IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

J. KYLE BASS and ERICH SPANGENBERG,

Petitioners

v.

FRESENIUS KABI USA, LLC,

Patent Owner

Patent 8,476,010

Inter Partes Review No.: IPR2016-00254

Petitioners' Responses To Patent Owner's Observations On Cross Examination

In response to Patent Owner's Observations On Cross Examination, Petitioners hereby respond, on an observation-by-observation basis, as follows:

Observation 1: Dr. Feinberg's testimony does not support Patent Owner's Conclusions or contradict his opinions as set forth in his declarations.

Patent Owner alleges that Dr. Feinberg's testimony is relevant to show that terminal sterilization is the only appropriate method of sterilizing the claimed formulations. But this testimony is not relevant to the claimed invention because the claims of U.S. Patent 8,476,010 ("the '010 patent") do not recite any particular sterilization method (Exhibit 1001, '010 patent, col. 27, l. 54 – col. 33, l. 13). Indeed, the '010 patent indicates that the invention is not limited to a particular sterilization technique: "[t]he present invention's composition is a sterile aqueous formulation and is prepared by standard manufacturing techniques using, for example, aseptic manufacture, sterile filtration or terminal sterilization by autoclaving" (id. at col. 7, ll. 31-34). The testimony cited by Patent Owner refers to a sterilization method used in the manufacture of commercial propofol (Diprivan), not to the claims of the '010 patent.

Patent Owner also alleged that Dr. Feinberg's testimony contradicts Dr. Feinberg's opinion that "Mannermaa, the '919 patent, and Lehr would have discouraged a POSA from using autoclave, they would not have discouraged a POSA from the claimed invention using other sterilization techniques." But the testimony cited by Patent Owner was not about Mannermaa, the '919 patent, or Lehr.

Rather, the testimony related to a document about the manufacture of Diprivan. Accordingly, none of the testimony contradicts Dr. Feinberg's explanation that "a POSA at the time of the invention of the '010 patent would have understood that the number of particulates shed from a stopper after autoclaving would have been significantly higher than the number of particulates shed from the stopper after treatment other sterilization techniques like aseptic manufacture" (Ex. 1044, Dr. Feinberg, Supplemental Decl., ¶ 23). "That is, the siliconized bromobutyl stopper with a different sterilization technique would have shed significantly fewer particulates than those reported in Mannermaa, and the '919 patent for the autoclave sterilization technique" (id.).

Observation 2: Dr. Feinberg's testimony does not contradict his opinions as set forth in his declarations.

Patent Owner alleges that Dr. Feinberg's testimony is relevant because it contradicts Petitioners' argument that a POSA would consider sterile filtration as an alternative to terminal sterilization by autoclave. But this testimony is not relevant to the claimed invention because the claims of the '010 patent do not recite any particular sterilization method (Exhibit 1001, '010 patent, col. 27, l. 54 – col. 33, l. 13). Indeed, the '010 patent indicates that the invention is not limited to a particular sterilization technique: "[t]he present invention's composition is a sterile aqueous formulation and is prepared by standard manufacturing techniques using, for

example, aseptic manufacture, sterile filtration or terminal sterilization by autoclaving" (id. at col. 7, ll. 31-34). The testimony cited by Patent Owner refers to a sterilization method used in the manufacture of commercial propofol (Diprivan), not to the claims or any other part of the '010 patent.

Observation 3: Dr. Feinberg's testimony does not contradict his opinions as set forth in his declarations.

Patent Owner alleges that Dr. Feinberg's testimony is relevant because it contradicts Petitioners' argument that a POSA would have been motivated to use aseptic manufacture or sterile filtration instead of consider sterile filtration as an alternative to terminal sterilization by autoclave. But this testimony is not relevant to the claimed invention because the claims of the '010 patent do not recite any particular sterilization method (Exhibit 1001, '010 patent, col. 27, l. 54 – col. 33, l. 13). Indeed, the '010 patent indicates that the invention is not limited to a particular sterilization technique: "[t]he present invention's composition is a sterile aqueous formulation and is prepared by standard manufacturing techniques using, for example, aseptic manufacture, sterile filtration or terminal sterilization by autoclaving" (id. at col. 7, ll. 31-34). The testimony cited by Patent Owner consists merely of responses to questions about whether Patent Owner's counsel read certain sentences from Exhibit 2061 correctly.

Patent Owner also alleged that Dr. Feinberg's testimony contradicts Dr. Feinberg's opinion that "Mannermaa, the '919 patent, and Lehr would have

discouraged a POSA from using autoclave, they would not have discouraged a POSA from the claimed invention using other sterilization techniques." But the testimony cited by Patent Owner was not about Mannermaa, the '919 patent, or Lehr. Rather, the testimony related to a different document (European Regulatory Guidance, Exhibit 2061). Accordingly, none of the testimony contradicts Dr. Feinberg's explanation that "a POSA at the time of the invention of the '010 patent would have understood that the number of particulates shed from a stopper after autoclaving would have been significantly higher than the number of particulates shed from the stopper after treatment other sterilization techniques like aseptic manufacture" (Ex. 1044, Dr. Feinberg, Supplemental Decl., ¶ 23). "That is, the siliconized bromobutyl stopper with a different sterilization technique would have shed significantly fewer particulates than those reported in Mannermaa, and the '919 patent for the autoclave sterilization technique" (id.).

Observation 4: Dr. Feinberg's testimony does not support Patent Owner's conclusions and does not contradict his opinions.

Patent Owner alleges that Dr. Feinberg's testimony is relevant because it allegedly shows that the prior art taught that drug product containers should be selected to allow terminal sterilization since it is the preferred sterilization method. But this testimony is not relevant to the claimed invention because the claims of the '010 patent do not recite any particular sterilization method (Exhibit 1001, '010 patent, col. 27, l. 54 – col. 33, l. 13). Indeed, the '010 patent indicates that the

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