No. 04-1350

In The Supreme Court of the United States

KSR INTERNATIONAL CO.,

Petitioner

v.

TELEFLEX INC., ET AL.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

The Biotechnology Industry Organization respectfully submits this brief as *amicus curiae* in support of respondents in this case.[1]

INTEREST OF *AMICUS CURIAE*

The Biotechnology Industry Organization ("BIO") is the largest trade association representing the biotechnology industry. BIO has more than eleven hundred members, including businesses, academic institutions, and biotechnology centers. Its members range from the largest Fortune 500 companies to the smallest start-ups.

BIO members have great interest in this case and the standards that are applied under the Patent Act to determine whether an invention is nonobvious and therefore patentable. BIO members expand the boundaries of science on a daily basis through their research and development of biomedicine, diagnostics, agricultural, and environmental products and services. That research and development is possible because the promise under the Patent Act of exclusionary rights for a limited period of time in validly patented subject matter serves as an incentive for investment. That investment results in

[1] Letters from petitioner and respondents indicating their consent to the filing of *amicus* briefs have been filed with the Clerk of this Court. Pursuant to Rule 37.6, *amicus curiae* states that no counsel for a party authored this brief in whole or in part, and no person or entity other than *amicus curiae* or its counsel made a monetary contribution to the preparation or submission of this brief.

innovative products that are used to improve the quality of millions of lives worldwide.

If investors fear that marketable biotechnology patents will be prone to invalidation under a new obviousness analysis, future biotechnology innovation will suffer from less investment.

SUMMARY OF ARGUMENT

I. Members of BIO and others working in the biotechnology sector have made significant contributions to previously unimaginable research discoveries. In agriculture, the growing worldwide adoption of genetically engineered crops with insect tolerance, herbicide tolerance or virus resistance in a variety of crops like cotton, corn, soybean, papaya, potato, canola and squash, has provided increased farm production to feed and clothe the world while also benefiting farmers with higher income and the environment with reduced herbicide and pesticide use. Research into plant-based fuels provides hope that the United States can lessen its dependence upon fossil fuels by making fuel alternatives, like ethanol and bio-diesel, more affordable. And biotechnology advances in the health care industry have created new therapies to treat many diseases and to address unmet medical needs throughout the world. Biotechnology inventions of new products, tests, drugs, and cures are made every day.

The objective standards under the current case law that govern the determination of whether an invention was obvious under 35 U.S.C. § 103(a), and therefore not patentable, have a direct impact on investment incentives in biotechnology, and thus the development of the previously described innovations. If those standards were to become less objective, as petitioner proposes, increased uncertainty about the availability of patent rights would deter investment

within the biotechnology industry. That would, in turn, negatively affect public health and welfare, which benefits greatly from biotechnology innovation.

The Federal Circuit's development of the law of obviousness is consistent with the intent of Congress in the Patent Act and the precedent of this Court. It provides objective bases upon which courts and the PTO can determine whether an invention is patentable. The teaching-suggestion-motivation test is a useful and objective inquiry that appropriately guards against hindsight in addressing the question of whether a person of ordinary skill in the art would have combined prior art references.

II. Petitioner and its *amici,* however, suggest a subjective inquiry that is substantially less predictable and untethered to concrete, factual findings. Petitioner proposes to replace the precedents of this Court and the Federal Circuit with an ill-defined and unworkable "test of validity for combination patents." Br. of Pet. at 24. Rather than require that the determination of obviousness be guided by objective findings of fact and by a determination of what a person of ordinary skill in the art would have done at the time of invention, petitioner proposes an amorphous standard that would permit patent examiners and judges to decide subjectively, with the benefit of hindsight, whether the technology at issue is worthy of being declared an "invention."

Congress and this Court's precedents, however, have rejected such a subjective standard for patentability. This Court held in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), that the legal question of obviousness under 35 U.S.C. § 103 must be guided by factual inquiries into the scope and content of the prior art, the differences between the prior art and the claims, the ordinary level of skill in

the pertinent art, and considerations such as commercial success, long felt unsolved needs, and the failure of others. These *Graham* inquiries provide an objective context as to what a hypothetical person with ordinary skill in the art at the time the invention was made would have done when faced with potentially divergent prior art references. The Federal Circuit, by requiring objective evidence of a teaching, suggestion, or motivation to combine the prior art, ensures that patent examiners and courts answer this question in a reliable manner.

III. Petitioner's suggested alternatives to this Court's and the court of appeal's application of Section 103 are fraught with uncertainty and risk of error. The suggestion that there be a separate obviousness test for combination-only patents is based upon nothing more than judicial rhetoric. The post-*Graham* case law, when viewed as a whole, confirms that this Court has never adopted such an approach. Indeed, it would be nonsensical to do so because virtually all technology involves the combination of preexisting art. Thus, any combination-only nonobviousness standard would either swallow the *Graham* rule, or require patent examiners and judges to make an unguided threshold determination into why some technologies involve combinations of pre-existing art while some others do not.

Adoption of petitioner's approach would have a profound effect on the biotechnology industry. Remarkable innovations in the fields of agriculture, energy, and medicine could be rendered obvious merely because they are combinations of pre-existing elements and methods. Inventors would have no predictable defenses against infringers seeking to invalidate biotechnology inventions many years, or even decades, after the ideas were first conceived.

ARGUMENT

I. SIGNIFICANT ADVANCEMENTS THROUGH BIOTECHNOLOGY RELY UPON INVESTMENT THAT IS PREDICATED ON AN OBJECTIVE AND PREDICTABLE TEST FOR OBVIOUSNESS

A. An Obviousness Analysis That Does Not Protect Against Hindsight Bias Would Negatively Affect Biotechnology Research And Development

An invention that is novel under 35 U.S.C. § 102 is nevertheless unpatentable if the differences between it and the prior art are such that the claimed subject matter as a whole would have been obvious, at the time the invention was made, to a person having ordinary skill in the pertinent art. 35 U.S.C. § 103(a); *Graham v. John Deere Co.,* 383 U.S. 1, 13-14 (1966). Making this seemingly simple determination of what a person with ordinary skill in the art would have seen as an obvious invention can be fraught with error. To that end, this Court and the Federal Circuit have required an objective examination of the scope and content of the prior art, its differences from the claimed invention, the level of ordinary skill in the art at the time of the invention, and other objective indicia of nonobviousness in order to determine whether a hypothetical person of ordinary skill *would have* been motivated, when faced with the circumstances and obstacles at that time, to arrive at the subject matter at issue. *Graham*, 383 U.S. at 16-17.

This Court's and the Federal Circuit's obviousness analysis ensures that the patent system does not "remove existent knowledge from the public domain" or "restrict free access to material already available." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Importantly, it also ensures that the obviousness

determination is based on objective evidence and guards against the inadvertent use of hindsight when addressing patentability – recognizing the simple fact that the human mind is biased by knowledge of what has actually happened when evaluating retrospectively the likelihood of that which has happened. *Graham*, 383 U.S. at 36.

But petitioner would have this Court relax, if not abandon, these objective, factually driven inquiries. Petitioner predicates a patentability standard on its view that patent examiners and judges should determine what was obvious, and what was not, through conclusory evaluations, unsupported by contemporaneous evidence. The result of petitioner's standard, BIO submits, would be determinations of obviousness that are unpredictable and infected with hindsight bias.

Petitioner's proposed standard could have a particularly profound effect on the biotechnology industry. First, many patentable inventions in biotechnology spring from known components and methodologies found in prior art. Researchers may recognize that a prospective invention is possible or desirable. Drawing on a great abundance of existing biotechnology techniques, reagents, and structures that can be combined in novel ways, such researchers may even be able to outline a possible method of achieving the invention. Yet, while any number of such new combinations may be logical to try, most advances in biotechnology are only won through trial and error, at great effort and expense, and with only a low probability of success in achieving the claimed invention at the outset. Having an apparent method to try to make an invention should not render obvious an invention that ultimately results from that process. *See* Br. of Intellectual Property

Law Professors in Supp. of Pet. at 8; Br. of Economists and Legal Historians in Supp. of Pet. at 17.

For example, after a new virus is discovered, scientists often apply well-known techniques to attempt to create a vaccine capable of protecting the population from infection. Yet the choice of how to apply a particular known technique can be crucial, because success for an individual vaccine candidate is unpredictable. What may seem, in retrospect, to be a straightforward application of a known technique to a known virus, often proves to be, in practice, very difficult or impossible to achieve. Thus, while one might have hoped to achieve a certain result, because of the unpredictability in the field, a skilled person would not have been able to envision the complete combination of elements that later result in the claims of an issued patent. It is crucial, therefore, to examine whether the prior art suggested or taught the combination of old elements in the particular manner claimed, as the Federal Circuit requires.

Second, there often is a long "passage of time between patent application filing and litigation with biotechnology inventions [that] can exacerbate the problem" of hindsight bias. *See* Lawrence M. Sung, *On Treating Past as Prologue*, 2001 U. Ill. J.L. Tech. Pol'y 75, 88 (2001). That is, in part, because biotechnology patents often exhibit significantly longer durations of commercial utility than subject matter from the mechanical and electrical fields. *Id*. at 78-79. Although this longer commercial utility can support bigger investments in the field, *see Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at $802 Million* (Tufts Center for the Study of Drug Development), Oct. 30, 2001, *available at* http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=11, it also means that biotechnology patents are sometimes not challenged

until years after they reach the market, when the hindsight problem is even greater.[2]

Accordingly, the biotechnology industry relies heavily upon the nonobviousness jurisprudence of this Court and the Federal Circuit to ensure that new biotechnology innovations are objectively evaluated for patentability. Fundamental changes to the nonobviousness requirement – particularly modifications that make the analysis unpredictable and more susceptible to hindsight bias – will threaten patent protection in an important and dynamic sector of the Nation's economy.

B. Research And Development In The Biotechnology Industry Is Particularly Expensive, Time-consuming, And Presents An Unusually High-risk Investment That Relies On An Objective And Predictable Application Of Obviousness Law

Innovation in biotechnology affects many facets of human existence. For example, biotechnology research into agriculture has increased harvests worldwide through the creation of higher yield, pest and herbicide resistant crops.[3] Biotechnology is responsible for new therapies to

[2] By contrast, in the computer and software industries, incremental product life cycles are often measured in months. *See* Br. of Business Software Alliance in Supp. of Pet. at 10. Thus, computer and software patents often face obviousness challenges much closer in time to the date of invention, which makes such technologies significantly less prone to hindsight-biased analysis.

[3] Studies by the National Center for Food and Agricultural Policy (NCFAP) (http://www.ncfap.org/whatwedo/biotech-us.php) found that in 2004, the eleven biotechnology crop varieties adopted by U.S. growers increased crop yields by 6.6 billion pounds, provided $2.3 billion in additional net returns for U.S. growers, and reduced pesticide applications by 62.0 million pounds.

treat heart disease, cancer, AIDS, stroke, septic shock, diabetes, anemia, cystic fibrosis, multiple sclerosis, lupus, kidney disease and liver disease. Many more inventions, however, have yet to make the transition from foundational knowledge to practical and safe solutions for health, nutrition, and energy needs. The biotechnology industry is responsible for more than 20 billion dollars of annual research investment, and provides employment to hundreds of thousands of individuals.

These benefits depend upon a patent system in which the biotechnology industry and its investors need not fear that innovations will be invalidated as obvious merely because they are combinations of preexisting technologies and methods. Research and development within the industry comes at a high cost, and every idea that is funded comes with a greater risk of failure than success. Investment thus is predicated on an expected return on investment in the form of products or services that are protected by patents whose validity can be fairly determined.

For example, in the pharmaceutical industry, medical achievements are the result of extensive research and development costs. *See NIH: Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 108th Cong., 1st Sess. 47 (2003) (testimony of Phylliss Gardner, M.D). ("The biotechnology industry is the most research and development-intensive and capital-focused industry in the world."). Virtually all of this investment is through private funding. *NIH: Moving Research from the Bench to the Bedside*, *supra*, at 49 (noting that 98 percent of research and development investment comes from the private sector). The investment that must be made to develop a single therapy is staggering – it can exceed $800 million and can take up to 14 years. *See Tufts Center for the Study of Drug*

Development Pegs Cost of New Prescription Medicine at $802 Million, News Release (Tufts Center for the Study of Drug Development), Oct. 30, 2001, *available at* http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=11; *see also* Ross Kerber, *Spread The Wealth Biotech Group Says States Need To Fund All Areas, Not Just Stem Cells*, Boston Globe, Jan. 15, 2005 at F1 ("[B]iotechnology's complicated drugs can take a decade or longer to reach the market, leading to billions of dollars of annual losses for the industry.").

Such investments are risky. For every successful pharmaceutical product, thousands of candidates are designed, screened, and rejected after large investments have been made. Only a small minority of drugs that advance to human clinical trials obtain FDA approval. *See* Tommy G. Thompson, *Remarks at the Milken Institute's Global Conference* (Apr. 26, 2004), *available at* www.hhs.gov/news/speech/2004/040426.html (noting that the chances that a biopharmaceutical product will achieve FDA approval are approximately one in 5,000).

Biotechnology innovations in the fields of agriculture and energy face similar risks, which are likewise justified by the potential rewards of a marketable product with patent protection. Accordingly, changes to the nonobviousness analysis could have dramatically negative effects on biotechnology innovations if, a decade or more after money has been expended to research, test, and develop a marketable product, the product is deemed obvious based upon hindsight-driven conclusions that the product now appears unremarkable, years after it was created.

II. THE FEDERAL CIRCUIT'S APPROACH IS CONSISTENT WITH THIS COURT'S PRECEDENTS AND PROVIDES FLEXIBILITY IN DETERMINING WHETHER AN INVENTION IS OBVIOUS BASED ON OBJECTIVE EVIDENCE

There is no reason to fundamentally alter the Section 103 nonobviousness standard. That nonobviousness standard, which the Court reviews today, reflects a cautious, incremental evolution of 150 years of this Court's precedents and Congress's response. The Federal Circuit's approach, steadily developed over more than two decades, is consistent with that precedent, and requires an objective inquiry that both protects preexisting knowledge that belongs in the public domain and guards against hindsight bias that threatens future innovation.

A. Section 103(a) Requires An Objective Nonobviousness Inquiry To Avoid Hindsight Bias

1. This Court has held that the nonobviousness requirement of Section 103 is a codification of the judicially created approach first set forth in *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851). In *Hotchkiss*, the Court indicated that ingenuity, rather than ordinary skill, was required for an invention to be patentable, even if novelty and utility were established. In invalidating a patent that involved the substitution of porcelain or clay for wooden or metal doorknobs, the Court held that an invention is not entitled to a patent unless it contains a "degree of skill and ingenuity [beyond that of] an ordinary mechanic acquainted with the business." *Id.* at 267.

This seemingly straightforward requirement confounded courts, patent examiners, and the patent bar for more than a century following *Hotchkiss*. In attempting to apply *Hotchkiss*, the question of what contained skill and ingenuity beyond the ordinary mechanic (*i.e.,* what was nonobvious) mutated into a subjective inquiry as to what constitutes an "invention." Through that subjective analysis, it became difficult to separate the hindsight lessons that were taught by the explanations by the inventor in the patent itself, from the actual abilities of an ordinary mechanic at the time before the invention or the patent explaining the invention was issued. Focus on what subjectively should be an "invention" thus "brought about a large variety of opinions as to its meaning both in the Patent Office, in the courts, and at the bar." *Graham*, 383 U.S. at 12. For example, in *Cuno Engineering Corp. v. Automatic Devices Corp.*, Justice Douglas's opinion for the Court rhetorically criticized the subject matter for not revealing a "flash of creative genius," 314 U.S. 84, 91 (1941), which gave rise to a perception that the manner in which an invention is arrived at is as important as whether it is novel, useful, and nonobvious.

During this same period, however, the Court recognized the dangers of hindsight bias. The Court astutely observed that "[k]nowledge after the event is always easy, and problems once solved present no difficulties." *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435 (1911).[4]

[4] Judge Learned Hand identified the problem of hindsight bias making inventions appear obvious after-the-fact because all inventions, at their core, are combinations of prior art, but he emphasized that such an after-the-fact perspective does not prevent an invention from being original:

> [D]efendant argues that the supposed invention is no more than a substitution of material familiar to the art in the

(Continued on following page)

2. Congress intervened in 1952 when it enacted Section 103 and statutorily mandated that patentability be governed by an objective nonobviousness standard. In *Graham v. John Deere Co.*, the Court first addressed the new statutory requirement. *Graham*, 383 U.S. at 3. The Court concluded that "[t]he major distinction" between *Hotchkiss* and Section 103 was that the statute "emphasized 'nonobviousness' as the operative test * * * rather than the less definite 'invention' language" employed in the judicial precedent. *Id.* at 14. Moreover, the Court emphasized that Congress, in enacting Section 103, sought to eliminate reliance upon any "flash of creative genius" requirement that may have stemmed from *Cuno Engineering*, *id.* at 15 & n.7, which the Court described as "rhetorical embellishment." *Ibid.*

The *Graham* Court specifically indicated the objectiveness of the inquiry under the new statutory provision by noting that, "[w]hile the ultimate question of patent validity is one of law, the § 103 condition * * * lends itself to several basic factual inquiries." *Id.* at 17. Those

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> same uses; an aggregation of which each part performs which it did before. We may concede as much arguendo, for the same may be said of every invention. All machines are made of the same elements; rods, pawls, pitmans, journals, toggles, gears, cams, and the like, all acting their parts as they always do and always must. All compositions are made of the same substances, retaining their fixed chemical properties. But the elements are capable of an infinity of permutations, and the selection of that group which proves serviceable to a given need may require a high degree of originality.

B. G. Corp. v. Walter Kiddie & Co., 79 F.2d 20, 22 (2d Cir. 1935) (Hand, J.).

factual inquiries help to ensure that determinations of nonobviousness are based upon objective rather than subjective criteria. *Ibid.* ("The emphasis on non-obviousness is one of inquiry, not quality * * * ."). Under *Graham*, the determination begins with the identification of the "scope and content of the prior art"; the assessment of the "differences between the prior art and the claims"; and the ascertainment of "the ordinary level of skill in the pertinent art." *Id.* at 17-18.

To additionally guard against judicial reliance on hindsight, the Court explained that objective measures of "secondary considerations" also are relevant, such "as commercial success, long felt unsolved needs, [and] failure of others." *Ibid.*; *see also id.* at 36 ("Such inquiries * * * may also serve to 'guard against slipping into use of hindsight,' and to resist the temptation to read into the prior art the teachings of the invention in issue.") (internal citation omitted).

3. Since *Graham* this Court has not altered its approach. The Court has looked to the factual *Graham* inquiries and objective evidence, *see United States v. Adams*, 383 U.S. 39, 63 (1966); *Sakraida v. Ag Pro, Inc.,* 425 U.S. 273, 281 (1976); *Dann v. Johnston*, 425 U.S. 219 (1976), and has reiterated its admonishment that "strict observance" of these requirements is necessary. *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62 (1969). For example, in *United States v. Adams*, 383 U.S. 39 (1966), the Court held that a water-activated, constant voltage battery was nonobvious and thus patentable. The Court rejected the argument that the battery "was not patentable because it represented either no change or an insignificant change as compared to prior battery designs." *Id.* at 48. The Court reasoned that that

obviousness argument would require a person with ordinary skill in the art to "ignore" long-accepted factors about the prior art, which would have deterred a person with ordinary skill in the art from investigating the combination used in the patent. *Ibid.*

B. The Federal Circuit's Consideration Of Whether There Is A Teaching, Suggestion, Or Motivation To Combine The Prior Art To Determine Obviousness Is Consistent With *Graham*

The Court in *Graham* understood that its approach would require development in the lower federal courts. While the Court mandated that "strict observance of the requirements" was necessary for the "uniformity and definiteness which Congress called for in the 1952 Act," the Court further recognized that there would be "difficulties in applying the nonobviousness test" which "should be amenable to a case-by-case development." *Graham*, 383 U.S. at 18.

1. Consistent with this Court's approach, the Federal Circuit makes the Section 103 obviousness determination using the *Graham* analysis. *See Alza Corp. v. Mylan Laboratories*, No. 06-1047, ___ F.3d ___, 2006 WL 2556356, at *2 (Fed. Cir. Sept. 6, 2006); *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). Far from departing from this Court's precedent, the court of appeals has applied *Graham* to determine "'whether a person of ordinary skill in the art, possessed with the understanding and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.'" *Alza Corp.*, 2006 WL 2556356, at *3

(quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1572 (Fed. Cir. 1996).

As part of that analysis, when different pieces of prior art each contain elements of an invention, the prior art can be combined to invalidate a patent on the invention only when there is some teaching, suggestion or motivation to combine the pieces of art to arrive at the claimed invention as a whole. This teaching-suggestion-motivation determination "informs the *Graham* analysis." *Alza Corp.*, 2006 WL 2556356, at *3. In other words, "[t]o reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, * * * [there must be] some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." *Ibid.* (quoting *In re Kahn*, 441 F.3d at 987); *see also In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985).[5] A mere recitation of the elements of an invention, combined by using the inventor's own disclosure as a roadmap, cannot make such an invention obvious. *Dembiczak*, 175 F.3d at 999.

The Federal Circuit's approach to applying *Graham* is necessary to objectively determine whether and how one

[5] Judge Hand had earlier stressed the need for courts to focus on such objective criteria. He asked questions such as "[if] the combination would have had practical value long before it appeared, if no impediment, technical, or commercial, stood in the way, if during that time others had been at work upon the same subject, and if the invention was at once accepted as an answer to the old need." *B. G. Corp. v. Walter Kiddie & Co.*, 79 F.2d 20, 22 (2d Cir. 1935) (Hand, J.).

skilled in the art would have relied upon multiple prior art references disclosing elements of a claimed invention. It is necessary to avoid the problem of hindsight bias that easily arises when one reviews a patent that lays out, in a clear and articulate manner, how the inventor created an invention. The late Chief Judge Markey explained the hindsight problem as follows: "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983).[6]

The Federal Circuit's approach also preserves the flexibility for case-by-case development expressly envisioned by *Graham*, including across different fields of art. The court of appeals has held that a teaching, suggestion or motivation to combine the relevant prior art "'may be implicit from the prior art as a whole, rather

[6] The government's claim that courts, in other contexts, can make difficult determinations that avoid hindsight misses the mark. Br. of the United States at 21. Although judges often have substantial backgrounds in determining the competency of counsel, what constitutes a reasonable use of force, and probable cause, *ibid.*, they have far less expertise in the underlying science that is often at issue in an obviousness case, particularly in many district courts where obviousness cases may seldom arise.

Indeed, perhaps the best evidence demonstrating the necessity of the teaching-suggestion-motivation test is the fact that the Federal Circuit has adopted and employed it for so long. This alone shows that that court – charged with providing consistency within a highly specialized field – views the requirement of applying *Graham* in such a manner as necessary to prevent imposition into the obviousness determination of judicial subjectivity, and ultimately hindsight-prone analyses.

than expressly stated in the references.'" *In re Kahn*, 441 F.3d at 987 (quoting *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000)). This inquiry requires consideration of specific references just as it requires consideration of common knowledge and common sense. *Dystar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, No. 06-1088, ___ F.3d ___, 2006 WL 2806466, at *11 (Fed. Cir. Oct. 3, 2006). The Federal Circuit mandates only that "rejections on obviousness grounds [ ]not be sustained by mere conclusory statements, [and that] instead, there must be *some* articulated reasoning with *some* rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d at 988 (emphases in original); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1322-1323 (Fed. Cir. 2005).

The Federal Circuit's approach thus requires that the decisionmaker ground its determination in specific proof, a requirement essential to the predictability of patentability. *See infra*, pages 26-30. But it does not require that the teaching, suggestion, or motivation be expressly written in the prior art, thus retaining flexibility in the form of proof utilized.

2. Contrary to claims by petitioner and its *amici*, the Federal Circuit's application of Section 103 and *Graham* has not led to the widespread creation or upholding of obvious patents. *See* Lee Petherbridge & R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness* (Aug. 18, 2006), *available at* http://ssrn.com/abstract=923309. Precedents from biotechnology show that, in a field where building blocks for new inventions and modes for research are often disclosed in the prior art, the Federal Circuit's test has ensured that innovative subject matter receives a patent while maintaining that the merely obvious combined use of preexisting technologies does not.

For example, in *In re Sastry*, 285 F.3d 1378 (Fed. Cir. 2002), the Federal Circuit addressed a biotechnology invention relating to a HIV vaccine which comprised two main components. The first component was a peptide to stimulate certain white blood cells to activate the body's cell-mediated immune response. The second component could be an immune helper cell-stimulating peptide, or one of three peptides that inhibit the HIV-infection of white blood cells. *Id.* at 1380. The patent examiner had rejected the patent claims as obvious based on the examiner's combination of three prior art references. On appeal, Sastry argued that, although the references separately taught both the first and second component peptides of his claims, the examiner had failed to provide a specific motivation to combine these elements to arrive at his claimed invention. *Id.* at 1380-1381. The Federal Circuit disagreed, and affirmed the patent examiner's rejection, noting that one of the references "provide[d] a roadmap for combining the two peptides of Sastry's claim 1 by disclosing two peptide-based compositions that [stimulate the cell-mediated immune response] and that contain peptides that satisfy the requirements of Sastry's second peptide." *Id.* at 1381. Thus, in this case the requisite motivation to combine the prior art was found in the references themselves.

In *Alza Corp.*, 2006 WL 2556356, the court of appeals found invalid as obvious a biotechnology patent for an orally administered extended release oxybutynin formulation that could be taken once a day, and would deliver the drug to the body at specified rates. The prior art included three other patents: one that taught a sustained release formulation of oxybutynin (albeit at rates that differed from the rates of the claimed invention); and two other patents that taught general

methods for achieving the release rates claimed in the Alza patent. Alza argued that the prior art failed to provide a motivation to adapt the prior art technology to oxybutynin. The Federal Circuit found otherwise, relying on "the general understanding at the time" within the scientific community. *Id.* at *7. Accordingly, the requisite motivation to combine the prior art was found not in the references themselves, but in the background knowledge of the skilled person at the time. *See also SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349 (Fed. Cir. 2000) (finding patent obvious based upon what a person with ordinary skill in the part would have done with the prior art).

Similarly, the Federal Circuit in *In re Mayne*, 104 F.3d 1339 (Fed. Cir. 1997), found a claimed biotechnology invention to be obvious and unpatentable. The claimed invention was directed to a "fusion protein," *i.e.*, a combination of two different proteins made with recombinant DNA technology. Mayne's fusion protein was a modified growth hormone, designed to avoid the side effects of introducing engineered proteins into animals. Once administered, the fusion protein is cleaved by enzymes to release the desired growth hormone component. At the time of the invention, growth hormones were known in the prior art, as were techniques for creating fusion proteins that were similarly cleaved upon ingestion. The question was whether there existed a motivation to combine these prior art teachings to arrive at the claimed invention. The Federal Circuit found that such a motivation did exist, based on evidence showing that growth hormone fusion proteins were achievable, that Mayne's cleavage technique had been taught for use with various desirable proteins, and that any remaining

differences between Mayne's fusion protein and the prior art were insignificant.

These precedents illustrate that, far from finding no new innovations obvious, the Federal Circuit has reasonably ensured that there is an objective basis for finding a claimed invention obvious. This standard is critical in fields, such as biotechnology, where innovation is often based upon combinations of well-known components and methods of research.

C. The Federal Circuit's Judgment Below Is Consistent With This Court's Precedents

Petitioner claims that the Federal Circuit's application of Section 103(a) in this case is "in open defiance of this Court's authority," but that claim is focused solely on the nature of the particular patented invention at issue in this case. Br. of Pet. at 16. The argument ignores the court of appeals' express application of *Graham*. Pet. App. 5a (court below acknowledging that "[a] patent claim is obvious, and thus invalid, when the differences between the claimed invention 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.'") (quoting 35 U.S.C. § 103 and citing *Graham*, 383 U.S. at 14).

Petitioner also ignores the procedural posture in which the instant dispute arises. The basis for the Federal Circuit's vacatur of the district court's judgment was not that the claimed technology was nonobvious. Rather, the Federal Circuit reversed because the district court, on summary judgment, improperly made credibility determinations with respect to disputed issues of material fact pertinent to the *Graham* inquiries. *See* Pet. App. 16a.

Because the dispute was resolved by the district court on summary judgment, petitioner was required to demonstrate that there were "no genuine issues of material fact," Pet. App. 4a, taking all inferences in the light most favorable to respondent. Moreover, as a matter of substantive law, petitioner had to demonstrate that the patent was invalid for obviousness "by clear and convincing evidence." *Id.* at 5a; *see also Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1 (1934). The critical issue is whether a genuine issue of material fact exists as to whether a person of ordinary skill in the art, at the time the invention was made, would have been motivated to combine the references to solve the problem addressed by the patent so that the invention was obvious under Section 103. Pet. App. 9a.

As to that question, KSR proffered only one declaration, which asserted nothing more than that the prior art "could have been" combined.[7] But that declaration was disputed because respondent proffered two contrary declarations as to the same issue. Pet. App. 16a. Accordingly, the district court erred when it resolved that issue on summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986) ("[I]t is clear * * * that at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.").

[7] Significantly, it is unclear whether the fact that a person of ordinary skill in the art "could have" combined the pre-existing technologies is relevant to the obviousness inquiry which, by the plain language of Section 103, examines what *would have* been done. As the Federal Circuit correctly noted, "'[o]bvious to try' has long been held not to constitute obviousness." Pet. App. 15a (quoting *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995)).

III. RETENTION OF THE *GRAHAM* FRAMEWORK IS IMPORTANT TO BIOTECHNOLOGY INNOVATION

Petitioner now purports to agree that the *Graham* analysis should be maintained, but the reasoning of its brief shows otherwise.[8] Petitioner repeatedly argues for what amounts to a more stringent standard of obviousness, particularly with respect to so-called combination patents, Br. of Pet. at 26, and contends that this Court should permit a district court to grant summary judgment on the defense of obviousness without resolving factual disputes necessary to support the conclusion because the question of patent validity is one of law. *Id.* at 38-40.

A. A Separate Test For So-Called Combination Patents Is Inconsistent With *Graham* And Should Not Be Adopted By This Court

In its petition for a writ of *certiorari*, petitioner suggested an analysis that would make it substantially easier for a patent to be invalidated on obviousness grounds. Petitioner had suggested that, "where a patent covers merely a combination of old elements, the patent will not be valid unless the combination produces 'a new or different function' or demonstrates a 'synergistic result.'" Pet. for Cert. at 14 (quoting *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969)); *see also*

[8] Perhaps inadvertently, the government states that "*extraordinary* skill" is required for patentability. Br. of the United States Supp. Pet. at 24. But that has never been the test under *Graham* or Section 103. This Court, and the plain language of Section 103(a), requires only that ordinary skill be the measurement as to what is obvious.

Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976); Br. of Pet. at 4-5.

Petitioner's position is now more oblique, but it still advocates for a separate, more stringent test for so-called combination patents. *See, e.g.*, Br. of Pet. at 22 n.17, 24, 26. Petitioner argues that the court of appeals has abandoned a separate standard for combination patents, *id.* at 28, and contends that the Section 103 analysis in *Anderson's-Black Rock* and *Sakraida* require some heightened showing for patentability – *i.e.*, some "synergistic result."

This argument is based upon a misreading of this Court's decisions and is inconsistent with congressional intent in enacting Section 103. The Court's use of the term "synerg[y]" was not intended to impose new standards on nonobviousness and, in fact, reflected applications of *Graham,* which, ever since it was decided, has been cited by this Court as controlling precedent. *See Anderson's-Black Rock*, 396 U.S. at 61; *Sakraida*, 425 U.S. at 280; *Dann v. Johnston*, 425 U.S. at 226. Indeed, to hold otherwise would turn back the clock nearly 50 years so that the emphasis would be on what constitutes an "invention" rather than on what is nonobvious, as required by Congress in Section 103. *Graham*, 383 U.S. at 14. [9]

[9] Indeed, many *amici*, including the United States, do not read *Anderson's-Black Rock* or *Sakraida* to impose any "synergistic" requirement on so-called combination patents. *See* Br. of United States in Sup. of Pet. at 14 (noting that there is no "definitive" combination test for nonobviousness); Br. of Intellectual Property Law Professors in Supp. of Pet. at 20; Br. of Ford Motor Company et al. in Supp. of Neither Party at 18; Br. of International Business Machines Corp. in Supp. of Neither Party at 14. *But see* Br. of Computer & Communications Indus. in Supp. of Pet. at 5.

In all events, outside the context of strictly mechanical inventions such as the one at issue in the instant dispute, a separate combination patent standard would be utterly unworkable. Almost all technologies involve combinations, in large part, of prior art – be it the joining of component elements or methodologies. *See In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000); *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998); *see also* H.T. Markey, *Why Not the Statute?*, 65 J. Pat. Off. Soc'y 331, 333-334 (1983) ("virtually all inventions are 'combinations,' and * * * every invention is formed of 'old elements' * * * . Only God works from nothing. Man must work with old elements"). As such, any combination-only standard would either engulf the entire *Graham* inquiry by applying to almost all circumstances, or it would require patent examiners and courts to make and justify threshold determinations into which combinations of prior art should be subject to a more stringent standard of patentability (as suggested by petitioner) and which ones should not be. *See* George M. Sirilla, *35 U.S.C. § 103: From Hotchkiss To Rich, The Obvious Patent Law Hall-Of-Famers*, 32 J. Marshall L. Rev. 437, 533 (1999) ("How can judges and patent examiners distinguish a combination patent from a regular one? Even if a distinction between the types of patents exists, what test would satisfy a nebulous 'synergism' requirement? Judge Rich denounced such a synergism requirement. 'The laws of physics and chemistry in accordance with which all inventions perform do not permit of judicially imagined magic accordingly to which 2+2=5. Wherever such a spurious test prevails all patents are invalid.' ") (quoting Giles S. Rich, *Laying the Ghost of the "Invention" Requirement*, 1 Am. Pat. L. Ass'n Q. J. 26, 44 (1972)).

B. *Graham*'s Emphasis On Factual Findings And Secondary Considerations Promotes Objectivity And Must Be Maintained

Petitioner's argument, focusing merely on its view that the technology at issue in the challenged patent is "simple and ubiquitous," Br. of Pet. at 6, would have this Court return the patent system to the era before the enactment of Section 103 and before *Graham*'s holding that the legal question of obviousness be firmly grounded in factual determinations. Petitioner argues, in effect, that obviousness can be resolved without rigorous inquiry in order to avoid the "burdens flow[ing] from the extremely high cost of litigating a patent case." *Id.* at 32.

However, the factual determinations that are part of the obviousness analysis as required by *Graham* bolster innovation by creating more objective certainty in the patent system.[10] That predictability attracts private resources to fund research and development, which in the biotechnology field comes at great cost. Accordingly, petitioner's request to reduce the burden and cost of litigation over obviousness issues will unquestionably

[10] In the prosecution of a patent application before the United States Patent and Trademark Office ("PTO"), factual findings are critical to the nonobviousness inquiry. Patents are granted by the PTO only after one of its examiners, who possesses specific expertise in the technological field at issue, undertakes a detailed examination of the technology and prior art. The underlying factual findings of the PTO in the Section 103 analysis are thus necessary for proper judicial review, and afforded appropriate deference, under the Administrative Procedures Act's substantial evidence standard. *Dickinson v. Zurko*, 527 U.S. 150 (1999). It is for this reason that Congress required that patents that have undergone such rigorous assessment "shall be presumed valid," 35 U.S.C. § 282, and cannot be lightly overturned based upon speculation detached from any objective criteria.

have a collateral, negative consequence on the public welfare, which it nowhere acknowledges.

Graham's emphasis on secondary considerations in evaluating nonobviousness is similarly critical. Oftentimes, objective evidence of why a patent may be nonobvious is derived from secondary considerations, such "as commercial success, long felt but unsolved needs, [and the] failure of others." *Graham*, 383 U.S. at 17. For nearly 150 years, these secondary considerations have been part of this Court's nonobvious analysis. *Ibid*; *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877); *Webster Loom Co. v. Higgins*, 105 U.S. 580 (1882); *Magowan v. New York Belting & Packing Co.*, 141 U.S. 332 (1891).

That is because the commercial success of an invention sought to be patented suggests it was nonobvious or else someone would have developed it earlier as an obvious means of further profit from the prior art. A long felt unsolved need in an area similarly suggests that an invention that comes along to meet the need was nonobvious or else others would have long ago developed it. And, the failure of others, of course, serves as a strong objective indication that an invention was not obvious or else others would not have met failure when they tried to develop it.

Thus, in *Goodyear Dental Vulcanite*, this Court recognized that an invention for dentures that substituted rubber for metal and other materials was patentable, in part because,

> To find a material, with a mode of using it, capable of being combined with the teeth in such a manner as to be free from the admitted faults of all other known combinations, had been an object long and earnestly sought. It had been a subject for frequent discussion among dentists

> and in scientific journals. The properties of vulcanite were well known; but how to make use of them for artificial sets of teeth remained undiscovered, and apparently undiscoverable, until [the inventor] revealed the mode. But when revealed its value was soon recognized, and no one seems to have doubted that the resulting manufacture was a new and most valuable invention.

93 U.S. at 494; *see also Webster Loom*, 105 U.S. at 591 (noting commercial success in concluding that a loom improvement combining preexisting devices was patentable); *Magowan*, 141 U.S. at 343 (noting that "as a fact not to be overlooked, and having much weight, that the [invention] went at once into such an extensive public use as almost to supersede all packings made under other methods, and that that fact was pregnant evidence of its novelty, value, and usefulness").

There is no basis for the Court now to disregard these important and objective indicia of nonobviousness, which are well-grounded in precedent. As a component of the *Graham* analysis, the secondary considerations provide context to Section 103 by providing the decisionmaker with an objective understanding of how the invention has changed its relevant field. Indeed, the secondary considerations often provide the necessary background as to why, or why not, well-known elements in the relevant scientific community were not before combined with success.[11]

[11] To effect this goal, this Court has ensured that the secondary considerations are relevant to the Section 103 analysis by requiring a nexus between the patent at issue and the evidence proffered in support of the secondary considerations. *Washburn & Moen Mfg. Co. v. Beat 'Em All Barbed-Wire Co.*, 143 U.S. 275 (1892); *McClain v.*

(Continued on following page)

Concrete factual findings and secondary considerations must continue to play a prominent role in establishing nonobviousness. Requiring the legal determination of obviousness to be based upon concrete facts will ensure that courts measuring the prior art and the expertise of a person with ordinary skill in the art will not take for granted the difficulties of combining well-known divergent elements and methodologies for new uses. Similarly, courts, when faced with technologies based upon prior art, will remain compelled to examine the context in which the invention was created, including long unmet needs in the field, past failures, and the extent of the patent's commercial success.

In sum, the instant dispute could easily affect the course of innovation in the life sciences. Biotechnologies such as inhalable insulin which allows millions of patients to forego frequent and painful needle sticks, drug-eluting stents which help avoid coronary artery reclosures, or environmental and agricultural innovations that have resulted in affordable bio-ethanol or enhanced biotechnology animal feeds, are all essentially based upon molecules, ideas, and methodologies that were known to some degree to the pertinent scientific community. After their widespread adoption, many such inventions come to be taken for granted, and may in retrospect even appear unremarkable to an accepting public. Without a nonobviousness standard that is firmly grounded in fact to

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Ortmayer, 141 U.S. 419, 428 (1891) (discounting the commercial success where there was no showing that the sales were due to the ingenuity of the subject matter rather than the "energy" by which they were marketed); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

guard against the temptation of hindsight, many such future inventions may never see the light of day.

CONCLUSION

For the reasons set forth above, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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