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 WISCONSIN ALUMNI RESEARCH FOUNDATION, REGENTS OF THE UNIVERSITY OF CALIFORNIA, BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM, WASHINGTON RESEARCH FOUNDATION, SCIENCE AND TECHNOLOGY CORPORATION @ UNM, RENSSELAER POLYTECHNIC INSTITUTE, AND RESEARCH CORPORATION TECHNOLOGIES, INC. AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICI CURIAE* [1]

Amici are universities, entities affiliated with universities, and entities involved in university technology management. *Amici* engage in and support scientific research, obtain patents on inventions arising from the research, license the technologies to companies for commercialization and then use the licensing income to underwrite further academic research.[2]

The academic sector drives research and innovation in the United States. By 2002, the sector accounted for an estimated 54% of the basic research conducted in this country.[3] The nonprofit research community carries out much of this work under the Patent and Trademark Law Amendments of 1980**,** commonly known as the Bayh-Dole Act ("the Act" or "Bayh-Dole"),[4] and its implementing regulations (37 C.F.R. 401). Congress passed the Act in 1980 to (a) nurture and spur research in the academic sector; and (b) promote university-industry collaborative relationships that would ensure that the fruits of university research reached and benefited the public.

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[1] The parties have consented to the filing of this brief in global consents to the filing of *amicus* briefs in support of any party that have been lodged with the Clerk. Pursuant to Rule 37.6, *amici* state that no counsel for a party has written this brief in whole or in part and that no person or entity, other than these *amici* or their counsel, has made any monetary contributions to the preparation or submission of this brief.

[2] In this brief, *amici* employ the shorthand term "technology transfer" to refer to this transfer of research results and new technologies from universities to the commercial marketplace.

[3] National Science Foundation, *Science and Engineering Indicators 2004, available at* http://www.nsf.gov/statistics/seind04/c5/c5s1.htm. In 2002, academic institutions spent $33 billion on research and development, of which $19 billion came from the federal government and $6.7 billion from the academic institutions themselves. National Science Foundation, *Science and Engineering Indicators 2004, available at* http://www.nsf.gov/statistics/seind04/c5/c5h.htm.

[4] 35 U.S.C. §§ 200-212.

Amicus Wisconsin Alumni Research Foundation ("WARF") was founded in 1925 as a nonprofit entity to promote, encourage and aid scientific investigation at the University of Wisconsin-Madison ("UW-Madison"). One of WARF's first accomplishments was to patent a vitamin D discovery that eventually eliminated the childhood disease rickets worldwide. Since its founding, WARF has processed approximately 4,800 inventions created by UW-Madison faculty and staff, obtained 1,540 U.S. patents on these inventions, entered into over 1,390 license agreements with companies around the globe and returned $800 million in licensing fee income to UW-Madison to fund research programs and initiatives.

The Bayh-Dole Act has made it possible for WARF to make the contributions to the public good that it does today. In the middle to late 1960s, government agencies kept title to inventions that had been funded with federal money. As a consequence, invention disclosures to WARF had fallen to barely one per month, and what few disclosures there were had fallen in quality.[5] The situation improved somewhat when Institutional Patent Agreements ("IPAs") were negotiated with (what is now) the Department of Health and Human Services ("HHS") in 1968 and the National Science Foundation ("NSF") in 1973. These IPAs gave WARF (and other universities) the right to elect to take title to inventions made with funds from those two agencies.[6]

Since the enactment of Bayh-Dole, invention disclosures to WARF have mushroomed. Today, WARF (a) manages over 720 pending and 880 issued U.S. patents on UW-Madison technologies, as well as 1,920 foreign equivalents; (b) offers

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[5] An "invention disclosure" is a document prepared by an inventor to describe the invention made for use in a potential patent application.

[6] The IPAs were evolutionary steps that led to the Bayh-Dole Act. In essence, the terms and provisions of the Bayh-Dole Act codified IPA provisions.

more than 3,800 technologies for licensing; (c) maintains more than 940 active commercial license agreements, as well as 460 academic licenses; (d) has over 160 license agreements with Wisconsin companies; and (e) holds equity in 40 UW-Madison spin-off companies. WARF's most important patents include the blood anticoagulant Warfarin; a coating process making pills easier to swallow; treatments for osteoporosis and cancer; magnetic resonance techniques; and a discovery known as the "Wisconsin Solution" that prolongs the use of transplant organs.

Amicus Regents of the University of California provides for technology transfer from ten campuses and five medical schools in the State, and from three national laboratories operated by the University of California system on behalf of the U.S. Department of Energy. Currently, there are more than 3,000 ongoing research projects supervised by 13,000 principal investigators.

In the last ten years alone, these efforts have led to three Nobel prizes and a long list of pioneering research discoveries in biochemistry, bioengineering, cell biology, disease procedures, developmental biology, endocrinology, genetics, immunology, neurobiology, oral biology, pharmacy and pharmacology. Those breakthrough discoveries include: the hepatitis B vaccine; a human growth hormone; a method to treat aneurysms by use of a catheter instead of opening the skull; cochlear implants to help the hearing impaired; a method for detecting feline immune deficiency virus; a method for detecting chromosome abnormalities; a laser system to enhance treatment of skin conditions; and a new atomic force microscope.

Amicus Board of Regents of the University of Texas System was founded in 1883. The University of Texas (UT) system is one of the largest systems of public higher education in the nation and the largest of six systems in Texas. Serving the broad academic and professional needs of a

diverse state, the UT System is composed of nine academic institutions and six health institutions, including four medical schools, two dental schools, and nine nursing schools. System-wide, the faculty includes nine Nobel laureates, 20 Pulitzer Prize winners, 37 members of the National Academy of Sciences, 50 members of the National Academy of Engineering, and 29 members of the Institute of Medicine.

As a direct result of the Bayh-Dole Act, the UT System makes significant contributions to the Texas economy through the discovery and commercialization of new technology, the attraction and growth of business, and the development of a well-educated workforce. Between 2001 and 2004, the University of Texas System was issued 422 patents, granted almost 500 licenses, and created 58 companies based on institutional research. UT System medical research has led to important discoveries such as kidney stone testing and medication, cancer cell detection, heart attack prevention and treatment, localized radiation therapy for cervical cancer, Hepatitis B medication, and pulmonary fibrosis. Discoveries from research at academic institutions include optical technology, improved heat transfer, point-of-care diagnostic testing, fuel cells that serve as artificial muscles, high quality pigments, diabetes and weight assessment for children, and biomedical engineering.

Amicus Washington Research Foundation ("WRF") was founded in 1981 to assist universities and other nonprofit research institutions in the State of Washington with commercialization of their technologies and to provide support, through gifts and grants, for scholarship and research. WRF is an independent private foundation whose operational revenue comes from retained funds from licensing and investing activities. WRF has made gifts and licensing disbursements to the University of Washington totaling more than $150 million.

WRF has benefited Washington State research institutions by licensing a variety of technologies to industry, including the basis for hepatitis B virus vaccine, blood clotting factors, recombinant insulin, and wireless technology supporting the "Bluetooth" protocol. The gifts from WRF have supported the creation of over 100 endowments for chairs, professorships, research fellowships and graduate stipends in science, medicine and engineering. Educational programs created and supported by WRF include the Center for Technology Entrepreneurship (University of Washington Business School) and the Program for Technology Commercialization (University of Washington Bioengineering). WRF was a founding supporter of technology "gap" funding programs at the University of Washington, the Fred Hutchinson Cancer Research Center, and Washington State University.

Amicus Science & Technology Corporation @ UNM (STC) is a wholly-owned 501(c)(3) corporation of the University of New Mexico. The organization's mission is to support the University of New Mexico and its partners as the source for innovation management and commercial development. STC receives over 100 new invention and copyright disclosures a year and it is actively engaged in the commercialization of technologies through licensing to established companies and the formation of new start-up companies via its Lobo Venture Lab. Additional information about STC and its activities can be found at stc.unm.edu

Amicus Rensselaer Polytechnic Institute is the oldest technological university in the United States, founded in Troy, NY in 1824 for the purpose of instructing persons "in the application of science to the common purposes of life." It is comprised of five schools: Architecture, Engineering, Humanities and Social Sciences, Management, and Science.

Rensselaer Polytechnic Institute commercializes technologies through a combination of the licensing of its technologies as well as new company formation via an active

entrepreneurial educational and technological business incubator program. Within the past ten (10) years, Rensselaer has processed over 560 invention disclosures, which has resulted in over 90 issued U.S. patents. Rensselaer has processed over 65 license agreements, 45 of which are still active. Its rich history of technology transfer also includes graduates of over 200 companies from its Technology Incubator Program. Overall, Rensselaer's technology transfer efforts have led to significant economic growth in upstate New York and the transfer of important technologies to the public in such areas as nanotechnology, materials science, energy, information technology, medical and biotechnology, and experimental media.

Amicus Research Corporation Technologies, Inc. is an independent technology management company that has been involved in providing commercialization services to academia and other institutions since its founding in 1912. It has been pivotal to the success of many important pharmaceuticals, diagnostics, biotechnology products, and new materials and processes. Recent products include three in the cancer area: the widely used therapeutic compounds Cisplatin and Carboplatin and the PSA (Prostate Specific Antigen) test for diagnosing and monitoring prostate cancer.

The academic technology transfer work required to accomplish these extraordinary results is always arduous, sometimes grueling, and for most institutions, only modestly remunera tive. University of Michigan President Mary Sue Coleman recently explained why universities nonetheless engage in technology transfer:

> Many people are often confused about why we are interested in technology commercialization, in nurturing startup companies, and in facilitating more patents and license agreements. It is not about the promise of future revenues that might be generated from this activity. You heard me correctly. It is not about the money. . . . Tech-

> nology transfer must serve our core mission: sharing ideas and innovations in the service of society's well-being.[7]

Amici submit this brief to provide the Court with an academic sector perspective on the patent validity issues underlying this case. The brief focuses on why the Federal Circuit's present approach properly applies the statute, and on the risks that weakening patents would pose to the technology transfer capabilities of the university sector and the continued vitality of the Bayh-Dole Act.

SUMMARY OF THE ARGUMENT

Amici recognize the Petitioner's argument as an attempt to weaken patents and to make it easier to challenge a patent based on obviousness. The present "teaching, suggestion, or motivation to combine" test is an important and appropriate guard against using hindsight to find an invention was obvious. The test is further consistent with the express language of 35 U.S.C. § 103(a) and with the precedent of this Court.

Amici further state that lowering a defendant's burden of proving obviousness would have a direct and negative impact on research, development, and commercialization of products by universities and U.S. companies. Over the last 25 years, universities have greatly expanded investment in new technology and have dramatically increased real-world commercialization through licenses and partnerships with U.S. companies. These actions were spurred in large part by legislation enacted in 1980 that allowed universities to obtain patent rights in inventions developed with federal funding. Without the incentives that accompany a strong patent system, this

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[7] AUTM U.S. Licensing Survey, FY 2004, available at http://www.autm.net/surveys/desp.surveyDetail.cfm?pid=28 (follow "Download PDF of abridged FY 2004 U.S. Survey Summary").

trend—and the beneficial research, commercialization and employment associated with it—could be at risk.

Amici urge the Court to maintain the current law on obviousness and to ensure that the law as applied by courts will keep the burden of proving invalidity on the party challenging the patent, as required by statute, 35 U.S.C. § 282, and to reject any attempt to shift the burden of proof to patent owners to show "synergy" or "extraordinary results" as urged by Petitioner.

ARGUMENT

I. LOWERING DEFENDANTS' BURDEN WOULD WEAKEN PATENTS AND DECREASE INVESTMENT IN NEW AND DEVELOPING TECHNOLOGY

The key to successful development and licensing of inventions generated within the university sector is a strong and viable patent system. The ability of the *amici curiae* to continue this publicly beneficial activity is dependent on whether they can obtain patents with an attached presumption of validity and can rely on the federal courts to protect their patents. Consequently, any changes which, through legislation or judicial interpretation, weaken the patent system will have a highly detrimental effect on the ability of the university sector to fulfill the premise and promise of the Bayh-Dole Act and therefore deprive the public of receiving the benefits of inventions and subsequent innovations which will improve the human condition.

Amici recognize the current law on obviousness, including the "motivation to combine" test, as vital to protecting the integrity of the patent system. The position urged by Petitioner in this case would dramatically weaken patents. It would invite potential infringers to disregard patents and refuse licenses, because a colorable obviousness defense

could always be created if the law presumed that a combination of known elements cannot be a patentable invention.

It is vital to avoid using hindsight to assess an invention. Impinging on that assessment is the fact that the number of scientific articles cataloged in the internationally recognized peer-reviewed set of Science and Engineering journals covered by the Science Citation Index (SCI) and Social Sciences Citation Index (SSCI) grew to nearly 700,000 in 2003 alone.[8] That repository of information, even absent other non-peer reviewed articles and publications, represents a huge library of information where, with the application of hindsight, uncombined elements of a given invention may be found with a diligent search. As a consequence, and without some effective guide, as the Court of Appeals has enunciated in the present case, one would be hard-pressed, perhaps even in most instances, not to find discrete elements of a disclosed and claimed invention with the application of hindsight based upon such disclosure.

There are many areas of technology where the results obtained from combining discrete elements are unpredictable, even by one skilled in the art. In that regard, one may be able to make a distinction between the mechanical and chemical or biochemical arts. But that is where the knowledge of one skilled in the particular art can provide a practical and measured approach to whether a patentable invention exists. Even that assessment is susceptible to distortion where hindsight is present during the evaluation. *See* D.A. Schkade & L.M. Kilbourne, *Expectation-Outcome Consistency and Hindsight Bias*, 49 Organizational Behav. & Hum. Decision Processes 108 (1991) (once an outcome is known, "it becomes difficult to accurately reconstruct a previous state of mind.") Indeed, as this Court recognized over 100 years ago, "[n]ow that [the

[8] National Science Foundation, *Science and Engineering Indicators 2006*, available at www.nsf.gov.

invention] has succeeded, it may seem very plain to any one that he could have done it as well." *Webster Loom Co. v. Higgins*, 105 U.S. 580, 591 (1882).

The Federal Circuit has recognized that the motivation standard applied in its analysis is inclusive of both explicit and implicit suggestions to combine prior art. This factor is extremely important because of the disparity in complexity and type of the technology to which the analysis must be applied. It fully supports a technology neutral position in application of the patent laws. The *amici curiae* believe that neutrality is an essential feature of a strong patent system, particularly in the face of many currently proposed reforms being driven by technology orientation.

Amici Curiae include leading research universities and related non-profit institutions in the United States that conduct and support research and development activities in connection with their primary educational mission. Some of the institutions have been transferring the results of the research conducted by them to the private sector through patenting and licensing for many years, even prior to the advent of significant federal funding for such research and development activities. The enactment of 35 U.S.C. §§ 200-212 (the Bayh-Dole Act) expanded the opportunity for the university and small business sectors to engage in technology transfer.

The seminal premise of the act changed the *ab initio* presumption of title to and, therefore, the ownership of, any invention made in whole or in part with federally-derived funds from the government to the respective non-profit entity or small business which had utilized such funds in the making of an invention. Under the Bayh-Dole Act the U.S. patent system was the designated vehicle for purposes of technology transfer.

Today there are some 300 universities which engage directly or indirectly through contractual arrangements in technology

transfer. This activity reflects the impact of the Bayh-Dole Act on academic technology transfer and that the federal government provided 62% of academic R&D expenditures in 2003 and which were estimated at $42 billion in 2004.[9] It is also significant that the bulk of the basic research (estimated at 54% in 2004) in the United States is conducted in the university sector. It is this research, which provides the basis for many new products and processes and sometimes the formation of whole new industries (witness the biotech industry), which heavily contributes to the United States maintaining its technological leadership in a global economy.

The Bayh-Dole Act is vital to transferring research results to the public and that ability and capability is the fundamental premise of the Bayh-Dole Act since the research is, for the most part, supported with taxpayer funds. Efforts by the university sector to validate that premise have exceeded the expectations of the influence of the Act. For example, 27,322 licenses/options were active in 2004 with the bulk of income derived from such contractual relationships being utilized in support of further research and development. In addition, since 1980, the year in which the Bayh-Dole Act was passed, 4,543 new companies have been formed based upon a license from an academic institution. Further, for the period from 1998 through 2004 a total of 3,114 products have been made commercially available from the licensing efforts of the university sector.[10]

As a practical matter, the greater need for the patent incentive lies primarily with universities, other non-profit organizations and small business. Technology transfer by universities and non-profits depends entirely on the underlying patent

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[9] National Science Foundation, *Science and Engineering Indicators 2006*, available at www.nsf.gov.

[10] AUTM U.S. Licensing Survey, FY 2004, available at http://www.autm.net/surveys.

position. Given the fact that most university-generated inventions are embryonic in nature and require a great deal of development and often are well ahead of their time in a commercial sense, the need for exclusivity in licensing can be critical. Any uncertainty which accompanies a patent and its scope and validity makes it a candidate for rejection of licensing by the private sector. That, in turn, means that the likelihood of development to a commercial product or process is much diminished and that the public will be deprived of its benefits.

Moreover, a large segment of university licensing is with small companies and, in fact, the Bayh-Dole Act requires that preference be given to licensing of small business. 35 U.S.C. § 202 (c)(7)(D). It has been recognized by the National Science Foundation that small businesses contribute the greatest number of jobs to the U.S. economy and it has been estimated that university licensing has translated into 260,000 jobs and further, the licensing of inventions from universities, teaching hospitals, research institutes and patent management firms added approximately $40 billion to the domestic economy.[11]

The university sector's contribution to many facets of the U.S. and global economy, and to the enhancement of the human condition, is reliant upon a viable, sound and technology-neutral patent system. As such, the question before this Court is vital to the continued effectiveness of university technology transfer. Any changes that weaken the patent system will ultimately also weaken the ability of the university sector to transfer the fruits of its research endeavors to benefit and improve the human condition.

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[11] AUTM U.S. Licensing Survey, FY 2003, available at http://www.autm.net/surveys.

II. THE PRESENT LAW ON OBVIOUSNESS PROPERLY FOLLOWS THE STATUTE AND SUPREME COURT PRECEDENT

The standards for patentable invention have been developing since the U.S. Constitution authorized Congress to provide for exclusive rights to inventors for their discoveries. U.S. Const. art. I, § 8. Courts and commentators have long recognized that most inventions are in fact new combinations of previously-known elements. Simply finding the elements of a patent claim separately in the prior art has never been sufficient to defeat patentability. Rather, courts focused on how the elements were combined. For example, the Court of Customs and Patent Appeals stated in 1943 that "[i]n considering more than one reference, or a reference alleged not to be in the art involved, the question always is: does such art suggest doing the thing which applicant has done?" *In re Fridolph*, 134 F.2d 414, 416 (C.C.P.A. 1943).

Congress first enacted legislation setting forth the non-obviousness requirement in 1952. 35 U.S.C. § 103. This Court has clarified that the 1952 Patent Act was not intended to change the general standards for patentability. It was intended to incorporate and codify the standards developed by the courts. *Graham v. John Deere*, 383 U.S. 1, 17 (1966). The express language of § 103 incorporated the concept of requiring more than individual elements. By focusing the analysis on "the subject matter as a whole," Congress required consideration of the claim elements taken together. By directing the analysis to the "time the invention was made," Congress precluded using hindsight to render an invention obvious. Thus, the question is not how the individual elements would be viewed by those skilled in the art after the fact, but whether the subject matter as a whole would have been obvious at the time of the invention.

This Court's decision in *Graham* identified factual inquiries basic to obviousness analysis: the scope and content

of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art. 383 U.S. at 17. The Court also recognized the difference between finding elements separately and finding the subject matter as a whole to be obvious. The Court discussed additional factual considerations as critical "to guard against slipping into the use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue." *Id.* at 36. This Court recognized long ago that inventions might seem "plain" or "simple" after someone else invented them. *Webster Loom Co. v. Higgins*, 105 U.S. 580, 589-91 (1882) (rejecting the argument that a "mere aggregation" of old, well-known devices cannot be patentable).

With statutory and Supreme Court guidance, courts continued to scrutinize the prior art to see if it in fact suggested the subject matter as a whole. *Application of Samour*, 571 F.2d 559, 563 (C.C.P.A. 1978) (for obviousness rejections under § 103, "the teachings of references can be combined only if there is some suggestion or incentive to do so.") The courts looked beyond the existence of old elements, even if they operated in a claimed combination in the way they had before.

In *Reeves Instrument Corp. v. Beckman Instruments, Inc*., 444 F.2d 263 (9th Cir. 1971), the Ninth Circuit Court of Appeals recognized that a litigation defendant will almost always be able to find the individual claim elements separately in the prior art. The court considered a challenge under § 103 to a patent relating to the problem of checking the operation of the numerous elements of an analog computer. The defendant first argued that "combination" patents are subject to special scrutiny, and that the patent in suit was invalid "because the claimed invention consists of old elements (amplifiers, potentiometers, switches etc.) which operate within the claimed combination in the same fashion as they have always operated in the prior art." 444 F.2d at 270.

This argument was squarely rejected by the court. In particular, the court carefully considered *Graham v. John Deere* and found that the defendant's argument "suggests an analytical approach to patentability which is directly contrary to the statutory language of § 103 which provides that the inquiry into patentability must be drawn to the 'subject matter as a whole' and not to the elements of a claimed combination and their individual novelty." *Id.* The *Reeves* court recognized that the argument, taken to its logical conclusion, would have the result of precluding patenting of "virtually every new mechanical or electrical device since the vast majority, if not all, involve the construction of some new device (or machine or combination) from old elements." *Id*. The court did not limit its reasoning to the electrical and mechanical arts but extended it also to the chemical arts, recognizing that "all chemical products are the result of combining known chemical elements." *Id*. at 270-271.

The Federal Circuit has followed the legal principles set out by this Court, by Congress, and by its predecessor court. It has continued to carefully apply the *Graham* factors in a way that follows the statutory directive to consider the invention as a whole, and to consider the state of the art at the time the invention was made. Because virtually all patents are combinations,[12] "[c]asting an invention as 'a combination of old elements' leads improperly to an analysis of the claimed invention by the parts, not by the whole." *Custom Accessories v. Jeffrey-Allan Industries*, 807 F.2d 955, 959 (Fed. Cir. 1986).

"Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole." *Ruiz v. A.B. Chance*, 357 F.3d 1270,

[12] Because 'every invention is formed of old elements,' a rule that such combinations are not patentable 'would destroy the system." Howard Markey, *Why Not The Statute*, 65 J. Pat. Off. Soc. 331 (1983).

1275 (Fed. Cir. 2004). As explained in *Ruiz*, "inventions are typically new combinations of existing principles or features. The "as a whole" instruction in title 35 prevents evaluation of the invention part by part." *Id.*

> Without this important requirement, an obviousness assessment might break an invention into its component parts (A+B+C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find it prior art components, would discount the value of combining various existing features or principles in a new way to achieve new results—often the very definition of invention.

357 F.3d at 1275.

In the obviousness analysis, the Federal Circuit has continued to look for a "motivation to combine" references, as its predecessor court had, and thereby avoid hindsight reconstruction. The "motivation to combine" test is not, however, as severe as Petitioner and supporting *amici* would have the Court believe. The Federal Circuit has not required that the suggestion or motivation be found in the express teachings of published materials. On the contrary, the Federal Circuit has applied the test in a flexible way that takes into account the particulars of each distinct factual setting. The motivation to combine may come from express statements in the prior art, but it also may come from the knowledge of one of ordinary skill in the art. *In re Thrift*, 298 F.3d 1357, 1363 (Fed. Cir. 2002), *In re Huston*, 64 U.S.P.Q.2d 1801, 1810 (Fed. Cir. 2002). Moreover, the suggestion or motivation may be found implicitly in the prior art, or even in the nature of the problem to be solved. *Alza Corp. v. Mylan Laboratories*, 80 U.S.P.Q.2d 1001 (Fed. Cir. 2006) (affirming judgment of invalidity under § 103 where one of skill in the art would

have been motivated to make the claimed combination, even without an express teaching or suggestion in the art.)

The current law thus takes into full account the statute's focus on a person having ordinary skill in the art. *See also Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1338 (Fed. Cir. 2005) (relying on undocumented knowledge of those skilled in the art and the nature of the problem to be solved to combine references); *Ruiz v. Chance*, 357 F.3d 1270, 1276 (stating that there is no "rule of law that an express, written motivation to combine" must exist to combine references, and identifying a motivation in the nature of the problem to be solved); *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1381 (Fed. Cir. 2005) (relying on expert testimony about undocumented general knowledge in the art for the suggestion test analysis); *Novo Nordisk A/S v. Becton Dickenson & Co.*, 304 F.3d 1216 (Fed. Cir. 2002) (affirming jury verdict because there was substantial evidence that a motivation to combine was within the ordinary knowledge of one skilled in the art.)

The current law on obviousness is therefore consistent with the statute and with the laws of this Court. In contrast, the position urged by Petitioner threatens to contradict 35 U.S.C. § 103 because it would shift the focus *away* from "the invention as a whole," and it would invite hindsight reconstruction rather than assessing the invention at the time it was made. 35 U.S.C. § 103.

The current law on obviousness also serves another important function: to ensure that determinations of obviousness are based on evidence, and not merely on a judge or jury's unsupported sense of common knowledge. For example, the Federal Circuit has reversed the Board of Patent Appeals where the Board relied only on a high level of skill in the art as the motivation to combine, rather than specific knowledge or specific principles. "The Board did not, however, explain what specific understanding or technological principle within

the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the field of art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Requiring some evidence of the motivation to combine teachings of multiple references also serves to provide an adequate record for appeal. In *Ruiz v. A.B. Chance*, 234 F.3d 654 (Fed. Cir. 2000), the Federal Circuit vacated the district court's obviousness ruling and remanded, directing the district court to more clearly present findings that supported the motivation to combine conclusion. The Federal Circuit later affirmed the district court's determination of obviousness, including the conclusion that the requisite motivation to combine was found "in the nature of the problem to be solved." 357 F.3d at 1275.

III. THE PETITIONER'S POSITION WOULD ALTER THE STATUTORY BURDEN OF PROOF OF 35 U.S.C. § 282

When Congress enacted 35 U.S.C. § 282 in 1952, it was careful to include both a presumption of validity for issued patents, and also to place the burden of proving invalidity on the party challenging it:

> The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

35 U.S.C. § 282. This statutory provision has been followed by courts and relied on by parties for over 50 years. Further, this Court has long held that invalidity must be proved by clear and convincing evidence. *Radio Corporation of America v. Radio Engineering Laboratories, Inc.*, 293 U.S. 1, 2-6 (1934). Despite this long-standing and fundamental point of

law, the Petitioner before this Court urges a change in the law that would dramatically alter the landscape and threaten to improperly shift the burden of showing validity to the patent owner.

In particular, Petitioner asks this court to eliminate the requirement that an obviousness challenge include some teaching, suggestion, or motivation to combine separate references in a way that leads to the claimed combination. In its place, Petitioner and supporting *amici* urge a "synergy of the elements" or "extraordinary result" test or, at a minimum, a presumption that a combination is suggested where its separate elements are known in the art and function in the claimed invention in the same way that they functioned in the prior art.

As explained above, this argument was rejected more than ten years before the Federal Circuit was formed as "an analytical approach to patentability which is directly contrary to the statutory language of § 103." *Reeves*, 444 F.2d at 270. The *Reeves* court evaluated the patent according to the *Graham* factors, and sustained its validity in light of the failure of others to solve the same problem, and on the defendant's failure to satisfy the statutory burden under § 282. *Id.* at 272, n. 6.

What the *Reeves* court recognized in 1971, what the *Custom Accessories* court recognized in 1986, is largely true today: most inventions are in fact combinations of known elements. A litigation defendant will be able to locate the separate elements in practically every case. If doing so meets its burden of proof, or even establishes a presumption of invalidity, then a patent owner will have the burden of proving the additional facts to sustain the validity of its issued patent in virtually every case. Requiring the patent owner to prove "synergy" or "extraordinary results" runs directly contrary to the burden of proof set forth in § 282.

It has never been the patent owner's affirmative burden to establish 'objective evidence' of nonobviousness in the first instance. The absence of such objective evidence does not require a holding of obviousness because such evidence is not an affirmative requirement for patentability under the statute. *Custom Accessories*, 807 F.2d at 960-61 (vacating obviousness finding where "the district court may have incorrectly placed the burden on the patentee to establish validity," and remanding for more detailed *Graham* findings).

The present law on obviousness ensures that the burden remains as statutorily prescribed by asking that the defendant produce some evidence of a teaching, motivation, or suggestion to combine references. As explained above, the suggestion need not be an express publication but can come from the knowledge of those skilled in the art or from the nature of the problem to be solved. But there must be some basis to combine references, or some evidence of what the knowledge or problem is. To rule otherwise would suddenly impose a new burden of proof on the owners of hundreds of thousands of issued patents, contrary to § 282. Further, doing so would radically decrease the incentive to invent and to invest in invention.

CONCLUSION

Amici believe the present "suggestion" test for obviousness provides important safeguards against hindsight and should not be dismantled.

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