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.

transformed bacteria, it is stimulated to express the cloned gene and to make useful quantities of the protein. To make a particular protein by expressing its cloned gene in bacteria (referred to as 'a recombinant process')[92] several steps must be performed.[93] First, the gene coding for the particular protein has to be isolated. Next, the isolated genes must be transferred to the host bacterium. This is typically performed by incorporating the gene into a cloning vector. A cloning vector is a portion of DNA that can be integrated into bacteria and that replicates itself each time the bacteria divide. A frequently used type of cloning vector is referred to as plasmid. A plasmid is a small circular loop of DNA originating in bacteria, which exists separately from the chromosome. Due to their small size, they can easily be isolated. Recombinant DNA technology can be used to modify plasmids. Such a modified plasmid can then be introduced into bacteria, where it replicates as the bacteria grows.[94] Even after a cloned heterologous gene has been introduced into a bacteria and replicated, it is not guaranteed that the gene will be expressed and encode for a protein. E. coli, for example, consists of genetic information for several thousand proteins. Often, a great number of those genes are not expressed at all. Thus, methods that 'turn on' the cloned gene are necessary. Many biotechnological inventions are directed to this field of research.[95]

E. Proteomic research

The determination of the genome changed the entire emphasis of protein studies of the past. It is now possible to comprehend the concrete impact that genetic information has on protein composition and structure. Moreover, it was discovered that different genes neither generate the same amount of proteins nor reveal the precise determination of circumstances under which protein synthesis is initiated. This specification of the total cellular protein output is therefore an important focus of current research efforts.[96]

92 Jollès, Pierre/Jörnvall, Hans, Proteomics in Functional Genomics, Protein Structure Analysis, Basel et al. 2002, XI.

93 Watson, James D., Molecular Biology of the Gene, Menlo Park, California 1987, 208. As for inventions in the field of recombinant technologies see Vossius, Volker/Jaenichen, Hans-Rainer, Zur Patentierung biologischer Erfindungen nach Europäischem Patentübereinkommen und Deutschem Patentgesetz - Formulierung und Auslegung von Patentansprüchen, GRUR 1985, 821, 821.

94 Whitford, David, Proteins: Structure and Function, Chichester, West Sussex, U.K., 315-316.

95 Fernandez, Dennis/Chow, Mary, Intellectual Property Strategy in Bioinformatics and Biochips, Journal of Patent and Trademark Office Society June 2003, 465, 470; Biochip companies, such as Affymetrix and Hyseq, are involved in developing assays, tools, and computational techniques for the disclosure and modification of gene expression profiles; In re O'Farell, 853 F.2d 894, 898.

96 Jollès, Pierre/Jörnvall, Hans, Proteomics in Functional Genomics, Protein Structure Analysis, Basel et al. 2002, XI.