



Defendants Slayback Pharma LLC and Slayback Pharma India LLP (“the Slayback Defendants”) submit this Stipulation to limit the Slayback Defendants’ invalidity contentions in this action, and to thereby make the specific proceedings identified below before the United States Patent and Trademark Office a true alternative to this action.

## **BACKGROUND**

1. On September 10, 2021, Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, “Plaintiffs”) started this Hatch-Waxman action by filing the Complaint [D.I. 1]. Plaintiffs alleged that the filing of the Slayback Defendants’ ANDA No. 216361 did infringe, and that the Slayback Defendants will infringe two patents, United States Patent Nos. 8,293,742 (“the ‘742 patent”) and 9,259,425 (“the ‘425 patent”) (collectively the “Patents-in-Suit”). The Slayback Defendants waived service of the Complaint and the Answer was due November 23, 2021. The Slayback Defendants filed their Answer [D.I. 9] on November 9, 2021, the Court conducted the Initial Scheduling Conference on February 10, 2021, the agreed-to Scheduling Order [D.I. 15] was entered February 15, 2022, and a Stipulated Discovery Confidentiality Order was submitted to the Court on March 19, 2022.

2. The Patents-in-Suit in this action are also the subject of Petitions for *Inter Partes* Review (“IPR”) filed November 7, 2021 by the Slayback Defendants

with the Patent Trial and Appeal Board (“PTAB”) of the United States Patent and Trademark Office. The Petition for IPR of the ‘742 patent is Paper No. 2 in IPR2022-00142 (“the ‘142 IPR”), and the Petition for IPR of the ‘425 patent is Paper No. 2 in IPR2022-00146 (“the ‘146 IPR”) (collectively, “the Related IPRs”).

3. The Petitions in the Related IPRs assert the following Grounds of invalidity:

| <b>U.S. Patent 8,293,742 the ‘142 IPR</b> |  |
|---|--|
| Ground 1                                  | Claims 1-2 anticipated by U.S. Patent 6,294,553  |
| Ground 2                                  | Claims 1-2 anticipated by Walters 1991   |
| Ground 3                                  | Claims 1-6 obvious over U.S. Patent 6,294,553 in combination with Norden 2002, U.S. Patent 6,242,442, Alphagan® Label 1998 and Federal Register 1988 |

| <b>U.S. Patent 9,259,425 the ‘146 IPR</b> |  |
|---|--|
| Ground 1                                  | Claims 1-6 anticipated by U.S. Patent 6,294,553  |
| Ground 2                                  | Claims 1-6 anticipated by Walters 1991   |
| Ground 3                                  | Claims 1-6 obvious over U.S. Patent 6,294,553 in combination with Norden 2002, U.S. Patent 6,242,442, Alphagan® Label 1998 and Federal Register 1988 |

4. On February 22, 2022, the Plaintiffs in this action filed a Preliminary Response in each of the Related IPRs.

5. Among other arguments in the Preliminary Responses, Plaintiffs argued that the PTAB should deny institution of the Related IPRs because “the

defendants have not agreed to forego any invalidity challenges in [this action] based on the grounds and art raised in the petition.”

6. The Slayback Defendants note for the Court that in an IPR unrelated to this action or the Patents-in-Suit, *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019 (“*Sotera IPR*”), the petitioner in the *Sotera IPR* relied on a broad stipulation filed in a parallel district court litigation, *Masimo Corp. v. Sotera Wireless, Inc.*, Case No. 3:19-cv-01100-BAS-NLS (S.D. Cal.) [D.I. 86], which stipulated that if the *Sotera IPR* was instituted in the parallel district court litigation the petitioner would not pursue any invalidity defense in the district court litigation that could have reasonably been raised in the *Sotera IPR*. *Sotera*, IPR2020-01019, Paper 12, p. 19 (PTAB Dec. 1, 2020) (precedential). The PTAB held in the *Sotera IPR* that the defendant’s broad stipulation in district court mitigated any concerns of duplicative efforts between the district court and the PTAB, and made the *Sotera IPR* a “true alternative” to the district court proceeding:

Petitioner’s stipulation here **mitigates any concerns of duplicative efforts between the district court and the Board**, as well as concerns of potentially conflicting decisions. *See Sand Revolution 12*. Importantly, Petitioner broadly stipulates to not pursue “any ground raised or that could have been reasonably raised.” Reply 6. As noted in *Sand Revolution*, such a broad stipulation better addresses concerns of duplicative efforts and potentially conflicting decisions in a much more substantial way. *Sand Revolution 12 n.5*. Accordingly, **Petitioner’s broad stipulation ensures that an inter partes review is a ‘true alternative’ to the district court proceeding.** *Id.*

Thus, we find that this factor weighs strongly in favor of not exercising discretion to deny institution under 35 U.S.C. § 314(a).

*Id.* (emphasis supplied).

7. Like the defendant in the *Sotera* IPR, the Slayback Defendants in this action seek to mitigate any concern of duplicative efforts between the Related IPRs and this action, and to thereby make the Related IPRs a “true alternative.”

Therefore, the Slayback Defendants **STIPULATE** as follows:

A. If the Patent Trial and Appeal Board (“PTAB”) institutes IPR in IPR2022-00142, the Slayback Defendants will not pursue in this action the specific grounds identified above in connection with U.S. Patent No. 8,293,742 (“the ‘742 patent”) and the claim(s) as originally issued, or any other ground for the ‘742 patent that was raised or could have been reasonably raised in an IPR (*i.e.*, any ground that could be raised under 35 U.S.C. §§ 102 or 103 on the basis of prior art patents or printed publications).

B. If the Patent Trial and Appeal Board (“PTAB”) institutes IPR in IPR2022-00146, the Slayback Defendants will not pursue in this action the specific grounds identified above in connection with U.S. Patent No. 9,259,425 (“the ‘425 patent”) and the claim(s) as originally issued, or any other ground for the ‘425 patent that was raised or could have been reasonably raised in an IPR (*i.e.*, any ground that could be raised under 35 U.S.C. §§ 102 or 103 on the basis of prior art patents or printed publications).

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