

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

STEADYMED LTD.,  
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,  
Patent Owner.

---

Case IPR2016-00006  
Patent 8,497,393 B2

---

Before LORA M. GREEN, JONI Y. CHANG, and  
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

HARLOW, *Administrative Patent Judge*.

DECISION  
Redacted Institution of *Inter Partes* Review  
37 C.F.R. § 42.108

## I. INTRODUCTION

Petitioner, SteadyMed LTD (“SteadyMed”), filed a Petition requesting an *inter partes* review of claims 1–22 of U.S. Patent No. 8,497,393 B2 (Ex. 1001, “the ’393 patent”). Paper 1 (“Pet.”). Patent Owner, United Therapeutics Corporation (“UTC”), filed a Preliminary Response on January 14, 2016. Paper 10<sup>1</sup> (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

For the reasons set forth below, we institute an *inter partes* review of claims 1–22 of the ’393 patent.

### A. Related Matters

The ’393 patent is asserted in: *United Therapeutics Corp. v. Sandoz, Inc.*, No. 14-cv-05499 (D.N.J.); *United Therapeutics Corp. v. Teva Pharmaceuticals U.S.A., Inc.*, No. 14-cv-05498 (D.N.J.); and *United Therapeutics Corp. v. Watson Laboratories, Inc.*, No. 15-cv-05723 (D.N.J). Pet. 1. SteadyMed is not party to the above identified litigations. *Id.*

---

<sup>1</sup> Paper 10 is the Unredacted Preliminary Response. Paper 8, filed concurrently with Paper 10, is a redacted version of the Preliminary Response.

*B. The '393 Patent*

The '393 patent, titled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®,” issued July 30, 2013, from U.S. Patent Application No. 13/548,446 (“the '446 application”) (Ex. 1002), filed July 13, 2012. Ex. 1001, [54], [45], [21], [22]. The '446 application is a continuation of U.S. Patent Application No. 12/334,731 (“the '731 application”) (Ex. 1002), filed on December 15, 2008, now issued as U.S. Patent No. 8,242,305 (“the '305 patent”). Ex. 1001, [63]. The '393 patent claims priority to U.S. Provisional Patent Application No. 61/014,232 (Ex. 2008), filed December 17, 2007. Ex. 1001, [60].

The '393 patent recites 22 product-by-process claims for prostacyclin derivatives, including treprostinil.<sup>2</sup> *Id.* at 17:51–21:16; Pet. 5; Prelim. Resp. 3. The process disclosed by the '393 patent takes advantage of carbon treatment and salt formation steps to remove impurities, eliminating the need for purification by column chromatography. *Id.* at 17:29–32; *see also id.* at 5:41–45 (“purification by column chromatography is eliminated . . . . [T]he salt formation is a much easier operation than column chromatography.”).

---

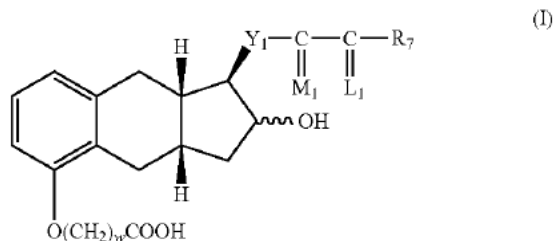
<sup>2</sup> The '305 patent, which issued from the parent to the application for the '393 patent, recites claims to a process for the preparation of prostacyclin derivatives comprising steps similar to those set forth in the product-by-process claims of the '393 patent. *Compare* Ex. 1001, 17:51–21:16, *with* Ex. 2007, 17:39–24:3.

The process for forming prostacyclin derivatives described in the '393 patent includes four steps: (a) alkylating a prostacyclin derivative to form an alkylated prostacyclin derivative; (b) hydrolyzing the alkylated prostacyclin derivative with a base to form a prostacyclin acid; (c) contacting the prostacyclin acid with a base to form a prostacyclin carboxylate salt; and (d) optionally reacting the prostacyclin carboxylate salt formed in (c) with an acid to form the desired compound, or pharmaceutically acceptable salt thereof. *Id.* at 1:65–3:19.

### C. Illustrative Claim

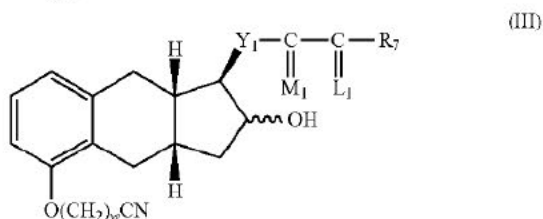
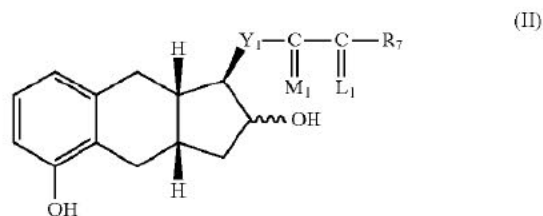
Each of the challenged claims is a product-by-process claim. Of the challenged claims, claims 1 and 9 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A product comprising a compound of formula I



or a pharmaceutically acceptable salt thereof, wherein said product is prepared by a process comprising

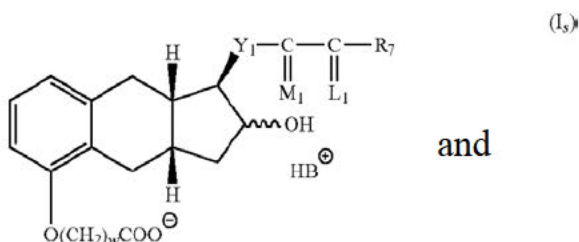
a) alkylating a compound of structure II with an alkylating agent to produce a compound of formula III,



wherein [recitation of Markush groups for the specified structures],

b) hydrolyzing the product of formula III of step (a) with a base,

c) contacting the product of step (h)<sup>3</sup> with a base B to form a salt of formula I<sub>s</sub>.



d) optionally reacting the salt formed in step (c) with an acid to form the compound of formula I.

---

<sup>3</sup> We note that the reference to “step (h),” rather than “step (b),” in claim 1 is an apparent typographical error. See Ex. 1001, 3:66–67 (“(c) contacting the product of step (b) with a base B to form a salt of formula IV<sub>s</sub>”); see also Pet. 25; Ex. 1009 ¶ 51.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.