EUROPEAN PATENT OFFICE
U.S. PATENT AND TRADEMARK OFFICE

CPC NOTICE OF CHANGES 1611

DATE: JANUARY 1, 2024

PROJECT MP11792

The following classification changes will be effected by this Notice of Changes:

Action	Subclass	Group(s)
SCHEME:		
Notes Deleted:	A61K	48/00
DEFINITIONS:		
Definitions Modified:	A61K	48/00

No other subclasses/groups are impacted by this Notice of Changes.

This Notice of Changes includes the following *[Check the ones included]*:

1. CLASSIFICATION SCHEME CHANGES

    ☐ A. New, Modified or Deleted Group(s)

    ☐ B. New, Modified or Deleted Warning(s)

    ☒ C. New, Modified or Deleted Note(s)

    ☐ D. New, Modified or Deleted Guidance Heading(s)

2. DEFINITIONS

    ☒ A. New or Modified Definitions (Full definition template)

    ☐ B. Modified or Deleted Definitions (Definitions Quick Fix)

3. ☐ REVISION CONCORDANCE LIST (RCL)

4. ☐ CHANGES TO THE CPC-TO-IPC CONCORDANCE LIST (CICL)

5. ☐ CHANGES TO THE CROSS-REFERENCE LIST (CRL)

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1. CLASSIFICATION SCHEME CHANGES

B. <u>New, Modified or Deleted Note(s)</u>

SUBCLASS A61K - PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES

Type*	Location	Old Note	New/Modified Note
D	A61K48/00	1. In this group the following expression is used with the meaning indicated: "gene therapy" means <u>in vivo</u> delivery of nucleic acids encoding for peptides by administration of these nucleic acids or by implanting cells transfected ex vivo with the nucleic acids encoding for the peptides. 2. Documents relating to new nucleic acids encoding for peptides, e.g. enzymes, and their use in gene therapy are classified in subclass C07K or in group C12N9/00 according to the encoded peptides, with the appropriate indexing codes relating to gene therapy. 3. Documents relating to new vectors and their use in gene therapy are classified in groups C12N15/85 - C12N15/90 according to the vectors, and the appropriate indexing codes, including those relating to gene therapy. 4. Documents describing cells genetically modified to express a gene of interest and their use in gene therapy are classified in C12N5/06 according to the cells, with the appropriate indexing codes relating to gene therapy. 5. Documents relating to new medical uses of peptides <u>per se</u>, which peptides may be encoded by nucleic acids, and wherein the nucleic acids may be administered directly or by implanting cells transfected ex vivo with the nucleic acids, are classified in	

		the appropriate groups A61K38/00 or A61K39/00 according to the encoded peptides, with the indexing codes relating, inter alia, to gene therapy.	

*N = new note, M = modified note, D = deleted note

NOTE: The "Location" column only requires the symbol PRIOR to the location of the note. No further directions such as "before" or "after" are required.

2. A. DEFINITIONS (modified)

A61K48/00

Definition statement

Replace: The existing Definition statement text with the updated text below.

Genetic material encoding proteins, the in vivo expression of which results in an in vivo therapeutic effect being attained. Cells can be used as delivery vehicle following ex vivo transfection with a nucleic acid encoding a therapeutic protein, enzyme or peptide if the therapeutic effect is a consequence of the ex vivo transfection step, i.e. arising as a result of the modification carried out. The protein in question may be expressed directly from the delivered nucleic acid sequence, or may, for example, be involved in a recombination process with a mutant, 'defective' gene, protein expression from the 'repaired' gene then ensuing at a time thereafter. The expression of the protein may be to replace / complement a 'defective protein', or may be to provide an entity (such as an enzyme) which is therapeutic (for example in the context of cancer therapy).

Relationships with other classification places

Replace: The existing Relationships with other classification places section text with the updated text below.

Transgenic animals are classified in A01K 67/027.

Proteins and peptides per se, encoded by the genetic material, are classified in the appropriate C07K subgroups, unless the protein is an enzyme. In this case the appropriate subgroup in C12N9/00 should be used. Then classification of the specific enzyme is also made in C12Y as invention.

If therapy arises only as a consequence of the cells per se being delivered, and not due to the manner in which the cells have been modified ex vivo, classification in the subclass for gene therapy should not be made.

References:

Delete: The Limiting references section and table.

Replace: The existing Informative references table with the updated table below.

Informative references:

Attention is drawn to the following places, which may be of interest for search:

Liposomes	A61K 9/127
Medicinal preparations comprising compounds having three or more nucleosides or nucleotides	A61K31/7088
Medicinal preparations containing materials or reaction products thereof with undetermined constitution	A61K 35/00
Medical use of proteins	A61K 38/00
Medical use of vaccines or antibodies	A61K39/00
Medicinal preparations characterised by the non-active ingredient	A61K 47/00
Specific therapeutic activities	A61P
Proteins	C07K 14/00
Antibodies	C07K 16/00
Cells	C12N 5/06
Viruses	C12N 7/00
Genetic engineering	C12N15/00
Antisense nucleic acids, siRNA	C12N 15/113
Vectors for animal cells	C12N 15/85
Viral vectors	C12N 15/86

Special rules of classification

Replace: The existing Special rules of classification section text with the updated text below.

An invention classification symbol should be given in A61K38/00 for the protein or peptide if the expression results from the nucleic acid delivered via gene therapy.

Enabling subject matter should be classified. More specifically, subject matter that pertains to the technical effect in question which the skilled person would be able to carry out based on the teachings of the application without undue burden, should be classified. Subject matter which is enabling but not clearly a technical contribution over the art should also be classified. Subject matter which is purely hypothetical or theoretical should not be classified. An example is when a particular substance is stated to be suitable for the treatment of a list of diseases but for which no data, even in an in

vitro or animal model setting, is made available. On the other hand, subject matter supported by data which may be for example derived only from an in vitro setting but which lends at least partial credibility to an in vivo treatment should be classified.