

INSITE VISION INC. v. SANDOZ, INC., Appeal No. 2014-1065 (Fed. Cir. April 9, 2015).
Before Prost, Newman, and Linn. Appealed from D.N.J. (Judge Cooper).

Background:

Sandoz filed an ANDA for a generic version of Azasite, a topical formulation of azithromycin for ocular administration for treating bacterial infections in the eye. Sandoz asserted that the Orange Book-listed patents were invalid and/or not infringed. In response, Insite sued Sandoz for patent infringement.

After claim construction, Sandoz conceded infringement but challenged the asserted claims on obviousness grounds. The district court found that Sandoz had failed to show by clear and convincing evidence that the claims were invalid for obviousness. Sandoz appealed, contending, *inter alia*, that the district court “misframed” the obviousness question facing a person of ordinary skill in the art at the time of the invention as the problem of developing improved topical treatments for ocular infections, rather than the narrower problem of topically administering azithromycin to treat conjunctivitis.

Issue/Holding:

Did the district court err in framing the obviousness question? No, affirmed.

Discussion:

The Federal Circuit held that framing the obviousness question is one of fact and found no clear error in the district court's decision.

The Federal Circuit noted that motivation sufficient to establish obviousness should not be limited to “the specific problem solved by the invention.” Contrary to Sandoz's contention, had the district court adopted the narrower problem in the obviousness inquiry, it could constitute “a form of prohibited reliance on hindsight,” because according to the Federal Circuit's previous holding, “[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.” The Federal Circuit recognized that “[o]ften the inventive contribution lies in defining the problem in a new revelatory way.”

Sandoz cited *Alcon* as primary authority. Yet, the Federal Circuit pointed out that the *Alcon* proposition (“if the prior art would motivate a person of skill in the art to make the claimed invention, even if that was not based on ‘the same motivation that the patentee had,’ the patent would have been obvious”) is consistent with the holding in this case that the district court did not clearly err in its finding, because determining a motivation in an obviousness inquiry is “a pure question of fact.”

Further, the Federal Circuit held that the district court's framing of the question did not prevent Sandoz from attempting to invalidate the asserted claims. Although the obviousness question is not limited to the cure of conjunctivitis, Sandoz could have prevailed by proving that it would have been obvious to use azithromycin in a topical treatment to cure this one infection. However, the Federal Circuit agreed with the district court that Sandoz had failed to show by clear and convincing evidence that the claims were invalid for obviousness.