secondary and tertiary structure of proteins. The claim was directed to the use of a peptide in the preparation of an agent for the treatment of diabetes mellitus. The Board of Appeal rejected the claim for a lack of sufficient disclosure under Art. 83 EPC, arguing that the patent application did not provide any evidence that the cited peptides were in fact performing the required biological activity. The skilled person therefore has to perform tests and experimentations that amount to an undue burden with no certainty of success. The board explained:

> "… that the biological activity of proteins is highly dependent on their secondary and tertiary structures, resulting from their primary structure… There is no basis in the application to conclude that any of the 31 peptides involved, or, if any, how many thereof will show secondary and tertiary structures, giving them properties that make them candidates for use in the treatment of diabetes mellitus."[477]

To sum up, the European sufficient disclosure requirement is met by adequately enabling practice of the full scope of the claim and disclosing in the specification at least one method. An inventor is required to provide sufficient information to 'make and use' the invention, but not to separately describe every single element of the patented subject matter. Applicants are required to provide the information necessary for a skilled person to carry out the invention in the whole area claimed without any undue experimentation.[478]

Finally, and in contrast to the U.S. situation, it is worth noting that the cases represented above suggest that neither Art. 84 EPC nor Art. 83 EPC are used as a basis for a separate written description doctrine. This understanding is consistent with the principle that the claims, rather than the patent description are the decisive element of patent scope, a principle confirmed by further EPC provisions.[479]

III. Conclusion

The comparison of both patent systems shows that a major distinction remains because the U.S. law does not contain an explicit exclusion of patentability due to ethical concerns. In sum, however, the requirements of both systems are in many ways comparable to each other.[480] The currently discussed reform of the U.S. legal system can be understood as a further step towards harmonization.[481] The analysis in this

477 T 0497/02, The General Hospital Corporation, No. of the Reasons 18.

478 Schulte/Schulte, PatG mit EPÜ, § 34, Nos. 362, 367. It is not sufficient that the invention can be carried out generally, it is rather necessary that the skilled person is able to release the claimed invention into practice, see Busse/Keukenschrijver, PatG, § 34, No. 236.

479 Schulte/Kühnen, PatG mit EPÜ, § 14, No. 12. Terms used within the patent claims must be interpreted in accordance to the skilled person's understanding, Busse/Keukenschrijver, PatG, § 14, No. 66.

480 Kleine, Tatjana/Klingelhöfer, Thomas, Biotechnologie und Patentrecht - Ein aktueller Überblick, GRUR 2003, 1, 10.

481 The National Academies' Board on Science, Technology and Economics and the Federal Trade Commission on modernizing U.S. patent law drafted recommendations that suggest

chapter has shown that the era of "genomics" did not require major changes of the patent law systems. The few cases of significant amendments, e.g., the renewal of Section 103 U.S.C.[482] - out of the dilemma where the inventor of a patentable composition of matter used in a process was unable to receive a process patent for the use of this patentable composition - must be considered as mere simplifications rather than a change of principle. It is, however, not guaranteed that the reasoning specified above is sufficient to handle protein folding structure-related claims. In particular, an increasing number of claims directed to protein structures are related to software. It will be interesting to see whether this sector, which is related to bioinformatics, will draw on principles developed for the patentability of computer-implemented inventions. The below case study will further examine this question.

several amendments related to litigation and validity of patents. The provisions that have been reviewed by the American Intellectual Property Law Association (AIPLA) are likely to make the U.S. patent-related litigation simpler and less expensive for small businesses. The recommendations include preserving a "flexible, unitary, open-ended patent system" to "reinvigorate the non-obviousness standard", to "institute a postgrant open review procedure", to "strengthen the USPTO capabilities", to "shield some research uses of patented inventions from infringement liability", to "limit the subjective elements of patent litigation," and to "harmonize the U.S., European, and Japanese patent examination systems". In addition, the proposals include having a period that allows the challenge of patents within a nine to twelve months period, and a first-to-file system; see DeSanti, Susan S./Cohen, William E./Levine, Gail F./Greene, Hillary J./Bye, Matthew, Wroblewski, Michael et al., To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, 2003; Merrill, Stephan A./Levin, Richard C., Myers, Mark B., A Patent System for the 21st Century, Washington D.C. 2004; American Intellectual Property Law Center, AIPLA Response to the National Academies Report entitled "A Patent System for the 21st Century", Washington D.C. 2005; as for the legislative process, see Kintisch, Eli, U.S. Patent Reform Begins Long journey Through Congress, 308 Science 2005, 1725. The proposals have been summarized in the Patent Reform Act of 2007 that was introduced on April 18, 2007 in both the House of Representatives and the Senate. As of the writing, it is still pending; see 2008 Patent Reform Update, Fish & Richardson PC, available at http://www.fr.com/news/articledetail.cfm?articleid=490, last checked on on January 21, 2008; see also statement of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office before the Committee on the Judiciary United States Senate, see "Patent Reform: The Future of American Innovation" June 6, 2007, available at http://www.uspto.gov/web/offices /com/speeches/2007 jun06.htm, last checked on January 21, 2008.

482 See Chapter 3 A II 4 a.

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.