Paper No.__
Filed: November 25, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC,

Petitioner,

v.

CELGENE CORPORATION

Patent Owner

Case IPR2015-01102
Patent 6,315,720

PATENT OWNER REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71(d)

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Pursuant to 37 C.F.R. § 42.71(d), Patent Owner Celgene Corporation ("Celgene") submits this Request for Rehearing in response to the Final Written Decision entered October 26, 2016 (Paper 75) ("Final Decision") by the Patent Trial and Appeal Board ("PTAB") regarding U.S. Patent No. 6,315,720 ("the '720 patent").

I. Statement of Relief Requested

In the Final Decision, the PTAB held that the claims of the '720 patent are unpatentable as obvious over Powell (Ex. 1006) and Dishman (Ex. 1007), in view of Cunningham (Ex. 1008), and in further view of Mundt (Ex. 1017), Mann (Ex. 1018), Vanchieri (Ex. 1019), Shinn (Ex. 1020), Linnarsson (Ex. 1021), Gronroos (Ex. 1022), Soyka (Ex. 1023), Hamera (Ex. 1024), Kosten (Ex. 1025), and Menill (Ex. 1026). Final Decision at 37.

In doing so, the PTAB overlooked and/or misapprehended Celgene's evidence and argument showing that claim 10 of the '720 patent would not have been obvious. Accordingly, Celgene respectfully requests that the PTAB vacate its decision with respect to claim 10, and confirm the patentability of that claim.

II. Legal Standard

"A party dissatisfied with a decision may file a single request for rehearing" that "specifically identif[ies] all matters the party believes the Board

misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." 37 C.F.R. § 42.71(d).

III. PTAB Overlooked and/or Misapprehended Evidence and Argument Showing that Petitioner Failed to Carry its Burden on Claim 10

Celgene respectfully submits that the PTAB overlooked and/or misapprehended Celgene's evidence and argument showing that Petitioner failed to carry its burden of proving claim 10 of the '720 patent obvious. As explained in the Patent Owner Response (Paper 41, "Response"), claim 10 requires obtaining the results of genetic testing from patients. *See* Response at 47-48.

The PTAB held that this claim would have been obvious allegedly because "genetic testing was a known diagnostic procedure as of the effective filing date," and because a geneticist spoke at an FDA Meeting where thalidomide was discussed. *See* Final Decision at 29-30.

While the PTAB noted Celgene's argument that the "references of record do not disclose or suggest genetic testing" (*id.* at 30), the PTAB did not address, and therefore overlooked, Celgene's evidence and argument in the Response demonstrating that the references of record did "disclos[e] various other types of tests,"—but ***not*** genetic testing—which "undermines Dr. Fudin's opinion that [genetic] testing was 'common.'" *See* Response at 47-48; *see also* Ex. 1006 at 901-02; Ex. 1007 at 900-01; Ex. 2059 ¶110-112; Ex. 2060 ¶110-111 (cited in Response at 47). The PTAB also did not address, and therefore overlooked, the

controlling case law in Celgene's Response, which holds that Dr. Fudin's unsupported opinion that genetic testing was common, is entitled to little weight, if any. *See* Response at 47.

Instead, the PTAB improperly placed the burden on Celgene, finding that Celgene allegedly "did not dispute that genetic testing was known in the art for obtaining diagnostic information." Final Decision at 30. In doing so, Celgene respectfully submits that the PTAB misapprehended Celgene's argument and misapplied the relevant law. *First*, Celgene did, in fact, dispute that genetic testing was either known in the art or "common." *See* Response at 47-48. *Second*, the burden was on Petitioner to prove that genetic testing was known, not on Celgene to prove that genetic testing was not known. As explained in the Response, Petitioner did not provide any evidence showing that genetic testing would be used, let alone that it would have been common. *See id.*

Further, the PTAB misapprehended Petitioner's evidence regarding the geneticist's statement at the FDA meeting. *See* Final Decision at 30 (citing Ex. 1012 at 137). Petitioner relied solely on a single passage of that statement (*see* Paper 54 at 23) that focuses on the geneticist acting as a clinical teratologist that might counsel patients on the risks of exposure. *See* Ex. 1012 at 137. Notably, the cited passage says ***nothing*** about genetic testing, nor does it suggest such testing.

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