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Paper 6
Entered: November 23, 2015

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

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

HARLOW, *Administrative Patent Judge.*

DECISION
Denying Authorization to File a Motion for Additional Discovery
37 C.F.R. § 42.51(b)(2)

I. INTRODUCTION

On November 19, 2015, we held a teleconference regarding Patent Owner, United Therapeutics Corporation's ("UTC's") request for authorization to file a Motion for Additional Discovery regarding whether Chirogate International Inc. ("Chirogate") should have been named as a real party-in-interest to this *inter partes* review proceeding. Petitioner, SteadyMed LTD ("SteadyMed") opposes this request. On the call were Judges Green, Chang, and Harlow, as well as counsel for the parties.[1] For the reasons set forth below, we do not authorize UTC to file a Motion for Additional Discovery.

II. ANALYSIS

During the teleconference, the parties made the following representations regarding the relationship between SteadyMed and Chirogate. SteadyMed purchases treprostinil from Chirogate. Ex. 2001, 8:16–17. SteadyMed and Chirogate are party to a publicly available Supply Agreement in which Chirogate warrants that it does not infringe third-party intellectual property rights in connection with its manufacture and sale of treprostinil to SteadyMed. *Id*. at 5:25–6:3. The Supply Agreement further provides that at SteadyMed's request, Chirogate will furnish a letter to SteadyMed contending that Chirogate's treprostinil manufacturing process does not infringe any third-party patent. *Id*. at 5:25–6:6, 8:19–22. The Supply Agreement does not include an indemnification clause. *Id*. at 8:22–

[1] A court reporter also was present on the call, and UTC filed a copy of the transcript as Exhibit 2001.

24. Counsel for SteadyMed in this proceeding does not represent Chirogate. *Id.* at 10:14–16.

UTC has identified US Patent No. 8,497,393 ("the '393 patent"), the patent-at-issue in this proceeding, as well as several additional patents, as covering treprostinil in the Food and Drug Administration's ("FDA's") Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"). Chirogate submitted a Drug Master File ("DMF") to the FDA related to its manufacture of treprostinil. *Id*. at 6:7–9.

UTC contends that additional discovery is warranted because SteadyMed would not have known which process-related treprostinil patent to target via *inter partes* review, absent instruction from its supplier, Chirogate. *Id*. at 6:17–21. UTC points to the DMF filed by Chirogate, and the fact that SteadyMed is not itself a drug manufacturer, as supporting the conclusion that SteadyMed would not have identified the '393 patent as an appropriate target for *inter partes* review without information from Chirogate. *Id*. at 11:21–12:11. UTC further argues that the Supply Agreement is "evidence of privity between the parties and coordination in relation to third-party patents." *Id*. at 11:18–21.

SteadyMed asserts that UTC's discovery request is premised on mere speculation that Chirogate is controlling this *inter partes* review. *Id*. at 7:10–14. SteadyMed states that the '393 patent was voluntarily identified by UTC as covering treprostinil in the Orange Book, and identifies the Orange Book as the source of SteadyMed's information regarding which patent to target in this proceeding. *Id*. at 8:2–10. SteadyMed contends that its

relationship with Chirogate is limited to that of customer and supplier, and notes that the Supply Agreement at the core of UTC's request does not include an indemnification obligation, or "indicate anything beyond that [Chirogate] would provide a letter contending that they don't infringe." *Id.* at 8:22–24.

We note that the determination of whether a party is a real party in interest is a "highly fact-dependent question" (Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012)) in which the focus is on the party's relationship to the *inter partes* review pending before the Board and the degree of control the party can exert over that proceeding. *See Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, Case IPR2014-01288, slip op. at 11 (PTAB Feb. 20, 2015) (Paper 13). We give due consideration to the analysis described in *Garmin Int'l, Inc. et al. v. Cuozzo Speed Techs., LLC*, Case IPR2012-00001, slip op. at 6–7 (PTAB Mar. 5, 2013) (Paper 26) (informative), to guide our determination whether a request for additional discovery meets the applicable "interests of justice" standard.

The *Garmin* panel found that the party requesting discovery "should already be in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that in fact something useful will be uncovered." *Garmin*, Case IPR2012-00001, slip op. at 7 (Paper 26). We find that UTC has not presented a threshold amount of evidence or reasoning tending to show beyond mere speculation that Chirogate was involved in any way with the filing of the present Petition. UTC has shown at best that Chirogate may have had some incentive to have a petition filed in this *inter*

partes review. UTC presents no persuasive evidence or reasoning, however, that Chirogate directed SteadyMed to target the '393 patent, was otherwise involved in the filing of this *inter partes* review, or that Chirogate has, or had, the opportunity to direct or control the filing or conduct of this proceeding. Thus, UTC has not established more than the mere possibility of finding something useful, and the mere possibility that something useful will be found is an insufficient basis for granting UTC's request.

III. ORDER

It is

ORDERED that UTC's request for authorization to file a Motion for Additional Discovery is DENIED.

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