

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

JUNO THERAPEUTICS, INC.,  
MEMORIAL SLOAN KETTERING CANCER  
CENTER, and  
SLOAN KETTERING INSTITUTE FOR  
CANCER RESEARCH,

Plaintiffs,

v.

KITE PHARMA, INC.,

Defendant.

C.A. No. 16-1243-RGA

**KITE PHARMA, INC.'S REPLY BRIEF  
IN SUPPORT OF ITS MOTION TO DISMISS**

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Dated: April 6, 2017

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This case should be dismissed for one simple reason: it does not yet belong in court. No one disputes that Juno must prove “a controversy of sufficient ‘immediacy and reality’ to create a justiciable controversy.” *E.g., Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008). But Juno has not done so (and, indeed, cannot). There is no immediate dispute to address: the FDA has not yet accepted and begun review of Kite’s submission, and approval of KTE-C19 remains entirely speculative as, after all, KTE-C19 is in an entirely new class of drugs the FDA has *never* previously considered, let alone approved. Juno tries to obfuscate the issue by noting that Kite separately appealed from a Patent Trial and Appeal Board (“PTAB”) decision addressing distinct issues. That effort to piggyback off of Kite’s separate appeal falls short because it conflates two entirely different proceedings: Kite’s appeal from an agency decision and Juno’s action in this Court. The former, which is authorized by statute, implicates a lower justiciability standard—as the Supreme Court and the Federal Circuit have held. *See, e.g., Massachusetts v. EPA*, 549 U.S. 497, 517-18 (2007); *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1172 n.2 (Fed. Cir. 2017). That appeal certainly does not indicate that Juno satisfied its burden to demonstrate “immediacy and reality” in *this* litigation. And in any event, even if this Court *could* exercise subject matter jurisdiction, it *should* not do so, because Kite’s activities all remain within a statutory safe harbor. This Court should dismiss Juno’s Complaint.

**I. JUNO HAS NOT MET ITS BURDEN OF PROVING SUBJECT MATTER JURISDICTION OVER ITS DECLARATORY INFRINGEMENT CLAIMS.**

**A. Juno’s Suit Is Not Real And Immediate Because FDA Approval Is Uncertain.**

As the declaratory judgment plaintiff, Juno bears the burden of establishing that its claims involve an actual dispute that is both real and immediate. *E.g., Clarus Therapeutics, Inc. v. Lipocine, Inc.*, Civ. A. No. 15-1004-RGA-MPT, 2016 WL 5868065, at \*2 (D. Del. Oct. 6, 2016) (Andrews, J.). Juno’s theory of liability presupposes that Kite will obtain FDA approval for

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