No 04-1350

In the Supreme Court of the United States

KSR INTERNATIONAL CO.,
Petitioner,

v.

TELEFLEX INC., *et al.*,
Respondents.

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

BRIEF OF AARP, PATIENTS NOT PATENTS, INC., THE PUBLIC PATENT FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1/]

AARP is a nonpartisan, nonprofit membership organization of over 36 million persons, age 50 or older, dedicated to addressing the needs and interests of older Americans. AARP seeks through education, advocacy and service to enhance the quality of life for all by promoting independence, dignity, and purpose. In its efforts to promote independence, AARP works to foster the health and economic security of individuals as they age by attempting to ensure the availability of quality and economical health coverage. As the country's largest membership organization, AARP has a long

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[1/] In accordance with Supreme Court Rule 37.6, AARP, Patients Not Patents and the Public Patent Foundation, state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amici*, its members and its counsel have made a monetary contribution to the preparation or submission of this brief. The written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

history of advocating for access to affordable health care and for controlling costs without compromising quality.

A decision in this case will determine whether a claimed invention, which involves a combination of existing technological knowledge, can be "obvious" and therefore unpatentable under 35 U.S.C. § 103(a) without proof of some prior "teaching, suggestion or motivation." The issue is important in the prescription drug arena because combination drugs either have been or are being developed for a multitude of diseases. Combination drugs frequently receive new patents which can eliminate generic entrants from the market for many years, resulting in a higher cost for prescription drugs.

Access to prescription drug treatments and generic medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar expended on prescription drugs.[2/] Prescription drug spending has skyrocketed over the last decade and a half. Since 1990, national health expenditures on prescription drugs have quadrupled from $40 billion to $188 billion in 2004. Since May 2004, AARP's Public Policy Institute has issued a series of reports that closely monitor the pricing actions of the pharmaceutical industry, demonstrating that the annual increases in prices for name brand pharmaceuticals far outstrips the rate of inflation.[3/] Access to generic drugs can help ameliorate the harm done by the high costs of prescription drugs, sparking AARP efforts at

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[2/] Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010*, at 2 (July 2000), http://www.familiesusa.org/assets/pdfs/drugod852b.pdf.

[3/] *See, e.g.*, Clifford Binder et al., AARP Public Policy Institute, *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans – First Quarter 2006 Update* (June 2006), *available at* http://assets.aarp.org/rgcenter/health/dd140_drugprices.pdf.

the state and national level to advocate for increased access to lower cost generic versions of drugs.

Patients not Patents ("PNP") is a nonprofit organization committed to reducing intellectual property barriers to affordable healthcare. PNP promotes reform of the patent system through litigation, advocacy and education. A substantial part of PNP's resources is devoted to challenging the validity of patents before the United States Patent & Trademark Office. Almost all of the challenges involve a question of obviousness, many of which also involve the application of the Federal Circuit's teaching-suggestion-motivation test to combination pharmaceuticals.

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization founded in 2003 to represent the public interest in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy and education. It is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

PUBPAT has argued for sound patent policy before this Court, the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the European Union Parliament, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property. PUBPAT has also requested that the Patent Office reexamine specifically identified wrongly issued patents causing significant harm to the public. PUBPAT is a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the question presented strikes at the heart of one of the most fundamental principles of patent law, the definition of

obviousness. More specifically, PUBPAT has an interest in ensuring that obviousness is maintained as a bar to patentability and that the Federal Circuit's teaching-suggestion-motivation requirement for the combination of known technologies to be obvious is rejected.

SUMMARY OF ARGUMENT

The Federal Circuit's "teaching-suggestion-motivation" test contradicts both the Patent Act and this Court's precedent. The test modifies the Patent Act and therefore is an improper judicial encroachment on the legislative powers of Congress. The Federal Circuit's test requiring that the exact same combination be explicitly suggested previously in order to prove "obviousness" grants unjustified rewards for non-innovative subject matter and prevents competitors from using common knowledge that should be freely available to all. Combination drugs have been developed for a multitude of diseases. Nearly half of the drugs approved by the Food and Drug Administration (FDA) in the 1990s were either new formulations or new combinations of compounds already approved. If the Federal Circuit's decision extending patent protection to non-innovative combinations is permitted to stand, generic drug entries into the marketplace will be delayed and consumers will be forced to pay significantly higher prices which many of them can not afford. The "teaching-suggestion-motivation" test should be rejected in accordance with 35 U.S.C. § 103(a).

I. THE IMPROPER GRANTING OF PATENTS TO COMBINATION DRUGS DELAYS THE ENTRY OF GENERICS INTO THE MARKETPLACE AT SUBSTANTIAL COSTS TO CONSUMERS.

The Federal Circuit itself has recognized that when patents are improperly granted to combination drugs, "competition in the marketplace is foreclosed and the public is forced to pay higher prices." *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368 (Fed. Cir. 2003) (finding the combination drug at issue "obvious" after noting more than

twenty prior articles and publications discussing the combination). The rising costs of prescription drugs have left many older Americans unable to afford necessary medications.[4/] There is "specific, empirical evidence that financial barriers compel older Americans to forgo needed drug treatment." Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 228 (2000).

Unfortunately, some combination drug products have delayed generic competition.[5/] Nicholas G. Barzoukas & Gerard M. Devlin, Jr., *Teaching Old Drugs New Tricks*, 162 N.J.L.J. 157 (Oct. 9, 2000); Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 250-251 (2001).

Combination drugs are being developed for a multitude of diseases. Although combination drugs can not be used by all patients, they can offer some patients more convenience and improve compliance. Jill Weschsler, *Combination Products*

[4/] Research shows that patients' response to the higher drugs costs is to reduce consumption. Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings From A 2003 Survey*, Health Affairs at 157-58 (Apr. 19, 2005), http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.152v1 (26.3 percent of all adults report not being able to purchase prescription drugs because of their high cost).

[5/] The improper use of combination drugs to delay the entry of generic drugs into the market is so pervasive that President Bush commented that "When a drug patent is about to expire one method some companies use is to file a brand new patent based on a minor feature such as …a specific combination of ingredients unrelated to the drug's effectiveness. In this way the brand name company buys time through repeated delays called automatic stays that frees the status quo as the legal complexities are sorted out. In the meantime, the lower cost generic drug is shut out of the market. These delays have gone on in some cases for 37 months or 53 months or 65 months. This is not how Congress intended the law to work." President's Remarks on Prescription Drugs, 38 Weekly Comp. Pres. Doc. 1816-1817 (Oct. 21, 2002), *available at* http://transcripts.cnn.com/TRANSCRIPTS/0210/21/se.01.html).

Raise Manufacturing Challenges: New Fixed-Dose Combination Drugs Aim to Enhance Safety and Efficacy, While Regulators Clear a Path for More Drug-Device Combination Product, Pharmaceutical Technology, Mar.1, 2005.[6/]

Nearly half of the drugs approved by the FDA in the 1990s were "new formulations" or "new combinations" of compounds already approved. Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, Nat'l Inst. for Health Care Mgmt, at 2 (Aug. 2000), *available at* http://www.nihcm.org/prescription.pdf. Pharmaceutical companies are requesting patents on a wide variety of combination drugs, including but not limited to combinations of antidiarrheal compounds (*McNeil*, 337 F.3d 1362), diabetes medication (*Takeda Chemical Industries, Ltd. v. Mylan Laboratories, Inc.*, 417 F. Supp.2d 341 (S.D.N.Y. 2006) and heart medication. A number of combination medications for coronary heart disease, a leading cause of death in the U.S, are currently being developed. Coronary heart disease will cost the United States an estimated $142.5 billion in 2006. *Generics Transform Statin Outlook*, 6/1/06 Med Ad News 12, *available at* 2006 WLNR 11923122. Combination drugs from Pfizer, AstraZeneca, AtheroGenics Inc., Servier and CV Therapeutics Inc. will account for nineteen percent of total coronary heart disease product sales in 2014, according to analysts from Decision Resources. *Id.* One class of heart medication that has been targeted for combination drugs are statins, which help lower low-density lipoproteins. Under previous guidelines, 36 million people qualified for statin therapy, while upper estimates on actual statin use were just above 15 million. Michael Johnson, *Drug Makers Rush to Fill Heart-Healthy Lifestyle Gap*, Drug Store News, Jan. 17, 2005.

[6/] An example of a new combination drug that will benefit some HIV patients is the recently released AIDS cocktail drug, Atripla. Atripla combines Viread, Emtriva and Sustiva into one dose. It is the first single dose, three-drug pill and costs approximately $1,150.00 for one month of treatment. *Single-dose 'cocktail' OK'd for U.S. HIV Patients*, CNN (July , 2006), http://www.cnn.com/2006/HEALTH/07/12/aids.pill.ap/index.html.

The Federal Circuit's incorrect interpretation of the obviousness standard, as applied in this case, provides incentives for seeking patent rights on obvious extensions of existing technologies and is contrary to the constitutional purpose of the patent system. Over the past two decades, Congress already has enacted a series of laws that have greatly increased the effective patent life enjoyed by brand name prescription drugs. Hunt, *supra*. Additionally, even if a new combination drug is not patented, drug manufacturers automatically receive an additional three year period of "exclusivity" for a combination drug not previously on the market, which precludes competitors from selling the new combination. 21 U.S.C. § 355 (c)(3)(D)(iii)-(iv); *McNeil*, 337 F.3d at 1368; Hunt, *supra* at 5.

The conventional wisdom is that patents for drugs should stimulate mostly breakthrough discoveries that modify treatment or prevention of a disease. Hunt, *supra* at 2. Administrators of the patent system recognized from the outset that patents ought not to be granted for every small advance in an art. *See, e.g.*, P.J. Federico, *Operation of the Patent Act of 1790*, 18 J. Pat. Off. Soc'y 237 (1936).

"By their nature, patents create an environment of exclusion, and consequently, cripple competition." *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1065-1066 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (2006). The improper granting of patents to combination drugs delays the entry of generics into the marketplace at substantial costs to consumers. A Medicare recipient who takes five drugs could save between $2,300 and $5,000 annually if s/he used generic, as opposed to brand name drugs. *More Studies Find More Savings if Seniors Use Generic Drugs*, SeniorJournal (March 3, 2006), http://www.seniorjournal.com/NEWS/MedicareDrugCards/6-03-03-MoreStudiesFind.htm.

II. THE FEDERAL CIRCUIT'S "TEACHING-SUGGESTION-MOTIVATION" CONTRADICTS THIS COURT'S PRECEDENT.

The Patent Act of 1952 provides the current law governing the issuance and validity of patents. *See* 35 U.S.C. § 100 *et seq.* "The Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is dependent upon three explicit conditions: novelty and utility as articulated and defined in section 101 and section 102, and nonobviousness . . . as set out in section 103." *Graham v. John Deere Co.*, 383 U.S. 1, 12 (1966). In *Graham* the Court, using a three-part factual inquiry for addressing obviousness, directed courts to determine (i) the scope and content of the prior art, (ii) the differences between the prior art and the claims and (iii) the level of the ordinary skill in the pertinent art. *Id.* at 17. The Federal Circuit's "suggestion" test essentially ignores the "person having ordinary skill in the art" and looks almost entirely to the contents of the prior art references to demonstrate obviousness.

The Federal Circuit's test further improperly elevates secondary considerations such as commercial success and prior art references to a mandatory consideration. The Court in *Graham* indicated that as an indicia of obviousness, "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." *Graham*, 383 U.S. at 17-18 *(emphasis added)*. However this Court has never held that those "secondary considerations" are mandatory. *See e.g., Dow Chemical Co. v. Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 330 (1945) (noting that secondary considerations such as commercial success "are relevant only in a close case where all other proof leaves the question of invention in doubt.").

This Court has held that a patent that "simply arranges old elements with each performing the same function it had been known to perform" is not patentable even if the combination produces "a more striking result than in previous

combinations." *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976). In a series of cases, this Court has held that the standard for a "combination" patent which aggregates two old elements is whether the alleged invention produces a "new or different function" from the old elements. *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 549 (1938) ("The mere aggregation of a number of old parts or elements, which in the aggregation, perform or produce no new or different function or operation than that therefore performed or produced by them, is not patentable invention."); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 60 (1969) ("The combination of putting the burner together with the other elements in one machine, though perhaps a matter of great convenience, did not produce a 'new or different function,' [citations omitted] within the test of validity of combination patents.") *Accord, Great A & P Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 151 (1950).

The Federal Circuit has outright dismissed this Court's standard for determining the validity of a combination patent. *See, e.g., Medtronic, Inc. v. Cardiac Pacemakers, Inc*, 721 F.2d 1563, 1566 (Fed Cir. 1983) (holding that there is no statutory basis for identifying "combination" patents and applying a more stringent obviousness test to such patents). By imposing its own "teaching-suggestion-motivation" test instead, the Federal Circuit has permitted claims drawn specifically to what this Court has prohibited—a combination of two old elements with the same function as the individual elements. *See Knoll Pharm. Co. v. Teva Pharm. USA, Inc.*, 367 F.3d 1381 (Fed. Cir. 2004).

In *Knoll*, the Federal Circuit reversed the district court's grant of summary judgment of invalidity based on obviousness. *Id.* The invention was for an analgesic (pain-relieving) composition comprising hydrocodone (Vicodin) and ibuprofen, two well-known analgesics. *Id.* The Federal Circuit acknowledged that such a combination was known in the prior art, but nevertheless reversed the district court's finding of invalidity because no reference specifically taught that combining these two well-known pain killers would produce a combination having pain-killing properties. "Although the

prior art appears to suggest combining an opioid, such as hydrocodone, with various NSAIDs, such as ibuprofen, we conclude, based on the evidence adduced by Knoll, that a genuine factual dispute exists as to the obviousness of the asserted claims which makes summary judgment based on the present record evidence improper. There appears to be no record of evidence of prior art teaching or suggesting the enhanced biomedical effect of the combination of hydrocodone and ibuprofen." *Id.* at 1384.

In dismissing this Court's clear precedent, the Federal Circuit held that the notion of a combination patent is too vague to be a useful legal concept. *Stratoflex v.Aeroquip Corp.*, 713 F.2d 1530,1540 (Fed. Cir. 1983) ("Virtually *all* patents are 'combination patents,' if by that label one intends to describe patents having claims to inventions formed of a combination of elements."). Although obviousness is a conclusion of law, the determination is based on a fact-intensive inquiry. Some fields of art, such as combination therapy, deal almost exclusively with combinations of existing elements.

The field of combination therapy has advanced principally through improvements in the manufacturing and formulation of drugs. Wechsler, *supra*. Examiners at the United States Patent and Trademark Office (PTO) are hamstrung by the Federal Circuit in that they cannot even use "common sense" to make an obviousness rejection. *See e.g., In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) ("'Common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority").

III. THE FEDERAL CIRCUIT'S "TEACHING-SUGGESTION-MOTIVATION TEST" MODIFIES THE PATENT ACT AND IS AN IMPERMISSIBLE JUDICIAL ENCROACHMENT ON CONGRESS' LEGISLATIVE POWERS.

In order to obtain a patent, an invention must be nonobvious in addition to being novel. The test for nonobviousness is an objective inquiry into whether "the

subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).[7/] This provision codified the test that had been used for over a century prior to the passage of the Patent Act. *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850); *see Graham*, 383 U.S. at 17 ("[S]ection [103] was intended merely as a codification of judicial precedents embracing the Hotchkiss condition, with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability.").

The Federal Circuit has developed a rigid rule that combinations of existing elements are nonobvious unless there is some prior "teaching-suggestion-motivation" to combine the known elements. *See, e.g.*, *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1351-1352 (Fed. Cir. 1998) (holding that the teaching-suggestion-motivation test is an "essential evidentiary component of an obviousness holding").

The Federal Circuit's "teaching-suggestion-motivation" test impermissibly modifies the Patent Act and adds requirements that are not included in the plain language of the statute. That test defines a basic element of patent eligibility, thereby impermissibly encroaching on Congress' legislative powers. If Congress had intended to modify the language of Section 103(a), as the respondent suggests, with a teaching-suggestion-motivation test, it could have done so; but Congress did not add such a restriction. *See Smith v. U.S.*, 508 U.S. 223, 229 (1993); *Northwest Airlines, Inc. v. Transport Workers Union of America, AFL-CIO*, 451 U.S. 77, 95 (1981) ("…we

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[7/] Section 103(a) specifically provides that: "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103(a).

consistently have emphasized that the federal lawmaking power is vested in the legislative, not the judicial, branch of government…").

CONCLUSION

The Federal Circuit's "teaching-suggestion-motivation test" is not supported by the text of the Patent Act or in any decision of this Court. The test modifies the Patent Act and therefore is an improper judicial encroachment on the legislative powers of Congress. In the pharmaceutical industry, combination drugs that improperly receive new patents can eliminate generic entrants from the market for many years, resulting in higher costs to consumers. The Federal Circuit's decision should be reversed.

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