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Endo Pharmaceuticals v. Actavis: An Analysis from a Transactional Perspective

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On March 31, 2014, the U.S. Court of Appeals for the Federal Circuit **vacated a denial of a preliminary injunction** in *Endo Pharmaceuticals, Inc. v. Actavis, Inc. and Actavis South Atlantic, LLC*, in a decision that underscores the importance of careful drafting and knowledge of the patent landscape in executing patent license agreements.

Endo Pharmaceuticals, Inc. sells Opana ER, which contains the painkiller called oxymorphone. Actavis, Inc., Actavis South Atlantic, LLC, and Roxane Laboratories, Inc. (collectively the **"Defendant-Appellees"**) attempted to market generic versions of Opana ER. After an initial patent infringement suit between Endo and Actavis, all parties entered into settlement and license agreements. The license agreement between Endo and Roxane, to which the license agreement between Endo and Actavis is similar, dictated that Endo would grant patent licenses for:

> "(a) any [U.S.] patents that are both (i) now owned by Endo…and (ii) issued as of the Effective Date of this Agreement, including the Opana ER Patents,
>
> (b) any [U.S.] patent applications that claim priority to the Opana ER Patents, including any continuation, continuation-in-part and divisional patent applications that claim priority to Opana ER Patents, and
>
> (c) any patents resulting from the reissue or reexamination of patents or patent applications comprised within clauses (a) and (b)…"

As a result of clauses (a) through (c), the license agreement granted express license rights to the Defendant-Appellees for three of Endo's Opana ER patents. As a limitation to the scope of the Licensed Patents, the license agreements contained provisions expressly barring any patent rights to Actavis and Roxane "whether by implication, estoppel or otherwise, other than as expressly granted herein." Roxane J.A. 4949 § 4.4. While the license agreements contained covenants not to sue, detailing that Endo would not assert that Defendant-Appellees' generic versions of Opana ER infringe, those covenants were limited to the Licensed Patents.

Subsequent to the license agreement, the USPTO issued two additional Endo patents relating to Opana ER. Endo then sued Actavis and Roxane, alleging that their generic versions of Opana ER violated these two newly issued patents, for which Actavis and Roxane did not have a license. Endo moved for a preliminary injunction to prevent further marketing of the Defendant-Appellees' generic versions of Opana ER. In response, Actavis and Roxane argued that they had an express license and an implied license to the later-issued patents, the latter license by reason of estoppel because Endo was effectively trying to deprive them of "the benefit of [the earlier] bargain." Roxane J.A. 4823; see also Actavis J.A. 2717.

With regard to the Defendant-Appellees' argument that they had an express license, the question goes to whether the subsequent Endo patents fall within the scope of clauses (a) through (c) of the prior agreements. The court held that the patents did not, focusing its analysis on clause (b).

According to the court, to satisfy clause (b), "a patent must make an express cross-reference to the nonprovisional application from which the prior patent issued." *Endo Pharmaceuticals, Inc. v. Actavis, Inc.*, No. 2013-1662, 2014 WL 1272846 *7, n. 1 (Fed. Cir. Mar. 31, 2014). The court found that none of the subsequent Endo patents were continuations of the patents governed by the license agreements because the subsequent patents did not cross-reference the Licensed Patents.

However, the subsequent patents did claim priority to a U.S. provisional application to which one of the Licensed Patents also claimed priority. On this basis, Actavis and Roxane argued the subsequent

patents satisfied clause (b). The court rejected those arguments, holding that a common provisional application was insufficient to satisfy clause (b). Instead, the later-issued patents would have had to cross-reference a Licensed Patent in order to be a "continuation" of a Licensed Patent.

The court explained that Actavis and Roxane were only granted licenses limited to specific patents and patent applications, not to entire subject matters. The court effectively held that estoppel does not grant an implied license to unrelated patents. Thus, Endo was not estopped from asserting the subsequent patents because the subsequent patents are not continuations of the Licensed Patents. Accordingly, the court vacated the district court's denial of a preliminary injunction and remanded for further proceedings.

From a transactional standpoint in drafting patent license agreements, the court suggested two provisions that would have expressly included the later-issued patents in the license and prevented Endo from suing the Defendant-Appellees for patent infringement.

First, in a situation where several patents have a provisional application in common, a licensee should include language that the licensed patents include "any application claiming a common priority date as the licensed patents." This language would have expressly made the subsequent patents Licensed Patents under the agreement.

Second, if properly drafted, a license agreement may provide an implied license to subsequent patents where the subsequent patents have the "same inventive subject matter" as the licensed patents. *Endo Pharmaceuticals, Inc. v. Actavis, Inc.*, No. 2013-1662, 2014 WL 1272846 *12 (Fed. Cir. Mar. 31, 2014) (citing *General Protecht Group, Inc. v. Leviton Manufacturing Co., Inc.*, 651 F.3d 1355, 1361 (Fed. Cir. 2011)). Such implied license was found when the license agreement at issue gave a license "to practice, and cause to be practiced…throughout the world, each Subject Invention." This language does not limit the license to specific patents. *Id.* (citing *AMP Inc. v. United States*, 389 F.2d 448, 454 (Ct. Cl. 1967)). Rather, such language grants a license to the overall concept and subject matter of the related patents, rather than a license to specific patents, regardless of whether such patents were issued or in existence at the time of the agreement.

Following *Endo*, transactional attorneys drafting patent license agreements should be careful to avoid these pitfalls. Given the court's analysis, it is crucial to identify the potential implications of future patents and adequately address their treatment in each patent license agreement. The results of the case may cost Actavis and Roxane the ability to market their generic versions of Opana ER, despite the consideration they paid to Endo in the settlement and license agreement. As this case demonstrates, courts will not rewrite written agreements between the parties, even when the rules of patent law may render the license ineffective.