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By ECF

Daniel E. O'Toole
Circuit Executive and Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Re: *Amgen Inc. and Amgen Manufacturing Limited v. Sandoz Inc.*, No. 15-1499

Dear Admiral O'Toole:

Yesterday evening, on August 26, 2015, Amgen Inc. and Amgen Manufacturing Limited ("Amgen") filed an "Emergency Motion" for an injunction pending en banc consideration and review. Because Amgen did not propose a schedule for resolution of its emergency motion, Sandoz Inc. proposes that it will oppose the motion no later than Monday, August 31, 2015.

Sandoz notes that Amgen has not requested any temporary administrative injunction pending resolution of its emergency motion. With good reason: no injunction, temporary or otherwise, is warranted. And any "emergency" is entirely of Amgen's own making. Over a month ago, on July 21, 2015, a panel of this Court issued its decision in this case. That decision "extend[ed] the injunction pending appeal through September 2, 2015," in order to allow Amgen "a period of time to assess and act upon its patent rights." Slip op. 21-22. Yet despite being well aware of the impending September 2 expiration of that injunction as well as its own plans to seek rehearing en banc, Amgen waited until days before the expiration to make a request of any court to extend the injunction. Moreover, Amgen still has not sought any injunction from any court based on any alleged patent rights.

As Sandoz will explain more fully in its opposition, the short motion that Amgen finally has made to this Court cannot justify the "extraordinary remedy" it requests. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Amgen makes no attempt to show that it has a strong likelihood of succeeding on the merits on the issue it presents in its en banc petition,

and it makes only passing reference to a contention that it will be irreparably harmed absent further injunctive relief. Mot. 3.

Most significantly, Amgen makes no attempt to show that the balance of interests weighs in its favor. It does not. Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA") to promote competition in the biologics market and reduce prices. The Food and Drug Administration approved Sandoz's filgrastim product Zarxio® on March 6, 2015, and a panel of this Court has determined that, under the BPCIA, Sandoz can commercially market Zarxio® on September 3, 2015. The interests of cancer patients, purchasers (including taxpayers through Medicare and Medicaid), and Sandoz all weigh heavily against any further injunctive relief, temporary or otherwise.

Respectfully submitted,

/s/ Deanne E. Maynard

Deanne E. Maynard

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on August 27, 2015.

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

Dated: August 27, 2015 /s/ Deanne E. Maynard

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