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By ECF

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***Biogen MA Inc. v. EMD Serono, Inc.*, No. 2019-1133**

Dear Colonel Marksteiner:

We write in response to Appellants EMD Serono, Inc. and Pfizer, Inc.'s citation to *INO Therapeutics LLC v. Praxair Distribution Inc.*, No. 2018-1019, -- F. App'x --, 2019 WL 4023576 (Fed. Cir. Aug. 27, 2019) as supplemental authority [D.I. 73].

The non-precedential opinion in *INO Therapeutics* has no bearing on this appeal, and is thus not pertinent or significant authority. *See* Fed. R. App. P. 28(j); Fed. Cir. R. 32.1(b). In response to Appellants' letter, however, Appellee Biogen notes as follows:

First, there is no contradiction between *INO Therapeutics* and the district court's JMOL opinion. Appellants' proffered contradiction presupposes that the district court

held that "method-of-treatment claims are *automatically* patent-eligible" [D.I. 73 at 1 (citing Appx70–73) (emphasis original)], but that was not the court's holding. Neither that sentence nor that sentiment appears in the court's decision. Rather, the court determined that the specific claims in the '755 patent at issue here—like the specific claims in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018)—are "directed to" a specific method of using a drug to treat a particular disease or diseases, rather than to a law of nature. Appx71. The district court's patent-eligibility discussion spans several pages precisely because that analysis cannot be reduced to—and the district court did not reduce it to—a categorical conclusion of "automatic" eligibility for all method-of-treatment claims. That the claims in *INO Therapeutics* were not eligible for patenting implies no error in the district court's reasoning or conclusion here.

Second, Appellants misstate *INO Therapeutics*. This Court did not hold that to be patent-eligible a method-of-treatment claim must "delve into the complexities of dosing to more effectively 'treat' different classes of patients." [D.I. 73 at 1 (citing *INO Therapeutics*, 2019 WL 4023576, at *7).] The problem with the claims in *INO Therapeutics* was not a lack of specific dosages. The problem was more fundamental: the claimed invention was to refrain from treating certain patients altogether because of potentially fatal complications. 2019 WL 4023576, at *4. This Court held that a method of "treatment" that involves withholding treatment because of the risk of natural complication "collapses into a claim focused on the natural phenomenon" itself. *Id*. at *6. Here, the '755 patent claims are infringed only by administering to a patient a therapeutically effective amount of a specified pharmaceutical composition for immunomodulation or treatment of various conditions and diseases.

Third, Appellants misstate the claims in this appeal, asserting that "Biogen's claims purport to monopolize the administration of any amount of IFN-β" and thus "preempt all therapeutic use of the natural phenomenon that IFN-β has antiviral properties." [D.I. 73 at 2.] The '755 patent claims do not cover the administration of native, human interferon-beta at all, much less monopolize it. The claims also do not cover the use of the natural anti-viral properties of interferon-beta in the body. Rather, the claims require the use of recombinant interferon-beta, and in a therapeutically effective amount to treat a patient whose body's natural interferon-beta is insufficient to treat the patient's condition or disease. Appellants improperly equate the native and recombinant proteins, an assertion that is already the subject of extensive briefing in this appeal (*see* Blue Br. [D.I. 28] at 14–30; Red Br. [D.I. 54] at 14–30; and Grey Br. [D.I. 56] at 1–14) and on which *INO Therapeutics* has no bearing.

Respectfully Submitted,

/s/ Nicholas Groombridge

Nicholas Groombridge

cc: All counsel of record (via ECF)

CERTIFICATE OF SERVICE

I hereby certify that, on September 6, 2019, I caused the foregoing to be filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the CM/ECF system.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Nicholas Groombridge
Nicholas Groombridge