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Celgene Fights Back Against PTAB's Determination of Unpatentability of Cancer-Related Patent Claims

Dec 1, 2016

Reading Time : **2 min**

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The petition for *inter partes* review was filed on April 23, 2015, by Kyle Bass through the Coalition for Affordable Drugs IV LLC. Mr. Bass is a hedge fund manager who gained notoriety in recent years for challenging the patentability of U.S. drug patents. In 2015, for example, Mr. Bass filed almost three dozen petitions for *inter partes* review.

In his petition, Mr. Bass alleged that all claims of the '501 Patent were obvious in light of three prior art references. IPR2015-01092, Paper 73 at 13. The claims of the '501 Patent recite a method for ensuring that teratogenic drug prescriptions, which can cause serious birth defects, are not filled for persons who are pregnant or who are at a high risk of becoming pregnant so as to prevent delivery of the teratogenic drug to a fetus. '501 Patent at Claim 1. Particularly, the '501 Patent discusses thalidomide, a teratogenic drug synthesized and marketed as a sedative in the late 1950s, but removed from the market in 1962 due to reports of severe birth defects. IPR2015-01092, Paper 73 at 3. Since thalidomide's removal from the market, Celgene has received FDA approval for the use of thalidomide to treat leprosy and certain cancers. IPR2015-01092, Paper 73 at 3. In addition, it is believed that thalidomide may be effective for treating AIDs-related ulcers and possibly inflammatory bowel diseases, Behcet's Disease, rheumatoid arthritis and macular degeneration. '501 Patent at 1:29-36.

In its response to the petition, Celgene presented evidence that a person having ordinary skill in the art would not have found certain claims of the '501 Patent obvious (IPR2015-01092, Paper 40 at 48-49), as well as evidence of secondary indicia of nonobviousness, including long-felt but unresolved need, industry praise and unexpected results. *Id.* at 55-58. The PTAB,

however, found Celgene's evidence unpersuasive and held all of the challenged claims unpatentable as obvious. IPR2015-01092, Paper 73 at 28-29, 33. The PTAB held that "a person of ordinary skill in the art would have been led to combine, in the manner claimed, the disclosures . . . to address the problem of limiting thalidomide access to patients likely to suffer serious adverse side effects, including birth defects in a developing fetus." *Id.* at 23–24.

In its Request for Rehearing, Celgene argues that the PTAB misapprehended arguments presented by Mr. Bass relating to claim 10 of the '501 Patent. Specifically, Celgene asserts that Mr. Bass wrongly stated that a prior art reference disclosed an element of Claim 10 – a misstatement by Mr. Bass upon which the PTAB expressly relied in its decision. IPR2015-01092, Request for Rehearing, filed 11/25/2016, at 3-4. Mr. Bass, however, never argued that the missing element was an obvious modification to the reference. *Id.* at 4. Mr. Bass's opposition to Celgene's Request for Rehearing is currently due on December 25, 2016. 37 C.F.R. §42.25.

Coalition for Affordable Drugs VI LLC v. Celgene Corp., IPR2015-01092 (PTAB, Nov. 25, 2016)

Categories

Patent Trial & Appeal Board | Inter Partes Review