

Blocking Patent Discounts Objective Indicia Of Non-Obviousness

Article By:

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In [*Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*](#), the Federal Circuit affirmed the district court decision finding four Acorda Orange Book-listed patents for Ampyra® invalid as obvious. Acorda raised a number of arguments on appeal, but this article focuses on the impact of a blocking patent on consideration of objective indicia of non-obviousness.

The Acorda Ampyra® Patents At Issue

Ampyra® (4-aminopurine sustained release tablets) is approved for improving walking in patients with multiple sclerosis (MS). The Orange Book-listed patents for Ampyra® include the four Acorda patents at issue in this case—U.S. Patent Nos. 8,00,826, 8,663,685, 8,354,437, and 8,440,703—and an earlier patent licensed from Elan, U.S. Patent No. 5,540,938.

The Elan patent claims methods of treating MS using a sustained release formulation of 4-AP, while the Acorda patents claim additional features including (1) administering a 10 mg dose twice a day; (2) at that stable dose for a treatment period of at least two week; (3) to achieve 4-AP serum levels of 15-35 ng/ml; and (4) to improve walking.

The Underlying ANDA Litigation

This appeal arose from ANDA litigation that involved defendants Roxane, Mylan Pharmaceuticals Inc. and Teva Pharmaceuticals USA, Inc. The defendants stipulated to infringement, but challenged validity. The district court upheld the Elan patent against their obviousness challenge, but found the asserted claims of the Acorda patents obvious. With regard to objective indicia of non-obviousness, the district court acknowledged evidence of commercial success, long felt need, and failure of others, but discounted it because the Elan patent was a “blocking patent” for the claimed methods. That is, because a would-be infringer or generic also would have to invalidate or license the Elan patent, the evidence pertaining to Ampyra® did not show the Acorda patents were non-obvious.

The Federal Circuit Decision:

The Impact of Blocking Patents on Objective Indicia of Nonobviousness

The Federal Circuit decision was authored by Judge Taranto. Judge Dyk joined in the decision. Judge Newman filed a dissenting opinion.

On appeal, Acorda argued that the district court improperly “applied a categorical rule that a blocking patent defeats the significance of ... objective indicia to the obviousness determination.” The Federal Circuit rejected that characterization, finding instead that the district court had properly considered the impact of the blocking patent “on the limited factual record created in this case.”

The Federal Circuit explained:

A patent has been called a “blocking patent” where practice of a later invention would infringe the earlier patent. The existence of such a blocking patent may deter non-owners and non-licensees from investing the resources needed to make, develop, and market such a later, “blocked” invention, because of the risk of infringement liability and associated monetary or injunctive remedies. If the later invention is eventually patented by an owner or licensee of the blocking patent, that potential deterrent effect is relevant to understanding why others had not made, developed, or marketed that “blocked” invention and, hence, to evaluating objective indicia of the obviousness of the later patent.

The Federal Circuit discussed three previous Federal Circuit decisions discussing blocking patents. In each of *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005) (*Merck I*), *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013) (*Galderma*), and *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724 (Fed. Cir. 2017) (*Merck II*), the earlier (blocking) and later patents were owned by the same entity. In *Merck I* and *Galderma* the earlier blocking patents were found to have “depressed incentives for others to invent [the claimed invention]” and “blocked” competition. In both cases, evidence of commercial success was discounted in the obviousness analysis because of the blocking patent. In *Merck II*, the court recognized that “Merck’s exclusive license to a blocking patent did not, all by itself, justify discounting evidence of commercial success” because “commercial success is a ‘fact-specific inquiry.’” But, the judgment of obviousness was affirmed in light of the evidence as a whole.

Citing *Merck II*, the Federal Circuit explained that “a blocking patent may or may not deter innovation in the blocked space by commercially motivated potential innovators.” The court listed a number of variables in addition to the risk of infringement liability that may be relevant to further innovation, but concluded:

[I]f all other variables are held constant, a blocking patent diminishes possible rewards from a non-owner’s or non-licensee’s investment activity aimed at an invention whose commercial exploitation would be infringing, therefore reducing incentives for innovations in the blocked space by non-owners and non-licensees of the blocking patent. Such a blocking patent therefore can be evidence that can discount the significance of evidence that nobody but the blocking patent’s owners or licensees arrived at, developed, and marketed the invention covered by the later patent at issue in litigation. But the magnitude of the diminution in incentive in any context—in particular, whether it was great enough to have actually deterred activity that otherwise would have occurred—is “a fact-specific inquiry.”

The Impact of the Elan Blocking Patent on Acorda’s Evidence

Turning to the case before it, the Federal Circuit noted that Acorda had exclusively licensed the Elan patent in the late 1990s, which was long before the period of commercial success it alleged for Ampyra®. The Federal Circuit agreed with the district court’s finding that “the risk of infringement

liability for marketing in the United States would have provided an independent incentive for a patentee not to develop the invention of the Acorda patents, even if those inventions were obvious.” Acorda argued against any blocking effect because of the safe harbor provisions of 35 U.S.C. § 271(e)(1), but the Federal Circuit commented that the safe harbor, although relevant, does not rule out infringement liability once the product is marketed.

The Federal Circuit agreed with the district court’s treatment of Acorda’s evidence of failure of others and long-felt need for similar reasons, finding that both could be attributed to the blocking effect of the Elan patent.

Judge Newman’s Dissent on Blocking Patents

Judge Newman would have given more weight to the evidence of objective indicia of non-obviousness, and reversed the district court’s judgment that the Acorda patents are invalid as obvious. Judge Newman opined that the majority panel erred in discounting the evidence of objective indicia by incorrectly reasoning that “no one other than the Elan patentees and their licensees could have practiced the invention of the Acorda patents without facing liability for patent infringement.” Judge Newman disagreed with the majority’s blocking patent theory, reasoning that the Elan patent did not block research using AP-4 (because of the safe harbor) or development of other possible treatments, and had not prevented the defendants from developing their generic products.

With respect to long-felt need and failure of others, Judge Newman believed Ampyra® met a long felt need against the backdrop of decades of failed research with 4-AP, including Elan having given up on its work with 4-AP after years of its own research.

Can Objective Indicia Ever Survive A Blocking Patent?

While the Federal Circuit emphasized that the impact of a blocking patent is a “fact-specific inquiry,” it admitted that it is a “difficult one as a practical matter.” The court recognized that “the challengers always retain the burden of persuasion on obviousness,” but surmised that “a court may ultimately be left, for its evaluation, with the solid premise of diminished incentives, plus some evidence (possibly weak or ambiguous) about the significance of the deterrence, together with a background sense of the general realities in the area at issue that can affect the weight to be given to the evidence in the specific case.” Once a district court makes such a “difficult” determination, its factual underpinnings would be entitled to deferential review.

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