No. 05-489

IN THE

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,

Petitioners,

v.

APOTEX CORPORATION, APOTEX, INC. AND TORPHARM, INC.,

Respondents.

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

Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Petitioner

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QUESTION PRESENTED

Amicus asks the Court to grant review on the question presented in the petition, which amicus casts as follows:

Under 35 U.S.C. § 102(b) a person is not entitled to a patent if it is anticipated. That is, a person is not entitled to a patent if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." This Court has established that accidental results, not intended and not appreciated, do not constitute anticipation. *Tilghman v. Proctor*, 102 U.S. 707 (1881); *Eibel Process v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923).

The question presented is whether the United States Court of Appeals for the Federal Circuit erred by departing from this standard to find that anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the art is created and relied on this erroneous standard to sever the issue of anticipation from the facts as found by the trial court and to find the patent in this case invalid as anticipated.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

CONSTITUTIONAL PROVISION

STATUTES

RULE

SCHOLARLY AUTHORITY

INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents more than thirty of the country's leading research-based pharmaceutical and biotechnology companies.[1] In 2004, PhRMA's members invested an estimated $38.8 billion in the research and development of new medicines. PhRMA's members recognize the importance of innovation to fighting crippling and deadly diseases and are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. Given the unavoidable costs of cutting-edge pharmaceutical research and development, PhRMA's members rely upon the availability of patents on their discoveries to recoup the costs of their investments. The Federal Circuit's decision in this case conflicts with the protection for patented inventions set forth in section 102 of the Patent Code, 35 U.S.C. § 102, and undermines the certainty of an entire class of patents, patents on previously unrecognized compounds, vital to the development of new and beneficial pharmaceuticals.

STATEMENT

> The patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing

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[1] GlaxoSmithKline, petitioners' corporate affiliate, is a member of PhRMA but has not participated in the decision to file or the preparation of this brief. In addition, undersigned counsel for PhRMA was counsel for petitioner SmithKlineBeecham Corporation in the trial and appellate proceedings ultimately resolved in *Apotex v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), an unsuccessful challenge by respondent Apotex, Inc. to the United States Food and Drug Administration's listing of certain other patents, not involved in the instant matter, in connection with the Paxil® drug product.

> patents, as well as negation of searches for the beneficial components of existing materials.

App. 59a (Newman, J., dissenting from denial of rehearing en banc).

Judge Newman's dissent from denial of rehearing below correctly notes the serious implications that flow from the Federal Circuit's decision in the instant case. The Federal Circuit, reversing the district court, held invalid a patent claiming a drug substance (crystalline paroxetine hydrochloride hemihydrate or "PHC hemihydrate") as lacking novelty over a prior art reference (U.S. Patent No. 4,007,196 or "the '196 patent"), even though: (1) the prior art did not "describe" the claimed compound, (2) there was no evidence that anyone in the prior art had ever produced the compound, and (3) no one had ever recognized or identified the compound before the named inventors.

Nevertheless, the Federal Circuit held that the '196 patent "inherently anticipates" the patent claim, finding the practice of the '196 patent "naturally results" in the later claimed chemical compound in unknown and unknowable amounts. App. 19a. In so holding, the Federal Circuit simply discarded the detailed factual findings made by the district court following a three-week bench trial, and, without finding those facts clearly erroneous, announced a new standard for "inherent anticipation" so vague and indeterminate as to allow a patent to be held invalid without any meaningful evidence that the claimed subject matter ever previously existed.

Recognition of that which has previously been overlooked is fundamental to invention. For example, the broad spectrum antibiotic tetracycline was discovered from

study of the existing Aureomycin antibiotic,[2] and discovery of a new crystalline form for ranitidine hydrochloride, more suitable for commercialization, lead to the anti-ulcer medication Zantac®.[3]

Because invention does not necessarily spring, like Athena, fully formed from the mind of its creator, but rather often develops gradually, through manipulation of known elements, the danger is great that a genuine and valuable advance will erroneously appear, through hindsight, to lack novelty. The law recognizes, and protects against, this danger through the imposition of strict standards on those who would attack a patent as invalid: the challenger must prove, with clear and convincing evidence, that the patent claim lacks novelty – that the claimed subject matter was previously, as a matter of clear fact, either "patented or described in a printed publication . . . or in public use or on sale . . . ." 35 U.S.C. § 102(b).

The Federal Circuit's departure from these requirements, and its creation of a new test for "inherent anticipation" that allows invalidation of a patent detached from any meaningful fact finding, has far reaching implications. Accordingly, PhRMA submits that review by this Court is warranted.

FACTUAL BACKGROUND

This case arose in 1998 when SmithKline sued Apotex under 35 U.S.C. § 271(e)(2) for infringing United States Patent No. 4,721,723 ("the '723 patent") by seeking FDA approval to sell a generic, paroxetine-based antidepressant.

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[2] *See Chas. Pfizer & Co. v. Barry-Martin Pharms., Inc.*, 241 F. Supp. 191 (S.D. Fla. 1965).

[3] *See Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1045-46 (Fed. Cir. 1995).

After an approximately three-week trial in January, 2003, the district court (Circuit Judge Richard R. Posner, sitting by designation) held that claim 1 of the '723 patent was not infringed and was not invalid under 35 U.S.C. §102. App. 181a-82a. Apotex had argued that the '196 patent "literally" anticipated claim 1 of the '723 patent – that is, that the prior disclosure of paroxetine compounds rendered invalid a patent on the later-discovered PHC hemihydrate. Judge Posner rejected this argument, labeling it "frivolous." *Id*. at 131a. Judge Posner wrote that there "is no mention of hemihydrate in the patent . . . and the hemihydrate polymorph of paroxetine was unknown either when the ['196] patent application was filed or in 1977 when the patent was granted." *Id*. Judge Posner also rejected Apotex's argument that claim 1 of the '723 patent was inherently anticipated by the '196 patent, finding that Apotex failed to establish inherency by the "clear and convincing evidence . . . required to invalidate a patent." *Id* at 132a.

SmithKline appealed the finding of non-infringement. Apotex cross-appealed on a finding the claims were not invalid based on a prior public-use, and its briefs on appeal did not argue for reversal of the trial court's findings rejecting inherent anticipation. On April 23, 2004, a Federal Circuit panel reversed the district court's claim construction. The panel, however, found the claims of the patent invalid under § 102(b) for public use. App 60a.

SmithKline petitioned the Federal Circuit to review the public use finding en banc. On April 8, 2005, the Federal Circuit granted SmithKline's petition, vacated "the panel's original opinion addressing the issue of experimental use" and remanded the case to the original panel. App. 57a. On the same day, the original panel issued a revised opinion, this time finding claim 1 of the '723 patent invalid as inherently anticipated by the '196 patent. App. 1a.

The panel, in its revised opinion, left the district court's findings of fact largely intact. App. 9a. Thus, it left undisturbed the lower court's findings that PHC hemihydrate had first been detected in 1985 and that no one could say when that compound had first come into existence. The panel's anticipation holding was instead based on an inference from the court's belief that PHC hemihydrate had been "unwittingly" made by SmithKline while attempting to practice the '196 patent and that "neither Apotex nor SmithKline can *presently* produce PHC anhydrate that does not contain at least trace amounts of PHC hemihydrate." *Id*. at 9a-10a (emphasis added).

Judge Newman dissented from the court's en banc order. She observed that the "findings of chemical fact by this court are devoid of scientific support" and correctly noted that:

> The district court's finding that it had not been established that the hemihydrate was produced in 1975 is in accord with the evidence, and surely has not been shown to be clearly erroneous. There is no evidence to support the panel's current finding that the '196 patent "discloses in an enabling manner the production of the PHC hemihydrate." The evidence before the district court did not show that disclosure and enablement, and did not show that the hemihydrate was produced in 1975, even inherently and undetected.

App. 57a-58a.

REASONS FOR GRANTING THE WRIT

A. The Federal Circuit's Fact-Finding Departs From the Federal Rules of Civil Procedure and Prior Opinions of This Court.

In holding the hemihydrate anticipated, the Federal Circuit made a finding of fact. Whether a patent is anticipated is a question of fact. *See Glaxo*, 52 F.3d at 1047.

And the facts that must be found are set forth in the Patent Code: "A person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." 35 U.S.C. § 102(b). What is more, to invalidate a patent, these facts must be shown with clear and convincing evidence. 35 U.S.C. § 282.

The Federal Circuit's decision in this case depends upon its finding, as a matter of clear fact, that "the '196 patent discloses a method of manufacturing [paroxetine] that naturally results in the production of PHC hemihydrate." App. 19a. The district court neither made that finding nor can that finding be inferred from the findings the district court did make. The district court found not only that it was a "reasonable inference" and "in all likelihood" that PHC hemihydrate did not exist until December 1984 but also that Apotex failed to prove by clear and convincing evidence that PHC hemihydrate "was inherent" in the prior art paroxetine products. App. 126a, 132a, 146a. The district court found that Apotex only demonstrated the appearance of PHC hemihydrate years after the discovery of earlier paroxetine compounds and that when considered in light of "uncertainties in the scientific community concerning provenance and causality of polymorphs," that bare correlation failed to prove inherency. *Id*. at 132a. The Federal Circuit provided no analysis as to why that finding constituted clear error by the district court.

This petition thus presents the important question of whether the court of appeals may reverse the district court and enter a judgment of patent invalidity for anticipation, a determination of fact, without following the requisite

procedures and providing the requisite deference under Rule 52(a) of the Federal Rules of Civil Procedure.[4]

This Court's precedents make clear that the answer to this question is no. Matters of patent anticipation, like all matters of fact, must be reviewed in accordance with the constraints of Rule 52(a). For example, in *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986) (per curiam), this Court vacated the Federal Circuit's reversal of a district court's finding of

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[4] Rule 52(a) of the Federal Rules of Civil Procedure provides that, "[f]indings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses." Fed. R. Civ. P. Rule 52(a). The deference mandated by Rule 52 reflects "an accommodation of the respective institutional advantages of trial and appellate courts." *Salve Regina College v. Russell*, 499 U.S. 225, 233 (1991). This Court has specifically articulated the proper institutional role for an appellate court reviewing a district court's factual findings:

> In applying the clearly erroneous standard to the findings of a district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues de novo. The authority of an appellate court, when reviewing the findings of a judge as well as those of a jury, is circumscribed by the deference it must give to decisions of the trier of the fact, who is usually in a superior position to appraise and weigh the evidence. The question for the appellate court under Rule 52 (a) is not whether it would have made the findings the trial court did, but whether "on the entire evidence [it] is left with the definite and firm conviction that a mistake has been committed.

Zenith Corp. v. Hazeltine, 395 U.S. 100, 123 (1969) (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948)). The standard of review requires the court to determine affirmatively that the district court's findings of fact were not supported by the evidence. *See Anderson v. Bessemer City*, 470 U.S. 564 (1985) ("Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.").

patent invalidity on obviousness grounds because the Federal Circuit did not explicitly find clear error. Just as this Court in *Dennison* required the Federal Circuit to apply Rule 52(a) when reviewing facts regarding the obviousness of a patent claim, this Court should also require the Federal Circuit to conform to Rule 52(a) when reviewing a district court's findings regarding anticipation.

In addition, in *Icicle Seafoods, Inc. v. Worthington*, 475 U.S. 709 (1986), this Court reversed the Ninth Circuit's attempt to review de novo the district court's determination that certain job activities qualified a group of on-board workers as "seamen" under 29 U.S.C. § 213(b)(6). As in this case, the Ninth Circuit purported to review the facts for clear error but "nowhere in its opinion did the [Ninth Circuit] ever mention any of the factual findings of the District Court, much less discuss or analyze them." *Id*. at 713. This Court rejected the Ninth Circuit's attempt to carve out a subject-dependant exception to Rule 52(a) and held that by relying on a factual finding not made by the district court, the Ninth Circuit failed to provide the deference mandated by Rule 52(a). *Id*. at 714. Rather than insert its own findings of fact, this Court explained that:

> If the Court of Appeals believed that the District Court had failed to make findings of fact essential to a proper resolution of the legal question, it should have remanded to the District Court to make those findings. If it was of the view that the findings of the District Court were "clearly erroneous" within the meaning of Rule 52(a), it could have set them aside on that basis. If it believed that the District Court's factual findings were unassailable, but that the proper rule of law was misapplied to those findings, it could have reversed the District Court's judgment. *But it should not simply have made factual findings on its own.*

Id. (emphasis added). *See also Amadeo v. Zant*, 486 U.S. 214 (1988) (reversing an Eleventh Circuit decision for failing to properly apply the clearly erroneous standard of review); *Anderson*, 470 U.S. at 580 (reversing a Fourth Circuit decision because the factual findings of the district court were not clearly erroneous); *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 858 (1982) (reversing a Second Circuit decision for "setting aside facts that were not clearly erroneous").

Like these prior cases, in this case the Federal Circuit also misconstrued the district court's findings of fact and inserted its own. As such, this Court's holdings in *Dennison* and *Icicle Seafoods* are directly on point, and the Federal Circuit ignored Supreme Court precedent by engaging in a de novo review of the facts. That reason alone justifies granting SmithKline's petition for certiorari as it is vitally important for the Courts of Appeals to follow established procedural law.

Dennison and *Icicle Seafoods* also demonstrate that Rule 52(a) does not allow for judicially created exceptions based on subject-matter, whether in the patent area or elsewhere, and this Court should grant SmithKline's petition to prevent the Federal Circuit from creating an exception to the clearly erroneous standard for anticipation determinations as well. Given the Federal Circuit's sole appellate jurisdiction over patent controversies, this Court should grant SmithKline's petition to prevent the misapplication of Rule 52(a) in patent controversies that remains otherwise unnoticed because of the unavailability of sister circuits to draw attention to problematic rulings.

B. The Federal Circuit's Erroneous Departure From The Settled Law Of Anticipation Invites Improper Fact-Finding And Requires Correction.

The requirements for patentability set forth in Section 102(b) of the Patent Code, upon which the Federal Circuit

based its decision, provide simply that a "person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." 35 U.S.C. § 102(b). As the plain language requires, this Court has long held that a challenger cannot invalidate a patent as anticipated without proving, clearly and convincingly, that the claimed invention was "described" in the prior art.

In *Tilghman v. Proctor,* 102 U.S. 707 (1881), the patent at issue claimed "the manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure." *Id.* at 709. Before the patented discovery, others had accidentally formed fat acids using the claimed process, but this Court held that such accidental production did not suffice to anticipate the patent: "We do not regard the accidental formation of fat acid . . . as any consequence in this inquiry . . . . Those engaged in the art . . . certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacture of such acids." *Id.* at 711.

The test for anticipation, this Court made clear, was a factual one – did the challenger show as a factual matter that the prior production was known and deliberate: "[i]f the acids were *accidentally and unwittingly produced*, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery." *Id.* (emphasis added). This requirement was reinforced in *Eibel Process Co. v. Minnesota & Ontario Paper Co.,* 261 U.S. 45 (1923), where this Court again rejected a patent challenge for lack of proof that the prior art anticipated the invention knowingly and deliberately: "we find no evidence that any pitch of wire, used before Eibel, had brought such a

result as that sought by him, and in the second place, if it had done so under unusual conditions, *accidental results, not intended and not appreciated, do not constitute anticipation*." *Id.* at 66 (citing *Tilghman*, 102 U.S. at 711) (emphasis added).

The requirement of proof of deliberate and knowing anticipation is carried forward to the present day. In *Continental Can Co. v. Monsanto Co.,* 948 F.2d 1264 (Fed. Cir. 1991) (Newman, J.), the Federal Circuit adopted the test for "inherent anticipation" outlined by this Court's decisions and its progeny: "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that [1] the missing descriptive matter is necessarily present in the thing described in the reference, and [2] *that it would be so recognized by persons of ordinary skill*." *Id.* at 1268 (emphasis added). Emphasizing the recognition prong, the Federal Circuit explained that "[t]his modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." *Id.* at 1269.[5]

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[5] The principle has also been applied repeatedly in the context of pharmaceutical patent cases. For example, after the antibiotic tetracycline was developed and patented, an accused infringer argued that the patent should be held invalid based on the purported presence of that antibiotic in trace amounts in the prior art Aureomycin antibiotic. The court rejected that attack, holding that "[t]he prior existence of tetracycline in trace amounts, unrecognized and of no use does not invalidate the patent." *Chas. Pfizer & Co. v. Barry-Martin Pharms., Inc.*, 241 F. Supp. 191, 194 (S.D. Fla. 1965) (citations omitted); *see also Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995)

The Federal Circuit decision here departs dramatically from these clear requirements for anticipation. The majority below held squarely that "anticipation *does not require a person of ordinary skill in the art to recognize* the inherent disclosure in the prior art at the time the prior art is created." App. 18a (emphasis added). As it was undisputed in the trial court record that no one recognized the existence of PHC hemihydrate at the time of the prior patent was issued in 1977, this departure from settled law allowed it simply to ignore the established facts. Indeed, the record is clear, and the trial court found, that PHC hemihydrate was unknown until it was discovered by SmithKline in 1985, shortly before the hemihydrate patent application was filed. The Federal Circuit's finding of anticipation is thus flatly inconsistent with this Court's precedents in *Tilghman* and *Eibel* as well as the Federal Circuit's own, now-overruled decision in *Continental Can*.

By discarding the requirement that alleged anticipation be proved, clearly and convincingly, to be knowing and deliberate, the Federal Circuit has unmoored anticipation from scientific fact. No longer is anticipation a factual inquiry concerning, in Judge Newman's words, what "technological facts are known to those in the field of the invention." *Continental Can*, 948 F.2d at 1269. Instead, under the Federal Circuit's decision, an accused infringer may now attempt to invalidate a patent by convincing a court that the prior art "naturally results" in production of the claimed subject matter at some indefinite time and in some unknowable amount – indeed, even if that production be unintentional and undetectable. This is not a meaningful factual inquiry, and, as the Federal Circuit's decision shows,

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(rejecting inherent anticipation attack on patent claiming a particular crystalline form of ranitidine hydrochloride, the active ingredient in Zantac®).

it invites the courts to invalidate patents without regard to the facts and without deference to the finder of facts.

Moreover, the Federal Circuit's new approach undermines the fundamental purpose of the Patent Code: "[t]o promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8. As this Court has observed, "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). That which is unrecognized in the prior art has not, by definition, been brought into the public domain through disclosure. It is only through investigation, and consequent disclosure through patenting, that the public can enjoy the new designs and technologies that exist unknown in the art. The Federal Circuit's ruling in this case of unwitting anticipation would deny the incentives of the Patent Code. Science and the useful arts are not advanced by precluding patents for the recognition of that which has long lain unknown.

The Federal Circuit's marked departure from the settled law of anticipation deserves correction. The court has plainly and deliberately departed from the law of anticipation, and done so in a way that allows it to ignore the detailed fact-finding of the trial court and the constraints of Rule 52(a). As the sole appellate court with jurisdiction over patent cases, it will never voluntarily relinquish the power it has now arrogated to itself to pass on the validity of issued patents, untethered by the record and the trial court's findings.

We expect the respondent, Apotex, will argue that the rule adopted by the Federal Circuit here is necessary to prevent a patentee from improperly using a later-filed patent to preclude practice of the prior art. However, whether an accused infringer is practicing the prior art and not the claimed invention is a factual question, and one not

supported by the findings of the trial court here. There is no suggestion in the trial court's findings that Apotex is in fact practicing the prior art, and, as discussed above, it is not even clear that the claimed PHC hemihydrate existed in the prior art, even in unrecognized form.[6] Indeed, as patent claims should ordinarily be construed to avoid claiming the prior art, such an argument by Apotex would be fundamentally misdirected and provides no warrant for distorting the law of anticipation as the Federal Circuit did here.

As Petitioners have argued, the Federal Circuit's decision casts a significant cloud on existing and future patents. Professor Donald Chisum, author of the leading patent law treatise, explains that the Federal Circuit's "broad" new doctrine of inherent anticipation "seems to allow a described process to anticipate every compound X that could result from that described process, based on later evidence that practicing the process produces at least a trace amount of X, whether or not X was relevant, expected, or detected." Donald Chisum & Michael Smith, "*SmithKline*: How the Expanding Inherent Anticipation Doctrine Affects Chemical

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[6] Moreover, whether or not Apotex is practicing the prior art so as to be outside the claims of a later-filed patent pertains to the issue of infringement, an issue on which PhRMA takes no position. The lack of findings regarding whether PHC hemihydrate existed in the prior art, however, distinguishes this case from another recent decision by the Federal Circuit on inherent anticipation, *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). In *Schering*, the Federal Circuit affirmed the district court's express finding that a particular, later-patented, active metabolite of a compound is necessarily produced when humans ingest that compound. *Id*. at 1381. As the earlier patent in that case claimed pharmaceutical use of an unidentified "active compound" produced upon ingestion, there was no issue in *Schering* whether the newly patented metabolite existed (albeit in uncharacterized form) in the prior art. *Id.* at 1376. In contrast, the district court in this case expressly refused to find that PHC hemihydrate existed in the prior art.

Patents," at 4, Apr. 8, 2005, http://www.mofo.com/docs/PDF/IPNewsletter0605.pdf. As a policy matter,

> it is not clear that a broad inherent anticipation rule is good: it places patentees in the uncomfortable position of not knowing whether their patents might be invalidated by a reference, perhaps not even closely related to their own research. For example, a patent on a new compound with pharmaceutical activity could be invalid if the compound was later shown to be a metabolite of some other drug, even if the other drug was used for a seemingly unrelated purpose.

Id. at 5. "Such heightened uncertainty," Professor Chisum concludes, "reduces incentives for research and for disclosure in the form of patents." *Id.*

In short, the holding below violates not just the requirements of section 102 of the Patent Code and Rule 52(a) of the Federal Rules of Civil Procedure, but equally the essential working assumptions of a fair regime for the promotion and protection of innovation and intellectual property. This Court's intervention is therefore warranted.

CONCLUSION

For these reasons, the petition should be granted.

Respectfully submitted,

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