

Client Alert

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Federal Circuit Decision: Proof of Non-Enablement Requires More Than Expert Testimony That the Requisite Experimentation Would Have Been “Difficult” or “Complicated”

Last week, in *Cephalon Inc. et al. v. Watson Pharmaceuticals Inc. et al* (Fed. Cir. Feb. 14, 2013), the U.S. Court of Appeals for the Federal Circuit affirmed a district court decision that Watson’s generic fentanyl formulation did not infringe Cephalon’s patent claims, but reversed the district court’s determination that the patent claims lacked enablement. This decision, which arguably raises the bar for proving lack of enablement of pharmaceutical patent claims, will undoubtedly be cited by patent holders fending off attacks of non-enablement and inadequate written description.

The case involved a formulation of fentanyl, sold by NDA holder Cephalon under the brand name FENTORA[®]. Cephalon sued Watson after the latter filed a Paragraph 4 certification against Cephalon’s patents directed to methods of administering a drug and an effervescent agent across the oral mucosa, wherein the effervescent agent promotes drug absorption in the mouth. The district court construed the claims as covering both (1) single-dosage form administration (*i.e.*, the drug and effervescent agent are contained in the same dosage form) and (2) two-dosage form administration (*i.e.*, the drug and effervescent agent are contained on different dosage forms). However, since the specification failed to disclose any teachings directed to two-dosage form administration, the district court held that the claims were non-enabled.

On appeal, the Federal Circuit reversed. It first noted that the burden of proving invalidity was Watson’s throughout the case and that the district court had erred by suggesting that the burden shifted to Cephalon after Watson had made out a *prima facie* case. Next, the court turned to the testimony of the parties’ experts. It found that the district court gave too much credit to Watson’s expert, who testified that co-administration of dosage forms would be “difficult” and “complicated.” According to the Federal Circuit, this “largely unsupported” testimony was insufficient to meet Watson’s burden of establishing undue experimentation.

The court explained that “the question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be “unduly extensive.” It gave examples of undue experimentation, such as experimentation taking 18–24 months, or where the specification teaches away from the claimed invention and the patentee had failed to make and use the claimed invention at the time the patent application was filed. Extensive experimentation in and of itself, the court noted, is not necessarily undue, especially “if it is merely routine, or if the specification in question provides a reasonable amount of guidance.”

This case has implications for both patentees and defendants. Section 112 challenges have become routine in patent litigation, with defendants charging patents claiming more than the disclosed embodiments as being non-enabled, inadequately supported, or both. For patentees, *Cephalon* is a welcome check on the growing tide of section 112 challenges. It indicates that such challenges can no

longer be sustained on mere expert testimony alone, but rather must be supported by detailed factual allegations evidencing undue experimentation and/or lack of possession. Patentees challenging the sufficiency of a defendant's expert testimony should look to draw as many parallels to *Cephalon* as possible.

On the other side of the ledger, a defendant challenging broad claims on section 112 grounds should make sure that its testifying expert details the reasons he/she has concluded the claims are not enabled or supported. For example, the expert should opine about the length of time it would take to arrive at the undisclosed embodiment, why the experimentation would be onerous and not merely routine or repetitive, how the specification not only lacks guidance but teaches away from the undisclosed embodiment, etc. In other words, an accused infringer's expert must pay more than just lip service to the *Wands* factors, but rather should explore each factor in detail and provide concrete evidence supporting his/her conclusion that the factors weigh against enablement or written description.

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