No. 13-369

In the Supreme Court of the United States

NAUTILUS, INC.,
Petitioner,

v.

BIOSIG INSTRUMENTS, INC.,
Respondent.

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

BRIEF OF AMICUS CURIAE AARP IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

AARP is a nonpartisan, nonprofit organization, with a membership that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families, such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse. 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 advocates for access to affordable healthcare and for controlling costs without compromising quality.

The proliferation of patents has increased the cost of medical devices and healthcare. Access to affordable healthcare is particularly important to the older population, which has higher rates of chronic and serious health conditions. This Court's decision clarifying the amount of specificity required in a patent application will impact the cost of healthcare

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[1] In accordance with Supreme Court Rule 37.6, AARP states that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than AARP, its members and its counsel have made a monetary contribution to the preparation or submission of this brief. Written consent of the parties has been obtained and will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

and consumer products. In light of the significance of the issue presented in this case, AARP respectfully submits this amicus curiae brief in support of the petitioners.

SUMMARY OF THE ARGUMENT

Ambiguous patents undermine competition, with no offsetting benefit to consumers. For over a century, patent applicants have been required to particularly point out and distinctly claim their invention. The Patent Act's presumption of validity does not dilute the Act's requirements that inventors describe their work in clear and exact terms.

The Federal Circuit's "insolubly ambiguous" standard, extends the patent system beyond the limits that Congress has approved and should be rejected. The test impacts virtually all patents including patents on medical devices and biotechnology. The test threatens continued scientific, technological, and other advances and increases consumer costs for healthcare and other consumer products.

ARGUMENT

I. The Federal Circuit's Tolerance of Ambiguous Patents Is Not in the Public Interest.

The public has a "paramount interest in seeing that patent monopolies... are kept within their legitimate scope." *Medtronic, Inc. v. Mirowski Family Ventures, L.L.C.*, 134 S. Ct. 843, 851 (2014) (*citing Precision Instrument Mfg. Co. v. Auto. Main. Mach. Co.*, 324 U.S. 806, 816 (1945)). When patents are improperly granted "… competition in the marketplace is foreclosed and the public is forced to pay higher prices." *See McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368 (Fed. Cir. 2003) (quoting the District Court's opinion, *McNeil-PPC, Inc. v. L. Perrigo Co.*, 207 F. Supp. 2d 356, 375 (E.D. Pa. 2002).

When prices are elevated due to improperly granted patents the cost of healthcare is elevated to the detriment of individuals and the general public. There is specific empirical evidence that financial barriers compel many older Americans to forgo needed medical treatment. *See, e.g.*, Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 226 (2000), *available at* http://bit.ly/1l371My (noting that high cost of prescription drugs compelled many older Americans to forgo needed drug treatment). While the Affordable Care Act has increased access to healthcare for many, older people and the American public still have significant

medical expenses. As an example, loss of hearing is a medical condition affecting 17 percent of American adults (37 million people) and nearly half of adults 75 and older.[2] However, hearing aids are neither covered by Medicare nor most private insurance companies. 42 C.F.R. § 411.15(d); Christensen, *supra* note 2. Likewise, coverage of hearing aids under Medicaid varies state to state with some states offering no coverage while others offer limited coverage. *See* Hearing Loss Ass'n of America, *Affordable Care Act* (*ACA) State Plans and Hearing Aids*, (last updated Aug. 2013), http://bit.ly/1bwnTZb. As a result, a "hearing aid wearer, over the wearer's lifetime, may spend tens of thousands of dollars acquiring and maintaining hearing aids." HHS, RFA-DC-12-003: Funding Opportunity Announcement, NIDCD Research On Hearing Health Care (R21/R33), CFDA 93.173 (May 19, 2011) at Part 2 §1, http://1.usa.gov/1c7zThz.

The Federal Circuit's "insolubly ambiguous" test has been used to exclude competing hearing aid products that are "readily installed and replaced by a user" even though the term "readily" is a subjective term lacking mathematical precision. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1366-67 (Fed. Cir. 2010) (holding that "the definiteness of

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[2] U.S. Dept. Health & Human Serv., NIH Fact Sheet on Hearing Aids, http://1.usa.gov/1mfYNPe; Jen Christensen, *Hearing Loss an 'Invisible,' and Widely Uninsured, Problem*, CNN (Jul. 10, 2012), http://cnn.it/1g5nlqf.

claim terms depends on whether those terms can be given *any* reasonable meaning") (emphasis added).

The "insolubly ambiguous" test has further limited competition in healthcare beyond hearing aid components. *See, e.g.*, *Kinetic Concepts, Inc. v. Blue Sky Medical Grp., Inc.*, 554 F.3d 1010, 1022 (Fed. Cir. 2009) (rejecting an argument that the term "selected stage of healing" was indefinite even though the definition was subjective and "the selected stage of healing may vary by wound"); *Eli Lilly & Co. v. Teva Parenteral Meds.*, *Inc.,* 2012 U.S. Dist. LEXIS 85369, *10, *33 (S.D. Ind. 2012) (upholding the "insolubly ambiguous" test in a case concerning an anti-cancer agent, noting that claims are indefinite only if they are "not amenable to construction" or are "insolubly ambiguous"); *Wyeth v. Abbott Labs.*, 2011 U.S. Dist. LEXIS 134479, *15-16 (D. N.J. 2011) (noting that claims are definite even if reasonable persons disagree, as long as no narrowing construction can properly be adapted).

The cost of litigating ambiguous terms is exceedingly high to both businesses and consumers. *E.g.*, *Energy Transp. Grp.*, *Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1355-56 (Fed. Cir. 2012) *cert. denied*, 133 S.Ct. 2010 (2013) (upholding a multi-million dollar judgment in a hearing aid patent dispute). Unfortunately, the costs of patent litigation "are inevitably passed onto consumers, regardless of the outcome of the case." Brianna Lennon, *Antitrust Implications of Technology Patents*, 1 ABA Young Lawyer Div. Antitrust Law Comm. Newsletter, 8, 9 (2012), *available at* http://bit.ly/1hhqFRX. Strict

compliance with 35 U.S.C. § 112 would reduce ambiguity and the litigation that flows from ambiguous terms.

II. The Federal Circuit's Standard For Claim Indefiniteness Conflicts With Both the Plain Language of the Patent Act and the Decisions of This Court.

The Patent Act mandates that patent specifications "…conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112(b). This rule has been in effect as early as 1870. Edward D. Manzo, *Patent Claim Construction in the Federal Circuit*, §2:23 n.1 (2012 ed.). Construing patent claims is critical to nearly every patent case. "Yet despite its monumental importance, patent claim construction remains one of the most confusing and difficult tasks undertaken by federal district judges." Joshua D. Sarnoff & Edward D. Manzo, *Preface* to Manzo, *Patent Claim Construction in the Federal Circuit*, Manuscript 7 (forthcoming Mar. 2014 ed.). The Federal Circuit has held that claims are "not indefinite" if they are "amenable to construction, however difficult that task may be." *Exxon Res. & Eng'g. Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (holding that ambiguous claims are permissible as long as they are not "insolubly ambiguous, and no narrowing construction can be properly adopted."). Moreover, the Federal Circuit has held that even if reasonable persons disagree about the scope of the claims that should not render

the claims indefinite. *Id.* This loosely defined standard allows for significant ambiguity contrary to the mandates of this Court. *Compare Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373-74 (Fed. Cir. 2004) (upholding patent by equating patent term "surrender value protected investment" with term "stable value protected investment" while acknowledging the patent uses the two terms in different ways and reflects "poor drafting practice."), *with United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236-37 (1942) (holding that "the statutory requirement of particularity and distinctness in claims is met only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise … An invention must be capable of accurate definition, and it must be accurately defined, to be patentable.")[3] *See also, Merrill v. Yeomans*, 94 U.S. 568, 573 (1876).

The "insolubly ambiguous" standard is inconsistent with the text and purpose of the Patent Act and this Court's precedent. *See United Carbon Co.* 317 U.S. at 236-37; 35 U.S.C. § 112. Courts should strictly enforce the stringent definiteness standard. Patent claims should be enforced only when the claims are clear enough that skilled artisans can identify their scope without litigation.

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[3] *United Carbon Co.* involved an interpretation of the precursor to Section 112(b), 35 U.S.C. § 33 (1932), which included the parallel requirement of claims that "particularly point out and distinctly claim the part, improvement or combination which he claims as his invention or discovery." *United Carbon Co.*, 317 U.S. at 232.

Markman v. Westview Instruments, Inc., 517 U.S. 370, 390 (1996) (noting that uncertainty discourages invention).

III. Ambiguous Patents Have a Chilling Effect on Scientific Research.

A questionable patent "may lead a competitor to forgo research and development in an area the patent supposedly covers, deterring follow-on innovation and new market entry." Julie Brill, Comm'r, Fed. Trade Comm'n, Keynote Address at the University of Colorado Law School Silicon Flatirons Center: The Intersection of Patent Law and Competition Policy, at 2 (2012), http://1.usa.gov/1bPR5Fa.

The proliferation of patents has blocked biomedical research. *See, e.g.*, Mildred K. Cho et al., *Effects Of Patents And Licenses On The Provision Of Clinical Genetic Testing Services*, 5 J. Molecular Diagnostics 3 (2003) (noting that more than half of laboratory directors in a survey decided not to develop or perform tests specifically because of intellectual property considerations). The "knowledge that a patent application has been filed can influence the decision to spend the time and resources to develop a clinical test because of the uncertain risk that a patent holder will later prevent the laboratory from continuing to provide this service." Jon F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 Clinical Chemistry 324, 327 (1999), *available at* http://bit.ly/1gmvaYJ.

IV. The Presumption of Validity Does Not Dilute A Patent Applicant's Duty to Clearly and Correctly Describe What He Has Invented.

The presumption of validity mandated by the Patent Act does not eviscerate a patent applicant's duty to clearly and correctly describe what he has invented and what exactly he is claiming. 35 U.S.C. § 112; 35 U.S.C. § 282 (b)(3)(A). Clarity is particularly important since the United States Patent and Trademark Office's determinations supporting the issuance of patents "…are reached under tight time constraints and on an *ex parte* basis allowing minimal opportunity to hear a third party's opposing views." Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* ch. 5, at 28 (Oct. 2003), http://1.usa.gov/1d7fQwQ; *see also,* Lichtman & Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 Stan. L. Rev. 45 (2007).

The presumption of validity can and should be curtailed in appropriate circumstances. *See e.g.,* U.S.C. § 282 (b); *see also, KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 426 (2007) ("We nevertheless think it appropriate to note that the rationale underlying the presumption – that the PTO, in its expertise, has approved the claim – seems much diminished" where the examiners had not considered the art in question.).

CONCLUSION

For the foregoing reasons, AARP respectfully urges the Court to grant the relief requested by petitioner; reject the Federal Circuit's "insolubly ambiguous" standard and mandate that patents strictly comply with 35 U.S.C. § 112.

Respectfully submitted,

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