How the Supreme Court Ghosted the PHOSITA: *Amgen* and Legal Constructs in Patent Law

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ABSTRACT: This Essay is an invited response to The Ghost in the Patent System: An Empirical Study of Patent Law's Elusive "Skilled Artisan," *by Professors Laura Pedraza-Fariña and Ryan Whalen. In their piece, Pedraza-Fariña and Ryan Whalen offer an empirical study and use it to argue for a new conception of the Person Having Ordinary Skill in the Art ("PHOSITA"), patent law's nod to the "reasonable person" construct.*

As Professors Pedraza-Fariña and Whalen suggest, the PHOSITA should be understood as a crucial concept in patent law, warranting more scholarly attention. Pedraza-Fariña and Whalen provide that attention. They assert, based on an original empirical analysis, that greater judicial engagement with the PHOSITA concept has not occurred—courts have instead continued to treat the PHOSITA construct superficially, and as a monolith. They offer two bases for this failure: (1) the lack of reconciliation between the empirical PHOSITA construct versus a set of normative aspirations that could be attributed to it; and (2) the failure of the courts to deploy the PHOSITA with a coherent set of normative commitments in mind. The antidote, say Pedraza-Fariña and Whalen, is to subdivide the monolithic PHOSITA into a set of doctrine-specific PHOSITAs, each formulated according to a blend of empirical and normative aspects tuned to the particular doctrine at issue. They summarize their prescriptions in a table that maps out the empirical and normative dimensions to these respective doctrine-specific PHOSITAs.

In this Response Essay, we offer two primary observations. First, in its most recent opinion on patent law—released after Pedraza-Fariña and Whalen's piece was published—the Supreme Court in Amgen v. Sanofi *displayed no interest in engaging with the PHOSITA construct and its subtleties. To the contrary, it utterly "ghosted" the ghost of the patent system (if we may), resolving a complex biotechnology enablement case about antibodies by*

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wallowing about in nineteenth century patent opinions dealing with nineteenth century inventions (of course) such as the telegraph, the incandescent light, and starch glue for wood veneer. Instead of taking the opportunity to refine the PHOSITA construct along empirical and normative lines, as Pedraza-Fariña and Whalen advocate, the Court treated the PHOSITA as a vaporous non-entity barely meriting mention. If there ever was a trend toward elucidating the PHOSITA's technical capacities and using them to drive case outcomes, the Supreme Court's Amgen *decision has brought that trend to a crashing halt—perhaps unwittingly and* sub silentio*, but a crashing halt nonetheless.*

Second, while we align with Pedraza-Fariña and Whalen's plea for acknowledging that normative aspirations undergird the PHOSITA construct, and we agree that those aspirations may supply a template for explaining and weighing empirical aspects of the construct, we part company with them when it comes to prescriptions. In particular, we are not convinced that dismembering the PHOSITA and reconstituting it as three separate constructs will improve decision making in patent cases. We contend that the enablement and obviousness PHOSITAs are the same construct and ought to stay that way. This is both a descriptive and normative argument, and it underscores that Pedraza-Fariña and Whalen's proposals are not normatively neutral, even though the authors profess not to be espousing any "specific normative baseline" for critical doctrines such as obviousness.

INTRODUCTION

In *The Ghost in the Patent System: An Empirical Study of Patent Law's Elusive "Skilled Artisan,"*[1] Professors Laura Pedraza-Fariña and Ryan Whalen offer an empirical study and use it to argue for a new conception of the Person Having Ordinary Skill in the Art ("PHOSITA"), patent law's nod to the "reasonable person" construct.[2]

As Professors Pedraza-Fariña and Whalen suggest, the PHOSITA should be understood as a crucial concept in patent law, warranting more scholarly attention.[3] Pedraza-Fariña and Whalen provide that attention. They argue that a trio of recent Supreme Court decisions[4] appeared to signal a greater solicitude for the PHOSITA, and an opportunity to develop its nuances.[5] They then assert, based on an original empirical analysis, that greater judicial engagement with the PHOSITA concept has not occurred—courts have instead continued to treat the PHOSITA construct superficially, and as a monolith.[6] They offer two bases for this failure: (1) the lack of reconciliation between the empirical PHOSITA construct versus a set of normative aspirations that could be attributed to it; and (2) the failure of the courts to deploy the PHOSITA with a coherent set of normative commitments in mind.[7] The antidote, say Pedraza-Fariña and Whalen, is to subdivide the monolithic PHOSITA into a set of doctrine-specific PHOSITAs, each formulated according to a blend of empirical and normative aspects tuned to the particular doctrine at issue.[8] They summarize their prescriptions in a table

1. Laura Pedraza-Fariña & Ryan Whalen, *The Ghost in the Patent System: An Empirical Study of Patent Law's Elusive "Skilled Artisan,"* 108 IOWA L. REV. 247 (2022).

2. Among other things, Pedraza-Fariña and Whalen look to the literature on the reasonable person construct, seeking insights for the PHOSITA. *Id.* at 280. There are points of analogy, to be sure, but it is also important to recognize the functional differences between the constructs. The reasonable person standard functions to force the analysis away from the decisionmaker's subjective predilections about acceptable behavior, substituting instead those of the hypothetical common person. Similarly, the PHOSITA construct functions to force the analysis away from the decisionmaker's subjective predilections about what amounts to invention or disclosure, substituting instead those of the hypothetical person of ordinary skill in the art. The difference is that in many tort cases, the judge or jury will have little difficulty adopting the sensibilities of the reasonable person, which should, almost by definition, be familiar to a layperson. Not so in patent cases. The perceptions of the PHOSITA should rarely mimic those of the lay person, and that is by design.

3. *Id.* at 249–50 (claiming that the PHOSITA "scaffolds every major patent doctrine"). Subject matter eligibility may be one exception; it is a major patent doctrine but is not moored tightly, if at all, to the perspective of the PHOSITA.

4. *Id.* at 251. *See generally* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007); Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014); Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318 (2015).

5. Pedraza-Fariña & Whalen, *supra* note 1, at 251.

6. *Id.* at 251–52.

7. *Id.* at 280.

8. *Id.* at 277–90.

that maps out the empirical and normative dimensions to these respective doctrine-specific PHOSITAs.[9]

In this Response Essay, we offer two primary observations. First, in its most recent opinion on patent law—released after Pedraza-Fariña and Whalen's piece was published—the Supreme Court in *Amgen v. Sanofi*[10] displayed no interest in engaging with the PHOSITA construct and its subtleties. To the contrary, it utterly "ghosted" the ghost of the patent system (if we may), resolving a complex biotechnology enablement case about antibodies by wallowing about in nineteenth century patent opinions dealing with nineteenth century inventions (of course).[11] What do inventions like the telegraph, the incandescent light, and starch glue for wood veneer have to do with antibodies? We think very little, unlike the Supreme Court.[12] Instead of taking the opportunity to refine the PHOSITA construct along empirical and normative lines, as Pedraza-Fariña and Whalen advocate, the Court treated the PHOSITA as a vaporous non-entity barely meriting mention. If there ever was a trend toward elucidating the PHOSITA's technical capacities and using them to drive case outcomes, the Supreme Court's *Amgen* decision has brought that trend to a crashing halt—perhaps unwittingly and *sub silentio*, but a crashing halt nonetheless.

Second, while we align with Pedraza-Fariña and Whalen's plea for acknowledging that normative aspirations undergird the PHOSITA construct, and we agree that those aspirations may supply a template for explaining and weighing empirical aspects of the construct, we part company with them when it comes to prescriptions. In particular, we are not convinced that dismembering the PHOSITA and reconstituting it as three separate constructs will improve decision making in patent cases. We contend that the enablement and obviousness PHOSITAs are the same construct and ought to

9. *Id.* at 291.

10. *See generally* Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).

11. *Id.* at 605–10 (discussing *O'Reilly* v. *Morse*, 15 How. 62, 14 L.Ed. 601 (1854), *The Incandescent Lamp Patent*, 159 U.S. 465 (1895), and *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928)). By no means are we making a blanket argument against the use of history in patent law analysis; we have used it liberally in our own writings. *See, e.g.*, Mark D. Janis, *Mr. Nicolson's Cane*, 59 ARIZ. L. REV. 647, 648 (2017) (discussing the "peculiar iconography" of patent law); Jason J. Du Mont & Mark D. Janis, *The Origins of American Design Patent Protection*, 88 IND. L.J. 837, 840, 848–74 (2013) (providing "a historical analysis of the design patent system's origins"); Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 64–68 (2000) (discussing the role of history in the written description requirement). Well, okay, maybe only one of us really has used history, though the other has gestured to it. *See* Timothy R. Holbrook, *Patent Anticipation and Obviousness as Possession*, 65 EMORY L.J. 987, 1009 (2016); Timothy R. Holbrook, *The Written Description Gap*, 45 LOY. U. CHI. L.J. 345, 352–53 (2013). Our argument against the use of history in *Amgen* is that the Court extrapolated ineptly from historical sources in this case, elevating them in importance over technical attributes of the PHOSITA.

12. *See Amgen*, 598 U.S. at 606 ("While the technologies in these older cases may seem a world away from the antibody treatments of today, the decisions are no less instructive for it.").

stay that way.[13] This is both a descriptive and normative argument, and it underscores that Pedraza-Fariña and Whalen's proposals are not normatively neutral, even though the authors profess not to be espousing any "specific normative baseline" for critical doctrines such as obviousness.[14]

I. *AMGEN*—A REQUIEM FOR SOMETHING NOT EVER QUITE ALIVE?

Professors Pedraza-Fariña and Whalen assert that the Supreme Court opened the door to a reconsideration and elevation of the PHOSITA in its decision in *KSR Int'l Co. v. Teleflex Inc.*[15] The authors characterize the Supreme Court's decision as a "revolution" and a "watershed decision."[16] Indeed, the authors note the potential spillover from *KSR* into other areas, such as claim construction, definiteness, and (of particular relevance here), enablement.[17]

If *Amgen* is any indication, the revolution discerned by Pedraza-Fariña and Whalen was short-lived, if it ever was alive. Faced with an important dispute over the enablement doctrine in a case involving complex antibody technology, the Court barely mentioned (let alone enfleshed) the PHOSITA. Viewed through the lens of Pedraza-Fariña and Whalen's arguments, *Amgen* could be taken as a reactionary decision, undermining the work that the Court did in *KSR* to elevate the prominence of the PHOSITA. Even if *Amgen* is not viewed as a significant step backwards, it is at best an ambiguous step sideways, adding nothing to our understanding of the role of the PHOSITA and potentially doing great damage to enablement doctrine by casually leaving the way open for further development of the notion of "full scope" enablement—a notion that might turn out to be unmoored entirely from the PHOSITA in future applications.

A. *THE HIGH STAKES IN* AMGEN

Amgen involved a dispute over antibodies designed to reduce levels of low-density lipoprotein ("LDL") cholesterol by blocking a protein ("PCSK9") that binds and degrades receptors used to reduce LDL.[18] Amgen's patent claimed the genus of antibodies that bind to specific amino acids on PCSK9 and block PCSK9 from interfering with the removal of LDL cholesterol from the bloodstream.[19] The claimed genus was large, arguably covering "millions" of antibodies that would carry out the two claimed functions.[20] The patent disclosed the structures of twenty-six antibodies that performed the claimed functions, along with two methods (the "roadmap" and "conservative

13. We take a slightly different view as to the PHOSITA to be invoked in infringement doctrines. *See infra* note 97 and accompanying text.

14. Pedraza-Fariña & Whalen, *supra* note 1, at 283.

15. *See generally* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

16. Pedraza-Fariña & Whalen, *supra* note 1, at 256–57.

17. *Id.* at 257–58.

18. Amgen Inc. v. Sanofi, 598 U.S. 594, 598 (2023).

19. *Id.* at 599.

20. *Id.* at 603.

substitution") for making other antibodies that would perform the claimed function.[21] Sanofi argued that the disclosure in Amgen's patent was inadequate to support Amgen's genus claims, such that the claims should be ruled invalid for violating the statutory requirement that the patent document "enable any person skilled in the art" to make and use the claimed invention.[22]

The dispute can be framed in terms of the capacities of the PHOSITA in antibody technology. Sanofi was arguing that a PHOSITA relying on the Amgen patent disclosure would have needed to engage in substantial trial and error to make the millions of antibodies covered by the claims, given the unpredictability of antibody technology and the limited guidance (according to Sanofi) provided in the patent disclosure.[23] Amgen was arguing that a PHOSITA armed with the Amgen patent disclosure could use the disclosed methods to reliably generate additional antibodies.[24] So understood, the case was an excellent vehicle for a deep dive into the characteristics of the relevant PHOSITA and for an illustration of how those characteristics could influence the outcome in the important patentability doctrine of enablement.

The trial court ruled for Sanofi and the Federal Circuit affirmed.[25] The Federal Circuit's opinion was notable in that the court concluded that the enablement requirement called for the patentee to teach the PHOSITA how to make and use "not only the limited number of embodiments that the patent discloses, but also the full scope of the claim."[26] This reference to "full scope" enablement was crucial. Taken to its extreme, it might be understood to require the patentee to delineate for the PHOSITA preparation methodologies for each and every one of the apparent millions of antibodies covered by the claims, a requirement that would be impracticable, if not impossible, to satisfy. [27] Moreover, although some prior Federal Circuit decisions had referred to "full scope" enablement, the Federal Circuit had not adopted this extreme version of the doctrine.[28] Resolving this question—and doing so by harnessing the PHOSITA construct and its potential subtleties—was another excellent reason for the Court to take up the case.

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21. *Id.*

22. 35 U.S.C. § 112(a) (2018).

23. *Amgen*, 598 U.S. at 599.

24. *Id.*

25. *Id.*

26. Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1086 (Fed. Cir. 2021) (specifying that this notion of "full scope" enablement was important "for claims that include functional requirements . . . especially where predictability and guidance fall short").

27. *See* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1175 (2008).

28. *See* Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 21–35 (2021) (tracking the evolution of the doctrine).

B. The Centrality of the PHOSITA in Enablement Analysis

As Professors Pedraza-Fariña and Whalen note, the Patent Act specifically references the PHOSITA (though not with that exact phrasing) in two places: in § 103's non-obviousness requirement and in § 112(a)'s discussion of the enablement requirement.[29] But neither provision offers any guidance on how to concretize the PHOSITA, leaving that task for common law development.

Although the PHOSITA is present in these two places, we do think that Pedraza-Fariña and Whalen give too much credit to the 1952 Patent Act for "standardiz[ing] the concept" of the PHOSITA and "establish[ing] its centrality."[30] Regarding its centrality, long before the 1952 Act, the PHOSITA concept (or its linguistic variants) figured in patent law analysis. One could even go so far as to say that the PHOSITA was present at the birth, given that language referencing the person skilled in the art appears in the 1790 Patent Act.[31] As for standardization, the 1952 Act undoubtedly standardized the *phrase* "person of ordinary skill in the art" (or close variants), and that was no small thing, but the Act left a great deal of work to be done in standardizing the *concept*. The Supreme Court's post-1952 obviousness jurisprudence illustrates the point. For example, the prominent role of the PHOSITA in the obviousness analysis articulated in *Graham v. John Deere Co.*[32] (and *KSR*) sharply contrasts with that in *Anderson's-Black Rock v. Pavement Co.* and *Sakraida v. Ag Pro, Inc.*[33]

Nevertheless, we do recognize that most of the development of the PHOSITA has occurred in connection with obviousness jurisprudence, not in

29. 35 U.S.C. §§ 103, 112(a) (2018) (mentioning "a person having ordinary skill in the art" and "any person skilled in the art," respectively).

30. Pedraza-Fariña & Whalen, *supra* note 1, at 253.

31. Patent Act of 1790, 1 Stat. 109 § 2 (1790) (requiring that the patent document disclose the invention sufficiently "to enable a workman or other person skilled in the art of manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same").

32. Graham v. John Deere Co., 383 U.S. 1, 17–25 (1966) (setting forth a three-part test for obviousness that focused on the PHOSITA).

33. *See generally* Anderson's-Black Rock v. Pavement Co., 396 U.S. 57 (1969) (resolving an obviousness dispute by invoking the legal principle of "synergism," without any serious analysis of the character of the relevant PHOSITA); Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976) (same).

other areas such as claim construction[34] or patent infringement.[35] In *KSR*, the Supreme Court said as much as it ever has about the nature of the PHOSITA. The PHOSITA, the Court indicated, is not so narrow-minded as to be solely consumed with the very problem that the inventor was subjectively attempting to solve with the claimed invention; rather, the PHOSITA is capable of analogizing to "*any* need or problem known in the field of endeavor at the time of invention."[36] The PHOSITA is "a person of ordinary creativity, not an automaton,"[37] and hence is capable of resorting to common sense. The PHOSITA is capable of engaging in trial and error, especially when motivated by technological or marketplace pressures: "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp."[38] This is a portrait of a hypothetical person equipped with baseline analytical skills acquired, presumably, through a combination of education and experience

34. In contrast to Pedraza-Fariña and Whalen, we would not expect much significant development of the PHOSITA construct to occur in the context of claim construction or definiteness cases, and the Court's prominent recent cases on those doctrines (*Teva Pharms. USA, Inc. v. Sandoz, Inc.* and *Nautilus, Inc. v. Biosig Instruments, Inc.*) bear out this expectation. *Teva* focused on the standard of review for claim construction, which only incidentally implicates the PHOSITA. As the Court noted, there could be factfinding as to a term's "particular meaning to a person of ordinary skill in the art at the time of the invention." Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 332 (2015). But that factfinding would still need to survive a legal analysis of "whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*." *Id.* Such an approach discounts the PHOSITA. Similarly, while *Nautilus* acknowledged that "[d]efiniteness is measured from the viewpoint of a person skilled in [the] art *at the time the patent was filed*," it also offered little to inform the construct. Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 908 (2014) (quoting Brief for Respond ent, Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014) (No. 13-369), 2014 WL 126 0426, at *55). As definiteness essentially is a corollary to claim construction, we are not surprised that these cases failed to advance the development of the PHOSITA.

35. Modern Supreme Court cases on patent enforcement similarly offer little on the nature of the PHOSITA. For example, in assessing the doctrine of equivalents in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, the Court only referred to a "skilled practitioner," with few additional details. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 37 (1997) ("a skilled practitioner's knowledge of the interchangeability between claimed and accused elements is not relevant for its own sake, but rather for what it tells the factfinder about the similarities or differences between those elements."). The PHOSITA is similarly absent in the Court's analysis of prosecution history estoppel. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 738 (2002) (discussing unforeseeability and tangential relationship rebuttal of the *Festo* pre sumption with no reference to the PHOSITA). While the "tangential relationship" rebuttal of the presumption of prosecution history estoppel would seem more directed to a patent attorney, the unforeseeability rebuttal certainly must be rooted in part in the PHOSITA and the state of the art, yet the Court had nearly nothing to say about that. Mark D. Janis & Timothy R. Holbrook, *Patent Law's Audience*, 97 MINN. L. REV. 72, 104–05 (2012). *KSR*'s more robust discussion of the PHOSITA may be the anomaly rather than an indication of a trend.

36. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420 (2007) (emphasis added).

37. *Id.* at 420–21.

38. *Id.* at 421.

in the field. It is a hypothetical person operating in the technical world but also aware of the market. In short, this PHOSITA is no mere dullard.

Some of these same PHOSITA characteristics can also be found in the enablement jurisprudence predating *Amgen*. Generally, these characteristics have been interjected into the analysis through the undue experimentation inquiry, which has been the primary analysis driving the modern enablement analysis, at least in Federal Circuit cases.[39]

Indeed, the undue experimentation inquiry could be said to define the enablement analysis. What we mean by that is the following. The enablement requirement has never demanded that inventors teach their inventions in such overwhelming detail that a mere layperson could replicate them. That would impose prohibitive costs without concomitant benefits to the public because the information needed to get a layperson up to speed would be readily available from other sources. Instead, the statute only requires that the inventor provide a disclosure sufficient to enable the PHOSITA to make and use the claimed invention.[40] The difference between the PHOSITA and the layperson is that the PHOSITA has acquired baseline analytical skills, background knowledge, and experience—that is, the sorts of characteristics discussed in the context of obviousness in *KSR*. In particular, the enablement jurisprudence has recognized that one of the intrinsic characteristics of the PHOSITA is the capacity for reasonable experimentation. From this emerges the undue experimentation inquiry: Courts have generally said that enabling a PHOSITA to make and use the invention means providing sufficient guidance such that a PHOSITA could arrive at the invention, even if the PHOSITA must undertake some experimentation—i.e., experimentation that is not "undue," but rather is reasonable.[41]

Fleeting references to undue experimentation can be found in pre-*Amgen* Supreme Court cases.[42] But the Federal Circuit has been primarily responsible for developing the inquiry. The seminal decision is *In re Wands*.[43] Coincidentally, and perhaps ironically, *Wands*, like *Amgen*, involved a patent involving antibodies: the "invention involves immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal

39. *See, e.g.*, Cephalon, Inc. v. Watson Pharms., Inc., 707 F.3d 1330, 1336–40 (Fed. Cir. 2013); ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940–43 (Fed. Cir. 2010); *Wands*, 858 F.2d at 736–39.

40. 35 U.S.C. § 112(a) (2011).

41. *See, e.g.*, Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc., 996 F.3d 1342, 1350–52 (Fed. Cir. 2021) (upholding jury's determination that the disclosure *was not* adequate to permit a PHOSITA to practice the invention without undue experimentation); Bayer Health care LLC v. Baxalta Inc., 989 F.3d 964, 981–82 (Fed. Cir. 2021) (upholding jury's determination that the disclosure *was* adequate to permit a PHOSITA to practice the invention without undue experimentation).

42. *See* Mins. Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916) ("Such variation of treatment must be within the scope of the claims, and the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.").

43. *See generally In re Wands*, 858 F.2d 731.

antibodies of the IgM isotype."[44] In *Wands*, the Federal Circuit confirmed that enablement is measured by whether the PHOSITA could practice the claimed invention without undue experimentation.[45] The court distilled eight non-exclusive factors that have come to be dubbed the *Wands* factors:

(1) the quantity of experimentation necessary,
(2) the amount of direction or guidance presented,
(3) the presence or absence of working examples,
(4) the nature of the invention,
(5) the state of the prior art,
(6) the relative skill of those in the art,
(7) the predictability or unpredictability of the art, and
(8) the breadth of the claims.[46]

Collectively, the *Wands* factors can be understood as identifying the skills and background for the factfinder that the hypothetical PHOSITA brings to bear when hypothetically perusing the patent document for evidence that the invention was disclosed in sufficient detail to satisfy the § 112(a) enablement requirement. And the inquiry defined by those factors illustrates the primacy of the PHOSITA in the enablement analysis.

For example, for antibody inventions such as those in *Wands* and *Amgen*, no one would argue that inventors must supply a disclosure in the form of a several-hundred-page tome tracing antibody research back to its inception in von Behring and Kitasato's 1890 diphtheria studies,[47] and facts elicited through the undue experimentation inquiry show why: a PHOSITA would already know all that. Likewise, it should be the rare case to argue that a patent document that expressly describes a handful of antibodies can as a matter of law enable only that handful and nothing more, because the relevant PHOSITA in antibody research, as in virtually all other fields, would surely have the capacity for *some* experimentation.[48]

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44. *Id.* at 733.

45. *Id.* at 737.

46. *Id.* (formatting added).

47. *See* Jonathan D. Kaunitz, *Development of Monoclonal Antibodies: The Dawn of mAB Rule*, 62 DIGESTIVE DISEASES & SCIS. 831, 831 (2017) (crediting von Behring and Kitasato with the discovery of antibodies).

48. This aspect of enablement analysis is critical, because without it, enablement would be reduced to the ministerial exercise of confirming that the claims recited, *ipsissimis verbis*, only what the patent document expressly disclosed and nothing more. That would be a dramatic departure from decades of patent jurisprudence and could result in a significant diminution of claim scope for many patents. Yet the Solicitor Generals seemed willing to take the law in that direction, suggesting that the enablement inquiry could be reduced to such legalistic bon mots as "where a patentee purports to invent an entire genus, it must enable the entire genus." Brief

The Supreme Court in *Amgen* had the opportunity to elaborate on how much capacity the relevant PHOSITA possessed, and how courts in the future might go about undertaking such calculations, perhaps drawing some lessons from *KSR*. Instead, as we detail below, the Court offered an analysis in which the already ghostly PHOSITA vanished entirely.

C. THE SUPREME COURT'S ENABLEMENT ANALYSIS IN AMGEN

The Court's opinion in *Amgen* begins with a lengthy primer on the technology, the groundwork one might expect antecedent to an inquiry into the relevant PHOSITA's capacity to extrapolate, through experimentation, from Amgen's disclosure.[49]

Nope.

Instead of wrestling with the technology and its intersection with the PHOSITA, explaining the importance of measuring the knowledge of the PHOSITA (and necessarily the PHOSITA's identity) to inform the teaching of the Amgen patent, the Court offered a nutshell recitation of the legal history of the enablement requirement at the Supreme Court, which amounted to a thimbleful of cases arising primarily in the mid- to late-nineteenth century.[50]

From this review of its own cases, the Court derived a set of enablement "principles," one of which was full scope enablement. The Court declared that if a patent claims an "entire class" of subject matter, it must "enable a person skilled in the art to make and use the entire class," which meant, the Court said, that the specification must "enable the full scope of the invention as defined by its claims."[51] On the other hand, the Court added another principle (or is it a corollary to the first?): full scope enablement did not mandate that "a specification must always describe with particularity how to make and use every single embodiment within a claimed class" because, in some cases, disclosing a few examples or a "general quality" of the claimed invention "may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset."[52] That all gives the appearance of evenhandedness, and it does at least gesture to the PHOSITA. But the principles are so abstract as to be largely meaningless. What the Court's discussion really demonstrates is the futility of attempting to resolve

for the United States as Amicus Curiae Supporting Respondents, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2022 WL 4386300, at *9.

49. The Court's technical discussion was based almost exclusively on the amici brief filed by various world-renowned scientists, including Nobel Prize winner Sir Gregory Paul Winter. *See Amgen Inc.*, 598 U.S. at 599–600. While clearly the authors of the amici brief are experts, we leave for another day considering whether it is appropriate for the Court to rely so extensively on evidence outside the record, seemingly under the guise of judicial notice. (Or perhaps we should conclude that the evidence was already implicitly present in the record, as an artifact of the substantial knowledge that the PHOSITA would possess.).

50. *Id.* at 605–11.

51. *Id.* at 610.

52. *Id.* at 610–11.

enablement disputes by deploying legal abstractions. The Court instead could have embraced the fact-bound nature of the enablement inquiry and need for case-by-case adjudication. A robust conception of the PHOSITA is critical in such an analysis.

The Court added a further corollary: § 112 permits "a reasonable amount of experimentation to make and use the patented invention."[53] The Court did not invoke the phrase "undue experimentation,"[54] nor did it cite *Wands* or the undue experimentation factors test, although it did observe that "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art."[55] What the Court did not seem to recognize is that the undue experimentation inquiry ought to be the heart of the analysis, providing, as it does, a mechanism for examining what background skills and knowledge a PHOSITA would bring to the patent disclosure, and what understanding the PHOSITA would take away from it. Again, enablement analysis ought to be steeped in the technical facts rather than being largely an exercise in reading patent law treatises.[56]

The Court's application of its "principles" shows how impoverished enablement law would become if the PHOSITA (and the surrounding constellation of technical facts) is relegated to a back seat in the analysis. The Court turned back to its review of its nineteenth century cases, noting (somewhat perplexingly) "[w]hile the technologies in these older cases may seem a world away from the antibody treatments of today, the decisions are no less instructive for it."[57] The Court asserted that Amgen was seeking to "monopolize an entire class of things defined by their function" in a manner analogous to the earlier cases[58]:

> Much as Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for wood veneering,

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53. *Id.* at 612.

54. We assume that in future case the Federal Circuit will treat unreasonable experimentation as synonymous with undue experimentation. *See, e.g.*, Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362, 1363–65 (Fed. Cir. 2023) (mem). The PTO has already instructed its exam iners to do so. USPTO, *Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in* Amgen Inc. et al. v. Sanofi et al., 89 Fed. Reg. 1563, 1565–66 (Jan. 10, 2024) (endorsing the continued use of the *Wands* factors).

55. *Amgen*, 598 U.S. at 612. The Court also asserted that "[t]he more one claims, the more one must enable," which could be said to reflect the "breadth of claims" factor from the *Wands* test. *See id.* at 610.

56. We think that Pedraza-Fariña and Whalen have a similar view. *See* Pedraza-Fariña & Whalen, *supra* note 1, at 285.

57. *See Amgen*, 598 U.S. at 606; *see also id.* at 613 ("While the technology at the heart of this case is thoroughly modern, from the law's perspective Amgen's claims bear more than a passing resemblance to those this Court faced long ago in *Morse*, *Incandescent Lamp*, and *Holland Furniture*.").

58. *Id.* at 613.

> Amgen seeks to claim 'sovereignty over [an] entire kingdom' of antibodies.[59]

But virtually any patent could be characterized as seeking exclusive rights over classes of things, and the modern statute (enacted some decades after the cases the Court cites) expressly authorizes claiming by function.[60]

In concluding that the claims were not enabled, the Court rejected Amgen's arguments that the claims were enabled "because scientists can make and use every undisclosed but functional antibody if they simply follow the company's 'roadmap' or its proposal for 'conservative substitution.'"[61] The Court rejected that contention, although not by tying it to the PHOSITA. Instead, it characterized the two approaches as "little more than two research assignments" requiring "trial-and-error" and making substitutions and then checking if they work, respectively.[62] The Court then, again, drew comparisons to its earlier cases. While conceding that these two approaches "might suffice to enable other claims in other patents" in a manner akin to *Incandescent Lamp*'s admonition that common qualities could suffice,[63] these methods "le[ft] a scientist about where Sawyer and Man left Edison: forced to engage in 'painstaking experimentation' to see what works."[64] The Court then rejected Amgen's various policy-related challenges.[65] Confirming the Court's focus on analogy and not technology, the Court concluded (with a pun), "[i]f the Court had not done so in *Incandescent Lamp*, it might have been writing decisions like *Holland Furniture* in the dark. Today's case may involve a new technology, but the legal principle is the same."[66]

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59. *Id.*

60. The Supreme Court expressed its opposition to the practice of functional claiming in *Halliburton Oil Well Cementing Co. v. Walker* 329 U.S. 1, 13 (1946). Congress partially overruled *Halliburton* when it enacted a provision now codified in 35 U.S.C. § 112(f), which permits functional claiming but limits the claim to structures disclosed in the specification that performs the function and equivalents to those structures. For views on the implications for modern patent practice, *see, e.g.*, Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 905 (2013) (analyzing and exploring how "the real problem with software patents" is that "software patent lawyers are increasingly writing patent claims in broad functional terms"); Mark D. Janis, *Who's Afraid of Functional Claims: Reforming the Federal Circuit's §112, ¶6 Jurisprudence*, 15 SANTA CLARA COMP. & HIGH TECH. L.J. 231, 234 (1999) ("reflect[ing] on the fear and loathing of functional claims" and undertaking a "historical synthesis" that leads "to the formulation of a two-track reform proposal" for the future of patent legislation).

61. *Amgen*, 598 U.S. at 613–14.

62. *Id.* at 614.

63. *Id.* at 614; *see* The Incandescent Lamp Pat., 159 U.S. 465, 472 (1895) ("If the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad.").

64. *Amgen*, 598 U.S. at 614.

65. *Id.*

66. *Id.* at 616.

D. THE IMPLICATIONS OF AMGEN *AND THE SUPREME COURT'S GHOSTING OF THE PHOSITA*

A few implications of *Amgen* are clear, albeit all too few. First, it seems apparent that courts will regularly parrot the language of "full scope" enablement, without coming any nearer to understanding what it means. For the Federal Circuit, we expect that judges who are inclined toward the extreme version of full scope enablement will have some room to indulge that preference without having to engage with the perspective of the PHOSITA.[67] Federal Circuit judges who are otherwise inclined will presumably lean on the Court's limiting corollary that enablement does not require that all embodiments of a given invention must be expressly described with particularity. We doubt whether an endless colloquy of this sort advances the enablement law.[68]

Second, lower courts may well pick up on the Court's apparent bias against functional claims, scrutinizing those claims closely for § 112 compliance. But the Federal Circuit's enablement and written description cases already reflected that bias.[69]

Third, and most relevant here, *Amgen* may embolden lower courts to conduct enablement analysis primarily as an exercise in case law analogizing, with little regard for the use of the PHOSITA construct. To be sure, the Court

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67. One of us saw this coming. Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 805 (2011) ("[P]art of the problem is that the court is finding the patent specifications inadequate when, from the viewpoint of the PHOSITA, they very well may be sufficient."). For other critiques, see Karshstedt, Lemley, and Seymore, *supra* note 28, at 55–56; Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 137 (2008) ("This reflects a recent interest in 'full scope' enablement which has appeared in other recent predictable-art cases, suggesting a single embodiment is no longer sufficient to enable a PHOSITA in these fields."). It did not take long for the Federal Circuit to invoke *Amgen* for the embrace of full scope enablement. *See In re* Starrett, No. 2022-2209, 2023 WL 3881360, at *4 (Fed. Cir. June 8, 2023). That said, the claim was for telepathy, so it is highly probable the claims were not enabled—although the argument seems inevitable that the relevant enabling disclosure had been conveyed telepathically anyway.

68. The embrace of an extreme form of full scope enablement would disrupt many aspects of patent law, an outcome we doubt the Court recognized. Consider some longstanding rules of infringement. To date there has been no requirement that a patent claim enable each and every accused infringing product that might fall within the scope of that claim, but under an extreme version of full scope enablement, such a requirement might be imposed. This could mean that the owner of a broad claim to a pioneering invention could not successfully assert that claim against subsequent developers of improvements. *See* Timothy R. Holbrook, *Equivalency and Patent Law's Possession Paradox*, 23 HARV. J.L. & TECH. 1, 12 (2009) (discussing this scenario and noting that "if the improvement were a non-obvious one, the original patent likely would not have enabled it."). Similar situations can arise if the earlier patent is practiced by using a newly discovered material. *See* Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459, 1510 (2016) (discussing a hypothetical that illustrates the point). There is much more to say on the subject, but because much of it is not germane to Pedraza-Fariña and Whalen's paper, we will leave it for another day.

69. *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc) (noting written description problems are "especially acute with genus claims that use functional language to define the boundaries of a claimed genus").

made limited reference to scientists and persons skilled in the art in its reasoning, but the Court gave no indication that evidence regarding the PHOSITA's skill set drove the analysis, or even weighed much in it. Instead, the Court made comparisons to earlier, far simpler technologies without accounting for how the state of any art has evolved. Antibodies may be more complex than lightbulbs or glue, but the skills of the ordinary artisan in antibody research have also evolved in the last one hundred plus years.

Amgen had posited two different methods that would enable the claimed invention, the roadmap, or the conservative substitution. The Court rejected those two approaches as "little more than two research assignments."[70] As to the former the Court noted that scientists would need "to create a wide range of candidate antibodies and then screen each" to see if it functioned.[71] As to the latter, the Court noted "[i]t requires scientists to make substitutions to the amino acid sequences of antibodies known to work and then test the resulting antibodies to see if they do too—an uncertain prospect given the state of the art."[72]

This passing attention to the PHOSITA is discouragingly superficial—and we presume that Pedraza-Fariña and Whalen would agree with that assessment. The conclusions about how much effort would be required references back primarily to its own discussion, informed by an amici brief and not the record in the case. There is no development as to whether such processes are in fact onerous or whether they are routine in the art. Who is the PHOSITA for making this assessment? What is the skill level? Would the act of reviewing this specification entail some level of creativity, or is the PHOSITA required to merely follow the instructions, like following a recipe without any personal additions?

Moreover, as we have previously noted, the focus of the Court's analysis is misdirected: it indulges more in case law comparison than engaging with the technological facts.[73] The Court's conclusion may confirm this: "[t]oday's case may involve a new technology, but the legal principle is the same."[74]

Ironically, in the long term, the Court's *Amgen* opinion may demonstrate through its deficiencies the wisdom of Pedraza-Fariña and Whalen's assertion that the PHOSITA should lie at the center of an enablement analysis.

II. REFLECTIONS ON PROPOSALS FOR A THREE-HEADED, NORMATIVE PHOSITA

Notwithstanding the harm that the Supreme Court's decision in *Amgen* may cause to efforts to develop a more robust PHOSITA, we also have some thoughts as to the proposals made by Professors Pedraza-Fariña and

70. *Amgen*, 598 U.S. at 614.

71. *Id.*

72. *Id.*

73. It surprises us that a Court that values textualism would treat the PHOSITA so casually, given that the text of § 112(a) specifies that it is the PHOSITA who must be enabled.

74. *Amgen*, 598 U.S. at 616.

Whalen about (1) the nature of the PHOSITA as both an empirical and normative creature; and (2) subdividing the PHOSITA into at least three doctrine-specific PHOSITAs.

We precede this discussion with a methodological quibble. The springboard for the analysis by Professors Pedraza-Fariña and Whalen is the level of the courts' engagement with the PHOSITA, a matter that the Article attempts to test empirically. This is tricky business. Their empirical analysis tests how much courts talk about the PHOSITA in their opinions, but we wonder whether that is a reliable proxy for the level of engagement. We can think of examples where it isn't. For instance, we can imagine a case in which the parties present extensive conflicting evidence on the characteristics of the PHOSITA, the court carefully sifts through the evidence, resolves the conflict, and reports the outcome of its determination in a matter of a concise sentence or two. Such an analysis might be recorded as an instance of low engagement, when, in reality, it is something considerably more. Of course, such an approach would not have the effect of grafting more flesh onto the PHOSITA in a public-facing judicial opinion. But courts may be wrestling more with the construct than may surface in their study.

A. THE PHOSITA AS A (PARTLY) NORMATIVE CREATURE

Based in part on their empirical study, Pedraza-Fariña and Whalen castigate courts for failing to reconcile the normative and positive dimensions of the PHOSITA, which connects to a further criticism that courts have failed to consider the normative role for the PHOSITA distinctly in three different areas, obviousness, enablement, and infringement. We agree as to the first aspect of their assessment but part ways as to the second.

We agree that the PHOSITA should be more than an empirical reflection of a person currently operating in the relevant technological art. The Pedraza-Fariña and Whalen analysis reminds us of claims made by Professor Graeme Dinwoodie in the trademark context, suggesting trademark law should not pretend to merely reflect what consumers actually think but instead should be more transparent about its often-buried normative commitments.[75] Decrying the "fetish of empiricism," Dinwoodie argues that trademark law should incorporate normative elements that shape consumer understanding and "achieve [desired] policy goals beyond validating [consumer] understanding."[76]

Likewise, courts considering the PHOSITA should do more than interrogate the nature of a technologist operating in the field. To do otherwise would leave patent law beholden to empirical assessments of technologists. Because technology is dynamic, patent law doctrines will always be unsettled at a certain level. An entirely empirical PHOSITA could lead to

75. Graeme B. Dinwoodie, *Trademark Law as a Normative Project*, SING. J. LEGAL STUD. (forthcoming) (manuscript at 26–28), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4344834 [https://perma.cc/SL93-A928].

76. *Id.* (manuscript at 1).

even less stability and potentially feedback loops that could send the law down an inappropriate path.[77] Because the PHOSITA is the fulcrum for so many doctrines in patent law, it is vital that courts recognize that the PHOSITA necessarily entails policy assessments that may impact the innovation landscape. We take Pedraza-Fariña and Whalen as agreeing with these points.

The really difficult step, however, is the one that follows: establishing the normative principles that (together with empirical attributes) animate the PHOSITA, or PHOSITAs, as it may be. Understandably, Pedraza-Fariña and Whalen seem to be saying that they don't want to go there; they say that they are only proposing that courts recognize the normative dimension of the PHOSITA, without purporting to establish any particular normative baseline.[78] That leaves us uneasy. It will be hard for courts to take consequential action on Pedraza-Fariña and Whalen's proposal if, as we suspect, there is no consensus on the normative principles that the PHOSITA is supposed to be reflecting. Moreover, we think that Pedraza-Fariña and Whalen do go there, particularly in their characterizations of the distinctions between the enablement and obviousness PHOSITAS, as we discuss next.

B. Is the PHOSITA Monolithic or Multifarious?

In both this piece and in earlier work, Pedraza-Fariña and Whalen suggest that the courts err by considering the PHOSITA to be a monolith.[79] Instead, they view the PHOSITA as three distinct constructs, one each for obviousness, enablement, and infringement.

We are unpersuaded. In particular, we are not convinced that the obviousness PHOSITA and the enablement PHOSITA are necessarily distinct. Moreover, we think that even more granularity may be required in the infringement context given the legal nature of some of the inquiries that surround the ultimate judgment of whether a patent is infringed.

Professors Pedraza-Fariña and Whalen suggest that the obviousness and enablement PHOSITA do and should differ on a number of dimensions. As to obviousness, they recognize that "*KSR* left open the question of *which* is the relevant innovation community," an important normative question.[80] The authors also reject the fiction that the obviousness PHOSITA, beyond having ordinary skill, is omniscient, knowing all of the relevant prior art.[81] In their view, the "perfectly informed PHOSITA" fails both normatively and

77. *Cf.* James Gibson, *Risk Aversion and Rights Accretion in Intellectual Property Law*, 116 YALE L.J. 882, 885 (2007) ("In other words, even if intellectual property owners are guileless or have no interest in gaming the system, and even if statutes and case law are not overly favorable to rights-holders, the combination of ambiguous doctrine and risk-averse licensing will, over time, cause entitlements to grow and public privilege to shrink.").

78. Pedraza-Fariña & Whalen, *supra* note 1, at 283 (regarding the normative baseline for the PHOSITA in obviousness).

79. Laura G. Pedraza-Fariña & Ryan Whalen, *A Network Theory of Patentability*, 87 U. CHI. L. REV. 63, 65 (2020).

80. Pedraza-Fariña & Whalen, *supra* note 1, at 282.

81. *Id.* at 283.

empirically. Finally, the obviousness PHOSITA "is a member of a community of researchers whose members attempt to innovate," meaning that the construct "has the highest, most direct form of expertise consisting of both codified and tacit knowledge."[82] That "PHOSITA is a researcher actively engaged in learning and research who both understands written documents *and* is steeped in everyday experimental life."[83]

In contrast, Pedraza-Fariña and Whalen view the enablement PHOSITA as merely "the *user* of the invention" as opposed to the more innovative obviousness PHOSITA.[84] Agreeing with Professors Mark Lemley and Dan Burk, the authors contend that an inventor may be different from an ordinary user.[85] Under this view, the enablement PHOSITA is not able "to meaningfully contribute to advances in the field."[86] Crucially, this PHOSITA is deemed to lack the tacit knowledge of the obviousness PHOSITA.[87]

We are not convinced that this distinction carries much water. In terms of knowledge of the prior art, minimally it is an open question whether the enablement PHOSITA also is omniscient as described in current caselaw.[88] It isn't clear to us, however, that the knowledge of the PHOSITA informs *who* the PHOSITA is. The construct is distinct from the knowledge this person has. In a related vein, *Graham* specifically calls out the level of ordinary skill in the art as a factor relevant to obviousness. The level of skill is distinct from who the identity of the PHOSITA is. This factor is not merely a construction of the PHOSITA.

Moreover, we tend to believe that both PHOSITAs should be charged with complete knowledge of the prior art. Why? First, obviousness does have a filter for prior art: the references must be analogous art.[89] Unlike anticipation, there is some winnowing down of the prior art. More importantly, the omniscient PHOSITA simplifies litigation by avoiding costly disputes over whether prior art should count for purposes of the analysis. We suspect that is why the America Invents Act failed to include a definition of prior art that was limited to what the PHOSITA could find through a

82. *Id.* at 284.

83. *Id.*

84. *Id.* at 285. For purposes of our discussion, we will focus on enablement as delineated in 35 U.S.C. § 112(a). We acknowledge that enablement is pervasive throughout patent law, which has interesting implications. *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 146–73 (2005). We think that the PHOSITA for these enablement situations, though, would be the same.

85. Pedraza-Fariña & Whalen, *supra* note 1, at 285 (quoting Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1189–90 (2002)).

86. *Id.*

87. *Id.*

88. 3 DONALD S. CHISUM, CHISUM ON PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 7.03 (2021) ("If the person with skill in the art under Section 112 is not presumed to know all the prior art, the question becomes—how much of the prior art can he be deemed to know?").

89. *See, e.g.*, Netflix, Inc. v. DivX, LLC, 80 F.4th 1352, 1358 (Fed. Cir. 2023).

reasonable search.[90] One of us has argued that public accessibility is the most relevant element of the prior art, not merely whether the PHOSITA would reasonably find it.[91] So, while it may seem unfair that an indexed PhD thesis available only in Germany counts as prior art, it actually simplifies the definition of prior art.[92]

An expansive source of knowledge for both PHOSITAs addresses a broader normative question: should we be awarding patents on innovations that are objectively obvious? Relatedly, do we want to encourage overly extensive disclosures in patent documents by narrowing the knowledge of the PHOSITA for purposes of enablement? These normative questions are broader in focus because they drive what the patent system is ultimately trying to achieve. Particularly for obviousness, we would be concerned that a reduction in the knowledge of the prior art could yield patents on inventions that are truly trivial based solely on excluding some prior art. Indeed, a PHOSITA not charged with complete knowledge of the prior art begins to feel reminiscent of the formalist teaching-suggestion-motivation to combine test used by the Federal Circuit and ultimately rejected by the Supreme Court in *KSR*.[93] That PHOSITA couldn't put two pieces of prior art together unless explicitly told to do so by the prior art, resulting in lots of patents being viewed as non-obvious. Similarly, a PHOSITA whose knowledge of the prior art is eclipsed would find many things non-obvious even if, objectively, the invention represented a trivial advance.

Most importantly, we think that there are reasons to afford the enablement PHOSITA with the same level of innovativeness and creativity as the obviousness PHOSITA. Reproducibility is important in science and technology.[94] The scientific world, however, is not divided into those who only reproduce the work of others and those that innovate. There is considerable overlap between the two as innovation proceeds, and replication is often used to advance innovation.[95] While enablement does assess whether the PHOSITA, drawing on the specification and the knowledge of the PHOSITA, can practice the claimed invention, we don't see a reason why the PHOSITA could not fill a gap. Of course, the Federal Circuit has made clear that the

90. *See, e.g.*, Patent Act of 2005, H.R. 2795, 109th Cong. (2005). Proposed § 102(b)(3) established limits on prior art, including defining "publicly known" as when the subject matter is "reasonably and effectively accessible" without resorting to "undue efforts."

91. Timothy R. Holbrook, *Patent Prior Art and Possession*, 60 WM. & MARY L. REV. 123, 162–63 (2018) (arguing that a capacious approach to prior art is more appropriate).

92. *In re* Hall, 781 F.2d 897, 897 (Fed. Cir. 1986). We still wonder how the litigants ever found this reference.

93. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 407 (2007). We do fear that the Federal Circuit has resuscitated such a formalist approach as well.

94. *See generally* Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845 (2017) (arguing that patent law "hamper[s] or even actively dissuade[s] reproducibility").

95. *Id.* at 853–54 ("In that spirit, scientists often attempt to replicate each other's experiments–both to generate hypotheses of their own and also to provide a further check on the peer-review process.").

novel aspects of the invention must be disclosed in the specification and cannot come from the PHOSITA's knowledge.[96] Nonetheless, we don't see any meaningful distinction between the two. Given that we are unpersuaded that the two PHOSITAs are distinct, we are not convinced that the added complexity would be helpful in practice. If enablement and obviousness are presented in the same case, we cannot imagine a jury being able to understand the subtle differences between the two.[97]

The Pedraza-Fariña and Whalen proposal to define the enablement PHOSITA as one bereft of any tacit knowledge perhaps best illustrates our concerns. First, for reasons mentioned above, we question whether such a definition is empirically justified. Second, the definition inescapably reflects a normative judgment about the extent of disclosure that the patent system ought to extract from inventors. We happen to disagree with that normative judgment, but it's more important that we point out that a normative judgment is embedded in the definition. Indeed, we would say that it's a crucial normative judgment that calls for a justification that the Pedraza-Fariña and Whalen paper does not give.

In contrast with obviousness and enablement, we think that the PHOSITA for infringement purposes may require even more issue-specific granularity. So, at a certain level, we agree with Professors Pedraza-Fariña and Whalen regarding the complex infringement landscape. Professors Pedraza-Fariña and Whalen ultimately do not attempt to resolve the debate among scholars, including us, about the appropriate normative construct in this context, although they do continue to use the PHOSITA term.

We appreciate that they recognize the complexity of infringement in terms of its technical and legal elements. And, while we agree with much of their descriptive account of the issues surrounding infringement, we think that a monolithic PHOSITA in that context is not the appropriate construct, as we noted in our earlier work.[98] In that Article, we argued that the design of patent law should create bridging heuristics to translate complex rules to audiences distant from the speaker of the law.[99] As we noted there, a myriad of doctrines impact the infringement analysis, many of which are legal. Claim construction, for example, is ultimately a legal question, though it can be based partially on technically rooted facts. Other elements, such as assessing

96. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997). *But see* Holbrook, *supra* note 67, at 798 (criticizing this rule based on the statutory text).

97. Indeed, one of us has gone as far as to argue that obviousness *is* enablement: obviousness shows the public was in constructive possession of the patent through a collective, enabling disclosure. The primary difference in the analysis is that the obviousness PHOSITA does not have to resort to the information disclosed in the patent. Holbrook, *Patent Anticipation and Obviousness as Possession*, *supra* note 11, at 1038 ("[T]he courts' focus on predictability and ease of development, based on the aggregate of the teachings of the prior art, demonstrates that, like the old cases suggested, obviousness is truly about determining whether the prior art has placed the invention in the possession of the public by providing an enabling disclosure.").

98. Janis & Holbrook, *supra* note 35, at 90–112.

99. *Id.*

whether an applicant has surrendered patent scope through arguments or amendments made during the patent prosecution process or through statements made in the specification are entirely legal in nature, so a singular infringement PHOSITA seems ill-fitted to do the necessary work in infringement.

We recognize that Professors Pedraza-Fariña and Whalen do not necessarily agree with our approach, although they are agnostic as to the proper construct. Our main pause with their approach is the retention of the term PHOSITA in this context. As our concern is the audience, the use of a PHOSITA in these legal arenas risks confusion and potentially inappropriate conflation with the PHOSITA elsewhere. We err on the side of invoking a reasonable competitor, an existing though seemingly moribund construct. Our view is that such a competitor would understand both the legal and marketplace landscape, permitting a more accessible approach to issues surrounding claim construction and infringement.

Finally, Professors Pedraza-Fariña and Whalen fault the courts for their failure to develop the PHOSITA hypothetical person. We wonder, however, if it would be better to locate these efforts elsewhere: the U.S. Patent and Trademark Office ("USPTO"). The courts encounter the PHOSITA generally after the patent has issued, but the USPTO encounters patent applications in the first instance. Given the expertise within the agency, the USPTO may be better situated for thinking about the PHOSITA construct. This could be achieved by formal rulemaking or by the Patent Trial and Appeal Board ("PTAB") squarely addressing the matter in the proceedings before it. Neither of these would be binding on the courts under current law, but efforts by the USPTO could provide a nudge to the courts, especially the Federal Circuit, to take the issue seriously.

Indeed, the PTAB has issued some decisions that have offered a construct of the PHOSITA that could be useful for courts. For example, in *Axionics, Inc. v. Medtronic, Inc.*, the PTAB engaged deeply with the identity of the PHOSITA in light of the parties' arguments.[100] The dispute there centered in part on whether the identity of the PHOSITA is defined by the specification or the claims, with the PTAB coming down in favor of the specification.[101] The PTAB, in contrast with many court decisions, performed a robust analysis of the PHOSITA that could serve as a model for the courts, if the courts will pay attention.

CONCLUSION

Professors Pedraza-Fariña and Ryan Whalen have made an important contribution to the literature surrounding the PHOSITA. Their empirical

100. Axionics, Inc. v. Medtronic, Inc., No. IPR2020-00679, 11–16 (P.T.A.B. Sept. 13, 2021).

101. *Id.*; *see generally* Pu-Cheng (Leo) Huang, *Should a PHOSITA Be Defined by the Specification or by the Claims?*, AM. INTELL. PROP. L. ASS'N, https://www.aipla.org/list/innovate-articles/should-a-phosita-be-defined-by-the-specification-or-by-the-claims [https://perma.cc/J95N-6PAS] (discussing *Axionics*).

results shed a light on the role—or lack thereof—that the PHOSITA plays in patent law. Sadly, *Amgen* demonstrates how easy it continues to be for courts to casually marginalize the PHOSITA. Additionally, while we agree that the PHOSITA should reflect normative aspects of patent law, we depart from some of their recommendations, especially with respect to differing PHOSITAs for obviousness and enablement, but we embrace their articulation of the normative goals in the infringement context. We would suggest, however, using a construct different than the PHOSITA to avoid confusion and to better effect those normative choices.