C. *Genetic coding of proteins*[80]

In order to produce a protein, a cell requires information about the sequence in which the amino acid must be assembled.[81] The cell utilizes a long polymeric molecule, DNA (deoxyribonucleic acid), to store this information. The amino acid sequence of a protein is genetically determined by the sequences of bases in a DNA molecule. The subunits of the DNA are called nucleotides.[82] DNA encompasses four nucleotides that are distinguishable from the base regions of the molecule. The four bases are adenine, guanine, cytosine, and thymine (referred to as A, G, C and T). The sequence of these bases along the DNA molecule determines which amino acids will be inserted in sequence into the polypeptide chain of a protein. DNA is synthesized in extremely long strands (called chromosomes) encompassing information encoding for the sequence of many proteins. The region of DNA on the chromosome that determines the sequence of a single protein is called a gene.[83] The process in which the data in a gene is utilized to synthesize a new protein is called gene expression. To express a gene, a copy of the gene as a molecule of RNA (ribonucleic acid) is made. RNA is a molecule very similar to DNA. One difference, however, is that RNA contains a different sugar (ribose instead of deoxyribose). Furthermore, the base thymine (T) of DNA is replaced in RNA by the structurally similar base, uracil (U).[84] The process of making an RNA copy of DNA is called transcription.[85] The transcribed RNA copy contains sequences of A, U, C, and G having the same information as the sequence of A, T, C and G in the DNA. The RNA molecule, referred to as messenger RNA (mRNA), then progresses to a location in the cell where proteins are synthesized. The information encoding the sequence of amino acids in a protein (the “genetic code”) is composed of serially reaching groups of three contiguous nucleotides. Each combination of three contiguous nucleotides, called a codon, determines one amino acid. The four bases A, G, C and U can be specified as triplets in 64 different ways, but there are only 20 amino acids to be translated. Thus,

80 Alberts, Bruce/Johnson, Alexander/Lewis, Julian, Molecular Biology of the Cell (4th ed.), New York 2002, 111-112.

81 CAFC decisions often provide a useful and clear illustration of the scientific background. The process of genetic coding and translation is explained in: In re O’Farrell 853 F.2d 894, 895-899 (Fed. Cir. 1988); for a detailed overview of the genetic coding of proteins see Vossius, Volker/Jaenichen, Hans-Rainer, Zur Patentierung biologischer Erfindungen nach Europäischem Patentübereinkommen und Deutschem Patentgesetz - Formulierung und Auslegung von Patentansprüchen, GRUR 1985, 821.

82 Alberts, Bruce/Johnson, Alexander./Lewis, Julian, Molecular Biology of the Cell, New York 2002, 98.

83 For a brief overview of the basics of genetics, see also Kraßer, Rudolf, Patentrecht: ein Lehr- und Handbuch zum deutschen Patent- und Gebrauchsmusterrecht, europäischen und internationalen Patentrecht, 5. Aufl., München 2004, 222.

84 Alberts, Bruce/Johnson, Alexander./Lewis, Julian, Molecular Biology of the Cell, New York 2002, 104-105.

85 Alberts, Bruce/Johnson, Alexander./Lewis, Julian,Molecular Biology of the Cell, New York 2002, 104.

most amino acids are encoded by more than one codon. In addition, three codons exist which do not encode any amino acid. They are called 'stop codons'.[86] Complicated cellular machinery is involved in the synthesis of proteins. Complexes of more than fifty different proteins associated with several structural RNA molecules (rRNAs), are called ribosomes.[87] These molecules 'read' the necessary information in the messenger RNA molecule, shift three nucleotides along the strand of RNA at a time, and add the amino acid determined by the codon to a growing polypeptide chain. When it arrives at a stop codon, the polypeptide chain is complete and detaches from the ribosome. This process of synthesizing a new polypeptide chain from the genetic information contained on the messenger RNA molecule with the aid of ribosomes is referred to as translation.[88] The messenger RNA can be used to synthesize many copies of the same protein. The translation of messenger RNA starts at the particular sequence of nucleotide that binds the RNA to the ribosome. The translation then continues by reading nucleotides, three at a time, until a stop codon is read. Reading errors might lead to entirely different peptides, most likely useless ones. [89]

D. Recombinant Protein Synthesis

If a human gene is transferred into a bacterium, this bacterium is able to synthesize the human protein.[90] The method of producing large quantities of identical copies of a gene by integrating it into prokaryotic cells and then replicating those cells is referred to as "DNA-cloning".[91] After having produced a significant amount of the

86 Alberts, Bruce/Johnson, Alexander./Lewis, Julian, Molecular Biology of the Cell, New York 2002, 106.

87 Alberts, Bruce/Johnson, Alexander./Lewis, Julian, Molecular Biology of the Cell, New York 2002, 107.

88 Alberts, Bruce/Johnson, Alexander./Lewis, Julian, Molecular Biology of the Cell , New York 2002, 106.

89 Alberts, Bruce/Johnson, Alexander./Lewis, Julian, Molecular Biology of the Cell, New York 2002, 107.

90 Human beings, animals, and plants are classified as eukaryotic organisms: their DNA is enclosed in chromosomes in a special part of the cell, the nucleus. In contrast, Bacteria (prokaryotic organisms) have a different organization. Their DNA is not included in a separate nucleus. Irrespective of the large differences between them, all organisms, whether eukaryotic or prokaryotic, encode proteins pursuant to the same rules that govern genes. While most commercially valuable proteins come from human beings or other eukaryotes, bacteria can be grown in huge amounts. Therefore, one strategy for producing a preferable protein is to shift the gene carrying the protein's information from the eukaryotic cell, where the gene normally occurs, into a bacterium. Bacteria bearing genes from a foreign source (heterologous genes) integrated into their own genetic machinery are said to be transformed. When transformed bacteria grow and divide, the integrated heterologous genes are replicated. It is possible to synthesize large amounts of transformed bacteria that encompass transplanted heterologous genes, see In re O'Farell, 853 F.2d 894, 898 (Fed. Cir. 1988).

91 Brown, Terence A., Gentechnologie für Einsteiger, Berlin 2002, 4-5.