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Paper No. 27
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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.*

ORDER
Joint Motion to Seal
37 C.F.R. §§ 42.14 and 42.54

Patent Owner's Unredacted Preliminary Response (Paper 10), as well as Exhibits 2003, 2004, 2005, and 2006, were filed under seal. Patent Owner concurrently submitted a Motion to File under Seal (Paper 7). Because we declined to rule on Patent Owner's Motion to File under Seal when we issued our Decision to Institute (Paper 12), that Decision was sealed, pending submission by the parties of agreed redactions to the Decision. Patent Owner's Unredacted Preliminary Response (Paper 10), and Exhibits 2003, 2004, 2005, and 2006 likewise remain provisionally sealed.

Pursuant to our Order on the Conduct of the Proceeding (Paper 16), the parties filed a Joint Written Statement (Paper 17), identifying the portions of the Decision to Institute that should remain under seal. The parties concurrently filed a Joint Motion to Seal those portions of the Decision to Institute (Paper 18). For the reasons set forth below, we grant-in-part the parties' Motion and enter a Redacted Decision to Institute (Paper 28) including some, but not all, of the redactions proposed by the parties.

There is a strong public policy in favor of making information filed in a post-grant review open to the public. Generally, the record of a post-grant review proceeding shall be made available to the public. 35 U.S.C. § 326(a)(1); 37 C.F.R. § 42.14. Our rules, however, "aim to strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,760 (Aug. 14, 2012).

Thus, the parties may move to seal certain information (37 C.F.R. § 42.14), but only "confidential information" is protected from disclosure (35 U.S.C. § 326(a)(7)). Confidential information means trade secret or other confidential research, development, or commercial information. 37 C.F.R. § 42.2. The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a). Sufficient facts must, therefore, be presented to demonstrate that the materials proposed for sealing are in fact confidential. *See Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, Case IPR2014-00736, Paper 37, slip op. at 2–3 (PTAB Apr. 6, 2015).

As an initial matter, we observe that certain of the proposed redactions to the Decision to Institute (Paper 12) would redact information made public in UTC's prior filings. For example, the following appears in UTC's Redacted Preliminary Response (Paper 8):

> The percent yield and purity levels of the final treprostinil product are compared to the former process in a chart on Ex. 2005, at p. 3, further demonstrating the differences that result in the final treprostinil product when all of steps (a)-(d) of claims 1 and 10[1] of the '393 patent are performed.
>
> * * *
>
> Finally, Ex. 2006, at pp. 3–4 states that, when the new process was implemented, "*it was observed that the purity of the treprostinil improved close to 100%*" . . . .

[1] Issued claim 9 of the '393 patent is identified as claim 10 in documents in the prosecution history for the '393 patent, and the Preliminary Response itself occasionally refers to claim 10, rather than claim 9, when discussing pre-issuance documents.

Redacted Prelim. Resp. 37–38 (emphasis added). Nevertheless, the parties propose that the statement "'the purity of the treprostinil improved close to 100%' for treprostinil prepared as described in claims 1 and 9 of the '393 patent as opposed to the prior process implemented by UTC" (Decision to Institute 17) be redacted from the publicly available version of Decision to Institute. Paper 18, 2; Paper 17, 22.

Similarly, the Redacted Preliminary Response (Paper 8) states that:

> *Ex. 2005 is a Process Optimization Report that provides results for batches resulting from step (d) of claims 1 and 10 in the '393 patent, which was performed on specific batches of the diethanolamine salt intermediate produced by steps (a)-(c)* . . . . The percent yield and purity levels of the final treprostinil product are compared to the former process in a chart on Ex. 2005, at p. 3, further demonstrating the differences that result in the final treprostinil product when all of steps (a)-(d) of claims 1 and 10 of the '393 patent are performed.

Redacted Prelim. Resp. 36–37 (emphasis added). However, the parties request redaction of the statement "Ex. 2005 is a Process Optimization Report that provides results for batches resulting from step (d) of claims 1 and 10 in the '393 patent, which was performed on specific batches of the diethanolamine salt intermediate produced by steps (a)-(c)" (Decision to Institute 19–20) from the publicly available version of the Decision to Institute. Paper 18, 2; Paper 17, 24–25. The parties likewise request redaction of the italicized portion of the sentence "[t]he Process Optimization Report discloses the impurity analyses for five batches of treprostinil identified by *UTC as having been prepared using the process*

recited in the '393 patent" (Decision to Institute 19) in the publicly available version of the Decision to Institute.

Because the above described information, appearing on page 17, lines 21–23, page 19, lines 20–22, and page 20, lines 1–3 of the Decision to Institute (Paper 12) was made public in UTC's Redacted Preliminary Response (Paper 8), we decline to redact that information from the public version of the Decision to Institute. We note, however, that certain information appearing on page 20 at line 3 of the Decision to Institute (Paper 12) has not been publicly disclosed in the parties' filings, and is confidential information concerning the manufacture of Remodulin®; as such, we grant the parties' request with respect to this information.

Regarding the proposed redactions to page 20 at lines 4–17 and footnote 7, as well as the proposed redactions to page 21 at lines 1–3 and 6–9 of the Decision to Institute (Paper 12), we agree with the parties that the disclosed numerical amounts and ranges, identity of the impurities detected, and particulars of the FDA treprostinil purity standard is confidential information concerning the manufacturing process for Remodulin®, submitted and held in confidence to the FDA, and susceptible to misuse by competitors seeking commercial advantage. *See* Paper 18, 4–5.

We observe, however, that certain of the proposed redactions are overbroad and encompass non-confidential information. For example, UTC states in its Redacted Preliminary Response (Paper 8) that:

> [T]he letter proposes that "the range of the specification for the HPLC assay for treprostinil be shifted from [redacted]% to [redacted]% [redacted]."

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