LOCKE LORD® QUICKStudy
Intellectual Property Practice
August 10, 2015

District Court Upholds Food Effect Limitation Inherency After Remand From the Federal Circuit

By: Alan B. Clement and Paul B. Sudentas

In December of last year, the Federal Circuit vacated and remanded the U.S. District Court for the District of Maryland's ("the Court") decision finding U.S. Patent No. 7,101,576 ("the '576 patent") invalid as obvious. *See Par Pharm., Inc. et al. v. TWi Pharms.*, 773 F.3d 1186 (Fed. Cir. 2014). The Federal Circuit held that the Court "applied the incorrect standard for inherency" regarding the claimed food effect and declined to affirm the inherency finding in the first instance. *Id.* at 1196 (noting "TWi failed to present evidence sufficient to demonstrated that the *claimed* food effect limitation necessarily are present in the prior art combinations.") (emphasis in original). Therefore, the Federal Circuit only vacated the Court's decision and remanded for further analysis on the inherency issue:

> Although we agree with the district court's analysis and conclusions on motivation to combine, reasonable expectation of success, and objective indicia of nonobviousness, we vacate the district court's judgment that the '576 patent is obvious, and remand for further analysis of the food effect limitation consistent with our precedent on inherency. The district court should also consider TWi's other grounds for invalidity, such as enablement, if necessary.

Id. at 1200-01.

On remand, the Court once again concluded that the food effect limitation was inherent and the asserted '576 patent claims are obvious and not enabled. *See Par Pharm., Inc. et al. v. TWi Pharms.*, No. CCB-11-2466, slip op. (D. Md. July 27, 2015).

The Claimed Food Effect is Inherent to the Combination of Compounds

The Court noted the Federal Circuit's two-part "'high standard' the parties must meet to show that a claim limitation is inherent in the prior art: 'the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed in the prior art.'" *Id.* at 2. Thus, the Court considered the threshold question of "to what degree must the food effect necessarily be reduced to meet the claimed limitations?" *Id.* at 6. TWi focused on the narrowest claimed food effect (C_{max} difference between fed and fasted states) because if that limitation was met, then the broader food effect limitations are also necessarily met. *Id.*

TWi presented three evidentiary inherency points: (1) the '576 patent contained an example that disclosed three different formulations which resulted in a difference in C_{max} that fell within the asserted claims; (2) Par's product, Megace® ES, is an embodiment of the claimed and demonstrated a difference in C_{max} that fell within the asserted claims; and (3) Par stipulated to the TWi's ANDA product, met the asserted claims. *Id.* at 7-8. Expert testimony explaining the "causal relationship between nanosizing and food effect reductions" supported the factual evidence. *Id.* at 8. The Court held that such evidence, and expert testimony, proved that the *claimed* food effect limitations are inherent in the prior art. *Id.*

Par counter-argued that "mere examples of megastrol formulations within the claimed particle size range that meet the food effect limitations cannot, alone, prove an inherent property" such that TWi needed to show that the food effect limitation would be necessarily present in *any* formulation that met the claims of the '576 patent. *Id.* and n.9. Par pointed to another example in the '576 patent showing two formulations not meeting the claimed limitations. *Id.* The Court, however, did not agree with Par's argument for two reasons: (1) Par did not point to any authority which required that TWi to show that the claimed food effect limitations are inherent to *every* formulation covered by the claims of the '576 patent; and (2) Par failed to present evidence that there existed any formulations which did not meet the claimed food effects – the Court noted that the example in the '576 patent cited by Par was data from a preclinical animal study as opposed to a study in humans. *Id.* at 9.

Accordingly, the Court held that TWi met its burden of proving that the claimed food effect limitations were inherent in the prior art. *Id.* at 9-10. This is in line with prior Federal Circuit decisions concerning food effect limitations in pharmaceutical patents such as *In re Kao*, 639 F.3d 1057, 1071 (Fed. Cir. 2011) and *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012).

Claimed Formulations Not Enabled to the Full Scope

In finding non-enablement, the Court recognized that where a claim covers a range, the specification must provide reasonable enablement of the scope of the range. *Id.* at 10-11 .

At trial, TWi presented expert testimony explaining why approximately two-thirds of the claimed particle size range (*i.e.*, "less than about 2000 nm") would not achieve the claimed food effect limitations noting that formulations using particle sizes less than 100 nm and greater than 750 nm would not meet the claimed food effect limitations. *Id.* at 11. Additionally, TWi relied on prior art demonstrating that the upper end of the particle size range did not achieve the claimed C_{max} reductions. *Id.*

Par argued, *inter alia*, that the specification is not required to describe "every conceivable embodiment of the invention." *Id.* at 12. In response, the Court noted that Par misconstrued TWi's enablement position and explained that "TWi argues [that] the specification has not enabled every value in a *claimed range* (something that is required)" rather than provide examples of every *claimed embodiment*. *Id.* at 12-13 (emphasis in original).

Based on the foregoing, the Court held that "the record reflect that *essentially no amount of experimentation* would have allowed a skilled artisan to achieve broad portions of the claimed particle size range *because scientific phenomena made that practically impossible*." *Id.* at 11-12 (emphasis added); *see also id.* at 14-15.

Conclusion

This decision provides further support to generic pharmaceuticals challenging patents with food effect limitations on both inherency and non-enablement grounds. Notably, this is not the first time that claimed food effect limitations were found to be inherent, nor is the first time that a pharmaceutical patent was found to not be enabled due to the patentees overreaching in claiming broad ranges. This decision reinforces that when assessing possible invalidity defenses: (1) evidence that a food effect claim limitations is inherent can be based on the patent examples themselves and the alleged infringing product; and (2) ranges claimed to provide a claimed food effect may be overbroad and, hence, non-enabling.

For more information on the matters discussed in this *Locke Lord QuickStudy*, please contact the authors:

Alan B. Clement | 212-812-8318 | aclement@lockelord.com
Paul B. Sudentas | 646-217-7716 | psudentas@lockelord.com