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Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

(54) **Title:** DETECTION OF EARLY-STAGE LUNG CANCER IN SPUTUM USING AUTOMATED FLOW CYTOMETRY AND MACHINE LEARNING

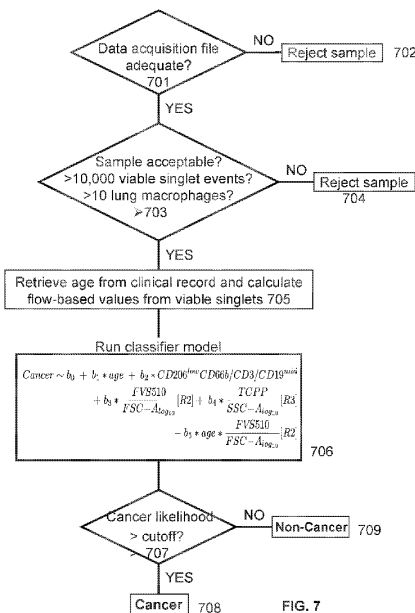


FIG. 7

(57) **Abstract:** A system and method for analyzing a sputum sample from a subject suspected of having lung cancer comprising obtaining a plurality of cells from the sputum sample from the subject, marking the plurality of cells with *i*) a plurality of cell lineage specific marker compositions, *ii*) a cell viability composition and *iii*) a tetra (4-carboxyphenyl) porphyrin (TCPP) composition; analyzing with the flow cytometer the plurality of cells marked with *i-iii* to obtain a subpopulation selected for cell size from the plurality of cells based upon an automatically selected bead size exclusion gate; from the cell size selected subpopulation, selecting a viable singlet population of cells using an automated non-debris gate and an automated singlets gate; from the viable singlet population of cells, obtaining flow cytometer values based upon the plurality of cell lineage specific marker compositions, the viability marker and the TCPP marker; applying a trained classifier to meta data from the subject and the flow cytometric values obtained; and generating, based upon the application of the trained classifier, a classification for the sputum sample wherein the classification is selected from a plurality of classification options comprising cancer and non-cancer.

[Continued on next page]

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