Exhibit No. ____

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.
Petitioner

v.

FRESENIUS KABI USA, LLC
Patent Owner

U.S. Patent No. 8,476,010
Issue Date: July 2, 2013

Title: PROPOFOL FORMULATIONS WITH NON-REACTIVE CONTAINER CLOSURES

Inter Partes Review No. Unassigned

EXHIBIT 1002 - DECLARATION OF THOMAS N. FEINBERG, PH.D.

Dr. Reddy's Laboratories
v.
Fresenius Kabi USA, LLC
U.S. Patent No. 8,476,010
Exhibit 1002

I, THOMAS N. FEINBERG, PH.D., hereby declare and state as follows:

1. I have been retained by the firm of Lerner, David, Littenberg, Krumholz & Mentlik, LLP ("the firm") as an expert in connection with the above-captioned matter. I am being compensated for my time. My compensation in this matter is not dependent or, or related to, the outcome of this matter. I have never before been retained by the firm in any capacity.

2. I reside in Chapel Hill, North Carolina and am a citizen of the United States of America.

3. I have a Ph.D. in Physical Chemistry from the University of North Carolina at Chapel Hill, which I received in 1991. Prior to that, I received an A.B. in Chemistry from Cornell University in 1985.

4. I have 19 years of experience in the pharmaceutical industry, with an emphasis on container/drug interactions, along with management of analytical R&D and quality control groups. I am presently the President of SCIO Analytical, LLC, which provides expert consulting services predominantly to pharmaceutical development organizations. Prior to founding SCIO Analytical, I was a Director of Development and Analytical Services for Catalent Pharma Solutions. All of my experience has been in contract analytical services, which has provided me with wide-ranging experience in product development issues and quality control.

5. I am, and have been, a member of several working groups and professional societies. A copy of my current *curriculum vitae* listing my professional and academic activities and my publications is attached hereto as Exhibit 1003.

6. I have over 20 publications/presentations/posters and have run workshops to teach regulatory and scientific expectations for container/product interaction (extractables & leachables) issues.

7. I have reviewed U.S. Patent No. 8,476,010 ("the '010 Patent"). A copy of the '010 Patent is attached hereto as Exhibit 1001. I have also reviewed the references identified in this declaration, which are also attached as exhibits.

8. I understand from counsel that patents are not written to be read by experts or by the general public. Instead they are written to be understandable to a person having ordinary skill in the appropriate art. I understand from counsel that factors relevant to the level of skill in the art include: the educational level of the inventor, the types of problems encountered in the art, prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. From my experience, I believe a person of ordinary skill in this art prior to July 10, 2003, when the application for the '010 Patent was filed, would have been: someone with

substantial research or industry experience in pharmaceutical drug product development, including experience with sterile drugs and their packaging, and having a master's degree or doctorate in a related technical field, such as analytical, physical or organic chemistry, chemical engineering, pharmaceutics or related subject matter. I consider myself to be a person of at least ordinary skill in this art, and would have been so in 2003.

9. I have been advised by counsel that the claims at the end of a patent define the scope of the rights granted to the patentee. Claim 1 of the '010 is directed to a sterile container in which a sterile propofol formulation is packaged. The propofol is present in the formulation in an amount of from 0.5% to 10% by weight, along with a solvent, present in an amount of from about 0% to about 10% by weight. As the patent explains, "all references to weight percent are meant to be weight percent by volume of the composition." ('010 Patent, col. 5, lines 33-35.) The container includes a closure which can be made of siliconized bromobutyl rubber, metal or siliconized chlorobutyl rubber. Finally, the packaged formulation must retain at least 93% of the initial propofol concentration (specified previously as 0.5% to 10% weight by volume) under a specified accelerated stability test. The accelerated stability test directs the sealed container to be agitated at a frequency of 300-400 cycles per minute for 16 hours at room temperature.

10. The term "siliconized" is used in claim 1 but it is not defined in the patent. A person of ordinary skill as of the date listed above would have understood this to mean "surface-treated with an organic silicone." "Silicone" is not defined in the patent either, but a person of ordinary skill would have understood it to mean "a general term describing a solid or liquid polymer made up of silicon-oxygen-silicon bonds in which hydrocarbon groups are bonded directly to all or a portion of the silicon atoms." This is a Glossary entry from Smith et al., "Siliconization of Parenteral Drug Packaging Components," 1998 Journal of Parenteral Science and Technology, Technical Report No. 12, at S12. ("Smith *et al.*") (Exhibit 1004). In summary, "siliconized" would mean a closure that is surface-treated with one or more siloxane polymers.

11. Typically siliconization will either be accomplished by surface coating a closure with silicone oil (such as polydimethylsiloxane) or bonding (and/or bridging) a closure with functionalized siloxane polymers designed to surface react with the closure under certain conditions.

12. Claim 17 which is dependent on claim 1 states "[t]he sterile pharmaceutical composition in a container according to claim 1, wherein the closure is coated with a material inert to propofol." Claim 18 is also dependent on claim 1 and states "[t]he sterile pharmaceutical composition in a container

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