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VIA ELECTRONIC FILING

Scott S. Harris
Clerk
Supreme Court of the United States
One First Street, N.E.
Washington, DC 20543

Re: Novartis Pharmaceutical Corp. v. HEC Pharm Co., Ltd., No. 22A272

Dear Mr. Harris:

The Circuit Justice is considering Novartis's application for a stay of the Federal Circuit's mandate in the above-captioned matter. I write to update the Circuit Justice and, as appropriate, the Court on a development in the district court today that is relevant to irreparable harm.

As noted in Novartis's reply (at 13 n.4), one generic company unrelated to HEC has asserted a right to commercialize its generic fingolimod product based on the Federal Circuit's decision, even though the Federal Circuit's mandate has not issued. Novartis accordingly is pursuing injunctive relief in the district court against that company, Mylan Pharmaceuticals, Inc. This afternoon, the district court (Circuit Judge Kent A. Jordan, sitting by designation) granted Novartis's application for a temporary restraining order after receiving sealed briefing and declarations from both sides (ECF Nos. 820-827) and presiding at an in-person hearing earlier today. A copy of the temporary restraining order is attached.

Relevant to this Court's consideration of the application, Judge Jordan found based on the record before him that a generic launch "will cause [Novartis] immediate and irreparable injuries from lost market share for fingolimod and sales of GILENYA® and the resulting effect on [Novartis's] business including in research and development, clinical, sales, marketing, managed care, and manufacturing." TRO at 2. He therefore granted the TRO until he can hear a motion for a preliminary injunction (set, by agreement, for hearing November 17), after expedited discovery and further briefing, unless the Federal Circuit's mandate issues before then. TRO at 3.

Judge Jordan's finding confirms the irreparable harm that would result from generic launch. And while HEC has tried to brush aside Chief Judge Stark's irreparable-harm finding because it was made at an earlier stage of the case, Judge Jordan's finding is, of course, based on conditions today.

I would appreciate your circulating this letter and the attachment to the Circuit Justice and the Court.



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Respectfully submitted,

/s/ William M. Jay
William M. Jay

cc: Peter K. Stris, Esq. (by e-mail)