JONES DAY

COMMENTARY

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IN SHORT

The Situation: In a Hatch-Waxman litigation, the claims recite oxymorphone with less than 0.001% of an impurity called 14-hydroxymorphinone. The prior art includes confidential communications from the FDA to oxymorphone manufacturers, requiring that the level of 14 -hydroxymorphinone in oxymorphone be reduced to less than 0.001%.

The Result: On appeal, the Federal Circuit clarified that such confidential communications may qualify as prior art under pre-America Invents Act ("AIA") §102(f). The Federal Circuit affirmed for lack of reasonable expectation of success because the FDA communications said nothing about how to attain the stated goal of reducing the impurity.

Looking Ahead: Post-AIA §102 does not contain a provision corresponding to pre-AIA §102 (f). Rather, the AIA created "derivation proceedings" and a cause of action for derivation. It remains to be seen whether (and how) such confidential communications may be used as prior art under post-AIA §102 in district court infringement suits.

The Federal Circuit recently affirmed a district court's nonobviousness determination in a Hatch-Waxman litigation. The court's reasoning in that case reinforces its previous holding that "knowledge of the goal does not render its achievement obvious," where there was no reasonable expectation of success. *Endo Pharm. Inc. v. Actavis LLC*, 922 F.3d 1365, 1377 (Fed. Cir. 2019) (quoting *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008)).

Mallinckrodt owns a patent claiming a certain pharmaceutical compound (oxymorphone hydrochloride) with less than 0.001% of a particular impurity (14-hydroxymorphinone). Oxymorphone is an opioid approved by the Food and Drug Administration ("FDA") for treating pain, but prior processes for making it yielded products containing 14-hydroxymorphinone, a potentially toxic impurity (also called the "ABUK" impurity). In 2004, through confidential communications with producers of oxymorphone, including Mallinckrodt, the FDA required that the ABUK levels in oxymorphone be reduced to less than 0.001%. After extensive experimentation, Mallinckrodt was able to achieve that impurity level and applied for a patent claiming oxymorphone hydrochloride with less than 0.001% of 14-hydroxymorphinone.

In the Hatch-Waxman litigation, the defendants sought to invalidate Mallinckrodt's patent claims as obvious, citing the FDA communications and certain prior-art processes for making opioids. The district court first concluded that confidential FDA communications were not prior art. *Endo*, 922 F.3d at 1373. But in any event, the district court found that the FDA communications did not offer any reasonable expectation of success because they "provided no substantive information about how the companies were to go about producing low-ABUK oxymorphone." *Id.* at 1374.

> As the Federal Circuit noted, knowledge of the goal does not render its achievement obvious.

On appeal, the Federal Circuit disagreed with the district court on the first issue—whether the FDA communications constituted prior art. Because Mallinckrodt's patent claims have an

effective filing date before March 16, 2013, the pre-AIA version of 35 U.S.C. §102 applies. See Leahy-Smith America Invents Act (AIA), Pub. L. No. 112–29, §3(n)(1), 125 Stat. 284, 293 (2011). The Federal Circuit explained that private communications between an inventor and a third-party may qualify as prior art under pre-AIA §102(f), even when the disclosure lacks "any teachings of how to accomplish a stated goal." *Endo*, 922 F.3d at 1373 n.9. As the court explained, "a reference need not work to qualify as prior art; it qualifies as prior art, regardless, for whatever is disclosed therein." *Id.*

Interestingly, the post-AIA version of §102 does not contain a provision corresponding to pre-AIA §102(f). Rather, the AIA created a "derivation proceeding" before the Patent Trial and Appeal Board under §135 and a cause of action for derivation in district courts under §291 for aggrieved patent applicants and patent owners. It remains to be seen whether (and how) confidential communications may be used as prior art to invalidate more recently filed patents under post-AIA §102 in district court infringement suits.

Because the district court in *Endo* considered the FDA communications in its obviousness analysis, the Federal Circuit ultimately affirmed the nonobviousness determination because the district court did not clearly err in finding no reasonable expectation of success. The Federal Circuit reasoned that although the FDA communications "introduced a market force incentivizing purification of oxymorphone to the level of the oxymorphone claimed" by Mallinckrodt, those communications only "recite[d] a goal without teaching how the goal is attained." *Endo*, 922 F.3d at 1376. Citing its decade-old precedent, the court explained that "knowledge of the goal does not render its achievement obvious." *Id.* at 1377 (citing *Abbott*, 544 F.3d at 1352). Here, "[t]he FDA communications convey[ed] nothing" that would have led a skilled artisan "to view [the prior art] teachings in a different light." *Id* at 1376-77. The Federal Circuit therefore affirmed the district court's finding of no reasonable expectation of success.

THREE KEY TAKEAWAYS

1. Confidential communications between an inventor and another may qualify as prior art under the pre-AIA version of 35 U.S.C. §102(f).
2. The AIA modified §102 and the post-AIA version does not have a provision corresponding to pre-AIA §102 (f).
3. The Federal Circuit's decision in *Endo v. Actavis* reinforces its decade-old precedent in *Abbott v. Sandoz* that "knowledge of the goal does not render its achievement obvious," where there was no reasonable expectation of success.

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