Patent Enforcement: MedTech and AI Updates

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Introductions

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Agenda

1. Litigation Activity: Consumer Medical Devices
2. Patent Eligibility
3. Novelty
4. Discovery of Training Set Data in Litigation
5. Discovery of AI Utilization by Experts

Litigation Activity in Consumer Medical Devices

Consumer Medical Devices

Apple Watch

- *Masimo v. Apple*
- *AliveCor v. Apple*

OuraRing

- *Oura Ring ITC Investigation v. Samsung, Reebok, Zepp, Nexxbase*
- *Samsung Ring ITC Investigation v. Ouraring*

Masimo v. Apple November 2025 Jury Verdict

QUESTION 1:

For each of the following patent claims, did Masimo prove by a preponderance of the evidence that Apple infringed the claim?

'776 Patent	YES (for Masimo)	NO (for Apple)
Claim 11	✓	
Claim 12	✓	
Claim 13	✓	
Claim 14	✓	

QUESTION 2:

What is the total reasonable royalty (in dollars) that Masimo has proven by a preponderance of the evidence should be awarded for Apple's infringement?

$ 634,313,913.00

Claim 11: A patient monitor configured to monitor at least a pulse rate of a patient by processing signals responsive to light attenuated by body tissue, **the patient monitor** comprising...:

Key issue for the jury: What is a patient monitor?

Masimo Corp. v. Apple Inc., C.D. Cal., No. 8:20-cv-48

Masimo v. Apple ITC Exclusion Order

Original Apple Watch design infringed on Masimo's other patents: The Federal Circuit affirmed a finding by the ITC that the pre-redesign Apple Watch's blood-oxygen sensors infringed on Masimo's asserted blood oxygen patents.

Asserted claim. A *user-worn device* configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:...

https://www.medtechdive.com/news/apple-fends-off-masimo-challenge-to-apple-watch-redesign/818158/?

Masimo v. Apple Redesigned Apple Watch

- **ITC:** The U.S. International Trade Commission affirmed a finding that Apple's redesigned Apple Watches do not infringe Masimo's asserted blood oxygen patents.
- **Redesign is non-infringing:** "sensor data from the Blood Oxygen app on Apple Watch" is now moved to "the paired iPhone, and results can be viewed in the Health app."

A **user-worn device** configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:

Masimo v. Apple Redesigned Apple Watch

Masimo	Apple
borne or carried on the person	configured to be worn on the user

Specification distinguished between “handheld or portable” embodiments and embodiments that “can be attached to the patient.”

Unpersuasive trial testimony that “anything one can carry is user-worn.”

Related Masimo patent filings specifically claimed “handheld” devices.

Other stages of the ITC contradicted Masimo’s claim construction.

Claims should be prepared to cover processes that are split between wearable form factors and handheld devices or computers

Oura Ring ITC Investigations

Oura Ring smart wearable platform

Machine-learning algorithms for measuring sleep

Asserted Patents in both investigations focused on hardware and sensors, not machine-learning algorithms

Oura Ring ITC Investigation

Other Oura patents focus on machine-learning algorithms

US 12,343,125, claim 11: “The method of claim 1, further comprising:

inputting the PPG signal into a machine learning classifier,

wherein determining the cardiovascular health metric is based at least in part **on inputting the PPG signal into the machine learning classifier**.”

Oura Ring ITC Investigation

Non-Oura Ring Accused Products

Samsung Galaxy Ring

Reebok Smart Ring

Zepp's Amazfit Helio Ring

Nexxbase's Luna Ring Gen 2

Challenges in Enforcing MedTech AI Patent Claims

Patent Eligibility

Patent Eligibility 101s

Step One: Are the claims directed to a patent-ineligible concept (laws of nature, natural phenomena, and abstract ideas)

→ **NO.** Patent-Eligible

→ **YES.** Step Two: Do the claims focus on an inventive concept that is not well-understood, routine, or conventional?

Preemption relevant in computer-implemented medical device cases

Recentive Analytics v. Fox Corp (Fed. Cir. 2025)

Holding: "Claims that do no more than apply established methods of machine learning to a new data environment are *not* patent eligible."

Broadcaster Programming Technology: optimizing schedules of live events and broadcasters' programming within certain markets and times, using machine learning models trained on historical data from live events or general training data

Covers any suitable machine learning technique: "a gradient boosted random forest, a regression, a neural network, a decision tree, a support vector machine, a Bayesian network, [or] other type of Technique."

CardioNet, LLC v. InfoBionic, Inc. (Fed. Cir. 2020)

Holding: heart rate variability measuring device **not invalid** because directed to improvements in measuring specific aspects of cardiac arrythmia

Cardiac Monitoring Technology: technology and techniques to detect atrial fibrillation and atrial flutter and distinguish them from other forms of cardiac arrythmia

Not directed to techniques that doctors already used: the written description did not disclose that doctors performed the same techniques as the claimed device in diagnosing atrial fibrillation and atrial flutter

Aon Re v. Zesty.AI (D. Delaware 2025)

Holding: claims reciting a specific use of multiple machine-learning classifiers to solve a specific technical problem **not invalid**

Property Imaging Technology: computer systems using multiple machine-learning classifiers to analyze aerial photography of buildings, determine the type of roof, and determine their condition

No preemption concern: No claims to the process of assessing the quality of a roof and practicing it with generic computer elements (including artificial intelligence)

Application to MedTech AI Cases

Abstract idea issues

- Claims processes that anyone can perform without a computer
- Claimed processes that doctors already perform

Inventive concept issues

- improving speed and efficiency of a pre-existing practice is not an inventive concept
- No inventive concept in bare use of or training machine learning techniques

Polar Electro OY v. Suunto OY et al. (D. Utah, 2024)

Personalized Heart Rate Monitor technology

Heart rate monitors can assess a person's energy consumption, but the relationship between a heart rate and energy expenditure varies between people, impeding accuracy.

Regression equations to calibrate relations between heart rate and energy consumption:

Polar Electro OY v. Suunto OY et al. (D. Utah, 2024)

Claim 5: A method for assessing a person's energy consumption during exercise, the method comprising:

measuring the person's heart rate information during exercise, the heart rate information including a heart rate parameter;

obtaining an energy consumption reference value from one or more performance parameters . . . with at least one of the performance parameters being a **maximal oxygen uptake**...;

assessing the person's energy consumption by means of a plurality of calculating parameters including at least the heart rate parameter and the energy consumption reference value, . . . **wherein the person's energy consumption is substantially linear dependent on the heart rate parameter**....

Polar Electro OY v. Suunto OY et al. (D. Utah, 2024)

Claim limitation: "**measuring the person's heart rate information during exercise,** the heart rate information including a heart rate parameter;"

But claim and specification **do not limit** "measuring" or "heart rate parameter"

Measuring a heart rate parameter can be accomplished simply by taking someone's pulse while exercising

Polar Electro OY v. Suunto OY et al. (D. Utah, 2024)

Claim limitations	Abstract Idea
obtaining an energy consumption reference value from one or more performance parameters . . . with at least one of the performance parameters being a maximal oxygen uptake…;	**Maximal oxygen update is VO2max**, which can be determined using pre-existing formulas and tables
assessing the person's energy consumption by means of a plurality of calculating parameters including at least the heart rate parameter and the energy consumption reference value, . . . wherein the person's energy consumption is substantially linear dependent on the heart rate parameter….	**Assessing energy consumption** through linear relationship "can be performed by pencil and paper"

Dental Monitoring v. Align Technology (N.D. Cal 2024)

Dental Imaging Technology

Defendant Align Technology and others design and manufacture dental aligners such as Invisalign.

Dental practitioner typically visually assesses a patient's aligner at regular sequences to decide whether to change the aligner.

Plaintiff Dental Monitoring has 200 pending and issued patents in remote dentistry and orthodontics.

Dental Monitoring v. Align Technology (N.D. Cal 2024)

Claim 1 of '409 recites: a method for acquiring an image of a dental arch of a patient, said method comprising the following steps:

activation of an image acquisition apparatus so as to acquire an image, called "analysis image," of said arch;

analysis of the analysis image by means of a deep learning device trained by means of a learning base;

determination, for the analysis image, as a function of the result of the analysis in the preceding step, of a value of an image attribute;

comparison of said image attribute value with a setpoint;

sending of an information message as a function of said comparison...

Dental Monitoring v. Align Technology (N.D. Cal 2024)

Claim 1 of the '409 patent only recites **a common practice long performed by dental practitioners.**

'409 patent

The most recent orthodontic treatments use images to assess the therapeutic situations. This assessment is conventionally performed by an orthodontist, which requires the patient to transmit these images to the orthodontist, even to make an appointment.

Bare recital of deep learning device limitation did not say more than that **it could be one of a subset of well-known options.**

In step 2), a deep learning device, preferably a neural network, is trained with the learning base.

A "neural network" or "artificial neural network" is a set of algorithms well known to a person skilled in the art.

The neural network may in particular be chosen from: the networks specializing in the classification of images, called "CNN" ("convolutional neural network"), for

Dental Monitoring v. Align Technology (N.D. Cal 2024)

No inventive concept

No inventive concept in improving processing efficiency

No inventive concept in training a deep learning device for operation in this field

Not an Abstract Idea

Overjet Inc. v. Videahealth Inc., D. Mass (2025)

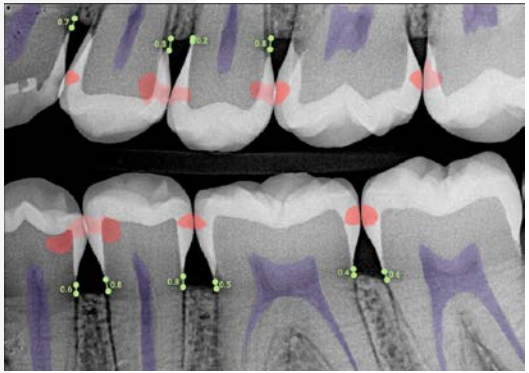
Osseo Imaging, LLC v. Dentsply Sirona, Inc., E.D. NY (2025)

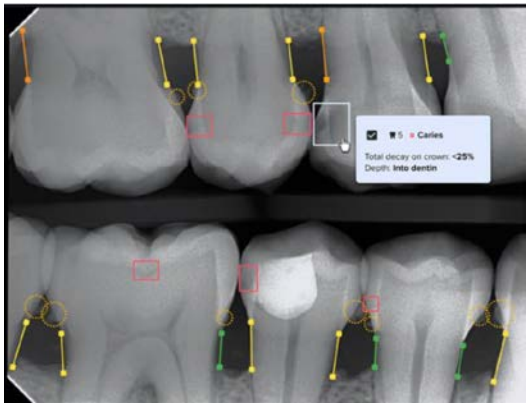
Overjet Inc. v. Videahealth Inc. (D. Mass 2025)

2D-Dental Imaging Technology

Plaintiff Overjet and defendant Videahealth use AI and "segmentation" approach to scan dental radiographic X-rays and detect dental diseases.

"Segmentation" outlines exactly where pathologies exist, in contrast to "bounded box" approach.





Overjet Inc. v. Videahealth Inc. (D. Mass 2025)

Specification identifies problem: measuring oral structures on a 2D dental radiograph, which requires external calibration objects to control for patient movement during x-ray imaging

Specification identifies technical solution: "using a patient's unique anatomical oral structures as calibration objects to make calibrated measurements without the need for an external calibration object."

Claims capture this improvement.

Overjet Inc. v. Videahealth Inc. (D. Mass 2025)

U.S. Patent No. 11,158,046: "Estimating Measurements of Craniofacial Structures in Dental Radiography"

Claim 1. A data processing system comprising: [a processor and memory] that cause the data processing system to perform functions of:
receiving a dental radiographic image that includes an oral structure;
selecting a segmenter and an object detector;
predicting masks and points of the oral structure using the segmenter and the object detector;
providing image metadata comprising the masks and points and the dental radiographic image to **a selector**;
selecting by the selector at least one measurement method. . . according to the dental radiographic image and the Image metadata;
calculating a sensor pixel to mm (millimeter) ratio using the measurement method; **and calculating a calibrated measurement of the oral structure using the sensor pixel to mm ratio and the image metadata.**

Overjet Inc. v. Videahealth Inc. (D. Mass 2025)

Not an Abstract Idea

Directed to technical improvement. Directed to technical improvement of calibrating without an external object, which "plainly qualifies as an improvement in the related technology" (*CardioNet, LLC*)

Specification did not state that process was already ordinarily performed. Specification explained that teeth could not ordinarily be imaged without an external calibration object

Claims did not recite bare use of machine learning technique. "Segmenter," "Object detector," and "selector" are separate machine learning models detailed in the specification. (*Aon Re v. Zesty.AI*).

Osseo Imaging, LLC v. Dentsply Sirona, Inc. (E.D. NY 2025)

3D-Dental Imaging Technology

Plaintiff Osseo owns patents related to a “dental and orthopedic densitometry modeling system” that includes “a controller with a microprocessor” connected to a memory device, an input device, an output device, and a three-axes positioning motor connected to X-ray equipment.

Defendant Dentsply Sirona provides “3D dental imaging systems.”

Osseo Imaging, LLC v. Dentsply Sirona, Inc. (E.D. NY 2025)

Specification identifies problem: Dental applications conventionally relied on tomography or sectional radiography techniques using scanning X-ray beams.

Specification identifies technical solution and implementation: applying densitometry techniques (typically used for bones) to gather densitometry data on teeth.

- A computer-controlled X-ray system scans dental and orthopedic structures using multiple X-ray energy levels.
- The system processes the scan data to generate a patient-specific tomographic densitometry model.
- The model can be displayed as a color-coded image showing variations in tissue and bone density.

Osseo Imaging, LLC v. Dentsply Sirona, Inc. (E.D. NY 2025)

Claim 1: A system for tomographically modeling dental and orthopedic structure densitometry, which includes:

a controller with a microprocessor and a memory device . . ., said controller including means for storing a pre-existing tomographical dental/orthopedic densitometry model. . .

a positioning motor connected to the microprocessor and movable in response to from said microprocessor;

X-ray equipment including an X-ray source and a detector array. . .

conversion means for converting a signal from said detector array. . .

an output device connected to said microprocessor and adapted for receiving a tomographical densitometry model from said microprocessor.

Osseo Imaging, LLC v. Dentsply Sirona, Inc. (E.D. NY 2025)

Claims capture this improvement. The claims here concern a technological solution to a technological problem—the computation, visualization, and comparison of densitometry data *otherwise not available in dentistry* for addressing early-stage dental pathologies and monitoring of osseintegration.

"this is not a situation 'where general-purpose computer components are added post-hoc to a fundamental economic practice or mathematical equation.'"

"Plaintiff's patents, as a whole, are directed to more than just the use of computers or tomography equipment, and **in fact provide for new functionalities otherwise unavailable."**

Progenics Medical Imaging v. MIM Software (D. Mass. 2025)

Plaintiffs: Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB ("Progenics").

Defendant: MIM Software Inc. ("MIM"), which sells imaging tools for radiation oncology, radiology, and nuclear medicine

Technology: Medical Imaging / Oncology Technology

Progenics Medical Imaging v. MIM Software (D. Mass. 2025)

Claim 1: A network-based system for generating a disease risk map for use as a decision-making support for evaluating risk of cancer or risk of recurrence of cancer, the system comprising:

[a processor and memory with instructions] which cause the processor to:

(i) access one or more medical images associated with a particular patient . . .;

(ii) perform an analysis of the one or more medical images associated with the particular patient using a machine learning algorithm, to generate the risk map, wherein the risk map comprises a visual representation of tissue overlaid with graphical denotations marking one or more regions of risk of cancer or risk of recurrence of cancer; and

(iii) cause display of the risk map via a graphical user interface . . . for presentation or review of the risk map by a user, wherein the analysis of the one or more medical images **comprises creation of a 3D image of the one or more regions of risk of cancer or risk of recurrence of cancer overlaid on the one or more medical images**, and **wherein the 3D image comprises geographic identification of one or more specific tissue region(s) overlaid on the one or more medical images.**

Progenics Medical Imaging v. MIM Software (D. Mass. 2025)

Inventive Concept

Physicians traditionally received separate anatomical and functional scans and had to manually “parse [the] two different types of scans to try to piece together the full picture” of cancer risk.

The patents automated creation of a “risk map” overlaid on medical images, including geographic identification of cancer-risk regions.

This overlaid risk-map visualization improved the traditional manual method of analyzing medical scans for cancer risk.

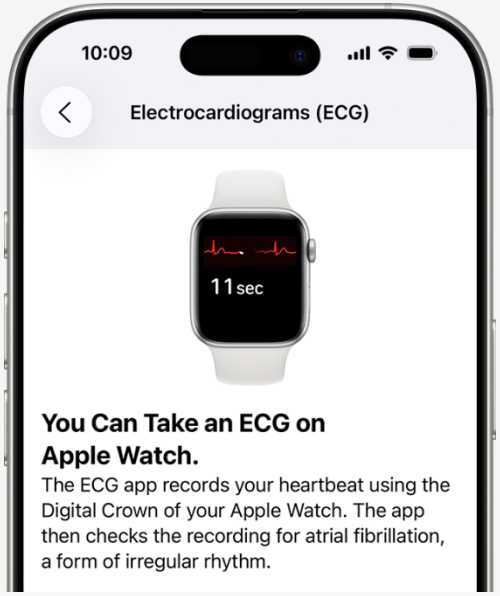
Bare recitation of machine learning alone insufficient for inventive concept.

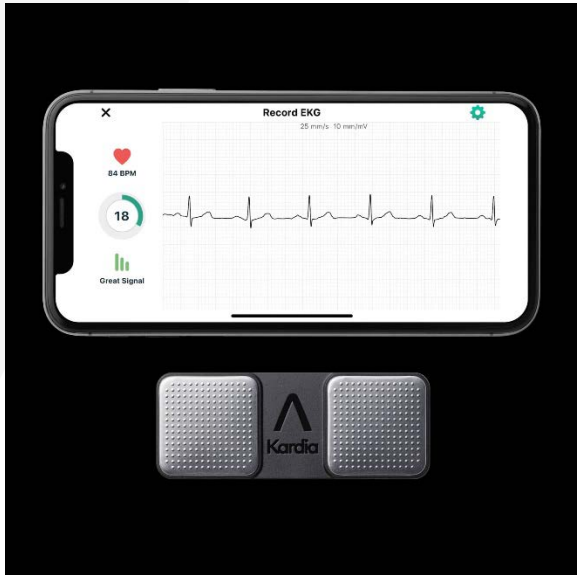
Challenges in Enforcing Med-Tech AI Patents

Obviousness

AliveCor v. Apple

AliveCor v. Apple: systems and methods to measure and analyzing physiological data to detect cardiac arrhythmias.





AliveCor v. Apple (Fed. Cir. 2025)

Technology at Issue. Wearable cardiac monitoring technology using ECG and PPG data to detect arrhythmias.

Dependent claims recite the bare usage of machine-learning algorithms. The use of machine learning is recited in dependent claims 7-9 and 17-19 of the ‘499 patent and dependent claims 3, 5, 6, 19, and 21-22 of the ‘731 patent.

For example, claim 7: “The method of claim 1, further comprising determining a presence of said arrhythmia using a machine-learning algorithm.”

“No claim requires a specific type of machine learning algorithm.”

AliveCor v. Apple (Fed. Cir. 2025)

Prior art (Hu 1997 and Li 2012) taught the use of machine learning to assess ECG data.

AliveCor argued that these references only showed machine learning in contexts other than arrhythmia detection.

Hu 1997 exemplified the detection of arrhythmia using ECG data, but nothing precluded a POSITA from using other heart rate parameters such as SpO_2 or PPG.

Li 2012's machine learning algorithm used multiple data inputs, and none of the AliveCor claims precluded using ECG data (or other data used in Li 2012) from being used in the algorithm.

At the pertinent date, a POSITA had "both interest and success in adapting machine learning to various biomedical applications."

Align Technology v. Dental Monitoring (PTAB 2025)

Recall the dental technology at issue. The patent relates to acquiring images of a patient's dental arch using mobile imaging devices and analyzing those images to guide orthodontic treatment decisions, for example related to Invisalign.

US 10,755,409 B2 Claim 1 expressly recites "analysis of the analysis image by means of a deep learning device trained by means of a learning base."

Align Technology v. Dental Monitoring (PTAB 2025)

Combination of two prior art references (*Salah* and *Carrier*) with a deep learning device disclosed by *Maninis*.

Patent Owner argued: *Maninis*'s deep learning device could only be trained on contours to identify an image only in contours, not on a learning base which includes historical images

Patent Owner's specification indicated that the learning base comprised more than 100,000 historical images of dental arches annotated with information for training.

But claim only recites "a deep learning device trained by use of a learning base."

Petitioner only needed to show a deep learning device capable of being trained by a learning base.

Challenges in Enforcing Med-Tech AI Patents: Obviousness

AliveCor v. Apple, Federal Circuit Appeal, 23-1512, 23-1513, 23-1514 (2025)

Align Technology v. Dental Monitoring, PTAB IPR2023-01369 (2025)

Claims reciting the bare usage of machine learning techniques in biomedical applications are vulnerable to prior art that teaches machine learning in other biomedical applications.

Challenges in Producing Training Data in Discovery

In re OpenAI ChatGPT Litigation (N.D. Cal. 2025)

Authors and copyright holders sued OpenAI entities for copyright infringement.

Dispute over whether OpenAI trained GPT-4 using datasets containing pirated copyrighted books and web content.

Plaintiffs sought production of OpenAI's "English Colang Dataset," a large training dataset allegedly used for GPT-4 training.

In re OpenAI ChatGPT Litigation (N.D. Cal. 2025)

Training Data Protocol

"Training Data" is defined broadly as data used to train relevant OpenAI large language models (LLMs). OpenAI reserves the right to supplement responsive training data later if additional responsive material is identified.

The protocol does not require native production of training datasets. Instead, plaintiffs receive inspection access to the data within a controlled environment maintained by OpenAI.

If plaintiffs want excerpts of training data produced, they must submit a "Print Request" identifying specific files, paths, and lines. OpenAI then decides whether:

- to produce the requested material, or
- object that the request is excessive or disproportionate under Rule 26.

In re OpenAI ChatGPT Litigation (N.D. Cal. 2025)

Failure of Training Data Discovery Protocol

Plaintiffs argued that OpenAI's inspection protocol made searches impractically slow

Plaintiffs sought native production of the dataset on a portable storage device for efficient searching

OpenAI argued that the dataset was too large and sensitive to export easily, and that its secure enterprise infrastructure was materially faster and more secure than any local plaintiff environment.

OpenAI also argued that the dataset reflected proprietary "special sauce" regarding how training data is processed for GPT-4.

In re OpenAI ChatGPT Litigation (N.D. Cal. 2025)

Court ordered OpenAI to produce the disputed training dataset.

The dataset was “relevant and necessary” to the copyright litigation and that the burden of production was not excessive if proper safeguards were implemented.

Meet and confer regarding transfer procedures and security protocols before production.

Challenges in Expert Witness Usage of AI

Conservation L. Foundation v. Shell Oil et al. (D. Conn, May 18, 2026)

Conservation's expert used ChatGPT workflow to cull a document production into a subset for further analysis

Expert did not review the full document production to confirm whether ChatGPT workflow missed additional produced documents

Court ordered Conservation to fully respond to interrogatories and RFPs that "call for disclosure of any artificial intelligence prompts and/or queries used . . . in the course of producing [the] expert witness report."

Kohls v. Ellison (D. Minn, January 10, 2025)

Plaintiff challenged Minnesota statute barring “deepfakes” on 1A grounds.

Minnesota moved for a preliminary injunction relying in part on expert declaration.

Expert declaration accidentally cited to fake, AI-generated sources. Court found no intent but still struck the declaration as unreliable.

Rule 11 may now require attorneys to ask their witnesses whether they have used AI in drafting their declarations and what they have done to verify any AI-generated content.

Kohls v. Ellison (D. Minn, January 10, 2025)

Experts violate Rule 11 when they **“abdicate their independent judgment and critical thinking skills in favor of ready-made, AI-generated answers.”**

Concord Music Group Inc. v. Anthropic PBC (NDCA, May 23, 2025)

Anthropic's expert declaration included AI-hallucinated citation.

Anthropic's counsel used Claude to reformat a citation, but Claude generated a fictitious article name with inaccurate authors.

But the original citation linked to an existing article found by humans.

Not a case where attorneys abdicated "their independent judgment and critical thinking skills in favor of ready-made, AI-generated answers."

Court struck the paragraph with the false citation.

Ferlito v. Harbor Freight Tools USA (E.D. NY, April 23, 2025)

Plaintiff's expert opined that maul was defectively designed, leading to axehead splitting from shaft mid-use.

After completing report, expert used ChatGPT to ask about the best way to secure an axehead to a handle, producing a response consistent with opinion.

Court found little risk that use of AI impaired expert's judgments in expert testimony, and did not strike report.

Expert Usage of AI

1. Confirm expert's usage of AI in drafting declarations

2. Confirm that experts exercise "their independent judgment and critical thinking skills" in forming opinions and do not rely on "AI-generated answers."

3. Be prepared to produce prompts used in generating expert reports and declarations

4. AI hallucinations regarding cases and other sources may lead to striking the declaration

Questions?

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