I. Introductory Remarks

1. Aim of the study

Determining compliance of the statutory requirements for patentability cannot be carried out by applying rules *per se*. A better approach is accomplished on a case-by-case basis. Thus, a case study is used to elucidate the legal principles. The following study is based on examples made available by the Trilateral Project WM4[483], which provides a report on comparative study of protein 3-D structure-related claims. The study initially provides background information and proceeds to illustrate how the European Patent Office (EPO), the Japanese Patent Office (JPO) and the United States Patent and Trademark Office (USPTO) are presently treating protein inventions in terms of patent law.[484] The rules set forth have not been officially adopted, but provide substantial guidelines for legal practitioners that seek patent protection.[485] The author will briefly present the approaches made by the USPTO and the EPO.[486] A further step will then examine the given suggestions in the light of existing patent law regulations. Under those circumstances in which the proposals from the EPO and USPTO lack clarity, the author will further develop the existing ideas and apply classical patent and case law principles that have been used in the field of chemistry and genomics. In summary, the following chapters attempt to document the types of patent claims that could be issued and to whom, and to illustrate differences in the criteria being applied by the USPTO and EPO.

Irrespective of the new techniques that have been developed due to advanced knowledge about protein structures, proteomic inventions have to comply with the same principles that have been applied for classical protein inventions in the past. Where these principles are not sufficient to cope with the challenge of 3-D inventions, further development is needed.

483 This case study is based on examples provided by the Trilateral Project WM4, Comparative studies in new technologies (biotechnology, business methods, etc.), Report on comparative study on protein 3-dimensional (3-D) structure related claims (Nov. 2002) (hereinafter Trilateral 3-D protein structure related claims Comparative Study), available at http://www.trilateral.net/, last checked on January 21, 2008.

484 The study has significant implication for the biotechnology industry, Shimbo, Itsuki/ Nakajima, Rie/Yokoyama, Shigeyuki/Sumikura, Koichi, Patent protection for protein structure analysis, 22 Nature Biotechnology 2004, 109, 109.

485 Vinarov, Sara D., Patent protection for structural genomics-related inventions, Journal of structural and functional genomics 2003, 191, 198.

486 Since it is not the subject matter of this analysis, the Japanese view will not be regarded.

2. Major fields of 3-D protein structure inventions

The number of inventions in the field of proteomics has significantly increased after the disclosure of the human genome. First of all, certainly the improved knowledge in genetics pushed forward the further disclosure of protein structures. Scientists, however, also started to focus intensely on protein research and increased investment. 3-D protein structure inventions play an important role in a number of fields. The following attempts to provide an examination of claims related to protein structural properties *per se*, including an analysis of claims to 3-D structure defined by structural coordinates and claims to protein crystals. The next chapter will then focus on proteomics and bioinformatics, including the assessment of claims to *in-silico* screening methods related to tertiary protein structure and identified compounds. Finally, claims directed to data related to structural features will be examined.[487]

II. Proteomics and protein structural properties *per se*

1. Structure defined by structural coordinates and protein crystals

a) Claims

As a first step, claims directed to the polypeptide *per se* are examined. The first group of cases consists of a claim related to a protein having the structure defined by structural coordinates and of another claim that refers to the crystalline form of a protein. The structure definition is based on NMR spectroscopy. With regard to the claim directed to the crystalline protein structure, one must consider that protein crystallization is only possible with a very low percentage of all existing polypeptides. Particularly, hydrophic, (for example membrane proteins) are not available in crystalline form, and it is generally possible to achieve crystalline forms of only 5 % of proteins.[488] Thus, the advantages of this particular claim do not reduce general difficulties of protein patenting.

The actual claims read as follows:

> Claim 1:
>
> An isolated and purified protein having the structure defined by structural coordinates as shown in a specific figure.

487 A number of articles focuses on the Trilateral Study conducted by the patent offices, see for example Masuoka, Kunihisa, Study on the Ways of Protection of Post-Genome Research Products, IIP Bulletin 2002, 84-95; Vinarov, Sara D., Patent protection for structural genomics-related inventions, Journal of structural and functional genomics 2003, 191-209.

488 Peters, Linde, Postgenomik, http://home.t-online.de/home/linde.peters/intro.htm#postgen0, Part IV, 3.