Chicago-Kent Journal of Intellectual Property

Volume 23 | Issue 1 Article 4

12-20-2023

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Recommended Citation

Michael Pomeroy, Balancing the Scales: Analyzing Motivation to Combine and Avoiding Impermissible Hindsight in 2023, 23 Chi.-Kent J. Intell. Prop. 81 (2023).

Available at: https://scholarship.kentlaw.iit.edu/ckjip/vol23/iss1/7

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Balancing the Scales: Analyzing Motivation to Combine and Avoiding Impermissible Hindsight in 2023

MICHAEL POMEROY

Many *inter partes* review ("IPR") proceedings involve determining whether the asserted patent claims are invalid as obvious under 35 U.S.C. § 103. When basing an obviousness challenge on a combination of prior art references, a party must show that the asserted combination renders the claimed invention obvious and that the person of ordinary skill in the art had a "motivation to combine" the references. The Federal Circuit treats motivation to combine as a question of fact. This paper examines what defines a "motivation" to combine under the current state of the law, and in particular, what a person of ordinary skill of art ("POSITA") would consider, and what they would ignore.

The requirements for establishing that a claimed invention in a granted patent would have been obvious have evolved over the years. The current statute for § 103 states:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.³

In addition, the analytical framework used to determine what is obvious has evolved. In an attempt to avoid the use of hindsight in an obviousness analysis, the predecessor to the Federal Circuit, the United States Court of Customs and Patent Appeals ("CCPA") asserted the rule that the combination of prior art is not obvious "unless the art also contains something to suggest the desirability of the proposed combination." The "TSM" test focused on a prior art reference teaching, suggesting or motivating a POSITA to combine said reference with another piece of prior art. The CCPA and then the Federal Circuit applied the TSM test for decades until it was called into question by the Supreme Court in KSR International Co. v. Teleflex. The test ensured that a patent challenger could not render a patent claim obvious

^{1.} KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418–19 (2007); Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1368 (Fed. Cir. 2016).

See, e.g., PAR Pharm., Inc. v. TWI Pharms., Inc., 773 F.3d 1186, 1196 (Fed. Cir. 2014) (citing Alza Corp. v. Mylan Lab'ys, Inc., 464 F.3d 1286, 1289 (Fed. Cir. 2006)).

^{3. 35} U.S.C. § 103, as amended by the America Invents Act. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 287 (2011) (codified at 35 U.S.C. § 103 (2018)). The America Invents Act did not fundamentally change the obviousness inquiry but did result in some modest changes. See MPEP § 2158 (9th ed. Rev. 7.2022, Feb. 2023) (now requiring obviousness to be determined before the effective filing date of the patent, rather than at the time the invention was made).

^{4.} *In re* Bergel, 292 F.2d 955, 956-57 (C.C.P.A. 1961).<u>4. *In re* Bergel</u>, 292 F.2d 955, 956-57 (C.C.P.A. 1961).

unless there is "something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." In its decision, the Supreme Court rejected any exclusive use of the TSM test in KSR, ruling that the TSM test was too "rigid" to be the sole measure of whether a POSITA would have been motivated to combine the teachings of the asserted references. The Supreme Court's decision in KSR gave more discretion to district courts as well as the eventual Patent Trial and Appeal Board ("PTAB"). The Federal Circuit confirmed this in a precedential decision in Axonics v. Medtronic issued in July 2023.

The Axonics case involves a Medtronic, Inc. patent directed towards a neurostimulation lead and method for implanting and anchoring the lead. The PTAB concluded that the Petitioner Axonics had failed to prove any challenged claim unpatentable. The Board found that, although the combined prior art met every limitation of the challenged claims, the Petitioner had not established a motivation to combine the prior art references, stating there was no motivation to combine "Young's lead with Gerber's plurality of electrodes so the plurality of electrodes is distal to all of the lead's tines."

Petitioner Axonics appealed, and the Federal Circuit overturned the PTAB's finding. In its ruling, the Federal Circuit concluded that the PTAB had "adopted a legally incorrect framing of the motivation-to-combine question." The Court stated that the PTAB improperly investigated "whether a relevant artisan would combine a first reference's feature with a second reference's feature to meet requirements of the first reference that are not requirements of the claims at issue." Instead, the Federal Circuit noted that the proper inquiry for a motivation to combine analysis is "whether the relevant artisan would be motivated to make the combination to arrive at the claims' actual limitations, which are not limited to [a reference's] context." Providing further clarification, the Court stated that a POSITA should not be

^{5.} Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1462 (Fed. Cir. 1984). This requirement was first developed by the Federal Circuit's predecessor, the U.S. Court of Customs and Patent Appeals. *See, e.g., In re* Bergel, 292 F.2d 955, 956–57 (C.C.P.A. 1961) ("The mere fact that it is possible to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.").

^{6.} KSR, 550 U.S. at 419.

^{7.} See, e.g., Adam Powell, KSR Fallout: Questions of Law Based on Findings of Fact and the Continuing Problem of Hindsight Bias 1 HASTINGS SCI. & TECH. L.J. 243, 248–53 (2009) (asserting that the Supreme Court injected more uncertainty into the determination by introducing a more flexible standard to be applied by district courts).

^{8.} Axonics, Inc. v. Medtronic, Inc., 73 F.4th 950, 957 (Fed. Cir. 2023).

^{9.} Id. at 951.9. Axonics,, 73 F.4th 950, 951 (Fed. Cir. 2023).

^{10.} Id. at 951-52.

^{11.} *Id.* at 955.

^{12.} *Id.* at 957.

^{13.} Id.

^{14.} *Id*.

limited to looking at the prior art *only* for what it taught or suggested, but for how the features of the prior art "might be combined" with another reference to reach the claimed invention. ¹⁵ The Court's analysis reinforced legal principles set forth in *In re Urbanski*, which provided that a POSITA can be motivated to combine references "even if that mean[s] foregoing the benefit" taught by a reference itself. ¹⁶

However, the Axonics decision raises more questions than it answers. For instance, what would a POSITA rely on for motivation to combine references under the present obviousness framework? What does it mean for a POSITA to ignore the contextual teachings of the prior art and instead look at how the features of one or more particular references "might be combined"? The Court's use of the phrase "might be combined" is similar to language the Federal Circuit has previously warned against using in motivation to combine analysis and is inconsistent with the guidance of KSR.¹⁷ As the federal circuit has stated, "the motivation-to-combine inquiry asks whether a skilled artisan 'not only could have made but would have been motivated to make the combinations . . . of prior art to arrive at the claimed invention." If a POSITA is not limited to what a prior art reference teaches or suggests in the context of the respective reference and may ignore taught benefits of that reference, how does that framework of analysis fit within the body of law that states that there cannot be a motivation to combine if a prior art reference teaches away from the combination?¹⁹

The *Axonics* decision is also at odds with well-established case law prohibiting the use of impermissible hindsight in the obviousness analysis²⁰—the very thing that the TSM test was created to avoid. Hindsight bias is a natural result of people's subjective and unconscious tendency to incorrectly assign a high predictability to a past event based on their present knowledge that the event has occurred.²¹ As applied to patents in an obviousness

^{15.} *Id.* at 958.

^{16.} Id. at 957; In re Urbanski, 809 F.3d 1237, 1244 (Fed. Cir. 2016).

^{17.} InTouch Techs., Inc. v. VGO Commc'ns, Inc., 751 F.3d 1327, 1352 (Fed. Cir. 2014) (finding expert applied hindsight and ruled patents valid as matter of law where invalidity expert's "testimony primarily *consisted* of conclusory references to her belief that one of ordinary skill in the art *could* combine these references, not that they *would* have been motivated to do so").

^{18.} Auris Health, Inc. v. Intuitive Surgical Operations, Inc., 32 F.4th 1154, 1158 (C.A.Fed., 2022).

^{19.} DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1326–27 (Fed.Cir.2009).

^{20.} Insite Vision Inc. v. Sandoz, Inc., 783 F.3d 853, 859 (Fed.Cir.2015) ("Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness."); See ActiveVideo Networks, Inc. v. Verizon Comme'ns, Inc., 694 F.3d 1312, 1327 (Fed.Cir.2012) ("[T]he expert's testimony on obviousness was essentially a conclusory statement that a person of ordinary skill in the art would have known, based on the 'modular' nature of the claimed components, how to combine any of a number of references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.").

^{21.} See Gregory N. Mandel, Another Missed Opportunity: The Supreme Court's Failure to Define Nonobviousness or Combat Hindsight Bias in KSR v. Teleflex, 12 LEWIS & CLARK L. REV. 323, 324 (2008)

analysis, hindsight bias generally disfavors patent owners, as inventions that were difficult to conceive may appear simple and trivial decades later. The potential impact of hindsight bias is further increased if the invention was successful enough to become commonplace to a person analyzing the challenged patent years after the patent issues.²² The current law dictates that "[c]are must be taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior references, combining the right references in the right way so as to achieve the result of the claims in suit."²³ KSR itself warned against hindsight, stating that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning."²⁴ For example, in Cook Group Inc. v. Boston Scientific Scimed, Inc., the Board held that Petitioner did not correctly analyze motivation to combine as it chose structural elements from several of the prior art reference's embodiments and proposed combining them "to create the claimed inventions using the claimed inventions themselves as a guide, which is quintessential hindsight."²⁵

For a petitioner filing an IPR based on an obviousness challenge, the tension between establishing a motivation to combine the cited references while avoiding hindsight bias presents a challenging tightrope not yet fully addressed. On one hand, a petitioner is supposed to (1) consider the claims as a whole and not just the individual limitations and (2) focus the analysis on whether a POSITA would have been motivated to combine references to arrive at the challenged claims.

On the other hand, the patent owner may be more susceptible to obviousness challenges now that the Federal Circuit has clarified that "the inquiry is not whether a relevant artisan would combine a first reference's feature with a second reference's feature to meet requirements of the first reference that are not requirements of the claims at issue." This may impact what a patent owner can assert as far as lack of motivation to combine for prior art references teaching away, as under the *Axonics* framework clarification, it is not whether one prior art reference teaches away from being combined with a second prior art reference, but instead, whether the prior art teaches away from being combined to create the claimed invention, even if that means sacrificing the benefits provided in the prior art. 27

^{22.} COMM. ON INTELL. PROP. RTS. KNOWLEDGE-BASED ECON., NAT'L RSCH. COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 87–88 (Steven A. Merrill et al. eds., 2004).

^{23.} See Grain Processing Corp. v. Am. Maize-Prods. Co., 840 F.2d 902, 907 (Fed. Cir. 1988) (quoting Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1012 (Fed. Cir. 1983).

^{24.} See KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

^{25.} Cook Group Inc. v. Boston Scientific Scimed, Inc., Case No. IPR 2017-00435, 1, 30 (P.T.A.B. Dec. 28, 2018) (Paper 94).

^{26.} Axonics, 73 F.4th at 957.

^{27.} Id. at 957; In re Urbanski, 809 F.3d 1237, 1244 (Fed. Cir. 2016).

When deciding to challenge a patent on obviousness grounds, a petitioner must walk a fine line without further clarification from the Courts. A petitioner must also articulate a motivation to combine references to meet the claimed invention without relying on hindsight. Even the Supreme Court and Federal Circuit have stated that hindsight bias involves picking and choosing elements of references to create the claimed invention; this is precisely what the Federal Circuit allowed in *Axonics* and chided the PTAB for not doing.²⁸ At present, there is no clear guidance on how a petitioner is to establish a proper motivation to combine cited references without risking improper hindsight bias. *Axonics* holds that a proper motivation to combine analysis asks a POSITA to look at the claims of a challenged patent; other precedent warns against only looking at the claims and using them as a roadmap or guide to combine references.²⁹

This leaves both petitioners and patent owners in difficult positions during IPR proceedings. Does a petitioner buttress its petition (and use valuable words) by explaining every possible motivation that a POSITA would have had to combine the cited references and explain why there is no hindsight reasoning in each of those analyses? Does a patent owner focus its arguments on a lack of motivation to combine or improper reliance on hindsight in its preliminary or patent owner response with the reasoning and support for such a motivation appearing to be a moving target? Without more guidance from the Federal Circuit or the Supreme Court concerning the requirements to prove or disprove an obviousness challenge under 35 U.S.C. §103, petitioners and patent owners will continue to shoot in the dark. Additionally, like the decision in Axonics, other PTAB decisions that apply the guidance set out in cases such as Am. Maize-Prods. Co or InTouch Techs., Inc. v. VGO Comme'ns, Inc. are susceptible to being reversed for not addressing improper hindsight, which is the inverse of this revised motivation to combine inquiry. Likewise, if the PTAB finds a challenged patent to be obvious under Axonics, that decision will likely face an appellate challenge for improper hindsight. Thus, the current body of law may have inadvertently introduced even more legal uncertainty into an already clouded analytical framework.

^{28.} See, e.g., Graham v. John Deere Co., 383 U.S. 1, 36 (1966) ("[Objective inquiries] may also serve to guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue.") (internal quotations and citations omitted); In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371, 1376 (Fed. Cir. 2004) ("[T]he suggestion to combine references must not be derived by hindsight from knowledge of the invention itself.").

^{29.} Compare Axonics, 73 F.4th 950 with, e.g., Am. Maize-Prods. Co., 840 F.2d 902, 907 (In Am. Maize-Prods. Co, the Federal Circuit rejected obviousness, stating expert used Asserted Patent as a guide and that the prior art references "have little relevance" to the Asserted Patent); see also InTouch at 1351 (Fed. Cir. 2014) (finding that Petitioner's expert's only motivation to combine was predicated on finding pieces of a "jigsaw puzzle" to find references that disclosed the claim's limitations).