

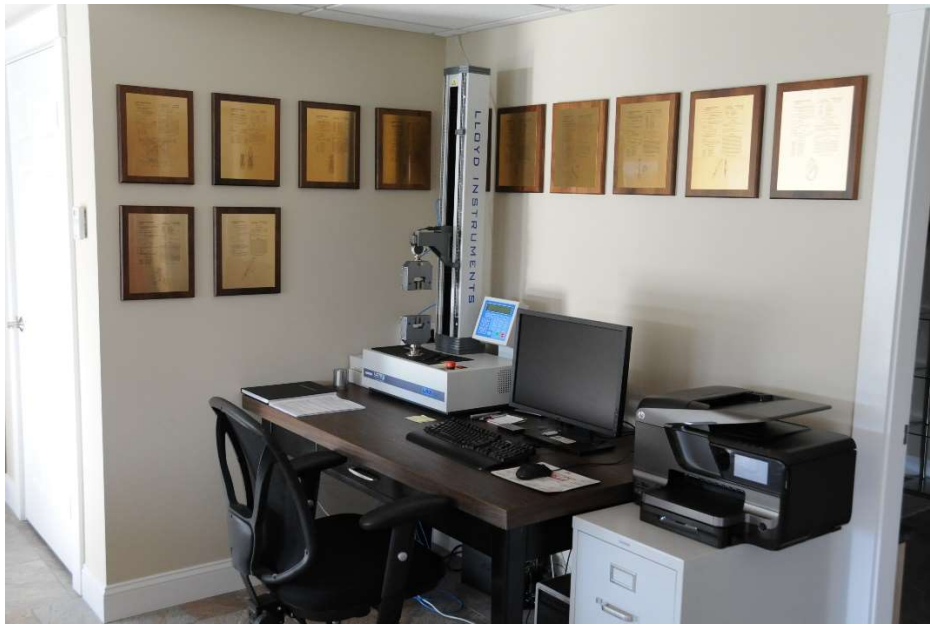
How a Medical Device Expert Witness Can Assist In a Case

By: Karl R. Leinsing, MSME, PE

Experienced Medical Device Experts can assist with a case in many different ways. First, they have industry knowledge of the medical device industry and can assist with prior art in patent litigation cases for example. They understand the technology and how claim terms are understood for one skilled in the art of medical device design, testing, and manufacturing. This firsthand information can then assist with proper claim construction, prior art search, and infringement analysis. Experience with medical device product development can also assist in determining what is obvious in the field in light of available prior art and what is not obvious as it pertains to patent validity. Experience with being a patent litigation expert allows the expert to better understand 35 U.S.C § 102 & 103 to determine if a claim is anticipated by prior art or is obvious per these sections respectively. There is also “written description”, “enablement”, and “indefiniteness” that must also be considered when evaluating the validity of a patent.

Medical device experts with access to their own laboratory and test equipment can test medical devices and report personal experience on the results. Addition of photographs and video of macroscopic and microscopic views create powerful demonstratives that are worth more than a 1000 words, especially when the expert has access to a CT scanner, Scanning Electron Microscope (SEM), and small bore scopes to look inside devices to see and create pictures and videos on how they operate. This in addition to making cross-sectional cuts of small parts encased in epoxy allows a full analysis of a device so that both parties in a case, including a judge and jury, can understand the operation and parts of a device. The pictures below show two areas of our lab depicting our calibrated and certified Class 10,000 clean room hood, microscope, oven, tensile/compression test equipment, and pressure/vacuum test equipment just to name a few.





Tests done using calibrated equipment can help both plaintiffs and defendants for medical device liability cases. Devices can be tested to see if they caused the injury and analysis can often lead to the root cause of the failure and/or injury. The results are then backed up by data, pictures, and/or video to support how the tests were performed and under what conditions.

Another more recent area where a medical device expert can assist with a case is in depositions of the other parties' experts or fact witnesses. An expert can assist with forming good technical questions and can help an attorney understand the answers that are given by the witness. Many times a properly asked and answered question during a deposition can make or break a case and having experienced technical support can be a great asset.

In conclusion; a medical device expert is a valuable asset to both patent litigation, trademark, arbitration, ITC, IPR, contract dispute, and liability cases and can assist in all parts of your case from initial document or patent review, to testing and analysis, pictures and video for demonstratives, writing reports, assistance with depositions, and finally confidence and knowledge for a thorough and easy to understand testimony with clear articulated answers under cross examination.

About the Author:

Karl Leinsing, MS, PE, is the President of ATech Designs, Inc. and focuses on medical device product development from concept to production since 1992. His medical device experience includes, but is not limited to, intravenous (IV) systems and pumps, needle-free IV valves, catheters, syringes, auto-injectors, pen injectors, insulin pumps, hernia repair, laparoscopic instruments and staplers, endometrial ablation, tissue sealers/cutters, nebulizers, inhalers (e-cigarettes), cardiovascular systems, mitral valve repair, abdominal aortic aneurysm (AAA) repair, spinal plates and screws, sleep apnea devices, CPAP devices, and peritoneal dialysis machines. Mr. Leinsing has been granted 39 patents (others pending), is the winner of five medical device design awards, has a medical device published on the cover of LIFE Magazine, is recognized as one of the top 100 medical device professionals in the country by MD&DI Magazine, serves on medical device product development boards, and has served as chairman for the Medical Device & Manufacturing (MD&M) Conference.