



PTAB Denies Institution of IPR Based on Petitioner's Failure to Rebut Strong Evidence of Objective Indicia of Non-Obviousness

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The patents under review are directed to methods of reducing the risk of adverse events, such as pulmonary edema, associated with treating a patient with inhaled nitric oxide gas. The specification of the patents describes a study, INOT22 that was conducted to assess the safety and efficacy of INOMax, an FDA-approved drug for treating neonates who have hypoxic respiratory failure associated with evidence of pulmonary hypertension. Based on the results of this study, the inventors determined that patients with pre-existing left ventricular dysfunction (LVD) had an increased risk of experiencing serious adverse events, such as pulmonary edema, upon administration of INOMax. Therefore, the patents have a common limitation, which excludes a child from treatment with inhaled nitric oxide if the child has LVD.

The petitioners argued that the patents are obvious based on the disclosures in three references that were not presented in the prior set of petitions. In both the prior and current sets of petitions, the PTAB found that the INOT22 study provides compelling evidence that the claims were not obvious to a person of skill in the art because several leading experts in the field designed this study without excluding children with pre-existing LVD. The PTAB found that although the petitioners' argument that the newly added references teach that children and neonates with LVD should be excluded from treatment, petitioners failed to rebut the evidence of secondary considerations because they do not explain why many experts in the field designed studies that did not exclude patients with pre-existing LVD if it were obvious to do so. In addition, the PTAB found that the newly added prior art references

should have been known to Praxair when it filed its original petitions. Therefore, the PTAB declined to institute IPR reviews for any of the claims of the challenged patents.

Praxair Distribution, Inc. v. Mallinckrodt Hospital Products, Nos. IPR2016-00777, IPR2016-00778, IPR2016-00779, IPR2016-00780, Paper 10 (PTAB, Sep. 22, 2016).

Categories

Patent Trial & Appeal Board

Inter Partes Review

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