

Processes To Make Key Ingredient In Similac® Baby Formula Are Protected

Glycosyn LLC Wins Significant Initial Determination Against Jennewein Biotechnologie GmbH

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Glycosyn LLC →

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WOBURN, Mass., Sept. 13, 2019 /PRNewswire/ -- Glycosyn LLC, a maker of human milk oligosaccharides (HMOs) which are key ingredients in widely-used baby formula Similac® today announced that an International Trade Commission administrative law judge has issued a Notice of Initial Determination that Jennewein Biotechnologie GmbH has infringed Glycosyn's U.S. Patent No. 9,970,018. The patent relates to methods of producing certain HMOs such as 2'-fucosyllactose (2'-FL). Administrative Law Judge Cameron Elliot found that Jennewein infringed Glycosyn's '018 patent and that Jennewein failed to show that any claim of the '018 patent was invalid.

Glycosyn's complaint alleged that Jennewein's submission to the Food and Drug Administration (FDA) showed that it infringed the claims of Glycosyn's patent by producing and selling for importation certain HMOs. One of the most important HMOs is 2'-FL, a type of milk sugar present in human breast milk, but not cow's milk, from which most conventional infant formula is made. This HMO is an

ingredient that is now added to several infant formula products. 2'-FL supplemented infant formula more closely resembles mother's milk and confers health benefits to babies such as promoting establishment of a healthy gut microbiome, prevention of disease, and development of immune function in early life.

Glycosyn's complaint contended that Jennewein was using a bioengineered bacterial strain that infringed Glycosyn's patented inventions. Infringement was found to have taken place, according to the Initial Determination, in 13 of 14 of Glycosyn's asserted claims. The matter is ITC Section 337 Investigation No. 1120.

"We are pleased with Judge Elliot's initial determination, which validates the strength of the patent portfolio protecting Glycosyn's technology," said John Garrett, co-CEO of Glycosyn. "Glycosyn has made substantial investments in researching and developing ways to efficiently and effectively produce human milk oligosaccharides. We remain committed to defending our intellectual property and will continue to assert our rights against companies that infringe on our patented technology."

Judge Elliot's decision is subject to final review by the International Trade Commission. A final determination on the violation and remedy is expected from the Commission by December, 2019.

About Glycosyn LLC.

Glycosyn LLC is a biotechnology company developing products based on molecules found in human milk that offer broad health benefits through promoting the establishment and maintenance of a healthy gut microbial ecology. Founded in 2002, Glycosyn was formed to commercialize discoveries from three decades of pioneering academic research by its three scientific founders, David Newburg, PhD; Ardythe Morrow, PhD, Cincinnati Children's

Research Foundation; and Guillermo Ruiz-Palacios, MD, Instituto Nacional de Ciencias Medicas y Nutricion-Mexico. They discovered natural, anti-infective components (oligosaccharides) in human breast milk that provide significant protection against infectious diarrhea. In 2007, Glycosyn hired John McCoy, PhD, an industry professional with over 30 years' experience in biotechnology as Chief Scientific Officer and established laboratory facilities in Massachusetts, USA.

SOURCE Glycosyn LLC