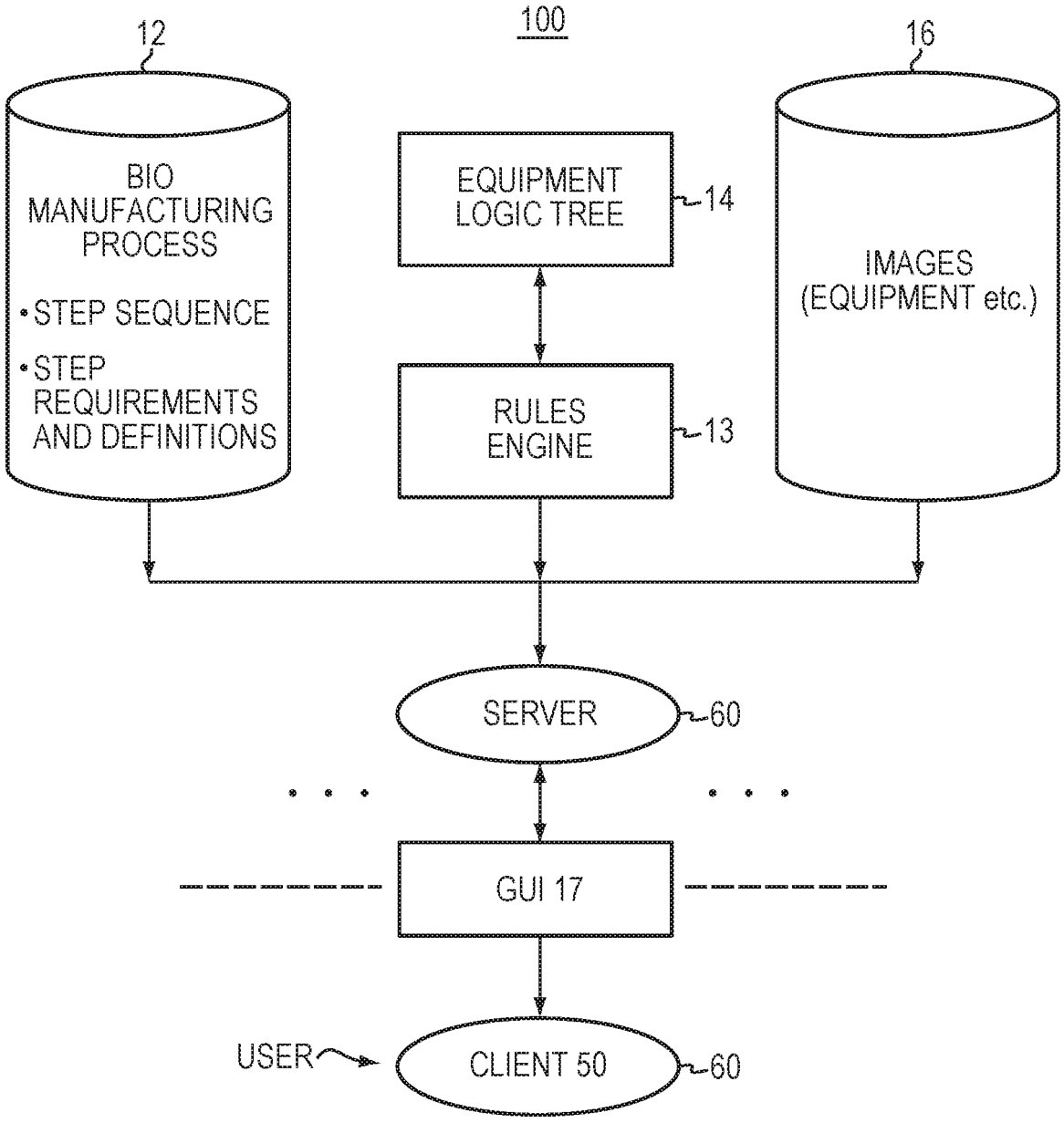

100
12
16
BIO MANUFACTURING PROCESS
• STEP SEQUENCE
• STEP REQUIREMENTS AND DEFINITIONS
EQUIPMENT LOGIC TREE
14
RULES ENGINE
13
IMAGES (EQUIPMENT etc.)
SERVER
60
GUI 17
USER
CLIENT 50
60

FIG. 1A

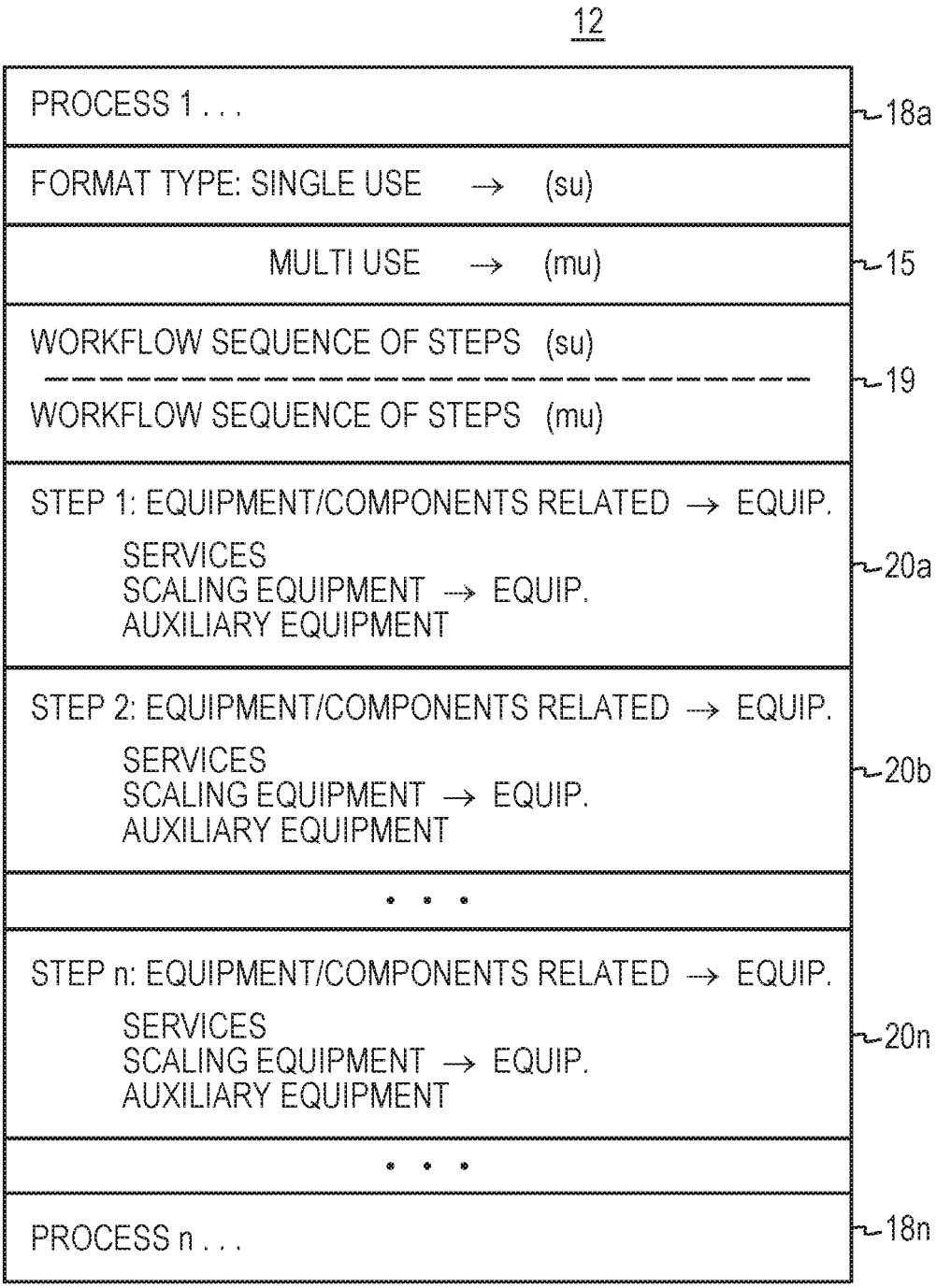

12
PROCESS 1 . . .
18a
FORMAT TYPE: SINGLE USE → (su)
MULTI USE → (mu)
15
WORKFLOW SEQUENCE OF STEPS (su)
WORKFLOW SEQUENCE OF STEPS (mu)
19
STEP 1: EQUIPMENT/COMPONENTS RELATED → EQUIP.
SERVICES
SCALING EQUIPMENT → EQUIP.
AUXILIARY EQUIPMENT
20a
STEP 2: EQUIPMENT/COMPONENTS RELATED → EQUIP.
SERVICES
SCALING EQUIPMENT → EQUIP.
AUXILIARY EQUIPMENT
20b
STEP n: EQUIPMENT/COMPONENTS RELATED → EQUIP.
SERVICES
SCALING EQUIPMENT → EQUIP.
AUXILIARY EQUIPMENT
20n
PROCESS n . . .
18n

FIG. 1B

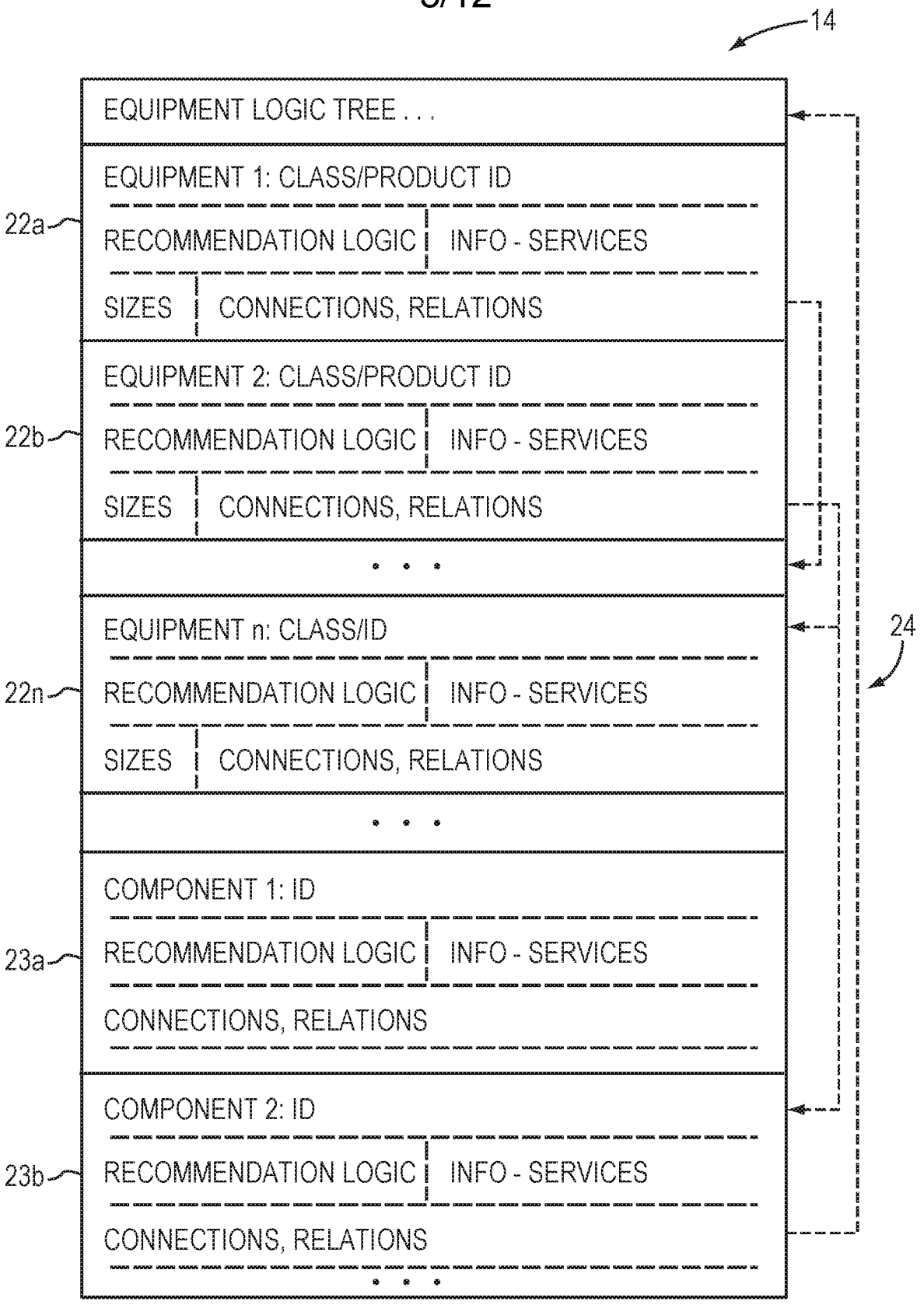

14
EQUIPMENT LOGIC TREE . . .
EQUIPMENT 1: CLASS/PRODUCT ID
22a
RECOMMENDATION LOGIC
INFO - SERVICES
SIZES
CONNECTIONS, RELATIONS
EQUIPMENT 2: CLASS/PRODUCT ID
22b
RECOMMENDATION LOGIC
INFO - SERVICES
SIZES
CONNECTIONS, RELATIONS
EQUIPMENT n: CLASS/ID
22n
RECOMMENDATION LOGIC
INFO - SERVICES
SIZES
CONNECTIONS, RELATIONS
24
COMPONENT 1: ID
23a
RECOMMENDATION LOGIC
INFO - SERVICES
CONNECTIONS, RELATIONS
COMPONENT 2: ID
23b
RECOMMENDATION LOGIC
INFO - SERVICES
CONNECTIONS, RELATIONS

FIG. 1C

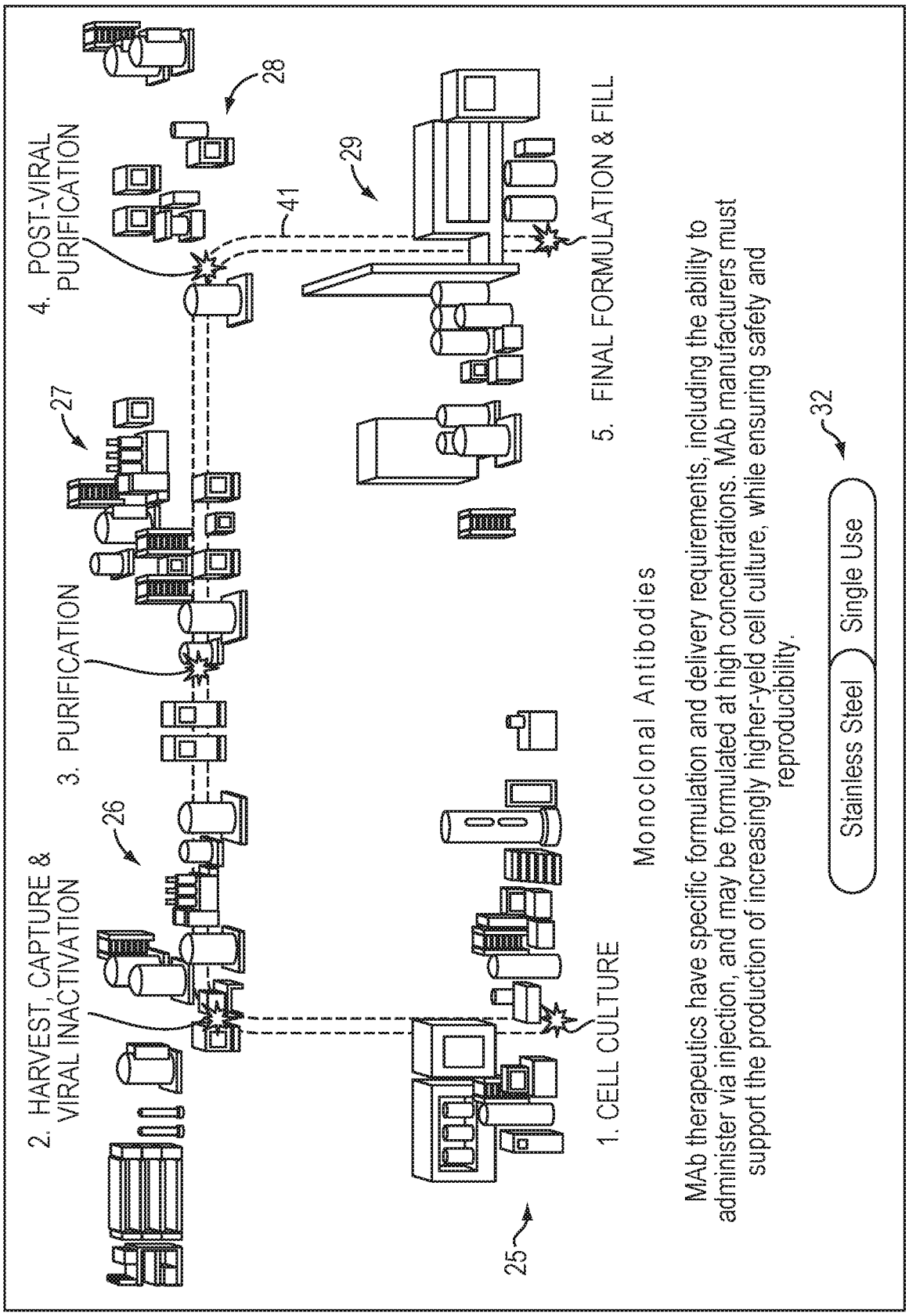

1. CELL CULTURE
2. HARVEST, CAPTURE & VIRAL INACTIVATION
3. PURIFICATION
4. POST-VIRAL PURIFICATION
5. FINAL FORMULATION & FILL
Monoclonal Antibodies
MAb therapeutics have specific formulation and delivery requirements, including the ability to administer via injection, and may be formulated at high concentrations. MAb manufacturers must support the production of increasingly higher-yeld cell culture, while ensuring safety and reproducibility.
Stainless Steel
Single Use
25
26
27
28
29
32
41

FIG. 2

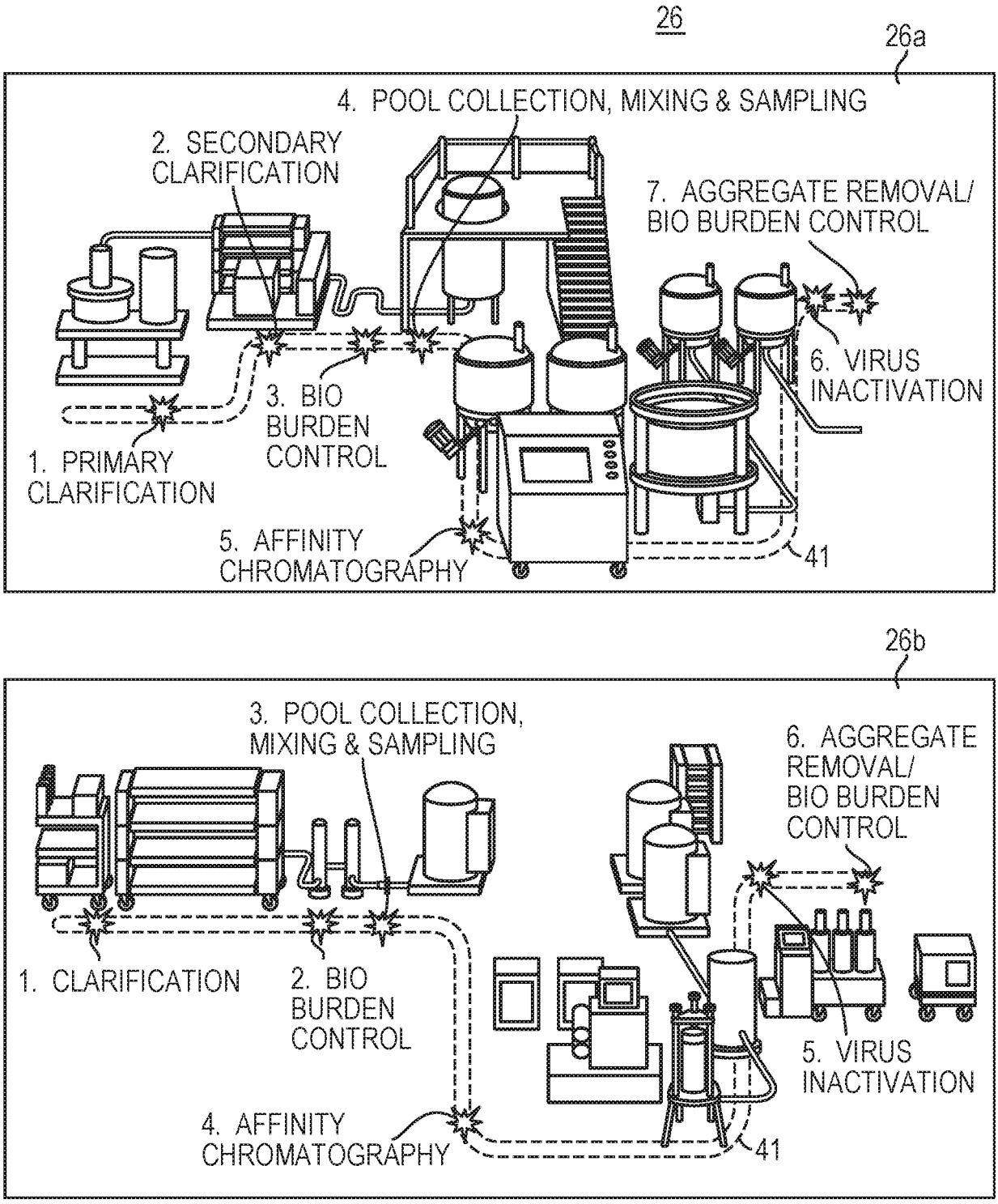

26
26a
4. POOL COLLECTION, MIXING & SAMPLING
2. SECONDARY CLARIFICATION
7. AGGREGATE REMOVAL/ BIO BURDEN CONTROL
6. VIRUS INACTIVATION
3. BIO BURDEN CONTROL
1. PRIMARY CLARIFICATION
5. AFFINITY CHROMATOGRAPHY
41
26b
3. POOL COLLECTION, MIXING & SAMPLING
6. AGGREGATE REMOVAL/ BIO BURDEN CONTROL
1. CLARIFICATION
2. BIO BURDEN CONTROL
5. VIRUS INACTIVATION
4. AFFINITY CHROMATOGRAPHY
41

FIG. 3A

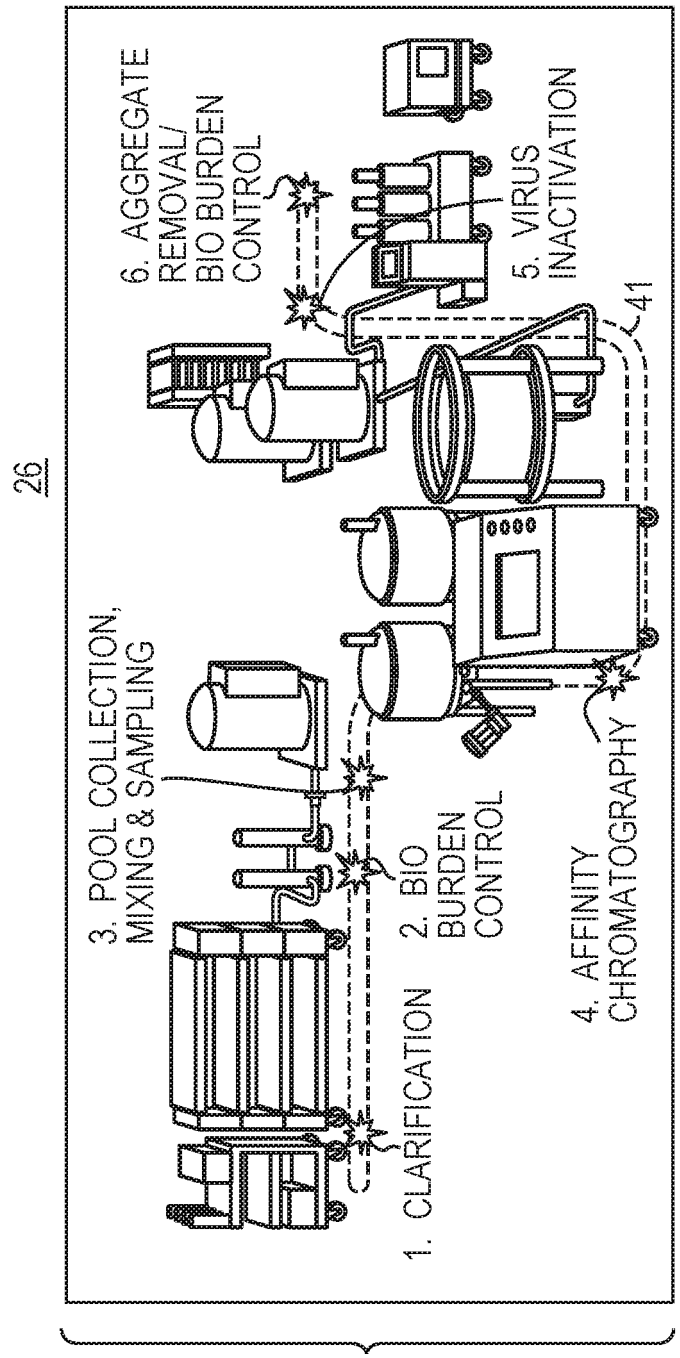

26
3. POOL COLLECTION, MIXING & SAMPLING
6. AGGREGATE REMOVAL/ BIO BURDEN CONTROL
5. VIRUS INACTIVATION
41
1. CLARIFICATION
2. BIO BURDEN CONTROL
4. AFFINITY CHROMATOGRAPHY
Each process step can be configured to be SU or MU to make a hybrid process. Logic rules exist to ensure only rational and viable combinations are constructed.

FIG. 3B

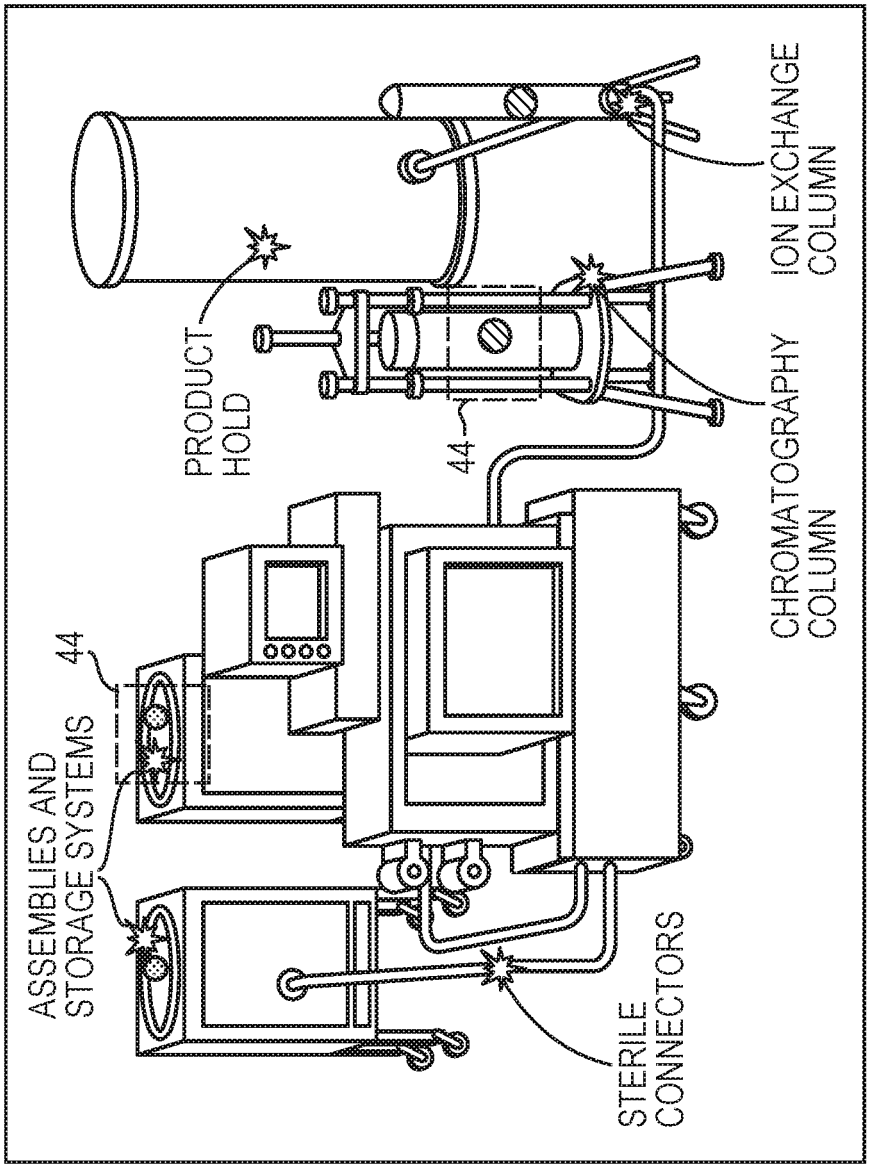

ASSEMBLIES AND STORAGE SYSTEMS
44
PRODUCT HOLD
44
ION EXCHANGE COLUMN
CHROMATOGRAPHY COLUMN
STERILE CONNECTORS

FIG. 4

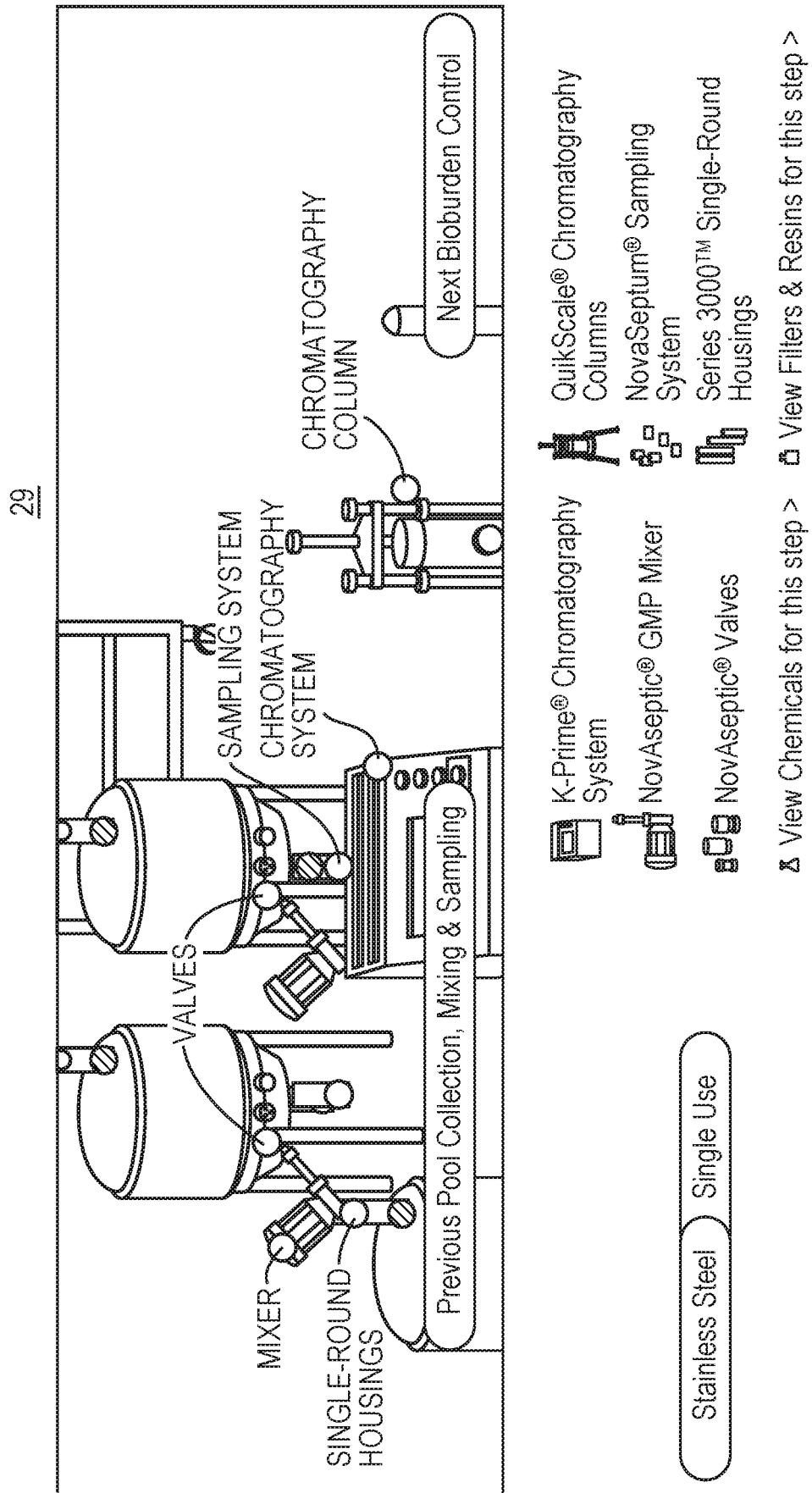

29
VALVES
SAMPLING SYSTEM
CHROMATOGRAPHY SYSTEM
CHROMATOGRAPHY COLUMN
MIXER
SINGLE-ROUND HOUSINGS
Previous Pool Collection, Mixing & Sampling
Next Bioburden Control
Stainless Steel
Single Use
K-Prime® Chromatography System
NovAseptic® GMP Mixer
NovAseptic® Valves
QuikScale® Chromatography Columns
NovaSeptum® Sampling System
Series 3000™ Single-Round Housings
View Chemicals for this step >
View Filters & Resins for this step >

FIG. 5A

9/12

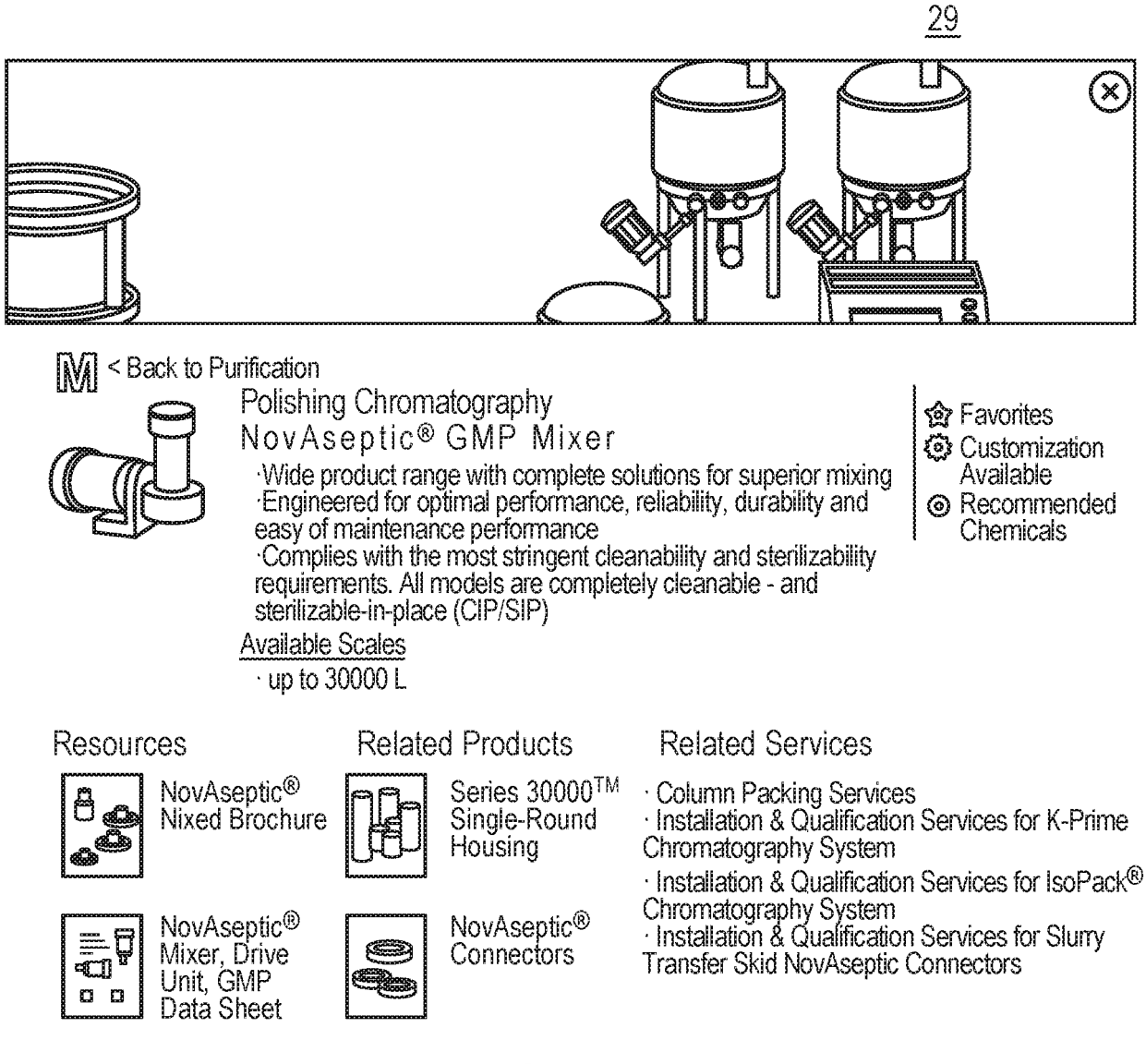


FIG. 5B

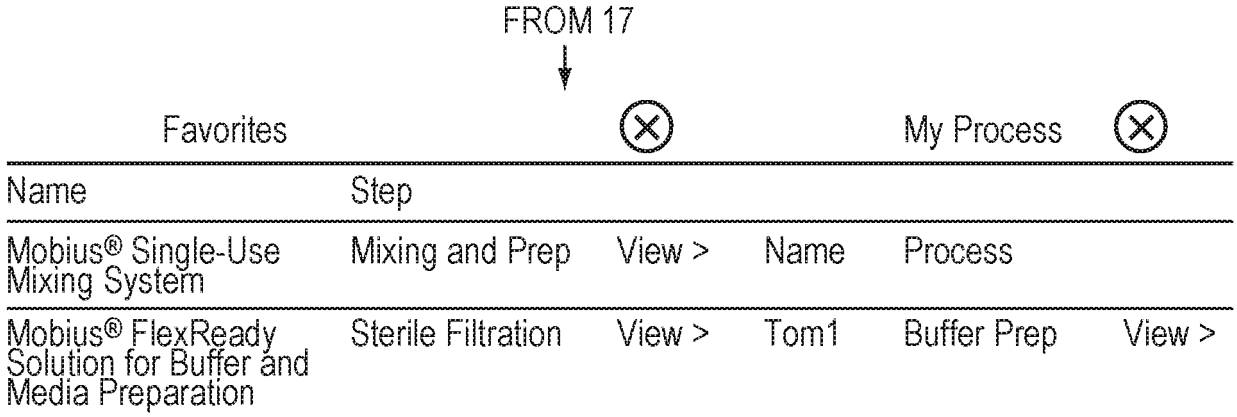


FIG. 6

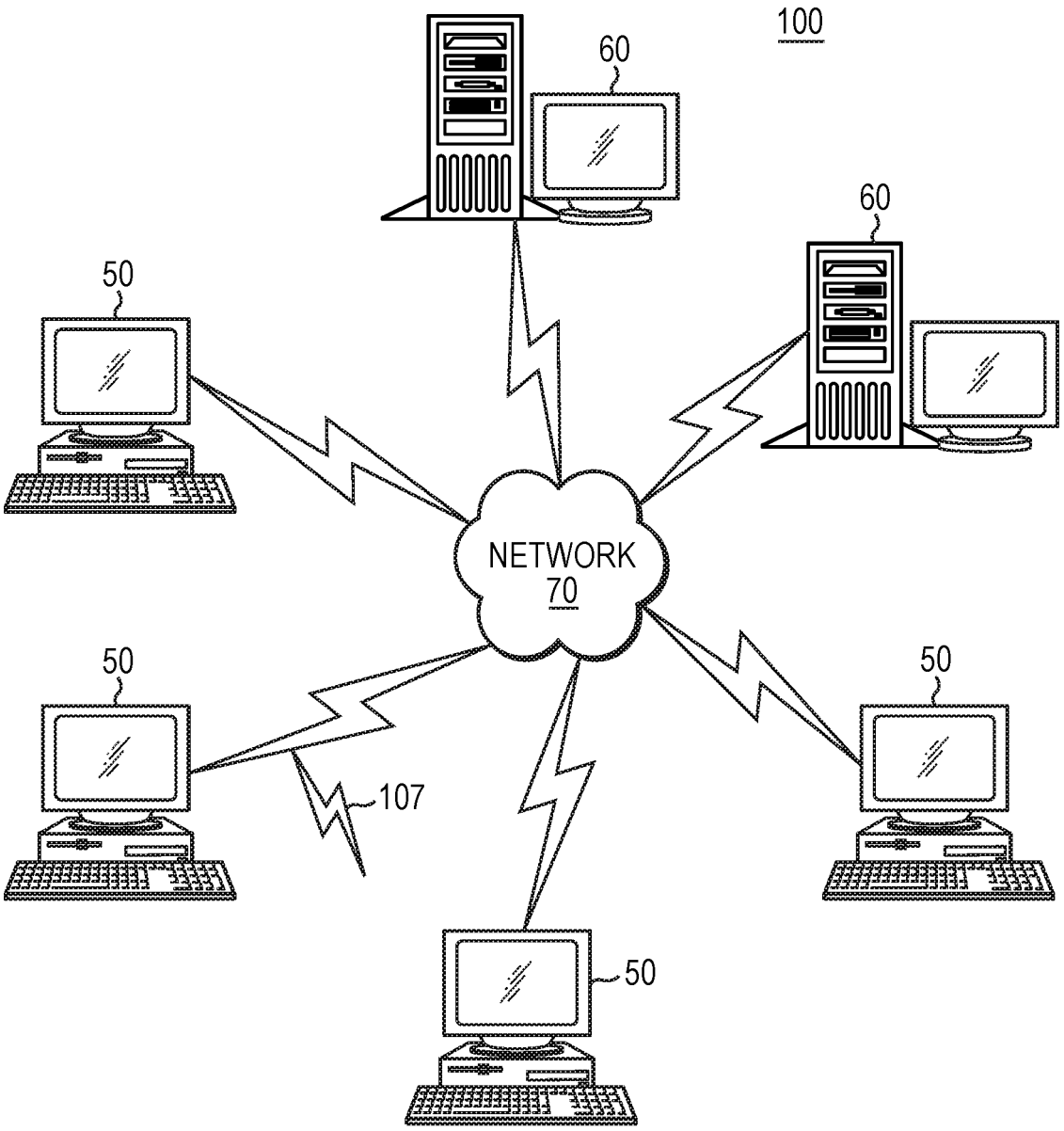


FIG. 7

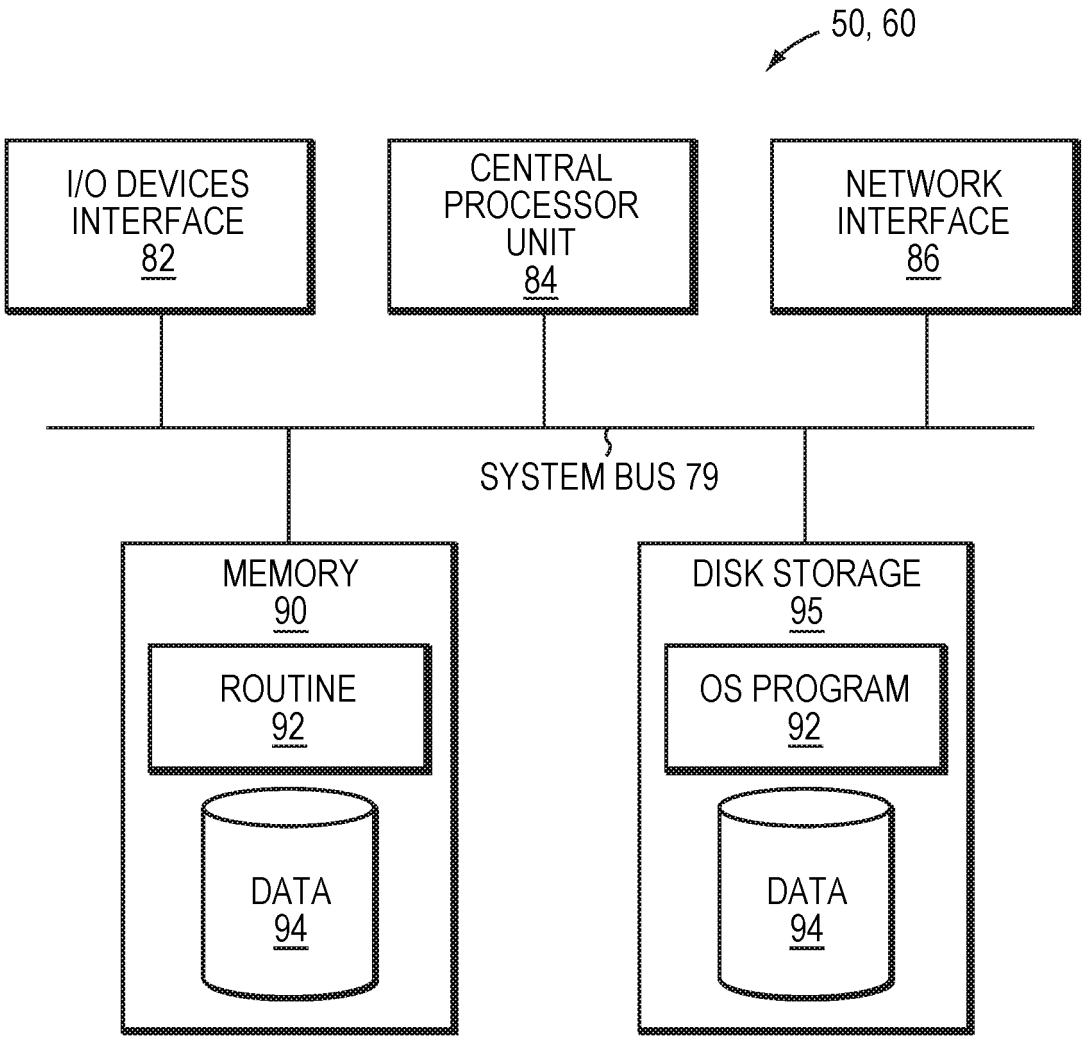

50, 60
I/O DEVICES INTERFACE 82
CENTRAL PROCESSOR UNIT 84
NETWORK INTERFACE 86
SYSTEM BUS 79
MEMORY 90
ROUTINE 92
DATA 94
DISK STORAGE 95
OS PROGRAM 92
DATA 94

FIG. 8

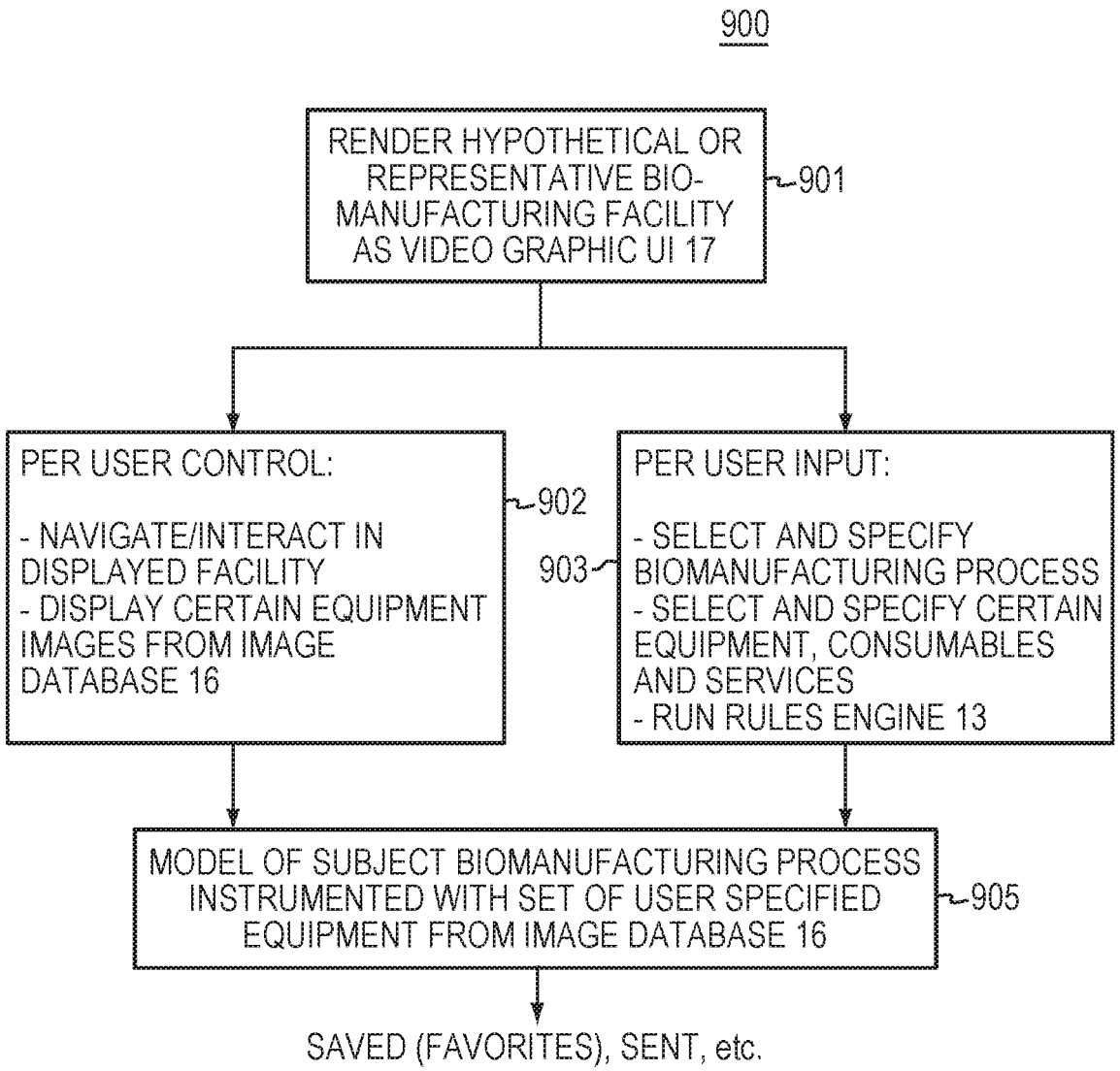

900
RENDER HYPOTHETICAL OR REPRESENTATIVE BIO-MANUFACTURING FACILITY AS VIDEO GRAPHIC UI 17
901
PER USER CONTROL:
- NAVIGATE/INTERACT IN DISPLAYED FACILITY
- DISPLAY CERTAIN EQUIPMENT IMAGES FROM IMAGE DATABASE 16
902
PER USER INPUT:
- SELECT AND SPECIFY BIOMANUFACTURING PROCESS
- SELECT AND SPECIFY CERTAIN EQUIPMENT, CONSUMABLES AND SERVICES
- RUN RULES ENGINE 13
903
MODEL OF SUBJECT BIOMANUFACTURING PROCESS INSTRUMENTED WITH SET OF USER SPECIFIED EQUIPMENT FROM IMAGE DATABASE 16
905
SAVED (FAVORITES), SENT, etc.

FIG. 9