

ALERT

Federal Circuit Patent Bulletin: *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*

May 9, 2016

“Unlike district court litigation—where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material—the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute.”

On May 9, 2016, in *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, the U.S. Court of Appeals for the Federal Circuit (O’Malley,* Wallach, Hughes) affirmed the U.S. Patent & Trademark Office (PTO) Patent Trial and Appeal Board (PTAB) inter partes review decision that U.S. Patent No. 7,566,537, which related to the sequencing by synthesis (SBS) method of labeling nucleotides in polynucleotide sequencing methods, was not invalid for obviousness under 35 U.S.C. § 103. The Federal Circuit stated:

The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention. “[F]ailure to consider the appropriate scope of the . . . patent’s claimed invention in evaluating the reasonable expectation of success . . . constitutes a legal error that [is] review[ed] without deference.” Under the Board’s uncontested construction, “claim 1 does not require removal of the protecting group to allow subsequent nucleotide incorporation,” let alone quantitative removal. Accordingly, it is of no moment that Zavgorodny’s protecting group would not be removed quantitatively in Tsien or Ju’s sequencing method—removal is simply not required by the claim of the ‘537 patent. The Board seemed to believe that the “reasonable expectation of success” inquiry looked to whether one would reasonably expect the prior art references to operate as those references intended once combined. That is not the correct inquiry—

Authors

Lawrence M. Sung
Partner
202.719.4181
lsung@wiley.law

one must have a motivation to combine accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue. The Board's reliance on the absence of a reasonable expectation of success was, thus, improper.

Yet this court "sit[s] to review judgments, not opinions." And while the Board conflated two different legal concepts—reasonable expectation of success and motivation to combine—it nevertheless made sufficient factual findings to support its judgment that the claims at issue are not invalid. It was IBS's burden to demonstrate both "that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." Kinetic Despite the loose language employed by the Board, its factual findings support its conclusion that the claims are not invalid.

IBS argued in its revised initial petition to the Board that the combination of Tsien or Ju with Zavgorodny was based entirely on a shared purpose: SBS. IBS argued that an ordinary artisan would have a motivation to combine Tsien or Ju with Zavgorodny: "[O]ne of ordinary skill in the art, in order to improve the efficiency, reliability, and robustness of the sequencing by synthesis method taught in Tsien, would have been motivated to use other protecting groups that meet the criteria of Tsien, such as the azidomethyl group taught by Zavgorodny." This argument follows immediately after IBS lists the "criteria for the successful use of 3'-blocking groups," which includes "quantitative deblocking."

The Board, therefore, was justified in finding that, "despite having acknowledged the quantitative deblocking requirement in Tsien, the Petition did not provide a specific or credible explanation why an ordinary artisan would have expected Zavgorodny's azidomethyl protecting group to meet Tsien's quantitative deblocking requirement under conditions suitable for use in Tsien's sequencing methods." While this shortcoming is irrelevant to a finding that there was no reasonable expectation of success in meeting the claims of the '537 patent, which do not require quantitative deblocking at all, it is central to a finding of no motivation to combine. This is because the petitioner's sole argument for why one of skill in the art would be motivated to combine Zavgorodny's azidomethyl group with Tsien's SBS method was because it would meet Tsien's quantitative deblocking requirement. "When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references." . . .

It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify "with particularity" the "evidence that supports the grounds for the challenge to each claim." "All arguments for the relief requested in a motion must be made in the motion. A reply may only respond to arguments raised in the corresponding opposition or patent owner response." Once the Board identifies new issues presented for the first time in reply, neither this court nor the Board must parse the reply brief to determine which, if any, parts of that brief are responsive and which are improper. As the Board noted, "it will not attempt to sort proper from improper portions of the reply."

IBS argued in its petition that "Zavgorodny teaches the desired property [in Tsien] that the azidomethyl group 'can be removed under very specific and mild conditions.'" Illumina presented evidence in its response that, "an ordinary artisan would not have considered Zavgorodny's conditions suitably mild for Tsien's sequencing

purposes.” IBS’s reply then argued, for the first time, “that an ordinary artisan would have considered it obvious to use deprotecting conditions other than those described in Zavgorodny.” But IBS chose which grounds of invalidity to assert in its petition and it chose not to assert this new one. Unlike district court litigation—where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material—the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute. While the Board’s requirements are strict ones, they are requirements of which petitioners are aware when they seek to institute an IPR.

IBS supported its new theory of invalidity by reference to new evidence, citing “a number of non-patent literature references which were not relied upon to support unpatentability in the Petition.” In these circumstances, we find that the Board did not err in refusing the reply brief as improper under 37 C.F.R. § 42.23(b) because IBS relied on an entirely new rationale to explain why one of skill in the art would have been motivated to combine Tsien or Ju with a modification of Zavgorodny.