No. 04-1350

In The Supreme Court of the United States

KSR INTERNATIONAL CO.,

Petitioner,

v.

TELEFLEX INC., AND TECHNOLOGY HOLDING CO.,

Respondents.

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

BRIEF OF CHEMISTRY AND BIOENGINEERING PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Federal Circuit has erred in holding that a claimed invention cannot be held "obvious", and thus unpatentable under 35 U.S.C. § 103(a), in the absence of some proven "'teaching, suggestion, or motivation' that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed."

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INTEREST OF THE *AMICI CURIAE*[1]

Collectively, *amici* have authored over 600 scientific publications and are inventors on over 200 U.S. patents and published patent applications. Other scientists have cited their patents and publications over 3,000 times.[2] *Amici* serve as editors and reviewers of various scientific journals and are recognized as leaders in their fields. They present seminars on their research around the country at various university and technical meetings. *Amici* have formed more than 5 companies, many of which are now publicly traded, and they serve on the boards of a host of other companies. *Amici* hold teaching positions at this country's elite universities. Hence, *amici* are highly qualified to comment on the test for obviousness. A brief summary of their research and a sampling of their awards appear below, along with links to their websites for more complete information.

Dr. David R. Walt is Professor of Chemistry at Tufts University and a Howard Hughes Medical Institute Professor. He is a Fellow of the American Association for

[1] Both parties have consented to the filing of this brief and written consents have been filed with the clerk. Pursuant to Supreme Court Rule 37.6, *amici* represent that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amici* and their counsel has made a monetary contribution to the preparation or submission of this brief. The names of the educational institutions are provided for identification purposes only, and the institutions have not reviewed or approved this brief.

[2] Statistics taken from searches of the following databases: Delphion, Dialog SciSearch, and United States Patent and Trademark Office (www.uspto.gov).

the Advancement of Science. He is a leader in the development of sensors with particular focus in fluorescent and fiber-optic biosensors. His pioneering research in the field of optical sensors has led to the explanation of fundamental principles as well as important applications of sensors. (http://ase.tufts.edu/chemistry/walt).

Dr. Barbara Imperiali is Professor of Chemistry and Professor of Biology at Massachusetts Institute of Technology. She is a Fellow of the American Academy of Arts and Sciences and was elected to the Royal Society of Chemistry. She developed strategies to engineer protein structure and function, and the design and implementation of new chemical sensor probes in the study of complex biological systems. (http://web.mit.edu/chemistry/www/faculty/imperiali.html).

Dr. Chad A. Mirkin is Professor of Chemistry and of Medicine at Northwestern University. He is a Fellow of the American Association for the Advancement of Science and has received the NIH Director's Pioneer Award and the Raymond and Beverley Sackler Prize. His research focuses on developing fabrication tools for nanotechnology and developing biosensors based on nanoparticles. (http://www.chem.northwestern.edu/~mkngrp).

Dr. Milan Mrksich is a Professor of Chemistry at the University of Chicago and is a Howard Hughes Medical Institute Investigator. He is a Fellow of the American Association for the Advancement of Science and has received the TR100 Young Innovator Award and the Searle Scholar Award. His research group has a broad interest in areas that intersect chemistry, biology, and materials with

an emphasis on biomaterials and biosensors. (http://chemistry.uchicago.edu/fac/mrksich.shtml).

Dr. Stephen Quake is a Professor of Bioengineering at Stanford University and is a Howard Hughes Medical Institute Investigator. His awards include the NIH Director's Pioneer Award, the TR100 Young Innovator Award, and a Packard Fellowship. He pioneered the development of integrated microfluidic devices for large scale automation of biological processes. (http://med.stanford.edu/profiles/Stephen_Quake/html).

Dr. Rustem Ismagilov is a Professor of Chemistry at the University of Chicago. His awards include Arthur C. Cope Scholar Award and the Presidential Early Career Awards for Scientists and Engineers. His research uses microtechnology to control and understand complex chemical and biological processes. He also develops technologies for obtaining the structures of proteins for use in drug discovery programs. (http://chemistry.uchicago.edu/fac/ismagilov.shtml).

SUMMARY OF ARGUMENT

Petitioner proposes gutting the Federal Circuit's "teaching-suggestion-motivation test" ("TSM test") for obviousness but does not propose any workable test to replace it. Petitioner identifies the so-called "synergy test"; however, neither Petitioner nor its *amici* provide a workable definition for "synergy," nor do they provide objective guidelines for its application. The most common definition of "synergy" requires that the "sum must exceed the

individual parts." From the perspective that "there is nothing new under the sun," most inventions are combinations of known elements. Fundamentally, many great inventions are simple and often elegant combinations of old elements. *Amici* believe that, if a "synergy" requirement is adopted as the means for determining obviousness, then most innovations will be deprived of patent protection. The ultimate result would be the stifling of future innovation.

Injecting a "synergy" requirement into the patent law also would call into question hundreds of thousands of previously allowed or issued patent claims; create a nearly incalculable burden on the U.S. Patent and Trademark Office ("PTO") to reexamine such claims; cause innumerable licenses to become suspect; and significantly increase the volume of litigation challenging existing patents.[3] Indeed, Petitioner admits that the outcome of this case will affect every pending U.S. patent application, every issued U.S. patent, and every U.S. federal court challenge to the validity of a patent.[4]

Changing the standard of obviousness by imposing a "synergy" requirement into the law likely will lead to unintended and ill results to many industries. The U.S. patent system is the most successful in the world. Not just

[3] *See* Harold C. Wegner, *Seven IP Cases on the Radar Screen for the October 2005 Term of the Court*, Sept. 7, 2005 (http://patentlaw.typepad.com/patent/WegnerSCOTUS05.pdf).

[4] Petition for Writ of Certiorari, *KSR International Co. v. Teleflex Inc. et al.*, No. 04-1350, at 1-2 (2005).

our economy, but the global economy, may be adversely affected by adoption of the "synergy" requirement Petitioner now proposes.

ARGUMENT

I. THE TSM TEST IS CONSISTENT WITH *GRAHAM* AND IS USEFUL FOR ASSESSING OBVIOUSNESS

In *Graham v. John Deere Co.*, this Court set forth the following standard for determining obviousness:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

383 U.S. 1, 17-18 (1966). Staying within these boundaries, the Federal Circuit's predecessor court implemented a suggestion test to assist with the determination of what subject matter one of ordinary skill in the art would consider obvious. *See Application of Bergel*, 292 F.2d 955, 956 (CCPA 1961). Similarly, the TSM test asks "whether a person of ordinary skill in the art, possessed with the understandings 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." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (internal citation omitted).

A. The TSM Test Is Consistent With *Graham*

The determination of nonobviousness must be based upon the perspective of one of ordinary skill in the art. *Graham*, 383 U.S. at 17-18; *see also Dystar Testilfarben GMBH v. C.H. Patrick Co.*, 2006 WL 28006466, at *6 (Fed. Cir. Oct. 3, 2006). Thus, during the examination of a patent application, the examiner is required to step into the shoes of one of ordinary skill in the art when performing an obviousness analysis. Indeed, for purposes of an obviousness rejection, an examiner may only cite against a patent application, references in the field of the applicant's endeavor or references that a person of ordinary skill in the art would reasonably be expected to look to for a solution to the problem – *i.e.*, "analogous art." *See In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). The analogous art test "has long been part of the primary *Graham* analysis articulated by the Supreme Court." *Kahn*, 441 F.3d at 986-87 (citing *Dann v. Johnston*, 425 U.S. 219, 227-29 (1976)). The Federal Circuit's TSM test "picks up where the analogous art test leaves off and informs the Graham analysis." *Id*. at 987.

B. The TSM Test Is A Useful Way To Assess Obviousness Under The *Graham* Standard

Amici are recognized by the PTO and the bar as persons of at least ordinary skill in their fields. As such, *amici* are called upon regularly for their opinions during

obviousness determinations. *Amici* realize that, although no test is perfect for all situations, any change in how obviousness is determined must be made with caution. A test that may work only for a limited type of patent-worthy inventions will not serve the purpose of the patent laws as set forth in the Constitution: "to promote the progress of science and the useful arts." U.S. Constitution, art. III, § 8, cl. 8. In their experience, *amici* have found that the TSM test allows a broad range of innovations to obtain patent protection, while it precludes such protection for claimed subject matter that persons of ordinary skill in the art would consider obvious. In contrast, and to the extent it can be understood, Petitioner's proposed "synergy" requirement would recognize only a sliver of innovations deserving of patent protection because many such inventions simply are not "synergistic."

Amici consult scientific publications during their research. They review the publications of their peers and comment on the measure of advancements for various scientific journals. They review grant applications of peers and provide recommendations for their funding to various agencies such as the National Institutes of Health, the National Science Foundation, the Defense Department, etc. Thus, *amici* have an understanding of what those of skill in their arts would recognize as a teaching, suggestion or motivation in the art. The TSM test is a practical test that allows *amici* to predict with reasonable accuracy whether conducting proposed research may result in a patentable invention. In contrast, the untenable "synergy test" proposed by Petitioner would preclude *amici* and other innovators from predictably defining or applying the test to enable them to evaluate the potential value of proposed research.

II. A "SYNERGY" ANALYSIS FOR ASSESSING OBVIOUSNESS IS INCONSISTENT WITH *GRAHAM*

A. A "Synergy" Requirement Would Improperly Exclude Legitimate Inventions And Improperly Include Subject Matter Not Patentable Under *Graham*

Petitioner fails to show how "synergy" relates to the determination of whether an invention would be obvious to one of ordinary skill in the art. *See Republic Indus., Inc. v. Schlage Lock Co.*, 592 F.2d 963, 971 (7th Cir. 1979) ("the concept [of synergism] does not bear any logical *ipso facto* relationship to obviousness"). Instead, Petitioner's proposed "synergy" requirement improperly recognizes only a small subset of innovations as patentable: those that somehow create a result greater than the sum of their parts or those for which one element of a combination functions differently in combination than it did individually. *See* Petitioner's Brief, pp. 4-5. Similarly, Petitioner's proposed "synergy" requirement would improperly award patent protection to "synergistic" combinations, even though such combinations are *known* in the art to be "synergistic." In at least these ways, the "synergy" requirement departs from *Graham*'s requirement to determine the differences between the prior art and the claim at issue. These differences are to be analyzed from the viewpoint of one of ordinary skill in the art, considering the invention as a whole.

1. A "Synergy Test" Would Improperly Exclude Inventions Having Unexpected Results

Under the current standard, even if the claim initially appears to be obvious, a finding of obviousness may

be avoided if one of ordinary skill in the art would consider the claimed subject matter to be unexpected in view of the prior art. *See United States v. Adams*, 383 U.S. 39, 51-52 (1966) (indicating that a greater than expected result is an evidentiary factor relevant to nonobviousness). Petitioner's proposed "synergy" requirement, however, excludes unexpected, but non-"synergistic" inventions that would be patentable under the *Graham* standard. "Unexpected" is not synonymous with "synergistic." *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 1268, 1366 (11th ed. 2003) (defining "unexpected" as "not expected; unforeseen" and "synergism" as "interaction of discrete agencies (as industrial firms), agents (as drugs), or conditions such that the total effect is greater than the sum of the individual effects").

The fact that a result is unexpected does not make it "synergistic." Unexpected results often are used to convince the PTO of the patentability of a claimed invention. *See, e.g., In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). For example, the combination of smaller versions of known elements in nanotechnology inventions typically leads to unexpected results that may be used to demonstrate nonobviousness under the current standard. These results, although unexpected, are not necessarily "synergistic."

2. A "Synergy Test" Would Improperly Include Subject Matter Not Patentable Under *Graham*

Although a "synergistic" result may be a type of an unexpected result, a "synergistic" result is not necessarily unexpected. Indeed, the results of some combinations are expected by those of skill in the art to have properties greater than the sum of the individual parts. For example,

in chemistry, combining certain metals with certain ligands results in complexes with catalytic properties – where neither the metals nor the ligands alone exhibit those catalytic properties. To the extent that a new combination of these metals and ligands is discovered that exhibits catalytic properties, that new combination may be "synergistic" under the proposed "synergy test." However, the result nonetheless may be expected by those of skill in the art, and hence, the combination may not qualify as patentable under the patent statute.

Thus, Petitioner's proposed "synergy test" would improperly allow patent protection for categories of inventions whose results may be "synergistic" but also may be expected. Yet, Petitioner's proposed test would improperly preclude patent protection for inventions involving results that are unexpected, but not "synergistic." Under the *Graham* analysis, however, such inventions with unexpected yet non-synergistic results may be patentable.

3. The "Synergy Test" Fails To Consider The Invention As A Whole

Section 103 compels consideration of the invention as a whole. *See* 35 U.S.C. § 103(a). Taking the discrete elements of an invention and comparing them to the prior art is improper. *See Graham*, 383 U.S. at 32. Consider, for example, a new chemical compound. All the underlying elements can be found in the prior art; hence, comparing them separately to the prior art would render the chemicals themselves obvious. Without comparing the invention as a whole to the prior art, the decision-maker misses what the person of ordinary skill thought was innovative, the compound itself. Only by looking through the eyes of

one of ordinary skill at the invention as a whole, *i.e.*, the compound, what it does, and/or what properties it has, etc., can the decision-maker appreciate its nonobvious features.

Petitioner's proposed "synergy test" violates this statutory mandate by looking exclusively to the functioning of the individual components of a combination after they have been combined. Petitioner's "synergy test" improperly assumes that it would have been obvious to take known components and combine them. *See Republic*, 592 F.2d at 971; Giles S. Rich, *Laying the Ghost of the "Invention" Requirement,* 1 AM. PAT. LAW ASS'N Q.J. 26, 34 (1972) (noting that "to invalidate [a "combination"] claim, it must be shown that the *combination* was obvious, not merely its components" (emphasis in original)). This unjustifiable assumption is essentially an improper "obvious to try" standard of obviousness. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1167 (Fed. Cir. 2006). In fact, the very choice of the components may be the essence of the invention. *See Republic*, 592 F.2d at 971 ("[*i*]*t is that act of selection which is the invention*" (emphasis in original)); *Adams*, 383 U.S. at 50 ("the issue is whether bringing [the components] together as taught by [the inventor] was obvious in the light of the prior art").

The determination of which elements to select and combine and in what proportions often leads to useful, novel, and nonobvious chemical compounds that find application in many different technological fields. The "synergy test" ignores what one of ordinary skill in the art would find nonobvious and precludes a determination of the nonobviousness of *making a combination*. As such, the "synergy test" "does not comport with the *Graham* mandate to apply section 103." *Republic*, 592 F.2d at 971.

B. The "Synergy Test" Previously Has Been Found To Be Unworkable

The "synergy test" previously has been rejected as unworkable by the lower courts. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1540 (Fed. Cir. 1983); *Republic*, 592 F.2d at 971. Although Petitioner relies on two post-*Graham* decisions by this Court, to support its argument that "synergy" should be a requirement of patentability, Petitioner takes the "synergism" language in these decisions out of context. *See Anderson's-Black Rock, Inc. v. Pavement Salvage Co., Inc.*, 396 U.S. 57 (1969) and *Sakraida v. Ag Pro, Inc,* 425 U.S. 273 (1976). Neither *Anderson's-Black Rock* nor *Sakraida* instituted a mandatory "synergy" requirement. *See Anderson's-Black Rock*, 396 U.S. at 61 (stating that "[a] combination of elements *may* result in an effect greater than the sum of the several effects taken separately" (emphasis added)); *Sakraida*, 425 U.S. at 282. Petitioner changes the Court's "may" to a "must" and concludes that "synergy" is a condition of patentability. *See* Petitioner's Brief, pp. 4-5. This Court has not held "that a 'synergy' test supersedes a finding of nonobviousness under the *Graham* analysis. To the contrary, each case quoted *Graham* with approval." *Republic*, 592 F.2d at 969.

Like Petitioner, some courts misconstrued the Court's references to "synergy" and added a "synergy" element to the *Graham* analysis for so-called "combination" patents. However, those courts struggled in their attempts to formulate a workable definition of "synergy." *See* George M. Sirilla, Giles S. Rich, *35 U.S.C. § 103: From Hotchkiss to Hand to Rich, the Obvious Patent Law Hall-of-Famers*, 32 J. MARSHALL L. REV. 437, 543 (1999). Even before the

formation of the Federal Circuit, many courts had abandoned a "synergy" requirement.[5]

In laying the "synergy" requirement to rest, the Seventh Circuit Court of Appeals pointed out that the various formulations of "synergy" revealed that "synergism is only a figure of speech, for in its literal sense synergism never has existed and never can exist in mechanical or hydraulic inventions when the term is defined as a whole result greater than the sum of its constituent parts." *Republic*, 592 F.2d at 970. The PTO also recognized that the Supreme Court's references to "synergy" did not constitute a modification of the *Graham* analysis and issued a directive to that effect in 1976. *See* Official Gazette of the United States Patent and Trademark Office, Vol. 949, No. 1, p. 4; *see also* MPEP § 2141.

A few years later, the Federal Circuit followed suit, clarifying that "synergy" is nowhere to be found in the statute and that, although the presence of "synergy" may point toward nonobviousness, it is not a requirement of patentability. *Stratoflex,* 713 F.2d at 1540. The TSM test was implemented to assist with the obviousness determination. *See Ashland Oil, Inc. v. Delta-Resins & Refractories, Inc.*, 776 F.2d 281, 297 (Fed. Cir. 1985). Unlike the proposed "synergy" test, the Federal Circuit's treatment of obviousness is consistent with this Court's precedents and the patent statute. *See Alza Corp. v. Mylan Labs., Inc.*,

[5] "Congress conferred exclusive jurisdiction of all patent appeals on the Court of Appeals for the Federal Circuit, in order to 'provide nationwide uniformity in patent law.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (quoting H.R. Rep. No. 97-312, at 20 (1981)).

2006 WL 2556356, at *3 (Fed. Cir. Sept. 6, 2006); *Kahn*, 441 F.3d at 985.

III. A "SYNERGY" REQUIREMENT WOULD RENDER MANY GREAT INNOVATIONS UNPATENTABLE

Injecting a "synergy" requirement into the patent law would render many past inventions unpatentable. Pioneering inventions such as the telephone, electric lamp, and airplane would likely not have been entitled to a patent under Petitioner's proposed "synergy test."

In 1876, Alexander Graham Bell obtained a patent on the telephone. *See* U.S. Patent No. 174,465. Bell characterized his invention as a "combination . . . of a permanent magnet or other body capable of inductive action, with a closed circuit." *Id*. at claim 2. In describing his invention, Bell stated that the "combined effect of A and B . . . is expressed by the curve A + B." *Id*. at p. 2. "A," which referred to a permanent magnet, and "B," which referred to a closed circuit, were known elements functioning as expected. There was no "synergy" produced by the new telephone. However, this lack of synergy did not stop the Court from affirming the validity of the patent. *See Dolbear v. American Bell Tel. Co.*, 126 U.S. 1 (1888).

Thomas Edison obtained a patent on the electric lamp in 1880. *See* U.S. Patent No. 223,898. Like Bell, Edison characterized his invention as a "combination" – more specifically, a "combination of carbon filaments with a receiver . . . " *Id.* at claim 2. Nowhere in the patent did Edison describe his invention as "synergistic."

Orville and Wilbur Wright ("the Wright brothers") obtained a patent on the airplane in 1906. *See* U.S. Patent No. 821,393. Not surprisingly, the Wright brothers characterized their invention as a "combination" but made no mention of any "synergistic" result produced by the claimed combination.

In more recent times, Dr. Kary Mullis combined a known enzyme with known oligomeric starting materials, and through cycles of heating and cooling, greatly increased the amount of DNA produced. His innovation, the Polymerase Chain Reaction ("PCR"), revolutionized biology, medicine, genetics, and forensic science. Dr. Mullis received a Nobel Prize for this innovation and obtained U.S. and worldwide patents. Mullis took known elements and, relying on a known property of DNA (that it dissembles at high temperature), came up with a more efficient way to obtain large amounts of DNA. This combination may not be "synergistic" but, nonetheless, it advanced the useful arts tremendously.

If "synergy" were a requirement, would these innovations have been patented? Likely they would not have been. Indeed, in the mechanical arts, there is no such thing as a component that functions differently in combination than it does individually. *Republic*, 592 F.2d at 970.

> A spring or a valve will always function as a spring or valve, alone or in concert with other components[;] mechanical elements can do no more than contribute to the combination the mechanical functions of which they are inherently capable [and, therefore,] the overall performance of the combination is always equal to the sum of the functions of the individual components.

Id.

In the chemical arts, virtually all compounds are made from existing elements. While certain elements retain their chemical properties when combined with other elements, many elements change their biochemical or electrochemical properties when combined with other elements. Such changes may be characterized as "unexpected," but not necessarily "synergistic." Indeed, nearly all things are made from existing components. To effectively preclude patent protection for new combinations of existing components by imposing a "synergy" requirement on patent applicants would render unpatentable even the most revolutionary inventions. As Giles Rich, one of the authors of Section 103, remarked, "[t]he laws of physics and chemistry in accordance with which all inventions perform do not permit the judic[i]ally imagined magic accordingly to which 2+2=5. Where such a spurious test prevails all patents are invalid." Rich, *Laying the Ghost of the "Invention" Requirement,* 1 AM. PAT. LAW ASS'N Q.J. at 44.

Under Petitioner's proposed "synergy test," many innovations, recognized by *amici* and others as revolutionary, would be rendered obvious.[6] This is simply inconsistent with our Constitution's mandate for patent protection to promote the progress of the useful arts.

[6] To the extent Petitioners argue that this conclusion is illusory because secondary considerations would rebut this conclusion, *amici* disagree. Secondary considerations require objective evidence that may not develop until well after the patent application is filed. Many recognized secondary considerations (such as commercial success, copying by others, licensing, etc.) are limited by the ability of various industries to adopt the invention. For example, because regulatory approval must be obtained for medical innovations before they can be placed on the market, patent applicants may be unable to demonstrate commercial success during the pendency of their applications.

CONCLUSION

In sum, very few, if any, inventions deserving of patent protection would be considered patentable under Petitioner's proposed "synergy test." This untenable "test" includes within its reach only a subset of inventions that would be patentable under the *Graham* standard. Unlike the proposed "synergy test," the current obviousness standard articulated by this Court in *Graham*, and applied correctly by the Federal Circuit for decades, properly balances the rewards to inventors with the interests of the public and maintains the high level of innovation and thriving technology that drives this country.

For at least the foregoing reasons, this Court should affirm the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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