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November 20, 2020

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Re: *Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof*, Inv. No. 337-TA-1207

Dear Elizabeth:

Respondent Regeneron Pharmaceuticals, Inc. hereby stipulates that, if the Patent Trial and Appeal Board ("Board") institutes one or both of the pending IPR petitions in IPR2020-01317 and IPR2020-1318 challenging the patentability of the claims of U.S. Patent No. 9,220,631, then Regeneron will not pursue the instituted invalidity grounds in the ITC investigation 337-TA-1207.

Specifically, the invalidity grounds in the two IPRs are as follows:

IPR2020-01317 Grounds

- Obviousness of claims 1-3, 5-9, 14-22, and 24 under 35 U.S.C. § 103 based on PCT Pat. Pub. WO 2011/006877 ("Sigg") in view of PCT Pat. Pub. WO 2009/030976 ("Boulange"), and if necessary, U.S. Pharmacopeia, *USP 789, Particulate Matter in Ophthalmic Solutions*, USP 34 NF 29 (2011) ("USP789");

- Obviousness of claims 4, 10 and 23 under 35 U.S.C § 103 based on Sigg in view of Boulange and Arno Fries, *Drug Delivery of Sensitive Biopharmaceuticals With Prefilled Syringes*, 9(5) DRUG DELIVERY TECH. 22 (2009) ("Fries"), and if necessary, USP789;

- Obviousness of claims 11-13 under 35 U.S.C § 103 based on Sigg in view of Boulange, and PCT Pat. Pub. WO 2007/149334 ("Furfine"), and if necessary, USP789;

- Obviousness of claim 25 under 35 U.S.C § 103 based on Sigg in view of Boulange, and the March 7, 2011 Record of Drugs.com, Macugen Prescribing Information, available

athttps://web.archive.org/web/20110307065238/http://www.drugs.com:80/pro/macugen.html ("Macugen® Label"), and if necessary, USP789;

- Obviousness of claim 26 under 35 U.S.C § 103 based on Sigg in view of Boulange, and James A. Dixon, et al. "VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration." *Expert opinion on investigational drugs* 18.10 (2009): 1573-1580 ("Dixon"), and if necessary, USP789.

IPR2020-01318 Grounds

- Claims 1-10 and 14-24 based on PCT Pat. Pub. WO 2008/077155 ("Lam") in view of *Certified English Translation* of Bruno Reuter and Claudia Petersen, "Die Silikonisierung von Spritzen: Trends, Methoden, Analyseverfahren," *TechnoPharm* 2, Nr. 4 (2012): 238-244 ("Reuter"), and if necessary, USP789;

- Claim 11-13 based on Lam and Reuter in view of Furfine, and if necessary, USP789;

- Claim 25 based on Lam and Reuter in view of Macugen® Label, and if necessary, USP789;

- Claim 26 based on Lam and Reuter in view of Dixon, and if necessary, USP789.

If the Board declines institution of IPR2020-01317 or IPR2020-1318, Regeneron reserves the right to pursue these non-instituted invalidity grounds in the ITC investigation.

Further, as we indicated in our November 20, 2020 email to you, Regeneron intends to move to terminate IPR2020-01318. If that motion is granted but the Board declines to institute trial in IPR2020-01317, then Regeneron reserves the right to pursue the above-identified invalidity grounds in the ITC investigation. If, however, the Board grants Regeneron's motion to terminate IPR2020-01318 and also institutes trial in IPR2020-01317, this stipulation applies and Regeneron will not pursue the above-identified grounds in the ITC investigation.

Best regards,

/s/ Brian E. Ferguson

Brian E. Ferguson

cc: Counsel of Record - via email