

RETROACTIVE APPLICATION OF IPR/OBVIOUSNESS (PRECEDENTIAL)

CELGENE CORPORATION v. PETER, Appeal No. 2018-1167 (Fed. Cir. July 30, 2019). Before <u>Prost</u>, Bryson, and Reyna. Appealed from Patent Trial and Appeal Board.

Background:

The case arose from multiple IPR challenges by the Coalition for Affordable Drugs VI LLC ("the Coalition") against Celgene's patents directed to methods for safely providing a hazardous tetratogenic drug to patients while avoiding the adverse side effects caused by the drug.

Before the PTAB, the Coalition asserted that the challenged claims were obvious in view of references on how to safely administer tetratogenic drugs. Celgene countered with evidence of unexpected results.

However, the PTAB found that the results would not have been truly unexpected. Thus, the PTAB held that the challenged claims were obvious.

Celgene appealed and raised a new issue of whether the retroactive application of IPR proceedings to pre-AIA patents was an unconstitutional taking under the Fifth Amendment as the patents were filed and issued before the enactment of the IPR procedures.

The Coalition declined to defend Celgene's appeal. Instead, the Deputy Director of the U.S. Patent and Trademark Office intervened under 35 U.S.C. §143.

<u>Issues/Holdings</u>:

- (1) Did the PTAB properly find that the challenged claims would have been obvious? Yes, affirmed.
 - (2) Is retroactive application of IPRs to pre-AIA patents an unconstitutional taking? No.

Discussion:

Regarding obviousness, Celgene argued that the evidence of unexpected results should have been given more weight. However, the Federal Circuit determined that substantial evidence supported the Board's assessment, and declined to reweigh the evidence on appeal.

Regarding the constitutional challenge, the Federal Circuit exercised its discretion to hear Celgene's constitutional challenge even though it was not raised before the PTAB. The Federal Circuit explained that resolving the constitutional issue was a question of law that was sufficiently briefed for its review, and that interests of justice warranted addressing the retroactivity question given the growing number of retroactivity challenges following *Oil States*.

Turning to the merits of Celgene's constitutional challenge, the Federal Circuit held that the retroactive application of IPRs to pre-AIA patents was not an unconstitutional taking. The Federal Circuit rejected Celgene's regulatory takings theory arguing that subjecting its pre-AIA patents to IPR, a procedure that did not exist at the time its patents issued, unfairly interfered with its reasonable investment-backed expectations without just compensation. In so doing, the Federal Circuit reasoned that "for the last forty years, patents have also been subject to reconsideration and possible cancellation by the PTO," and "IPRs do not differ significantly enough from preexisting PTO mechanisms for reevaluating the validity of issued patents to constitute a Fifth Amendment taking." Although Celgene identified a number of differences between *ex parte* and *inter partes* reexamination predecessors and IPRs, the Federal Circuit stated that those differences did not outweigh the far more significant similarities of purpose and substance to effectuate an unconstitutional taking.

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