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Sample of My Product Liability, Intellectual Property and Breach of Contract Cases

RECENT CASES

The Advantage of Using My Firm:
My firm Core Devices conducts basic research to design, develop and manufacture innovative medical devices for healthcare outside traditional hospital settings, as well as provides consulting and expert witness services to law firms. My company's experience is steeped in product design and manufacturing, a solid knowledge of standards governing same and regulatory requirements. I have been designing and developing medical devices for over 20 years. Collectively we have over 100 years of experience with numerous patents issued to our experts. I am proud to say that we understand medical devices intimately, because we have experience developing them, and continue to conduct research on surgical, respiratory, diagnostic, monitoring and therapeutic devices.

I have served as an expert witness on product liability, patent litigation and breach of contract cases for attorneys representing plaintiffs as well as defendants, drawing from decades of research and development and manufacturing of surgical and respiratory devices. Below are sample cases that I worked on in the last 18 months, as well as outcome.

Sample of Cases:

1. *Petition for Inter Pates Review (IPR) case filed with USPTO (Ongoing)*
   I am serving as expert witness for Fish & Richardson on an IPR in progress, to challenge the validity of several issued patents, pursuant to 37 CFR 42.104(B) and CFR 42.8(b)(2). Previous to this, I represented Fish and Richardson on a patent infringement case filed with the International Trade Commission (ITC) and the United States Patent and Trademark Office (USPTO). The IPR involves masks that are used in CPAP machines for treatment of sleep apnea.

2. *BMC Medical (Petitioner) v. ResMed (Patent Owner)* – Patent Infringement Case
   Petition for *IPR* of claims 9–19, 23–36, 40, and 63 of U.S. Patent No. RE 44,453 E
   This case involved a foreign firm (petitioner) infringing upon a United States patent owned by Patent Owner and for CPAP machines. It was prosecuted at the International Trade Commission (ITC) and United States Patent and Trademark Office (USPTO). Patent Owner sued Petitioner for patent infringement. Petitioner responded by filing an IPR claiming patent invalidity. Petitioner asserted as defense that Patent Owner's patent was invalid and obvious at the time of the filing of the patent, and could have been reproduced by combining prior arts cited. As an expert, my role was to determine whether Patent Owner's invention was obvious and not patentable. Further, whether a person skilled in the art would have at the time of the infringed patent been able to combine teachings of the prior arts cited by Petitioner to come up with Plaintiff's invention, therefore invalidating the claimed invention. In my declaration, I argued that one skilled in the art would not have combined any of the prior arts cited by Petitioner to replicate Patent Owner's invention, and that Petitioner did not show how it could be feasibly combine the prior arts cited to reproduce Patent Owner's invention and therefore infringed upon Patent Owner's patent. **Result: Patent Owner won the important claims.**

USPTO ruled that "Taking into account the Petition and Patent Owner's Preliminary Response, we determined that there was a reasonable likelihood that challenged claims 9–19, 23–36, 40, and 63 are unpatentable. Pursuant to 35 U.S.C. § 314, we instituted inter partes review, on January 21, 2015, as to claims 9–19, 23–36, 40, and 63 of the '453 patent. Paper 7 ("Dec."). After institution, Patent Owner filed a Patent Owner Response (Paper 12, "PO Resp."). Petitioner filed a reply to the Patent Owner Response. Paper 13 ("Pet. Reply")."

On claims 23 and 24, the judges found that Petitioner had not demonstrated a sufficient basis to combine the structures of Dobson and Wilson to arrive at the apparatus of claims 23 and 24.

3. ***Todd Fruge and Susan Fruge (Plaintiffs) v. Ethicon US, LLC, et al.*** *(Active)*
This is an active product liability case. I was retained by Plaintiff's to serve as an expert witness. The clip applier used during laparoscopic cholecystectomy surgery malfunctioned and the clips scissored allowing bile to leak. This resulted in prolonged hospitalization, complications and multiple surgeries to rectify. About 6 months later, after the incident, the manufacturer Ethicon recalled the device. The recall notice was only sent to the hospital.

4. ***In the case of Jackson v. John Doe (An Oxygen Concentrator Manufacturer)***, a patient died due to loss of electricity to an oxygen concentrator during an electrical power outage. In general, care givers providing care to patients on oxygen concentrators are advised to switch their patients over to bottled oxygen in the case of an event such as power failure or product malfunction, that causes the device to shut off or deliver oxygen at a level of purity less than 90 percent of clinically accepted standard. Typically, patients on home oxygen therapy have about half dozen oxygen bottles in the vicinity of an oxygen concentrator. Oxygen concentrators are required to have special alarms systems to warn customers when these events occur. These requirements are articulated in ISO and ASTM Standards governing design of oxygen concentrators, and enable compliance with FDA Quality System Regulation and Design Control. However, they are not life support devices. The FDA acknowledges that these devices are not life support machines. Oxygen concentrators are Class II Devices. In this case, there was a power failure and the patient died. Plaintiff sued the manufacturer, alleging that the oxygen concentrator its child was on is a life assisting device, and should have had a battery backup power supply. Defendant argued otherwise, stating the oxygen concentrator supplied to Plaintiff had alarm systems that would have warned Plaintiff of power failure, and that Plaintiff had ample time to switch their child over to compressed oxygen tank. Furthermore, based on my declaration, the FDA does not consider oxygen concentrators to be life-support devices. Plaintiff was trained on how to change over from electrical power to compressed gas in the event of electricity failure. Plaintiff was negligent by not following instructions. **Result: Plaintiff settled case before trial.**

5. ***Jackson v. Invacare (Settled)*.**
I served as an expert witness for defendants (Invacare) and dealer (Apria) on this case that was prosecuted in Fresno, California. Plaintiffs claimed that an Invacare oxygen concentrator was defectively designed because when a power outage hit the neighborhood the concentrator stopped working. The 6-year old boy using the device (their son), who had failing lungs caused by chemotherapy and was likely terminal absent a lung transplant, died after an extended period of time with no oxygen and what appears to be no effective CPR for at least the 10 minutes based on records, while the mother claims she could not get a nearby backup tank started. The testimony and evidence showed that the mother had been warned by the concentrator delivery man and had been given a manual describing what to do if there was a power outage. She had experience switching him to stand-alone tanks, and had done so for over a year. I declared that based on my experience home oxygen concentrators are not required to have battery backup system in the event of power loss, and that its absence in the oxygen concentrator was not a design defect, and would have been state of the art and industry standards in 2004 when it was manufactured to have alarm systems. Further, these devices are described in the manual as not life sustaining equipment, unlike ventilators. **Result: Case was settled before trial.**

6. ***Pulse Oximeter Case (Defendant and Plaintiffs names withheld)*.**
This case is similar to Jackson v. Invacare and involves a Pulse Oximeter. Pulse Oximeters measure the oxygen level in the blood. Finger pulse oximeters have integrated sensors, while hand-held versions and multi-parameter monitors have separate probes. The probe measures oxygen level as well as alarms when the oxygen saturation level falls below clinically acceptable standard. In general, they beep when a patient's oxygen saturation level falls below the acceptable level. The probe attached to the patient on the night of his demise did not have an alarm. As a result, attendant nurses did not know that the patient's oxygen saturation level had critically dropped. Attorney for Plaintiff alleged that were it not for lack of an alarm system, his client would have been alive. He argued that the pulse oximeter is a life support device and therefore should have alarmed. Again, in this case, the FDA does not classify pulse oximeters as life support or sustaining devices. I testified that unlike a ventilator that is a life support machine and requires alarm systems, a pulse oximeter is not. **Result: Defendant won.**

7. ***UC Irvine – Failure of Endo-GIA anastomotic stapling device*** during colorectal surgery. I was retained as an expert to design evaluation, including predicate design analysis to determine whether failure was due to manufacturing defect or surgeon error. I concluded that failure was due to design. **Result: Plaintiff won.**

8. ***University of Texas – Southwest Medical Center Dallas*. *Failure of Endo-GIA anastomotic stapling device*** during colorectal surgery. This case involved failure of Endo-GIA anastomotic stapling device during colorectal surgery. I conducted design evaluation, including predicate design analysis to determine whether failure was due to manufacturing defect or surgeon error. **Result: Plaintiff won.**

9. ***Rodriguez, et al (Plaintiff) vs. Manufacturer of Prosthetic Medical Device (Defendant)*** – Breach of Contract Claim.
   I served as an expert witness for Defendant on this case, to provide testimony on FDA requirements. This involved a prosthetic device. Plaintiff alleged that the device did not function as claimed and caused him pain. Defendant moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), arguing that the claims against Defendant are preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), and that Plaintiff failed to state a claim upon which relief can be granted. Defendant provided documentary evidence that the FDA approved its prosthetic device. The court affirmed. The district court granted summary judgment to Defendant on the products liability claims and Deceptive Trade Practices Act (DTPA) claims under Rule 56, and dismissed the breach of contract claim under Rule 12(b)(6). Plaintiff appealed from the district court's dismissal of his state law products liability, deceptive trade practices and breach of contract claims against Defendant.

Sincerely,

John I. Izuchukwu, Ph.D., PE.