No. 14-647

IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., HOFFMANN–LA ROCHE, INC., F. HOFFMANN–LA ROCHE, LTD., AND GENENTECH, INC.,
Petitioners,

v.

NATCO PHARMA LIMITED AND NATCO PHARMA, INC.,
Respondents.

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

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INDUSTRY ORGANIZATION AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing leading research-based pharmaceutical and biotechnology companies. PhRMA's members are the primary source of the many new drugs and biologics introduced each year. PhRMA's members invest billions of dollars in discovering and developing new medicines, including $51 billion in 2013 alone. *See* PhRMA, 2014 Biopharmaceutical Research Industry Profile 27 (2014), *available at* http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf ("*2014 Industry Profile*").

Biotechnology Industry Organization ("BIO") is the world's largest trade association, representing over 1100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members research and develop biotechnological healthcare, agricultural, environmental, and industrial products. BIO members range from startup entities and university spinoffs to Fortune 500 multinational corporations, though the majority of BIO members are small companies that have yet to bring prod-

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[1] The parties have consented to the filing of this brief. Counsel of record for all parties received timely notice of the intent to file this brief. No counsel for a party authored this brief in whole or in part, and no person other than amici, their members, or their counsel made a monetary contribution to its preparation or submission. Petitioners and Respondents are not PhRMA member companies. A complete list of PhRMA's member companies is available online at http://www.phrma.org/about/member-companies. Petitioners, but not Respondents, are BIO members. A complete list of BIO's members is available online at https://www.bio.org/articles/bio-members-web-site-links.

ucts to market or attain profitability, and thus depend on venture capital and other private investment for their growth.

Medical advances such as those made by PhRMA's and BIO's members require enormous investments in research and development. The protections of patent law provide incentives for companies to take on the huge risks of drug development, and biopharmaceutical innovation requires stability and predictability in patent law because patent filing decisions often must be made years in advance of developing and marketing an FDA-approved drug.

The Federal Circuit's recent expansion of the obviousness-type double patenting doctrine upsets that stability. PhRMA and BIO accordingly support the petition for certiorari in this case.

INTRODUCTION

The Federal Circuit's decision in this case expands the judicially created doctrine of obviousness-type double patenting at a time when the doctrine should be declining in use, if not disappearing entirely, as a result of statutory changes that resolved the primary problem the doctrine was designed to address. This judicial expansion of the doctrine without regard to its original purpose transforms it from a tool used to prevent the extension of a patent's term through the subsequent patenting of obvious variants into a trap that invalidates or cuts short the term of an already-issued patent. That fundamental shift disrupts established patent law, takes away patent term benefits that Congress intended to confer, and introduces significant uncertainties into investment in biopharmaceutical research and development. This Court's review is neces-

sary to define the scope of the double patenting doctrine and to restore critical patent-law incentives for future biopharmaceutical innovation.

The double patenting doctrine was originally developed at a time when a patent's term ran from the date of issuance. In that context, the doctrine prevented a patent owner from extending its period of exclusion through later-issued claims that were the same or not patentably distinct from an already-issued claim. The original rationale for the double patenting doctrine, however, has steadily eroded since 1995 when Congress changed the way that patent terms are calculated, switching from a term of seventeen years running from the date of issuance to a term of twenty years running from the date of the earliest application to which a patent claims priority. This switch to calculating a patent's term from the application date effectively eliminates the opportunity for gamesmanship for patent applications filed in the past two decades.

But rather than allowing the doctrine of double patenting to fade away, the Federal Circuit has instead expanded the doctrine far beyond its original purpose. The decision in this case holds—for the first time—that a *later*-issued patent with a shorter effective patent life between issuance and expiration can cause a patent owner to lose already-vested rights in an *earlier*-issued patent. The Federal Circuit has thus taken a judicial creation designed to prevent a new patent from extending an existing period of exclusivity and applied it in exactly the opposite way.

This unwarranted expansion deprives patent owners of valuable property rights without any basis in the statute, threatens to undermine provisions Congress enacted to compensate for administrative delay, and

creates substantial uncertainty. This Court should grant the petition and reverse.

REASONS FOR GRANTING THE WRIT

The decision below warrants this Court's review for three principal reasons.

First, the decision expands the judicially created double patenting doctrine far beyond the text of the Patent Act or the doctrine's original purpose. This expansion is part of a larger pattern of extending the doctrine without regard to statutory changes that have substantially diminished, if not eliminated, the need for it. This Court's guidance is needed to break this pattern and make clear that courts should not expand the double patenting doctrine, and thereby deprive patent owners of valuable property rights they are entitled to by statute, absent clear direction from Congress.

Second, even apart from this pattern of improper expansion, the Federal Circuit's decision in this case warrants review because it upends the established doctrinal framework for double patenting and, for the first time, allows a *later*-issued patent to shorten the term of an *earlier*-issued patent. Before the Federal Circuit's decision, the double patenting doctrine prevented a patent owner from *expanding* its period of exclusivity, but did not affect the patent owner's rights in its original patent. The new rule allowing a later-issued patent to *shorten* the term of an *already-issued* patent makes it impossible to calculate the term of an issued patent with certainty as long as patent applications relating to similar subject matter are still pending. In addition, it upsets licenses and business decisions that have already been made in reliance on the old rule. The Federal Circuit's decision also threatens to disrupt the

carefully calibrated system of incentives Congress created when it authorized patent term adjustments to compensate for the PTO's delay in examining the patent and patent term extensions to compensate for the FDA's delay in approving new drugs.

Third, the uncertainty created by the Federal Circuit's unwarranted expansion of the double patenting doctrine tends to undermine the incentive to invest in research and development of potentially significant new biopharmaceutical therapies.

I. THE FEDERAL CIRCUIT'S NEW RULE CONTINUES A PATTERN OF IMPROPERLY EXPANDING THE JUDICIALLY CREATED DOCTRINE OF DOUBLE PATENTING

Obviousness-type double patenting is a judicially created doctrine that goes beyond any of the grounds for invalidating a patent that Congress authorized in the Patent Act. When a patent owner loses its rights under the doctrine, it is not because the invention was anticipated or obvious in light of the prior art specified in the statute, 35 U.S.C. §§ 102-103, or because the inventor failed to enable, describe, and particularly point out and distinctly claim the invention, *id.* § 112. It is instead because the courts decided that going beyond the statute and using the inventor's own disclosure to limit its rights was needed to address a particular problem: preventing a patent owner from effectively extending its patent term by obtaining a subsequent patent on a trivial variation of the patented invention.[2] *See Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955,

[2] This case deals solely with the application of the doctrine of obviousness-type double patenting to multiple patents owned by the same entity. The application of the doctrine to patents owned by different entities is a distinct question that does not arise in this case. See Pet. App. 20a.

967 (Fed. Cir. 2001); *see also In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

The problem that motivated the creation of the doctrine was largely an artifact of the old system in which a patent's term lasted for seventeen years *from the patent's date of issuance*. Under that system, an applicant could use successive continuation applications to try to claim features of an invention many years after the filing of the original patent application, which allowed it to benefit from the priority date of the original application while obtaining successive patents with terms that ran from the date of issuance.

The doctrine of double patenting prevented applicants from exploiting this system to extend a patent's period of exclusivity beyond the period provided by Congress. The doctrine had no effect on the first patent to issue, but to the extent a subsequent patent contained claims that were the same or only trivially different, courts would invalidate those later claims unless the patent owner filed a terminal disclaimer restricting the later patent to the same term as the original patent. *See Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315, 319 (1866) (when a subsequent patent claims the same invention as an already-issued patent, "[t]he last, not the first, is void"); *Eli Lilly*, 251 F.3d at 967 n.5 ("double patenting precludes [a claim] of the [second-issued] patent from extending beyond the termination date of the [first-issued] patent"); *Perricone* v. *Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005) ("A terminal disclaimer can indeed supplant a finding of invalidity for double patenting.").

The concerns that motivated the creation of the doctrine of double patenting substantially diminished after Congress amended the Patent Act to adopt a

twenty-year patent term measured *from the date of the earliest application to which the patent claims priority*. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) (implementing patent term transition from seventeen years from issuance to twenty years from priority filing date). To obtain a second, later expiring patent under the new system, the applicant generally must give up any claim to the earlier priority date and expose its patent to all the intervening prior art. *See* Pet. App. 20a. Even then, the publication of its original application eighteen months after filing, *see* 35 U.S.C. § 122(b), will limit any opportunity for delay by transforming the applicant's own disclosure into prior art that could be cited against subsequent applications.

It was against this backdrop of a diminishing need for the doctrine of obviousness-type double patenting that the Federal Circuit inexplicably chose to expand the doctrine in this case. That expansion comes on top of other recent, highly questionable judicial extensions of the doctrine in the last decade. *See Sun Pharm. Indus., Ltd.* v. *Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010) (rejecting a patent for any new use of a compound disclosed in the specification of a patent claiming the compound); *Geneva Pharm., Inc.* v. *GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003) (rejecting a patent on a particular use of a compound based on the disclosure of the use in the specification of a patent claiming the compound). The combined effect of these changes has been to make the doctrine of obviousness-type double patenting significantly harsher and incoherent at the very time that it should be fading away as obsolete.

The strong dissent in this case invoked the doctrine of "judicial restraint" and noted that "courts should be

reluctant to create or expand judge-made exceptions to statutory grants." Pet. App. 19a. But that warning went unheeded, and the majority below once again expanded the double patenting doctrine, impairing valuable property rights without even attempting to ground its decision in the text of the Patent Act. This Court's guidance is urgently needed to put a stop to this pattern and to make clear that the double patenting doctrine should not be expanded absent express direction from Congress.

II. THE FEDERAL CIRCUIT'S NEW DOUBLE PATENTING RULE TAKES AWAY GRANTED PATENT RIGHTS AND THREATENS TO INTERFERE WITH OTHER PROVISIONS OF THE PATENT ACT

A. The Federal Circuit's Decision To Shorten The Terms Of Issued Patents Is Unprecedented

Even apart from the Federal Circuit's larger pattern of improperly expanding obviousness-type double patenting, the particular expansion in this case warrants review. The Federal Circuit has upended over a century of established law by allowing a *later* patent to invalidate or shorten the term of an *earlier* patent. This shift transforms the double patenting doctrine from one that prevents the subsequent *extension* of a patent's term into one that *truncates* the term of an existing patent, and thus improperly erodes valuable property rights.

The Federal Circuit ignored the serious problems that arise when the term of an issued patent is shortened after the fact. Before the decision below, the double patenting doctrine locked in the term of the first patent to issue. The term could not be extended by subsequent claims on the same invention or trivial var-

iants, but neither could it be shortened by subsequent developments. The term was what it was, and patent owners, licensees, and competitors could plan accordingly.

Under the Federal Circuit's new rule, the actual term of the first patent to issue remains unknown as long as any application that might give rise to an allegation of double patenting remains pending because at any point a second patent that cuts short the term of the first patent could issue. This uncertainty regarding the term of already-issued patents will chill investment, licensing, and the formation of valuable business partnerships.

The Federal Circuit's decision also upsets the reliance interests of individuals and businesses. This Court has warned:

> Courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community…. The responsibility for changing [settled law] rests with Congress. Fundamental alterations in these rules risks destroying the legitimate expectations of inventors in their property.

Festo Corp. v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (citation omitted).

Today's patents were developed under a patent-law regime in which a later-issued patent would not shorten the term of an earlier-issued patent. Biopharmaceutical innovators managed their patent portfolios and made significant investments in research and development of new drug therapies in reliance on that patent-law framework. For example, had Petitioners known that the issuance of their second patent would shorten

the existing term of their first patent, they might have abandoned the second patent before it issued. Similarly, licenses and other contracts might have been drafted differently to account for the new uncertainty the Federal Circuit has injected into the process. Changing the rules in the middle of the game, as the Federal Circuit did here, could throw into question an array of biopharmaceutical patents and undermine longstanding patent-law incentives to investigate and develop new drug therapies.

B. The Federal Circuit Ignored The Importance Of A Patent's Effective Term, Which Depends On Its Issue Date

The Federal Circuit's analysis reflects a fundamental misunderstanding of the double patenting doctrine. The Federal Circuit focused exclusively on the expiration date of the two patents at issue in this case and mechanically held that the earlier-expiring patent truncated the term of the later-expiring patent regardless of which patent issued first. The panel reasoned that the uniform focus on the date of issuance and repeated holdings that double patenting affects only the later-issued patent in all previous cases simply reflected the fact that, in a system where patent terms were measured from issuance, the issue date could serve as a proxy for the expiration date. Pet. App. 12a. The panel decided that, in a system where patent terms are calculated from the date of the priority application, a patent's issue date no longer should matter in the double patenting analysis. Pet. App. 12a-13a. The panel thus took the very change that has diminished the need for the double patenting doctrine and used it to try to justify an expansion of the doctrine.

The panel's argument that issue dates are irrelevant is not correct. The date of issuance determines the *effective* patent term, defined as the time between the issuance and expiration of the patent. It is this effective patent term that drives the incentives to invest in the patented invention because it is only during this term that the right to exclude can be enforced. A shorter effective term thus provides fewer incentives for investment.

The Federal Circuit's new broadening of the double patenting doctrine expands the category of patents that may be used in double patenting challenges, making effective patent terms shorter and more uncertain. This is a particular problem for biopharmaceutical patents, which can be most valuable near the end of their terms when a drug has gained widespread acceptance.

C. The Federal Circuit's Decision Threatens Congress's Carefully Calibrated System For Restoring A Patent's Term To Compensate For Administrative Delay

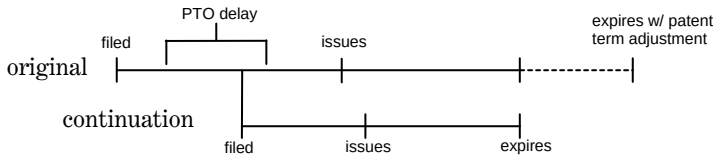
Congress was acutely aware of the importance of a patent's effective term and has taken steps to carefully calibrate that term and the incentives it provides. One of the most serious consequences of the Federal Circuit's expanded double patenting doctrine is that it has the potential to interfere with the patent term adjustments and extensions that Congress specifically authorized to compensate for administrative delay.

Congress has provided two methods of extending a patent's effective term as compensation for agency delays involving the patent. First, under 35 U.S.C. § 154(b), Congress authorized patent term adjustments to add back time lost due to delays in patent examination at the U.S. Patent and Trademark Office. For ex-

ample, if the PTO fails to take initial action on a patent application within fourteen months, fails to respond to the applicant's reply within four months, or causes other types of delay specified in the Patent Act, the term of its patent is adjusted to compensate for the delay. *Id.*; 37 C.F.R. § 1.705(a).

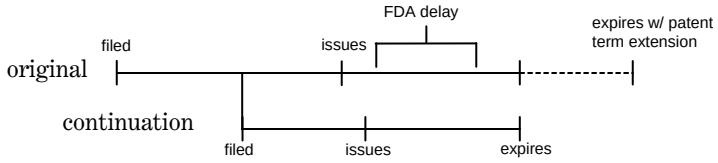
Second, under 35 U.S.C. § 156, Congress authorized patent term extensions to restore time lost during premarket approval process by the U.S. Food and Drug Administration or the U.S. Department of Agriculture. Congress recognized that "[e]ffective patent terms are influenced by many factors, including Federal premarketing and premanufacturing regulations" and decided to extend the patent term of certain new products "[a]s compensation for the loss of patent term due to government review." H.R. Rep. No. 98-857, pt. 1, at 17-18 (1988).

The Federal Circuit's new double patenting rule has the potential to create serious problems because not all related patents receive the same adjustment to or restoration of their terms. For example, a pioneering patent application may take a longer time to be examined, resulting in a patent term adjustment. Continuation applications or other applications related to that issued patent may take a shorter time, and may not result in any patent term adjustment. But under the Federal Circuit's new rule, if the two inventions are not deemed patentably distinct, a later-issued patent that resulted from a fast-moving continuation application without any patent term adjustment might cut off the patent term of a pioneering patent that issued earlier but was entitled to an adjusted term.



For example, in the diagram above, if the Federal Circuit's rule were applied without an exception to account for § 154, the earlier expiration date of the continuation application would cut off the entire final segment of the original patent's adjusted term (indicated by the dashed line), completely eliminating the patent term adjustment that Congress granted the patent owner to compensate for the effective loss of patent life caused by the PTO's delay in reviewing the patent application.

Similarly, a patent covering a new drug that underwent years of FDA review before being approved might be awarded a patent term extension under § 156, while later patents related to the same therapy would not. If the Federal Circuit's rule were applied without an exception for § 156, it could allow the later-issued patent to cut off the additional patent term that Congress granted on the original patent.



Thus, by ignoring Congress's concern about a patent's effective term, the Federal Circuit's new rule not only strays beyond the original justification for the double patenting doctrine, but also threatens to undermine the specific mechanisms that Congress created

to ensure that administrative delay does not erode a patent's effective term.

III. Certainty And Stability Are Important To Encouraging Investment In Biopharmaceutical Innovation

Patents are particularly important to biopharmaceutical innovation given the research-intensive nature of medical research, the risk involved, and the substantial investment needed to discover and develop products that meet FDA approval requirements.

A. The Incentives Provided By Patent Protection Are Critical To Drug Discovery

Biopharmaceutical research and development is an extremely costly and risky enterprise. The biopharmaceutical industry spends more than $51 billion dollars annually on research and development. *See* PhRMA, *2014 Industry Profile* 27. Studies estimate that it costs on average approximately $2.6 billion to bring a new therapeutic product to market. *See* Tufts Center for the Study of Drug Development, *Cost of Developing a New Drug* 5 (Nov. 18, 2014), *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (summarizing findings of Grabowski and Hansen) ("*Tufts Briefing*").

Apart from the cost, the process of developing drug therapies is lengthy and subject to a high degree of uncertainty. For every drug therapy that makes its way into human testing, thousands of potential therapeutics fail in research. *See* PhRMA, *2014 Industry Profile* 48; Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science & Cents: Exploring the Economics of Biotechnology* 87, 89 (Duca & Yücel eds., 2002). Even the small

fraction of compounds that make it to human testing must then undergo years of clinical trials costing hundreds of millions of dollars. Less than twelve percent of the compounds that enter this clinical testing ultimately receive approval by the FDA. *See Tufts Briefing* 17.

The process of discovering therapeutic uses of drugs has only grown more expensive and uncertain in recent years. The estimated cost of developing and bringing a drug to market has more than doubled from the late 1990s to the early 2010s. *Compare Tufts Briefing* 5, *with* DiMasi & Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Manage. & Decis. Econ. 469, 470 (2007). Research and development efforts are now more focused on serious chronic or degenerative diseases that often pose greater scientific obstacles to drug discovery. Studies estimate that it now takes, on average, ten to fifteen years to bring a successful new drug to market. *See* DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 153 (2003).

The returns on investment made possible by patent protection for the relatively few successful products have led to remarkable advancements in drug therapies in the last several decades. The public has benefitted significantly from new medicines that have led to greater life expectancies and improved quality of life for those suffering from disease. One study has estimated that new drug treatments are responsible for 50 to 60 percent of the increase in cancer survival rates since 1975. *See* Lichtenberg, Nat'l Bureau of Econ. Research Working Paper No. 10328, *The Expanding Pharmaceutical Arsenal in the War on Cancer* 2 (2004). Indeed, new drug treatments are estimated to account for 40 percent of the overall increase in human life expectancy between 1986 and 2000. *See* Lichten-

berg, Nat'l Bureau of Econ. Research Working Paper No. 9754, *The Impact of New Drug Launches on Longevity* 21 (2003) (new drugs accounted for nearly ten months of a two-year increase in longevity among the population of the fifty-two sample countries).

Patent-law incentives continue to spur biopharmaceutical innovation in a range of areas, including efforts to develop therapies for cancer and other serious diseases. Biopharmaceutical companies currently have more than 5,000 medicines in development, *see* PhRMA, *2014 Industry Profile* 38, including more than 3,000 medicines that may treat various forms of cancer, more than 600 medicines that may address neurological disorders such as Parkinson's disease and Alzheimer's disease, and approximately 450 medicines that may treat heart disease and stroke. *See* PhRMA, *The Biopharmaceutical Pipeline: Evolving Science, Hope for Patients* 2 (2013), *available at* http://www.phrma.org/sites/default/files/pdf/phrmapipelinereportfinal11713.pdf. These and other medicines under development could lead to vital new drug therapies for patients.

B. The Expanded Double Patenting Rule Creates Uncertainty

The Federal Circuit's new rule forces innovators to choose between either risking invalidation of a patent for obviousness-type double patenting, or disclaiming as a protective measure any part of the patent term that extends beyond the expiration of the earliest-expiring related patent. *See* 35 U.S.C. § 253(b) (allowing terminal disclaimers). The stakes are high: now if a patent owner guesses incorrectly and does not file a terminal disclaimer giving up part of the effective patent term, then the patent may be invalidated for double patenting.

Complicating this choice is the uncertainty in predicting when a particular patent will issue and how much patent term adjustment or patent term restoration it will be awarded. Risk-averse patent owners are likely to respond to this uncertainty by liberally filing terminal disclaimers, potentially sacrificing years of patent life to avoid the even harsher penalty of invalidation.

This Court's review is needed to prevent this erosion of the incentives that encourage biopharmaceutical innovation by granting review and reversing.

CONCLUSION

The petition for writ of certiorari should be granted, and the judgment of the Federal Circuit should be reversed.

Respectfully submitted.

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