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**VIA ECF**

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April 7, 2021

Hon. Alison J. Nathan  
United States District Court  
Southern District of New York  
40 Foley Square, Room 2102  
New York, NY 10007

Re: **Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, et al., Case No. 1:20-cv-05502-AJN (S.D.N.Y.)**

Dear Judge Nathan:

Pursuant to Your Honor's Individual Rule of Practice 1.A., Defendants Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation ("Novartis") respectfully advise the Court that tomorrow Novartis will file in the related proceeding before the International Trade Commission ("ITC") - *Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof*, USITC No. 337-TA-1207 (I.T.C. June 19, 2020) ("ITC Action") - the Complainants' Unopposed Motion to Terminate The Investigation in Its Entirety Based on Withdrawal Of Complaint And To Stay The Procedural Schedule And Request For Expedited Treatment ("Motion").

Yesterday, Novartis informed the ITC's Office of Unfair Import Investigations ("OUII" or "Staff")<sup>1</sup> and counsel for Regeneron Pharmaceuticals, Inc. ("Regeneron") of the Motion and sought their respective consent for the filing. The OUII consented promptly. Regeneron has provided no

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<sup>1</sup> The OUII "[p]erforms substantive litigation activities as an independent party representing the public interest in section 337 investigations by developing relevant information and advocating on behalf of the public an independent position on the issues so that the Commission and its Administrative Law Judges can discharge the statutory decision-making responsibilities in such investigations." See <https://www.usitc.gov/offices/ouii>.

confirmation that it would not oppose Novartis's Motion. Novartis also has informed the Chambers of the Administrative Law Judge (attached as Exhibit 1) of tomorrow's impending Motion.

As will be explained in the Motion, which Novartis will file with this Court tomorrow, the Administrative Law Judge recently granted Novartis's motion for partial summary determination in the ITC Action that Regeneron infringed U.S. Patent No. 9,220,631 (the "'631 Patent"), a determination stemming from Regeneron's concession that it infringes the '631 patent. Mem. in Supp. Compls.' Mot. for Partial Summ. J. as to Direct Infringement, *Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof*, USITC Inv. No. 337-TA-1207, at 20 (Feb. 18, 2021).

In its prehearing brief<sup>2</sup>, the OUII expressed its preliminary view that, after Novartis proved a violation of Section 337 on the merits, the ITC should delay the implementation of any remedy by at least three years, if it issues one at all. Although Novartis disagrees with the OUII's position, Novartis "takes seriously the concerns the Staff noted in its prehearing brief" and "will instead, pursue relief in district court." In terminating the ITC Action, Novartis will conserve substantial resources of the parties and of the ITC.

In addition to public interest considerations, the OUII's brief supported Novartis's positions that Regeneron infringes the '631 Patent and that the patent is not invalid based on prior invention (35 U.S.C. § 102(g)), indefiniteness or lack of written description (35 U.S.C. § 112).

But the OUII asserted that the '631 Patent may be invalid as obvious (35 U.S.C. § 103) and for failing to identify the correct inventors under 35 U.S.C. § 102(f). Novartis disagrees with the OUII's interpretation of the fact and expert record and the relevant caselaw, and firmly believes that Regeneron cannot prove the invalidity of the '631 Patent at trial by clear and convincing evidence.

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<sup>2</sup> A public version of the prehearing brief should be filed shortly, and Novartis will submit a copy to the Court immediately thereafter.

Novartis notes the OUII's prehearing brief is just that – a brief submitted by a party to the case advocating its position on the issues in the case. Certainly, the OUII's prehearing brief is not a finding (binding or otherwise) by the ITC (or its Administrative Law Judges).<sup>3</sup>

In light of the OUII's position on the public interest, tomorrow Novartis will, in addition to withdrawing the ITC complaint, promptly ask via letter the U.S. District Court for the Northern District of New York to lift the stay in *Novartis Pharma AG et al. v Regeneron Pharmaceuticals, Inc.*, Case No. 1:20-cv-00690-TJM-CFH (N.D.N.Y.) ("N.D.N.Y. Action").<sup>4</sup> Novartis will vigorously prosecute its patent infringement claim in the U.S. District Court for the Northern District of New York. Upon filing the letter with the N.D.N.Y., Novartis's Patent Counsel at Goodwin Proctor will promptly reach out to counsel for Regeneron to meet and confer on a schedule for that Action.

In light of this development, and consistent with Your Honor's Individual Rule of Practice 3.E., Novartis respectfully reiterates Novartis's request that the Court schedule oral argument on Novartis's Motion to Dismiss, Transfer, or Stay. (See ECF No. 40).

Respectfully submitted,



Ian Simmons  
of O'MELVENY & MYERS LLP

<sup>3</sup> According to the Federal Circuit, ITC determinations do not have preclusive effect on district courts because Congress cautioned that the "Commission's findings neither purport to be, nor can they be, regarded as binding interpretations of the U.S. patent laws in particular factual contexts." *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1559 (Fed. Cir. 1996) (citing S. REP. No. 1298, 93d Cong., 2d Sess. 196 (1974), reprinted in U.S.C.C.A.N. 7186, 7329).

<sup>4</sup> As explained in Novartis's September 4, 2020 Memorandum of Law in Support of Novartis's Motion to Dismiss, Transfer, or Stay (ECF No. 41), and as the Court may recall, the N.D.N.Y. Action was filed by Novartis but stayed by Regeneron, all prior to the filing by Regeneron of this action.



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cc: Elizabeth J. Holland  
William G. James  
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Attachment

# EXHIBIT 1

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