15-1210

No. 15-

IN THE

Supreme Court of the United States

CUBIST PHARMACEUTICALS, INC.,
Petitioner,

v.

HOSPIRA, INC.,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1 (1966), this Court recognized the relevance of "objective indicia" of nonobviousness (also known as "secondary considerations")—including the long-felt need for the patented invention, the failure of others to arrive at the invention, and the invention's subsequent commercial success—in determining whether a patent's claims were obvious to a person of ordinary skill in the art. In this case, the district court created, and the Federal Circuit affirmed, two categorical limitations on the consideration of objective indicia of nonobviousness that exist nowhere in the Patent Act or this Court's jurisprudence.

The questions presented are:

1. Whether a court may categorically disregard objective indicia of a patent's nonobviousness merely because the considerations apply to one commercial embodiment of a patented invention, rather than all embodiments.

2. Whether a court may categorically disregard objective evidence of a long-felt need for a patented invention merely because the need is not expressly recited in the patent claims.

RULE 29.6 DISCLOSURE STATEMENT

Cubist Pharmaceuticals LLC (formerly known as Cubist Pharmaceuticals, Inc.) is a wholly-owned subsidiary of Merck & Co., Inc. Merck & Co., Inc. is not owned by any parent corporation and, to its knowledge, no other publicly held corporation owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

CASES

TABLE OF AUTHORITIES—Continued

STATUTES

TABLE OF AUTHORITIES—Continued

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Cubist Pharmaceuticals LLC (formerly known as Cubist Pharmaceuticals, Inc.) respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit (App. 1a-34a) is reported at 805 F.3d 1112. The Federal Circuit's erratum correcting its original opinion (App. 35a) is unreported. The Federal Circuit's denial of Cubist's combined petition for panel rehearing and rehearing *en banc* (App. 97a-98a) is unreported. The memorandum opinion of the United

States District Court for the District of Delaware finding the asserted claims of Cubist's patents invalid as obvious (App. 37a-96a) is reported at 75 F. Supp. 3d 641.

JURISDICTION

The district court had subject-matter jurisdiction over this case under 28 U.S.C. §§ 1331, 1338, 2201, and 2202. The Federal Circuit's judgment was entered on November 12, 2015. App. 1a. Cubist filed a timely combined petition for panel rehearing and rehearing *en banc* on December 14, 2015, which was denied on January 22, 2016. App. 97a-98a. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

INTRODUCTION

This case concerns significant and unwarranted changes to the standard for evaluating the obviousness of patent claims. Through the decisions below, the district court and Federal Circuit have effectively removed from consideration a key element in the obviousness test that this Court set out in *Graham* v. *John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)—objective indicia of nonobviousness—in a sizable share of patent cases, including the case at bar. The changes announced below will restrict a patent owner's ability to rely on relevant, probative evidence bearing on patent validity, particularly when claims recite a genus of multiple embodiments not all of which have the same characteristics.

The patents at issue in this case relate to daptomycin, a powerful antibiotic for the treatment of life-threatening bacterial infections. Although the prior art disclosed daptomycin, it was Cubist that first discovered particular methods for administering, and pro-

cesses for manufacturing, daptomycin in a way that made it consistently safe and effective for use in patients. Cubist's commercial embodiment of the claimed inventions, Cubicin®, was widely recognized as a breakthrough treatment for serious bacterial infections. Many follow-on manufacturers, including respondent Hospira, sought to capitalize on Cubist's discovery, and Cubist brought suit to protect its intellectual property.

At trial in the district court, Hospira argued that Cubist's asserted patent claims were invalid as obvious. In response, Cubist presented extensive, real-world evidence that this was not so. Specifically, Cubist showed that there was a long-felt need for the claimed inventions, that the inventions displayed unexpected properties, that drug development leader Eli Lilly had tried and failed to discover safe and effective methods of administering daptomycin, and that Cubicin has been a great commercial success.

Such evidence, generally called "objective indicia" or "secondary considerations" of nonobviousness, is highly relevant when adjudicating an obviousness defense. It is one of four factors this Court identified for evaluation in assessing obviousness, stating that it may "serve to 'guard against slipping into use of hindsight.'" *Graham*, 383 U.S. at 17, 36. Indeed, the Court has accorded significant weight to objective indicia of nonobviousness for over a century. *See, e.g.*, *Expanded Metal Co.* v. *Bradford*, 214 U.S. 366, 381 (1909); *Keystone Mfg. Co.* v. *Adams*, 151 U.S. 139, 143-145 (1894).

The district court nonetheless categorically disregarded Cubist's strong objective indicia evidence, based on two unprecedented bright-line rules nowhere

supported by the Patent Act or this Court's jurisprudence:

- First, the court held that all objective indicia of nonobviousness must be "coextensive" with the scope of the claims at issue to receive significant weight in the obviousness analysis (App. 79a).
- Second, the court held that patent claims must expressly recite the long-felt need met by the claimed invention (App. 92a).

The Federal Circuit affirmed the district court's ruling, holding that the district court did not commit "reversible error" with respect to Cubist's method of administration patents, and "sustain[ing] the district court's determination" with respect to its patents on manufacturing high purity daptomycin. App. 26a, 33a, 35a.

Under these rules, courts could disregard evidence of objective indicia of nonobviousness unless it related to commercial embodiments that practice *the full scope* of a patent's claims, and any long-felt need would have to be recited in the claims themselves before it could be given weight in an obviousness analysis. Such rigid rules have no basis in law or common sense; the effect in this case was to disregard Cubist's extensive and probative objective indicia that its methods of manufacturing and administering Cubicin were groundbreaking and not obvious to skilled artisans. More broadly, a requirement that objective indicia be "coextensive" with a claim's full scope will almost always be unmet whenever asserted claims have multiple embodiments—a frequent characteristic not only of pharmaceutical patents, but of patents in other fields as well. The new requirement that claims specifically recite any long-felt need will almost never be satisfied, as patent claims are supposed

to recite the patented *invention*, not prior art problems that the invention solves.

This Court has not considered the doctrine of objective indicia in decades, likely because the lower courts were generally able to apply it faithfully. The decisions below signal an unwarranted diversion from this Court's precedent that cannot stand. This Court should grant the petition, vacate the judgment below, and remand for further consideration of Cubist's objective indicia of nonobviousness.

STATEMENT

A. Cubist's Inventions And The Development Of Cubicin

Cubicin is an antibiotic used to treat serious infections caused by a bacterium called methicillin-resistant *Staphylococcus aureus*, or MRSA. App. 39a. MRSA bacteria infect approximately 80,000 Americans each year, resulting in 11,000 deaths. CAJA 1143-1144. Prior to the discoveries at issue here, only one antibiotic—vancomycin—was available to treat serious MRSA infections. Vancomycin did not work for everyone, and when vancomycin failed, patients died. App. 17a; CAJA 488, 763-765, 1144.

The active ingredient in Cubicin is daptomycin, a potent antibacterial agent for treating MRSA. App. 39a. Prior to the inventions at issue, no daptomycin treatment was commercially available, even though skilled artisans had been trying to develop daptomycin treatments since the early 1980s. Despite a long-felt need for a serious MRSA treatment, and despite eight years of ultimately failed efforts by drug development expert Eli Lilly, no safe and effective dosing regimen had been found, and no commercially scalable purifica-

tion method had been discovered. CAJA 764, 887-888, 2242. After Cubist arrived at surprising solutions to both problems, Cubist was able to develop daptomycin into a commercially available drug to treat life-threatening infections. Since the FDA's approval of Cubicin in 2003, gross revenues of Cubicin have totaled over $3 billion. App. 40a; CAJA 1346.

1. Invention Of The Method of Administration Patents

Cubicin is indicated to treat complicated skin and skin structure infections, bloodstream infections (bacteremia) and heart infections (endocarditis) caused by MRSA. App. 39a-40a; CAJA 1144. These are serious infections that require hospitalization and, particularly in the case of bacteremia and endocarditis, can be fatal if untreated. CAJA 488, 1144. Before Cubicin, vancomycin was the only available treatment for these serious infections. CAJA 1144.

Clinicians had long felt a need to develop an alternative to vancomycin for treating serious MRSA infections. Not all patients responded to vancomycin, and those that failed to respond risked death. Moreover, clinicians expected that MRSA might eventually develop resistance to vancomycin, as it had with prior antibiotics. When that happened, unless another treatment was available, there would be no way to treat these deadly infections. CAJA 488, 763-765, 1143-1145.

Eli Lilly, one of the world's leading pharmaceutical companies, spent years and significant resources trying to develop daptomycin into a safe and effective drug to treat serious MRSA infections. After discovering daptomycin, Lilly spent approximately eight years trying to develop it, founding a team in 1983 of chemists, toxi-

cologists, pharmacologists, microbiologists, and clinicians. CAJA 764, 825-826, 6846. Lilly conducted nineteen human clinical trials, along with numerous *in vitro* and animal studies. CAJA 2178-2179, 2242, 6725-6783.

Despite this effort, Lilly failed to find a dosing regimen for daptomycin that could treat serious infections without causing toxicity. CAJA 776-779. Lilly first tried administering 2 mg/kg[1] of daptomycin once daily to patients, but patients suffering from serious infections did not respond to treatment and Lilly was forced to suspend the study before it was completed. App. 20a; CAJA 768-770, 5936, 5939. Lilly then tripled the daily dose to 3 mg/kg every 12 hours, but that regimen still failed to treat patients with *S. aureus* endocarditis.[2] App. 20a-21a; CAJA 771-774, 6490. Finally, Lilly tried administering 4 mg/kg every 12 hours, but this dose led to serious unexplained skeletal muscle toxicity which, again, forced Lilly to halt its study. App. 21a; CAJA 777-779. After Lilly informed the FDA of these serious adverse events, the agency put all daptomycin clinical studies on hold, forbidding the further administration of daptomycin to patients. CAJA 779-780, 6847.

Lilly could not determine the cause of this skeletal muscle toxicity, and thus was unable to develop a dosing regimen that could safely and effectively treat seri-

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[1] The term "mg/kg" refers to the amount of daptomycin in milligrams (mg) administered per kilogram (kg) weight of the patient. CAJA 768.

[2] Lilly recognized that it was particularly important that daptomycin be able to treat endocarditis, because patients with bacteremia are predisposed to endocarditis, and clinicians are unable to tell whether a patient has only a lower grade infection or also endocarditis. Because untreated endocarditis can be fatal, daptomycin's clinical and commercial success required effectiveness against endocarditis. CAJA 488, 800-801, 1138-1141, 1292-1293.

ous infections. Lilly eventually suspended further development of daptomycin and turned its attention to other candidates for treatment of MRSA. App. 17a; CAJA 778-783, 837-839, 6846.

In 1997, six years after Lilly ceased work on daptomycin, Cubist licensed the compound from Lilly. Cubist initially planned to develop an oral or topical treatment that would avoid skeletal muscle toxicity. CAJA 2242, 5113. But Cubist scientists, impressed by daptomycin's potential, decided to study its toxicity by conducting a series of studies in dogs. These studies showed that, surprisingly, larger doses of daptomycin administered once daily were *less toxic* than smaller doses administered multiple times a day. App. 17a; CAJA 189-190, 1161-1166. This was unexpected; at the time of the invention, persons of ordinary skill in the art generally understood that smaller, more frequent doses of a drug would be safer and more effective than larger doses administered less frequently. Specifically, it was thought that larger doses would lead to higher concentrations of drug in the blood, which would increase toxicity, and longer intervals would lead to lower trough concentrations of drug in the blood between doses, which would decrease efficacy. CAJA 782, 784, 813-814, 1147.

The results of Cubist's dog studies, and of subsequent clinical trials which demonstrated the safety and efficacy of once-daily daptomycin dosing in humans, were published in prestigious journals including *Antimicrobial Agents and Chemotherapy*, *Clinical Infectious Diseases*, and *The New England Journal of Medicine*. Cubist's results surprised the field; it was thought at the time that daptomycin simply could not be used to treat serious infections, since doses large

enough to be effective also appeared to be toxic. CAJA 1146-1149, 5766-5774, 5775-5787, 6849-6854.

Cubist obtained two patents (the Method of Administration Patents) covering the dosing methods it had discovered. Asserted claims 16, 17, 34, and 35 of U.S. Patent No. 6,468,967 ('967 patent) and 51 and 52 of U.S. Patent No. 6,852,689 ('689 patent) are directed to methods for administering therapeutically effective amounts of daptomycin using larger amounts and longer intervals, which surprisingly minimize skeletal muscle toxicity. App. 17a-18a; CAJA 179, 195. The dosing regimens recited in those claims are the same as those described in the FDA-approved label for Cubicin, and are also the only approved dosing regimens for daptomycin.

2. Invention Of The High Purity Patents

Finding a safe and effective dosing regimen for daptomycin was not the only challenge Cubist faced before it could bring daptomycin to market. Cubist also needed to develop a purification method that would allow daptomycin to be developed on a commercial scale.

Cubist first tried producing daptomycin using a purification method described in Lilly's Investigational New Drug Application for daptomycin. That method resulted in a daptomycin composition containing unsafe levels of dangerous contaminants known as endotoxins. Moreover, Lilly's method only enabled recovery of approximately 2-5% of the daptomycin created. This yield was too low for daptomycin to be developed on a commercial scale. App. 85a, 91a-92a; CAJA 887-888, 890-891, 901, 910, 4245.

However, as part of its effort to remove endotoxins so that daptomycin would be safe for use in clinical trials, Cubist made a surprising discovery: daptomycin

molecules aggregate into clumps or "micelles" at acidic pH, and break apart into single molecules again at neutral pH. App. 28a-29a, 93a; CAJA 901-902. By taking advantage of this unexpected property, Cubist developed a purification method that reduced endotoxins to undetectable levels. CAJA 117, 901-904, 906-907, 973-974. This method also increased the yield of daptomycin from 2-5% to 25-35%. This increase in yield enabled daptomycin production on a commercial scale. App. 91a-92a; CAJA 910-911, 1121-1122.

Cubist obtained two patents (the High Purity Patents) that describe the commercial-scale manufacturing methods that Cubist invented: U.S. Patent Nos. 8,058,238 ('238 patent) and 8,129,342 ('342 patent). The asserted claims of the High Purity Patents—claims 91, 98, and 187 of the '238 patent and 23 and 53 of the '342 patent—are product-by-process claims directed to the highly pure form of daptomycin produced using Cubist's methods of manufacture. App. 26a-28a; CAJA 119-121, 123-124, 158-160. The common specification of the High Purity Patents repeatedly emphasizes that one purpose of the invention was to address the need for a process that could be "easily scaled for commercial production." CAJA 100. For example, the specification states that "[t]here is a need for a commercially feasible method to produce more highly purified daptomycin and, if possible, to increase its yield after purification" and that "[t]he instant invention addresses these problems by providing commercially feasible methods to produce high levels of purified lipopeptides [such as daptomycin]." CAJA 101; *see also* CAJA 101-104 (3:50-66, 5:9-11, 5:56-58, 8:66-9:3, 10:34-37).

B. District Court Proceedings

In 2012, Hospira filed two applications with the FDA seeking approval of generic versions of Cubicin. Both included "Paragraph IV" certifications, stating (*inter alia*) that Cubist's Method of Administration and High Purity Patents were invalid. App. 51a-53a; *see* 21 U.S.C. §§ 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV). Cubist filed the present suit in response, seeking a declaration that Hospira's generic daptomycin products would infringe the asserted patents.[3] Hospira counterclaimed that the asserted patents' claims were invalid because, among other things, they would have been obvious to a person of skill in the art at the time of the invention. App. 2a-3a. Hospira subsequently stipulated to infringement of the asserted patent claims. Stip. 1-3, No. 12-367, D.I. 88 (D. Del. July 25, 2013).

At trial, Cubist presented extensive evidence that the asserted claims could not have been obvious at the time of the invention, given the objective, real-world evidence from that time. With respect to the Method of Administration Patents, Cubist showed that: (1) there had been a long-felt need for a new antibiotic to treat serious MRSA infections; (2) others (in particular Eli Lilly) tried and failed to discover a dosing regimen that would enable daptomycin to treat such infections safely; (3) the invention produced the unexpected result that larger daptomycin doses administered less frequently were safe and effective; and (4) following FDA approval, the invention achieved great commercial suc-

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[3] A fifth patent, United States Patent No. RE39,071, was also asserted in the present suit. The district court found that patent was valid and infringed, and this finding was affirmed by the Federal Circuit. App. 16a. That patent, which is scheduled to expire on June 15, 2016, is not at issue in this petition. Suppl. Info. For Patent Cases, No. 12-367, D.I. 2 (D. Del. Mar. 21, 2012).

cess. With respect to the High Purity Patents, Cubist showed that (*inter alia*) there had been a long-felt need for a way to manufacture highly-pure daptomycin on a commercial scale, a need that was satisfied by Cubist's patented invention.

After a bench trial, the district court issued an opinion that disregarded Cubist's evidence of objective indicia. With respect to the Method of Administration Patents, the district court did not deny the connection between each of the above objective indicia of nonobviousness and the claimed inventions. App. 79a-82a. Nevertheless, because the district court found that "the nexus is strongest for the use of Cubicin to treat [*S. aureus* endocarditis]," while "the claims cover bacterial infections generally," it categorically refused to give these objective indicia substantial weight. App. 80a-81a; *see also* App. 79a-82a. That was because the court created a bright-line rule that objective indicia of nonobviousness "must be commensurate in scope—'*coextensive*'—with the claimed features of the invention." App. 79a (emphasis added).

With respect to the High Purity Patents, the district court similarly disregarded Cubist's evidence of the long-felt need for a commercial-scale purification process. The court expressly found that, "[u]sing the processes outlined in the purity patents, ... Cubist was able to obtain yields between 25% and 35%, making daptomycin a commercially viable drug for the first time." App. 92a. Nevertheless, the court held that this evidence did not affect the obviousness analysis because, "[a]lthough the processes described in the purity patents may have ultimately led to more efficient pro-

duction, *the claims themselves do not speak of yield.*" *Id.* (emphasis added).[4]

Ultimately, the district court held the asserted claims of the Method of Administration and High Purity Patents invalid as obvious. App. 96a.[5]

C. Federal Circuit Proceedings

In a published opinion, the Federal Circuit affirmed the district court's decision that the Method of Administration and High Purity Patents were obvious, and specifically affirmed the district court's ruling on objective indicia of nonobviousness.

For the Method of Administration Patents, the Federal Circuit acknowledged that "prior art daptomycin treatment methods had not proved effective" for treating *S. aureus* endocarditis. App. 24a-25a. Nevertheless, it endorsed the district court's decision not to give significant weight to Cubist's evidence regarding long-felt need, failure of others, unexpected results, and commercial success, because the evidence did not apply to the treatment of *all* infections covered by the claims. App. 24a-26a, 79a-82a. In its original opinion, the Fed-

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[4] The district court also found that it was "not clear why there would be a need to develop a commercially viable purification process," because daptomycin was considered a "dead drug" due to Lilly's abandonment of its development in 1991. App. 92a-93a. The district court did not discuss whether daptomycin was still considered a "dead drug" in January 2000, when the High Purity Patents' provisional application was filed—nine years after Lilly abandoned the drug and three years after Cubist licensed it. CAJA 2242, 6846.

[5] Certain claims of the Method of Administration and High Purity Patents were also found invalid as anticipated. App. 96a. However, the Federal Circuit affirmed the district court's decision on the basis of obviousness alone. App. 16a.

eral Circuit stated that the district court did not commit "legal error" in its analysis of the secondary consideration evidence. App. 26a. However, after Cubist petitioned for rehearing, the panel issued an "erratum" to its opinion changing the word "legal" to "reversible," such that the opinion now reads: "We are not persuaded that the district court committed *reversible* error in its analysis of the secondary consideration evidence." App. 26a, 35a (emphasis added). The panel neither corrected nor addressed the district court's statement that objective indicia of nonobviousness must be coextensive with the claimed invention. *Id.*

The Federal Circuit also sustained the district court's holding disregarding Cubist's evidence of long-felt need for a commercially viable method to manufacture daptomycin. App. 33a. In doing so, the Federal Circuit specifically recited the district court's statement that "the asserted claims [of the High Purity Patents] did not refer to production-scale purification." *Id.* The Federal Circuit denied Cubist's petition for rehearing and rehearing en banc. App. 97a-98a.

REASONS FOR GRANTING THE PETITION

I. THE COURT SHOULD GRANT CERTIORARI TO RESTORE THE PROPER ROLE OF OBJECTIVE INDICIA OF NONOBVIOUSNESS

Since this Court's opinion in *Graham*, which confirmed objective indicia of nonobviousness as one of four factors to be evaluated in assessing obviousness, the Court has not provided further guidance regarding the role and proper analysis of objective indicia. That is likely because this Court's review was not previously needed: prior to the Federal Circuit's ruling in this case, that court had generally applied the *Graham* doctrine appropriately, noting that objective indicia of

nonobviousness are important and must be considered in every case.

That changed with the Federal Circuit's published opinion in this case. By affirming the district court's analysis as not containing any "reversible error" regarding objective indicia for the Method of Administration Patents, the Federal Circuit sanctioned the removal of the fourth *Graham* factor in a large number of cases. The Federal Circuit further weakened objective indicia regarding long-felt need for an invention by affirming the district court's opinion that any long-felt need must be recited in a patent's claims. The Court should grant certiorari to restore objective indicia to their proper role in the obviousness analysis.

A. Evaluation Of Objective Indicia Of Nonobviousness Is A Critical And Required Step In The Obviousness Analysis

An invention is not patentable "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious ... to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. For the past fifty years, this obviousness inquiry has been governed by the Court's opinion in *Graham* v. *John Deere Co. of Kansas City*. 383 U.S. 1 (1966); *see KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 406-407 (2007) ("the [*Graham*] factors continue to define the inquiry that controls").

Graham set out four factual inquiries that determine whether a patented invention is obvious. Those facts are: (1) the "level of ordinary skill in the pertinent art"; (2) the "scope and content of the prior art"; (3) the "differences between the prior art and the claims at issue"; and (4) "secondary considerations" of nonobvious-

ness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Graham*, 383 U.S. at 17. A factfinder must consider evidence of secondary considerations before reaching a conclusion on obviousness. *In re Fielder*, 471 F.2d 640, 644 (C.C.P.A. 1973) ("[S]uch evidence must *always* be considered in connection with the determination of obviousness."); *see also, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075-1080 (Fed. Cir. 2012) (assessment of secondary considerations is required).

In *Graham*, the Court emphasized the importance of secondary considerations, noting that they may "serve to 'guard against slipping into use of hindsight'" and help courts "resist the temptation to read into the prior art the teachings of the invention in issue." 383 U.S. at 36 (quoting *Monroe Auto Equip. Co.* v. *Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)). The Court also highlighted the role of secondary considerations in providing evidence that is "more susceptible of judicial treatment than are the highly technical facts often present in patent litigation," and in so doing assisting the judiciary in "discharg[ing] the technological duties cast upon it by patent legislation." *Id.* This was not new; the importance of secondary considerations has been reflected in the Court's patent jurisprudence for over a hundred years. *See, e.g., Expanded Metal Co.* v. *Bradford*, 214 U.S. 366, 381 (1909) ("It may be safely said that if those skilled in the mechanical arts are working in a given field, and have failed, after repeated efforts, to discover a certain new and useful improvement, that he who first makes the discovery has done more than make the obvious improvement which would suggest itself to a mechanic skilled in the art, and is entitled to protection as an in-

ventor."); *Keystone Mfg. Co.* v. *Adams*, 151 U.S. 139, 143-145 (1894) (The fact of a patented product's success in displacing an existing product "is always of importance, and is entitled to weight, when the question is whether the machine exhibits patentable invention").

Prior to the ruling below, the Federal Circuit itself had emphasized the critical role that secondary considerations play in obviousness analysis, noting that "evidence of secondary considerations may often be the most probative and cogent evidence in the record." *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); *see also id.* at 1538-1539 (evidence of secondary considerations "may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art."); *Pro-Mold & Tool Co.* v. *Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996) ("It is the secondary considerations that are often most probative and determinative of the ultimate conclusion of obviousness or nonobviousness.").

B. Contrary To The Federal Circuit's Holding, It Is Error To Disregard Objective Indicia Of Nonobviousness Merely Because They Do Not Apply To All Embodiments

In this case, the district court created, and the Federal Circuit affirmed, a new, restrictive rule that "secondary considerations must be ... 'coextensive' ... with the claimed features of the invention" in order to be afforded substantial weight in the obviousness analysis. App. 79a; *see* App. 26a, 35a. Under that standard, if an inventor presented evidence regarding secondary considerations related to *one* embodiment of the patented invention, a court would disregard that evidence unless

the inventor could present evidence that applied to *all* possible embodiments. That categorical rule would disregard secondary considerations in a large number of cases, with no basis in law or common sense.[6]

Neither the district court nor the Federal Circuit cited any authority supporting their new restriction on objective evidence of nonobviousness. Nor could they have: the Federal Circuit previously recognized that objective indicia of nonobviousness can be given significant weight even if not coextensive with the full scope of the claim. *See In re Glatt Air Techniques, Inc.*, 630 F.3d 1026, 1030 (Fed. Cir. 2011) (rejecting Patent Office's argument that an applicant "needed to submit commercial success evidence from multiple embodiments for that evidence to be commensurate in scope with claim 5"); *In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2008) (patentee "need not sell every conceivable embodiment of the claims in order to rely upon evidence of commercial success, so long as what was sold was within the scope of the claims"); *Applied Materials, Inc.* v. *Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996) ("[A] patentee need not show that all possible embodiments within the claims were successfully commercialized in order to rely on the success in the marketplace of the embodiment that was commercialized.").

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[6] Prior to the present case, the question whether the scope of a secondary consideration was "coextensive" with the scope of a patent claim was potentially relevant to a distinct inquiry: whether the patentee should be afforded a *presumption* of a nexus between the secondary consideration and the patent claim. *Brown & Williamson Tobacco Corp.* v. *Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) (setting out criteria for presumption of nexus). As Cubist did not contend that it should be afforded such a presumption, the "coextensive" inquiry should have been irrelevant to this case.

The approach below would have the effect of vitiating objective indicia of nonobviousness as an element to be considered in many cases. Objective indicia will frequently arise only for commercial embodiments that are actually placed in the market, thus satisfying a need and earning praise and commercial success. Ruling that those indicia of nonobviousness are off-limits unless the claims are coextensive with the commercial embodiment essentially requires the patentee to practice the full range of a claim to avoid invalidity—a wholly impractical proposition that the Federal Circuit has previously rejected. *See Glatt*, 630 F.3d at 1030 (noting that it would be "unlikely that a company would sell a product containing multiple, redundant embodiments of a patented invention. ... Under [this] logic, there would never be commercial success evidence for a claim that covers more than one embodiment.").

The negative consequences from the application of the district court's new rule are apparent in the present case. The Federal Circuit acknowledged that prior art methods for administering daptomycin had "not proved effective" in treating *S. aureus* endocarditis infections, "the most serious targeted infection." App. 20a-21a, 24a-25a. Nonetheless, the Federal Circuit found no "reversible error" in the district court's ruling, which disregarded Cubist's secondary considerations evidence because it did not show a long-felt need for, failure of others or unexpected results regarding, or the commercial success of, treatment of *other* infections using the patented inventions. App. 26a, 35a, 79a-82a.[7]

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[7] The Federal Circuit all but acknowledged that the district court committed "legal error" when it removed that phrase from its original opinion in an erratum, replacing it with the statement that the error was not "reversible." App. 26a, 35a. The Federal Circuit's amended opinion now rules that a district court's legally-

As a result of this holding, the lower courts ignored the long-felt need to develop daptomycin into a treatment for serious MRSA infections, even though this need had existed since the 1980s. CAJA 488, 763-765, 1138-1141, 1144-1145. They also disregarded Lilly's eight-year failed effort to find a safe and effective dose of daptomycin for serious infections, and the subsequent publication of Cubist's discoveries in the most prestigious journals in the field. App. 17a, 20a-21a; CAJA 764, 764-782, 825-826, 839, 1146-1149, 5766-5787, 6846, 6849-6854. Finally, they overlooked the $3 billion of revenue from Cubicin, made possible by Cubist's patented inventions. CAJA 1346.

The new rule thus artificially restricted the fourth *Graham* factor in this case, and will do so in any case involving a claim to a genus, where fewer than all possible species are developed and marketed. Taken to its logical conclusion, the district court's analysis would render objective factors irrelevant for most genus claims, contrary to the law that had prevailed until the decision below. *See, e.g., Leo Pharm. Prods., Ltd.* v. *Rea*, 726 F.3d 1346, 1349-1350, 1358-1359 (Fed. Cir. 2013) (relying on objective indicia relating to a single pharmaceutical compound from within a broad genus claim); *Procter & Gamble Co.* v. *Teva Pharm. USA, Inc.*, 566 F.3d 989, 992, 998 (Fed. Cir. 2009) (secondary

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erroneous evaluation of objective indicia can be disregarded as long as the district court "weigh[s] the secondary consideration evidence against the other evidence of obviousness and conclude[s] that the secondary consideration evidence was not sufficiently strong to overcome the showing of obviousness arising from an analysis of the prior art." App. 26a. But the district court's weighing of objective indicia against other evidence of obviousness cannot cure the legal errors that led it to ascribe too little weight to the objective indicia in the first place.

consideration of long-felt need deserved substantial weight when it related to treatment of only one of the many medical conditions falling under the asserted method claim). That departure from existing law will have a negative impact in pharmaceutical cases, *see id.*, as well as in cases from a variety of other industries, *see, e.g.*, *Rambus Inc.* v. *Rea*, 731 F.3d 1248, 1257 (Fed Cir. 2013) (agency erred in finding that objective evidence relating to high-speed memory systems was not commensurate with patent claims on the ground that claims embraced both high-speed and slow memory devices); *Gillette Co.* v. *S.C. Johnson & Son, Inc.*, 919 F.2d 720, 721, 725 (Fed. Cir. 1990) (evidence of commercial success relating to one embodiment of shaving cream from within a broad genus claim supported nonobviousness). Indeed, the new rule would undermine Federal policies designed to encourage pharmaceutical companies to address the needs of relatively small patient populations, such as children or patients with rare diseases. *See, e.g.*, Orphan Drug Act, Pub. L. No. 97-414, § 1(b), 96 Stat. 2049, 2049 (1983) (Congressional finding that it is "in the public interest" to incentivize the development of orphan drugs which treat diseases affecting "small numbers of individuals residing in the United States"); 21 U.S.C. §§ 355a(b), (c) (granting six months of market exclusivity to certain drug manufacturers and sellers who conduct pediatric studies). A requirement that secondary considerations be coextensive with the full scope of patent claims would, in many cases, result in courts disregarding evidence showing that the needs of these small but very important patient populations had been met. This would greatly impede public policy by diminishing patent protection for orphan drug and pediatric indications.

The rigid, categorical disregard of secondary considerations evidence in this case is precisely the kind of approach this Court has emphatically rejected. In *KSR International Co.* v. *Teleflex Inc.*, this Court reviewed the Federal Circuit's use of a "teaching, suggestion, or motivation" test, which required that "some motivation or suggestion to combine the prior art teachings" appear in certain categories of evidence in order for an invention to be found obvious. 550 U.S. at 407 (quoting *Al-Site Corp.* v. *VSI Int'l, Inc.*, 174 F.3d 1308, 1323-1324 (Fed. Cir. 1999)). In rejecting that test, the Court observed that "[t]hroughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach[.]" *Id.* at 415. Accordingly, the Court rejected the Federal Circuit's "rigid rule that limits the obviousness inquiry[.]" *Id.* at 419. The rule announced by the lower courts here is no different: it has no support in the statute or this Court's case law, and instead creates an unnecessary, inflexible barrier to consideration of evidence that this Court in *Graham* ruled is important in combatting hindsight.

This Court should grant review to correct the legal error introduced below, which incorrectly disregarded objective indicia of nonobviousness that clearly apply to the claimed invention.

II. THE COURT SHOULD GRANT CERTIORARI TO DISAPPROVE THE ERRONEOUS REQUIREMENT THAT LONG-FELT NEED IS NOT TO BE CONSIDERED UNLESS EXPRESSLY RECITED IN A PATENT'S CLAIMS

A long-felt need for a patented invention is one type of secondary consideration that courts consider in the obviousness analysis. *Graham*, 383 U.S. at 17-18. Prior to the Federal Circuit's opinion in this case, it was settled law that the long-felt need met by the invention

need not be expressly recited in a patent claim for it to be considered as objective evidence of nonobviousness. *See, e.g.*, *Eli Lilly & Co.* v. *Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1373-1374, 1380 (Fed. Cir. 2006) (holding that the patentee established that the claims at issue satisfied a "long-felt need for a safer, less toxic, and more effective clozapine-like drug," where the claims did not recite the satisfaction of such a need); *Procter & Gamble*, 566 F.3d at 998 (affirming district court's conclusion that claimed inventions satisfied long-felt need for drug to treat osteoporosis, where the asserted compound and composition claims did not recite treatment of any condition). This makes sense: a patent claim provides notice of the boundaries of the invention claimed, rather than the underlying reason that the invention was created. 35 U.S.C. § 112(b) (claims shall "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention"). Given that patent claims typically do not recite secondary considerations at all, a rule that precludes consideration of long-felt needs not recited in the claim would prevent consideration of such evidence in virtually all cases.

That problem is evident here. The High Purity Patents disclosed a long-needed breakthrough method for producing high-yield, high-purity daptomycin. Hospira did not dispute before the district court that such a method was long needed by the industry; indeed, Lilly's methods from the 1980s and 1990s were only able to produce a yield of 2-5%, and daptomycin had been licensed by Cubist for 3 years before Cubist was able to arrive at the High Purity Patent method. App. 91a-92a; CAJA 887-888, 910, 2242. Nevertheless, while acknowledging that Cubist's processes "may have ultimately led to more efficient production," the district

court gave that finding no substantial weight because "the claims themselves do not speak of yield." App. 92a. Once again, neither the district court nor the Federal Circuit cited any authority supporting the disregard of the long-felt need evidence in this case.[8]

A new requirement that patent claims must expressly recite any long-felt need would dramatically re-

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[8] The Federal Circuit appears to have looked past the district court's error by focusing its long-felt need discussion on "[Eli] Lilly's decision not to pursue its research into daptomycin," which it held was "based on economic considerations, not on the absence of methods of obtaining sufficiently high purity levels." App. 33a. But that observation pertains to a time period nine years before the filing of the patent-in-suit. App. 41a-42a (filing date of January 20, 2000); CAJA 826, 839, 6846 (Lilly abandoned daptomycin in 1991). The objective indicia must rather be evaluated as of the date of filing. *Procter & Gamble*, 566 F.3d at 998 ("[W]e look to the filing date of the challenged invention to assess the presence of a long-felt and unmet need."). At the time of filing, Cubist had resumed work on the drug, discovered how to safely and effectively administer it for serious infections, and was conducting clinical trials. CAJA 182, 189-190, 2241-2242. Thus, the primary barrier to commercialization at that time was the lack of a commercial-scale purification process (CAJA 887-888)—a problem solved by the High Purity Patents. If the Federal Circuit's opinion is left undisturbed, it would both confuse the appropriate time at which long-felt need should be assessed and leave in place the district court's unsupported requirement of express recitation of long-felt needs in patent claims.

The district court's ruling was notably based on a *combination* of its improper requirement that the claims recite the long-felt need (which it called a "nexus problem") and its conclusion that there was not "necessarily" a need for higher yield because "many believed daptomycin was a 'dead drug'" after Lilly's failure. App. 92a-93a ("[I]t is not clear why there would be a need to develop a commercially viable purification process. Also taking into account the nexus problem, the court is not convinced by Cubist's long-felt but unmet need argument.").

duce the number of cases in which otherwise strong evidence of long-felt need is considered in the obviousness analysis. Patent claims covering chemical compounds, for example, frequently do not recite the long-felt need that the compound satisfies, and yet are supported by strong long-felt need evidence, as the Federal Circuit has found in prior cases. *See, e.g.*, *Leo Pharm. Prods.*, 726 F.3d at 1349-1350, 1359 (reversing agency finding of obviousness, based in part on long-felt need "for a single formulation to treat psoriasis," where patent included compound claims that did not recite any such need or use); *Eli Lilly*, 471 F.3d at 1373-1374, 1380 (claims at issue satisfied a long-felt need for a "safer, less toxic, and more effective clozapine-like drug," where the claims did not recite the satisfaction of such a need); *Pfizer Inc.* v. *Teva Pharm. U.S.A., Inc.*, 882 F. Supp. 2d 643, 656-658, 670-671 (D. Del. 2012) (finding long-felt need for "improved anticonvulsant treatment ... successfully addressing the needs of refractory patients and offering superior properties over then-existing therapies, such as a lack of drug-drug interactions, good pharmacokinetics, and a lack of protein binding"—none of which was recited in the patent claims), *aff'd*, 555 F. App'x 961 (Fed. Cir. 2014). Upending the expectation of patent drafters in that regard would jeopardize billions of dollars in research and development from recent decades that culminated in inventive discoveries. Conversely, the requirement imposed below serves no rational purpose, especially where—as here—the need and the invention's satisfaction of it are recited in the patent *specification* itself. CAJA 101 (3:36-38, 50-52).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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