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(54) **SYSTEMS AND METHODS FOR
MANUFACTURING LIPOSOMES**

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(57) **ABSTRACT**

The present invention provides apparatus and processes for producing liposomes. By providing a buffer solution in a first reservoir, and a lipid solution in a second reservoir, continuously diluting the lipid solution with the buffer solution in a mixing chamber produces a liposome. A therapeutic agent, such as nucleic acid, is included in one of the buffer solution or the lipid solution. Upon mixing a liposome encapsulating the therapeutic product is substantially instantaneously formed. Thereafter the liposome solution formed is immediately diluted with buffer solution to enhance homogeneity and maintain small particle size.

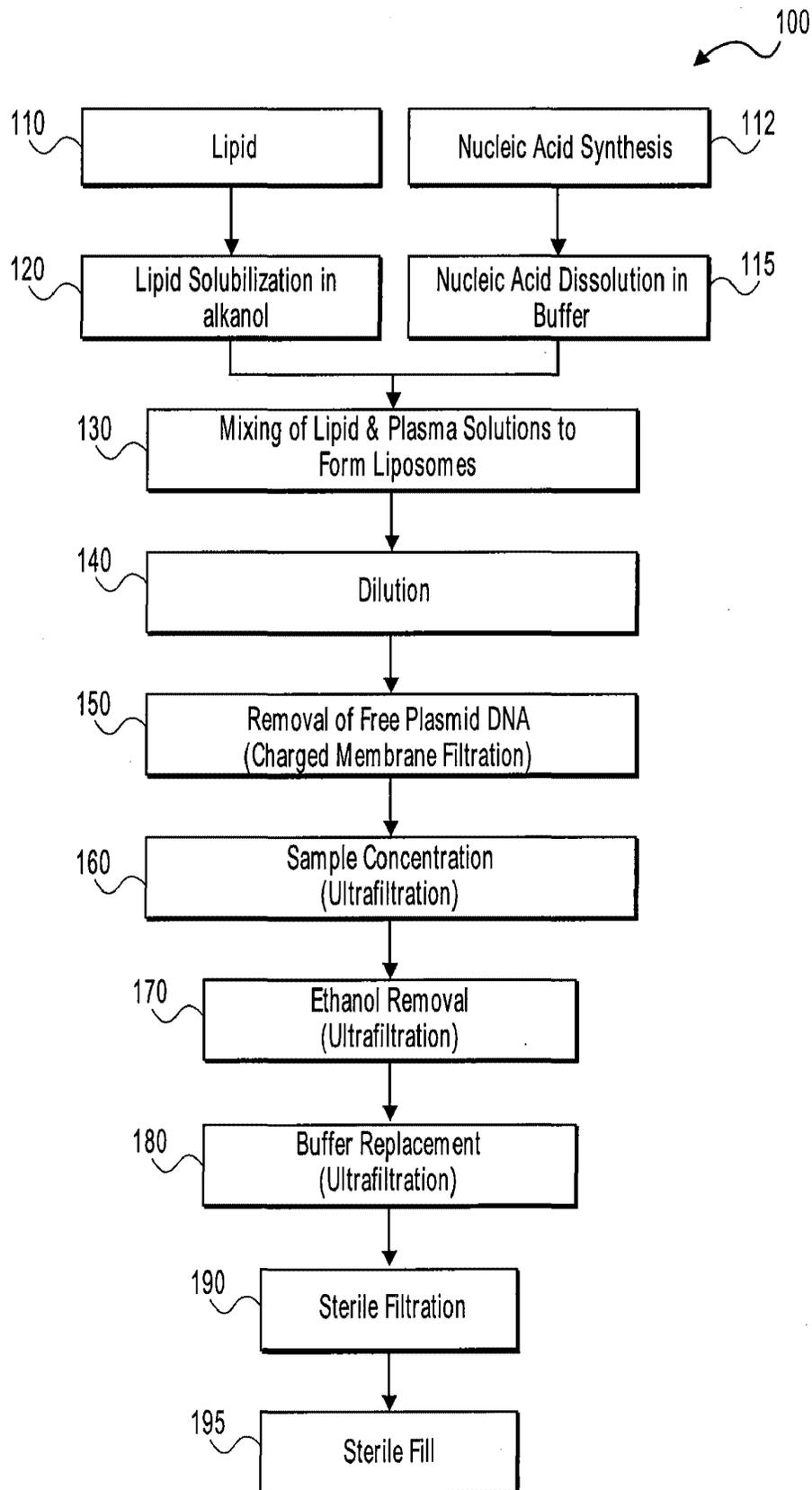


FIG. 1

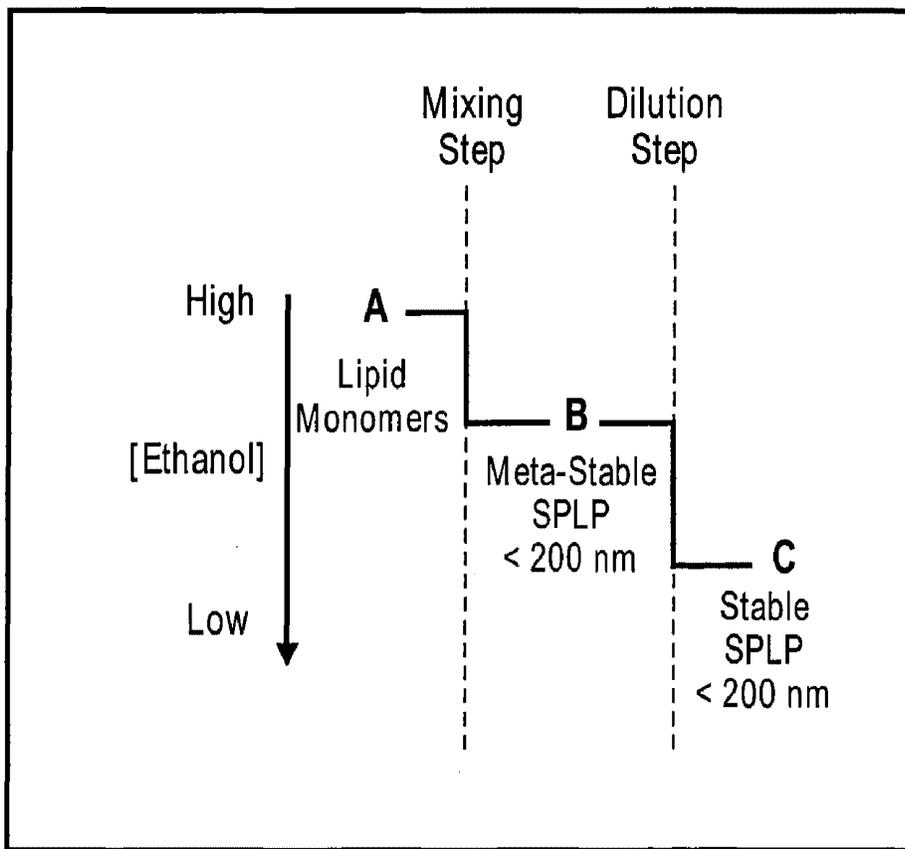


FIG. 2

SNALP2 Process

(Spontaneous Vesicle Formation - Stirred Tank Direct Dilution)

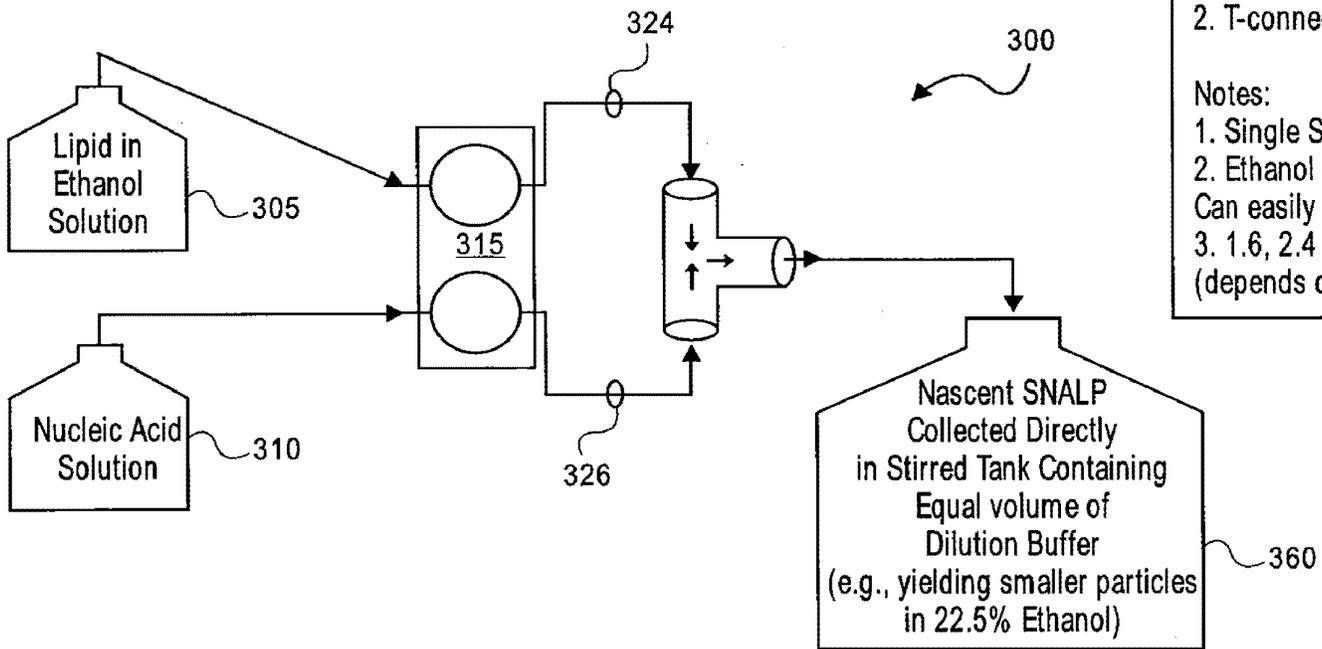
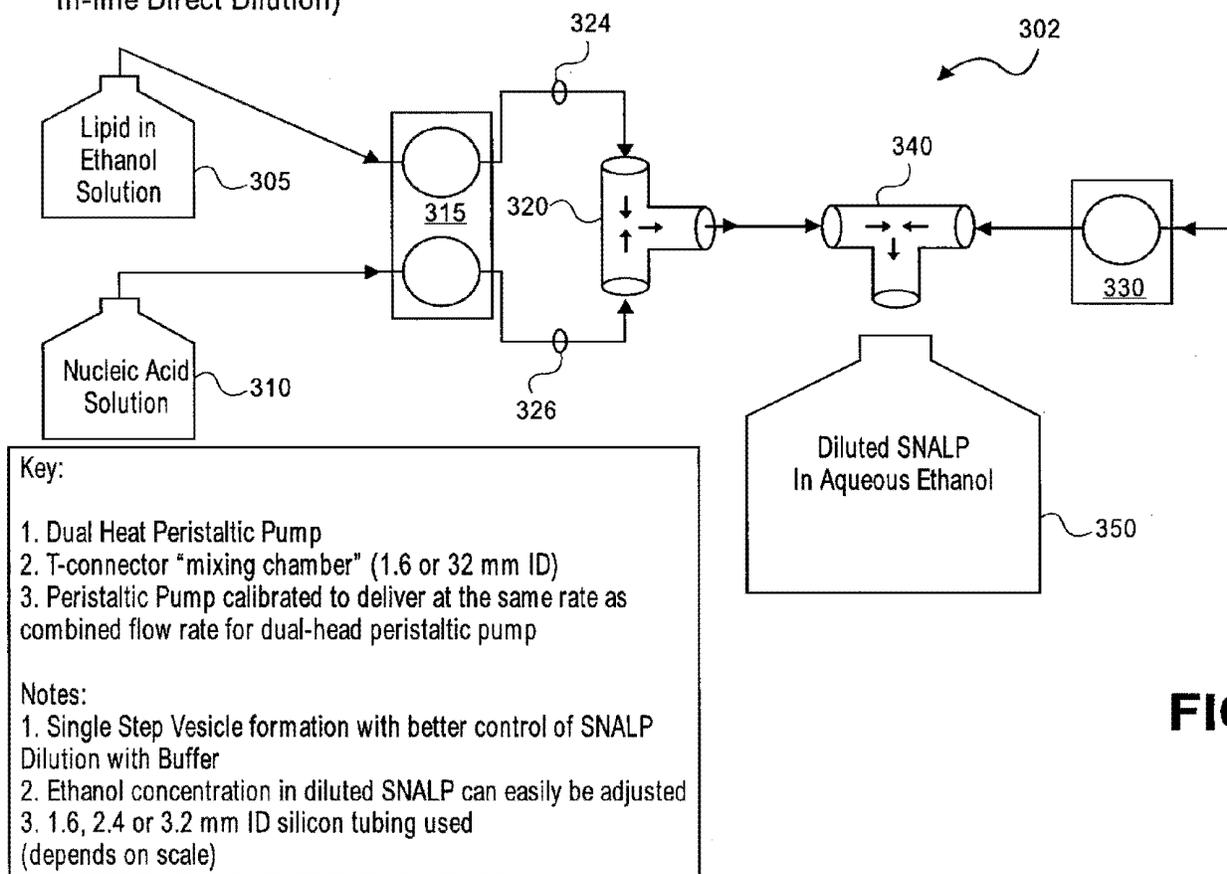


FIG.

SNALP3 Process

(Spontaneous Vesicle Formation -
In-line Direct Dilution)



FIG

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