

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC.  
Petitioner,

v.

THE BOARD OF REGENTS OF THE UNIVERSITY OF MICHIGAN  
Patent Owner.

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Case IPR2013-00041  
Patent 5,746,775

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Before MICHAEL P. TIERNEY, THOMAS L. GIANNETTI, MICHAEL J.  
FITZPATRICK, and RAMA G. ELLURU, *Administrative Patent Judges*.

ELLURU, *Administrative Patent Judge*.

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

A conference call was held on Monday, July 29, 2013, with respective counsel for the parties and Judges Tierney, Giannetti, Fitzpatrick, and Elluru. Counsel for Patent Owner (University of Michigan) requested the call to discuss discovery dispute(s) between the parties and the procedure for each party's litigation counsel to participate in this trial proceeding and to gain access to confidential information.

University of Michigan sought authorization to file a motion to compel Petitioner (St. Jude) to review documents St. Jude exchanged with the FDA in obtaining approval to commercialize and market certain products, and to produce any documents therein responsive to certain requests by the University of Michigan. University of Michigan stated that St. Jude commercialized those products pursuant to a license from University of Michigan and they were marked with University of Michigan's patent. University of Michigan represented that the documents *may* contain information: (1) relating to secondary considerations of non-obviousness, including information establishing a nexus between the improvement over the prior art embodied in St. Jude's products and their commercial success (*e.g.*, comparative analysis with competitor products), and (2) information as to the selection of animal testing models and the suitability of certain models for testing the products for which St. Jude sought FDA approval. University of Michigan further stated that it has been diligently seeking these documents and noted the Board's prior conference call addressing the parties' discovery disputes.

St. Jude opposed the desired authorization contending that the magnitude of the burden on St. Jude to review and produce the requested documents does not justify the undertaking and that University of Michigan's request was untimely.

As to the burden, St. Jude represented that “two pallets” of documents would have to be reviewed for responsive documents. As to timing, St. Jude noted that University of Michigan’s Patent Owner Response is due this Friday, August 2, 2013, and that the first time University of Michigan requested the narrowed scope of the FDA documents currently sought was two weeks ago. St. Jude contended that it has already produced marketing information relating to competitor products, and thus, any responsive FDA documents as they relate to possible “nexus” information likely would be cumulative to documents already produced. St. Jude also noted that it produced approximately 1000 pages of documents as a result of the Board’s prior conference call on discovery.

University of Michigan’s request for authorization to file a motion to compel discovery is DENIED. The statutory standard for discovery in an *inter partes* review is “necessary in the interest of justice.” 35 U.S.C. § 316(a)(5). The mere possibility of finding useful information is insufficient to demonstrate that the requested discovery is necessary in the interest of justice. *See* Decision – “On Motion for Additional Discovery” in Case IPR2012-00001 (*Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, (Paper 26), p. 6). The burden is on the party requesting discovery to show that it already is in the possession of evidence tending to show beyond speculation that useful information will be uncovered from the requested discovery. *Id.*

Here, several factors weigh in favor of denying authorization to file a motion to compel discovery. Foremost, University of Michigan has not established beyond speculation that the requested documents will contain useful information. With respect to University of Michigan’s contention that the FDA documents may include the requisite nexus information to establish commercial success of St.

Jude's products, we agree with St. Jude that such information is likely already available in marketing materials produced by St. Jude. With respect to the contention that the requested FDA documents may shed light on the reliability of prior art animal testing models, University of Michigan's request is based on speculation. Such information is likely to be found in the publicly available prior art. Furthermore, while the parties represented that they have been discussing the discovery of the requested documents and that St. Jude produced document pursuant to the last discovery call, University of Michigan has not shown that it acted timely in making the current request. Accordingly, we determine that University of Michigan has not made a threshold showing sufficient to warrant granting authorization to file a motion to compel discovery.

The parties also sought guidance on the preferred practice for permitting the parties' litigation counsel to participate in this trial proceeding and to gain access to confidential information. The parties should submit for entry by the Board a proposed protective order, such as the default protective order provided in the *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012). Once a protective order has been entered, the parties' respective litigation counsel should sign the acknowledgment provided with the protective order so that they can have access to confidential information submitted in this trial proceeding. Participation in the proceeding is governed by 37 C.F.R. § 42.10. Appearance by counsel who is not a registered practitioner requires a motion to appear pro hac vice under subsection (c) of that rule.

In consideration of the foregoing, it is hereby

**ORDERED** that University of Michigan's request for authorization to file a motion to compel discovery is *denied*; and,

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**FURTHER ORDERED** that the parties are authorized to submit a proposed protective order for entry in this trial proceeding.

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