Obviousness Rejections: Rebutting the Prima Facie Case

A Lexis Practice Advisor® Practice Note
adapted from *Top Tips for Overcoming Section 103 Obviousness Rejections*,
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This practice note suggests to patent prosecutors how to rebut a patent examiner's prima facie case of obviousness. For a discussion of how to attack the examiner's prima facie case, thus possibly eliminating the need for rebuttal, see Obviousness Rejections: Attacking the Prima Facie Case.

In this practice note, we discuss the rebuttal of a prima facie case of obviousness in the context of the examination of U.S. patent application claims by a patent examiner. Note that the same principles apply in the context of inter partes patentability challenges before the USPTO's Patent Trial and Appeal Board (PTAB), because, just like before the examiner, the claims do not have a presumption of validity before the PTAB. However, in PTAB proceedings, the initial burden of persuasion is on the petitioner, the rebuttal burden is on the patent owner, and PTAB operates as an adjudicator of the parties' arguments. For a discussion of obviousness in the context of federal court litigation, see Obviousness in Patent Litigation.

Rebutting the Prima Facie Case

Only if an examiner establishes a prima facie case of obviousness does the burden of going forward shift to the applicant. See In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990); In re Giannelli, 739 F.3d 1375, 1379 (Fed. Cir. 2014); In re Brandt, 886 F.3d 1171, 1176 (Fed. Cir. 2018). (Similarly, in an inter partes PTAB proceeding, "once a challenger has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence." Prometheus Laboratories, Inc. v. Roxane Laboratories, Inc., 805 F.3d 1092, 1101 (Fed. Cir. 2015)).

To rebut the examiner's prima facie case, the applicant may produce evidence of nonobviousness. When rebuttal evidence is submitted in response to a prima facie case of obviousness during prosecution, the examiner must then consider all of the evidence anew, irrespective of the strength of the prima facie case. See In re De Blauwe, 736 F.2d 699, 706 (Fed. Cir. 1984); In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976); In re Huai-Hung Kao, 639 F.3d 1057, 1066 (Fed. Cir. 2011).

If present, objective evidence cannot be disregarded. See MPEP § 716.01(a), § 716.01(d), § 2142, § 2145; Apple Inc. v. International Trade Com'n, 725 F.3d 1356, 1365 (Fed. Cir. 2013); TriMed v. Stryker, 608 F.3d 1333, 1343 (Fed. Cir. 2010). If the examiner finds the evidence insufficient, a full explanation must be provided to the applicant. General statements do not meet this requirement. MPEP § 716.01.

In Ex parte Thompson, 2014 Pat. App. LEXIS 1715 (P.T.A.B. March 21, 2014) (designated informative on April 14, 2020), the examiner rejected the claims as having been obvious, unpersuaded that evidence of long-felt but unmet need and failure of others rebutted the prima facie case of obviousness. The PTAB reversed, finding that the examiner failed to properly consider the objective evidence of non-obviousness. The PTAB acknowledged that the objective evidence may not outweigh the prior art-based evidence of obviousness. However, "that still does not obviate the requirement that this prior art-based evidence must be

properly considered in conjunction with other evidence of secondary considerations of non-obviousness and weighed appropriately in determining whether the claimed invention would have been obvious at the time of the invention." 2014 Pat. App. LEXIS 1715, at *19 .

Rebuttal by Submission of Objective Evidence of Nonobviousness

You may rebut a prima facie case of obviousness by submitting objective evidence of nonobviousness with a supported explanation of the nexus between the evidence and the claimed invention. The merits of the claimed invention must be shown to be responsible for the objective evidence of nonobviousness. Commercial success, for example, attributable to marketing efforts does not have the required nexus between the objective evidence and the merits of the claimed invention. You must also show how the objective evidence is commensurate in scope with the claimed invention. MPEP § 2145.

Objective indicia of nonobviousness provide an indication of the economic and motivational issues relevant to the claimed invention and tend to shed light on whether the skilled artisan would have found it obvious to modify the prior art in such a way as to arrive at the claimed invention. This evidence can include a showing of unexpected superiority over the prior art as well as other objective indicia of nonobviousness, such as commercial success or a long-felt need. Often, evidence of multiple objective indicia will be submitted at the same time. The types of indicia might, after due consideration, be presented in the specification of the application when filed, or in the form of an affidavit or declaration during prosecution, are the following:

- The criticality or unexpected results of the invention (but take into consideration how that evidence might affect written description and enablement requirements)
- The invention's resolution of a long-felt need
- The failure of others to find a solution to the problem plaguing the art
- The commercial success of the invention
- The industry's acquiescence in the invention's merit through licensing it
- The copying of the invention by others
- Disbelief and acclaim by experts in the art of the invention's success
- Admissions of nonobviousness by an adversary
- Near-simultaneous invention by others

Evaluating the obviousness of the subject matter as a whole requires considering the objective evidence of nonobviousness along with the other so-called *Graham* factual inquiries. See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17–18 (1966).

For an examiner, the PTAB, or a court to credit such objective evidence, the applicant must establish a nexus between the evidence and the merits of the claimed invention. MPEP § 716.01(b). This nexus between the evidence and the claimed invention "is a legally and factually sufficient connection." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988). The objective evidence must also be commensurate in scope with the claims. MPEP § 716; Allergan, Inc. v. Apotex Inc., 754 F.3d 952, 965 (Fed. Cir. 2014); Polaris Indus. v. Arctic Cat, Inc., 882 F.3d 1056, 1072 (Fed. Cir. 2018). The objective evidence will fail to rebut a prima facie case of obviousness if there is found to be no nexus to the merits of the claimed invention, or that the evidence is not commensurate in scope with the claims, or that, on balance, the objective evidence does not outweigh the showing of obviousness.

In Ex parte Whirlpool Corp., 2013-008232 (PTAB Oct. 30, 2013) (designated "informative" April 14, 2020), the PTAB reversed an examiner's rejection for obviousness. The patent owner submitted 11 declarations related to industry praise, copying, commercial success and long-felt but unmet need, but the examiner concluded that the patent owner had not established a nexus between the objective evidence and the merits of the claimed invention. The PTAB found, however, a sufficient nexus to demonstrate nonobviousness, explaining as follows: " We agree with the Examiner that some of Patent Owner's secondary-considerations evidence ... refers to features ... not found in claim 1.... But we disagree that no nexus is therefore shown. An invention may be praised or commercially successful for reasons other than the claimed invention but a nexus may still exist as long as it can be shown that such praise or success is also due in part to the claimed invention." Whirlpool at *15-16. The PTAB also found that the objective evidence of commercial success was sufficiently tied to the claimed and novel combination of an ice maker mounted above a door-mounted ice storage bin. Whirlpool at *16.

On long-felt need, in Ex parte Thompson, the PTAB outlined three elements that must be shown for long-felt but unmet need: (1) the need must have been a persistent one that was recognized by ordinarily skilled artisans; (2) the long-felt need must not have been satisfied by another before Appellant's invention; and (3) the invention must, in fact, have satisfied the long-felt need. 2014 Pat. App. LEXIS 1715, at *8.

To be persuasive, objective evidence must be supported by actual proof, not simply argument. See MPEP § 716.01(c).

Showing Unexpected Results by Comparative Testing

An applicant can rebut a prima facie case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. MPEP § 716.02. If a person of ordinary skill in the art would have been surprised by the applicant's results, then the invention should not have been obvious.

An applicant may include support for the unexpected results in the specification. Specifically, an applicant could describe in the application the property or properties of the claimed invention alleged to exhibit unexpected results. See In re Geisler, 116 F.3d 1465, 1470 (Fed. Cir. 1997); In re Davies, 475 F.2d 667, 671 (CCPA 1973); In re Stewart, 222 F.2d 747, 754 (CCPA 1955); see also Ex parte Engelhardt, 208 U.S.P.Q. 343, 352 (Bd. Pat. App. 1980) (finding a prima facie case of obviousness unrebutted and noting that the application did not teach any special or unusual properties for the claimed compound).

The most common and effective way that applicants establish unexpected results is by performing comparative testing. In addition to the requirements pertaining to all objective evidence outlined above (nexus, commensurate in scope with the claims, not bare assertion), the courts, examiners, and the PTAB have the following further requirements on such evidence:

- **Test against the closest prior art disclosure.** An applicant must compare his invention to the closest prior art. Further, within the closest prior art reference, the applicant must test against the closest disclosure from that reference. See MPEP § 716.02(e). If presenting rebuttal evidence such as test results, interview the examiner, and try to agree on what kind of testing will be persuasive before the tests are initiated. Also, it bears mention that it may be difficult, both factually and legally, to ascertain the closest prior art.
- **Unexpected results must be commensurate with claims.** An applicant must show that the unexpected results are commensurate in scope with the claims. It is possible that testing one species could be sufficient if there is some sort of supporting evidence, such as proof that equivalence of the other species would have been obvious to one skilled in the art. See MPEP § 716.02(d).
- **Unexpectedness must be shown.** The applicant must show that results are actually unexpected. The claimed invention must exhibit unexpected results that differ in kind, not just degree, from the prior art. See Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293, 1306 (Fed. Cir. 2015) ("We also conclude that the district court did not clearly err in finding that the claimed formulation exhibited 'unexpected results,' which differed in kind, not just in degree, from the prior art."). In other words, the unexpectedness must be sufficient "to secure the validity of the claims in suit." Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1381 (Fed. Cir. 2005). See MPEP § 716.02.

Before commissioning comparative testing, you should agree with the Examiner on a reasonable scope of the testing deemed adequate to the Examiner.

For any testing, particularly testing to be presented in a declaration, be on high alert. Do not let falsity of data or any other kind of affirmative egregious misconduct sneak in. Such could lead to the ruination of the resulting patent under the doctrine of unclean hands or for inequitable conduct.

Conclusion

If the examiner's prima facie case is difficult to attack, you may need to rely on rebuttal evidence. As with submission of evidence attacking the examiner's prima facie case, submission of rebuttal evidence requires careful thought and planning. Do not throw a declaration or comparative testing protocol together in haste leading to harmful mistakes. As noted just above, be aware that the duty of candor (Rule 56) applies. Inconsistent or non-disclosed data may pose dangers. Also, declarations may create prosecution history estoppel.

advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors and Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm) cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with these authors. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.

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A significant portion of Tom's current practice is focused on AIA post-grant proceedings, including how to enhance the strength of patents in the pharmaceutical space to protect against post-grant challenges. He has served as lead counsel in numerous patent interferences, reissues, and reexaminations; as counsel in numerous AIA post-grant proceedings; and as an expert witness in patent litigation. Tom directed the preparation of two highly complex IPRs for possible use in settling litigation.

Tom has been extensively involved in counseling, due diligence, prosecution and prelitigation for matters involving major drugs such as Kalydeco®, Orkambi®, Aloxi®, Tecfidera®, Lorcaserin®, Pulmicort® Respules®, Taxotere®, Eloxatin®, Lantus®, Crestor®, Targretin®, Brilinta®, Halaven®, Allegra®, Apidra®, Epiduo Gel®, Rilutek®, Ramipril®, Jakafi®, Duexis®, Viracept®, and other drugs such as Rimonabant®, VX-661, and HMPL 0004®, in clinical trials prior to FDA approval. He successfully reissued the patent for the low molecular weight heparin drug, Lovenox®, a blockbuster product.

For more than 25 years, Tom has served as principal teacher of the Patent Resources Group (PRG) Chemical Patent Practice course, a comprehensive course on U.S. chemical patent law taught twice a year; he coauthors the multi-volume treatise used in the course. He originated PRG's Orange Book and Due Diligence courses, which help prepare patent owners, through effective application drafting and prosecution, to withstand the rigors of AIA's inter partes review (IPR) and post-grant review (PGR). He presents analyses of U.S. Court of Appeals for the Federal Circuit patent decisions for many state bar association groups and has spoken at numerous national trade and bar association meetings such as the Intellectual Property Owners Association, American Intellectual Property Law Association (AIPLA), and American Bar Association. Tom has lectured at many law schools in both the United States and China, and at the Patent Office of the State Intellectual Property Office (SIPO) of the People's Republic of China. He has participated in multiple Strafford Webinars on patent law topics, including several that deal with AIA post-grant proceedings.

Over the years, Tom has been recognized by *Intellectual Asset Management* as a leading patent prosecutor in the D.C. area, and nationally for post-grant procedures. *The Legal 500 U.S.* recognized him for patent portfolio management and licensing. Tom was inducted into the *LMG Life Sciences* Hall of Fame and recognized as the Patent Strategy & Management Attorney of the Year: District of Columbia.

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