Grappling With A Bright-Line Patent Expert Admissibility Test

By **Daniel Moffett, Jonathan Hernandez and Megan Mahoney** (April 20, 2023)

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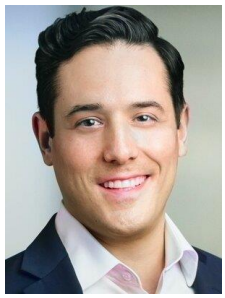

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Many of the fundamental principles of patent law are evaluated from the perspective of a hypothetical person of ordinary skill in the art, or POSA.

The U.S. Court of Appeals for the Federal Circuit in Kyocera Senco Industrial Tools Inc. v. U.S. International Trade Commission grounded this theoretical construct in reality last year by requiring that experts meet the definition of a POSA before opining on any issue analyzed through the lens of a POSA.[1]

Though courts have always been free to consider the level of skill in the art when exercising their discretion to admit expert testimony, Kyocera's bright-line approach comes with unintended consequences and raises additional questions about a court's role as gatekeeper.

The Role of the POSA in Expert Admissibility Pre- and Post-Kyocera

The POSA is a hypothetical construct in patent law that aids in determining the scope and meaning of claim terms, obviousness of a claimed invention, substantiality of differences between a claimed invention and accused product, and more.

Similar to the reasonable person in negligence cases, the POSA is the lens through which fact-finders view the asserted patent and prior art.[2]

A POSA is generally defined as an individual having an ordinary level of skill in the relevant field of technology, with knowledge of all pertinent prior art as it existed at the time of the invention.[3]

The level of skill in the art is typically presented as a particular level of education in an area of study, a number of years working in a relevant field, or both. Parties often propose competing definitions of the precise level of skill a POSA should possess, but historically, this has not been a heavily litigated issue.

While the POSA plays an important role in patent litigation, it was not used as a bright-line admissibility test for expert testimony before Kyocera. Instead, as in other areas of the law, district courts had wide latitude to determine the admissibility of expert testimony in their role as gatekeeper.[4]

Even where an expert admitted to not being skilled in the specific patented subject matter, as recognized by the Federal Circuit in 2010 in SEB SA v. Montgomery Ward & Co., a court had discretion to admit the testimony if the expert had relevant technical expertise related to the claimed invention and there was an "adequate relationship between [the expert's] experience and the claimed invention."[5]

Courts regularly considered the level of skill in the art when assessing whether an expert was qualified to assist the fact-finder, but controlling law did not require them to exclude an expert who did not meet the definition of a POSA.

Instead, differences between an expert's background and the POSA's background were typically considered ripe grounds for cross-examination.[6]

Kyocera established a new, bright-line expert admissibility test that limits the discretion of courts in their role as gatekeeper. The Federal Circuit held that an expert must possess at least an ordinary skill in the art, as it is defined in the particular case, to opine on issues applying the POSA standard.[7]

In effect, Kyocera requires a court to exclude an expert who fails to meet the specific definition of skill in the art applied in that case, instead of considering an expert's qualifications as a whole and determining whether they are qualified to aid the fact-finder in viewing the patents and prior art through the lens of a POSA.

The Federal Circuit characterized its holding in Kycoera as consistent with precedent, but in its own application of the holding and as subsequently applied by lower courts, Kyocera appears to implement a new, rigid expert admissibility requirement.

The patents at issue in Kycoera were directed to fastener driving tools, and the infringement allegations related to the importation of gas spring nailers.

During claim construction at the International Trade Commission, noting a lack of opposition, the administrative law judge adopted the respondent's definition of a POSA as a person having a degree in mechanical engineering and at least two years of experience in power nailer design.

The complainant's technical expert possessed advanced engineering degrees and "vast experience with fastener driving tools" — but no experience specifically in designing power nailers. The ALJ excluded the expert's testimony on the doctrine of equivalents, but determined that he was qualified to opine on literal infringement.

On appeal, however, the Federal Circuit held that the ALJ abused its discretion in considering the expert's testimony as to infringement, or any other issue analyzed through the lens of a POSA, because an expert must possess at least an ordinary skill in the art.

Because the expert did not have the requisite power nailer design experience of a POSA, as defined, the Federal Circuit held that his testimony was neither relevant nor reliable.

Difficulties in Applying Kyocera

Since its issuance, lower tribunals have begun to grapple with the impact of Kyocera's expert admissibility test, and these subsequent decisions applying Kyocera highlight potential unintended consequences and unanswered questions.

A New Litigation Battleground

Because of the importance of expert testimony in patent cases, Kyocera may elevate what was often a minor, noncontentious issue in a patent lawsuit to a potentially dispositive fight.

In light of Kyocera, litigants are now likely to propose a narrow definition of the level of skill in the art that is tailored to exclude their opponent's expert.

The party on the losing end of this issue may find themselves with an expert who is not

permitted to testify as to the ultimate issue of obviousness, or even testify at all.

Moreover, because disputes about the level of skill are rarely resolved until late in a case, or even before trial, it is unlikely that a party would be permitted to secure a substitute expert. Having no rebuttal expert could end up being dispositive at trial.

In an opinion issued following a bench trial, for example, the U.S. District Court for the District of Delaware relied on Kyocera in Bial-Portela & CA SA v. Alkem Laboratories Limited to exclude the testimony of both parties' experts on validity and "underlying technical questions" in September 2022.[8]

The court defined a POSA as someone with a medical degree in a particular field and a doctoral degree in another field, among other qualifications.

The defendant's expert had a doctoral degree in the relevant field, but no medical degree, and the plaintiff's expert was a licensed physician in the relevant field, but did not have the requisite doctoral degree.

Applying Kyocera, the court excluded the testimony of both experts. Because the POSA determination was made during trial, neither party had the opportunity to secure a new expert that met the court's definition.

Although the court, as fact-finder in the bench trial, noted that the exclusion of both experts ultimately had no bearing on its invalidity finding, the late exclusion of an expert in a jury trial on the same basis could have a substantial effect on the outcome of various factual determinations at trial.

Complex and Confusing Differences in the Relevance of Expert Testimony

Kyocera's bright-line admissibility test expressly applies to opinions on issues involving the POSA standard, but preserves lower tribunals' discretion to allow the same expert to testify on related issues.

Given how parties are likely to approach defining a POSA post-Kyocera, this may create a situation where two experts, both having similar backgrounds but only one meeting the POSA definition to the letter, have a differing scope of admissible testimony — one may testify on the state of the art and the prior art but is precluded from testifying on obviousness, while the other may testify on all issues.

These differences in what experts are qualified and permitted to opine on would likely be difficult for courts to administer at trial without unduly prejudicing one of the parties, and may confuse the fact-finder as to the relevance of particular testimony.

For example, the Patent Trial and Appeal Board excluded an expert's testimony in July 2022 in Avail Medsystems Inc. v. Teladoc Health Inc. on "any issue that is analyzed through the lens of an ordinarily skilled artisan," but found him qualified to opine about the technology and prior art in general.[9]

The PTAB noted that petitioner's expert had advanced degrees and extensive experience in the relevant field, and gave weight to that testimony, but determined that the expert's testimony on issues applying the POSA standard must be excluded based on Kyocera because his experience did not meet the definition of a POSA.

While the PTAB, as both gatekeeper and fact-finder, was capable of compartmentalizing an expert's testimony in this fashion, instructing a jury as to how and when to consider an expert's testimony, and expecting the jury to accomplish those instructions, is a different matter.

The Reach of Kyocera's Rationale

Courts and practitioners also face an open question regarding how far the rationale in Kyocera should reach. Specifically, the Federal Circuit held that to be qualified to opine "from the vantage point" of a skilled artisan, "an expert must at a minimum possess ordinary skill in the art."[10]

However, if an expert must have the same vantage point as a POSA, who is presumed to have a defined set of skills and knowledge of all pertinent prior art at the time of the invention, then it would also make sense to require an expert to have been a POSA as of the patent's effective date.

In Osseo Imaging LLC v. Planmeca USA Inc., the District of Delaware in February considered, and rejected, that proposition, but it did not engage in an analysis of Kyocera in reaching its conclusion.[11]

Although a timing requirement likely pushes the hypothetical POSA construct too far, another district court may apply Kyocera more literally and exclude an otherwise qualified expert because they attained the relevant level of skill in the art after the patent was filed.

Courts May Work Around Kyocera to Retain Gatekeeper Role

As courts continue to grapple with Kyocera, including addressing those issues discussed above, litigants can expect further clarity on the bright-line admissibility rule.

In the interim, litigants should closely consider their proposed level of skill in the art, and that of their opponent, in selecting an expert and pursuing Rule 702 motions. For their part, courts can minimize the effects of Kyocera, and recapture their gatekeeping role, by selecting a broad, yet appropriate, POSA definition. Kyocera itself provides a good example.

The Federal Circuit noted that the asserted claims "generally relate to linear fastener driving tools, like portable tools that drive staples, nails, or other linearly driven fasteners."

Had the ALJ defined the level of skill to require expertise in fastener driving tools generally, as opposed to nailer specifically, the claimant's expert would likely have qualified as a POSA, and the ALJ would have been free to engage in its traditional expert gatekeeping role.

Conclusion

Recent applications of Kyocera demonstrate that this decision has already had a significant effect on how litigants and district courts should approach expert admissibility.

In particular, where previously little attention was devoted to resolving minor differences in the proposed levels of skill in the art, such minor differences may now affect whether a party can present expert testimony on obviousness or infringement to the fact-finder.

Accordingly, parties must remain vigilant regarding their proposed definition, their

opponent's proposed definition and whether either side's expert actually meets that definition.

While courts continue to work out the best way to apply Kyocera, proffering a broader POSA definition could provide one avenue for avoiding an untimely expert exclusion under Kyocera, and return discretion to the court.

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[1] Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n, 22 F.4th 1369 (Fed. Cir. 2022).

[2] In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

[3] Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 962 (Fed. Cir. 1986).

[4] SEB S.A. v. Montgomery Ward & Co., 594 F.3d 1360, 1373 (Fed. Cir. 2010).

[5] Id. See also Mytee Prods. v. Harris Research, Inc., 439 F. App'x 882, 887 (Fed. Cir. 2011).

[6] See Teva Neuroscience, Inc. v. Watson Pharma, Inc., No. CIV.A. 10-5078 CCC, 2013 WL 1966048, at *6 (D.N.J. May 10, 2013) (finding an expert's qualifications as a POSA was more properly a subject for cross examination); John Mezzalingua Assocs., Inc. v. PCT Int'l, Inc., No. SA-09-CV-00410-RF, 2011 WL 13175092, at *5 (W.D. Tex. Aug. 10, 2011) (same).

[7] Kyocera, 22 F.4th at 1377.

[8] Bial-Portela & CA. S.A. v. Alkem Lab'ys Ltd., No. CV 18-304-CFC-CJB, 2022 WL 4244989, at *8 (D. Del. Sept. 15, 2022).

[9] Avail Medsystems, Inc. v. Teladoc Health, Inc., No. IPR2022-00444, 2022 WL 2903454, at *10 (P.T.A.B. July 21, 2022). See also Incyte Corp. v. Concert Pharms., Inc., No. PGR2021-00006, 2022 WL 1613509 (P.T.A.B. May 11, 2022) (admitting expert testimony as to drug design and administration but not the treatment of hair loss based on the definition of a POSA); cf. Takeda Pharm. Co. Ltd. v. Norwich Pharms., Inc., No. CV 20-8966 (SRC), 2022 WL 17959811, at *33 (D.N.J. Dec. 27, 2022) (noting that testimony on "any salt-related topic" should be excluded because expert did not meet the definition of a POSA).

[10] Kyocera, 22 F.4th at 1377.

[11] Osseo Imaging, LLC v. Planmeca USA Inc., No. 1:17-CV-01386-JFB, 2023 WL 1815975, at *2-3 (D. Del. Feb. 8, 2023).