UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

US INVENTOR INC., TINNUS ENTERPRISES, LLC, STRAGENT, LLC, 360 HEROS, INC., RAMZI MAALOUF, LARRY GOLDEN, WORLD SOURCE ENTERPRISES, LLC and E-WATCH, INC.,	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 2:21-cv-00047**
DREW HIRSHFELD, in his official capacity Performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director, United States Patent and Trademark Office,	§	
Defendant.	§	

RESPONSE TO DEFENDANT'S NOTICE OF NEW AUTHORITY

Plaintiffs agree with Defendant that the Federal Circuit's March 12, 2021 decision in *Mylan Laboratories Ltd. v. Janssen Pharmaceutica, N.V.* "will assist the Court in consideration of the pending motion for preliminary injunction."

Dismissal of Mylan's appeal and denial of mandamus relief is consistent with Plaintiffs' statement that the "USPTO has plenary authority, unreviewable on appeal or mandamus, to deny review of any AIA trial petition for any reason." (ECF#7, at 4). The *Mylan* decision adds one small qualification: that mandamus review of an institution decision is possible if, and only if, there is a "colorable constitutional claim." (Slip Op. at 11-12). Mylan as an IPR petitioner did not present such a claim with its argument that the *Fintiv* standards exceeded the Board's statutory authority when used to deny institution.

Defendant is perhaps encouraged that the *Mylan* outcome denied review of statutory challenges mirroring those presented in the co-pending *Apple v. Iancu* case in the Northern District of California (Case No. 5:20-CV-06128-EJD, cross-motions argued March 11, 2021). In that case, big tech plaintiffs argue (as did Mylan) that the *Fintiv* rules exceed the scope of the Board's statutory authority, and unlawfully shorten the limitations period for filing an IPR. But these are not the arguments Plaintiffs present here, where Plaintiffs instead seek to strengthen and make procedurally lawful the *Fintiv* rules. Also, the present case arises under the Administrative Procedure Act, not on review of any particular institution decision. The *Mylan* outcome actually confirms and vindicates Plaintiffs' main argument in this case:

> Congress ceded to the Director absolute discretion to deny AIA trial institution, but on an important condition. The Director first had to consult with stakeholders before he would use this power, via mandatory notice-and-comment rulemaking. This has not yet occurred.

(ECF#7, at 7).

If Defendant intends to suggest that broad substantive discretion equates with immunity from APA rulemaking requirements, he is not correct. Agencies that possess broad discretion on a topic often channel that discretion in promulgated rules. *Graham v. Ashcroft*, 358 F.3d 931, 932 (D.C. Cir. 2004) ("In *Vitarelli* [*v. Seaton*, 359 U.S. 535, 539-40 (1959)], the Supreme Court held that even agencies with broad discretion must adhere to internally promulgated regulations limiting the exercise of that discretion."); *see also Watkins v. United States Bureau of Customs*, 643 F.3d 1189, 1198 (9th Cir. 2011) ("It is a familiar rule of administrative law that an agency must abide by its own regulations.") (citation omitted). After notice-and-comment rulemaking, patent holders would gain a right to stability of whatever the rules may be, such that a present or future Director could not lawfully withdraw them without notice.

March 15, 2021

Respectfully submitted,

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