UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

ALLERGAN, INC.,

Patent Owner

U.S. Patent No. 8,642,556
Issued Date: February 4, 2014
Title: Methods of Providing Therapeutic Effects
Using Cyclosporin Components

IPR Case No.: IPR2017-00579
Patent No. 8,642,556

Motion for Joinder
Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 and 42.122(b)

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. § 42.22, and 37 C.F.R. § 42.122(b), Teva Pharmaceuticals USA, Inc., ("Teva") respectfully submits this Motion for Joinder, together with a petition for *inter partes* review of U.S. Patent No. 8,642,556 ("the '556 patent"), seeking cancellation of claims 1-20 of the '556 patent ("the Teva IPR") and joinder of this proceeding with *Mylan Pharmaceuticals Inc., v. Allergan, Inc.*, Case IPR2016-01129 (the "Mylan IPR" or "IPR 1129").

This Motion for Joinder is timely under 37 C.F.R. §§ 42.22 and 42.122(b), as it is submitted within one month of December 8, 2016, the date on which the Mylan IPR was instituted. *See* Mylan IPR, Paper 8.

Teva submits that joinder is appropriate because it will: (1) promote efficient determination of the validity of the '556 patent in a single proceeding without prejudice to first petitioner Mylan Pharmaceuticals Inc. ("Mylan") or patent owners Allergan, Inc. ("Allergan" or "Patent Owner") because Teva's petition raises the ***identical*** grounds of unpatentability instituted by the Board in the Mylan IPR (*see, e.g.*, *Motorola Mobility, Inc. v. Softview, Inc.* IPR2013-00256, Paper No. 10 (granting motion for joinder under similar circumstances)); (2) not affect the schedule in the Mylan IPR nor increase the complexity of that proceeding, minimizing costs; and (3) minimize burden because Teva will agree to

consolidated filings[1] and discovery and will accept a back-seat, "understudy" role in the joint proceedings.[2] Absent joinder, Teva could be prejudiced if the Mylan IPR is terminated before a final written decision is issued, as Teva's interests will not be adequately represented before the Board. Accordingly, joinder should be granted.

This Motion for Joinder and accompanying Petition are timely under 37 C.F.R. §§ 42.22 and 42.122(b), as they are submitted within one month of December 8, 2016, the Mylan IPR's institution date. *See* Mylan IPR, Paper 8 (Decision).

II. STATEMENT OF MATERIAL FACTS

1. Petitioner and other entities are involved in litigation over the '556 patent and related patents in the action styled *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., et al.,* No. 2:15-cv-01455, filed by Allergan, Inc. in the

[1] Teva agrees to consolidated filings for all substantive papers in the respective proceedings, except for motions that do not involve Mylan. Teva agrees to incorporate its filings with those of Mylan in a consolidated filing, subject to the ordinary rules for one party on page limits.

[2] To the extent the Board considers granting Teva's motion for joinder, Teva is willing to take a passive role. For example, Teva agrees not file additional papers, not file additional pages to Mylan's papers, not present any new, additional, or supplemental arguments, not cross-examine Allergan's expert or attempt to offer a rebuttal expert of its own, and not present any arguments at oral hearings. *See e.g., Samsung Elec. Co., Ltd. v. Arendi S.A.R.L.*, IPR2014-01518, Paper 10 at 6 (PTAB Mar. 18, 2015) (allowing joinder where movants takes a "limited understudy role" without a separate opportunity to actively participate). Only if Mylan drops out of the proceedings for any reason, will Teva cease its passive role.

Eastern District of Texas (EX1023). Petitioner also identifies the following pending actions involving the '556 patent: *Allergan, Inc., v. Innopharma, Inc. and Pfizer, Inc*., No. 2:15cv1504, in the Eastern District of Texas.

2. On June 3, 2016, Mylan filed its petition for *inter partes* review seeking cancellation of claims 1-20 of the '556 patent. (Mylan IPR, Paper 3.)

3. The Mylan IPR petition included the following five grounds for challenging the validity of the '556 patent:

Ground 1: Claims 1-20 are anticipated under 35 U.S.C. § 102(b) by Ding '979;

Ground 2: Claims 1-20 are obvious under 35 U.S.C. § 103 over Ding '979 and Sall;

Ground 3: Claims 14 and 19 are obvious under 35 U.S.C. § 103 over Ding '979, Sall, and Glonek;

Ground 4: Claims 11, 18, and 20 are obvious under 35 U.S.C. § 103 over Ding '979, Sall, and Acheampong; and

Ground 5: Claim 19 is obvious under 35 U.S.C. § 103 over Ding '979, Sall, Glonek, and Acheampong.

4. On September 9, 2016, Patent Owner filed a Preliminary Response. (Mylan IPR, Paper No. 7)

5. December 8, 2016, the Board instituted review of claims 1-20 of the ’556 patent in the Mylan IPR with respect to Grounds 1-5. (Mylan IPR, Paper 8.)

6. On December 6, 2016, the Board entered a scheduling order in the Mylan IPR setting various dates, including the oral argument set for August 17, 2017. (Mylan IPR, Paper 10)

7. Teva’s petition in this proceeding proposes that claims 1-20 of the ’556 patent should be cancelled in view of Grounds 1-5, as set forth in the Mylan IPR petition.

8. Teva’s petition in this proceeding presents the identical grounds on which the Mylan IPR was instituted.

9. Teva’s petition in this proceeding proposes the same claim construction positions as the petition in the Mylan IPR, and relies upon the same exhibits.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

Joinder of this proceeding with the Mylan IPR will not enlarge the Mylan IPR nor negatively affect its case schedule. But, a decision not to grant Teva’s motion for joinder could severely prejudice Teva. Thus, joinder is appropriate and warranted.

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of *inter partes* review proceedings. The statutory provision governing joinder of *inter partes* review proceedings is 35 U.S.C. § 315(c), which reads as follows:

> (c) JOINDER.--If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

Under 35 U.S.C. § 315(c), the Board has authority to join a second *inter partes* review proceeding to an instituted first *inter partes* review proceeding. The motion for joinder must be filed within one month of institution of the first *inter partes* review proceeding. 37 C.F.R. § 42.122(b).

In exercising its discretion to grant joinder, the Board considers the impact of substantive and procedural issues on the proceedings, as well as other considerations, while being "mindful that patent trial regulations, including the rules for joinder, must be construed to secure the just, speedy, and inexpensive resolution of every proceeding." *See Dell, Inc. v. Network-1 Security Solutions, Inc.,* Case IPR2013-00385, Paper No. 17 (July 29, 2013) at 3. The Board should consider "the policy preference for joining a party that does not present new issues

that might complicate or delay an existing proceeding." *Id.* at 10. Under this framework, joinder of the present IPR with the Mylan IPR is appropriate.

"A motion for joinder should: (1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified." *Id.* at 4 and *Macronix Int'l Co. v. Spansion,* IPR2014-00898, Paper 15 at 4 (Aug. 13, 2014). The Board should also consider "the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding." *See Dell, Inc. v. Network-1 Security Solutions, Inc.*, Case IPR2013-00385, Paper No. 17 (July 29, 2013) at 3. Under this framework, joinder of the present Teva IPR with the Mylan IPR is appropriate.

B. Joinder Will Not Impact the Mylan IPR's Case Schedule

Joinder in this case will not impact the Board's ability to complete its review of the '556 patent in a timely manner. 35 U.S.C. § 316(a)(11) and associated rule 37 C.F.R. § 42.100(c) provide that *inter partes* review proceedings should be completed and the Board's final decision issued within one year of institution of the review. In this case, joinder will not affect the Board's ability to issue the decision within this required one-year timeframe because the Petition filed in the present Teva IPR is substantially identical to the Mylan IPR. Indeed, in

circumstances such as these, the PTO anticipated that joinder would be granted *as a matter of right*. *See* 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) ("The Office anticipates that joinder will be allowed *as of right* – if an inter partes review is instituted on the basis of a petition, for example, a party that files an identical petition will be joined to that proceeding, and thus allowed to file its own briefs and make its own arguments.") (emphasis added).

As such, Teva raises no issues that are not already before the Board in the Mylan IPR. Teva's petition seeks review of claims 1-20 of the '556 patent based on ***the identical grounds and combination of prior art*** considered by the Board in instituting review in the Mylan IPR. Indeed, Teva's petition is substantially identical to the corresponding Mylan IPR (Mylan IPR, Paper 3). There are no substantive differences. Further, Teva's petition proposes the same claim construction positions as the petition in the Mylan IPR, and relies upon the same exhibits.

Teva will agree to proceed in the instant IPR based only upon the arguments and evidence advanced by Mylan and accept a back-seat, "understudy" role in those joined proceedings, without any right to separate or additional briefing or discovery, unless authorized by the Board upon a request to address an issue that is unique to Teva. Only if Mylan drops out of the proceedings for any reason, will Teva cease its understudy role.

To the extent that Teva's petition in this proceeding differs from the petition that Mylan filed in IPR 1129, Teva agrees to withdraw all additional arguments, as well as its supporting declaration of Dr. Chambliss, and proceed in IPR 1129 based on the arguments and evidence provided by Mylan in IPR 1129. Teva agrees to assume a primary role in IPR 1129 only if Mylan ceases to participate in IPR 1129. In other words, Teva requests permission to be added to the case caption as a petitioner in IPR 1129, without any active participation or involvement that is separate from Mylan, unless authorized by the Board upon a request pertaining to an issue unique to Teva alone.

Teva expects that any cross-examination(s) carried out by Mylan will occur within the timeframe normally allotted by the rules to one party. As such, the time will not need to be extended in light of the joinder.

In order to further simplify the proceeding, Teva will rely on the same expert as Mylan, should Mylan permit it.[3] If Mylan allows Teva to retain the same expert, then Teva will withdraw its expert declaration of Dr. Chambliss and rely solely on the declaration and testimony of Mylan's expert, Dr. Amiji. The Board has previously acknowledged that such concessions on the part of a party seeking to

[3] In the event that Mylan does not agree to allow Teva to retain Mylan's expert, and the Board determines it would not be able to complete these proceedings within the one-year timeframe as a result of having to provide the Patent Owners with the opportunity to additionally depose Dr. Chambliss, Teva would in that case agree to withdraw Dr. Chambliss's declaration and instead rely solely on the declaration of Mylan's expert, Dr. Amiji.

join are sufficient to minimize the impact on the original proceeding (*see SAP America Inc. v. Clouding IP, LLC*, IPR2014-00306, Paper 13, page 4).

Even if, through no fault of its own, Teva were required to proceed with its own expert, there would be no impact on the Board's ability to complete its review in a timely manner. Moreover, there would be only a modest impact on the Patent Owner, given that little additional preparation would be needed for the deposition of Teva's expert beyond that required for the deposition of Mylan's expert.

C. Joinder Will Enhance Efficiency by Avoiding Duplicate Efforts and Inconsistencies

Joinder is appropriate because it is the most expedient way to secure the just, speedy, and inexpensive resolution of two related proceedings in a single *inter partes* review. *See* 35 U.S.C. § 316(b); 37 C.F.R. § 42.1(b). Otherwise, determining the same validity questions in separate concurrent proceedings could duplicate efforts, and create a risk of inconsistent results and piecemeal review. Accordingly, a joined *inter partes* review will avoid inefficiency and potential inconsistency and result in a final written decision without any delay.

This Motion for Joinder is timely under 37 C.F.R. §§ 42.22 and 42.122(b), as it is submitted within one month of December 8, 2016, the date on which the Mylan IPR was instituted. *See* Mylan IPR, Paper 8 (Decision).

D. A Joined Proceeding Avoids Prejudice to Teva and Will Not Prejudice Mylan or Allergan

Joinder is also warranted in order to permit Teva to protect its interests related to the validity and interpretation of the '556 patent claims, and Teva could be prejudiced if it is not permitted to participate in the Mylan IPR. For example, allowing a joined *inter partes* review would avoid potential inconsistency and avoid prejudice to Teva in the event that Mylan and Allergan reach a resolution of their disputes during the pendency of the Mylan IPR. 35 U.S.C. § 317(a) provides that an *inter partes* review "shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner" unless the Board has already reached its decision on the merits. If no petitioner remains after settlement, "the Office may terminate the review." *Id*. Here, if Allergan and Mylan settled, the Mylan IPR could terminate without proceeding to a final written decision, prejudicing Teva.

Permitting joinder will not prejudice Allergan or Mylan. Teva raises no issues not already before the Board, so joinder will not affect the timing of the Mylan IPR or the content of Mylan's Patent Owner response. Teva also believes that given the procedural safeguards proposed below, any additional costs to Allergan and Mylan associated with its participation in the Mylan IPR will be minimal, and not so great as to justify the potential prejudice to Teva if the Mylan IPR was otherwise terminated before a final written decision by the Board.

E. Joinder will not prejudice Patent Owner or Mylan

Permitting joinder will not prejudice Allergan or Mylan. Teva's proposed grounds for instituting an IPR are identical to those proposed by Mylan in its petition. Joinder will not affect the timing of the Mylan IPR, and any extension to the schedule that may be required is permitted by law and the applicable rules. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.100(c).

IV. CONCLUSION

For all the foregoing reasons, Teva respectfully requests this proceeding be joined with the Mylan IPR.

Although Petitioner believes that no fee is required for this Motion, the Commissioner may charge any additional fees which may be required for this Motion to Deposit Account No. 502880.

Respectfully submitted,

Dated: January 6, 2017

/Gary J. Speier/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), this is to certify that on January 6, 2017, I caused to be served a true and correct copy of the foregoing "MOTION FOR JOINDER PURSUANT TO 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 AND 42.122(b)" on this 6th day of January, 2017:

by FedEx Priority Overnight® on the Patent Owner at the correspondence address of the Patent Owner as follows:

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and by FedEx Priority Overnight® on counsel of record for Allergan in IPR2016-01129 for U.S. Patent No. 8,642,556:

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