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“Blocking Patent” Deterrence Effect May Discount Secondary Considerations for Follow-On Patents

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The US Court of Appeals for the Federal Circuit affirmed a district court’s obviousness determination, finding that a patentee’s exclusive, in-licensed “blocking” patent limited the weight of secondary factors favoring non-obviousness of its follow-on patents. *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.*, [Case Nos. 17-2078, -2134](#) (Fed. Cir. Sept. 10, 2018) (Taranto, J) (Newman, J, dissenting).

Acorda Therapeutics owns four US patents directed to use of a sustained-release formulation of 4-aminopyridine (4-AP; Ampyra®) for improving gait function or speed in patients with multiple sclerosis (MS). Acorda is also an exclusive licensee of a patent from Elan Corp. that broadly covers methods of treating MS using a sustained-release formulation of mono- or di-aminopyridines. The Acorda patents require the recited dose (10 mg), dosing regimen (twice daily), duration of therapy (two weeks) and pharmacokinetics (serum levels of 15–35 ng/ml) of the drug, which are not expressly taught by the Elan patent.

Acorda filed an abbreviated new drug application litigation asserting the Acorda and Elan patents against several generic drug companies, including Roxane Laboratories, which had sought US Food and Drug Administration approval to market generic versions of Ampyra. Roxane stipulated to patent infringement, but claimed that the Elan and Acorda patents were invalid due to obviousness.

The district court upheld the validity of the Elan patent but found the Acorda patent claims invalid as obvious. The district court found that, in view of the prior art, a person of ordinary skill would have been motivated to improve the walking ability of MS patients by administering a stable dose of 10 mg of 4-AP twice daily, with a reasonable expectation of success. Further, the recited pharmacokinetic aspects were found to be inherent to dosing. While acknowledging evidence of commercial success, long-felt need and failure of others, the district court held that the weight of these secondary *indicia* of non-obviousness was discounted: not only did the in-licensed Elan patent deter third-party innovation in this blocked space, but Elan and Acorda were incentivized not to develop the follow-on patents immediately. Acorda appealed.

On appeal, Acorda argued against the district court’s determination of obviousness and contended that it was improper for the district court to hold that a blocking patent negated secondary factors supporting non-obviousness. The Federal Circuit disagreed on both counts. The Court found that the prior art of record rendered obvious all asserted claims of the Acorda patents, and agreed with the district court’s determination that the Elan patent deterred third parties from investing the resources necessary to make, develop and market a “blocked” invention because of the risk of infringement liability and associated monetary or injunctive remedies. The Court explained that where the earlier (blocking) and later patents were owned by or licensed to the same entity (such as in the instant case), the effect of the blocking patent is especially relevant to evaluating objective *indicia* of the obviousness of the later patent.

Judge Newman dissented, stating that the district court used hindsight to select “separate limitations from separate sources, and retrospectively [fit] them into the Acorda template.” Citing “decades of failure” with an unpredictable drug having a “narrow toxic-to-therapeutic range” and severe side effects, she stated that the record supported Acorda’s position. In Newman’s opinion, the statutory safe harbor for research on patented



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subject matter would have reduced the threat of blocking patents. She lamented that the majority had misconstrued what constitutes commercial success. Lastly, she noted that the Patent Trial and Appeal Board's *inter partes* review decision upheld the validity of the Acorda patents and that issues relating to privity, estoppel and finality from that decision had not been explored here.

Practice Note: In patent validity challenges based on obviousness, it may be worthwhile to investigate whether the patentee was an owner or exclusive licensee of an earlier blocking patent that can form the basis to argue reasonable reluctance to speedy file and/or license a follow-on patent.

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