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INTELLECTUAL PROPERTY LAW

Intellectual Property Alert:

Clinical Trials: When is the Right Time to File for a Patent?

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September 20, 2017 — Not uncommonly, clinical investigators ask, "When is the right time to file a patent application?" One case under consideration at the U.S. Court of Appeals for the Federal Circuit may give some guidance on this question. A panel of that court heard the appeal of *Sanofi v. Watson Laboratories* (Nos. 16-2722, 16-2726) at oral hearing on Thursday, Sept. 7, 2017. The appeal was the consequence of Abbreviated New Drug Application (ANDA) litigation, in which Sanofi initially sued eight generic drug-maker defendants for alleged infringement of its patents relating to its anti-arrhythmia drug Multaq® (400 mg dronedarone tablets).

One of the Sanofi patents (U.S. 8,318,800) is directed to a pharmaceutical composition, and one (U.S. 8,410,167) is directed to methods of reducing risk of cardiovascular hospitalization by administering the drug to a patient who has at least one of six named risk factors. The defendants had filed applications with the U.S. Food and Drug Administration (FDA) for approval to market generic versions of Multaq®.

The judge in the U.S. District Court for the District of Delaware (*Sanofi v. Glenmark Pharmaceuticals*, 204 F.Supp.3d 665 (2016)) found that the defendants had not proven that the method patent was invalid for obviousness. The primary reference prospectively disclosed a Phase I clinical study and stated "…it is expected that treatment with this compound will result in a significant reduction in the need of rehospitalization for cardiovascular reasons." The defendants argued that the authors' statement of expected results demonstrated that a person of skill in the art would have had a reasonable expectation of success in practicing the claimed invention. The district court had found that the statement was merely a statement of a scientific hypothesis that the study was designed to test and did not provide a reasonable expectation of success.

During oral argument, defendants urged that a hypothesis was legally sufficient to show obviousness, and to support its position, cited to section 2107.03 (IV) of the Manual of Patent Examining Procedure (MPEP) (guidelines for examination of applications for compliance with the utility requirement). One judge of the panel noted that the MPEP does not have the status of law. Even if a hypothesis is sufficient to show utility, however, it may not be sufficient to show obviousness.

At the trial the patentee had presented expert testimony that interpreted and contextualized the authors' statement of expectations within the document as a whole, *i.e.*, that it was a mere hypothesis

or hope rather than an expectation of success. The appellate court will likely give deference to the district court's determination that this testimony was credible.

Indeed, such a finding would be consistent with positions that the Patent Trial and Appeals Board (PTAB) has taken in other cases. For example, in an unrelated proceeding, the PTAB denied a petition to institute *inter partes* review based on an Internet posting of a clinical trial (*Coalition for Affordable Drugs v. Biogen MA Inc.* (IPR2015-01136)). The PTAB stated that FDA Phase II studies may or may not establish that a drug works to treat a particular disease or condition. Moreover, the PTAB stated that prior to completion and evaluation of Phase II, a person of skill in the art would not necessarily understand that the drug is useful for treatment of the disease or condition. The PTAB distinguished between a hope and a reasonable expectation of success. The PTAB's position is consistent with the district court's in the *Sanofi* case.

As a general rule, filing before initiation and publication of clinical studies may prevent the need to litigate the issue of whether the hypothesis of a clinical study provides a reasonable expectation of success in the context of an obviousness attack under 35 U.S.C. §103. More importantly, it may avoid a potentially more devastating attack for anticipation under 35 U.S.C. §102. If a challenger can make an anticipation attack, the patentee will have no opportunity to argue that there was no reasonable expectation of success, because a reasonable expectation is not required to prove anticipation.

Click here to listen to the oral arguments in *Sanofi v. Watson Laboratories*.