Trials@uspto.gov Paper: 85 Tel: 571-272-7822 Entered: October 4, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and AKORN INC.

Petitioners,

v.

SAINT REGIS MOHAWK TRIBE, Patent Owner.

Case IPR2016-01127 (8,685,930 B2)

Case IPR2016-01128 (8,629,111 B2)

Case IPR2016-01129 (8,642,556 B2)

Case IPR2016-01130 (8,633,162 B2)

Case IPR2016-01131 (8,648,048 B2)

Case IPR2016-01132 (9,248,191 B2)¹

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, Administrative Patent Judge.

ORDER
Conduct of the Proceedings
37 C.F.R § 42.5

-

¹ Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings.

A conference call for the above-captioned proceedings was held on September 26, 2017. Counsel for Petitioners Mylan Pharmaceuticals, Inc. ("Mylan"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Akorn Inc. ("Akorn") (collectively, "Petitioners"), Patent Owner Saint Regis Mohawk Tribe ("Tribe"), and exclusive licensee Allergan Inc. ("Allergan") participated. A transcript of the call has been filed as Exhibit 1143.

The primary purpose of the call was to discuss Mylan's request for authorization to file a motion for additional discovery concerning any agreements between the Tribe and Allergan, as well as certain other settlement agreements referenced in the agreements that have already been made of record (Ex. 2086 and Ex. 2087). In particular, Mylan seeks:

all agreements incorporating references to Allergan license grants, any side agreements, supplemental agreements, agreements to agree, term sheets, documents sufficient to show all drafts of the assignment, license agreement, [and] documents sufficient to show communications between Allegan and the Tribe or the Tribe's attorneys regarding IPRs or patents including any marketing material.

Ex. 1143, Tr. 12:18–13:4. Mylan further seeks "any documents showing good and valuable consideration that the Tribe gave to Allergan as part of this transaction." *Id.* at 13:5–7. Mylan's counsel indicated during the call that these documents are relevant to the question of whether the Tribe is the true owner of the challenged patents in these proceedings and whether Allergan has retained sufficient rights to the patents such that these proceedings can continue notwithstanding the Tribe's assertion of sovereign immunity. *Id.* at 14:3–20.

In response, the Tribe's counsel represented during the call:

Your Honor, first, there are no other agreements. Let me be unequivocal as I possibly can, there are no side agreements, there are no license-back agreements, there are no expansion of license rights agreements. There are no give-back agreements. There are no agreements at all in any way, shape, form, or fashion that have not already been produced in the case, none, zero, nada.

Id. at 25:7–15. The Tribe's counsel additionally represented "there are no term sheets, there never were any term sheets in the case." Id. at 21:18–20. With respect to the prior settlement agreements referenced in the agreements made of record, the Tribe's counsel indicated "[t]hey were simply listed as encumbrances and simply meaning that any time a patent owner takes ownership of a patent that they take it subject to prior license agreements." Id. at 27:12–16.

Upon considering the parties' arguments, we do not authorize Mylan to file a Motion for Additional Discovery. Additional discovery is warranted only when granting the discovery is "necessary in the interest of justice." 35 U.S.C. § 316(a)(5); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). The Board has outlined several factors (the "*Garmin* factors") useful in evaluating whether granting additional discovery would be in the interests of justice, including the requirement that the request is based on "more than a possibility and mere allegation":

The mere possibility of finding something useful, and mere allegation that something useful will be found, are insufficient to demonstrate that the requested discovery is necessary in the interest of justice. The party requesting discovery should

```
IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2); IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2); IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)
```

already be in possession of evidence tending to show beyond speculation that in fact something useful will be uncovered.

Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC, IPR2012-00001, Paper 26, 6–7 (PTAB Mar. 5, 2013) (precedential) (emphases added).

Mylan has not demonstrated that the additional discovery it seeks satisfies this first *Garmin* factor. In particular, Mylan has not identified any specific basis to suggest that there exist additional agreements between Tribe and Allergan relating to the challenged patents that have not already been produced. To the contrary, the Tribe's counsel represented unequivocally during the call that no such agreements or term sheets exist. Moreover, to the extent that there may have been any other communications or draft agreements, Mylan has not shown why those documents would be "useful" to the issue of the Tribe's ownership in the patents. As further noted by Allergan's counsel during the call, the license agreement between Tribe and Allergan indicates that "the license agreement represents the entire agreement and understanding between the parties." Ex. 1143, Tr. 31:18–32:8. Likewise, Mylan has not shown why any prior settlement agreements between Allergan and other third parties would be relevant to the issue of the Tribe's ownership.

During the call, Allergan's counsel also sought leave to withdraw as counsel in this proceeding on the basis that Allergan is not the patent owner. *Id.* at 19:14–21. Given the current dispute concerning the true ownership of the challenged patents, we denied that request at this point. We indicated that Allergan's counsel may renew that request after briefing on the Tribe's motion to dismiss is completed.

```
IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2); IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2); IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)
```

The parties also discussed a request the Board received via email on September 26, 2017, from the Association for Accessible Medicines ("AAM") to file an amicus brief supporting Petitioners' opposition to the Tribe's motion to terminate. The Tribe's counsel stated that if AAM is permitted to file an amicus brief, then other tribes should be permitted to file amicus briefs in support of the Tribe's motion. Petitioners stated they did not support the filings if they would result in further delay of these proceedings. Having considered AAM's request and the parties' arguments, we deny AAM's request to file an amicus brief. An email will be sent to AAM to notify them of our decision.

Accordingly, based on the foregoing, it is:

ORDERED that Mylan's request for authorization to file a motion for additional discovery is *denied*;

FURTHER ORDERED that Allergan's counsel's request to withdraw in this proceeding is *denied without prejudice*; and

FURTHER ORDERED that the parties are to notify the Board by joint email within five business days of entering this Order whether this Order contains any confidential information that should remain under seal. Otherwise, this Order shall be opened to the public after five business days.

.

PETITIONER MYLAN:

Steven W. Parmelee
Michael T. Rosato
Jad A. Mills
WILSON SONSINI GOODRICH & ROSATI
sparmelee@wsgr.com
mrosato@wsgr.com
jmills@wsgr.com

PETITIONER TEVA:

Donald R. Steinberg
David L. Cavanaugh
Michael H. Smith
Wilmer Cutler Pickering Hale and Dorr LLP
6 don.steinberg@wilmerhale.com
david.cavanaugh@wilmerhale.com
michaelh.smith@wilmerhale.com

PETITIONER AKORN:

Mark Nikolsky Vadim Cherkasov mnikolsky@mccarter.com vcherkasov@mccarter.com

PATENT OWNER:

Dorothy P. Whelan Michael Kane FISH & RICHARDSON P.C. whelan@fr.com PTABInbound@fr.com

Alfonso Chan Joseph DePumpo SHORE CHAN DEPUMPO LLP achan@shorechan.com jdepumpo@shorechan.com