

No. _____

In the Supreme Court of the United States

UNITED THERAPEUTICS CORP.,
Petitioner,

v.

STEADYMED LTD.,
Respondent.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

On June 12, 2017, the Court granted review in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, No. 16-712, 2017 U.S. LEXIS 3727, at *1 to consider the following question presented:

Whether *inter partes* review—an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury?

Id. This case also involves an *inter partes* review proceeding in which the PTO invalidated Petitioner's patent and, therefore, this petition presents the same question as *Oil States*.

**PARTIES TO THE PROCEEDINGS AND RULE
29.6 CORPORATE DISCLOSURE STATEMENT**

The parties to the proceedings include all those listed on the cover. Petitioner United Therapeutics Corp. (“United Therapeutics”) is a Delaware corporation. United Therapeutics has no parent corporation, and BlackRock, Inc., collectively through different BlackRock entities, may own 10% or more of its stock.

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PETITION FOR WRIT OF CERTIORARI

Petitioner United Therapeutics respectfully submits this petition for writ of certiorari to review the judgment of the U.S. Court of Appeals for the Federal Circuit.

OPINION AND ORDERS BELOW

The Federal Circuit panel order disposing of the case is available at 702 F. App'x 990 (Fed. Cir. Nov. 14, 2017) (Mem). *See* App.1-2. The opinion and order of the PTAB is unreported. *See* App. 3-94.

STATEMENT OF JURISDICTION

The Federal Circuit entered its judgment on November 14, 2017 making the petition for writ of certiorari due on or before February 12, 2018. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

In Article I, Section 8 of the United States Constitution grants to Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[.]”

The Seventh Amendment of the United States Constitution provides:

In Suits at common law, where the value
in controversy shall exceed twenty

dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

The provisions of 35 U.S.C. §§ 311-319, which govern *inter partes* review, are set forth in the Appendix. App. 152-163.

INTRODUCTION

On June 12, 2017, this Court granted certiorari in *Oil States* to consider the issue of “[w]hether *inter partes* review, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.” *Oil States*, 2017 U.S. LEXIS 3727, at *1. This petition presents the same question. This is an appeal from an *inter partes* review proceeding in which the PTO held United Therapeutics’s U.S. Patent No. 8,497,393 (“the ’393 patent”) invalid. On appeal, the Federal Circuit entered its judgment against United Therapeutics.

Because the question presented here is identical to *Oil States*, this Court should hold this petition pending the outcome of *Oil States*. If the Court in *Oil States* determines that *inter partes* review proceedings are unconstitutional, it should grant this petition, vacate the decision below, and remand for further consideration.

STATEMENT OF THE CASE

This petition arises after a Federal Circuit appeal from the final written decision of the United States Patent and Trademark Office Patent Trial and Appeal Board (“the PTAB”) on a petition for *inter partes* review (“IPR”) of claims 1-22 of the ’393 patent. The petition for IPR was filed by SteadyMed, Ltd. (“SteadyMed”). The ’393 patent is entitled “Process to Prepare Treprostinil, The Active Ingredient in Remodulin®” and claims both an improved process for making treprostinil as well as an improved treprostinil product. Appx92-Appx106.¹ United Therapeutics has spent significant resources researching and developing safer and more effective treprostinil-based therapies for pulmonary arterial hypertension—a fatal disease characterized by increased pressure in the pulmonary vasculature and that often results in heart failure. These research and development efforts have resulted in several therapies now approved by FDA.

On October 1, 2015, SteadyMed filed a petition with the PTAB for IPR of claims 1-22 of the ’393 patent (IPR2016-00006). App. 164-229. On December 2, 2015, more than a month before United Therapeutics filed its preliminary patent owner response under 35 U.S.C. § 313, the Federal Circuit issued its decision in *MCM Portfolio LLC v. Hewlett Packard Co.*, 812 F.3d 1284 (Fed. Cir. 2015), which held that IPRs do not violate Article III or the

¹ “Appx” citations refer to the documents filed in the Federal Circuit Appendix.

Seventh Amendment. *Id.* at 1292-93. Thus, any challenge in the agency to the constitutionality of IPRs would have been futile in the face of controlling precedent. *Weinberger v. Salfi*, 422 U.S. 749, 767 (1975) (agency hearing futile because no authority to decide constitutionality); *Johnson v. Robison*, 415 U.S. 361, 368 (1974) (noting presumption that agencies cannot decide constitutional questions); *Bradley v. Sch. Bd. of City of Richmond*, 416 U.S. 696, 712 (1974) (“[I]f subsequent to the judgment and before the decision of the appellate court, a law intervenes and positively changes the rule which governs, the law must be obeyed, or its obligation denied.”). A party is not required to make a futile argument to preserve an issue except for a “known right or privilege.” *Curtis Publishing Co. v. Butts*, 388 U.S. 130, 142-43 (1967) (no waiver even where earlier cases hinted at potential change in law).

The PTAB then instituted trial on April 8, 2016. App. 95-151. The PTAB issued its final written decision invalidating claims 1-22 of the '393 patent on March 31, 2017. After the PTAB's final written decision, this Court granted certiorari in *Oil States*. United Therapeutics subsequently argued in its appeal to the Federal Circuit that the constitutionality issue pending before this Court in *Oil States* should control the outcome of this case. *See*, Fed. Cir. D.I. 27 at 54; Fed. Cir. D.I. 37 at 24-27. UTC therefore preserved this issue for this petition given that this Court had not granted certiorari on the same issue in *Oil States* until after the final written decision of the PTAB. The Court of Appeals for the Federal Circuit affirmed the PTAB's final

written decision on November 14, 2017 under Federal Circuit Rule 36 without opinion.

Before the IPR decision issued, United Therapeutics had commenced suit against two defendants for patent infringement of the '393 patent. Specifically, United Therapeutics brought suit against Watson Labs., Inc. on July 22, 2015 (before the IPR petition was filed) in the United States District Court for the District of New Jersey for infringement of the '393 patent as well as other United Therapeutics's patents. (The "Watson Litigation," Civil Action No. 3:15-cv-05723). On March 31, 2016, United Therapeutics also brought suit against Actavis Labs in the United States District Court for the District of New Jersey for patent infringement of the '393 patent as well as other United Therapeutics's patents. (The "Actavis Litigation," Civil Action No. 3:16-cv-01816). The Watson Litigation is currently stayed pending resolution of IPR decisions on two other patents in suit. The Actavis Litigation is currently set for trial starting July 9, 2018.

**REASONS FOR HOLDING OR GRANTING THE
PETITION**

I. The Court Should Hold the Petition Pending Resolution of *Oil States* and Grant, Vacate, and Remand this case Should it Conclude that *Inter Partes* Review Proceedings at the Patent Office are Unconstitutional

This case involves the exact same issue as in *Oil States*, 2017 U.S. LEXIS 3727, in which the Court granted certiorari. In the pending *Oil States* case, the Court will decide whether adversarial IPR proceedings violate the Constitution by extinguishing private property rights through a non-Article III forum without a jury.

This case arises from the PTO's review of the validity of United Therapeutics's '393 patent in an IPR proceeding, in which the PTO invalidated the patent without a jury proceeding and in a non-Article III court. Given that this Court will address the same substantive question in *Oil States* as in this case, this Court should hold this petition, consistent with its ordinary practice, pending the resolution of *Oil States*.

Each of the reasons for granting the petition detailed by *Oil States* applies here and are adopted by United Therapeutics. In short, those reasons include this Court's long-standing recognition in its precedent that patents constitute private property and, therefore, the deprivation of private property through a non-Article III court administrative proceeding without a jury violates both Article III

and the Seventh Amendment of the Constitution. For these reasons, as *Oil States* argued, the Federal Circuit's decision in *MCM Portfolio*, 812 F.3d 1284 was wrongly decided when it concluded that the PTAB's invalidation of previously issued patents was constitutional because patents are public rights, not private property. *Oil States* also correctly detailed other reasons the Court should accept review, including the economic impact of this new, unconstitutional administrative system of invalidating patents and the confusion created by the process in the patent arena. The Court found these arguments sufficiently compelling to grant review in *Oil States*.

If this Court determines that IPR proceedings at the PTO are unconstitutional, this Court should grant certiorari on this petition, vacate the decision below, and remand for further consideration.

CONCLUSION

United Therapeutics respectfully requests that this Court hold its petition pending this Court's resolution of *Oil States*. Should the Court find that the PTO's administrative proceedings for adjudicating the validity of issued patents are unconstitutional, United Therapeutics respectfully requests that this Court grant this petition, vacate the decision below, and remand for further action consistent with that decision.

DATED: February 9, 2018

Respectfully submitted,

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