

cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024-03943 Filed 2-26-24; 8:45 a.m.]

BILLING CODE 3510-08-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD738]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public hybrid meeting of its Risk Policy Working Group to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, March 12, 2024, at 9 a.m.

ADDRESSES:

Meeting address: This meeting will be held at the Hilton Garden Inn, 100 High Street, Portsmouth, NH 03801; telephone: (603) 431-1499.

Webinar registration URL information:

https://zoom.us/webinar/register/WN_W_gl369EQKmGn7iFlqQLXQ.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Risk Policy Working Group (RPWG) will address the terms of reference (TORs) approved by the New England Fishery Management Council (Council), including progress made in reviewing the Council's current Risk Policy, and Risk Policy Road Map (TOR 1). They will also continue the development of a revised risk policy (TOR 2). The RPWG will outline a possible new approach and consider the

process of implementing the risk policy with ABC control rules and other management decisions.

Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 21, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024-03888 Filed 2-26-24; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2023-0053]

Updated Guidance for Making a Proper Determination of Obviousness

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is publishing this updated guidance to provide a review of the flexible approach to determining obviousness that is required by *KSR Int'l Co. v. Teleflex Inc.* (KSR). The focus of this document is on post-KSR precedential cases of the United States Court of Appeals for the Federal Circuit (Federal Circuit), to provide further clarification for decision-makers on how the Supreme Court's directives should be applied. While highlighting the requirement for a flexible approach to

the obviousness determination, this updated guidance also emphasizes the need for a reasoned explanation when reaching a conclusion that a claimed invention would have been obvious. This updated guidance, together with the direction provided in the Manual of Patent Examining Procedure (MPEP), serves as operable guidance for USPTO personnel when applying the law of obviousness.

DATES: This guidance is effective on February 27, 2024.

FOR FURTHER INFORMATION CONTACT:

Kathleen Kahler Fonda, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at Kathleen.Fonda@uspto.gov or 571-272-7754; or Steven J. Fulk, Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at Steven.Fulk@uspto.gov or 571-270-0072.

SUPPLEMENTARY INFORMATION: More than 15 years have passed since the Supreme Court's unanimous decision regarding the obviousness of a claimed invention under 35 U.S.C. 103 rendered in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727 (2007). Since then, the Federal Circuit has helped to refine the contours of the obviousness inquiry. This updated guidance serves as a reminder for USPTO personnel of the flexible approach to obviousness that is required under KSR and Federal Circuit precedent.

This guidance does not constitute substantive rulemaking and hence does not have the force and effect of law. It has been developed as a matter of internal Office management and is not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based on the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow this guidance is neither appealable nor petitionable.

The Office does not intend to announce any new Office practice or procedure by way of this updated guidance. This guidance is based on the Office's current understanding of the law and is believed to comport with the binding precedent of the Supreme Court and the Federal Circuit. Furthermore, it is meant to be consistent with the Office's present examination policy. However, if any earlier guidance from the Office, including any section of the current MPEP (9th Edition, Rev. 07.2022, February 2023), is inconsistent with the updated guidance set forth in this notice, Office personnel are to

follow this guidance. This updated guidance will be incorporated into the MPEP in due course.¹

I. The America Invents Act Impacted the Time Focus of the KSR Inquiry

As a preliminary matter, it is noted that *KSR* was decided prior to the March 16, 2013, effective date of the prior art provisions of the Leahy-Smith America Invents Act, Public Law 112–29, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. 1–390 (2012)) (AIA). In keeping with the shift from a first-to-invent statutory scheme to one based on a first-inventor-to-file approach, Congress amended 35 U.S.C. 103 to change the time focus of the obviousness inquiry from “at the time the invention was made” to “before the effective filing date of the claimed invention.”² When determining obviousness in a case governed by the AIA, Office personnel should interpret references to “at the time of invention” in *KSR* (see, for example, 550 U.S. at 420, 127 S. Ct. at 1742) as if they referred to the statutory time focus under the AIA, which is “before the effective filing date of the claimed invention.” See MPEP 2158.³

II. The Graham Inquiries Continue To Control Obviousness Determinations After KSR

The Supreme Court’s decision in *KSR* clearly reaffirmed the approach to obviousness announced in *Graham v. John Deere Co.*, 383 U.S. 1, 86 S. Ct. 684 (1966) (*Graham*). At the outset of the *KSR* decision, Justice Kennedy, writing for a unanimous Court, quoted the Court’s decades-earlier obviousness decision in *Graham*:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved

needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

KSR, 550 U.S. at 406, 127 S. Ct. at 1734 (quoting *Graham*). Referring to this analysis as “objective,” the Court then unambiguously stated that *Graham* remained the law of the land: “While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls.” *Id.* at 406–07, 127 S. Ct. at 1734. Since *KSR*, the Federal Circuit has frequently emphasized the centrality of the *Graham* inquiries. See, for example, *Novartis Pharms. Corp. v. West-Ward Pharms. Int’l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019); *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1047–48 (Fed. Cir. 2016); and *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1332 (Fed. Cir. 2012). Thus, USPTO personnel continue to ground obviousness determinations in the objective inquiries announced in *Graham*. See MPEP 2141, subsections I and II.

III. The Federal Circuit’s Implementation of KSR Has Reiterated a Flexible Approach to Obviousness

A hallmark of the *KSR* approach to obviousness, for which the Supreme Court found basis in *Graham*, is flexibility. *KSR*, 550 U.S. at 415, 127 S. Ct. at 1739. The *KSR* court mandated flexibility in at least two respects: first with regard to the proper understanding of the scope of the prior art, and second with regard to appropriate reasons to modify the prior art. In its cases decided since *KSR*, the Federal Circuit has reiterated these two aspects of flexibility, which are important to a proper determination of obviousness. These aspects are discussed in subsections III.A and III.B of this notice. Subsection III.C concludes the discussion with the important concept, evident in post-*KSR* Federal Circuit decisions, that the flexible approach does not relieve the decision-maker of the need to provide articulated reasoning that is grounded in fact.

A. Flexible Approach To Understanding the Scope of Prior Art

The Supreme Court’s directive to employ a flexible approach to understanding the scope of prior art is reflected in the frequently quoted sentence, “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 421, 127 S. Ct. at 1742. In this section of the *KSR* decision, the Supreme Court instructed the Federal Circuit that persons having ordinary skill in the art (PHOSITAs)

also have common sense, which may be used to glean suggestions from the prior art that go beyond the primary purpose for which that prior art was produced. *Id.* at 421–22, 127 S. Ct. at 1742. Thus, the Supreme Court taught that a proper understanding of the prior art extends to all that the art reasonably suggests, and is not limited to its articulated teachings regarding how to solve the particular technological problem with which the art was primarily concerned. *Id.* at 418, 127 S. Ct. at 1741 (“As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”). “The obviousness analysis cannot be confined . . . by overemphasis on the importance of published articles and the explicit content of issued patents.” *Id.* at 419, 127 S. Ct. at 1741.

Federal Circuit case law since *KSR* follows the mandate of the Supreme Court to understand the prior art—including combinations of the prior art—in a flexible manner that credits the common sense and common knowledge of a PHOSITA. The Federal Circuit has made it clear that a narrow or rigid reading of prior art that does not recognize reasonable inferences that a PHOSITA would have drawn is inappropriate. An argument that the prior art lacks a specific teaching will not be sufficient to overcome an obviousness rejection when the allegedly missing teaching would have been understood by a PHOSITA—by way of common sense, common knowledge generally, or common knowledge in the relevant art.

For example, in *Randall Mfg. v. Rea*, 733 F.3d 1355 (Fed. Cir. 2013), the Federal Circuit vacated a determination of nonobviousness by the Patent Trial and Appeal Board (PTAB or Board) because it had not properly considered a PHOSITA’s perspective on the prior art. *Id.* at 1364. The *Randall* court recalled *KSR*’s criticism of an overly rigid approach to obviousness that has “little recourse to the knowledge, creativity, and common sense that an ordinarily skilled artisan would have brought to bear when considering combinations or modifications.” *Id.* at 1362, citing *KSR*, 550 U.S. at 415–22, 127 S. Ct. at 1727. In reaching its decision to vacate, the Federal Circuit stated that by ignoring evidence showing “the knowledge and perspective of one of ordinary skill in the art, the Board failed to account for critical background information that could easily explain why an ordinarily

¹ This notice does not address the impact, if any, of artificial intelligence on the obviousness inquiry. The Office continues to seek input from the public on that question and will issue additional notices as warranted.

² Although the AIA made several other changes to § 103 (for example, “subject matter sought to be patented” was replaced with “claimed invention”), none of these additional changes is believed to impact the obviousness inquiry.

³ See also *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 25 F.4th 1354, 1365 (Fed. Cir. 2022) (applying *KSR* to claims governed by the AIA); Dmitry Karshedt, *Nonobviousness: Before and After*, 106 Iowa L.R. 1609, 1636 n.199 (2021): “Although the anchoring date has since changed from the invention date to the effective filing date, the substantive reasoning of *KSR* is fully applicable to the AIA’s first-to-file regime.”

skilled artisan would have been motivated to combine or modify the cited references to arrive at the claimed inventions.” *Id.*

Consistent with its directive in *Randall* to focus on a PHOSITA’s perspective on the prior art, the Federal Circuit in *Zup, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365 (Fed. Cir. 2018) held that there would have been a reason to combine prior art elements known to aid in stability for riders of water recreational devices, even without an express teaching of simultaneous use of those elements. *Id.* at 1372–73. The Federal Circuit drew attention to what a PHOSITA in the field of water recreational devices would have known: “Given the consistent focus on rider stability in this industry, it would have been obvious to one of skill in the art to have a rider use both the handles and the foot bindings at the same time while maneuvering between riding positions.” *Id.* at 1373 n.2. Thus, the Federal Circuit credited a PHOSITA with knowledge of the industry’s concern for rider stability—a matter that could be viewed as common sense.

The Federal Circuit has made it clear that the flexible approach to understanding prior art as mandated by the Supreme Court also extends to the issue of whether a prior art disclosure is analogous art to the claimed invention. To be used in an obviousness rejection, a prior art disclosure must be analogous art to the claimed invention. *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2004). The Federal Circuit reads *KSR* as “direct[ing] us to construe the scope of analogous art broadly” because “familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238 (Fed. Cir. 2010), quoting *KSR*, 550 U.S. at 402, 127 S. Ct. at 1727. Consistently, in *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374 (Fed. Cir. 2019), the Federal Circuit recalled the alternative “same field of endeavor” and “reasonably pertinent” tests for analogous art, and stated that “an analysis of whether an asserted reference is analogous art should take into account any relevant evidence in the record cited by the parties to demonstrate the knowledge and perspective of a person of ordinary skill in the art.” *Id.* at 1379, 1383–84. More recently in *Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352 (Fed. Cir. 2023), the Federal Circuit noted the flexible approach under *KSR* as applied to the “same field of endeavor” test: “We have affirmed findings of analogous art where the

references shared a general field of endeavor.” *Id.* at 1359, citing *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001 (Fed. Cir. 2016); and *In re Mettke*, 570 F.3d 1356, 1359 (Fed. Cir. 2009).

The flexible approach to understanding the prior art is reflected in USPTO guidance provided at MPEP 2141, subsection III: “Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art.” MPEP 2141, subsection II.C, and MPEP 2141.03 provide guidance regarding the level of ordinary skill in the art. Office personnel are directed to MPEP 2141.01(a) for guidance on analogous art. Consistent with *KSR* and subsequent Federal Circuit case law, when evaluating the prior art from the perspective of a PHOSITA, Office personnel must take that person’s “ordinary creativity” into account.

B. Flexible Approach to Providing a Reason To Modify the Prior Art

Federal Circuit case law since *KSR* confirms that the flexible approach to obviousness encompasses not only how to understand the scope of prior art, but also how to provide a reasoned explanation to support a conclusion that claims would have been obvious. Consistent with *KSR*, the Federal Circuit makes it clear that the obviousness analysis is not “confined by a formalistic conception of the words teaching, suggestion, and motivation.” *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 795 (Fed. Cir. 2021), quoting *KSR*, 550 U.S. at 419, 127 S. Ct. at 1741. To be sure, the Federal Circuit continues to use the word “motivation” in its obviousness jurisprudence. However, it is evident that the term is no longer understood in a rigid or formalistic way. See, for example, *Norgren Inc. v. Int’l Trade Comm’n*, 699 F.3d 1317, 1322 (Fed. Cir. 2012) (“A flexible teaching, suggestion, or motivation test can be useful to prevent hindsight when determining whether a combination of elements known in the art would have been obvious.”); *Outdry Techs. Corp. v. Geox S.p.A.*, 859 F.3d 1364, 1370–71 (Fed. Cir. 2017) (“Any motivation to combine references, whether articulated in the references themselves or supported by evidence of the knowledge of a skilled artisan, is sufficient to combine those references to arrive at the claimed process.”)

In keeping with this flexible approach to providing a rationale for obviousness, the Federal Circuit has echoed *KSR* in identifying numerous possible sources that may, either implicitly or explicitly, provide reasons to combine or modify the prior art to determine that a claimed

invention would have been obvious. These include “market forces; design incentives; the ‘interrelated teachings of multiple patents’; ‘any need or problem known in the field of endeavor at the time of invention and addressed by the patent’; and the background knowledge, creativity, and common sense of the person of ordinary skill.” *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013), quoting *KSR*, 550 U.S. at 418–21, 127 S. Ct. at 1741–42. Furthermore, the Federal Circuit has explained that a reason to optimize prior art parameters may be found in a PHOSITA’s desire to improve on the prior art. *In re Ethicon, Inc.*, 844 F.3d 1344, 1351 (Fed. Cir. 2017) (“The normal desire of artisans to improve upon what is already generally known can provide the motivation to optimize variables such as the percentage of a known polymer for use in a known device.”). The Federal Circuit has also clarified that a proposed reason to combine the teachings of prior art disclosures may be proper, even when the problem addressed by the combination might have been more advantageously addressed in another way. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197–98 (Fed. Cir. 2014) (“Our precedent, however, does not require that the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away.”) (emphasis in original).

One aspect of the flexible approach to explaining a reason to modify the prior art is demonstrated in the Federal Circuit’s decision in *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 796 (Fed. Cir. 2021), which confirms that a proposed reason is not insufficient simply because it has broad applicability. Patent challenger Intel had argued in an inter partes review before the Board that some of Qualcomm’s claims were unpatentable because a PHOSITA would have been able to modify the prior art, with a reasonable expectation of success, for the purpose of increasing energy efficiency. *Id.* at 796–97. The Board had disagreed with Intel, in part because it viewed Intel’s energy efficiency rationale as “no more than a *generic* concern that exists in many, if not all, electronic devices” (emphasis in original). *Id.* at 797. Citing *KSR* and reversing the Board on this point, the Federal Circuit explained that “[s]uch a rationale is not inherently suspect merely because it’s generic in the sense of having broad applicability or appeal.” *Id.* The Federal Circuit further pointed out its pre-*KSR* holding “that *because* such improvements are ‘technology-

independent,’ ‘universal,’ and ‘even common-sensical,’ ‘there exists in these situations a motivation to combine prior art references *even absent any hint of suggestion* in the references themselves.’” *Id.*, quoting *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006) (emphasis added by the Federal Circuit in *Intel*). However, the Federal Circuit was also quick to point out that a generally applicable rationale would not be legally sufficient if it were asserted without explanation and in a merely conclusive way. *Id.*

When formulating an obviousness rejection, Office personnel may use any clearly articulated line of reasoning that would have allowed a PHOSITA to draw the conclusion that a claimed invention would have been obvious in view of the facts. MPEP 2143, subsection I, and MPEP 2144. Acknowledging that, in view of *KSR*, there are “many potential rationales that could make a modification or combination of prior art references obvious to a skilled artisan,” the Federal Circuit has also pointed to MPEP 2143, which provides several examples of rationales gleaned from *KSR*. *Unwired Planet*, 841 F.3d at 1003.

C. Flexible Approach to Obviousness Does Not Negate the Need for Articulated Reasoning and Evidentiary Support

As discussed above, *KSR*’s flexible approach to the obviousness inquiry disallows “[r]igid preventative rules that deny factfinders recourse to common sense.” 550 U.S. at 421, 127 S. Ct. at 1742. Nevertheless, “[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” MPEP 2142. Although this approach is flexible, a proper obviousness rejection still requires the decision-maker to provide adequate analysis based on evidentiary support. This theme is a frequent one in post-*KSR* Federal Circuit jurisprudence. See, for example, *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1330 (Fed. Cir. 2009) (“We reiterate that, on summary judgment, to invoke ‘common sense’ or any other basis for extrapolating from prior art to a conclusion of obviousness, a district court must articulate its reasoning with sufficient clarity for review.”); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377 (Fed. Cir. 2012) (“The mere recitation of the words ‘common sense’ without any support adds nothing to the obviousness equation.”); *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016) (“[R]eferences to

‘common sense’—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified.”); *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017) (“[T]he flexibility afforded by *KSR* did not extinguish the factfinder’s obligation to provide reasoned analysis.”). The Federal Circuit has itself called attention to its own repeated emphasis on this requirement since *KSR*. See *Van Os*, 844 F.3d at 1361, quoting *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013) (“Since *KSR*, we have repeatedly explained that obviousness findings ‘grounded in “common sense” must contain explicit and clear reasoning providing some rational underpinning why common sense compels a finding of obviousness.’”); *Arendi S.A.R.L.*, 832 F.3d at 1362 (“[O]ur cases repeatedly warn” that common sense cannot substitute for reasoned analysis and evidentiary support.).

This updated guidance reinforces the directive that Office personnel are required to provide a clear articulation of their reasoning, grounded in relevant facts, when making a determination that a claim would have been obvious under 35 U.S.C. 103. As has been discussed, precedential case law requires such an analysis. Furthermore, “[t]he goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity.” MPEP 706. Thus, clearly articulated obviousness rejections serve the goal of compact prosecution and allow patent practitioners and Office personnel to conclude patent examination or other USPTO proceedings at the earliest possible time.

IV. All Evidence Relevant to the Question of Obviousness That Is Properly Before the Decision-Maker Must Be Considered

When reaching a determination of obviousness in view of *KSR*’s flexible approach as discussed above, decision-makers must consider all relevant evidence that is properly before them. An important theme in the law of obviousness is that the inquiry under *Graham* and *KSR* is not limited to the first three *Graham* factors (*i.e.*, scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art). Rather, when the so-

called secondary considerations of the fourth factor (also known as objective indicia of nonobviousness) have been made an issue in the case, the decision-maker is not free to ignore them. *In re Huai-Hung Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011) (“[W]hen secondary considerations are present, though they are not always dispositive, it is error not to consider them.”); *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (“This court has explained, moreover, that the obviousness inquiry requires examination of all four *Graham* factors.”).⁴

The requirement to consider all relevant evidence is part of the establishment of a *prima facie* case of obviousness. In the context of patent examination and reexamination, MPEP 2142 explains that “[t]he legal concept of *prima facie* obviousness is a procedural tool” that “allocates who has the burden of going forward with production of evidence in each step of the examination process.” At the outset of examination, the patent examiner who issues an obviousness rejection bears the burden of explaining how a preponderance of the evidence supports the conclusion that the claims would have been obvious. *Id.* If objective indicia of nonobviousness are properly before the examiner, such as by way of incorporation into the written description as filed or submission of an evidentiary declaration after the filing date, the examiner must consider those indicia, even before the issuance of a first Office action. A decision-maker “must always consider any objective evidence of nonobviousness presented in a case.” *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010) (referring to a district court as the decision-maker, but also applicable to USPTO decision-makers) (internal citations omitted). “Whether before the Board or a court, this court has emphasized that consideration of the objective indicia is *part* of the whole obviousness analysis, not just an afterthought.” *Leo Pharm. Prod., Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013) (emphasis in original).

At each stage of USPTO proceedings, Office personnel must reweigh all evidence that is relevant and properly of record at that time. Newly submitted

⁴ For a list of additional Federal Circuit cases directing decision-makers to consider all the *Graham* factors when determining obviousness, including all evidence of obviousness or nonobviousness that is before the decision-maker, see *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1076–77 (Fed. Cir. 2012).

evidence in rebuttal of an obviousness rejection must not be considered merely for its knockdown value against any previously-established *prima facie* case. See MPEP 2145, and in particular, the cases cited in examples 1–3. Evidence submitted to rebut a determination of obviousness is important because it may constitute “independent evidence of nonobviousness.” *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1319 (Fed. Cir. 2010), quoting *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Such evidence “may often be the most probative and cogent evidence of nonobviousness in the record.” *Ortho-McNeil*, 520 F.3d at 1365, quoting *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002).

It follows from the directive to consider all relevant evidence that the mere existence of a reason to modify the teachings of the prior art may not necessarily lead to a conclusion that a claimed invention would have been legally obvious. *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1346–47 (Fed. Cir. 2017). When stepping into the shoes of a PHOSITA, the decision-maker should seek to understand the “complete picture” regarding the PHOSITA’s perspective on obviousness, having due regard for additional evidence that may weigh against any *prima facie* case. *Id.* at 1346. In determining whether a claimed invention would have been obvious, Office personnel are charged with weighing all the evidence of record, including evidence of obviousness and evidence of nonobviousness. “If this weighing shows obviousness by a preponderance of the evidence, then the claims at issue were unpatentable.” *ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1366 (Fed. Cir. 2016).

Without diminishing the need to consider all relevant evidence when making a determination about obviousness, the Federal Circuit has made it clear that an expert’s conclusory opinion about a matter relevant to the obviousness inquiry may be unavailing unless accompanied by factual support. See, for example, *Ethicon*, 844 F.3d at 1352 (concluding in the context of an ex parte appeal that the Board properly gave little weight to conclusory expert testimony regarding objective indicia); *Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*, 24 F.4th 1406, 1417 (Fed. Cir. 2022) (agreeing with the Board, in the context of an inter partes review proceeding, that the proffered expert testimony was “incomplete, unspecific, and ultimately conclusory” and

therefore not entitled to controlling weight). Consistently, in the context of proceedings before the PTAB, Office regulations provide that “[e]xpert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.” 37 CFR 42.65(a); see also *Xerox Corp. v. Bytemark, Inc.*, No. IPR2022–00624, 2022 WL 3648989, at *6 (PTAB 2022) (precedential) (The USPTO Director affirmed that because “the cited declaration testimony is conclusory and unsupported, [it] adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.”). Further, during the examination of an application or the reexamination of a patent, any objective evidence of nonobviousness must be submitted by way of an affidavit or declaration; attorney arguments alone cannot take the place of such evidence in the record where the evidence is necessary. See 37 CFR 1.132; MPEP 716.01(c) and MPEP 2145, subsection I.

Consistent with Federal Circuit precedent, Office personnel are directed to consider all objective evidence that has been properly made of record and is relevant to the issue of obviousness at MPEP 2141, subsection II.

V. Office Personnel Will Continue To Apply Reasoning to Facts in Order To Reach a Proper Legal Determination of Obviousness

Any legally proper obviousness rejection must identify facts and then articulate sound reasoning that leads to the conclusion that the claims would have been obvious to a PHOSITA. “Obviousness is a question of law based on underlying facts. . . .” *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1331 (Fed. Cir. 2019). During patent examination, making factual findings concerning the content of the prior art is often the first step when considering whether or not a claimed invention would have been obvious. As discussed above, the obviousness determination may also involve other facts, such as those presented in an evidentiary declaration. After making appropriate findings of fact, Office personnel must use reasoning in accordance with *Graham* and *KSR* to determine whether a claimed invention would have been obvious in view of all relevant facts. Office personnel must explain on the record how the conclusion of obviousness was reached. See MPEP 2141, subsection II: “Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103.” See also MPEP 2142.

In keeping with the flexible approach to obviousness in *KSR* and *Graham*, there is no one-size-fits-all approach to crafting an obviousness rejection. See *KSR*, 550 U.S. at 415, 127 S. Ct. at 1739. Different technologies or different factual situations may lend themselves to different formats for presentation of the relevant facts, or to different lines of reasoning to explain the legal conclusion of obviousness. Office personnel are called on to use their legal and technological expertise to determine how best to explain an obviousness rejection. See *Hyatt v. Kappos*, 625 F.3d 1320, 1343 (Fed. Cir. 2010), *aff’d* and remanded, 566 U.S. 431, 132 S. Ct. 1690 (2012). Any legally proper obviousness rejection will be characterized by findings of fact and a reasoned explanation showing why the claimed invention would have been obvious to a PHOSITA. See, for example, *In re Biedermann*, 733 F.3d 329, 335–36 (Fed. Cir. 2013); *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017).

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2023–HQ–0016]

Submission for OMB Review; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by March 28, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.