

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALKERMES PHARMA IRELAND LTD.
and ALKERMES, INC.,
Petitioners,

v.

OTSUKA PHARMACEUTICAL CO., LTD.,
Patent Owner.

Case IPR2017-00287
Patent 9,125,939 B2

Before SUSAN L. C. MITCHELL and JACQUELINE T. HARLOW,
Administrative Patent Judges.

HARLOW, *Administrative Patent Judge.*

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

On April 3, 2017, a conference call was conducted among counsel for Petitioners, Alkermes Pharma Ireland Ltd. and Alkermes, Inc. (collectively, “Alkermes”), counsel for Patent Owner, Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), and Judges Mitchell and Harlow. The purpose of the call was to address Alkermes’ request for authorization to file two motions: a motion for pre-institution discovery, and a motion to file a reply to Patent Owner’s Preliminary Response (Paper 10).

During the call, Alkermes explained that its motion for pre-institution discovery would seek the production of information concerning the public accessibility of three documents that Alkermes asserts as prior art against U.S. Patent No. 9,125,939 B2 (“the ’939 patent”): Keck (Ex. 1007),¹ Citrome (Ex. 1008),² and the BMS/Otsuka Press Release (Ex. 1028).³ Alkermes contends that Keck, Citrome, and the BMS/Otsuka Press Release were authored or issued by employees of Otsuka or Otsuka itself. Alkermes, therefore, requests authorization to file a motion seeking pre-institution discovery directed to obtaining information regarding the date of release for

¹ Keck et al., *Aripiprazole versus placebo in acute mania*, Abstracts of the 2002 Annual Meeting of the American Psychiatric Association (2002).

² Citrome et al., *Pharmacokinetics and safety of aripiprazole and concomitant mood stabilizers*, Abstracts of the 2002 Annual Meeting of the American Psychiatric Association (2002).

³ *Data Demonstrate Aripiprazole Significantly Improved Symptoms of Acute Mania in Patients With Bipolar Disorder; New Data Presented Today at American Psychiatric Association Annual Meeting*, PR Newswire (2002).

each of the above-referenced exhibits. Alkermes additionally requests authorization to file a motion to file a reply to Patent Owner's Preliminary Response, in order to address to the public accessibility arguments made by Otsuka in its Preliminary Response.

Otsuka opposes Alkermes' requests. In this regard, Otsuka points out that irrespective of Otsuka's contribution to the content of the documents, each of the references for which Alkermes seeks discovery is a third party document, and is not published by Otsuka itself. Otsuka argues also that pre-institution discovery is an extraordinary remedy, and one not appropriate here, because Alkermes was required to make a threshold showing of public accessibility in its Petition. Otsuka further asserts that Alkermes' request for authorization to file a motion to file a reply is premature, because it presumes that the sought-after discovery would yield information that supports Alkermes' position.

We recognize, and are sympathetic to, Alkermes' concerns regarding Otsuka's efforts to distance itself from references Otsuka itself had a hand in creating by challenging not the fact of publication and dissemination of those references, but rather, the sufficiency of Alkermes' evidentiary showing with regard to public accessibility.

We nevertheless deny Alkermes' requests for authorization. As an initial matter, we note that Alkermes' discovery requests are premised on Alkermes' speculation that Otsuka maintains particular types of records regarding scientific meeting abstract and press release submissions. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, slip

op. at 7 (PTAB Mar. 5, 2013) (Paper 26) (precedential) (“[T]he requester of information should already be in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered.”).

Furthermore, even if such records exist, it is unclear how they would be useful in establishing the public accessibility of Keck, Citrome, and the BMS/Otsuka Press Release, as those documents were published by third parties, not Otsuka itself. For example, the public accessibility of Keck and Citrome depends upon the date on which the American Psychiatric Association made the New Research Abstracts for its 2002 Annual Meeting available to the interested public, not the date on which Otsuka or its employees submitted abstracts to the meeting organizers. Similarly, the public accessibility of the BMS/Otsuka Press Release turns on the date PR Newswire published that release, not the date on which Otsuka authorized publication. *See id.* (“[U]seful’ means favorable in substantive value to a contention of the party moving for discovery.”).

Lastly, the fact that Keck, Citrome, and the BMS/Otsuka Press Release were published by—and disseminated to—third parties underscores that the information sought could, and should, have been obtained by other means. *See id.* at 6 (“Information a party can reasonably figure out or assemble without a discovery request would not be in the interest of justice to have produced by the other party.”).

Accordingly, we *deny* Alkermes' request for authorization to file a motion for pre-institution discovery, and Alkermes' request for authorization to file a motion to file a reply to Patent Owner's Preliminary Response.

ORDER

It is hereby:

ORDERED that Petitioners' request for authorization to file a motion for pre-institution discovery is *denied*;

FURTHER ORDERED that Petitioners' request for authorization to file a motion to file a reply to Patent Owner's Preliminary Response is *denied*.

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