No. 18-692

IN THE
Supreme Court of the United States

MYLAN PHARMACEUTICALS INC., *et al*,

Petitioners,

v.

UCB, INC., *et al.*,

Respondents.

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 PETITIONERS

JULIE SIMON MILLER
MICHAEL S. SPECTOR
AMERICA'S HEALTH INSURANCE PLANS
601 Pennsylvania Ave., NW
Washington, DC 20004

ANNA-ROSE MATHIESON
Counsel of Record
SUSAN YORKE
CALIFORNIA APPELLATE LAW GROUP LLP
96 Jessie Street
San Francisco, CA 94105
(415) 649-6700
annarose@calapplaw.com

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

CONSTITUTIONS & STATUTES

OTHER AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

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

The undersigned respectfully submits this amicus curiae brief in support of petitioners.[1]

INTEREST OF AMICUS CURIAE

America's Health Insurance Plans (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, communities, 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 is committed to practical solutions that reduce consumer costs and increase patient access to needed medication, so AHIP has a strong interest in ensuring that claims of patent invalidity are resolved efficiently and effectively. To that end, AHIP has filed amicus briefs in other significant cases bearing on issues of drug patents, including *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018);

---

[1] No counsel for any party authored this brief in whole or in part, and no person other than amicus or its counsel have made any monetary contribution intended to fund the preparation or submission of this brief. All parties to this case received timely notice under Rule 37.2(a) of amicus's intent to file this brief, and all parties consented to the filing of this brief.

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).

SUMMARY OF ARGUMENT

Patents are available only for true innovations—those acts of creativity that add to the sum of useful knowledge. Duplicative or obvious products should not be rewarded with a grant of monopoly power. To distinguish novel inventions from obvious ones, this Court has made clear that only a flexible, expansive approach will suffice.

But the Federal Circuit continues to apply rigid legal rules when assessing the obviousness of pharmaceutical compounds. Its cramped analysis impermissibly elevates the showing required to prove obviousness. That heightened standard makes it more difficult for generic drug companies to combat gamesmanship by brand-name manufacturers, and it encourages the grant of more duplicative patents in the first place.

This abstract legal error causes very real harm. Prescription drug prices spiral up at ever-increasing rates, and drugs protected by patent monopolies cause the bulk of this price growth.[2] While brand-name drugs comprise only 10% of all dispensed prescriptions in the United States, they account for 72% of drug spending.[3]

---

[2] IMS Institute for Healthcare Informatics, *Global Medicines Use in 2020: Outlook and Implications* 9, 13 (Nov. 2015), *available at* https://s3.amazonaws.com/assets.fiercemarkets.net/public/005-LifeSciences/imsglobalreport.pdf.

[3] Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860 (Aug. 2016).

As a recent article from the Journal of the American Medical Association explains, "[t]he 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."[4] Yet drug makers have significant incentives to maximize their market exclusivity period by seeking duplicative patents in order to block generic entry for as long as possible.[5]

The costs and delays caused by these duplicative and improper patents cause significant harms to American citizens. They mean that consumers must pay higher prices, both through direct payments for prescription medications and through increased insurance premiums. For those who cannot afford expensive branded medications, these delays may mean no access at all to needed treatments.

This case presents an ideal opportunity for this Court to clarify that rigid legal tests for obviousness are as unwelcome in the realm of pharmaceutical compounds as they are in the sphere of mechanical patents. By doing so, the Court can reaffirm the basic constitutional and statutory principles underlying the

---

[4] *Id.* at 861.

[5] References to "prescription drugs" or "drugs" in this brief include biologics, complex medications that "are generally derived from living material—human, animal, or microorganism." U.S. Food & Drug Administration, *Frequently Asked Questions About Therapeutic Biological Products*, https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredeveloped andapproved/approvalapplications/therapeuticbiologicapplications/ucm113522.htm (last visited Dec. 19, 2018). References to "generics" include biosimilars.

patent power, encourage innovation, and protect patients and consumers.

ARGUMENT

I. The Constitution, Congress, and this Court all prohibit obvious patents.

When functioning properly, the patent system serves the public good. It spurs important research by offering inventors limited-term monopolies on their products, in return for public access to those discoveries upon expiration of that limited term. But that careful balance can only be maintained when patents are novel, non-obvious, and for a properly limited term. For duplicative or obvious patents, consumers are saddled with the costs of a patent monopoly without any corresponding benefits.

A. The Federal Circuit's use of artificially rigid tests departs from constitutional and statutory directives and flouts this Court's precedent.

The federal patent power derives from Article I, section 8, of the Constitution, which authorizes Congress "[t]o promote the Progress of * * * useful Arts, by securing for limited Times to * * * Inventors the exclusive Right to their * * * Discoveries." U.S. Const. art. I, § 8, cl. 8.[6] That provision "is both a grant of

[6] *See generally* Dotan Oliar, *Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Power*, 94 Geo. L.J. 1771, 1800-01 (Aug. 2006) (explaining that the Framers drafted the Patent Clause against an "anti-monopolistic background" that included concerns about "governmental favoritism" and England's oppressive use of exclusive commercial arrangements).

power and a limitation." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5 (1966).

Based on the constitutional language, this Court has long held that Congress may not "enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby." *Id.* at 6. Nor may it "authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Id.*

In keeping with that constitutional mandate—and in an effort to codify this Court's early jurisprudence on the issue—Congress enacted the Patent Act of 1952. *Id.* at 3-4, 14-15. Under 35 U.S.C. § 103, a patent for a claimed invention may not be obtained "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." When correctly applied, the provision serves a crucial purpose: it screens out trivial inventions that merely combine known art to predictable success. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

The non-obviousness requirement "is the 'ultimate condition' of patentability—the single most significant doctrine dividing those ideas worth granting a patent on from run-of-the-mill work that does not deserve a patent."[7] It is thus of paramount importance

---

[7] Mark A. Lemley, *Expecting the Unexpected*, 92 Notre Dame L. Rev. 1369, 1371 (Jan. 2017); *see also* John F. Duffy, *Inventing*

that lower courts—and initial patent reviewers—have a clear understanding of how to assess obviousness.

The Federal Circuit misunderstood that inquiry here, applying an artificially rigid test that cabined its analysis. And not for the first time. In *KSR*, this Court reversed a similar decision of the Federal Circuit, emphasizing that artificially rigid legal tests are contrary to a proper understanding of obviousness. *KSR* dealt with the validity of the teaching, suggestion, or motivation (TSM) test, a legal framework created by the Federal Circuit to guide its obviousness inquiry. *KSR*, 550 U.S. at 407. Under that test, "a patent claim is only proved obvious if 'some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art." *Id.*

In unanimously rejecting "the rigid approach of the Court of Appeals," the Court explained that "[t]hroughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach * * * ." *Id.* at 415. The Court acknowledged that the principle underlying the TSM test, that the existence of a known reason to combine the prior art can bear on obviousness, was a

---

Invention: A Case Study of Legal Innovation, 86 Tex. L. Rev. 1, 2 (Nov. 2007) (The obviousness doctrine "is widely understood to be so fundamental to the proper functioning of the patent system that it can be accurately described as the 'final gatekeeper of the patent system,' the 'ultimate condition of patentability,' and 'the heart of the patent law.'" (Footnotes omitted.)).

"helpful insight." *Id.* at 418. But helpful insights, the Court cautioned, "need not become rigid and mandatory formulas." *Id.* at 419. Indeed, when a helpful insight is applied rigidly, it demonstrates a fundamental misunderstanding of the concept of obviousness. *Id.* at 422; *see also id.* at 421 ("Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.").

The lead compound test applied by the Federal Circuit here thwarts the directives laid out by this Court in *KSR*. Like the test in *KSR*, the lead compound test imposes an inflexible threshold requirement, which must be met before the court can proceed to the flexible, multi-factor analysis articulated in *Graham* and reaffirmed by this Court in *KSR*.[8] *See, e.g., Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012) (describing its obviousness analysis as a "two-part inquiry," with satisfying the lead compound test as the first, essential, step to demonstrating obviousness). The lead compound test is thus "exactly the type of rigid application that [this] Court warned against in *KSR v. Teleflex*."[9]

---

[8] The lead compound test "requires a challenger to show that elements in prior art identified (i) the lead compound, (ii) each individual step thereafter and (iii) the resulting invention, even though the lead compound was not part of the patent claim." Douglas L. Rogers, *Federal Circuit's Obviousness Test for New Pharmaceutical Compounds: Gobbledygook?* 14 Chi.-Kent J. Intell. Prop. 49, 54 (Fall 2014).

[9] Briana Barron, *Structural Uncertainty: Understanding the Federal Circuit's Lead Compound Analysis*, 16 Marq. Intell. Prop. L. Rev. 401, 416 (Summer 2012). Numerous academics

There are minor differences between this case and *KSR*, most notably the fact that *KSR* involved a patent for a mechanical invention, while the lead compound test applies to chemical compounds.[10] The underlying principles governing the obviousness inquiry, however, remain the same regardless of the nature of the patented art. Put simply, the meaning of the word "obvious" in 35 U.S.C. § 103 should not differ depending on the context.[11]

In sum, the test applied by the Federal Circuit in this case cannot be squared with this Court's directives in *KSR* and artificially limits the courts' review of challenged patents. In granting review, this Court would provide invaluable guidance to the lower courts—and to the patent office—by affirming that

---

have observed that the lead compound test is plainly inconsistent with the principles articulated in *KSR*. *See, e.g.*, Rogers, *Federal Circuit's Obviousness Test*, *supra* note 8, at 54 (explaining that "the Federal Circuit developed [the lead compound] test before *KSR* and continues to apply essentially the same test now, even though it is inconsistent with *KSR*"); David Tseng, *Not All Patents Are Created Equal: Bias Against Predictable Arts Patents in the Post-KSR Landscape* 13 Chi.-Kent J. Intell. Prop. 165, 179 (Fall 2013) ("The lead compound analysis appears to be in stark contradiction to the Supreme Court's disapproval of the rigid application of rules to determine obviousness."); Barron, *Structural Uncertainty*, *supra*, at 423 (explaining that the lead compound test is inconsistent with *KSR*).

[10] *See* Katherine M. L. Hayes, *Three Years Post-KSR: A Practitioner's Guide to "Winning" Arguments on Obviousness and a Look at What May Lay Ahead*, 9 Nw. J. Tech. & Intell. Prop. 243, 244 (Fall 2010) ("*KSR*'s impact has differed based on the patented art. While *KSR* has only tweaked chemical patent inquiries, its effect on mechanical patent validity has been substantial.").

[11] Barron, *Structural Uncertainty*, *supra* note 9, at 423.

the basic principles governing obviousness apply with equal force regardless of the nature of the art at issue.

B. This case illustrates how the application of rigid legal tests can protect duplicative patents.

Not only does the application of artificially rigid tests directly contravene this Court's precedent, it also leads to bad results. The non-obviousness requirement is fundamental to ensuring that patents serve their most basic purpose: "to add to the sum of useful knowledge." *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950). But when, as here, the Federal Circuit erects rigid barriers to proving obviousness for pharmaceutical compounds, more improper patents survive, and consumers suffer.

This case provides a good example of how the application of the lead compound test can undermine the basic premise of the patent system. Through the application of that rigid standard, respondents have been permitted to obtain and defend multiple patents on the same antiepileptic drug. If left unchecked, they will have successfully secured a monopoly on that drug for more than a quarter century.

And because respondents have simply built upon prior art without significant additional innovation, their later patents have added little, if anything, to the sum of useful knowledge. Any rigid test that permits such evergreen monopolies—without requiring true invention in the interim—cannot stand because it does not serve the basic constitutional principles on which the patent system is founded. *See Graham*, 383 U.S. at 6 ("Innovation, advancement, and things

which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of * * * useful Arts.' This is the standard expressed in the Constitution and it may not be ignored.")

The flaws inherent in the lead compound test not only insulate bad patents from review, they also flow upstream, encouraging the grant of more duplicative patents. That is so because, as this Court has observed, there should be a "close[] concurrence" between the standards articulated in judicial precedent and those applied by the administrative body in granting patents. *See id*. at 18-19 ("While we have focused attention on the appropriate standard to be applied by the courts, it must be remembered that the primary responsibility for sifting out unpatentable material lies in the Patent Office.").

Accordingly, the Federal Circuit's application of artificial constraints on obviousness likely makes it easier to obtain a duplicative pharmaceutical patent at the outset.[12]

Moreover, the cost and difficulty of litigation—combined with the discouraging rigidity of the current legal standards—mean that duplicative pharmaceuti-

---

[12] *Cf*. Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 Case W. Res. L. Rev. 691, 741 n.214 (Spring 2004) ("Strengthening the obviousness standard will make it harder to extend patent life through double-patenting * * * .").

cal patents, once issued, may be more likely to survive.[13] In placing a heavy threshold burden on patent challengers seeking to demonstrate obviousness, the lead compound test may discourage challenges to bad patents and force settlements that deprive consumers of access to generic medicines for years or even decades.

As discussed below, the evergreening of pharmaceutical patents causes real harm to consumers. By allowing duplicative patents for chemical compounds, the lead compound test contributes to skyrocketing costs for essential drugs and limits patients' access to needed medicine. It also discourages true innovation by rewarding companies for rehashing timeworn pharmaceutical technology that should have long since entered the public domain. Those results are flatly at odds with the fundamental goals of the patent system.

II. Duplicative patents contribute to rising drug prices and harm American consumers.

As this Court is well aware, patents represent grants of "'public rights.'" *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018). Congress designed the patent system to spur innovation through a limited period of monopoly, and then provide greater consumer access and decreased costs when competitors enter the market.

---

[13] *See* Rogers, *Federal Circuit's Obviousness Test*, *supra* note 8, at 54 (explaining that the lead compound test for pharmaceutical compounds "generally makes it more difficult than under *KSR* to prove obviousness").

Duplicative patents thwart this plan, stifling innovation and driving up costs. And the harms of improper patents are particularly acute in the pharmaceutical context.[14]

A. Patents on prescription drugs significantly and directly affect consumer costs.

Rising prescription drug prices are a serious problem for our nation and economy. The United States spends 18% of its gross domestic product on health care, up from just 7% in 1970.[15] A significant portion of that health care spending goes toward prescription drugs.[16] As of February 2018, the nation spent approximately $354 billion annually on prescription

---

[14] I-Mak, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving up Drug Prices* 11 (2018), *available at* http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

[15] Altarum Institute, Center for Sustainable Health Spending, *Insights from Monthly National Health Spending Data Through December 2015* 1 (Feb. 16, 2016), *available at* https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Spending-Brief_February_2016.pdf; Medicaid and CHIP Payment and Access Commission, *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; Centers for Medicare & Medicaid Services, *NHE Fact Sheet*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (last visited Dec. 19, 2018).

[16] *See* Altarum Center for Value in Health Care, *Health Sector Economic Indicators: Insights from Monthly National Health*

drugs.[17] That represents a 4.2% increase over 2017,[18] and drug prices continue to increase both nationally and globally.[19]

Patented drugs cause the bulk of this spiraling price growth. Although brand-name drugs represent only 10% of all dispensed prescriptions in the United States, they account for 72% of drug spending.[20] Between 2008 and 2015, prices for the most commonly used brand-name drugs increased by 164%, far in excess of the 12% increase in the consumer price index.[21] In 2015, prices for existing brand-name drugs reached a double-digit growth rate for the fourth consecutive year, while prices for generic drugs increased less than 1%.[22] More recently, over the first seven months

---

Spending Data through February 2018 2 (April 13, 2018), *available at* https://altarum.org/sites/default/files/uploaded-related-files/SHSS-Spending-Brief_April_2018.pdf.

[17] *Id.*

[18] *Id.* at 3.

[19] *See* Office of the Assistant Secretary for Planning and Evaluation, Department of Health & Human Services, *Observations on Trends in Prescription Drug Spending* 7 (Mar. 8, 2016), *available at* https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending ("Expenditures on prescription drugs are rising and are projected to continue to rise in the coming years as a share of total health care spending."); IMS Institute for Healthcare Informatics, *Global Medicines Use in 2020*, *supra* note 2, at 1, 16.

[20] Kesselheim, et al., *High Cost of Prescription Drugs*, *supra* note 3, at 860.

[21] *Id.*

[22] Anne B. Martin et al., *National Health Spending: Faster Growth in 2015 as Coverage Expands and Utilization Increases*,

of 2018, there were 96 price increases on brand-name drugs for every price cut.[23] And experts expect the upward trend on drug spending to continue.[24]

As noted earlier, "[t]he 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."[25] Typically, the presence of generic medications can cut branded drug prices by half or even

---

36 Health Affairs 166, 174-75 (Jan. 2017). In 2014, brand-name drug prices grew by 15.4% while prices for generics grew by only 0.2%. S&P Dow Jones Indices, *Healthcare Expenditures for Commercial Plans up 3.2% in the Year to February 2014: S&P Healthcare Claims Indices* (June 30, 2014), *available at* http://press.spglobal.com/2014-06-30-Healthcare-Expenditures-for-Commercial-Plans-up-3-2-in-the-Year-to-February-2014-S-P-Healthcare-Claims-Indices?asPDF=1.

[23] Linda A. Johnson & Nicky Forster, *AP Investigation: Drug Prices Continue to Rise Despite Trump Promise,* NBC 7 San Diego (Sept. 25, 2018), https://www.nbcsandiego.com/news/health/AP-Investigation-Drug-Prices-Going-Up-Despite-Trump-Promise-494246131.html?_osource=taboola-recirc.

[24] 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 (citing 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).

[25] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 3, at 861.

more.[26] "Drug prices decline to approximately 55% of brand-name drug prices with 2 generic manufacturers making the product, 33% with 5 manufacturers, and 13% with 15 manufacturers."[27] And a 2012 government study estimated that "generic drugs * * * saved the US health care system $1 trillion during the previous decade."[28]

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, consumers and businesses who pay higher and higher premiums because of rising drug prices, and hardworking taxpayers who fund public programs like Medicaid and Medicare.

B. Some brand-name companies use duplicative or obvious patents to artificially prolong their monopolies on lucrative drugs.

Manufacturers of name-brand pharmaceuticals reap huge benefits from patents; these grants of public rights give them a period of monopoly on the drugs they develop and allow them to extract from the pub-

---

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

[27] Kesselheim et al., *High Cost of Prescription Drugs*, *supra* note 3, at 861.

[28] *Id*.

lic the maximum possible returns on their investments.[29] *See Oil States Energy Servs.*, 138 S. Ct. at 1373-74. Because the monopoly power of a patent confers huge benefits, companies do everything they can to retain that power. Those efforts may include "seeking and obtaining many patents of questionable validity" and "engaging in frequent and costly patent litigation" for improper purposes.[30]

Respondents' conduct in attempting to obtain duplicative patents for their lucrative drug is hardly unique—indeed, such attempts to "evergreen" a patent are a key part of the business strategy of many name-brand drug manufacturers.[31] Consider, for example, the medication Humira (adalimumab), which

---

[29] *See id*. at 860 ("Drug prices are higher in the United States than in the rest of the industrialized world because, unlike that in nearly every other advanced nation, the US health care system allows manufacturers to set their own price for a given product.") In 2016, total U.S. expenditures on pharmaceutical drugs were $480 billion. Two-thirds of this total ($323 billion) was captured by drug manufacturers in the form of net revenues. Nancy L. Yu, Preston Atteberry, & Peter B. Bach, *Spending on Prescription Drugs in the U.S.: Where Does All the Money Go?*, Health Affairs Blog (Jul. 31, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top-stories.

[30] Alfred B. Engelberg, Aaron S. Kesselheim, & Jerry Avorn, *Balancing Innovation, Access, and Profits — Market Exclusivity for Biologics*, 361 New Eng. J. Med. 1917, 1919 (Nov. 12, 2009), *available at* http://www.nejm.org/doi/full/10.1056/NEJMp0908496#t=article.

[31] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 Can. Med. Ass'n J. E385, E385 (June 11, 2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/.

costs over $50,000/year and is the top selling medication in the world.[32] The original patent on Humira expired in 2016, and the FDA has already approved a biosimilar (generic) version.[33] Yet the company that owns Humira has acquired a web of over 70 other ancillary patents to protect Humira, the "'vast majority'" of which it obtained within the last two years before its original patent expired.[34]

---

[32] Johnson, *FDA Regulation of Follow-On Biologics*, *supra* note 26, at 1; Amy Brown, Evaluate Grp., *EP Vantage 2017 Preview* 5 (Dec. 2016), *available at* http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[33] U.S. Food & Drug Administration, *FDA Approves Amjevita, a Biosimilar to Humira* (Sept. 23, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm. Humira is a "biologic," which as explained above is a relatively new category of high-priced specialty medications made from living material. *See supra* note 5.

[34] Dan Stanton, *AbbVie: Humira's Patent Maze Will Keep US Biosimilars Away Until at Least 2022*, BioPharma Reporter (Nov. 3, 2015), https://www.biopharma-reporter.com/Article/2015/11/03/AbbVie-Humira-s-patent-maze-to-keep-US-biosimilars-at-bay-until-2022; *see also* Andrew Pollack, *New Patents Aim to Delay Generics of Biologics*, N.Y. Times, July 15, 2016, at B1, *available at* https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html?mcubz=1. The follow-on patents AbbVie obtained for Humira include 22 patents for method of treatment (*e.g.*, giving Humira to patients by injection), and 24 patents on different ways to make Humira. Stanton, *Humira's Patent Maze*, *supra*.

The company that owns Humira is attempting to use these patents to "cocoon Humira by tying up competitors in expensive and lengthy court battles."[35] As the CEO told investors on an earnings report conference call, "[a]ny company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate, which [we] intend[] to enforce vigorously."[36] "[W]e believe the litigation process and our intellectual property estate will protect Humira from biosimilar entry until 2022."[37]

Another classic example of evergreening involves the heartburn treatment, Prilosec.[38] Prilosec was the world's best-selling pharmaceutical drug in 2001.[39]

---

[35] J. Duncan Moore Jr. & Kristen Schorsch, *How AbbVie Has Won the Humira Fight—So Far*, Crain's Chicago Business (Nov. 5, 2016), http://www.chicagobusiness.com/article/20161105/ISSUE01/311059994/how-abbvie-has-won-the-humira-fight-so-far. Or, as a recent article put it, "Abbvie has built a thick patent fence around its cash cow." Mari Serebrov, *Amgen-Abbvie Agreement Erases Uncertainty for Humira Biosimilar*, BioWorld, http://www.bioworld.com/content/amgen-abbvie-agreement-erases-uncertainty-humira-biosimilar-0 (last visited Dec. 18, 2018).

[36] The Street, *AbbVie (ABBV) Earnings Report: Q3 2015 Conference Call Transcript* 9 (Oct. 30, 2015), *available at* https://s.t.st/media/xtranscript/2015/Q4/13346337.pdf.

[37] *Id*. at 11.

[38] Cynthia M. Ho, *Should All Drugs Be Patentable?: A Comparative Perspective*, 17 Vand. J. Ent. & Tech. L. 295, 315 (Winter 2015); *see also* Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 Colum. L. Rev. 1471, 1489-91 (Oct. 2008).

[39] Ho, *Should All Drugs Be Patentable?*, *supra* note 38, at 318.

The patent on the active ingredient for that drug expired in 2001, but the manufacturer obtained additional patents, such as a patent for the internal coating on Prilosec pills, in an effort to delay generic entry into the market.[40] The manufacturer also patented a minor variation of the chemical compound in Prilosec and marketed it as a new and ostensibly improved drug, Nexium.[41] It then strategically released Nexium one month before Prilosec's patent was set to expire—and before any generics could enter the market—and withdrew Prilosec from the prescription pharmaceutical market.[42] That strategy was "highly successful in prompting most consumers to switch from Prilosec to Nexium" and enabled the manufacturer to largely maintain its monopoly over prescription heartburn medication.[43]

This Court has long made clear that "any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws." *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 256 (1945). Yet, as the examples above and this case illustrate, companies with valuable patents are throwing research and development funding into gaining ancillary patents that they can use to protect their lucrative brand-name drugs even

---

[40] *Id.* at 315.

[41] *Id.* at 318; *see also* Cheng, *An Antitrust Analysis of Product Hopping*, *supra* note 38, at 1490 n.112.

[42] Ho, *Should All Drugs Be Patentable?*, *supra* note 38, at 319.

[43] *Id.* at 318.

after the original patent expires. Artificially rigid tests shield those duplicative patents from challenge and improperly extend monopoly power, contributing to rising drug prices and harming the public.

C. Duplicative patents threaten the delicate balance between spurring innovation and enabling public access to inventions.

The existence of duplicative patents drives up costs for consumers, insurance companies, and the government. When a patent issues inappropriately or a monopoly is improperly prolonged, prices for the patented technology remain artificially high.

In addition to increasing costs, high drug prices limit patients' access to needed medicine. High drug prices limit access both directly, through increased out-of-pocket costs, and indirectly, by raising health insurance premiums for everyone. This, in turn, may force some patients to rely on less effective over-the-counter medicine or simply forgo treatment all together. Indeed, in 2016, 11% of Americans went without a needed prescription medicine because they could not afford it.[44] And patients are nearly three times more likely to abandon their prescription for a

[44] Board of Governors of the Federal Reserve System, *Report on the Economic Well-Being of U.S. Households in 2016* 28 (May 2017), *available at* https://www.federalreserve.gov/publications/files/2016-report-economic-well-being-us-households-201705.pdf.

brand-name drug than for a generic one.[45] Prescription abandonment, in turn, can negatively impact patient health and may, in some cases, lead to hospitalization or death.[46]

The existence of improper patents can also stifle innovation. Scientists may be chilled from cutting-edge research for fear of legal issues created by the invalid patents. 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.[47] Even the "knowledge that a patent application has been filed

---

[45] Chester Davis, Jr., CEO of Ass'n for Accessible Medicines, Statement to the Senate Health, Education, Labor and Pensions Committee: *The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay* 6 (Oct. 17, 2017), *available at* https://www.help.senate.gov/imo/media/doc/Davis6.pdf.

[46] *Id.*; *see also* Scott Gottlieb, Commissioner of Food and Drugs, Speech at Pharmaceutical Care Management Association PBM Policy Forum (April 19, 2018), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm605143.htm ("High prices at the pharmacy counter can lead to patients abandoning prescriptions, worsening health outcomes, and raising overall health care costs.").

[47] Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 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.

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."[48]

Duplicative patents impose real burdens on Americans and subvert the goals of the patent system. And, in the pharmaceutical context, improperly extending a patent monopoly can have life-or-death repercussions. 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.

CONCLUSION

Amicus respectfully urges this Court to grant the petition for certiorari.

---

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

Respectfully submitted,

JULIE SIMON MILLER
MICHAEL S. SPECTOR
AMERICA'S HEALTH
INSURANCE PLANS
601 Pennsylvania Ave., NW
Washington, DC 20004

ANNA-ROSE MATHIESON
Counsel of Record
SUSAN YORKE
CALIFORNIA APPELLATE
LAW GROUP LLP
96 Jessie Street
San Francisco, CA 94105
(415) 649-6700
annarose@calapplaw.com

December 2018