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Paper No. 82
Entered: March 31, 2017

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.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Petitioner, SteadyMed LTD ("SteadyMed"), filed a Petition on October 2, 2015, 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 ("Prelim. Resp.").[1] We determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that SteadyMed would prevail with respect to at least one challenged claim. Pursuant to 35 U.S.C. § 314, we instituted trial on April 8, 2016, as to claims 1–22 of the '393 patent. Paper 12 ("Dec.").[2]

After institution, UTC filed a Patent Owner Response. Paper 31 ("PO Resp.").[3] SteadyMed filed a Reply to the Patent Owner Response. Paper 51 ("Pet. Reply").[4]

In addition, SteadyMed filed a Motion to Exclude Evidence (Paper 63, "Pet. Mot. Exclude").[5] UTC filed an Opposition (Paper 66, "PO Opp. Exclude"), and SteadyMed filed a Reply (Paper 72, "Pet. Reply Exclude"). UTC likewise filed a Motion to Exclude Evidence (Paper 65, "PO Mot.

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[1] Paper 8 is a redacted version of the Patent Owner Preliminary Response.
[2] Paper 78 is a redacted version of the Decision on Institution.
[3] Paper 76 is a redacted version of the Patent Owner Response to Petition.
[4] Paper 52 is a redacted version of the Reply to Patent Owner's Response.
[5] Paper 62 is a redacted version of Petitioner's Motion to Exclude Evidence.

Exclude"). SteadyMed filed an Opposition (Paper 68, "Pet. Opp. Exclude"),[6] and UTC filed a Reply (Paper 71, "PO Reply Exclude").

Oral hearing was held November 29, 2016.

This final written decision is entered pursuant to 35 U.S.C. § 318(a). We have jurisdiction under 35 U.S.C. § 6.

We hold that SteadyMed has demonstrated by a preponderance of the evidence that claims 1–22 are unpatentable under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). SteadyMed's Motion to Exclude is *dismissed*. UTC's Motion to Exclude is *denied*.

A. Related Matters

The '393 patent is asserted in several cases in the District of New Jersey. Pet. 1; Paper 4; Paper 15; Paper 21.

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

[6] Paper 67 is a redacted version of Petitioner's Opposition to Patent Owner's Motion to Exclude Evidence.

'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.[7] *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 ("[P]urification by column chromatography is eliminated . . . . [T]he salt formation is a much easier operation than column chromatography.").

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.

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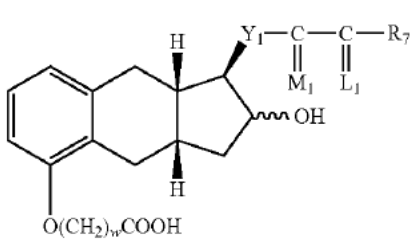
[7] The '305 patent, which issued from the parent to the application for the '393 patent, recites claims to a process for the preparation of prostacyclin derivatives comprising steps similar to those set forth in the product-by-process claims of the '393 patent. *Compare* Ex. 1001, 17:51–21:16, *with*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

C. Illustrative Claim

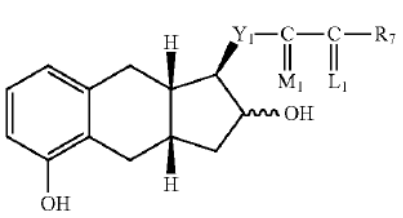
Each of the challenged claims is a product-by-process claim. Of the challenged claims, claims 1 and 9 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter.

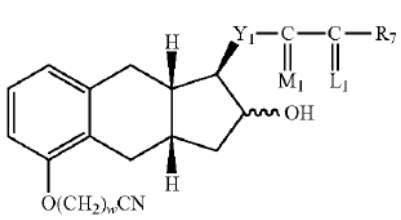
1. A product comprising a compound of formula I



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,

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