Sheinberg, Samuel I.

From: [redacted]
Sent: Friday, July 10, 2020 12:53 PM
To: Berg, Karen E.; Carson, Timothy; Sheinberg, Samuel I.; Six, Anne; Whitehead, Nora; Musick, Vesselina
Subject: FW: Pharma Exclusive License Question

From: Walsh, Kathryn E.
Sent: Friday, July 10, 2020 12:53:19 PM (UTC-05:00) Eastern Time (US & Canada)
To: [redacted]
Cc: [redacted]
Subject: FW: Pharma Exclusive License Question

Agree with your take, [redacted]

From: [redacted]
Sent: Thursday, July 9, 2020 4:51:38 PM (UTC-05:00) Eastern Time (US & Canada)
To: [redacted]
Cc: [redacted]
Subject: Pharma Exclusive License Question

I hope you are all well and staying safe. I have a question about a co-exclusive license in the pharmaceutical space.

My client plans to enter into a collaboration agreement that contains an IP license and an agreement to collaborate on the development and commercialization of a compound inside and outside the United States. The U.S. portion of the IP license for the compound is styled as "co-exclusive" between the licensee and licensor. It grants the licensee the right to research, develop, use, make, sell, and commercialize the compound in the U.S., but retains rights for the licensor.

The licensor explicitly retains (1) the co-exclusive right (with the licensee) to research, develop, use, make, sell, and commercialize the compound in the U.S.; (2) the right to manufacture the compound for the purpose of the collaboration's development or commercialization in the U.S. until the product transitions to the licensee (approximately the first year); and (3) the right to research and develop the compound anywhere in the world to the extent necessary to research, develop, use, make, sell, or commercialize the compound in the U.S.

The collaboration agreement envisions that all decisions within the collaboration will be made by consensus. If the parties are unable to agree, the licensee shall have final authority with respect to U.S. development and commercialization decisions. The agreement further states that (1) the licensee and licensor will co-develop the product in the U.S. under the collaboration plan; (2) the licensor will take the lead role in commercializing the product containing the compound in the U.S for the first year, and thereafter the licensee will take the lead role with participation by representatives of the licensor; (3) the licensee and licensor will both be responsible for medical education related to the compound in the U.S.; and (4) the licensor will take primary responsibility for the manufacture of compounds for the collaboration's development and commercialization in the U.S., subject to an option that licensee may exercise upon certain conditions.

We do not think that the license transfers "all the commercially significant rights" to the U.S. IP because the license does not "allow *only* the recipient of the exclusive patent to use the patent." *See* 16 C.F.R. 801.1(o) (emphasis added). Under the retained rights contained in the license, the licensor will explicitly retain commercially significant rights to research, develop, commercialize, make and sell the compound in the U.S. to fulfill its role in the collaboration. And those rights are not merely "co-rights … to assist the [licensee] in developing or commercializing the product covered by the patent." *See id.* at 801.1(q). The licensor's retention of rights in the license is not limited to "assist" the licensee; it retains those rights to fulfill its in role the collaboration, as discussed above. Let us know if you agree.

[redacted]

[redacted]

[redacted]

[redacted]