

# SECTION I

### Joint Statement of the Issues

Hospira asserts claim 6 of U.S. Patent No. 8,648,106 and claim 8 of U.S. Patent No. 9,616,049 (“Asserted Claims”). Fresenius Kabi (FK) counterclaims as to several other related claims in these and related patents for regulatory purposes, as the FDA will request judgments in order to clear patent issues where (as here) there are other generic filers. Hospira objects at least on the ground of mootness to any further litigation on non-asserted patents and claims.

The claims relate to ready-to-use (“RTU”) compositions of the sedative dexmedetomidine in a sealed glass container. The RTU compositions are for administration to a patient without dilution or reconstitution. (D.I. 69.) FK stipulated to infringement of the Asserted Claims. (D.I. 93.) The remaining issue for trial is whether FK can prove by clear and convincing evidence that the Asserted Claims are invalid. FK alleges the following invalidity bases:<sup>1</sup>

- **35 U.S.C. § 102, Anticipation / On-Sale / Offer for Sale:** FK alleges that the Investigational New Drug Application (IND) prepared by Orion is prior art because it was subject to two different commercial sales and offers for sale, and the disclosed product was ready for patenting before the priority date. Hospira alleges neither transaction constituted an invalidating sale of a claimed RTU dexmedetomidine product. Any alleged sale was not for commercial purposes and did not involve a formulation that was ready-for-patenting.
- **35 U.S.C. § 103, Obviousness:** FK asserts that the Asserted Claims would have been obvious to a skilled artisan under 35 U.S.C. § 103 by January 2012. Hospira asserts that the subject matter was not obvious at least because there was no reasonable expectation of success in developing the claimed RTU dexmedetomidine formulations. In addition, the success of Hospira’s commercial RTU product (Precedex Premix) further indicates non-obviousness. FK alleges that any such success lacks nexus to the claimed features.
- **35 U.S.C. § 103, Obviousness Inherency:** With respect to the ‘106 patent, FK alleges that the claimed stability is an inherent property of the claimed formulation. Hospira alleges that the stability is not inherent in the formulations.
- **35 U.S.C. § 112:** FK contends that, if the stability limitation of the ‘106 patent is not inherent, then the asserted claims are not enabled and indefinite because the patent does not teach how to obtain the claimed stability. Hospira responds that the patent adequately describes the claimed stability and how to attain it.
- **35 U.S.C. § 102(f)/Inventorship:** FK alleges that the named inventors did not invent the subject matter of the patents-in-suit. Another company (Orion) and others within Hospira conceived of an RTU dexmedetomidine composition in a sealed glass container. Hospira responds that the inventors are properly named because they actually developed the claimed RTU composition.

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<sup>1</sup> The brief description provides a general overview of the main issues, and is not a waiver of any arguments not specifically mentioned herein.