Additional Discovery of Clinical Trial Data in Inter Partes Review (IPR)

In *Apotex, Inc. et al. v. Novartis AG* (IPR 2017-00854, paper 47 dated Feb. 5, 2018), petitioner Apotex sought, and was granted, discovery of a Phase III clinical trial protocol from patent owner Novartis. The patent at issue in the IPR, U.S. 9,187,405, claims a method for treating relapses in relapsing-remitting multiple sclerosis by orally administering fingolimod “at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen.” In its petition for IPR, Apotex alleged that the prior art taught that 0.5 mg of fingolimod was known to be an effective maintenance dose for treating multiple sclerosis. Novartis responded that to the extent that the prior art taught the use of 0.5 mg of fingolimod, it was only in the context of a treatment wherein the maintenance dose is preceded by a loading dose, something that is explicitly denied from the claimed methods. See paper 8 at 25.

After the Patent Trial and Appeal Board (PTAB) instituted the IPR, Novartis elaborated on its position in its response (paper 27), stating that the effectiveness of 0.5 mg as a maintenance dose in the absence of a loading dose, as required by the claims, was a surprising discovery. Although its briefing is heavily redacted, it appears that Novartis asserted that its Phase III clinical trial was aimed at showing the effectiveness of a 1.25 mg per-day dose, and that the study included a 0.5 mg dosing only at the suggestion of the U.S. Food and Drug Administration (FDA). Novartis supported this assertion with an expert declaration authored by a member of the advisory board that helped Novartis design the Phase III clinical trial. After deposing Novartis’s expert, Apotex moved for additional discovery, seeking several documents, including Novartis’s Phase III clinical trial protocol.

In granting Apotex’s request for the Phase III clinical trial protocol, the PTAB applied the standard set forth in *Garmin Int’l v. Cuozzo Speed techs. LLC*, case IPR2012-00001. The PTAB granted additional discovery based on Apotex’s strong showing under *Garmin*’s first factor, which requires the petitioner to show more than “the mere possibility of finding something useful, and mere allegation that something useful will be found” in the protocol, as required under *Garmin* Factor 1. 

Order at 4. The PTAB gave little weight to Novartis’s counterargument that it would be unduly burdensome to identify the version of the protocol that was provided to the FDA.

It is noteworthy that in addition to the Phase III clinical trial protocol, Apotex requested three other documents: (1) minutes of a meeting with the FDA, (2) Novartis’s briefing book for an end of Phase II meeting, and (3) an unredacted version of a particular exhibit. The PTAB denied Apotex’s request as to each of these documents because the existence of useful information in those documents was said to be speculative.

This case demonstrates that additional discovery, including clinical study data, may be available to IPR petitioners when the subject matter of that additional discovery is clearly at issue in the case, and where evidence shows that the requested discovery contains useful information. Here, Apotex appears to have relied upon statements made by Novartis’s expert to demonstrate the existence of useful information within the requested discovery. In deposing declarants, an IPR petitioner should consider whether the patent owner’s declarants can substantiate the existence of useful information within the possession of the patent owner. A patent owner, on the other hand, should consider whether its arguments raise the potential for additional discovery, and if so, whether the IPR petitioner will have a means for testing Novartis’s position here against statements it made to the FDA in submitting the protocol and is, thereby, “useful” to Petitioner’s case. Moreover, in pointing to the statements of Dr. Lublin and Ms. Farrell, Apotex demonstrates more than a ‘mere allegation that something useful will be found’ in the protocol, as required under *Garmin* Factor 1.”
mechanism by which to demonstrate the existence of useful information within the patent owner’s possession.

David N. Farsiou, a Partner in the Philadelphia office of Baker & Hostetler, has extensive experience in all aspects of patent practice, including litigation, due diligence, portfolio management, and post-grant proceedings at the U.S. Patent and Trademark Office (USPTO). David leads the Biotechnology, Chemical, and Pharmaceutical practice team for the firm. He can be reached at dfarsiou@bakerlaw.com

Timothy J. Doyle is an Associate with Baker & Hostetler and focuses his intellectual property practice in the pharmaceutical and chemical industries. He draws on his extensive background as a research chemist in the chemical and pharmaceutical industries to assist clients in those industries with patent prosecution, freedom-to-operate and validity opinions, and patent litigation. He can be reached at tdoyle@bakerlaw.com