Filed on behalf of: Corcept Therapeutics, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner

v.

CORCEPT THERAPEUTICS, INC.,
Patent Owner

Case PGR2019-00048
U.S. Patent No. 10,195,214

PATENT OWNER'S AUTHORIZED SUR-REPLY IN FURTHER SUPPORT OF ITS PRELIMINARY RESPONSE

Teva's new arguments do not change the fact that institution would be an inefficient use of Board resources. The new arguments are based on: (1) the false assertion that the District Court "adopted" Corcept's schedule, such that any trial decision "would likely come well into 2021"; and (2) the misguided premise that the lack of finality of a preliminary injunction ("PI") decision would negate the inefficiency of institution. Reply, 1-3. Each of these arguments lacks merit.

First, while Teva references dates that Corcept had proposed for the close of fact and expert discovery, it omits that the District Court ***did not adopt Corcept's proposal***. Ex. 1063. Teva argued to the Court that its ANDA already has tentative approval from the FDA, and thus the case should not extend "beyond the 30-month stay." Ex. 2003. As a result, the Court is well aware of the ramifications of not issuing a trial decision prior to the August 2020 expiration of the 30-month stay. Moreover, the current lack of a trial date does not support Teva's position. Teva has specifically stated that it "does not agree not to launch its ANDA Product at-risk pending the issuance of the district court's decision." Ex. 2047. Thus, ***before*** the stay expires, the Court will ***necessarily*** issue a decision, if not after trial then on a PI. Either way, that decision will come months ***before*** the November 2020 date for the Board to enter a final written decision ("FWD") in this PGR. POPR at 6-7.

Second, Teva's arguments that a PI determination is insufficiently final to render consideration of Teva's petition inefficient are unconvincing. Teva

speculates that a PI decision "may not involve validity [of the '214 patent] at all" (Reply at 3), but Teva has submitted 135 pages of invalidity contentions directed to the '214 patent (and has not asserted any legitimate non-infringement argument with respect to the '214 patent). Thus, any PI will necessarily involve the validity of the '214 patent, and specifically the same obviousness defenses presented in Grounds 1 and 2 of the Petition. Ex. 2002. As such, even if Teva is correct that final resolution of the validity of the '214 patent in the district court will not occur until after a FWD, institution would still result in ***three*** adjudications on the obviousness arguments presented in the Petition within a matter of months: (1) the district court's PI decision before August 2020; (2) the Board's FWD in November 2020; and (3) the District Court's decision following trial shortly thereafter. This alone would be duplicative and wasteful, let alone that both the Board's and the District Court's decisions would each be subject to appeal, potentially resulting in ***five*** decisions on the same defenses in a short time frame.

Congress did not intend for PGR to result in such duplication. "Post grant reviews were meant to be quick and cost effective ***alternatives to litigation***." Ex. 2001 at 9 (emphasis added). Teva's Petition was not filed as an alternative to litigation; instead, Teva has hired the same attorneys to simultaneously make the same obviousness arguments based on the same references (POPR at 6) in both proceedings. This is contrary to Congressional intent, and should not be permitted.

None of the cases Teva cites support its position—or contradict Corcept's. Unlike here, the parallel district court litigation in *Facebook* "ha[d] been stayed." IPR2018-01622, Paper 8 at 1. In *Mylan*, unlike here, the Petitioner was not taking "two bites at the apple" because the Petitioner "agree[d] to not pursue in the district court action any specific ground that the Board institute[d]," and there was no possibility of a PI. IPR2018-01682, Paper 19 at 14-15. Finally, the *Intuitive Surgical* and *Samsung* cases state that denial of institution is "based on specific circumstances and not the mere presence of district court litigation." *See* IPR2018-01500, Paper 10 at 14. Here, it is not the *mere presence* of a co-pending district court case that counsels in favor of denial; it is the fact that Teva will force two separate tribunals (not to mention potentially the Federal Circuit) to issue multiple decisions adjudicating the same obviousness arguments based on the same combination of references—which fail to demonstrate unpatentability under any standard of review—within a short amount of time of one another. Congress did not intend for patent owners to have to defend against invalidity defenses in multiple, consecutive fora, nor did it intend for the Board to waste its time adjudicating such disputes. While the duplicative costs may not be an issue for Teva, one of the world's largest pharmaceutical companies, they are an issue for Corcept, a small, one-product company. The Board should exercise its discretionary authority to deny institution of this Petition pursuant to § 324(a).

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Respectfully Submitted,

F. Dominic Cerrito (Reg. No. 38,100)
Eric C. Stops (Reg. No. 51,163)
Daniel C. Wiesner (pro hac vice)
Frank C. Calvosa (Reg. No. 69,064)
John Galanek (Reg. No. 74,512)
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com
ericstops@quinnemanuel.com
danielwiesner@quinnemanuel.com
frankcalvosa@quinnemanuel.com
johngalanek@quinnemanuel.com

Counsel for Patent Owner

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