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

cuit has characterized claim construction as "the central issue of every patent appeal".[739] Indeed, since the decision in *Markman v. Westview Instruments, Inc*.[740], it has taken on paramount significance, often of case-dispositive nature. In *Markman I*, the Federal Circuit (en banc) ruled that "the interpretation and construction of patent claims, which determine the scope of the actual patent right, is a matter of law exclusively for the court."[741] In *Markman II,* the Supreme Court decided that claim construction was an issue for the judge rather than the jury.[742] Furthermore, the Supreme Court affirmed *Markman I,* stating that claims must be compared with the accused product or process in order to determine whether each limitation of the claim is met, either literally or under the doctrine of equivalents. Claim construction must be handled carefully, since any mistake can distort the entire infringement analysis.[743] After *Markman II*, the Federal Circuit stated that claim construction is purely a matter of law with no underlying or subsidiary issues of fact.[744] Hence, the Federal Circuit reviewed a district court's reasoning regarding claim construction without deference. Claim construction therefore is a question of law, which is reviewed *de novo* on appeal, "including any allegedly fact-based questions that are presented".[745]

Patent claims must be construed "objectively and without reference to the accused device.[746] A court first evaluates the intrinsic evidence, such as the patent itself, its claims, written description, and the prosecution history. As for the prosecution history, all relevant arguments made which are included in the specification must be considered.[747] The starting point for ascertaining the meaning of a patent claim is its language. In general, terms in a patent claim are given their ordinary meaning to one of ordinary skill in the relevant art. The meaning of a claim term is as it would be

to be so made after (1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product."

739 Sulzer Textil v. Picanol, 358 F.3d 1356, 1366 (Fed. Cir. 2004); Minco v. Combustion Engineering, 95 F.3d 1109, 1114 (Fed. Cir. 1996).

740 Markman vs. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc). ("Markman I"), affirmed in 517 U.S. 370 (1996) ("Markman II") (claim construction is an issue for the judge rather than the jury)

741 Markman I, 52 F.3d 967, 977.

742 Markman II, 517 U.S. 370, 391(1996).

743 Markman II, 517 U.S. 370 at 370. See also Weiss, Robert C./Miller Todd R., Practical tips enforcing and defending patents, 85 Journal of the Patent and Trademark Office Society 2003, 791, 793.

744 Cybor, 138 F.3d, 1448 (Fed. Cir. 1998)

745 Cybor, 138 F.3d, 1448, 1455 ("[The Supreme] Court held that the totality of claim construction is a legal question to be decided by the judge."), also Weiss, Robert C./Miller Todd R, Practical tips enforcing and defending patents, 85 Journal of the Patent and Trademark Office Society 2003, 791, 794.

746 Vivid Tech., 200 F.3d, 795, 803 (Fed. Cir. 1999) ("[T]hose terms need to be construed that are in controversy").

747 Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1014 (Fed. Cir. 2006) ("In determining the meaning of the disputed claim limitation, court looks principally to the intrinsic evidence of record, examining the patent claim language itself, the written description, and the prosecution history, if in evidence.")

interpreted by one skilled in the art, until clear evidence is provided that proves that the inventor intended a different meaning. In order to determine what the ordinary meaning is, a court may rely on general and technical dictionary definitions.[748] In addition to such "intrinsic" evidence, the court may also use "extrinsic evidence", such as treatises, inventor testimony, dictionary definitions, and expert testimony to interpret patent claims to determine the meaning of the claims to a person having ordinary skill in the art.[749] The extent to which one should rely on such evidence, rather than intrinsic evidence in the specification and prosecution history is largely in dispute. In *Phillips v. AWH Corp.*,[750] the CAFC thoroughly discussed the limitations of extrinsic evidence. The Court explained that "[extrinsic evidence] is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."[751] Nevertheless, the court emphasized that "… extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean".[752] In summary, courts rarely rely on inventor testimony regarding meaning, both because of the obvious interest of the inventor and because the inventor's meaning is not directly relevant to the understanding of the person skilled in the art.[753] Hence, claim construction presupposes the consideration of various elements, such as used terms, the definition provided in the specification, the prosecution history, arguments made by the applicant, the disclosure of the prior art, and knowledge of those skilled in the relevant art. Further extrinsic evidences include treatises or inventor and expert testimony.[754]

748 Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc) ("[R]ecourse to the specification is limited to determining whether the specification excludes one of the meanings derived from the dictionary, whether the presumption in favor of the dictionary definition of the claim term has been overcome by an explicit definition of the term different from its ordinary meaning or whether the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." citation omitted); Weiss, Robert C./Miller Todd R , Practical tips enforcing and defending patents, 85 Journal of the Patent and Trademark Office Society 2003, 791, 800f.

749 Panduit Corp. v. HellermannTyton Corp., 451 F.3d 819, 827 (Fed. Cir. 2006) ("However, if the language of the contract is ambiguous, then the court may consider extrinsic evidence to determine the intent of the parties.")

750 Phillips v. AWH Corp., 415F.3d 1303, 1313 (Fed. Cir. 2005)(en banc)

751 Phillips v. AWH Corp, 415F.3d 1303, 1313.

752 Phillips v. AWH Corp, 415F.3d 1303, 1313.

753 Weiss, Robert C./Miller Todd R., Practical tips enforcing and defending patents, 85 Journal of the Patent and Trademark Office Society 2003, 791, 809.

754 Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996) ("Only if there were still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court have resorted to extrinsic evidence, such as expert testimony"); Weiss, Robert C./Miller Todd R., Practical tips enforcing and defending patents, 85 Journal of the Patent and Trademark Office Society 2003, 791, 800. Since Vitronics, the District court became more lenient, see Pitney Bowes, 182 F.3d 1298, 1309 (Fed. Cir. 1999) ("[I]t is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is

After the claim has been construed, the second step of claim construction requires that every element in each asserted claim must be compared to the accused product or process. If each element is found in the product or process being used, literal infringement is established. This is often called the "all-elements" rule.[755] In sum, the patent claims, understood by a person skilled in the art, are the decisive element of claim construction. Furthermore, patent files can be used to interpret the claims and this interpretation is made from the time of infringement.[756]

2. Doctrine of equivalents

If literal infringement is not established, the patent may still be infringed under the doctrine of equivalents according to which "[t]he scope of the patent is not limited to its literal terms but instead embraces all equivalents to the claims described."[757] The idea of extending claims beyond their literal meaning had been addressed in early U.S. case law.[758] In the decision *Winans v. Denmead*[759], the Supreme Court ruled on three major points, stating that "specifications are to be construed liberally" and the terms "cylindrical and conical" are to cover "octagonal and pyramidal".[760] In *Sanitary Refrigerator Co. v. Winters*,[761] the Supreme Court further determined that the "Triple Identity Test" or "function-way-result-test" were an appropriate means for defining equivalents. Pursuant to this method, equivalents exists if a product "performs substantially the same function in substantially the same way to obtain the same result".[762] The applicable principle is that "if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape".[763] In *Graver Tank*[764], the

not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field.").

755 Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005 (Fed. Cir. 2006).

756 Warner-Jenkinson v. Hilton Davis, 520, U.S. 17 (1997); W.E. Hall Co., Inc. v. Atlanta Corrugating, 370 F.3d 1343, 1353 (Fed. Cir. 2004).

757 Doctrine of Equivalents defined in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002) (Festo VIII). The doctrine was first adopted in Winans v. Denmead, 56 U.S. 330 (1854) and further developed in Graver Tank v. Linde, 339 U.S. 605, (1950) and Warner-Jenkinson v. Hilton Davis, 520 U.S. 17 (1997). The "Festo Litigation" is of major importance for what is considered equivalent, see below at footnotes 767, 780ff.

758 Goodyear Dental Vulcanite Co. V. Davies, 102 U.S. 222, 228 (1880); Bergen-Babinecz, Katja/Hinrichs, Nikolaus/Jung, Roland/Kolb, Georg, Zum Schutzbereich von US-Patenten: Festo und eine deutsche Sicht, GRURInt. 2003, 487, 490.

759 Winans v. Denmead, 56 U.S. 330 (1854); Chisum, Donald, Chisum on Patents, Volume 5A, § 18.02[1], stating "Winans v. Denmead (1853) was the first decision to use the doctrine of equivalents to do serious damage to the literal meaning of the language of a patent claim."

760 Winans v. Denmead, 56 U.S. 330, 341, 332.

761 Sanitary Refrigerator Co. v. Winters, 280 U.S. 3 (1929).

762 Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42, 50.

763 Union Paper-Bag Machine Co. v. Murphy, 97 U.S. 120 (1877).

Supreme Court made a further statement, ruling that an alternative method for determining equivalents is the 'insubstantiality of differences test'. The question that emerges in the context of this method is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.[765] The 'modern' doctrine of equivalents has been substantially characterized by the more recent '*Festo*-litigation'.[766] Since *Festo* primarily focuses on limitations of the doctrine rather than its pre-conditions, these decisions are illustrated below.[767]

The reach of non-literal infringement is restrained by a number of legal tenets, such as the "all elements" rule, the prior art, public dedication, and the doctrine of prosecution history estoppel. The "all elements-rule" requires that equivalency exists only for an accused product or process that contains all of the limitations of a claim, either literally or equivalently. Thus, a skilled artesan must examine the doctrine of equivalents element by element. In the event of a missing element, there is no infringement unless an equivalent for this missing element exists.[768] In *Warner-Jenkinson*[769], the Supreme Court stated in this context:

> "It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."[770]

Hence, the all-elements rule sets the level of generality of the invention at which equivalents and a literal presence are to be determined. *Warner-Jenkison*, however, fails to explain what constitutes an "element" or limitation that sets that level.

The restraint of non-literal infringement by the prior art rule has been established in *Wilson*[771], where the Federal Circuit ruled that

764 Graver Tank v. Linde Air Products Co., 339 U.S. 605 (1950), see also Bergen-Babinecz, Katja/Hinrichs, Nikolaus/Jung, Roland/Kolb, Georg, Zum Schutzbereich von US-Patenten: Festo und eine deutsche Sicht, GRURInt. 2003, 487, 488.

765 Graver Tank v. Linde Air Products Co., 339 U.S. 605 at 609; some parts of literature follow the view that the 'function-way-result' test must be conducted in the course of the 'insubstantiality of differences test', see Bergen-Babinecz, Katja/Hinrichs, Nikolaus/Jung, Roland/Kolb, Georg, Zum Schutzbereich von US-Patenten: Festo und eine deutsche Sicht, GRURInt. 2003, 487, 488.

766 The Festo litigation started in 1994 when the District Court for the District of Massachusetts held that Shoketsu had infringed patents belonging, the Festo company under the doctrine of equivalents; see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 1994 WL 1743984 (D.Mass 1994) (Festo I). With regard to this 'modern' doctrine of equivalents, see Sarnoff, Joshua, The Doctrine of Equivalents and Claiming the Future after Festo, 14 The Federal Circuit Bar Journal 2004, 403.

767 See end of same subchapter, Chapter 4 B I 2.

768 Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1016 (Fed. Cir. 2006). („Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.").

769 Warner-Jenkinson v. Hilton Davis, 520 U.S. 17 (1997).

770 Warner-Jenkinson v. Hilton Davis, 520 U.S. 17, 29.

771 Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677 (Fed. Cir. 1990)

> "a patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims … since prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim."[772]

As a possible test for the prior art limitation of equivalents, the court evaluated the construction of a hypothetical claim literally, including the asserted equivalent, and tested whether its scope was permissible in the light of prior art. For the court such testing was preferable, since it "permits a more precise analysis than determining whether an accused product would have been obvious from the level of prior art".[773]

Pursuant to the public dedication rule, patentees who fail to claim predictable alternatives and draft claims more narrowly than what is disclosed by the provided written description cannot rely on the doctrine of equivalents.[774] Rejecting the application of the doctrine, Judge Rader in *Sage* concluded:

> "The claim at issue defines a relatively simple structural device. A skilled patent drafter would foresee the limiting potential of a [narrowly drawn structural limitation]. No subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation into the claim. If Sage desired broad patent protection …, it could have sought claims with fewer structural encumbrances… However, as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure."[775]

Pursuant to the Federal Circuit's decision in *Maxwell* a subject matter disclosed in the specification but not claimed is "dedicated to the public".[776] A patentee shall be prevented from filing narrow claims, avoiding examination of broader claims but seeking to extend the patent scope through the doctrine of equivalents.

A further key limitation on the scope of equivalents is the prosecution history.[777] This doctrine states that a patentee cannot recapture through equivalents what he has surrendered during patent prosecution. This rule has been substantially characterized by the above-mentioned '*Festo*-litigation'.[778]In the decision *Festo Corp. v. Shoketsu Kinyoku Kogyo Kabushiki Co*. (2002)[779], the Supreme Court reversed an *en banc* Federal Circuit decision[780] which had held that, if a claim is narrowed for any reason

772 Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 684.
773 Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 684. See also Sarnoff, Joshua, The Doctrine of Equivalents and Claiming the Future after Festo, 14 The Federal Circuit Bar Journal 2004, 403, 447.
774 Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, at 1424-25 (Fed. Cir. 1997).
775 Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, at 1420 (Fed. Cir. 1997), also Adelman, Martin J./Rader, Randall R./Thomas, John R./Wegner, Harold C., Cases and materials on patent law, St. Paul 2003, Chapter 15, Section 15.2.
776 Maxwell v. J. Baker Inc., 86 F.3d at 1106-1107 (Fed. Cir. 1996).
777 Geißler, Bernhard, Noch lebt die Äquivalenzlehre, GRURInt 2003, 1, 4-6.
778 See footnote 758.
779 Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002) (Festo VIII).
780 Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 564 (Fed. Cir. 2000) (en banc) (Festo VI).

related to patentability during prosecution, resorting to the doctrine of equivalents for the claim element at issue is totally barred ("complete bar" rule).[781]The Supreme Court ultimately adopted to a "flexible bar" approach under which even narrowed claims could still be entitled to some range of equivalents.[782] The Federal Circuit on remand determined, to some extent, the manner in which issues of prosecution history estoppel would be assessed.[783] All narrowing amendments made to comply with any provision of the patent laws give rise to a presumption that equivalents have been surrendered. This presumption, however, can be rebutted in various ways, each of which appears difficult to establish. The rebuttal examination is a legal issue for the judge to decide, even though it includes underlying factual issues. Legal practitioners frequently complain that the *Festo* litigation and the resulting rules of prosecution history estoppel have added a high degree of unpredictability to the doctrine of equivalents. The examination of what is considered an unacceptable diversion/narrowing amendment certainly depends on a case-by-case analysis and might often be difficult to predict. Applicants, however, know that if they surrender subject matter they might later have to suffer the most consequences. Hence, it is likely that most if not all applications will avoid surrender.[784]

In *Warner-Jenkinson*, the court also concluded that the time for determining equivalency is the time of infringement.[785] It must be emphasized that the question of whether equivalency exists is based on the post-issued/later-arising knowledge of technological interchangeability of elements. Thus, a product or process may be held equivalent if it encompasses a technological element either invented after the patent is issued or discovered to be a substitute after that time. This principle applies whenever the later-arising technological substitute was, or could have been, considered by the inventor as part of the invention, provided that the substituted element does not entirely negate the claimed limitation it does not represent. Consequently, the doctrine of equivalents expands the patent's scope over time.[786] Hence, the purpose of the U.S. doctrine of equivalents is principally to address the unforeseeable. A patent drafter must include every foreseeable application in his claim to anticipate how new technology would be applied in a fashion that every reasonable drafter of patent claims would also foresee.

781 Teague, Brian J., Festo and the Future of the Doctrine of Equivalents, 3 Journal of Intellectual Property 2004, 1-19, 3.
782 Festo VIII., 535 U.S. 722, 738 (2002).
783 Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., No. 95-1066, 2003 WL 22220526 (Fed. Cir. 2003) (Festo IX).
784 Sarnoff, Joshua, The Doctrine of Equivalents and Claiming the Future after Festo, 14 The Federal Circuit Bar Journal 2004, 403, 430.
785 Warner-Jenkinson v. Hilton Davis, 520, U.S. 17, 19.
786 Sarnoff, Joshua, The Doctrine of Equivalents and Claiming the Future after Festo, 14 The Federal Circuit Bar Journal 2004, 403, 410.

II. Claim construction and Doctrine of equivalents under German law

1. Claim Construction

The core provisions for the interpretation of claims are Art. 69(1) EPC, and § 14 GPA, which state:

> The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

The rule is read in light of the Protocol on the Interpretation of Art. 69 of the Convention. Art. 1 of the Protocol states:

> "Art. 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties."

Thus, the first sentence deals with the interpretation of claims, ruling that claims should not be read literally and descriptions and drawings only serve the purpose of resolving any ambiguity existing in the claims. The second sentence does not refer to the interpretation of claims. It clarifies, rather, that one cannot go beyond the claims to what, on the basis of the specification and drawings, it appears that "the patentee has contemplated". Finally, the last sentence indicates that, in constructing the scope of protection according to the content of the claims but avoiding literalism, the courts of the contracting states should aim at "a fair protection for the patentee with a reasonable degree of certainty for third parties."[787]

An illustrative example of claim construction is provided by the earlier mentioned decision of Amgen/TKT[788], where the English House of Lords had to decide whether TKT's 'GA-Epo' (Dynepo), produced by a process called "gene activation", infringes Amgen's patent related to the recombinant 'Epo'.[789] The presentation of the decision is particularly useful in demonstrating the different steps of claim interpretation.[790] The process of TKT's gene activation involved the introduction of a nu-

787 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, 2004 WL 2330204, Meier-Beck, Peter, Aktuelle Fragen der Schutzbereichsbestimmung im deutschen und europäischen Patentrecht, GRUR 2003, 905, 905.

788 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, 2004 WL 2330204, see also Chapter III Part A 2 C (b). As for earlier decisions on the subjects see Welch, Andreas, Der Patentstreit um Erythropoietin , GRURInt. 2003, 579, 592.

789 Chapter 3 A II 3 a.

790 As remarked by Rüdiger Rogge, then presiding judge of the 10th (intellectual property) Senate of the Bundesgerichtshof, "decisions of other countries on the extent of protection af-