No. 10-972

IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Respondent.

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 AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are the primary source of the many new drugs and biologics introduced each year. In 2009, biopharmaceutical companies, including PhRMA's members, invested more than $65 billion in discovering and developing new medicines. *See* PhRMA, Pharmaceutical Industry Profile, at 26 (2010), *available at* http://www.phrma.org/sites/default/files/159/profile_2010_final.pdf.

The medical advances made by PhRMA'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. Biopharmaceutical innovation requires a measure of 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.

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[1] The parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the intention of PhRMA to file this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus or their counsel made a monetary contribution to its preparation or submission. Petitioner Eli Lilly and Company is a PhRMA member company. A complete list of PhRMA's member companies is available online at http://www.phrma.org/about/member-companies.

The Federal Circuit's recent expansion of the obviousness-type double patenting doctrine not only upsets that stability, but threatens innovation by severely impairing incentives companies like PhRMA's members otherwise have to invest in research and development of new therapeutic uses of existing drug compounds. PhRMA accordingly supports the petition for certiorari in this case.

INTRODUCTION

The Federal Circuit's decision below disrupts established patent law and introduces significant new uncertainties into investment in biopharmaceutical research and development. Its new categorical double patenting rule ignores the reality of biopharmaceutical innovation, where new and non-obvious uses for existing compounds are often discovered long after the compound is first discovered. The decision impairs economic incentives for researchers to investigate and develop new biopharmaceutical therapies, potentially depriving the public of important new treatments for complex diseases such as cancer. Moreover, this new bright-line rule erodes the patent laws' core policy of promoting scientific disclosure. This Court's review is necessary to define the scope of the double patenting doctrine and to restore critical patent-law incentives for future biopharmaceutical innovation.

The judicially-created obviousness-type double patenting doctrine has long performed a gap-filling role in cases where the statutory obviousness inquiry under § 103 of the Patent Act, 35 U.S.C. § 103, did not operate to prevent the same patent owner from obtaining a second patent on a trivial variation of a patented invention. In those circumstances, the obviousness-type double patenting rule serves the purpose of preventing

a party from obtaining an improper time-wise extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent. *See Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); *see also In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

But this judicially crafted, gap-filling doctrine has been bounded by common sense in three ways: First, a patent that is not obvious under the statutory obviousness requirements of § 103 is also not obvious under the more circumscribed inquiry of obviousness-type double patenting. *See In re Land*, 368 F.2d 866, 884 (C.C.P.A. 1966). Second, because the doctrine is concerned only with what was claimed in the two patents, the specification of the earlier patent may not be used as "prior art" against the later claimed invention. *See In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986). Third, the doctrine does not confuse "domination" of one patent over another with double patenting.[2] *Id.* at 1577-1578

The Federal Circuit's decision below upends this established framework by adopting a categorical rule barring the same party from obtaining a patent on *any* use of a compound previously disclosed in that party's patent claiming the compound. *See* Pet. App. 12a. This

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[2] A patent on a chemical *compound* may be said to "dominate" all uses of the compound, because no one may use the compound in any way without infringing the patent. Upon expiration of that patent, however, others may use the compound except for any specific uses on which patent protection continues; a later patent on a specific *use* of the compound would not extend the patent rights on the *compound* itself. The case at issue concerns a specific use of the compound gemcitabine. Upon expiration of the patent on the *compound*, others were free to use it for any purpose other than the specific anticancer *use* patented by petitioner.

new bright-line rule thus violates these long-standing common sense boundaries. Under the new rule, the statutory test for obviousness is irrelevant to obviousness-type double patenting; the patent specification can be used for all it teaches; and double patenting is confused with domination. This radical expansion of this judge-made doctrine is inconsistent with established law and warrants review and reversal by this Court.

REASONS FOR GRANTING THE WRIT

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

First, the Federal Circuit's unwarranted expansion of the double patenting rule threatens to undermine economic incentives to invest in research and development of potentially significant new biopharmaceutical therapies. The new bright-line rule upsets settled investment-backed expectations of the innovation community and presents a significant obstacle to the patenting of new therapeutic uses for existing compounds. It thus risks cutting off potentially critical developments for the treatment of serious diseases, such as Alzheimer's disease, Parkinson's disease, and many forms of cancer, to the detriment of patients in need of innovative medical therapies. The decision also significantly undermines the patent laws' purpose of promoting scientific disclosure.

Second, the decision below expands the common-law double patenting rule well beyond its original purposes, and brings the rule into direct conflict with the Patent Act. The Federal Circuit has adopted a categorical rule barring the same entity from obtaining a patent for *any* new use of a compound that was disclosed in the specification of a patent claiming the compound. Not only does that rule depart from precedent;

it is also inconsistent with the Patent Act's statutory obviousness inquiry, and conflicts with this Court's precedent addressing obviousness in the double patenting context.

I. THE FEDERAL CIRCUIT'S BROAD DOUBLE PATENTING RULE THREATENS BIOPHARMACEUTICAL INNOVATION

Biopharmaceutical research and development is subject to enormous economic uncertainty, and patent-law incentives are critical to promoting innovation in this area. The Federal Circuit's decision disrupts those incentives, and discourages research into developing new therapeutic uses for existing biopharmaceutical compounds. This Court's review and reversal of the Federal Circuit's decision is warranted to maintain patent-law incentives that encourage biopharmaceutical innovation.

A. Discovery Of Drug Therapies Requires The Critical Incentives Provided By Patent Protection

The Federal Circuit's erroneous expansion of double patenting doctrine impairs incentives for discovery of new drug therapies by denying critical patent protection for newly developed uses of previously patented compounds.

Biopharmaceutical research and development is an extremely costly and risky enterprise. The biopharmaceutical industry spends more than $65 billion dollars annually on research and development. *See* PhRMA, Pharmaceutical Industry Profile 2010, at 26. Recent studies estimate that it costs on average approximately $1.3 billion to bring a new therapeutic product to market. *See* DiMasi & Grabowski, *The Cost of Biopharma-*

ceutical R&D: Is Biotech Different?, 28 Manage. & Decis. Econ. 469, 477 (2007)

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, Pharmaceutical Industry Profile 2010, at 27; 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 very few compounds that make it that far must then undergo years of clinical trials costing hundreds of millions of dollars. Four of five compounds that even reach clinical trials will fail, and thus only the remaining one-fifth ultimately receive approval by the Food and Drug Administration (FDA). *See* Tufts Center for the Study of Drug Development, Impact Report 8, No. 3, *New Drugs Entering Clinical Testing in Top 10 Firms Jumped 52% in 2003-2005* (May/June 2006).

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 increased more than 60% between 2000 and 2005 alone. *See* PhRMA, Pharmaceutical Industry Profile 2010, at 29. 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).

Recent changes in the regulatory environment for biopharmaceuticals have also increased the cost and uncertainty of investment in drug research and development. Biopharmaceutical companies now face significant post-market surveillance and other post-approval requirements, which increase the time period for a drug to break even on the substantial investment necessary. In addition, the complexity of clinical trials and number of procedures required has increased substantially over time with the number of procedures per trial protocol increasing 65% between 1999 and 2005 and the average clinical trial length increasing 70% over the same period. Tufts Center for the Study of Drug Development, Impact Report 10, No. 1, *Growing Protocol Design Complexity Stresses Investigators, Volunteers* (2008). Changes in the regulatory and economic environment have also led to substantial competition from generic drugs, significantly reducing returns to biopharmaceutical innovators. *See* Grabowski & Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 Manage. & Decis. Econ. 491, 500-501 (2007) (finding that "a larger number of drugs [are] experiencing initial generic entry and generic competition now encompasses even very modest selling drugs").

Given the enormous cost and uncertainty of biopharmaceutical research, patent protection is vital. The risk of investment must be rewarded if new drug therapies are to be developed. Patent protection is significantly more important to finding new medicines and drug therapies than to innovation in most other industries. *See generally* Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 850-858 (2002); Barfield & Calfee, *Biotechnology and the Patent System* 24-36 (2007).

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* Lichtenberg, 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 nearly 3000 medicines in development, *see* PhRMA, Pharmaceutical Industry Profile 2010, at i, including more than 800 medicines that may treat various forms of cancer, more than 500 medicines that may address neurological disorders such as Parkinson's disease and Alzheimer's disease, and approximately 300 medicines that may treat heart disease and stroke. *See* PhRMA, Fact Sheets and Policy Papers, at http://www.phrma.org/research/publications/fact-sheets-and-policy-papers (last visited Feb. 28, 2011). These and other medicines

under development could lead to vital new drug therapies for patients.

B. The Expanded Double Patenting Rule Impairs Incentives To Develop New Drug Therapies

The Federal Circuit's new rule threatens to undermine economic incentives for research and development of new medical therapies, particularly for complex diseases. In particular, the rule fails to account for the unpredictable reality of biopharmaceutical research, which often involves the investigation and development of new therapeutic uses for a compound long after the compound and its possible uses are first identified.

The success or failure of a compound for a particular therapeutic purpose *cannot* be predicted from the outset. A biopharmaceutical compound is typically first patented as a compound in connection with its use for treating one or more particular conditions. But there are strong odds against any compound's success in treating any condition, and therefore few patented compounds ultimately succeed with respect to their first potential indications.

Indeed, that is what happened with the drug in question in this case, demonstrating the often surprising and unpredictable character of biopharmaceutical discovery. Gemcitabine was first thought useful as an anti-viral therapy, and Lilly sought a patent on that basis. But the compound did not succeed in its originally intended use. Subsequent investigation of the compound revealed, however, that gemcitabine had anti-cancer properties, much to the surprise of the researchers. *See* Pet. 10.

Even after a drug is approved, research and development on that drug typically continues, and new uses for the drug are often discovered after its initial approval. For example, biotherapeutics such as Enbrel®, Remicade®, and Humira®, approved for the treatment of rheumatoid and psoriatic arthritis, were subsequently approved to treat a variety of conditions, including Crohn's disease, ulcerative colitis, and ankylosing spondylitis. The Congressional Budget Office has observed that "approved new on-label uses can become the primary source of demand for a drug, suggesting that the new use is more valuable to patients than the original use." Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* 15 (2006); *see also* Said et al., Boston Consulting Group White Paper, *Continued Development of Approved Biological Drugs: A Quantitative Study of Additional Indications Approved Postlaunch in the United States* 3 (2007) (47% of approved biologics had at least one new approved indication after initial approval). New uses are often developed long after approval of a drug's initial indication, making patent protection for the new use especially important. *See* Said et al., *supra*, at 3 (finding that "[one] third of new indications were approved more than seven years after the approval of the initial indication")

This dynamic character of drug research and development is particularly apparent in efforts to treat complex diseases such as cancer. Indeed, the process of developing effective cancer therapies generally continues even long after initial approval of a medicine by the FDA for human use. One study has observed that "the true clinical value of a therapy often cannot be fully captured in the clinical trial data submitted for initial FDA approval." Chan et al., Boston Healthcare White

Paper, *Recognizing Value in Oncology Innovation* 1 (Mar. 2010). Once further post-approval investigation is undertaken, it is often true that a cancer therapy's full clinical value is "much greater than recognized at the time of initial FDA approval." *Id.* For example, according to the National Institutes of Health website, the company that developed the drug Avastin® has undertaken 286 clinical trials involving the drug (more than 100 of which are ongoing today, years after the drug's initial approval to treat colorectal cancer in 2004), including clinical trials for ovarian, pancreatic, and esophageal cancers. *See* http://www.clinicaltrials.gov/ct2/results?term=avastin&spons=Genentech (last visited Feb. 28, 2011).

The development of new valuable medical therapies encompasses both newly approved as well as older drugs. For example, researchers have developed a use for galantamine, originally intended to treat polio and paralysis, in the treatment for Alzheimer's disease. *See* Ashburn & Thor, *Drug Repositioning: Identifying and Developing New Uses for Existing Drugs*, 3 Nature Reviews 673, 678 (Aug. 2004). Ropinrole, which was originally developed for hypertension, is now marketed as a therapy to treat symptoms of Parkinson's disease. *See id.* Developments such as these are by no means uncommon. As one commentator has observed, "[i]n this new era, the most important advances in treatment often come from products which have been on the market for a while but whose properties were not completely understood until intensive research *after* the drug was introduced." Calfee, *The Golden Age of Medical Innovation*, The American (Mar./Apr. 2007).

While potentially less costly than developing an entirely new compound, developing a new therapeutic use requires substantial investment in research and devel-

opment costs and time, and carries a significant risk of failure. Any new therapeutic use must go through phase II and phase III clinical trials directed at that use and the FDA approval process. It can take from 3 to 6 years to develop and obtain approval for such a new use. *See* Said et al., *supra*, at 5. The cost of research to establish a new therapeutic use for an existing compound typically runs to well over $100 million and can be much greater depending on the nature of the clinical trials involved. *See* Grabowski & Moe, *Impact of Economic, Regulatory, and Patent Policies on Innovation in Cancer Chemoprevention*, Cancer Prevention Research 2 (2008); *see also* Said et al., *supra*, at 6 (noting that post-approval development costs "are likely high and represent an important part of the overall R&D investment involved in researching and developing new therapeutic biologics").

A sound patent protection regime needs to take account of the cost and risk realities of this discovery process—especially in the area of biopharmaceutical discovery, where the right of exclusivity awarded by patent protection is critical to progress and innovation. To foster the process of drug discovery and the development of new therapeutic uses, patent protection must not be narrowly limited by an earlier patent's disclosures of the inchoate or general purposes for which a compound was first thought useful. Rather, the patent laws should incentivize innovators to continue to develop new non-obvious uses for compounds.

The Federal Circuit's new categorical double patenting rule impairs incentives for promising research into new uses for existing compounds. The rule effectively disqualifies for patent protection *any* use that is deemed to have been disclosed in some way in an earlier compound patent. Under this *per se* rule, research-

ers can no longer be confident that new non-obvious uses of existing compounds will receive the patent protection they warrant. At a minimum, the decision invites still more costly litigation over double patenting issues, as parties comb compound patents to identify disclosures that might arguably invalidate patents on later-developed therapies.

The Federal Circuit's decision threatens particular disruption to the investment-backed expectations of researchers in the biopharmaceutical field. The significant economic risk involved in developing safe and effective drug therapies requires stable and predictable patent law protections. *See Eli Lilly & Co.* v. *Barr Labs., Inc.*, 251 F.3d 955, 976 (Fed. Cir. 2001) (Newman, J., dissenting) ("In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law"). Gemcitabine and other compounds were developed under a patent-law regime with a double-patenting rule focused narrowly on preventing a patentee from obtaining two patents claiming the *same invention* (or obvious variations thereof). 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.

Changing the rules in the middle of the game, as the Federal Circuit did here, could throw into question a broad array of biopharmaceutical patents and undermines longstanding patent-law incentives to investigate and develop new uses for existing compounds in the treatment of disease. As a result, patients may be deprived of important advances in the treatment of diseases such as cancer and Alzheimer's disease.

In addition, the Federal Circuit's new double patenting rule discourages innovation by precisely the party—the holder of the original compound patent—normally in the best position to develop new therapeutic uses for their drug. The original patent holder is uniquely positioned to leverage its own scientists' experience with and knowledge of the compound. Because the holder of the original compound patent can prevent any new use of the compound from being marketed, its cooperation is critical even when another party seeks to develop the new use. By specifically restricting the original patentee's ability to patent new uses, the decision below impairs patent-law incentives at the point where they are important for the development of new medicinal therapies.

C. The Federal Circuit's Decision Discourages Scientific Disclosure—A Primary Purpose Of The Patent Laws

The Federal Circuit's decision also undermines the patent laws' core policy of promoting scientific disclosure. *See Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) ("the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure"); *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U. S. 470, 489 (1974) (with respect to a patentable invention, "the federal interest in disclosure is at its peak; these inventions, novel, useful and nonobvious, are 'the things which are worth to the public the embarrassment of an exclusive patent'" (quoting *Graham* v. *John Deere Co.*, 383 U.S. 1, 9 (1966) (quoting Thomas Jefferson))).

Disclosure is meant to spur innovation by adding information to public knowledge. This is particularly important in research intensive industries, like the bio-

pharmaceutical industry. However, the new double patenting rule discourages patent applicants from providing full disclosure of the potential uses of a compound or any other invention. The rule instead incentivizes patent applicants to include the minimum disclosure necessary to demonstrate patentability out of concern for the likely impact of such disclosure on the patentability of future discoveries. That incentive, antithetical to the purpose of the patent law, is evident in this case: the decision below effectively punished the petitioner for disclosing in its patent application for gemcitabine the possible anticancer use. Such disclosures, which might have been built upon by others in the future, are likely to disappear from future patent disclosures. That result is both inconsistent with a central purpose of the patent laws, and highlights the essential error of the court of appeals' new *per se* double patenting rule.

This Court should grant review to reverse the Federal Circuit's decision and restore appropriate patent-law incentives in this area.

II. THE EXPANDED DOUBLE PATENTING RULE IS INCONSISTENT WITH THE PATENT ACT

Beyond deterring the development of potentially beneficial drug therapies, the new "double patenting" rule announced by the Federal Circuit is inconsistent with governing precedent and sound public policy. The court's categorical bar on the patentability of new uses of existing compounds based solely on a previous patent disclosure of the use runs counter to the statutory—and appropriately contextual—"obviousness" inquiry prescribed by the Patent Act. The Federal Circuit's decision also departs significantly from controlling precedent.

A. The New Rule Is Inconsistent With The Patent Act's Obviousness Inquiry

The Federal Circuit's decision expands obviousness-type double patenting well beyond its traditional narrow bounds, bringing the doctrine into conflict with the broader statutory obviousness inquiry under the Patent Act. The Court should grant review to re-establish the bounds of double patenting doctrine.

Section 103 of the Patent Act defines the statutory standard for obviousness. Under § 103, an invention is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103. Courts apply a multi-faceted analysis to determine whether an invention is non-obvious over the prior art. The analysis takes into account (1) "the scope and content of the prior art;" (2) "differences between the prior art and the claims at issue;" (3) "the level of ordinary skill in the pertinent art;" and (4) "secondary considerations" such as "commercial success, long felt but unsolved needs, failure of others [that] give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham*, 383 U.S. at 17-18).

Obviousness-type double patenting, by contrast, is a limited, judicially created doctrine that reflects the principle in § 101 of the Patent Act that each invention is entitled only to a single patent. The doctrine has thus been recognized to present "the same basic question as [obviousness under] § 103 ... but in *narrower*

aspect." *In re Jezl*, 396 F.2d 1009, 1013 (C.C.P.A. 1968) (emphasis added); *see also In re Ornitz*, 376 F.2d 330, 334 (C.C.P.A. 1967) ("Where it is possible to conduct the broader inquiry permitted by sections 102(e) and 103 because the references are 'prior art,' it does not make sense to resort to the narrower inquiry which underlies a 'double patenting' rejection").

Until now, the law has been clear that a patent that is not obvious over the prior art based on a § 103 statutory obviousness analysis is *a fortiori* not subject to rejection for obviousness-type double patenting. *See Procter & Gamble Co.* v. *Teva Pharms. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009); *In re White*, 405 F.2d 904, 906 (C.C.P.A. 1969); *In re Jezl*, 396 F.2d at 1013; *In re Land*, 368 F.2d 866, 879 (C.C.P.A. 1966). Indeed, the doctrine of obviousness-type double patenting was developed in part to address the situation where patents are not citable as reference against each other. *See In re Ornitz*, 376 F.2d at 334.

The Federal Circuit has now thrown this framework into doubt. The decision below abandoned the narrow double patenting inquiry in favor of a categorical rule rejecting the availability of a patent for "*any* use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound." Pet. App. 11a-12a (emphasis added). No obviousness analysis is conducted under this bright-line rule, and none was conducted by the Federal Circuit in the case below. The result is a greatly expanded double patenting doctrine that now threatens to invalidate a broad range of patents that would not be subject to rejection under a statutory obviousness inquiry.

The facts of this case illustrate the potential conflict between statutory obviousness and the newly expanded double patenting rule. Here, the claims of the earlier patent are prior art to the claims of the later patent. In a separate proceeding, the later patent was found to be *non-obvious* in view of the same earlier patent under § 103 by a federal district court after a trial. *See* Pet. 14-15. Under longstanding precedent, that determination would generally preclude, *a fortiori*, rejection based on a double patenting analysis. But that was not the case here under the Federal Circuit's new categorical rule.

Thus, the new rule sets up the perverse result that a third party could obtain a patent to a non-obvious use (including the claimed anticancer therapy here), while the original holder of the compound patent could not. The Federal Circuit's decision thus supplants the statutory obviousness inquiry as to the holder of the original patent. That makes little sense: either a novel and non-obvious development is patentable to all, or to none, and the result should not vary depending on patent ownership. Subjecting the holder of the original compound patent to a different and more stringent patentability standard disincentivizes the very party usually in the best position to investigate new uses for the compound, to the detriment of patients in need of such therapies and the public health. *See supra* pp. 13-14.

This conflict with § 103 is particularly problematic because double patenting is a *judicially* crafted rule. Such rules may not impinge on congressionally enacted statutes. *See Northwest Airlines, Inc.* v. *Transport Workers Union of Am.*, 451 U.S. 77, 95 (1981) ("federal common law is subject to the paramount authority of Congress" (internal quotation marks omitted)). The Court should grant review to define careful limits on

double patenting doctrine to ensure the doctrine does not impinge on the statutory obviousness inquiry prescribed by the Patent Act.

B. The Decision Conflicts With This Court's Precedent And Settled Patent-law Principles

Review is also warranted because the decision below squarely conflicts with this Court's own double patenting precedent. In *Miller* v. *Eagle Mfg. Co.*, 151 U.S. 186, 199 (1894), the Court explained in the double patenting context that "an inventor may make a new improvement on his own invention of a patentable character" and that in such cases "a later patent may be granted where the invention is clearly distinct from, and independent of, one previously patented." *Miller* also makes clear that double patenting concerns what is *claimed* by the patents at issue and that a prior patent's *disclosures* do not themselves pose a bar to a later patent on a distinct invention. As the *Miller* Court stated, "where the second patent covers matter *described* in the prior patent, essentially distinct and separable from the invention covered thereby and *claims* made thereunder, its validity may be sustained." *Id.* at 198 (emphasis added).

The Federal Circuit's new rule is at odds with the claims-based inquiry prescribed by *Miller*. In adopting a categorical rule based on whether a use is disclosed in the specification of a prior patent—without any consideration of the prior patent's claims—the Federal Circuit disregarded the teaching of *Miller* that only the *claims* are relevant to a double patenting analysis.

The panel's decision is, in fact, the culmination of a series of recent Federal Circuit decisions that have disrupted established double patenting rules, and under-

mined the stability of patent law. It has consistently been the law that double patenting analysis concerns only a patent's *claims*, not its disclosures. *See General Foods Corp.* v. *Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992) ("Double patenting is altogether a matter of what is claimed."); *In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986) (in obviousness-type double patenting analysis "the patent disclosure may not be used as prior art."); *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970) (same).

In two recent cases, however, the Federal Circuit expanded the scope of the double patenting inquiry to encompass the specification, and not simply the claims, of the prior patent. *See Pfizer, Inc.* v. *Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008); *Geneva Pharms., Inc.* v. *GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003). In each case, the court of appeals rejected patents on a particular use of a compound based on the disclosure of the use in the specification of the compound patent. The Federal Circuit justified its approach on the ground that the relevant patent claim did not "adequately disclose the patentable bounds of the invention" and that examination of the specification was therefore necessary to interpret the patent claims. *Geneva*, 349 F.3d at 1385. In focusing the double patenting inquiry on the specification, however, the Federal Circuit departed from the limited claims-based analysis applied in prior cases.

But the categorical double-patenting rule announced by the panel in this case represents yet a further significant departure from the claims-based analysis of *Miller* and prior decisions. The Federal Circuit's new approach rejects the patentability of any use based *solely* on previous disclosure of the use in the prior patent's specification. That rule finds no support in *Ge-*

neva or *Pfizer*. Unlike those cases, examination of a prior patent's disclosures under the new categorical rule does not have any necessary connection to interpreting the scope of the patent's claims.

The novelty (and error) of this new categorical approach was rightly recognized by the dissenters from rehearing en banc in the Federal Circuit. In her dissent, Judge Newman, joined by Chief Judge Rader (the author of the opinion in *Geneva*) made clear that *Geneva* did not intend to upset the established rule that "the law of double patenting is concerned only with what is patented—that is what is claimed." Pet. App. 135a. She further criticized the panel decision for misreading *Geneva* to apply to the circumstances of this case, and applying the double patenting rule where there could be no improper time-wise extension of the gemcitabine compound patent right by the patent on gemcitabine's anticancer use, since upon expiration of the compound patent, all would be free to make, use or sell gemcitabine for any purpose other than the anticancer use. *See id.* at 139a-140a. This "change of law," Judge Newman noted, would "negatively impact the patentability of later-discovered uses" and "serves no public purpose in areas in which commercial development requires patent protection." *Id.* at 141a.

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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