Disclosure of the Invention

Embodiments of tThe ~~present~~ invention provides an integrated apparatus enabling Electrically Mediated Therapeutic Agent Delivery (EMTAD) to be accomplished in a safe, consistent, and cost effective manner. Embodiments of tThe present invention allows effective intramuscular, intradermal, and/or subcutaneous administration of therapeutic or prophylactic agents such as nucleic acids, drugs, antibodies, and proteins.

In one aspect, it is~~the present invention~~ provided an apparatus for the delivery of an electrical field which facilitates the intracellular delivery of a therapeutic agent to a predetermined site within the tissue of a patient. In this aspect, the apparatus will comprise a plurality of penetrating electrodes arranged in a predetermined spatial relationship, a fluid reservoir for containing a therapeutic agent, said reservoir operatively connected to at least one injection orifice, an actuator configured to transmit said therapeutic agent through said orifice to the predetermined site within the tissue of the patient, operative connections for the penetrating electrodes, said fluid reservoir, and said injection orifice wherein said structural means is configured to allow disposition of said plurality of electrodes and said injection orifice within the tissue of a patient according to a predetermined spatial relationship, each electrode with a cross sectional area contributing to the total cross sectional area of all electrodes, and structural means incorporating an inanimate source of energy operatively connected to said actuator and wherein the source of energy is configured to apply a force of at least 0.25 pounds (1.1 Newtons) through said fluid reservoir to said therapeutic agent. The inanimate source of energy is also operatively connected to the plurality of electrodes for deploying the electrodes without substantial distortion of said electrode, wherein the source of energy is sufficient to impart a force of at least 1000 pounds per square inch (0.7 kilograms per square millimeter) of total cross sectional area of all electrodes at the initiation of the deployment of the electrodes and wherein said source of energy is sufficient to impart a force of at least 500 pounds per square inch (0.35kg/square millimeter) of cross-sectional area of the electrodes at the end of the deployment of said electrodes, such that the electrodes are deployed without substantial distortion within the tissue of a patient. The apparatus will also comprise ~~means for generating~~ an electrical field generator which facilitates the intracellular delivery of a therapeutic agent, which means is operatively connected to said electrodes at least in their deployed state.

Another aspect ~~of the invention~~ provides the apparatus with structural means configured to accept a fluid reservoir for containing a therapeutic agent, or with the fluid reservoir itself, where the reservoir is operatively connected to at least one injection orifice, and actuation means configured to transmit the therapeutic agent through the orifice to the predetermined site within the tissue of the patient.

Other aspects ~~of the invention~~ include such apparatus configured to accept replaceable therapeutic agent fluid reservoir subassemblies, electrode subassemblies, and a combination thereof. Also included are include means for priming the automated mechanisms incorporated in the applicator upon insertion of the cartridge, identifying the model or type of cartridge that has been inserted, and protecting the user and patient from accidental injury associated with the usage of the apparatus.

Additional aspects ~~of the invention~~ include such apparatus configured to improve the functionality and ergonomics of the Applicator (i.e. the user interface) in a number of ways. The inanimate source of energy can be positioned alongside the fluid reservoir, so as to reduce the