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November 22, 2019

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. (collectively, "Appellants")'s citation to *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019) as supplemental authority [D.I. 84].

Repeating an argument from their Blue Brief, Appellants first contend that the patent-in-suit claims the therapeutic use of polypeptides "made in a very large genus of host cells" but does not disclose whether or how therapeutically effective compounds can be made in those cells without undue experimentation. Firstly, as set forth in Biogen's Red Brief, this factual assertion was properly rejected by the jury as there was substantial evidence, including testimony from Appellants' own expert, that "many types of cells had been used as host cells" by the relevant priority date. (Red Br. at 37-38.)

Secondly, Appellants' argument is based on how the compounds to be administered in the claimed method are made, not what those compounds are. By contrast, the focus in *Idenix* was on the identity of compounds to be used in the claimed method—specifically, which 2'-methyl-up nucleosides were enabled and described—not how to make those compounds. In the instant case, however, the evidence was precisely what was missing in *Idenix*. The patent in *Idenix* failed to disclose or enable the use of a compound with a 2'-fluoro-down substituent like the accused product; "the compound in question [was] conspicuously absent." 941 F.3d at 1165. In this case, however, the patent-in-suit not only describes in detail recombinant interferon-beta-like polypeptides made in non-human hosts that have biological activity like native human interferon-beta, but also includes a dependent claim—claim 2—directed at the precise amino-acid sequence of Appellants' accused product. (Red Br. at 42.)

Likewise, whereas the patent in *Idenix* failed to provide any "method of distinguishing effective from ineffective compounds for the compounds reaching beyond the formulas disclosed in the '597 patent," 941 F.3d at 1164, here the patent-in-suit describes in detail evidence that recombinant interferon-beta-like polypeptides have biological activity comparable to that of native human interferon-beta, and provides a process for confirming whether any particular recombinant interferon-beta-like polypeptide in fact exhibits such activity. *See, e.g.*, Appx136–140 & Appx141 ('755 Patent at col. 37:17–46:38 & col. 48:28–35); (Red Br. at 37–39). That the evidence before the jury in *Idenix* could permit only a verdict of invalidity does not affect the jury's conclusion about the very different evidence in this case.

Appellants also claim that *Idenix* holds that in method-of-treatment patents the therapeutic compounds themselves must be described and enabled. Quite the contrary. The district court in *Idenix* construed the "method of treatment" preamble to be merely a "narrowing functional limitation" on the compounds themselves, and neither party challenged that construction on appeal. 941 F.3d at 1155 (citing *Idenix Pharm. LLC v. Gilead Scis., Inc.*, 2016 WL 6802481, at *5 (D. Del. Nov. 16, 2016)). Instead, the parties agreed and this Court accepted that the only question presented was whether the genus of chemical compounds themselves were described and enabled, with the parties' arguments focusing exclusively on "the presence of various possible substituents at the 2'-up and 2'-down positions." *Id.* at 1154. *Idenix* thus never addresses, and casts no doubt on, the Section 112 issue presented by this appeal: whether the district court correctly instructed the jury that, "Here, it is the method of treatment that must be" described and enabled, "not the proteins to be used or the way they are made." Appx47670–47672.

Idenix applied settled law to the particular facts of that case. It is no way inconsistent with the jury's rejection of Appellants' Section 112 defenses on the facts of this case.

Respectfully Submitted,

/s/ Nicholas Groombridge

Nicholas Groombridge

cc: All counsel of record (via ECF)

CERTIFICATE OF SERVICE

I hereby certify that, on November 22, 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