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-

cleotide sequence into the genome of a human cell upstream of the erythropoietin gene. The nucleotide sequence "effectively overrode the regulator, which normally switched off the gene, and thus switched it on." TKT's cells contained endogenous erythropoietin DNA with respect to the coding regions, but also an exogenous promoter construct that was introduced upstream of that endogenous DNA.[791] Amgen's patent claimed the expression of erythropoietin in mammalian cells using DNA inserted in a hybrid vector of bacterial plasmid and viral genomic origins. Amgen only asserted the infringement of claim 19 and 26, since TKT did not produce any GA-erythropoietin in the United Kingdom and the alleged infringement was based on TKT's importation of 'GA-EPO'.[792] The critical issue the House of Lords had to discuss was whether a skilled person would classify "host cell" as meaning a cell which is host to the DNA sequence coding for 'Epo'.[793] A different understanding put forward by Amgen was that it can involve a sequence which is endogenous to the cell such as the human 'Epo' gene expressing 'GA-Epo', as long as the cell is host to some exogenous DNA. In the TKT method, such a cell hosts the "gene activation sequence".[794] As a first step, the judge interviewed a number of skilled persons as witnesses, all of whom said that they would have interpreted Claim 1 to be directed to a "DNA sequence coding for 'Epo' which had been isolated or synthesized and was suitable for expression in a host cell."[795] Furthermore, the judge relied on the language used in the patent description. The court concluded that the terms "for use in securing expression … of a polypeptide" refer to the DNA encoding for 'Epo' instead of the control sequence which "switches on" the expression of endogenous DNA. This interpretation, the judge reasoned, was supported by paragraph (b) of Claim 1, which broadened the claim to sequences that hybridized under stringent conditions to "the protein coding regions".[796] The judges therefore concluded that a person skilled in the art would not classify the endogenous coding sequence that expressed TKT's 'Epo' as falling within claim 1.[797] The Amgen/TKT decision shows that the issue of whether a patent claim can cover later-arising technologies is decided on the level of claim construction.

The patentable subject matter is understood objectively and does not depend on the subjective perception of the patentee. It is not the court's task to detect what the inventor intended to claim but what he claimed in fact. Each feature of the subject matter must be interpreted objectively.[798] The claims are read giving the words, the

forded by Art. 69 EPC can be seen as important contributions to the jurisprudence of Germany," cited by Lord Hoffman in Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 74.

791 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 8.
792 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 7.
793 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 53.
794 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 53.
795 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 54.
796 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No. 55.
797 Kirin-Amgen Inc v. Hoechst Marion Roussel, [2005] R.P.C. 9, No 58.
798 Benkard/Ullmann, Patentgesetz, § 14, No. 75.

meaning, and scope that they normally have in the relevant art.[799] In contrast to American patent law, it is not customary under the European patent law system to rely on the prosecution history for claim interpretation.[800] Facts of the prosecution history can only be used for the determination of scope if reported in the patent specification. The German Federal Supreme Court, for example, interpreted a declaration of the patent applicant that patent protection is not sought for a certain embodiment in light of the principle "venire contra factum proprium".[801] Accordingly, a patentee could not claim the patent to cover such an embodiment in a later trial against an alleged infringer, if the patent was based on such waiver and the infringer had been part of the earlier proceedings.[802] Furthermore, not the time of infringement, but the time of priority, is decisive.[803]

2. Doctrine of equivalents

As in the US, a patent claim can be infringed literally, or under the doctrine of equivalents, directly or indirectly. As claim construction rules, the principles developed for the determination of equivalents rely on the Protocol on the interpretation of Art. 69 EPC. The protocol was amended after the revision of the European Patent Convention in 2000. The newly added Art. 2 states for equivalents that "[f]or the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims. "[804] This rule fails to provide a definition of equivalents. Therefore, it permits national courts to interpret the doctrine of equivalents in a flexible and fair way. The word "elements" aims to fit with claim language used for chemical inventions.[805] Patent claims have to be understood not only as the starting point but also as the decisive element.[806] The major goal of a scope extension under the doctrine of equivalents is to combine fair protection for the patentee with a reasonable degree of certainty for third parties. On the one hand, an applicant cannot be required to foresee all potential cases where a competitor may depart from the literal meaning of the

799 BGH, 30 IIC 932 (1999) – Tension Screw (Spannschraube); Meier-Beck, Peter, Aktuelle Fragen der Schutzbereichsbestimmung im deutschen und europäischen Patentrecht, GRUR 2003, 905, 906.
800 Benkard/Scharen, EPÜ, Art. 69, No. 27.
801 BGH, 25 IIC 420, 420 (1994) - Moistening Device I (Weichvorrichtung I).
802 Busse/Keukenschrijver, PatG, § 14, No. 74.
803 Benkard/Scharen, EPÜ, Art. 69, No. 64.
804 Meier-Beck, Peter, The Scope of Patent Protection - The test for Determining Equivalents, 36 IIC 339, 340 (2005); who notes that Art. 69(1) EPC remains unchanged and merely lays down by what means the extent of protection should be determined.
805 Nack, Ralph/Phélip, Bruno, Diplomatic Conference for the Revision of the European Patent Convention, Munich, 20 – 29 November 2000, 32 IIC 200, 207 (2001).
806 See Chapter 4 B II 2.V.

claims.[807] On the other hand, the principle of legal certainty requires that a person using the patent must be able to understand with ease what is protected.[808] The suitable standard for determining equivalents is considered to be the person skilled in the art.[809]

a) Moulded Curbstone

Before 1978, patents were granted under the „Three-Parts-Doctrine“ (Dreiteilungslehre). Under this approach, the patent scope was based on the patentable subject matter.[810] The patentable subject matter was considered the technical teaching included in the patent claims and understood by the skilled person without inventive activity, but in light of the patent description, potential drawings, skilled knowledge and the state of the art.[811]

The newer law is summarized in the case of *Moulded Curbstone.*[812] In this decision, the invention was a moulded curbstone, which assured safe and reliable drainage of rainwater accumulating at the side of a street. The alleged infringer had used conventional stones in the form of cubes or bricks and conventionally rounded curbstones. The German Federal Supreme Court confirmed the doctrine of equivalents, stating that:

> "[t]he question is whether a person skilled in the art … is able to clear up the problem solved by the invention with equally effective means, i. e. to achieve the desired success with other means which also lead to the same result. Solutions, which the average person skilled in the art can determine due to his professional knowledge as being equally effective based on considerations oriented to the invention paraphrased in the claims, will generally fall within the scope of protection of the patent."[813]

807 BGH, 24 IIC 507 (1993) – Helium Injection (Heliumeinspeisung); Meier-Beck, Peter, The Scope of Patent Protection - The test for Determining Equivalents, 36 IIC 339, 340 (2005).

808 BGH, GRUR 1992, 594, 596 - Mechanische Betätigungsvorrichtung; Reimann, Thomas/Köhler, Martin, Der Schutzbereich europäischer Patente zwischen Angemessenheit und Rechtssicherheit - Anmerkungen zu den Entscheidungen des BGH 'Kunststoffrohrteil', 'Custodiol I', 'Custodiol II', 'Schneidmesser I', 'Schneidmesser II', GRUR 2002, 931, 931; Meier-Beck, Peter, The Latest Issues in German Patent Infringment Proceedings, 32 IIC 505, 511 (2001).

809 Meier-Beck, Peter, The Scope of Patent Protection - The test for Determining Equivalents, 36 IIC 339, 341 (2005). With regard to literal claim construction, the person skilled in the art analyzes and considers the patent claim against the background of his technical knowledge, using description and drawings to assist in claim interpretation.

810 RGZ 2, 325 - Mülltonne; RG GRUR 1940, 543, 545 - Hochglanzphotographien; RG GRUR 1942, 51 - Wischdochte; RG GRUR 1944, 22f - Wellblechofenbekleidung.

811 Lindenmaier, Fritz, Der Schutzumfang des Patentes nach der neueren Rechtssprechung, GRUR 1944, 49, 53; Busse/Keukenschrijver, § 14 No. 13.

812 BGH 18 IIC 795 (1987) – Moulded Curbstone (Formstein).

813 BGH 18 IIC 795, 799 (1987) – Moulded Curbstone (Formstein).

In addition, the court ruled that "the defense that the embodiment attacked and claimed to be an equivalent does not represent a patentable invention in view of the prior art is admissible."[814]Accordingly, the defendant of an infringement process can defend himself, arguing that the claimed embodiment "is known from the prior art, but also by the fact that it is obvious in view of the prior art" ("*Moulded Curbstone* objection").[815] This general understanding of the law comports with the legal framework adopted by most member states of the EPC, although significant differences with respect to the method of determination of scope, or the exact protection granted, remain.[816]

b) Further Decisions

The ruling established in *Moulded Curbstone* was confirmed several times by the German Federal Supreme Court. In its decision *Ione Analysis,*[817] the court stated that the mere approval of an equal effect is not sufficient for equivalents. Rather, the person skilled in the art must be able to predict and determine the means necessary to achieve the equal effect. Accordingly, if the patent claims do not suggest to a person skilled in the art that the described protocol can be modified and still achieve equal effects, equivalents do not exist. This standard, the court emphasized, is required by the principle of legal certainty.[818] The importance of legal certainty has been affirmed in the decision *Handle Cord for Battery* in which the German Federal Supreme Court criticized the decision of the lower court to interpret the claims predominantly on the grounds of the patent description.[819] The claims must entirely describe the essential elements of the invention. Recapitulating, the court ruled that the claims are no longer merely a point of departure but the decisive basis ("massgebliche Grundlage") for determining the extent of protection. As for equivalents, a skilled person should thus be able to determine the equivalent scope on grounds of the claim, his general skills in the art, and simple experimentation.[820]

The German Federal Supreme Court has developed clear guidelines for dealing with equivalents in a number of cases related to the question of whether figures or measurements allow some degree of approximation (and if so, to what degree). Below,[821] a concrete claim analysis under German law will closely examine the deci-

814 BGH 18 IIC 795, 800 (1987) – Moulded Curbstone (Formstein).
815 BGH 18 IIC 795, 800 (1987) – Moulded Curbstone (Formstein); Meier-Beck, Peter, The Scope of Patent Protection - The test for Determining Equivalents, 36 IIC 339, 344 (2005). The author formulates the question of whether the variant, having regard to the state of the art, lacks novelty, or is obvious to a person skilled in the art.
816 Domeij, Bengt, Pharmaceutical Patents in Europe, Stockholm 2000, 314.
817 BGH, 22 IIC 249 (1991) – Ione Analysis (Ionenanalyse).
818 BGH, 22 IIC 249, 255 (1991) – Ione Analysis (Ionenanalyse).
819 BGH, 22 IIC 104 (1991) - Handle Cord for Battery Case (Batteriekastenschnur).
820 BGH, 22 IIC 104, 106 (1991) Handle Cord for Battery Case (Batteriekastenschnur).
821 Chapter 4 c IV 3 b) aa).

sions of *Plastic Pipe,* [822] *Custodiol I*[823], *Custodiol II*[824], *Cutting Blade I*[825] and *Cutting Blade II*[826]. The major principles derived from these cases will then be applied to 3-D protein structure related claims. Also, the principles regarding the cases in which infringement is based on inventive activity will be reviewed and – if necessary – applied to the context of proteomic inventions. In principle, the time for determining infringement is the priority date.[827]

III. Research/Experimental Use Exemption

Finally, this chapter will briefly discuss the limitations of patent protection through the means of experimental use exemption. This is not primarily a question of how the patent scope is determined. Nevertheless, the question of appropriate scope must take into account that a sufficient research exemption enables scientists to use patented knowledge without establishing infringement. This possibility assigns a different weight to the question of what the public can expect from an inventor in exchange for the public protection of his intellectual property rights.

1. Germany

The German Patent System provides an explicit statutory research exemption.[828] According to Section 11 No. 2 GPA, research is explicitly excluded from the patent right.[829] The provision provides that "the rights conferred by a patent shall not extend to acts done for experimental purposes that are related to the subject-matter of the patented invention." The German Federal Supreme Court dealt intensively with

822 BGH, 34 IIC 302 (2003) – Plastic Pipe (Kunstoffrohrteil).
823 BGH, GRUR 2002, 523 – Custodiol I.
824 BGH, 34 IIC 197 (2003) – Custodiol II.
825 BGH, 33 IIC 873 (2002) - Cutting Blade I (Schneidmesser I).
826 BGH, GRUR 2002, 519 – Cutting Blade II (Schneidmesser II).
827 BGH, 33 IIC 525, 535 (2002) – Snow Removal Plate (Räumschild); Kraßer, Rudolf, Patentrecht: ein Lehr- und Handbuch zum deutschen Patent- und Gebrauchsmusterrecht, europäischen und internationalen Patentrecht, 5. Aufl., München 2004, 753; Busse/Keukenschrijver, PatG, § 14, No. 90.
828 Kraßer, Rudolf, Patentrecht: ein Lehr- und Handbuch zum deutschen Patent- und Gebrauchsmusterrecht, europäischen und internationalen Patentrecht, 5. Aufl., München 2004, 812-816; see further Straus, Joseph, On the Admissibility of 'Biological Equivalents Tests' During the Patent Term for Obtaining a Regulatory Approval for Patented Drugs by Third Parties, AIPPI Journal of the Japanes Group November 1998, 211; Herrlinger, Karolina A., Die Patentierung von Krankheitsgenen: dargestellt am Beispiel der Patentierung der Brustkrebsgene BRCA 1 und BRCA 2, München 2005, 234.
829 Straus, Joseph, Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall, GRUR 1998, 314, 318.