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(54) **METHOD OF TRANSCUTANEOUS IMMUNIZATION USING ANTIGEN**

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(57) **ABSTRACT**

Related U.S. Application Data

(63) Continuation of application No. 11/109,948, filed on Apr. 20, 2005, now abandoned, which is a continuation of application No. 09/311,720, filed on May 14, 1999, now abandoned, which is a continuation-in-part of application No. 09/257,188, filed on Feb. 25, 1999, now Pat. No. 6,797,276, which is a continuation-in-part of application No. 09/309,881, filed on May 11, 1999, now abandoned.

Transcutaneous immunization can deliver antigen to the immune system through the stratum corneum without physical or chemical penetration to the dermis layer of the skin. This delivery system induces an antigen-specific immune response. Use of skin-active adjuvants is preferred. Although perforation of intact skin is not required, superficial penetration or micropenetration of the skin can act as an enhancer; similarly, hydration may enhance the immune response. This system can induce antigen-specific immune effectors after epicutaneous application of a formulation containing one or more antigen and adjuvant. The formulation may initiate processes such as antigen uptake, processing, and presentation; Langerhans cell activation, migration from the skin to other immune organs, and differentiation to mature dendritic cells; contacting antigen with lymphocytes bearing cognate antigen receptors on the cell surface and their stimulation; and combinations thereof. Systemic and/or regional immunity may be induced; immune responses that result in prophylaxis and/or therapeutic treatments are preferred. Antigen and adjuvant activities in the formulation may be found in the same molecule, two or more different molecules dissociated from each other, or multiple molecules in a complex formed by covalent or non-covalent bonds. For antigens and adjuvants which are proteinaceous, they may be provided in the formulation as a polynucleotide for transcutaneous genetic immunization. Besides simple application of a liquid formulation, patches or other medical devices may be used to deliver antigen for immunization.

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