### *A. Introductory Remarks*

Patent law should strike a reasonable balance between the competitive concerns of open access and exclusivity. Open access can facilitate knowledge distribution and collaboration in advancing science. Exclusivity can ensure interest and financial investment in scientific research and development.[730] When the first DNA sequence patents were granted, a lively debate about their adverse effect on research and development emerged. The debate climaxed when the NIH filed a patent application, which included an enormous number of cDNA without any indication of function.[731] Although the USPTO finally rejected the NIH application, existing concerns persisted.[732] Specifically, several observers raised the question of whether future innovations related to a certain protein structure could potentially infringe existing DNA claims. In this case, it was argued, R&D expenditures by companies that do not possess any cDNA patents could be severely limited, thus leading to an undersupply of innovative capacity.[733]

The issue was regarded particularly pressing because at the time of the first DNA patents, it was not understood how the now abundant genetic information could be transformed into medical and pharmaceutical applications. In particular, many researchers expected that genetic information would be used quite directly in medical treatments, for example in the form of gene therapies.[734] Others, however, hypothesized that other aspects of the encoded protein, for example its tertiary structure, would have to be identified first. Given this information, it would then be possible to develop sensible therapies. In this situation, however, a DNA patent with a very broad scope would likely be detrimental to a dynamic biotechnological progress. Consequently, the question of whether the scope of protection of DNA patents would provoke infringements by (yet unrealized) proteomic inventions was discussed intensively.[735] On the one hand, the idea of allowing a company to patent a genetic sequence that has been around since the beginning of life was perceived as

730 Sung, Lawrence M., Patenting nonassociated polymeric structures (NAPS): implications for structural genomic data release, 4 Journal of Structural Functional Genomics 2003, 211, 211.

731 Straus, Joseph, Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall, GRUR 1998, 314, 314.

732 See Chapter 3 A II 2 a.

733 Widge, Alik, Patent Pending: A Primer on Gene Patents, Pittsburgh 2003, 3-4; available at http://www.amsa.org/pdf/genepatents.pdf, last checked on January 21, 2008.

734 Widge, Alik, Patent Pending: A Primer on Gene Patents, Pittsburgh 2003, 4, available at http://www.amsa.org/pdf/genepatents.pdf, last checked on January 21, 2008.

735 Service, Robert F., Gene and Protein patents get ready to go head to head, 294 Science 2001, 2082.

moderately alarming. On the other hand, the design of new gene-based pharmaceuticals in the U.S. requires years of commitment and immense capital investments. Without the ability to receive protection, companies would have no means of recovering the costs of their investments and innovation would be blocked.[736]

With genetic patent holders typically owning exclusive rights to the recombinant produced protein, basic conflicts between 3-D related claims and DNA patents are expected to emerge. However, a detailed examination of potential conflicts may also reveal that their relevance is limited, and that the patent system does strike an appropriate balance between open access and exclusivity. In the end, the issue is reduced to a thorough analysis of claim construction regarding both literal and equivalent infringement. The following chapters attempt to provide such an analysis, focusing on the scope of 3-D protein structure related claims. First, general aspects of claim construction and its relation to the scope of protection of biotechnological inventions will be discussed. Second, chapter IV. C. seeks to explore the scope of recombinant protein claims with regard to infringement through the use of 3-D protein structures.

### *B. Claim construction in the U.S. and in Europe*

#### I. Claim construction and doctrine of equivalents in the U.S.

##### 1. Claim Construction

In the U.S., the determination of infringement depends in the first place on claim construction.[737] In case of a conflict, the court must interpret whether or not a used product/process falls within what is covered by the patent scope.[738] The Federal Cir-

736 Fernandez, Dennis/Chow, Mary, Intellectual Property Strategy in Bioinformatics and Biochips, Journal of Patent and Trademark Office Society June 2003, 465, 466.

737 NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement" [citation omitted]); Sarnoff, Joshua, The Doctrine of Equivalents and Claiming the Future after Festo, 14 The Federal Circuit Bar Journal 2004, 403, 404.

738 35 U.S.C. Section 271 (a) states: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention during the term of the patent therefor, infringes the patent." As for the infringement of process patents, Section 271 (g) U.S.C. provides that: "Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product, which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action of infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered