No. 19-1058

IN THE
Supreme Court of the United States

HOSPIRA, INC.,

Petitioner,

v.

ELI LILLY AND COMPANY,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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BRIEF OF AMERICA'S HEALTH INSURANCE PLANS AS AMICUS CURIAE IN SUPPORT OF PETITIONER[1]

America's Health Insurance Plans (AHIP) respectfully submits this brief as amicus curiae in support of the petitions for writ of certiorari in Nos. 19-1058 and 19-1061.[2]

INTEREST OF AMICUS CURIAE

AHIP is a national association whose members provide coverage for health care and related services to millions of Americans every day. These services improve and protect the health and financial security of consumers, families, businesses, and the nation. AHIP advocates for public policies that expand access to affordable health care coverage through a competitive marketplace that fosters choice, quality, and innovation.

Increases in prescription drug costs are a leading driver of rising health care costs. AHIP seeks practical solutions that reduce consumer costs and increase

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[1] No counsel for a party authored the brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than the amicus curiae, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief. Amicus provided all parties with notice of its intent to file this brief more than ten days before the deadline, and all parties consented to the filing of this brief.

[2] Both petitions for certiorari are from the same Federal Circuit decision. AHIP supports both petitions, but takes no position on whether the Court should set both petitions for argument on the merits.

patient access to needed medication, so AHIP has a strong interest in ensuring that our legal system efficiently resolves claims of patent invalidity. To that end, AHIP has filed amicus briefs in other significant cases about drug patents, such as *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016); and *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (2018).

INTRODUCTION AND SUMMARY OF ARGUMENT

Rising prescription drug prices are a serious problem for our nation and economy. Americans spent around $384 billion on prescription drugs just last year,[3] and drugs protected by patent monopolies make up the bulk of these costs.[4] While brand-name drugs account for only 10% of all dispensed prescriptions in the United States, they account for 79% of drug spending.[5] These costs impose heavy tolls on consumers and businesses who pay higher premiums, on hardworking taxpayers who fund public programs like Medicaid and Medicare, and on patients who cannot afford life-saving medications.

Competition from generic medications is one of the most effective ways to reduce drug prices and increase patient access to critical medications.[6] Congress recognized this fact decades ago and passed the Hatch-

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[3] Altarum Ctr. for Value in Health Care, *Insights from Monthly Nat'l Health Spending Data Through December 2019* 2 (Feb. 2020), *available at* https://altarum.org/sites/default/files/uploaded-publication-files/SHSS-Spending-Brief_Feb_2020-v2.pdf.

[4] IQVIA Inst. for Human Data Science, *Medicine Use and Spending in the U.S.* 54 (May. 2019), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023.

[5] *Id.*

[6] Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 861 (Aug. 2016), *available at* https://phhp-bahealthscience-new.sites.medinfo.ufl.edu/files/2016/09/jsc1600151.pdf.

Waxman Act, 21 U.S.C. § 355, to promote generic drug development. The Act encourages generic drug companies to design around existing patents to develop non-infringing bioequivalent medications.

Prosecution history estoppel plays a key role in this process. It allows generic manufacturers to rely on the decisions that brand-name drug manufacturers made during the patent process, and provides a zone of non-infringing territory in which generics may safely develop. But internal division within the Federal Circuit imperils this zone.

The decision below allows patent holders to recapture patent claims that they knowingly surrendered to the public even after generic manufacturers have relied on the express terms of the patent. That runs directly contrary to the policies underlying patent law, prevents critical generic medications from reaching the public, and undermines Congress's central purpose in enacting Hatch-Waxman.

This case provides an ideal opportunity for the Court to correct the Federal Circuit's misunderstanding of the law, enforce the constitutional text, and protect American consumers from rising drug prices. The Court should grant review.

ARGUMENT

I. The Scope of Prosecution History Estoppel Raises an Important Question with Broad Impact on Public Health and Drug Affordability.

Companies have strong incentives to seek broad patents, and often file initial patent applications that claim patents over material that is obvious, anticipated by prior art, and otherwise unpatentable. When those claims are rejected by a patent examiner, the companies have a variety of options: Challenge the rejection, draft a carefully tailored claim that disclaims only the unpatentable material, or draft a much narrower claim that might speed up the patent process.

This Court has long recognized the defense of prosecution history estoppel, which applies when "the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733-34 (2002). In those circumstances, the patent owner may not try to retroactively broaden the patent by arguing "that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Id.*

A. Prosecution history estoppel is critical to ensuring affordable prescription drugs.

Prosecution history estoppel drives many pharmaceutical patent cases because of the Hatch-Waxman Act (formally known as the Drug Price Competition

and Patent Term Restoration Act of 1984, 98 Stat 1585). Before passage of the Act, generics were only available for a small portion of medications.[7] Congress passed the Act to spur increased development of generic alternatives and ensure they were available to the American public. H.R. Rep. No. 98–857, pt. 1, at 14 (1984).[8]

Under the Hatch-Waxman Act, a generic manufacturer need not complete the expensive drug trials required for initial approval of a medication if the generic product is bioequivalent to the brand name product—that is, if it delivers the same amount of active ingredient in the same amount of time. 21 U.S.C. § 355(j)(2)(A)(ii), (iii), (iv); *PLIVA*, 564 U.S. 604, 628.

To receive permission to market a generic drug, the applicant must also certify that the patent on the name-brand product is invalid or not infringed by the generic product (a process known as paragraph IV certification). 21 C.F.R. § 314.94(a)(12)(i)(A)(4). But because the generic must be bioequivalent to the

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[7] In 1983, only 35% of top-selling branded drugs with expired patents had generic competition, and the generic market share was only 13%. In 2012, generics reached 84% of dispensed prescriptions. Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 Acta Pharm. Sinica B 297, 298 (Sept. 2013), *available at* https://www.sciencedirect.com/science/article/pii/S2211383513000762#bib12.

[8] The purpose of the Hatch-Waxman Act is to "make available more low cost generic drugs by establishing a generic drug approval procedure." H.R. Rep. No. 98–857, pt. 1, at 14 (1984); *see PLIVA, Inc. v. Mensing*, 564 U.S. 604, 627-28 (2011).

name-brand drug, the generic medication will generally fall within the scope of the doctrine of equivalents, which provides that "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997). Thus, until a patent expires or a court declares it invalid, generics can generally only develop where a defense such as prosecution history estoppel applies.

When (as here) the patent applicant deliberately surrendered certain equivalents when seeking a patent, the Federal Circuit has often applied prosecution history estoppel to find that the generic manufacturer does not infringe a patent that it carefully designed around.

Consider, for example, the common anti-depressant medication Wellbutrin. When seeking a patent on a sustained release formulation the manufacturer narrowed the scope of its claims, specifying that its patent covered only formulas containing hydroxypropyl methylcellulose. *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1350 (Fed. Cir. 2004). Relying on that amendment, a generic manufacturer developed a substitute using hydroxypropyl cellulose instead. *Id.* at 1351. Glaxo promptly sued, as brand-name manufacturers generally do whenever generics enter the market. *See id.*

The Federal Circuit took up the issue shortly after this Court's decision in *Festo*. The court ruled that

prosecution history estoppel applied, rejecting the patent holder's claim that it should be allowed to recapture the territory it had deliberately ceded during patent prosecution by invoking the tangential exception. *Glaxo Wellcome*, 356 F.3d at 1349. This allowed the generic manufacturer to deliver non-infringing generic substitutes for the popular medication before the patents expired, providing huge savings for consumers.[9]

The common hypertension medication Univasc provides another example. When Warner-Lambert first sought a patent for a component of those tablets, the patent examiner rejected the claim as obvious, and the company narrowed the scope of its claim in response. *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1373 (Fed. Cir. 2007).

Relying on that amendment, a generic manufacturer sought to market a generic alternative. *Id.* Warner-Lambert sued the generic manufacturer for infringement, but the Federal Circuit affirmed a finding of prosecution history estoppel. *Id.* at 1372-73. The generic manufacturer was thus able to deliver affordable blood pressure medication—and generic versions of this medication saved Americans around

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[9] The current price for Wellbutrin is at least 45 times as much as the generic equivalent. *See* WebMDRx, *Wellbutrin XI Prices and Coupons*, https://www.webmd.com/rx/drug-prices/wellbutrin-xl (last visited Mar. 25, 2020); Ass'n for Accessible Meds., *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 32 (2019), *available at* https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

$32.4 billion in 2018.[10] The availability and accessibility of a generic alternative also increases the likelihood that patients can take their hypertension medication without interruption, which saves countless lives.[11]

That's how the system is supposed to work. When name-brand drug manufacturers make a conscious choice to surrender certain territory, generic manufacturers should be able to rely on the clear terms of the patents to develop and market a generic alternative.

But in the decision below, the Federal Circuit ruled that the brand-name manufacturer could have a do-over and retroactively expand its patent to cover territory it now wishes it had claimed. That decision artificially broadens and extends patent monopolies, raises the costs of medication, and causes deep harms to consumers and their communities.

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[10] Ass'n for Accessible Meds., *The Case for Competition, supra* n.9, at 21.

[11] Americans were more than twice as likely to leave already-filled prescriptions for brand-name drugs at the pharmacy than they were for generic medications. *Id.* at 14. Patients must take hypertension medication without interruption if they are to reduce their risk of kidney failure, stroke, blindness, and heart attack. U.S. Food & Drug Admin. Office of Women's Health, *Medicines to Help You: High Blood Pressure* 2 (May 2011), *available at* https://www.fda.gov/media/81967/download.

B. The availability of generic alternatives slashes costs and gives consumers greater access to life-saving medications.

In the pharmaceutical context, blocking the entry of generic alternatives costs billions of dollars and can have life-or-death repercussions.

The United States spends 18% of its gross domestic product on health care, up from just 7% in 1970.[12] As of 2019, the nation spent about $384 billion annually on prescription drugs.[13] And experts forecast prescription drug spending to reach over $600 billion by 2023.[14]

Patented drugs make up the bulk of these costs.[15] As noted, brand-name drugs account for only 10% of all dispensed prescriptions but 79% of drug spending.[16] Between 2009 and 2018, prices for the most commonly used brand-name drugs increased by

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[12] Altarum, *Insights from Monthly Nat'l Health Spending Data*, *supra* n.3, at 1; Medicaid & CHIP Payment & Access Comm'n, *Report to Congress on Medicaid and CHIP* 3 (June 2016), *available at* https://www.macpac.gov/wp-content/uploads/2016/06/June-2016-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

[13] Altarum, *Insights from Monthly Nat'l Health Spending Data*, *supra* n.3, at 2.

[14] IQVIA Inst. for Human Data Science, *The Global Use of Medicine in 2019 and Outlook to 2023* 8 (Jan. 2019), *available at* https://informatori.it/wp-content/uploads/2019/03/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf.

[15] IQVIA, *Medicine Use and Spending in the U.S.*, *supra* n.4, at 54.

[16] *Id.*

190%, far more than the consumer price index.[17] While pressure from federal policymakers and new state laws have worked together to somewhat slow price increases for branded drugs, prices still continue to climb.[18]

The "only form of competition that consistently and substantially decreases prescription drug prices occurs with the availability of generic drugs, which emerge after the monopoly period ends."[19] Typically, the presence of generic medications can cut branded drug prices by half or even more.[20] "Drug prices decline to approximately 55% of brand-name drug prices with 2 generic manufacturers making the product,

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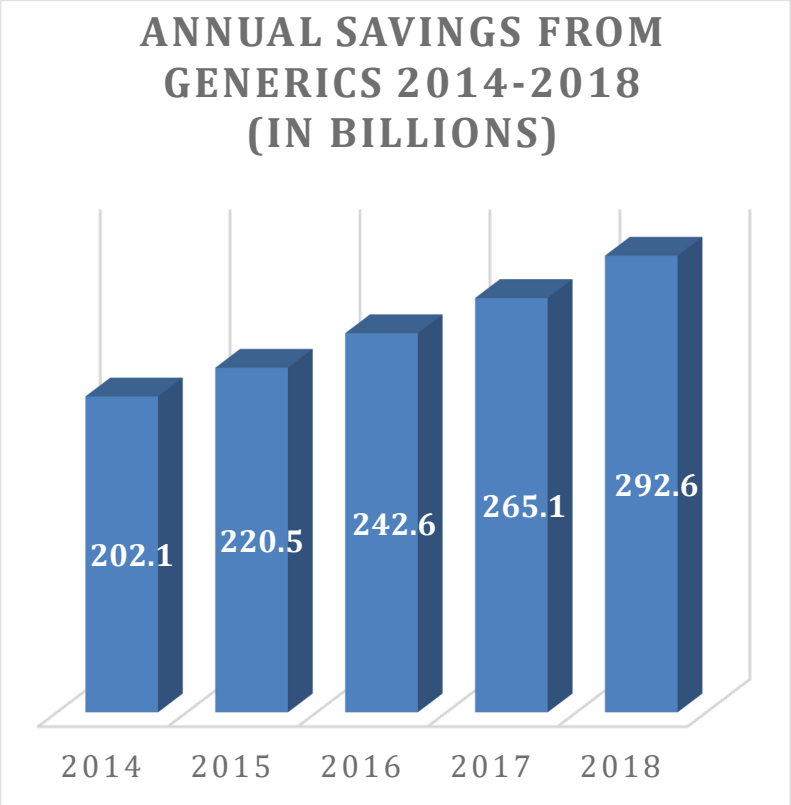
[17] Stephen W. Schondelmeyer & Leigh Purvis, AARP Public Policy Inst., *Brand Name Drug Prices Increased More Than Twice as Fast as Inflation in 2018* (Nov. 2019), *available at* https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf.

[18] *Id.*; *see also* IQVIA, *The Global Use of Medicine*, *supra* n.14, at 10-11; Divya Grover, *Costly Drugs to Weigh on U.S. Employers' Expenses in 2018: Survey*, Reuters (Sept. 18, 2017), http://www.reuters.com/article/us-usa-healthcare-survey/costly-drugs-to-weigh-on-u-s-employers-expenses-in-2018-survey-idUSKCN1BT1FR; Mercer, *Mercer Survey Finds Employers Hold Health Benefit Cost Increases to 4.3%, Maintaining Stable Growth* (Sept. 18, 2017), https://www.mercer.us/our-thinking/healthcare/mercer-survey-finds-employers-hold-health-benefit-cost-increases-to-43-maintaining-stable-growth.html).

[19] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* n.6, at 861.

[20] Judith A. Johnson, *FDA Regulation of Follow-On Biologics* 2 (Cong. Research Serv., Apr. 26, 2010), *available at* https://primaryimmune.org/wp-content/uploads/2014/05/Biosimilars_Congressional_Research_Service_Report.pdf.

33% with 5 manufacturers, and 13% with 15 manufacturers."[21] And a recent study estimated that "generic drugs have saved the U.S. health care system nearly two trillion dollars" from 2009 to 2018.[22]



[21] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* n.6, at 861.

[22] Ass'n for Accessible Meds., *The Case for Competition*, *supra* n.9, at 10.

While the patent system has benefits, the existence of a patent monopoly for a prescription drug comes at a heavy price for patients who cannot afford life-saving medications. It causes Americans and businesses to pay higher and higher premiums because of rising drug prices. And it imposes hardships on taxpayers who fund public programs like Medicaid and Medicare.

II. The Federal Circuit's Overly Broad Interpretation of the Tangential Exception Undermines Innovation.

Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose: protecting against situations where the patent holder inadvertently surrendered claims over material they had no words to describe. *Festo*, 535 U.S. at 734. While this Court has recognized an exception to prosecution history estoppel when the amendment had only a "tangential relation to the equivalent in question," *id.* at 740, neither law nor policy support applying that exception when the patentee knew how to describe a claim yet knowingly surrendered it anyway.

A. The tangential exception does not encompass knowing surrender of a claim.

Under constitutional authority to "promote the progress of Science and useful Arts," U.S. Const., art. I, § 8, cl. 8, Congress enacted patent laws that reward innovation with a temporary, limited monopoly. "But in rewarding useful invention, the 'rights and welfare of the community must be fairly dealt with and effec-

tually guarded.' To that end the prerequisites to obtaining a patent are strictly observed, and when the patent has issued the limitations on its exercise are equally strictly enforced." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964) (citation omitted).

"[L]ike any property right," a patent's "boundaries should be clear." *Festo*, 535 U.S. at 730. The patent claim must describe the invention in exact terms, 35 U.S.C. § 112, "as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo*, 535 U.S. at 731.

Although precision is statutorily required, the doctrine of equivalents recognizes the limits of language to describe innovation. *Id.* The doctrine allows a patentee to claim minor variations that it inadvertently left out when drafting the patent claim. *Id.* at 733. The doctrine aims to protect inventors from copyists who would "exploit[] the limits of the patent's language" and the "unintended idea gaps" for which the inventor had no words. *Id.* at 731 (quoting *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967)).

As this Court has repeatedly cautioned, though, "the doctrine of equivalents can create substantial uncertainty about where the patent monopoly ends." *Id.* at 727. "To reduce the uncertainty . . . competitors may rely on the prosecution history, the public record of the patent proceedings." *Id.* "When the patentee responds to [a] rejection by narrowing his claims, this prosecution history estops him from later arguing

that the subject matter covered by the original, broader claim was nothing more than an equivalent. Competitors may rely on the estoppel to ensure that their own devices will not be found to infringe by equivalence." *Id.*

The patent holder in this situation needs no protection from the limits of language. By drafting the amendment, the patent holder "recognized and emphasized the difference between the two phrases" and the difference "thus disclaimed must be regarded as material." *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (1942).

Festo announced three exceptions to prosecution history estoppel, but each of these is directed at inadvertent surrender, situations when "the patentee could not reasonably be expected to have described the insubstantial substitute in question." 535 U.S. at 740-41.

Those exceptions have no place in resolving this dispute. Eli Lilly knew how to draft a broad pemetrexed claim, as shown by its European equivalent to the claim at issue. Hospira Pet. 15; Dr. Reddy Pet. 10-11, 14. To avoid rejection based on prior art, it narrowed its claim to products using "pemetrexed disodium." Petitioner carefully avoided infringement by using a different pemetrexed compound. Yet the Federal Circuit found that even though petitioner had scrupulously designed around the patent, and stayed within ceded territory, they still infringed on it, since in hindsight the court determined that Eli Lilly could have used broader language and still secured a patent.

That rule creates a zone of uncertainty for manufacturers of generic medications. It does not "apprise the public of what is still open to them." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373, (1996) (quoting *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891)). It makes it risky for companies to put their resources into developing generic medications. And as explained below, that uncertainty harms innovation and the American public.

B. The uncertainty created by the decision below stifles innovation and leads to gamesmanship.

The scope of a patent must be clear. As this Court explained in *Festo*, "[t]his clarity is essential to promote progress, because it enables efficient investment in innovation." 535 U.S. at 730-731. "A zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942).

This clarity is particularly important in the pharmaceutical industry, because unclear patents can chill the development and delivery of new products. This same deleterious impact is echoed in other facets of health care. In a survey of clinical laboratory directors, more than half reported deciding not to develop a new clinical genetic test because of concern about an existing patent or license, and a quarter reported that they had stopped performing a genetic test because of

a patent or license.[23] Even 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."[24]

Prosecution history estoppel provides certainty to generic manufacturers. It allows them to scrutinize the terms of patents and design an alternative knowing that they can avoid claims of infringement. In hearings before the Federal Trade Commission, "[p]harmaceutical and biotech representatives testified that they use patent information disclosures required by the patent statutes to direct their research and development (R&D) into areas not claimed by the patents. Representatives from generic pharmaceutical firms discussed how patent disclosures guide their

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[23] Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Servs.*, 5 J. Molecular Diagnostics 3, 7 (Feb. 2003), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1907368/#__ffn_sectitle; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698 (May 1, 1998), *available at* http://science.sciencemag.org/content/280/5364/698.full.

[24] Jon F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 Clinical Chemistry 324, 327 (March 1999), *available at* http://clinchem.aaccjnls.org/content/45/3/324.full.pdf.

efforts to 'design- around' patents, so that they can develop non-infringing generic versions of brand-name drug products."[25]

This process of designing around existing patents "is not an esoteric or narrowly specialized activity—it is prevalent. As early as 1960, a majority (57%) of professional managers of innovation development consider competitors' patent claims and manage designs around them as a staple of their practice."[26]

Nor is designing around patents somehow suspect. "Designing around patents is, in fact, one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose." *Slimfold Mfg. Co., Inc. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991). And designing around patents often leads to "new and superior products or processes . . . that probably would not have been developed, at least as soon, in the absence of the need to 'invent around.'"[27]

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[25] Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* Ch. 3, pp. 1-2 (Oct. 2003), *available at* https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

[26] Ron D. Katznelson & John Howells, *Necessity is the Mother of Inventing Around: How Circumventing Edison's Lamp Patent Stimulated Downstream Development & Competition* 2-3 (Feb. 14, 2018), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2464308.

[27] Katznelson & Howells, *Necessity is the Mother of Inventing Around*, *supra* n.26, at 6-7 (citing National Research Council, *The Role of Patents in Research, Part 1* 14 (1962)).

Yet this sort of design-around innovation requires that the bounds of a patent are clear and predictable. A study of Thomas Edison's patent for the incandescent lightbulb provides a good illustration.[28] Edison's patent has often been described as blocking innovation, but the authors analyzed later patent applications and concluded this was true only when the scope of the patent was ill-defined.[29] After a court decision firmed up the exact boundaries of Edison's patent, there was a "precipitous surge" in inventions and non-infringing patents by other manufacturers.[30]

Patent language must be clear and dependable to permit this sort of innovation. But the Federal Circuit's decision allows patent holders to knowingly cede territory when seeking a patent, then reclaim that same territory years later after a generic manufacturer has committed to bringing a generic alternative to market. That sort of bait-and-switch harms innovation, increases costs for consumers, and inhibits the ability of the generic manufacturers to provide needed medication.

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[28] *Id*.

[29] *Id*. at 11-12.

[30] *Id*. at 26-27. And these design-around innovations provided public benefits, just as companies that create generic medications further the public good in ways Congress sought to spur. As a contemporary of Edison put it, "enforcement of the '898 Edison patent 'had the effect of stimulating the inventive capacity of the electricians employed by rival interests, with the result that at least two new types of lamp have been put upon the market, which apparently bid fair to be commercially successful.'" *Id*. at 27 (citing Franklin L. Pope, *Electricity*, The Engineering Magazine, Oct. 1893, at 96, *available at* https://books.google.com/books?id=hfVAAQAAMAAJ).

This Court should grant review and reverse the Federal Circuit's broad rule, which fosters a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014) (quoting *United Carbon Co.*, 317 U.S. at 236).

III. Open Disagreement Within the Federal Circuit Warrants this Court's Review.

Doctrinal stability in the field of patent law is essential. "One of the fundamental purposes behind the Patent and Copyright Clauses of the Constitution was to promote national uniformity in the realm of intellectual property." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (citing The Federalist No. 43, at 309 (B. Wright ed. 1961)).

Congress created the Federal Circuit largely because of the "special need for nationwide uniformity" in patent law. S. Rep. No. 97-275, at 2 (1981); *see also id.* at 5 (Congress designed the Federal Circuit to provide "a forum that will increase doctrinal stability in the field of patent law."); Richard H. Seamon, *The Provenance of the Federal Courts Improvement Act of 1982*, 71 Geo. Wash. L. Rev. 543, 577-80 (2003).

Yet this Court has had to step in many times when the Federal Circuit has allowed the doctrine of equivalents to create uncertainty. In a foundational case on prosecution estoppel, for instance, this Court granted review because of the Court's "concern" that the Federal Circuit's interpretation of the doctrine of equivalents "has taken on a life of its own, unbounded by the patent claims." *Warner-Jenkinson*, 520 U.S. 17, 28-29.

As this Court explained, "[t]here can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Id.* at 29. The Court announced that the doctrine of equivalents must be applied objectively, element-by-element, and limited by prosecution history estoppel. *Id.* at 33. The Court cautioned: "It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." *Id.* at 29-30.

More recently, the Court stepped in because the Federal Circuit was invoking an "amorphous" standard to assess patent invalidity for indefiniteness. *Nautilus*, 572 U.S. 898, 913. To solve the problem, the Court announced a definiteness standard that relies on prosecution history estoppel to deliver certainty within the limits of language: "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 901. The Court cautioned against allowing uncertainty to persist, since that would deter innovation and hamper public good. *Id.* at 909-10.

As explained thoroughly in the petitions for certiorari, the Federal Circuit has fractured internally over how to apply the tangential exception to prosecution history. Dr. Reddy Pet. 17-24; Hospira Pet. 27-30. That court has reached an impasse and cannot fulfill its "mandate to achieve uniformity in patent matters" with respect to prosecution history estoppel. *Panduit Corp. v. All States Plastic Mfg. Co., Inc.*, 744

F.2d 1564, 1574 (Fed. Cir. 1984), *disapproved on other grounds in Richardson-Merrell, Inc. v. Koller*, 472 U.S. 424 (1985). As explained above, this uncertainty decreases generic alternatives to expensive prescription medications. That leaves consumers, employers and the government with higher costs, and reduces consumer access to important—and potentially life-saving—medications. This Court should grant review.

CONCLUSION

For all these reasons, the Court should grant the petition for certiorari and reverse the decision below.

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March 2020