IP Alert: Should “Blocking Patents” be Used as a Blunt Weapon or as a Factor in a Sophisticated Economic Analysis?

Should “Blocking Patents” be Used as a Blunt Weapon or as a Factor in a Sophisticated Economic Analysis?

By Sarah A. Kagan

In recent oral arguments in a dispute over the obviousness of U.S. patents covering the use of $1.7 billion/year drug Ampyra® for the alleviation of walking disorders in multiple sclerosis patients, counsel for both the patentee (Acorda Therapeutics) and the challenger (Roxane Laboratories) dwelled on the granular elements of the prior art teachings for most of their time before a panel of

the Court of Appeals Federal Circuit. Acorda Therapeutics, Inc. v. Roxane Labs., Inc., Appeal Nos. 2017-2078, 2134. Judges Newman, Dyk, and Taranto presided over the June 7, 2018 oral argument. Patentee Acorda tried to highlight the uncertainties in the prior art, which, it argued, failed to teach or suggest the absolute dose and the flat dosing regimen of the claimed methods. The challenger Roxane highlighted the prior art teachings that pointed to at least trying the claimed method. This portion of the argument was very fact-intensive, and the judges did not exhibit any propensity to find fault with the district court's underlying fact findings supporting its legal conclusion of obviousness.

The panel exhibited some level of skepticism, however, of the way the district court used a "blocking patent" in weighing the objective indicia of non-obviousness. A blocking patent is an earlier patent that dominates a later patent whose non-obviousness is at issue. Typically, a single party owns the two patents, or the later patentee has a license to practice the earlier patent. A blocking patent is often used by a patent challenger as a tool to undermine the nexus between commercial success and the features of the invention of the later patent. Here, the district court found that Acorda, the patentee, had shown several non-obviousness indicia, including commercial success, long-felt but unmet need, and failure of others, as well as showing a nexus of the commercial success to the claimed features. But the district court discounted the objective indicia because of the existence of a blocking patent (Elan's U.S. 5,540,938) licensed to Acorda. The district court wrote, "The risk of such liability [for patent infringement] would have provided an independent incentive for a patentee (sic) not to develop the invention of the Acorda Patents, even if these inventions were obvious." Acorda Therapeutics, Inc. v. Roxane Labs., Inc., No. 14-882, 2017 WL 1199767 (D. Del. Mar. 31, 2017), slip opinion at page 83.

During Acorda's arguments on appeal, Judge Taranto indicated that a product-specific analysis might be required to determine how much of an economic disincentive the blocking patent posed. Judge Dyk asked whether third parties in the real world would compete to research and develop new therapies within the space of a dominant patent. Judge Newman asserted that third parties could challenge a dominant patent using a Hatch-Waxman proceeding. Judge Newman was so interested in this question that she immediately engaged Roxane's counsel in this debate before he started his argument. Later, during Roxane's argument time, the panel resumed its lively debate on the use of blocking patents. Judge Taranto elaborated on his theory that a court should perform an economic analysis on the particular product and the particular market to determine empirically what the effect of the particular blocking patent would have been, rather than using a categorical rule. Judge Taranto stated that a categorical rule could not be correct. Rather, the proper question to ask is whether economically it would have been worth it to a third party, knowing the risk, to proceed with the research and development. Where, Judge Taranto asked Roxane's counsel, are the fact findings in the district court's decision on which such a decision should have been based? Judge Dyk stated that in the real world, a third party would not embark on the research and development

without first having a license to the dominant patent. Judge Taranto asked how the judges would know that without any testimony on the subject.

Roxane's counsel, sensing that the conversational tide was turning, stated that in each of precedential blocking patent cases Merck,[1] Galderma,[2] and Syntex,[3] the Federal Circuit had remanded the case to the district court to consider the relevance of the blocking patent. This comment may signal a wish for such a result in the current case.

During the oral argument, Judge Taranto also asked both Acorda's and Roxane's counsel whether a third party would have been protected from infringement liability under 35 U.S.C. §271(e)(1) for research and development work up until Food and Drug Administration (FDA) approval. Both Acorda's and Roxane's counsel indicated that it would. This question and answer hint at a possible justification for the court to back away from the Merck absolute bar. The Merck court explained its bar stating, "Financial success [commercial success] is not significantly probative of that question [non-obviousness over prior art] in this case because others were legally barred from commercially testing the Lunar news ideas." However, as both Acorda and Roxane agreed, under 35 U.S.C. §271(e)(1), parties may perform pre-clinical and clinical studies with impunity, even if such studies have a commercial goal. Judge Taranto hinted that this might provide a wrinkle that the court might use to justify stepping back from Merck's absolute bar. Judge Taranto noted during the hearing that the Federal Circuit's Merck blocking patent case was decided in January 2005, before the Supreme Court's June Integra**[4]** decision. Integra held that the safe harbor of 35 U.S.C. §271(e)(1) extends to pre-clinical studies. The relative timing of the two cases might permit the Acorda panel to urge that the framework under which the Federal Circuit instituted Merck's absolute bar changed with the decision in Integra.

Currently the blocking patent doctrine is a blunt weapon wielded by infringement defendants, typically generic drug companies. The Acorda v. Roxane appeal may give the Federal Circuit the opportunity to turn the doctrine into a more sophisticated tool of economic analysis.

Click here to listen to oral arguments in Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.

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[1] Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364 (Fed. Cir. 2005)

[2] Galderma Laboratories, L.P. v. Tomar, Inc., 737 F.3d 731 (Fed. Cir. 2013)

[3] Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371 (Fed. Cir. 2005)

[4] Merck KGaA v. Integra Lifesciences I, Ltd, 545 U.S. 193 (2005)

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