

sions of *Plastic Pipe*,<sup>822</sup> *Custodiol I*<sup>823</sup>, *Custodiol II*<sup>824</sup>, *Cutting Blade I*<sup>825</sup> and *Cutting Blade II*<sup>826</sup>. 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.<sup>827</sup>

### 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.<sup>828</sup> According to Section 11 No. 2 GPA, research is explicitly excluded from the patent right.<sup>829</sup> 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 (Kunststoffrohrteil).

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.

the question of research exemption in its *Clinical Trials* cases.<sup>830</sup> In *Clinical Trial I*, the defendants were conducting clinical studies with the active substance interferon gamma to ascertain further indications.<sup>831</sup> The Federal Supreme Court determined that it was in the public interest that clinical trials for finding further medical uses be excluded from patent infringement, but only if the tests are performed in the course of knowledge acquisition.<sup>832</sup> According to the Court's view, it was irrelevant that the tests also could be used for obtaining regulatory marketing approval:

“Since the patent act, without further restrictions, exempts from the effect of the patent any act for test purposes that focuses on the subject matter of the invention, it cannot be of any consequence to the admissibility of such tests for what purposes they are being conducted, whether they are intended, possibly, to substantiate an application of pharmaceutical approval, or whether they represent a purely scientific research project.”<sup>833</sup>

Based on the above, all testing activities are exempted provided they are performed in the course of knowledge acquisition and are directed to the subject matter of the invention. This includes methods used in order to determine the effects of substances, which were disclosed in previous applications.<sup>834</sup> In *Clinical Trials II*, the defendant conducted clinical trials to confirm results obtained in animal tests and at the same time to gather data necessary for the pharmaceutical approval and marketing of his product.<sup>835</sup> The conducted process resulted in a recombinant, human Erythropoietin (“EPO”) called rHu Epo-Merckle. The plaintiff alleged that the amino acid sequence of this “Epo” product corresponded exactly with the amino acid sequence of his patented “Epo”, why the patent was infringed.<sup>836</sup> The District Court held that the patent was infringed and the Higher District Court rejected the defendant's appeal. The Higher District Court found that the conducted activities were not directed to further development and improvement of the patented compound, but rather were “undertaken only in order to obtain data for the legal pharmaceutical permission and therefore served commercial interests rather than scientific purpos-

830 See BGH, 28 IIC 103, 103 (1997) - *Clinical Trials I* (Klinische Versuche I); [1998] R.P.C. 423

*Clinical Trials II*; Federal Constitutional Court, 1 BvR 1864/95 of 05/10/2000, paragraphs No. 1 - 38, [http://www.bverfg.de/entscheidungen/rk20000510\\_1bvr186495en.html](http://www.bverfg.de/entscheidungen/rk20000510_1bvr186495en.html), last checked on January 21, 2008. See also Garde, Tanuja, The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104, 35 IIC 241, 255 (2004).

831 BGH, 28 IIC 103, 103 (1997) - *Clinical Trials I* (Klinische Versuche I).

832 BGH, 28 IIC 103, 103 (1997) - *Clinical Trials I* (Klinische Versuche I).

833 BGH, 28 IIC 103, 111 (1997) - *Clinical Trials I* (Klinische Versuche I).

834 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 Japanese Group November 1998, 211, 225-226.

835 [1998] R.P.C. 423, 423 - *Clinical Trials II* (Klinische Versuche II), with an early and detailed analysis of the underlying decision of the lower district court, see Straus, Joseph, Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen, GRUR 1993, 308, 311; further Garde, Tanuja, The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104, 35 IIC 241, 256 (2004).

836 [1998] R.P.C. 423, 427 - *Clinical Trials II* (Klinische Versuche II).

es.<sup>837</sup> The German Federal Supreme Court held that the defense of experimental use applies to all experimental acts that are directed to the subject matter of the invention.<sup>838</sup> The exemption would be granted “regardless of the purpose for which these results will ultimately be used.”<sup>839</sup> Thus, section 11 No. 2 GPA “exempts clinical experiments with a protective agent even in a case where these experiments were exclusively ... carried out in order to obtain data” for pharmaceutical approval.<sup>840</sup> Accordingly, the alleged research activities were found to be permissible under Section 11 No. 2 GPA.<sup>841</sup>

In 2000, five years after the *Clinical I* ruling of the Federal Supreme Court, the Federal Constitutional Court addressed the question of whether the exemption for clinical trials to find further indications of the active agent of interferon gamma (used in the drug polyferon) was constitutional.<sup>842</sup> The exclusive licensee of the patent to polypeptides with human interferon gamma properties complained that the lower court’s reading of Section 11 No. 2 GPA, to “regard clinical trials which involve a pharmaceutical drug under patent protection as acts of use to which the effects of the patent do not extend”, was not compatible with Art. 14(1), sentence 1 GG, which set forth the protection of ownership.<sup>843</sup> The Federal Constitutional Court confirmed the ruling of the lower court, affirming that “unlimited protection of the patent .... is not justified in cases in which this hinders technical development.”<sup>844</sup> The Federal Constitutional Court admitted, that the clinical trials at issue could lead to the grant of use patents which otherwise would not have been obtained, but found that this was something the patentee had to tolerate, as he could “only be rewarded for their own contribution to technical advancement.”<sup>845</sup> Therefore, the court concluded that the lower court’s reading of Section 11 No. 2 GPA did not infringe Art. 14(1), sentence 1 GG.<sup>846</sup>

837 [1998] R.P.C. 423, 423 - Clinical Trials II (Klinische Versuche II). See also Garde, Tanuja, The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104, 35 IIC 241, 257-258 (2004).

838 [1998] R.P.C. 423, 432-433 - Clinical Trials II (Klinische Versuche II).

839 [1998] R.P.C. 423, 431 - Clinical Trials II (Klinische Versuche II).

840 [1998] R.P.C. 423, 432 - Clinical Trials II (Klinische Versuche II).

841 [1998] R.P.C. 423, 438 - Clinical Trials II (Klinische Versuche II).

842 Federal Constitutional Court, 1 BvR 1864/95 of 05/10/2000, paragraphs No. (1 - 38), available at [http://www.bverfg.de/entscheidungen/rk20000510\\_1bvr186495en.html](http://www.bverfg.de/entscheidungen/rk20000510_1bvr186495en.html), last checked on January 21, 2008.

843 Federal Constitutional Court, 1 BvR 1864/95 of 05/10/2000, paragraphs No. 1, available at [http://www.bverfg.de/entscheidungen/rk20000510\\_1bvr186495en.html](http://www.bverfg.de/entscheidungen/rk20000510_1bvr186495en.html), last checked on January 21, 2008.

844 Federal Constitutional Court, 1 BvR 1864/95 of 05/10/2000, paragraphs No. 30, available at [http://www.bverfg.de/entscheidungen/k20000510\\_1bvr186495en.html](http://www.bverfg.de/entscheidungen/k20000510_1bvr186495en.html), last checked on January 21, 2008.

845 Federal Constitutional Court, 1 BvR 1864/95 of 05/10/2000, paragraphs No. 31, available at [http://www.bverfg.de/entscheidungen/rk20000510\\_1bvr186495en.html](http://www.bverfg.de/entscheidungen/rk20000510_1bvr186495en.html), last checked on January 21, 2008.

846 Federal Constitutional Court, 1 BvR 1864/95 of 05/10/2000, paragraphs No. 36, available at

It remained questionable whether the research exemption provided by the German courts covers the special case of bioequivalence trials.<sup>847</sup> Bioequivalence trials are carried out to prove for a third party, e.g., the marketing approval institution, that a generic product is bioequivalent, i.e. produces same effects like a patented substance.<sup>848</sup> Based on the above, the general rule laid down in the *Clinical Trial* cases is that the research exemption under German law covers any act conducted for the acquisition of knowledge, notwithstanding the purpose for which this knowledge is eventually used. Hence, the law requires finality with respect to the testing activity and its specific purpose. The testing activity must refer to the patented subject matter and its technical teaching and be performed for gaining knowledge about its decisive properties, effects and uses. Furthermore, studies and research must be undertaken for the advancement of technological progress. Finally, even if all these requirements are met, clinical trials may still not be covered by the research exemption, if they were performed to such an extent that a justification on research grounds is no longer valid.<sup>849</sup>

Bioequivalence trials exclusively focus on showing that a generic drug product has identical properties as the patented product.<sup>850</sup> They serve the main purpose of demonstrating that a generic drug has properties identical to a patented pharmaceutical. The properties, and effects, including side effects of the active patented ingredient, however, have already been analyzed and are generally known at the time the bioequivalent trial is conducted. Typically, bioequivalence is tested early on in order to enter the market as soon as possible after a patent expires. Thus, instead of clarifying properties, effects, possible uses and production feasibility of the patented drug, bioequivalence trials reflect competitive goals, such as an optimized marketing price. Their performance neither intends to ascertain knowledge about the patented subject matter, nor relates to its technical teaching. Under the principles developed in *Clinical Trials I* and *II* and confirmed by the Federal Constitutional court, bioe-

[http://www.bverfg.de/entscheidungen/rk20000510\\_1bvr186495en.html](http://www.bverfg.de/entscheidungen/rk20000510_1bvr186495en.html), last checked on January 21, 2008.

- 847 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, November 1998, 211, 229.
- 848 Straus, Joseph, On the Admissibility of “Biological Equivalents Tests“ during the Patent Term for Obtaining a Regulatory Approvla for Patented Drugs by Third Parties, AIPPI Journal, November 1998, 211, 217. As defined in 21 CFR 320.1(e), bioequivalency means “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.”
- 849 Straus, Joseph, On the Admissibility of „Biological Equivalents Tests“ during the Patent Term for Obtaining a Regulatory Approvla for Patented Drugs by Third Parties, AIPPI Journal, November 1998, 211, 229.
- 850 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, November 1998, 211, 217.

quivalence trials must therefore be considered patent infringement. Any research that obviously does not result in any contribution to the technological progress cannot justify an exemption from a patent.<sup>851</sup>

The question of whether bioequivalent test activities fall under the research exemption must be decided differently under the subsequently adopted Bolar-type exemption.<sup>852</sup> In September 2005, the Bolar-type exemption of the EU Directive 2004/27/EC on the Community Code relating to medicinal products for human use was implemented into the German Patent Law.<sup>853</sup> Section 11 No. 2(b) GPA now exempts all trials and studies that are necessary to obtain marketing approval for the European Union or for one of the Member States. These activities, including trials conducted by generic product manufacturers, are typically not covered by the research exemption, since the experiments have an obvious commercial motivation and are not of a purely scientific nature.<sup>854</sup>

## 2. U.S.

The U.S. patent system has long provided an experimental use exception.<sup>855</sup> Its jurisprudential origin is *Whitmore vs. Cutter, 1 Gall.*<sup>856</sup>, where the court determined that an infringer must have the intention to use a patented invention for commercial profit. The court held that

851 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, November 1998, 211, 230.

852 The term “bolar” is derived from *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, in which the Federal Circuit reversed the lower court’s decision in *Roche*, and determined that “use” under Section 271(a) U.S.C. to cover any “use” of patented subject matter, including using a patented compound to ascertain knowledge for obtaining the approval of a generic version of that compound. See *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 865-66 (Fed. Cir. 1984). As a result, the U.S. Congress adopted Section 271(e)(1); Vihar R. Patel, Are patented research tools still valuable? Use, intent, and a rebuttable presumption: a proposed modification for analyzing the exemption from patent infringement under 35 U.S.C. § 271(e)(1), 47 IDEA 407, 413.

853 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0027:EN:HTML>, last checked on January 21, 2008. Art. 10(6) of the Directive reads as: „Conducting the necessary studies and trials with view to the application of paragraphs 1, 2, 3, and 4 [of Art. 10 2004/27/EC] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products“.

854 Pfaff, Esther, “Bolar” Exemptions - A Threat to the Research Tool Industry in the U.S. and the EU?, 38 IIC 258, 259 (2007).

855 Herrlinger, Karolina A., Die Patentierung von Krankheitsgenen: dargestellt am Beispiel der Patentierung der Brustkrebsgene BRCA 1 und BRCA 2, München 2005, 262.

856 *Whittemore v. Cutter, 1 Gall. 429, 29 F. Cas, 1120, 1121 (C.C.D. Mass. 1813).*

“it could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”<sup>857</sup>

In *Madey v. Duke*<sup>858</sup>, the CAFC substantially narrowed the experimental use exception. Madey, a former Professor at Duke University, owned two patents covering equipment in the laboratory of Duke. After a dispute, he left the university. Nevertheless, Duke continued to use some of the patented instruments. Subsequently, Madey sued Duke for, among other things, infringement of the two patents.<sup>859</sup> The Court found that the conducted research is not exempted from patent infringement.<sup>860</sup> Instead, the Court concluded that a “very narrow and strictly limited experimental use defense” is solely available if the use of the invention is “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”.<sup>861</sup> Furthermore, one can only rely on the defense if the use is “in furtherance of the alleged infringer’s legitimate business, regardless of commercial applications” or of its status as profit or non-profit.<sup>862</sup>

With regard to inventions involving biotechnological material, Section 271(e)(1) U.S.C. provides an exception from infringement for activities involving the development and submission of information for U.S. Food and Drug Administration (FDA) approval.<sup>863</sup> The provision states that

[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

857 *Whittemore v. Cutter*, 1 Gall 429, 29 Fed. Cas. 1120, 1121. By “philosophical” experiments Justice Story was referring to “natural philosophy,” the term later used for what we today understand as “science”, see *Integra Lifesciences I, Ltd. v. Merck KgaA*, 331 F.3d 860, (C.A.Fed. (Cal.) 2003), 875 (FN8).

858 *Madey v. Duke University*, 307 F.3d 1351, (Fed. Cir. 2002), cert. denied by Duke University v. Madey, 539 U.S. 958 (2003).

859 *Madey v. Duke University*, 307 F.3d 1351, 1352-1353; Garde, Tanuja, *The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104, 35 IIC 241, 245-246* (2004).

860 *Madey v. Duke University*, 307 F.3d 1351, 1362, see also Lentz, Edward T., *Pharmaceutical and Biotechnology Research After Integra and Madey*, 23 *Biotechnology Law Report* 2004, 265, 271.

861 *Madey v. Duke University*, 307 F.3d 1351, 1362.

862 *Madey v. Duke University*, 307 F.3d 1351, 1362.

863 The rule to permit experimentation with patented inventions by exempting from infringement those activities that are related to seeking regulatory approval from the federal government is also referred to as “clinical research exemption”, see Steffe, Eric K./Shea, Tomothy J., JR., *Drug Discovery and the Clinical Research Exemption from patent Infringement*, 22 *Biotechnology Law Report* August 2003, 369, 369.

In *Merck and Integra*<sup>864</sup>, the US Supreme Court dealt with the question of whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U. S. C. §271(e)(1).<sup>865</sup> The Federal Circuit Court had clearly confirmed previously the application of this rule, allowing a broader interpretation of experimental use exception “solely for uses reasonably related to the development and submission of information”.<sup>866</sup> The Federal Circuit held that Merck’s research was not clinical testing to supply information to the FDA, but only biomedical research to identify pharmaceutical compounds, which is why Integra’s patents were infringed.<sup>867</sup> The U.S. Supreme Court reasoned that the legislator did not intend Section 271(e)(1) to be so narrowly interpreted and that any infringing activity related to pre-clinical research cannot be classified as infringement::

“The use of patented compounds in preclinical studies is protected under §271(e)(1) at least as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments will produce the types of information relevant to an IND or NDA. The statutory text makes clear that §271(e)(1) provides a wide berth for the use of patented drugs in activities related to the federal regulatory process, including uses reasonably related to the development and submission of any information under the FDCA.”<sup>868</sup>

On remand from the Supreme Court, the CAFC applied the broad interpretation of the research exemption to the Integra case and reversed the district court’s judgment of infringement.<sup>869</sup> Applying the principles set forth by the Supreme Court, the CAFC concluded that the allegedly infringing experiments were conducted “for the purposes of determining the optimum candidate angiogenesis inhibitor and proceeding with commercial development of the selected candidate in compliance with regulatory procedures.”<sup>870</sup> The Court determined that the FDA research exemption depends on “whether the threshold biological property and physiological effect had already been recognized as to the candidate drug.”<sup>871</sup> Therefore, the fact that Merck’s experiments “contributed to scientific knowledge does not deprive them of

864 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). The earlier Federal Circuit’s decision *Merck KGaA v. Integra Lifesciences I*, 331 F.3d 860 (Fed. Cir. 2003) was vacated and remanded. See also Lentz, Edward T., *Pharmaceutical and Biotechnology Research After Integra and Madey*, 23 *Biotechnology Law Report* 2004, 265.

865 The exemption is governed by the Hatch-Waxman Act (1985): It shall not be an act of infringement to make, use, offer to sell, or sell... or import... a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs... (§ 35 U.S.C. § 271(e)(1)).

866 *Merck KGaA v. Integra Lifesciences I*, 331 F.3d 860, 868.

867 *Merck KGaA v. Integra Lifesciences I*, 331 F.3d 860, 866-868.

868 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 193. The ruling of the Supreme Court directly applies the reasoning of *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U. S. 661, 665-669.

869 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334 (Fed. Cir. 2007).

870 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1340.

871 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1347.

a safe-harbor benefit of Section 271(e)(1) when the requirement therefore was met.<sup>872</sup>

Although the *Merck* decision did not establish a clear research exception, it clarified the scope of the legislative exception for research in the context of drug and medical device development for regulatory approval. Neither the Supreme Court nor the CAFC examined on remand whether there exists any historical experimental use exemption to infringement. The CAFC avoided the question of how a case based on research-tool patents should be decided, referring to a post-hearing letter in which the parties had stated that those were not at issue.<sup>873</sup> In a dissenting opinion, Judge Rader disagreed with the conclusion that the court had not ruled on the questions of research tools patents, finding that two of these patented processes “have no application outside the laboratory”.<sup>874</sup> From his view, the leading opinion “expands the exemption beyond the Supreme Court limits on the provision to eliminate protection for research tool inventions.”<sup>875</sup> Under the Supreme Court ruling, the § 271(e)(1) exemption covers research related to information that will ultimately be submitted to the FDA, not “patented processes and tools beyond the scope of the patented compounds” covered by such a research exemption.<sup>876</sup>

In sum, the European patent system provides a much broader opportunity to conduct free research than the U.S. system. The German case, where even activities related to the commercialization of the product are covered, is a good example. Further harmonization of both systems<sup>877</sup>, e.g., an adaptation of the European standard in the U.S., may create conditions preventing US scientists from conducting their research abroad where broader research is allowed without causing any risk of patent infringement.<sup>878</sup>

872 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1347.

873 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1348.

874 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1349.

875 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1348.

876 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1348.

877 The different approaches of the European and U.S. patent law system are also caused by different university cultures. In Europe, universities usually are public institutions, whereas universities in the U.S. are often organized in a similar fashion to private companies. In spite of being a public institution, the University of California, for example, is the leading patent holder in the biotech sector, Malakoff, David, Intellectual property. NIH roils academe with advice on licensing DNA patents, 303 *Science* 2004, 1757, 1757.

878 The decision of *Bayer v. Housey* strongly emphasized the incentive of scientists to conduct research abroad. Garde, Tanuja, The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104, 35 *IIC* 241, 259 (2004). Nevertheless, the Human Genome Organization (‘HUGO’) recommends that the European model of experimental use exception is used as a universal template, see Straus, Joseph, HUGO Statement on the Scope of Gene Patents, Research Exemption, and Licensing of Patented Gene Sequences for Diagnostics, 2003, 2.

### C. Use of 3-D protein structure (concrete claim analysis)

As mentioned earlier, the first patents on gene sequences did raise concerns regarding their potentially undue scope of protection.<sup>879</sup> Did these critical voices prove to be correct? To answer this question, it is important to ask whether claims on later disclosed structural properties depend on previously granted gene patents or other intellectual property rights. Patent dependency refers to a situation in which a new invention cannot be used without the infringement of an earlier one. It applies, although the scope of protection of the earlier patent does not include the technical teaching of the later one as such. The German case law did solve this situation of conflict by determining that the use of a dependent patent without the approval of the earlier patentee is not allowed.<sup>880</sup> However, the holder of the earlier patent is not allowed to use the later invention without the approval of this patentee. Thus, the right of the earlier patentee to prohibit the use of the later patent does not result in a right to actually use the later-issued patent.<sup>881</sup> Patent dependency, however, is only established if the later-developed invention can be carried out without any further inventive activity of the person skilled in the art. In *Segmentation Device for Trees*, the plaintiff owned the German patent No. 29 18 622 (the “contract patent”) for the process for segmenting logs into wood products. The defendant was the proprietor of German patent No. 35 14 892 (the ‘892 patent’) to a “process and device for chipping wood, in particular for segmenting logs with waney surfaces by chipping.”<sup>882</sup> The parties concluded a license agreement. Thereby, the plaintiff granted the defendant a license for the “contract patent” in exchange for a certain license fee. The German Federal Supreme Court had to decide whether the license agreement covered the use of defendant’s ‘892 patent. The lower court held that the patented invention of the defendant was a further development of the contract patent that fine-tuned and adjusted its technology. More specifically, it had to be seen as an equivalent of the contract patent, which a person skilled in the art would be able to predict and carry out. Therefore, the invention of the defendant was considered an equivalent means, which depended on the contract patent and was covered by its scope of protection.<sup>883</sup> The German Federal Supreme Court found that the additional cutting blade used within the patented process of the patentee could only be considered an equivalent device to the technology covered by the process patent if it did not involve any in-

879 Chapter 3 A II 2 a); see also Straus, Joseph, Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall, GRUR 1998, 314; further Pietzcker, Rolf, Die sogenannte Abhängigkeit im Patentrecht, GRUR 1993, 272.

880 Busse/Keukenschrijver, PatG, § 9, No. 39.

881 Straus, Joseph, Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall, GRUR 1998, 314, 316; siehe auch: Krieger, Ulrich, Abhängige Patente und ihre Verwertung (Frage 97), GRURInt. 1989, 216, 216.

882 BGH, 26 IIC 261, 262 (1995) - Segmentation Device for Trees (Zerlegevorrichtung für Baumstämme).

883 BGH, 26 IIC 261, 266 (1995) - Segmentation Device for Trees (Zerlegevorrichtung für Baumstämme).