HOPE reference was published, all of the patients in the HOPE study had been given therapeutic doses of ramipril. Pet. App. 14a n.12. The court explained that this "actual administration of ramipril treated or ameliorated hypertension, which as [petitioners] acknowledge[], is a risk factor for stroke." *Ibid.* The HOPE study therefore necessarily disclosed the administration of ramipril to patients in order to "reduc[e] the risk of stroke" by "treat[ing] or ameliorat[ing] hypertension." *Ibid.* For that reason, efficacy in treating stroke was an inherent—not a fortuitous or occasional—result of the HOPE process.[1]

The court of appeals further explained that "newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." Pet. App. 13a (internal quotation marks omitted); *id.* at 15a. Because efficacy was inherent in the HOPE study's method and that method was "[i]n all relevant respects * * * identical" to petitioners' claimed method, *id.* at 16a, the court concluded that the HOPE study inherently anticipated petitioners' claims. See *id.* at 14a & n.12. And even if the HOPE study's authors had not yet *verified* ramipril's effectiveness in treating or preventing stroke, they clearly understood

---

[1] As petitioners point out (Pet. 20), Judge Lourie disagreed with the majority's conclusion, arguing that "there is no evidence in the record to prove that HOPE discloses administration sufficient to inevitably treat or prevent stroke." Pet. App. 23a. That factbound disagreement about whether the Board's decision was supported by substantial evidence does not warrant this Court's review.

its *potential* efficacy, since the objective of the study was to confirm the hypothesis that ramipril is effective for those purposes. Subsequent research indicated, moreover, that the dosages of ramipril administered during the HOPE study are effective in "treat[ing] or ameliorat[ing] hypertension," which "is a risk factor for stroke." *Ibid.*

The court of appeals' decision is thus consistent with both *Ansonia Brass* and *Tilghman*. As in *Ansonia Brass*, the method at issue—the administration of ramipril to treat stroke—had already been disclosed to the public, and petitioners' invention differed from the HOPE study only in its recognition of the HOPE method's efficacy. And unlike in *Tilghman*, where the assertedly inherent result was an accidental byproduct of the pre-existing process, ramipril's efficacy was the necessary and intended result of the HOPE study's administration of ramipril to stroke-prone patients. Unlike the inventor in *Tilghman*, petitioners did not create a new process to achieve a result that was only incidentally present, if at all, in the prior art. Rather, they claimed the same process that had already been disclosed in the HOPE study, and they simply included the efficacy of that process as an element of their claims. In these circumstances, the court of appeals correctly concluded that the '824 application was inherently anticipated by the HOPE study. That case-specific conclusion does not warrant this Court's review.

c. The decision below does not conflict with any other Federal Circuit decision.

Contrary to petitioners' argument, the Federal Circuit has not held that recognition of an inherent feature in the prior art is necessary for anticipation. Petitioners rely (Pet. 19) on the court's statement in *Continental*

Can Co. USA, Inc. v. *Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991), that "persons of ordinary skill" must believe that the "missing descriptive matter" in a prior reference is "necessarily present in the thing described." But, as the Federal Circuit explained in *Schering*, *Continental Can* addressed only the question whether the allegedly inherent feature was in fact present in the prior art. *Schering*, 339 F.3d at 1377-1378. Thus, "in *Continental Can*, this court did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference." *Id.* at 1378.

Petitioners' reliance (Pet. 19) on *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990), is similarly misplaced. In that case, the Federal Circuit applied the *Ansonia Brass* rule that the "discovery of a new property or use of a previously known composition" is not sufficient for patentability, and held that the claimed compositions were anticipated because they were chemically identical to existing compositions. *Id.* at 708. And in *Metabolite Labs., Inc.* v. *Laboratory Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (2004) (*Lab. Corp.*), cert. granted in part, 546 U.S. 975 (2005), writ dismissed as improvidently granted, 548 U.S. 124 (2006), the Federal Circuit held only that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category," and that the claimed inherent feature was not "necessarily present" in the prior art. That principle has no application here.[2]

---

[2] The Court in *Lab. Corp.* granted certiorari to consider the separate question whether the claimed process was invalid as a law of nature under Section 101. See *Laboratory Corp.*, 548 U.S. at 132 (Breyer, J., dissenting from dismissal of the writ as improvidently granted).

Petitioners also rely (Pet. 23) on opinions by Judges Newman and Lourie, dissenting from the denial of rehearing en banc in *Schering*, 348 F.3d 992, 993, 995 (Fed. Cir. 2003), and *Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955, 976 (Fed. Cir. 2001), cert. denied, 534 U.S. 1109 (2002), as well as Judge Newman's vacated panel opinion in *Elan Pharmaceuticals* v. *Mayo Foundation*, 304 F.3d 1221 (Fed. Cir. 2002). But individual judges' disagreement with the rule that prior recognition of an inherent feature is not required for anticipation does not create the sort of conflict within the Federal Circuit that warrants this Court's review.

3. Even if the question whether prior art can anticipate an invention when persons of ordinary skill in the art did not recognize its efficacy warranted this Court's review, this case would not be a suitable vehicle for deciding it. Although the court of appeals correctly observed that recognition of ramipril's efficacy was not necessary to a finding of anticipation, Pet. App. 13a, the court's decision makes clear that persons of ordinary skill in the art *would* have understood that ramipril was likely beneficial for the prevention and treatment of stroke. The court emphasized that the study was "based on substantial evidence that ramipril improved cardiovascular health, including by treating stroke risk factors," *id.* at 15a; that the HOPE study "explicitly disclosed the administration of ramipril to patients 'at high risk for cardiovascular events such as myocardial infarction and stroke,'" *id.* at 10a; and that prior stroke was one of the criteria for patient participation in the study, *ibid.* The court of appeals also observed that the PTO treats human clinical trials as "reasonably predictive of having the asserted therapeutic utility," that the PTO typically grants patents on treatment methods "before

the conclusion of clinical trials," and that it was undisputed that "HOPE's authors could have obtained the patent claims at issue based [on] the HOPE reference." *Id.* at 15a-16a (internal quotation marks omitted). The court of appeals' decision therefore demonstrates that the HOPE study would have led a person of ordinary skill in the art to recognize ramipril's efficacy for treating stroke.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General
STUART F. DELERY
Acting Assistant Attorney General
SCOTT R. MCINTOSH
JEFFREY CLAIR
Attorneys

NOVEMBER 2012