NO. 18-____

In the Supreme Court of the United States

MYLAN PHARMACEUTICALS INC., MYLAN INC., ALEMBIC PHARMACEUTICALS LTD., SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Petitioners,

—v—

UCB, INC., UCB BIOPHARMA SPRL, RESEARCH CORPORATION TECHNOLOGIES, INC., HARRIS FRC CORPORATION,

Respondents.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. This Court has long held that "no patent can issue for an invention actually covered by a former patent, especially to the same patentee." *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894). Because what is already known to the public cannot be taken from it, the issuance of a second patent to an obvious portion of a patented invention is precluded. Petitioners respectfully request this Court to clarify:

> Whether, under this Court's well-settled precedent, a patentee may obtain a second patent on the same invention actually covered by a former patent to the same patentee.

2. Holding a claimed invention is obvious requires deciding factual questions, such as the scope and content of the prior art, and the differences between the prior art and the claims at issue. 35 U.S.C. § 103; *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). This inquiry is flexible, expansive and technology-neutral. § 103; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Federal Circuit subverts this principle by applying its own restrictive, technology-specific threshold test. Petitioners respectfully request this Court to clarify:

> Whether, under 35 U.S.C. § 103, a patent may be obtained when the differences between the claimed invention and the prior art were obvious to a person having ordinary skill in the art, but—before addressing the *Graham* factors—a judge decides that an undisputed prior-art reference does not meet the Federal Circuit's restrictive "lead compound test".

PARTIES TO THE PROCEEDING

THE PARTIES BELOW WERE CONSOLIDATED IN THE FEDERAL CIRCUIT, FED. CIR. DKT. 2016-2610

Petitioners and Defendant-Appellants Below

- Mylan Pharmaceuticals, Inc.
- Mylan, Inc.
- Alembic Pharmaceuticals Ltd.
- Sun Pharma Global FZE
- Sun Pharmaceutical Industries, Ltd.

Respondents and Plaintiffs-Appellees Below

- UCB, Inc.
- UCB Biopharma Sprl
- Research Corporation Technologies, Inc.
- Harris FRC Corporation

Respondents and Defendants-Appellants Below

- Accord Healthcare, Inc.
- Actavis, Inc. n/k/a Allergan Finance, LLC
- Amneal Pharmaceuticals LLC
- Amneal Pharmaceuticals of New York, LLC
- Apotex Corp
- Apotex, Inc.
- Aurobindo Pharma Ltd.
- Aurobindo Pharma USA, Inc.
- Breckenridge Pharmaceutical, Inc.
- Cadila Healthcare Limited
- Intas Pharmaceuticals Ltd., the parent company of Accord Healthcare, Inc.
- MSN Laboratories Pvt. Ltd.

- Watson Laboratories, Inc. Florida, n/k/a Actavis
- Laboratories, FL, Inc.
- Watson Pharma, Inc. n/k/a Actavis Pharma, Inc.
- Zydus Pharmaceuticals (USA) Inc.

RULE 29.6 CORPORATE DISCLOSURE STATEMENTS

Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan, Inc., which is indirectly owned by Mylan, N.V., a publicly held company. No publicly-held company holds 10% or more of Mylan N.V.'s stock.

Alembic Pharmaceuticals Limited has one parent corporation, Alembic Limited. Alembic Limited is a publicly-held corporation owning 10% or more of Alembic Pharmaceutical Limited.

Sun Pharmaceutical Industries, Ltd. does not have a parent corporation, and no publicly-held corporation owns 10% or more of its stock.

Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Holdings, which in turn is a wholly owned subsidiary of Sun Pharmaceutical Industries, Ltd.

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The opinion of the Federal Circuit (App.1a-43a) is reported at *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313 (Fed. Cir. 2018). The district court's opinion (App.44a-159a) is reported at *UCB, Inc. v. Accord Healthcare, Inc.*, 201 F.Supp.3d 491 (D. Del. 2016).

JURISDICTION

The court of appeals entered judgment on May 23, 2018. App.1a. On August 24, 2018, the court denied a timely petition for rehearing en banc. App.162a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The U.S. Constitution provides that Congress shall have the authority:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

U.S. Const. art. I, §8, cl. 8.

The Patent Act provides the statutory basis for obviousness, in pertinent part:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. §103 (2012).[1]

The Patent Act provides the statutory basis for enablement, in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same*. . . .

35 U.S.C. §112, ¶1 (2012) (emphasis added).

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[1] The patent-at-issue is subject to the provisions in effect before the amendments made by the Leahy-Smith America Invents Act ("AIA"), Pub. L. 112-29, 125 Stat. 284 (2011). These amendments, however, do not materially affect the fundamental questions of patent law at issue in this case.

STATEMENT OF THE CASE

This case will define Americans' access to affordable essential medicines. At issue is whether patent law allows the patenting of pharmaceutical compounds that were already dedicated to the public. This issue directly affects millions of families, as well as businesses, and federal and state governments, who untenably suffer exorbitant prescription-drug prices.

This Court's intervention is necessary to reconcile the legal fiction of the Federal Circuit's restrictive approach to obviousness with the realities of pharmaceutical development and tactical patenting. Respondents undisputedly received three separate patents covering the same antiepileptic drug ("AED") compound, lacosamide. Worse yet, the chemical structure of lacosamide—and how to make and use it—were already known to the public. Serial patenting of the same invention without further innovation has extended Respondents' monopoly over lacosamide to more than a quarter century. Patent law should not authorize tactical patenting to obtain extended exclusivity for timeworn technologies.

The Federal Circuit has departed from Congressional mandate and this Court's guidance in two critical ways.

First, the Federal Circuit has failed to give meaningful effect to this Court's precedents against double-patenting a single invention. As this case illustrates, even when a patentee explicitly represents that it has patented the same invention twice, the Federal Circuit

allows the patentee to retain the last-filed and later-expiring patent, thus extending the patentee's exclusivity beyond the term Congress contemplated.

The Federal Circuit's error stems from its imbalanced application of the hypothetical "person of ordinary skill in the art" (or "POSA"). This hypothetical person has long been recognized as the appropriate standard by which a patent's disclosure and the prior art are judged. To justify the grant of a patent, a patentee must provide sufficient disclosure that would allow the person of ordinary skill to make and use his invention with reasonable certainty. Yet, when challenging a later-filed patent, the Federal Circuit treats the patent's identical disclosure as insufficient to support the same finding that the person of ordinary of skill would know how to make and use that same invention. The Federal Circuit thus treats the same person, at the same relevant time, as a highly-skilled artisan for granting patents but as an "automaton" for challenging patents.

Second, the Federal Circuit's routine application of a rigid legal test for pharmaceutical patents, known as the "lead compound test," is untethered from the text of § 103 and this Court's guidance on the law of obviousness. The Federal Circuit's error is again rooted in an imbalanced approach to how the hypothetical person of ordinary skill would view the scope and content of the prior art.

The first step of the Federal Circuit's test requires a patent challenger to prove that the person of ordinary skill would "select" a specific prior-art lead compound for further development. This threshold requirement improperly acts as gatekeeper to this Court's *Graham*

factors and subverts the holistic, multi-factor objective obviousness inquiry into a single, subjective, threshold question. If a judge rejects the selected lead compound, that lead compound is deemed to be irrelevant prior art, thus ending the obviousness inquiry and preventing the otherwise expansive obviousness inquiry this Court requires. The district court here did just that, despite making findings showing the claims would have been obvious otherwise.

The Federal Circuit's deviations from obviousness doctrine are not esoteric questions of patent law. They distort the market by favoring improperly obtained rights to old pharmaceutical technologies that should be in the public domain. In passing the Hatch-Waxman Act, Pub. L. 98-417, 98 Stat. 1585 (1984), to reform the pharmaceutical market and the patent system's role in it, Congress incentivized generic drug companies to challenge invalid patents. Yet, the Federal Circuit shields these patents by unilaterally granting pharmaceuticals a highly protective obviousness standard. This unauthorized subversion of legal standards frustrates innovation and access to medicines that are squarely in the public domain. This Court should grant certiorari to correct the Federal Circuit's flawed interpretation of Supreme Court precedent, to give effect to the plain language of the Patent Act, and to restore uniformity to this important area of law.

A. Lacosamide, the Prior Art, and the State of Technology

This case concerns the validity of U.S. Patent RE38,551 ("the '551 patent"), which claims the phar-

maceutical compound "lacosamide". App.4a. Lacosamide is the active ingredient in an AED marketed as Vimpat®. *Id.*

1. The Two Ways to Describe Lacosamide

The technology-at-issue can be explained in two ways. First, lacosamide can be described as the patent-at-issue does: a chemical compound with known components that can be substituted in three known chemical positions. Second, lacosamide can be described by how it differs from a prior art compound known as "107e": the same chemical structure but conventionally purified to maximize its antiepileptic effect.

(1) Lacosamide belongs to a class of compounds called "functionalized amino acids" ("FAAs"), known to exhibit anticonvulsant activity. *See* App.4a-5a. FAAs have a common structure that allows substitutions at only three chemical positions. App.4a. These three positions are represented by the variables R, R1, and R3. *Id.*

At the time of the '551 patent's filing, benzyl and methyl were often used at the R and R1 positions, respectively. *See* App.35a, App.123a-124a. Lacosamide has benzyl at R and methyl at R1, with methoxymethyl at R3. App.5a.

(2) Lacosamide's chemical components never change, but those components can be positioned in three-dimensional space in one of two ways. One spatial positioning of the compound is referred to as the "R-enantiomer", the other is the "S-enantiomer". App.4a-5a; *see also* App.56a-57a. These relative positions are similar to one's right and left hands: both have five fingers, but each hand is a mirror image of the other.

Accordingly, the compound as claimed is actually an R-enantiomer mixture. *See* App.120a.

2. The Difference Between the Prior Art and the Claimed Compound

In 1987, nine years prior to the '551 patent's application filing, Phillippe LeGall published a thesis disclosing fifteen FAAs as anticonvulsants ("LeGall").[2] App.71a-72a. LeGall explained that one of those compounds, 107e, "may have good anticonvulsant activity" because it was structurally similar to another effective anticonvulsant compound known at the time. App.74a. Compared to lacosamide, compound 107e is structurally identical, with the same substitution pattern (*i.e.*, benzyl at R, methyl at R1, and methoxymethyl at R3). App.41a-42a.

The *only* difference between compound "107e" and "lacosamide" as claimed is the relative purity of the enantiomer mixtures. Compound 107e contains 50% of the R-enantiomer, whereas the contested claims require purification to at least 90% of the R-enantiomer. *See* App.6a-7a, App.120a. No one disputes that, when the '551 patent was filed, a person of skill knew how to purify FAAs and understood that an FAA's R-enantiomer, rather than its S-enantiomer, conferred the compound's anticonvulsant activity. *See* App.122a, App. 145a-146a, n.31. Accordingly, at the time of the invention, a person of ordinary skill would have known how

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[2] LeGall is prior art under 35 U.S.C. § 102(b). App.71a-72a. The Patent Office did not consider LeGall when it examined the application that issued as the '551 patent. App.74a.

and why to isolate the R-enantiomer from prior art compound 107e in excess of 90%. *See* App.122a-123a.

B. Respondents' History of Tactically Patenting Lacosamide

No one disputes that Respondents obtained multiple patents covering lacosamide. The compound was synthesized, tested and tactically claimed with varying specificity. In all, Respondents serially received three patents that cover lacosamide and publicly represented that two of those patents claim lacosamide. By their own statements, Respondents have patented the same invention more than once.

1. Respondents Claim Lacosamide Again and Again

In late 1994, Respondents synthesized and tested lacosamide. App.64a, App.129a.

In January 1995, Respondents received U.S. Patent No. 5,378,729 ("the '729 patent"), its first patent directed to FAAs effective for use as an AED. *See* App.74a-75a. With lacosamide already in hand, the '729 patent claimed a broad genus of FAAs where, like lacosamide, the R and R1 positions were benzyl and methyl, respectively, and the R3 position was claimed as a variable that allowed for the selection of methoxymethyl. Accordingly, no one disputes that the '729 patent covers lacosamide. App.103a.

In August 1995, Respondents received a second patent, U.S. Patent No. 5,654,301 ("the '301 patent"),

also directed to FAAs used as AEDs.[3] *See* App.78a. This time, Respondents added claim 45 encompassing a different genus of FAAs during prosecution. App. 128a-129a. Rather than explicitly claim each of lacosamide's components, the genus inverted the R positions claimed by the '729 patent. Whereas R3 was previously claimed as a variable and R and R1 held constant, now R3 was claimed as methoxymethyl, and R and R1 were claimed as variables. The variables permitted the selection of benzyl and methyl, at R and R1 respectively. *See* App.80a-82a. Accordingly, no one disputes that the '301 patent covers lacosamide. *See* App.81a.

With both the '729 and the '301 patents, Respondents stated that the FAAs generically disclosed were effective as AEDs. *See* App.75a-App.76a, App.80a, App. 82a. The patents, however, did not specifically describe lacosamide nor provide explicit guidance to make and use lacosamide. *See id.* Instead, the patents relied on the level of skill of those in the art to understand what had been invented.

In 2004, Respondents received a third patent, the '551 patent, again directed to FAAs used as AEDs.[4] *See* App.85a. The '551 patent claimed lacosamide directly and is the patent-at-issue in this case. *See* App.86a.

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[3] Unlike the '729 patent, the '301 patent is not prior art to the '551 patent. App.78a. But, as described below, the '301 patent was the proper subject of an obviousness-type double-patenting analysis. *Id.*

[4] The '551 patent is a reissuance of U.S. Patent No. 5,773,475, which originally issued in 1998. Reissuance was sought to correct a priority claim; the claims did not change. App.85a, App.105a-106a.

2. Respondents Represent that the '301 Patent *and* the '551 Patent Cover Lacosamide

Respondents submitted three New Drug Applications ("NDAs") for Vimpat® to the FDA. In 2008, Vimpat® was approved, and subsequently launched that same year. App.55a.

In the first two NDAs, Respondents listed the '301 patent in the FDA's "Orange Book," App.78a, thus representing to the agency, and the public, that the '301 patent covered lacosamide. *See* 21 U.S.C. § 355 (b)(1) ("The applicant shall file with the [NDA] the patent number and the expiration date of any patent which claims the drug . . . and with respect to which a claim of patent infringement could reasonably be asserted[.]"); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

By listing the '301 patent, Respondents received certain statutory benefits: (1) an avenue to sue a generic drug applicant for patent infringement before the drug is marketed, *see* 35 U.S.C. § 271(e)(2)(A); and (2) a 30-month regulatory stay of FDA-approval for a generic drug application, *see* 21 U.S.C. § 355(j)(5)(B)(iii).

In its third NDA, Respondents listed the '551 patent in the Orange Book as also covering lacosamide. App.85a.

After Vimpat®'s approval, Respondents petitioned the Patent Office to extend the patent terms of both the '301 patent and the '551 patent. App.87a. To extend the '301 patent's term, Respondents represented to the Patent Office that the '301 patent "claim[s]

. . . lacosamide." The Patent Office agreed. App.87a-88a.

For the '551 patent, Respondents similarly represented that the '551 patent claims lacosamide. Again, the Patent Office agreed. *See* App.87a. The Patent Office informed Respondents that only one patent could receive an extension, so Respondents elected to extend the later-expiring '551 patent. App.87a-88a.

With the '551 patent originally set to expire in 2017, Respondents received an additional five years of patent protection for lacosamide, extending their exclusivity over the compound to 2022. Respondents have had exclusive rights to lacosamide starting in 1995 based on the '729 and '301 patents, and continuing until the '551 patent expires in 2022. Respondents will have enjoyed over 27 years of patent protection on the same compound: lacosamide.

C. The District Court's Decision

Petitioners sought approval to market generic versions of Vimpat® by filing Abbreviated New Drug Applications ("ANDAs") at the FDA. App.107a-108a. Respondents sued Petitioners for infringement of the '551 patent under the Hatch-Waxman Act. App.44a-45a. During trial, Petitioners asserted that lacosamide was obvious over claim 45 of the '301 patent, which invalidated the '551 patent due to impermissible double-patenting. Petitioners also asserted that lacosamide was, *inter alia*, obvious under § 103 based on LeGall, which disclosed the structurally identical compound, 107e.

1. Obviousness of Lacosamide Under Double-Patenting

Following this Court's guidelines, a party is prohibited "from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); *accord Miller v. Eagle Mfg.*, 151 U.S. 186, 196-97 (1894). The district court applied the Federal Circuit's obviousness-type double-patenting analysis, in which "the court 'determines whether th[e] differences [between the claims in a commonly-owned earlier patent] render the claims [of the later patent] patentably distinct.'" App.16a (quoting *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014)). The analysis mirrors an obviousness analysis. *See* App.109a-111a.

The district court determined that, like lacosamide, claim 45 of the '301 patent has methoxymethyl at the R3 position, but permits a number of options for the R and R1 positions. These options included benzyl and methyl (as previously claimed by Respondents in the '729 patent). *See* App.81a-82a. However—despite the prior patents being directed to effective anticonvulsants—the district court concluded that absent experimental data proving its effect, a person of ordinary skill would not have had a "reasonable expectation" in forming an AED with benzyl at R and methyl at R1. *See* App.122a-129a. Lacosamide thus was held not obvious over claim 45 of the '301 patent. App.130a.

2. Statutory Obviousness of Lacosamide Under 35 U.S.C. § 103

The factual findings made by the district court that show obviousness of lacosamide over LeGall's prior art FAA compound, 107e, include:[5]

(1) LeGall's compound 107e is an unpurified equal mix of lacosamide forms (R-/S-enantiomers). App.72a.

(2) LeGall hypothesized that, due to structural similarities between compound 107e and another known compound, compound 107e "may have good anticonvulsant activity." App.74a.

(3) A person of ordinary skill would have known that purifying any FAA to substantially include only its R-enantiomer would result in an AED with far greater effectiveness. App.122a-123a.

(4) A person of ordinary skill would have known that compound 107e's properties derived from its R-enantiomer. App.145a-146a n.31.

(5) A person of ordinary skill would have known how to isolate the R-enantiomer from any FAA. *Id.*

Respondents did not offer any evidence that would support findings contrary to those above. *See* App.72a-

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[5] The district court explained "[e]ssentially all of the discussion . . . in the context of double patenting applies equally with respect to obviousness." App.143a. Accordingly, findings of fact applied in the district court's obviousness-type double patenting analysis similarly apply to the statutory obviousness decision.

74a, App.122a-123a. Yet, instead of concluding that these findings were sufficient to prove the obviousness of lacosamide, the district court first analyzed whether it could even consider LeGall, and its disclosure of compound 107e, as relevant prior art. *See* App.145a-148a. This analysis was entirely predicated on the court's determination that, as a matter of law, it "must apply a 'lead compound analysis[]' . . . because the claims at issue disclose a chemical compound." App. 145a. As the district court acknowledged, the test "favor[s] Plaintiffs . . . because [it] *require[s] Defendants to prove more things*—mak[ing] it *more difficult* for Defendants to prove the claims of the patent-in-suit are invalid for obviousness." App.143a-144a (emphasis added).

> The lead compound test requires two steps:
>
> First, the court determines whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts. . . . A lead compound. . . is "a compound in the prior art that would be *most* promising to modify in order to improve upon its . . . activity and obtain a compound with better activity." . . .
>
> The second inquiry in the analysis is whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success.

Otsuka Pharm. Co., Ltd. v. Sandoz, Inc., 678 F.3d 1280, 1291-92 (Fed. Cir. 2012) (emphasis added) (citations omitted); *see also* App.145a-146a.

Applying the test's first step, the district court determined that Petitioners were required to prove whether a person of ordinary skill "would know that compound 107e . . . possessed promising or desirable properties sufficient to warrant [the person's] attention." App.145a-146a n.31. In answering that question in the negative, based primarily on the lack of experimental data associated with the compound, the district court concluded that the person of ordinary skill would not have "selected" compound 107e "as a starting point" for further development as an AED. *See* App.147a-148a. Thus, the scope and content of LeGall and the remaining *Graham* factors were not considered as the Court intended, and the district court's obviousness analysis ended prematurely. Lacosamide was held not obvious over the prior art.

The district court highlighted the dispositive nature of the lead compound test, and its threshold "selection" step, concluding:

> These facts are sufficient to show that a POSA would have found it obvious to isolate the R-enantiomer of any FAA [*e.g.*, compound 107e] *that was selected for further development*.

App.123a (emphasis added). In other words, but for the test's first step, a person of skill would have found lacosamide obvious over compound 107e.

D. The Federal Circuit's Decision

On appeal to the Federal Circuit, Petitioners explained that the district court committed two critical legal errors in assessing the obviousness of lacosamide. First, Petitioners argued that lacosamide had been previously patented within the genus claimed by claim 45 of the '301 patent. Petitioners argued that the presumed, *and relied upon*, enablement of the '301 patent established that a person of ordinary skill would have had "a reasonable expectation of success [in making lacosamide] as a matter of law." App.24a. Second, Petitioners argued that "the district court erred by using a lead compound test because this case merely involves purification[.]" App.26a. A panel majority affirmed the district court's conclusions that lacosamide was not obvious under both theories.

The Federal Circuit declined to accept Petitioners' first argument concerning double patenting. The majority concluded that "such a result would have a chilling effect on genus claiming in the chemical arts as there would be double patenting in all chemical compound cases where a parent patent claims a genus." App.25a. The majority thus affirmed the district court's conclusion that lacosamide was not obvious over claim 45 of the '301 patent, despite the fact that Respondents relied on the same enabling disclosure to gain market exclusivity over exactly one species: lacosamide. *Id.*

With regard to Petitioners' second argument, the majority *said* that a lead compound test was not required in this case, stating "an obviousness rejection by an examiner, or a challenge in court, may be based on the closest prior art[.]" App.28a. Nonetheless, the court identified no other basis for affirmance than the

district court's application of the lead compound test: "*In any event, even if a lead compound analysis is required here*, we hold that the district did not clearly err in finding that a person of ordinary skill in the art would not have selected compound 107e as a lead compound." *Id.* (emphasis added). Thus, even though it determined that the entire foundation of the district court's obviousness analysis was legally erroneous (*i.e.*, the district court's belief that it "*must* apply a 'lead compound analysis[,]'" App145a (emphasis added)), the Federal Circuit affirmed the district court's obviousness analysis, which *exclusively* relied on the rigid lead compound test and the limited evidence permitted past its threshold inquiry. *See* App.28a-29a ("*Based on this evidence*, we see no clear error in the district court's fact findings and sustain its conclusion that the asserted claims of the '551 patent would not have been obvious.") (emphasis added).

Chief Judge Prost dissented, taking issue with the majority's affirmance on the issue of double patenting. App.32a. She pointed to three legal errors in the district court's decision. First, she determined that the district court erred by requiring experimental data to establish that a person of ordinary skill would have had a reasonable expectation of success in using lacosamide when the prior art showed that the selected substituents (benzyl and methyl) "will work." App.38a. Second, Chief Judge Prost determined the district court erred by discounting strong evidence that a person of ordinary skill would have had a reasonable expectation of success in selecting the specific substituents to create an FAA having an anticonvulsant effect. App.39a-40a. Finally, Chief Judge Prost determined the district

court erred when it failed to consider LeGall in its double-patenting analysis. App.41a-43a.

REASONS FOR GRANTING THE PETITION

This case presents questions of exceptional importance to patients, healthcare providers, the pharmaceutical market, and the patent community. Underlying both issues is the Federal Circuit's failure to uphold foundational concepts of obviousness for chemical compounds, which has allowed serial patenting of public-domain technologies to pervade this technology.

The Patent Act codified the legal standard for obviousness in 1952, and this Court confirmed that standard in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). The standard, like all other requirements the Patent Act imposes, aims to uphold "the underlying policy of the patent system that 'the things which are worth to the public the embarrassment of an exclusive patent,' as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly." *Id.* at 10-11. Obviousness is a question of law; an objective analysis based on multiple factors:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial

> success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Id. at 17-18. These *Graham* factors, reinforced by this Court's later decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), must be applied flexibly, expansively, and realistically.

Losing sight of the overarching principles underlying obviousness, the lower courts have deviated from *Graham* and erred in the aforementioned ways:

First, despite Respondents' representations that it had obtained exclusive rights to lacosamide with two distinct patents, the Federal Circuit allowed Respondents to circumvent the prohibition against double-patenting and obtain another patent covering what had already been conveyed to the public. The court did so by applying a restrictive and asymmetric standard for the person of ordinary skill. Specifically, the Court refused to recognize that, when a patentee's earlier-claimed genus has enabled a person of ordinary skill to make and use a certain species, that same genus should also make the species obvious to that person of ordinary skill. Failing to apply a balanced level of ordinary skill protects a harmful practice that pervades the pharmaceutical market: patent misuse via the ever-greening of monopolistic rights over compounds already given to the public beyond the limited term Congress authorized. *See generally* I-MAK, *Overpatented, Overpriced: How*

Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices.[6]

Second, the Federal Circuit's lead compound test departs from this Court's obviousness precedents by improperly restricting the scope and content of the prior art, which is exacerbated by an unrealistic view of the person of ordinary skill. As the district court explicitly recognized, this test imposes an additional threshold to prove chemical obviousness. In this case, but for the patent-at-issue being directed to a pharmaceutical compound, the district court would have found the invention obvious. The Federal Circuit's technology-specific, restrictive test finds no support in either the text of the Patent Act or the precedent of this Court.

This Court should grant review to correct the misapplication of well-established law and restore consistency to double-patenting and obviousness law as applied to pharmaceutical patents.

I. EACH PATENTABLE INVENTION IS ENTITLED TO ONLY ONE PATENT

The principle that an inventor is entitled to, at most, a *single* patent per invention should not be controversial. *See Miller*, 151 U.S. at 198 (declaring "no patent can issue for an invention actually covered by a former patent, *especially to the same patentee*[.]") (emphasis added). The Constitution grants Congress the authority "[t]o promote the *Progress* of Science and useful Arts, by securing for *limited Times* to Authors

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[6] Available at: http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf (last visited Nov. 18, 2018).

and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8 (emphasis added); *see also Graham*, 383 U.S. at 6 ("Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.' This is the standard expressed in the Constitution and it may not be ignored."). Thus, embedded in the enumerated grant of Congressional authority is a *quid pro quo* that the Founders recognized benefits society: a limited financial incentive for those willing to invest their creative and scientific talents in exchange for the public's immediate knowledge of their discoveries. Upon expiration of the exclusive right, the public then receives unencumbered use of those creations.

This Court has explained that a patentee is not entitled to a second later-expiring patent on the same invention. *Miller*, 151 U.S. at 198. The second patent instead "must consist in something more than a mere distinction of the breadth or scope of the claims of each patent[; otherwise] the second patent is absolutely void." *Id.* Plainly, a patentee may "not take out a subsequent patent for a portion of his first invention, and thereby extend his monopoly beyond the period limited by law." *O'Reilly v. Morse*, 56 U.S. 62, 114 (1853).

The Federal Circuit, following this Court's precedent, has referred to this prohibition as the doctrine of obviousness-type double-patenting. The doctrine embraces principles associated with § 103, which—in theory—prohibit a patentee from obtaining claims in a later-expiring patent that "are not patentably distinct from claims in a commonly owned earlier patent." *Eli*

Lilly, 251 F.3d at 967. "[T]he fundamental reason for [this] rule is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *Id.* at 968.

Respondents' representation that it patented the same invention—lacosamide—in an earlier patent is sufficient to invalidate the '551 patent under the clear precedent of this Court. The Federal Circuit, however, has circumvented this Court's proscription by applying an imbalanced and flawed understanding of the hypothetical person of ordinary skill in the art.

A. Respondents Admit to Serially Patenting the Same Claimed Invention

After synthesizing and testing lacosamide in 1994, Respondents sought exclusive rights to the compound with the genus covered by claim 45 of the '301 patent. Respondents then unequivocally put the world on notice—via sworn statements to two federal agencies—that the '301 patent covered lacosamide within its bounds, giving Respondents rights to exclude others from making and using lacosamide. Respondents' subsequent claiming of lacosamide in the '551 patent, and public admission that it also covers lacosamide, constitutes *per se* evidence that the same patentee received a second invention "actually covered by a former patent." *Miller*, 151 U.S. at 198. Under this Court's precedent concerning double-patenting, the '551 patent is void.

B. The Federal Circuit's Imbalanced Treatment of Ordinary Skill Permits Respondents' Serial Patenting

Despite Respondents' representations that both the '301 patent and the '551 patent cover lacosamide and thus are *not* "distinctly different and independent from that covered by the first patent," *Miller*, 151 U.S. at 198, the courts nonetheless failed to give meaning to this Court's principles against the improper extension of rights and invalidate the second patent. They applied a level of ordinary skill that is facially at odds with the level Respondents relied upon to gain exclusive rights to lacosamide with the '301 patent.

The level of skill in the art is measured no later than the time of a patent's filing for both enablement and obviousness. *See* 35 U.S.C. § 103(a); § 112, ¶1. Thus, the knowledge and abilities attributable to those in the art must be *exactly the same* when assessing whether a patent has enabled an invention or rendered a later-filed patent obvious. *See* 3 Donald S. Chisum, Chisum on Patents § 7.03[2][b] (2018) ("[T]he 'person skilled in the art' within the meaning of Section 112 is the same as the 'person having ordinary skill in the art' within the meaning of Section 103 on non-obviousness").

To obtain a patent, a patent applicant must provide "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable any person skilled in the art* to which it pertains[.]" 35 U.S.C. § 112, ¶1 (2012) (emphasis added). This enablement requirement does not require a detailed description of each and every embodiment of the claimed invention. Instead, the disclosure may rely on the skill

of those in the art to discern, with enough certainty that "is not greater than is reasonable," the subject matter disclosed and claimed. *Minerals Separation Ltd. v. Hyde*, 242 U.S. 261, 270 (1916).

With obviousness, the artisan's skill also determines whether the differences between a claimed invention and what came before it are obvious. *See* 35 U.S.C. § 103(a). In *KSR*, this Court explained that the hypothetical "person having ordinary skill" embraces realistic notions; one recognizing an ordinary person's "inferences and creative steps." *KSR*, 550 U.S. at 418. Like enablement, the person of ordinary skill does not require "precise teachings" to know what is obvious. *Id.* A person of skill is one "of ordinary creativity, not an automaton." *Id.* at 421.

No one disputes that the '301 patent claimed lacosamide as a species. *See* App.81a. However, the '301 patent did not describe lacosamide's structure. App.80a. It also did not provide experimental data showing lacosamide's anticonvulsant effects. App.82a. Instead, the '301 patent's disclosure relied on the high level of skill of those in the art to understand, with reasonable certainty, "the manner and process of making and using" the invented genus and its species, *including* lacosamide. *See* 35 U.S.C. § 112. This understanding allowed Respondents to obtain, and expressly proclaim, exclusive rights over lacosamide without actually disclosing lacosamide. To claim exclusive rights to lacosamide, Respondents necessarily contended (and thus admitted) the '301 patent provided knowledge of the compound to the public—knowledge that could be conveyed without explicitly describing, or providing data for, lacosamide.

Yet, paradoxically, under the Federal Circuit's obviousness reasoning, the same '301 patent did not provide the same person of ordinary skill with the same reasonable certainty because it did not describe lacosamide's specific structure and its specific effects as an AED.[7] *See* App.19a-25a. In other words, unless the '301 patent provided "precise teachings" to make and use lacosamide, that person would not have considered the compound obvious. In addition to being in clear tension with the level of skill assumed by the '301 patent, this approach improperly reduces the person of skill to "an automaton" for purposes of assessing obviousness. *See KSR*, 550 U.S. at 421.

When faced with this logical inconsistency, the Federal Circuit expressed concern that proper application of double-patenting would prevent patenting any species. App.24a-25a. Yet the Federal Circuit's concern overlooks the full scope of the *Graham* factors, which provides a well-established path for seemingly obvious inventions to show patentability through "secondary considerations". *See Graham*, 383 U.S. at 17-18 (listing examples such as "commercial success, long felt but unsolved needs, failure of others"); *KSR*, 550 U.S. at 415.

According to Respondents, the '301 patent conveyed the knowledge necessary to provide the public with lacosamide, as required by the bargain delineated by the Patent Act. *Cf. Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390, 400-01 (1926) ("The

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[7] This is despite, as Chief Judge Prost's dissent points out, the specific structure was actually disclosed by the prior art in LeGall. *See* App.41a-43a. As discussed more below, this failure to consider LeGall is just another, related symptom of the Federal Circuit's improper restriction of the scope and content of the prior art.

invention is made public property as much in the one case as in the other."). Logically, this same knowledge should render lacosamide obvious. The Federal Circuit's inconsistent and restrictive application of the person of ordinary skill allowed Respondents to extend their exclusive rights beyond the statutory limit. *See* Douglas L. Rogers, *Double Patenting: Follow-On Pharmaceutical Patents that Suppress Competition*, 14 Nw. J. Tech. & Intell. Prop. 317, 350 (2017) ("Put simply, a patentee should not be allowed to argue on the one hand he has invented the full scope of a genus but on the other hand subsequently defend a challenge to its species patent on the ground that he had not really invented the full scope of the genus at the time of the genus application.").

II. THE FEDERAL CIRCUIT'S RIGID LEAD COMPOUND TEST CONTRAVENES THE PLAIN LANGUAGE OF THE STATUTE AND THIS COURT'S CONTROLLING PRECEDENT

The Federal Circuit's approach to obviousness for pharmaceutical compounds produces incongruous results in its § 103 analysis.

In *KSR*, this Court re-affirmed the principles of the obviousness inquiry outlined in *Graham*, describing an approach that is "expansive and flexible." *KSR*, 550 U.S. at 415. There, the Court addressed the Federal Circuit's application of the "teaching, suggestion, or motivation" test ("TSM"). *Id.* at 407. According to the Court, what may have started as a "helpful insight" had transformed into a "rigid and mandatory formula[]"—one that led to an overly restrictive view of the prior art and the person of ordinary skill. *Id.* at 418-19.

The lead compound test, a pre-*KSR* innovation, is cut from the same cloth as TSM. *See, e.g.,* Briana Barron, *Structural Uncertainty: Understanding the Federal Circuit's Lead Compound Analysis,* 16 Intell. Prop. L. Rev. 401, 416 (2012) ("[T]he [lead compound] test is exactly the type of rigid application that the Supreme Court warned against in *KSR v. Teleflex.*"). First developed as a "helpful insight" to prevent hindsight, this case exemplifies the test's evolution into a rigid, threshold formula that is "untethered to the statutory text" of Section 103 of the Patent Act. *Cf. Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915 (2014).

Here, the district court held that, under Federal Circuit law, it "*must* apply a 'lead compound analysis.'" App.145a (emphasis added). Dutifully, the district court applied the mandatory formula, which required the judge to artificially limit the scope and content of the prior art and set an unrealistic standard for the person of ordinary skill. After deciding the test's first "selection" step failed, LeGall—a prior art reference found to expressly disclose lacosamide's structure in a form that would have been obvious to purify—was not considered when determining the "obviousness or nonobviounsess of the subject matter." *KSR*, 550 U.S. at 406 (quoting *Graham*, 383 U.S. at 17-18). The truncated obviousness analysis was dispositive: LeGall and the factual findings concluding that the skilled artisan would have found it obvious to purify any FAA compound were not given effect in determining the ultimate legal question of obviousness. App.123a.

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious . . . to a person having ordinary skill in the art. . . . " 35 U.S.C. § 103 (2012). The lead compound test flouts this plain language, misapplies the obviousness framework set forth in *Graham*, and disregards this Court's clear guidance in *KSR*.

Despite this controlling law, the Federal Circuit persists in applying a rigid, technology-specific analysis to pharmaceutical-compound patents. *See* 2 Donald S. Chisum, Chisum on Patents § 5.04B[6][d] (2018) ("Ironically, Federal Circuit decisions after the Supreme Court's *KSR* (2007) emphasized that prima facie obviousness required not only a structurally similar prior art compound but also a motivation to select that compound as a 'lead' compound for further research and, in addition, to modify that compound. This trend was ironic because *KSR* was critical of any 'rigid' application of a suggestion test and [has] been generally understood as stabilizing or even raising the patentability bar, not lowering it."). The rigidity of the Federal Circuit's lead compound test is exemplified by this case—where even the exact same structural compound—does not qualify as a "lead" compound.

A. The Lead Compound Test Improperly Constrains the First *Graham* Factor and Creates an Artificial Threshold

The first factual determination under *Graham* is to determine the scope and content of the prior art. *Graham*, 383 U.S. at 17. This initial step is essential for the obviousness inquiry because, as a matter of bedrock patent law, a person of ordinary skill is presumed to know and understand every reference in the

prior art. *See, e.g.*, *Mast, Foos & Co. v. Stover Mfg. Co.*, 177 U.S. 485, 493 (1900) (explaining that the person of ordinary skill in the art is "chargeable with a knowledge of all preexisting devices"); *Duer v. Corbin Cabinet Lock Co.*, 149 U.S. 216, 223 (1893) ("[H]e is deemed, in a legal point of view, to have had this and all other prior patents before him.").

The first step of the lead compound test unnecessarily restricts the first *Graham* factor by limiting what the court can consider as relevant prior art. That is, unless a challenger can first show that a known compound would have been "selected" as "most promising" by the skilled artisan for "further development," the differences between that compound and what is claimed are not assessed. *See Otsuka*, 678 F.3d at 1291-93 (requiring identification of a "lead compound" before "structural differences between the proposed lead compound and the claimed invention" are assessed); *accord* App.146a ("[T]he [c]ourt must first consider whether a POSA would have selected the asserted prior art compound as a lead compound.. . . If so, the [c]ourt must next consider whether it would have been obvious to move from the prior art compound to the patented compound.") (internal quotations omitted).

Such an approach impermissibly alters the *Graham* framework, which requires a factfinder to determine the full scope and content of the prior art and compare it to the claims-at-issue. The first "selection" step assumes, *a priori*, a nearly comprehensive teaching away of all prior-art compounds until proven otherwise. This shifts the burden to the challenger to show that the art had identified some ideal lead that was the "most promising" to pursue. The inquiry, in turn, transforms

from a holistic understanding into a constrained and blinkered understanding of the prior art.

The restrictive first step of the lead compound test rewrites this Court's fundamental guidance and acts as a stringent evidentiary filter for the scope and content of the prior art. This artificial threshold finds no textual support in the statute, and is directly contrary to the holdings of *Graham* and *KSR*.

B. The Lead Compound Test Ignores the Skill and Creativity of the Person of Ordinary Skill

The lead compound test also runs contrary to *KSR*'s teaching that the obviousness analysis embraces the realities of the person of ordinary skill and the process of discovery—one that includes numerous reasons that may drive the skilled artisan to seek a given option. In *KSR*, the Court embraced the view that even without certainty of success, the person of ordinary skill may still pursue a known option that would be "obvious to try"—a concept that had been previously restricted by the Federal Circuit:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR, 550 U.S. at 421.

The lead compound test inverts this flexible approach provided by *KSR*. For instance, here, rather than considering whether purification of a known, promising compound, 107e, would have been "obvious to try" based on a "good reason," the district court intentionally ignored this possibility. Instead the court explained, under the lead compound test's first step, a person of ordinary skill would only consider a compound as "lead" if it was "most promising" to modify to obtain a compound with "better activity." *See* App.26a-27a (defining "lead compound"). Accordingly, despite the district court finding that purifying an FAA, with a suspected anticonvulsant effect, like 107e, presented an "identified, predictable solution[], a person of ordinary skill ha[d] good reason to pursue. . . " its hands were tied. *Id.*

This restrictive test not only runs afoul of *KSR*, but is particularly unsuitable for cases, just like this one, that admittedly deal with *routine* purification of a *known* mixture of *known* enantiomers—the mainstay of the chemist's art. *See, e.g.*, *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) ("[T]he purified compound is prima facie obvious over the [unpurified] mixture even without an explicit teaching that the ingredient should be concentrated or purified."); *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990) (en banc); *cf.* Mark A. Lemley, *Expecting the Unexpected*, 92 Notre Dame L. Rev. 1369, 1378 (2017) ("[S]cientists in the field are motivated to separate the enantiomers by the likelihood that there would be at least some substantial improvement in the efficacy of the drug, so they are motivated to separate the mixture even apart from the possibility of a multiplier effect.").

Furthermore, if chemical properties are to be considered, simply requiring "better activity" disregards every other real-world, objective reason a person of skill might have in selecting or further developing a compound. These reasons include increased stability, decreased cost, ease in making, ease in sourcing, ease in handling, blocking patents or any other practical consideration. Under Federal Circuit precedent, however, none of these considerations would factor into the obviousness analysis with its restrictive first step. Instead, the test invites subjective, post-hoc expert testimony as to the promise of "better activity."

The prejudicial nature of the lead compound test is made more apparent in this case with the Federal Circuit's suggestion that the lead compound test is not necessarily a requirement. The court explained that "[a] lead compound analysis is not required in analyzing obviousness of a chemical compound, when *in the inventing process*, there was no lead compound." App.28a (emphasis added).[8] That is, whether an *inventor* sought a "lead" dictates whether an examiner or a challenger in court must meet the lead compound test in proving

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[8] *But see Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1352 (Fed. Cir. 2010) ("Proof of obviousness based on structural similarity *requires* clear and convincing evidence that a medicinal chemist of ordinary skill would have been [1] motivated *to select* and then [2] *to modify* a prior art compound (*e.g.*, a lead compound) to arrive at a claimed compound with a reasonable expectation that the new compound would have similar or improved properties compared with the old.") (emphasis added); *Ateliers de la Haute-Garonne v. Broetje Automation USA Inc.*, 717 F.3d 1351, 1358 n.3 (Fed. Cir. 2013) ("[Even if] these decisions of precedent have been superseded by conflicting panel decisions.. . . if conflict had arisen, the rule is that the earlier panel decision controls unless overruled en banc.").

obviousness. This cannot be. The subjective actions of the inventor (rather than the objective actions of a hypothetical artisan) cannot set case-specific legal standards for obviousness. This conclusion, in essence, mirrors an error *KSR* identified: the obviousness inquiry cannot be dictated by "look[ing] only to the problem the patentee was trying to solve." *KSR*, 550 U.S. at 420.

The effect of the lead compound test is similar to the hard application of the TSM test rejected in *KSR*. Both are artificial additions to the *Graham* factors that limit the teachings of the prior art and restrict the understandings of a person of ordinary skill. Indeed, the artificial "selection" step of the lead compound test is one that the district court explicitly acknowledged requires a challenger "to *prove more things*—mak[ing] it *more difficult* for [challengers] to prove . . . obviousness." App.143a-144a (emphasis added). The Federal Circuit's "more difficult" standard for pharmaceutical patents does not accord with § 103. *See* § 103 (requiring courts to determine "the differences between the subject matter sought to be patented and the prior art"); *see also Derby v. Thompson*, 146 U.S. 476, 481-82 (1892) ("[W]e are bound, in passing upon his device, to assume that he had them *all* [prior art] before him.") (emphasis added); Douglas L. Rogers, *Federal Circuit's Obviousness Test for New Pharmaceutical Compounds: Gobbledygook?*, 14 Chi.-Kent J. Intell. Prop. 49, 100 (2014) (Section 103 "requires a comparison of prior art to the claim, whereas the Federal Circuit test starts with comparing prior art to a lead compound, which is not even part of the claim. . . . ").

Rigidly restricting the scope of relevant prior art and excluding the practical insights of those skilled in

the art biases the obviousness inquiry against patent challengers. It requires challengers to prove their case without the benefit of the skilled artisans' holistic appreciation of prior art teachings and motivations. As the district court's findings show, when the differences between lacosamide and the prior art compound 107e are viewed from the perspective of a person of ordinary skill in the art with normal creativity—and without an additional gatekeeping filter—lacosamide would have been obvious. *Supra* at section III.B.

C. The Federal Circuit's Approach Erects Unnecessary, Judge-Made Barriers to Proving Old Technologies Obvious

The lead compound test is another judicial augmentation of the *Graham* factors. As with the rigid TSM test, the stated rationale for the lead compound test is that it acts as a prophylactic against hindsight. *See Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 970 (Fed. Cir. 2014) ("A patent challenger, however, must demonstrate the selection of a lead compound based on its 'promising useful properties,' not a hindsight-driven search for structurally similar compounds.") (citing *Daiichi,* 619 F.3d at 1354). However, as this Court appreciates, the dangers of hindsight bias have long been understood and are already necessarily guarded against in *every* proper obviousness inquiry:

> The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. *See Graham*, 383 U.S. at 36

> (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into use of hindsight'"). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

KSR, 550 U.S. at 421. Such preventative rules against hindsight are unnecessary when evidence of obviousness is proven upon showing a skilled artisan's appreciation for the scope and content of the prior art *at the time of the invention*. *Graham*, 383 U.S. at 36.

This technology-specific attempt to prevent hindsight is unauthorized. Congress has already modified the patent system to balance the pharmaceutical market's competing interests. "The goal of the [Hatch-Waxman] act is to better balance two competing interests in the pharmaceutical industry: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008). This balance includes an opportunity for patentees of new pharmaceuticals to extend their patent term lost by the federal approval process. While promoting competition frustrated by invalid pharmaceutical patents, Congress did not choose to raise the bar for proving those pharmaceutical patents obvious. *See generally* Hatch-Waxman Act, Pub. L. 98-417, 98 Stat. 1585 (1984). The Federal Circuit's self-made pharmaceutical-specific approach is thus ultra vires.

III. THE FEDERAL CIRCUIT'S RIGID AND UNAUTHORIZED APPROACH TO OBVIOUSNESS CREATES PERVERSE RESULTS

The Federal Circuit's approach to obviousness of pharmaceutical compounds contravenes the statutory mandate and basic policy that underlies the patent system to ill effect. This case illustrates how the public must pay twice for the same knowledge.

Both errors by the courts below granted Respondents exclusive rights to a compound that was structurally known and obvious to purify since 1987. Respondents also benefitted from the exclusive rights afforded by multiple patents on the same invention. Indeed, Respondents tactically prosecuted patent applications to receive *three* patents that iteratively covered lacosamide: the '729 patent, which specifically claimed lacosamide's R and R1 positions; the '301 patent, which specifically claimed its R3 position; and the '551 patent, which specifically claimed all three. Respondents' patent-claiming shell-game ensures that the same commercial embodiment, Vimpat®, received extended patent protection—in the form of 27 years from issuance of the '729 and the '301 patents—with no further investment and without providing additional return to society.

Such tactics amount to an abuse of the patent system and contribute to an untenable status quo that leaves one in four families struggling to pay for medically necessary prescription drugs. Kaiser Health Tracking Poll: September, 2016, The Henry J. Kaiser

Family Foundation.[9] The crisis has grown so desperate that 19 million Americans purchase their medicines abroad due to high drug prices. Kaiser Health Tracking Poll: November, 2016, The Henry J. Kaiser Family Foundation.[10]

This scourge on the patent system affects more than just patients. Insurers, such as the federal and state governments, as well as small and large businesses, must pare healthcare coverage to ensure solvency. When such patent shenanigans occur as a matter of course, patients suffer real-world medical and financial consequences that generic pharmaceutical companies are well-positioned, and legislatively incentivized, to address.

Abuse of the patent system to protect public-domain technologies results in delayed competition and effectively taxes citizens and employers with billions in patent arbitrage. As this case demonstrates, double-dipping on "innovation" costs borne by the public is unjustifiable, as a matter of law and policy, when there is *no* tangible advancement in technology and *no* public benefit. Petitioners are generic companies that fully understand that without innovation and a balanced patent system there would be no generic pharmaceutical industry. Congress acknowledged that many pharmaceutical patents are erroneously granted and thus incentivized the same generic industry to challenge unwarranted patents to ensure patients do

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[9] Available at: https://www.kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/.

[10] Available at: https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-november-2016/.

not continue to pay monopolistic drug prices for old technologies. The Federal Circuit cannot frustrate this Congressional mandate. Pharmaceutical patenting is overdue for correction.

IV. This Case Is an Ideal Vehicle to Correct the Federal Circuit's Erroneous Practice and to Reaffirm the Law of Obviousness

This case is an ideal vehicle to decide the questions presented because it provides a stark example of how the Federal Circuit's flawed double-patenting doctrine permits patentees to tactically claim the same invention multiple times. This case also illustrates how the Federal Circuit's formulaic lead compound test forces district courts to ignore facts sufficient to prove prima facie obviousness under the *Graham* factors.

Furthermore, this case is well-suited for this Court to provide guidance on analyzing obviousness of chemical compounds structurally similar to prior art compounds under *KSR* and *Graham*. Although the problem may seem confined to pharmaceutical compounds, the issues at bar risk pervading other areas of technology. Indeed, recognizing the significant advantage they give pharmaceutical patentees, some commentators have suggested that these deviations from the *Graham* factors be extended to all technologies. *See generally* David J. Martens, et al., *Lead Prior Art Methodology: Applying Lead Compound Case Law to Other Disciplines for Enhanced Objectivity*, 27 Santa Clara High Tech L.J. 551 (2011); David Tseng, *Not All Patents are Created Equal: Bias against Predictable Arts Patents in the Post-KSR Landscape*, 13 Chi.-Kent J. Intell. Prop. 165 (2013). The Court should state forthrightly that pharmaceutical compounds—or any species

of invention—are not exempt, either explicitly or by implication, from this Court's teachings on obviousness under the Patent Act. As long as old drugs receive perpetual exclusive rights, patients and those who pay for their care will suffer.

Respectfully submitted,

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