A. Statutory Background and Fundamental Case Law in Europe and the U.S.

I. Introduction

As outlined in chapter II above, the tertiary structure is the single most important determinant of a protein's biological function.[159] Research related to drug design that is conducted on grounds of the tertiary folding type has a more reliable basis than studies that solely involve the knowledge of primary structures. The goal of this chapter is to provide an overview of the legal terrain faced by those seeking to patent protein 3-D structure related claims. The requirements of the patentability of proteomic claims depend on statutory background on the one hand and existing case law related to chemical, biotechnology and software inventions on the other. Thus, as a first step, the applicable law will be presented regarding the patentable subject matter, industrial application/utility, specification/written description, enablement and novelty and/or inventive step.

Next, the major case law will be examined. Cases related to biotechnological material will be used to exemplify how patent law systems have coped with the new genomic technologies. Since proteins are considered chemical compounds, the legal treatment of molecular structures will also be reviewed. One particular focus will be the patenting of primary structure-related protein inventions, where problems have mainly occurred regarding the novelty and inventive step requirement. Patent examiners have resolved these issues by applying certain principles, which will be developed in detail below. Such a comprehensive description will form the basis of subsequent chapters, which discuss the applicability of traditional patent law standards to 3-D, or proteomic, structures.

II. Applicable law in the U.S. and Europe

In order to be granted a patent in compliance with American patent law, at least the following criteria must be met: subject matter eligibility and utility (35 U.S.C. § 101), written description (35 U.S.C. § 112 1), enablement (35 U.S.C. § 112 1), clarity (35 U.S.C. § 112 2) novelty, no loss of rights (35 U.S.C. § 102), and non-obviousness (35 U.S.C. § 103). European patents are granted for any invention that is susceptible to industrial application, is new and involves an inventive step (Art. 52 I EPC). According to the practice of the EPO, an invention as understood in patent

159 See at Chapter 1 B II 2.