Should an Obviousness Analysis Start With Motive?

Adding motivational requirements for allowing prior art to be used to start an obviousness analysis might effectively remove knowledge from the public domain.

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A foundational principle of U.S. patent law is that technologies in the public domain must remain free for all to use. *Bonita Boats v. Thunder Craft Boats*, 489 U.S. 141, 146 (1989); *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). Appropriately, U.S. patent law precludes patenting technology that is demonstrably "known." But it also reserves for the public a margin of safety between actual public knowledge and true innovation by preventing one from patenting simple manipulations or extensions of publicly known technology. While such extensions of technology may not exist per se, allowing them to be patented risks misappropriating public knowledge. U.S. patent law considers such extensions of technology to be "obvious," and just as

known technology is unpatentable, so too is obvious technology. In this way, the law favors the general interests of society over those of a particular inventor. Every obviousness analysis is therefore, in actuality, an attempt to draw a boundary line between what is in the public domain, or flows from it, and what can be protected by an inventor.

Every obviousness analysis starts by using the half-century old *Graham* factors, which include determining: (1) the scope and content of the prior art; (2) the differences between the patent claims sought by the applicant and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. *Graham*, 383 U.S. at 17-18. The analysis also "entails consideration of whether a person of ordinary skill in the art 'would have been *motivated* to combine the teachings of the prior art references to achieve the claimed invention, and … would have had a reasonable expectation of success in doing so.'" *Insite Vision v. Sandoz*, 783 F.3d 853, 859 (Fed. Cir. 2015) (emphasis added). Motivation has historically been considered when questioning the propriety of combining references or modifying a reference. But more recently, some have argued that motivation should be considered much earlier in the analysis—that there needs to be a motivation to *start* an obviousness analysis at a particular point.

For example, in the past, one could analyze the obviousness of a chemical compound by searching for the closest structural analog in the prior art and then considering if there was sufficient motivation and knowledge to modify that known structure. The closeness of the structure alone justified the use of that reference as a starting point. But beginning around 2000, the courts began to require a patent challenger to identify an additional reason to start with that particularly close structure. *See* e.g. *Yamanouchi Pharm. Co. v. Danbury Pharmacal,* 231 F.3d 1339 (Fed. Cir. 2000). The prior art had to represent a "lead compound"—a compound that was *the* most promising and also offered promise that it could be improved if modified. *See* Michael H. Teschner & Keir J. LoIacono, *Structure Has Little To Do With Structural Obviousness*, 212 N.J.L.J. 69 (S-5) (Apr. 15, 2013); *but see Galderma Labs v. Tolmar*, 737 F.3d 731, 737 (Fed. Cir. 2013) (the Federal Circuit acknowledging that obviousness does not *necessarily* require starting with an approved commercial product).

For some time thereafter, the additional motivation requirement was limited to this one relatively small corner of U.S. patent law. But that, too, may be expanding. In 2003, Helsinn Healthcare sought to patent an allegedly stabilized form of palonosetron, a drug known as early as 1993 for treating chemotherapy-induced nausea and vomiting (see, e.g., U.S. Patent No. 5,202,333). In 2016, Dr. Reddy's Labs challenged Helsinn's U.S. Patent No. 9,173,942 in a Post Grant Review proceeding at the U.S. Patent and Trademark Office (USPTO). As the primary modification embodied in Helsinn's claims was improved stability of otherwise known

palonosetron formulations, Dr. Reddy's provided references suggesting the claimed storage-stable formulations were obvious. In response, before addressing the teachings of this prior art or its combinability, Helsinn argued that one would not even look to stabilize palonosetron because: (1) any enthusiasm for drugs using palonosetron's mechanism of action had faded; (2) there was a new class of drug with lots of promise that dominated research; and (3) the market would not invest in what would be, at best, a "me too" drug. *See Dr. Reddy's Labs v. Helsinn Healthcare*, PGR2016-00007, Paper 10, at 18-29 (Patent Owner's Prelim. Resp., May 18, 2016) (the authors represented Dr. Reddy's). According to Helsinn, absent a motivation to look at *known* palonosetron formulations to begin with, one should not even entertain an obviousness analysis.

In another USPTO proceeding known as an inter partes *r*eview, Amneal Pharmaceuticals challenged U.S. Patent No. 9,034,376, one of many covering an extended-release version of oxycodone owned by Purdue Pharma. *See Amneal Pharm.* v. *Purdue Pharma,* IPR2016-01413. Before addressing whether the asserted prior art rendered the claims obvious, Purdue argued that there were several possible research directions known in the art at the time and that one would not start with the direction embodied in the asserted claims. *Id.*, Paper 17, at 33-35 (Patent Owners' Resp., Apr. 10, 2017) (the authors represented Amneal). Purdue asserted that other starting points were more appropriate than those argued by Amneal because they were closer to the original commercial product and/or the subject of discussion in other publications. Therefore, according to Purdue, one would not consider obviousness from another known, but arguably "less desirable" starting point, albeit one that was closer *technologically* to that claimed.

In all three of these instances, a new gatekeeper was proposed. According to the respective patentees, before one looked at how the *Graham* factors apply and whether the result rendered the claims obvious, the patent challenger needed to identify a specific reason to justify starting the analysis at a particular point, above and beyond the closeness of the art to what was claimed. In the *Yamanouchi* example, the fact that a particular prior art reference disclosed the closest structure, standing alone, was allegedly not enough reason; instead, one had to show that it was a promising choice for modification to become an active drug. In the *Dr. Reddy's* example, even though palonosetron formulations were known, one had to show why there would be any interest in even considering it for further development. And in the *Amneal* example, there were several equally valid and known routes of exploration, but the challenger allegedly needed to have a reason to start with any one particular route. If no further justification was identified, these patent owners suggested that one need not even engage in an obviousness analysis.

Because protecting the public's right to public domain knowledge is so fundamental, requiring a lead compound, or other motivation, to *begin* an obviousness inquiry is simply incorrect. To guard the public domain, one must go to the closest technological point(s) and begin the inquiry there. Indeed, that is exactly what the *Graham* factors require. *Graham* does not ask whether that technology is in vogue, considered most promising, or represents a technology that the industry thinks is all played out. Rather, what is relevant is that the knowledge, favored or not, is public and that it is the closest prior art to the claim in question—nothing more. Only by going to the closest point in the public domain, for its own sake, can one determine if a claimed invention falls within the metes and bounds of the public domain's penumbra reserved as a statutory safeguard—whether the claimed invention is obvious.

Ironically, adding motivational requirements for allowing prior art to be used to start an obviousness analysis might effectively remove knowledge from the public domain. For example, if one must only use the most commercially-desirable, objectively-best, or most popular current technology as a starting point, then non-preferred, but clearly disclosed combinations of molecules, ingredients, components, or method steps, suddenly would not count. And it is as if they do not exist. Not only is that contrary to precedent (*see In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004)), but the result could be a patent claim encompassing and effectively removing this less preferred, but known or obvious, technology from the public domain. And, on a more practical level, requiring a motive to start an obviousness inquiry would place a new requirement on USPTO examiners, making it far more difficult for them to police and protect the public domain. Such a requirement would also take the U.S. patent system further away from prominent worldwide practices, which have no such requirements, just at a time when the industry is rightly demanding harmonization

Factors such as the developmental environment at the time of the invention, the industry's perception of the usefulness and acceptance of a technology, and the like, can play a role in an obviousness analysis. But the proper place for one to interject these considerations is in questioning whether someone would modify that technology or combine it with other technology—the traditional role of motivation—not whether one would *start* there.

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