Mr. Van Horn retired from the Patent and Trademark Office in 1998 and joined the firm of Finnegan, Henderson, Farabow, Garrett & Dunner where he is a partner in the firm's Chemical/Metallurgical Practice Group and head of the Patent Prosecution Section.

Mr. Van Horn was awarded the Department of Commerce Gold Medal in 1983 and was awarded the Jefferson Medal in 2001.

The Chief Judge for this year's selection committee was Michael Kirk, the Executive Director of the American Intellectual Property Law Association, and a past winner of the Federico Award. Associate judges were Don Martens, of Knobbe Martens Olson and Bear, and Gary Griswold, of 3M Innovative Properties.

The Erosion Of Compound Protection In Germany: Implementation Of The EU Directive On The Legal Protection Of Biotechnological Inventions — The German Way

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ABSTRACT

In 1998, the European Parliament and the Council passed directive 98/44/EC entitled "The legal protection of biotechnological inventions" ("Directive"). Germany was obliged to implement the Directive into national law no later than July 30, 2000. In the beginning of 2005, Germany implemented most provisions of the Directive accordingly, *i.e.* in a one to one manner. However, the German legislator also added a major change to the German Patent Act ("GPA") which differs from the Directive. The scope of patent protection conferred for a sequence or a partial sequence of a gene whose structure is concordant to the structure of a natural sequence or partial sequence of a human gene must be limited in the patent claim to the use disclosed in the patent application ("purpose-limited compound protection"). The insertion of this provision in the amended GPA which constitutes German patent law as of February 28, 2005, raises a number of questions concerning the patenting of nucleic acids before the German Patent Trademark Office ("GPTO").

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We will demonstrate, however, that European Patents granted for the contracting state Germany by the European Patent Office ("EPO") should not be affected by the amendments in the GPA. Furthermore, there are several reasons why only patent applications for biotechnological inventions filed nationally at the GPTO *after* the date of implementation (February 28, 2005) should be subject to the new provisions in the GPA.

I. The Directive And Its History

In 1998, after nearly 10 years of controversial discussions the European Parliament and the Council passed by a large majority the Directive 98/44/EC on the legal protection of biotechnological inventions. Recital 3 asserts that a primary reason for passing the Directive was that an "effective and harmonious protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology."[4]

At present there is no existing regional patent system that is solely governed by the laws of the European Union.[5] The European patent system is based on an independent international treaty,[6] the European Patent Convention ("EPC").[7] The European patent is granted by the EPO. It represents a bundle of national patents. In parallel there are the national patent systems in each country.

Hence, the Directive is based on the intent of the European Union to regulate and harmonize national and regional patent law amongst its Member States. In accordance with Article 15 of the Directive the EU Member States were obliged to implement the Directive into national law no later than July 30, 2000. Further the States newly joining the EU

4 DIRECTIVE 98/44/EC of the EUROPEAN PARLIAMENT and of the COUNCIL 1998 on the legal protection of biotechnological inventions of July 6, 1998, OJ L 213/13.

5 The so called "Community Patent" is being discussed amongst the EU Member States since the 1960ies, but unlike the community trademark and the community design patent it has never been enacted.

6 Contracting states of the European Patent Convention are Austria, Ireland, Belgium, Iceland, Bulgaria, Italy, Switzerland, Liechtenstein, Cyprus, Lithuania, Czech Republic, Luxembourg, Germany, Monaco, Denmark, Netherlands, Estonia, Poland, Spain, Portugal, Finland, Romania, France, Sweden, United Kingdom, Slovenia, Hellenic Republic, Slovakia, Hungary and Turkey.

7 In addition, the Kingdom of the Netherlands submitted an interim application to the President of the Court of Justice of the European Community that aimed at postponing the implementation of Directive 98/44/EC, on the grounds of the urgent need of the Member States not to be forced to implement Directive 98/44/EC. By an injunction of July 25, 2000, the President of the Court rejected that application.

were also obliged to implement the Directive as part of the "acquis communautaire" (the acquired laws of the Community).

In 1998, the Kingdom of the Netherlands with the support of Italy and Norway brought an action for annulment of Directive 98/44/EC before the Court of Justice of the European Community (ECJ).[7] On October 9, 2001, the Court dismissed the action.[8] This judgment is of particular importance since the ECJ took the opportunity to confirm the validity and applicability of the Directive.[9,10]

The main provisions of Directive 98/44/EC have been incorporated into the Implementing Regulations to the EPC by a Decision of the Administrative Council of the European Patent Organisation of June 16, 1999.[11] The new rules, Rule 23b *et seq.* and Rule 28(6), adopt the essential provisions of the Directive, in particular Articles 4, 5 and 6. Moreover, Rule 23b establishes that Directive 98/44/EC is a supplementary means of interpreting these rules as well as the relevant provisions of the Convention. The Boards of Appeal, which are not bound by any instructions and must comply only with the provisions of the Convention and its Implementing Regulations, may, therefore, refer to the Articles of the Directive and the attached recitals to support their decisions. Certain decisions reached by Opposition Divisions of the EPO refer explicitly to Directive 98/44/EC.[12] The Enlarged Board of Appeal confirmed in its *Novartis* decision[13] the relevance of the Directive for the EPC.

Thus, the patentability of biotechnological inventions is assessed by the EPO based on a one-to-one implementation of the Directive, *i.e.* European Community law. As the Implementing Regulations to the EPC are applied consistently with regard to all Contracting States designated in the European patent application, a harmonization of the rules determining the patentability of biotechnological inventions will be achieved on the level of the EPC.

8 ECJ Judgement of October 9, 2001 - C - 377/98; published (in German) in GRURInt 2001, 1043ss.

9 Report from the COMMISSION to the EUROPEAN PARLIAMENT and THE COUNCIL - Development and implications of patent law in the field of biotechnology and genetic engineering. [COM (2002) 545 final, 1.3, p. 8].

10 OJ EPO 7/1999, p. 437.

11 Certain political circles raised the criticism that the implementation of the Directive should have been performed at the level of the Diplomatic Conference, pursuant to Art. 172 EPC.

12 Decision of an Opposition Division of the EPO of June 20, 2001, OJ EPO 6/2002, p.293; cf. footnote 52.

13 G1/98 Novartis, OJ EPO 111 (2000).

II. The EU Directive And Its Divergent Implementation In Germany

A. Concerns in Europe

Although the Directive was finally passed after 10 years of intense debates by a large majority and despite the fact that the ECJ confirmed its validity, basically the same political circles continued the same debate in the context of its implementation on national levels. In particular France, Germany and Austria were amongst the countries that heavily debated certain aspects of the Directive. Ethical questions and the boundaries of patentability defined by alleged ethical questions played an important role in these debates. Furthermore, there was the fear of deadlocking innovation, *e.g.* where the first patentee of a gene-sequence could block further innovation of possible later inventors using the same gene-sequence for a different purpose. One particularly intensively debated question was the scope to be conferred by patents relating to elements isolated from the human body. Critics of a compound protection for (human) gene sequences included not only the lobbyists of non-governmental organizations (*e.g.* Greenpeace) and members of left wing parties, but also members of religious organisations and the conservative parties. They argued biotech-inventions were not comparable to "traditional" chemical inventions due to additional "information" contained in the gene sequences which go beyond the chemical composition of the sequence itself.

France and Germany, as well as other continental European Member States, were sued by the European Commission for non-implementation of the Directive. The ECJ through its judgement of October 28, 2004 held that Germany had infringed its obligation under the Directive.[14] The ECJ ruled similarly against France,[15] Austria,[16] Belgium[17] and Luxembourg[18] as well.

B. Germany's Implementation

As outlined above, one question which was debated particularly intensively in Germany as well as in other European states was the scope to be conferred by patents relating to elements isolated from the human

14 ECJ, judgement of October 28, 2004 - C-5/04.
15 ECJ, judgement of July 01, 2004 - C-448/03.
16 ECJ, judgement of October 28, 2004 - C-4/04.
17 ECJ, judgement of September 09, 2004 - C-454/03.
18 ECJ, judgement of September 09, 2004 - C-450/03.

body. In 2003, the German government finally released its draft for implementation of the Directive and proposed a literal, one-to-one implementation of the Directive. However, it was amended in the German Federal Parliament (*Deutscher Bundestag*): In its 146th session on December 3, 2004 the German Federal Parliament decided against a one-to-one implementation of the Directive by inserting a subsection (4) into § 1a of the GPA, limiting the scope of protection conferred by patents on certain biotechnological inventions. The amended GPA came into force on February 28, 2005.[19] The new § 1a GPA,[20] in an unofficial English translation, reads as follows:

§ 1a GPA

(1) The human body, at the various stages of its formation and development, including germ cells and the simple discovery of one of its elements, including the sequence or partial sequence of a gene cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be concretely disclosed in the application by indicating the function fulfilled by the sequence or partial sequence.

19 BGBl. Part I Nr. 6 2005 (28. Jan. 2005) pages 146 and following.
20 The German wording of § 1a GPA is as follows:

(1) Der menschliche Körper in den einzelnen Phasen seiner Entstehung und Entwicklung einschließlich der Keimzellen sowie die bloße Entdeckung eines seiner Bestandteile, einschließlich der Sequenz oder Teilsequenz eines Gens, können keine patentierbaren Erfindungen sein.

(2) Ein isolierter Bestandteil des menschlichen Körpers oder ein auf andere Weise durch ein technisches Verfahren gewonnener Bestandteil, einschließlich der Sequenz oder Teilsequenz eines Gens, kann eine patentierbare Erfindung sein, selbst wenn der Aufbau dieses Bestandteils mit dem Aufbau eines natürlichen Bestandteils identisch ist.

(3) Die gewerbliche Anwendbarkeit einer Sequenz oder Teilsequenz eines Gens muss in der Anmeldung konkret unter Angabe der von der Sequenz oder Teilsequenz erfüllten Funktion beschrieben werden.

(4) Ist Gegenstand der Erfindung eine Sequenz oder Teilsequenz eines Gens, deren Aufbau mit dem Aufbau einer natürlichen Sequenz oder Teilsequenz eines menschlichen Gens übereinstimmt, so ist deren Verwendung, für die die gewerbliche Anwendbarkeit nach Absatz 3 konkret beschrieben ist, in den Patentanspruch aufzunehmen.

(4) If the subject matter of the invention is a sequence or partial sequence of a gene the structure of which is concordant to the structure of a natural sequence or partial sequence of a human gene, then its use, for which the industrial application is concretely described in accordance with subsection 3, has to be included into the patent claim.

C. The Divergences from the Directive

When comparing the GPA to the Directive, the following divergences can be found between § 1a GPA and the Directive: Subsection (1) introduces the words "including germ cells" after the word "development."[21] Subsection (3) in addition to disclosing the industrial applicability in the patent application demands that "the function fulfilled by the sequence or partial sequence" be indicated in the application. Subsection (4) is completely new[22] *i.e.* it does not mirror the wording of Article 5 of the Directive.

According to the Reasons of the Legal Committee of the German Federal Parliament for the recommended decision for the German Federal Parliament (preparing the 2nd/3rd reading in the Parliament) ("the Reasons of the Legal Committee"),[23] subsection (4) was added to § 1a GPA with the clear intent to limit the scope of protection for a sequence or a partial sequence of a gene the structure of which is concordant to the structure of a natural sequence or partial sequence of a human gene to the *use* or *purpose*,[24] for which the industrial application — and the function — was concretely described in the description. However, it is important to understand that the purpose-limited compound protection created by added subsection (4) only applies to certain nucleic acids. It does *not* apply to other classes of substances, particularly not to the encoded proteins.

21 In line with Article 5 (1) of the Directive § 1 (a) GPA states that the human body, at the various stages of its formation and development, cannot constitute patentable inventions. It was the intent of the German legislator to clarify that this definition explicitly encompasses germ cells. Thus, amendment in § 1a (1) GPA with which the words "including germ cells" was inserted.

22 German language text: 1. In Absatz 1 sind nach dem Wort "Entwicklung" die Wörter ", einschließlich der Keimzellen," einzufügen. 2. Folgender Absatz 4 ist anzufügen: "(4) ist Gegenstand der Erfindung eine Sequenz oder Teilsequenz eines Gens, deren Aufbau mit dem Aufbau einer natürlichen Sequenz oder Teilsequenz eines menschlichen Gens übereinstimmt, so ist deren Verwendung, für die die gewerbliche Anwendbarkeit nach Absatz 3 konkret beschrieben ist, in den Patentanspruch aufzunehmen."

23 Deutscher Bundestag, Drucksache (printed paper) - 15/4417, report of the Legal Committee.

24 The German term is „Zweck."

III. Implications For The Practitioner And The Applicant

The divergence in the wording of § 1a (3) GPA from Art. 5 (3) of the Directive and the introduction of § 1a (4) into the GPA raises numerous questions.

A. Limitation of the Scope of Protection for German Patents Prosecuted Before the German Patent and Trademark Office

To what extent did the German Legislator actually want to limit the scope of compound protection for nucleic acids by adding § 1 a (4) in the GPA? As already briefly addressed above, this becomes clear from the Reasons of the Legal Committee for § 1 a (4) GPA, stating that

> *...[the insertion of § 1 (a) (4) GPA]* limits the scope of compound protection for gene sequences the structures of which are concordant to the structure of a natural human sequence to the "use" disclosed in the patent application... [25]

A majority of representatives of the German Federal Parliament took the position that patents for gene sequences should be *restricted to the object of the invention.* In order *to ensure that protection does not reach so far that one may obtain patents on future possibilities or functions, which have not been invented.*

Thus it is clear, that with this remarkable and discriminating decision, the German legislator said "Good bye!" to absolute compound protection at least for naturally occurring human DNA sequences, even if they were to fulfil all patentability criteria for chemical compounds/compounds of nature. Only purpose-limited compound protection for such DNA sequences will be available in Germany at least if and when the applicant seeks protection under the GPA at the GPTO. However, it is unclear as to which sequences this restriction will apply. It is conceivable from the wording of the law that even derivatives of naturally occurring human nucleic acid sequences and non-human nucleic acid sequences might be concerned; see section 3.4, infra.

25 Reasons of the legal committee, Deutscher Bundestag Drucksache (printed paper) 15/4417, report of the Legal Committee, p. 9 to Amendment No 2.

B. Understanding § 1a (3) GPA and defining the term "function"

In order to understand the term "function" one must first take into account that the various official languages of the Directive are inconsistent in that they slightly differ in wording.

The *English version* of the Directive states in Article 5 (3):

The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.[26]

The (translated) *German version* of the Directive states in Article 5 (3):

The industrial application of a sequence or a partial sequence of a gene must be disclosed *concretely* in the patent application.[27]
(emphasis added)

The German legislator however uses a different wording in § 1 (3) GPA:

The industrial application of a sequence or a partial sequence of a gene must be *concretely*[28] disclosed in the application *by indicating the function fulfilled by the sequence or partial sequence.*
(emphasis added)

In the Reasons the legislator asserted that the provision of § 1 a (3) GPA is in line with Article 5 (2) of the Directive.[29] However, it is stressed that the legislator took on board the recitals of the Directive as well. Specifically, recitals 20 to 25 are mentioned.[30]

Recitals 22 to 24 read (in the following we quote the English version of the Directive):

26 Note, that the varying official languages of the Directive have differing translations.

27 Note, that the varying official languages of the Directive have differing translations.

28 As before: The German wording of the Directive contains the word „konkret" (English: concretely) whereas, the English wording of the Directive does not contain the word "concretely." Likewise, e.g. rule 23e (3) of the Implementing Regulations of the EPC lacks the word "concretely" in the English language version whereas the German and the French version contain the word "konkret," i.e. "concrètment" respectively.

29 Deutscher Bundestag, Drucksache (printed matter) – 15/1709 p. 13/E/To Article1 to No 2 lit b).

30 Deutscher Bundestag, Drucksache (printed matter) – 15/1709 p. 13/E/ To Article 1 to No 2 lit b).

> (22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; **whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;**
>
> **(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;**
>
> **(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;**
> (emphasis added)

At the very least, the wording of § 1a (3) GPA raises the question of whether or not the knowledge of *the actual biological,* in vivo, *function of the protein* encoded by the gene claimed in the patent application now is a patentability requirement in Germany or whether "function" may be interpreted to mean industrial applicability a long established requirement for patentability under European and German patent law (Articles 52 and 54 EPC, §§ 1 and 5 GPA).

The German wording clearly reaches further than the wording found in the Directive (Art. 5 (3)) and also in the EPC (Rule 23e (3) of the Implementing Regulations) which merely state: "The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."

In 2002, a decision by an Opposition Division of the EPO called "ICOS"[31] provided some guidance on the interpretation of Rule 23e (3) of the Implementing Regulations. Here a gene was claimed. The Opposition Division addressed, in reference to a claim for a gene sequence, the question of industrial applicability in the decision:

31 OJ 06, 2002; Decision of the opposition division dated June 20, 2001; ICOS.

(i) Potential *uses* of the invention are disclosed in the specification (p. 3.4) which however are based *on a proposed function* of the V28 protein as a receptor which is not sufficiently disclosed in the specification (see section 5 above). Thus, the *potential uses* disclosed in the application are speculative, *i.e.* are not specific, substantial and credible and as such are not considered industrial applications.
(emphasis added)

It can be concluded from this decision that the patentability requirement formulated in Rule 23e (3) of the Implementing Regulations was not considered to be fulfilled by speculations on the possible functions of a protein encoded by the disclosed gene. A function in the meaning of the EPC is any function which contributes causally to a technically utilizable achievement.[32]

In the Reasons of the legislator for the Amendment to the GPA[33] it is stated:

for the use of a sequence or a partial sequence for the production of a protein or a partial protein, one must designate which protein or partial protein is being produced and which "mission" (another translation would be "task" or "job")[34] it has. General specifications concerning the commercial applicability such as 'for medical purposes' are not sufficient, in contrast, a concrete description of the *function* and *the industrial applicability* of the gene is demanded.
(emphasis added)

One may now assume that the German legislator had the designation of the biological function as a new patentability requirement in mind. Should this interpretation apply, the skilled and experienced practitioner can foresee endless problems arising. The following are two such examples:

Most *biologists* would agree (i) that the *function of a telomerase gene is in fact the expression of a telomerase protein, i.e.* a catalytic enzyme. The telomerase enzyme in turn has a certain *enzymatic activity* namely (ii) *nucleic acid synthesis activity* at chromosomal ends (designated p and q), which in turn leads to (iii) the *elongation of*

32 Optionen bei der Umsetzung der Richtlinie EG 98/44 über den rechtlichen Schutz biotechnologischer Erfindungen, page 65, ISBN 3-033-00103-3.

33 Reasons of the government - Deutscher Bundestag, Drucksache (printed paper) 15/1709, p. 13, E/ to Art. 1 to number 2 lit. b.

34 The German wording in the document according to footnote 34 is „und welche Aufgabe es hat."

chromosomes which in turn has the effect (iv) that in many organisms *life span is prolonged*. Which of the above (i), (ii), (iii) or (iv) will suffice to satisfy the function requirement under § 1 a (3)?

As another example, we could take a putative collection of novel marker genes. Imagine, the applicant has identified 6 novel marker gene alleles the expression of which the applicant can experimentally prove, is associated with a 95% chance of developing colorectal cancer. The applicant is thus clearly able to demonstrate the utility of these genes. According to the wording of the amended GPA the examiner could reject the application on the grounds that the application lacks designation of the "biological function" of the 6 novel genes.

The latter example raises another question: Must one designate the "biological function" of a gene in terms of what the encoded protein does even in the event that the nucleic acid serves as a diagnostic tool or a marker? The Reasons of the legislator - as quoted above - suggest that this was not intended:

for the use of a sequence or a partial sequence for the *production of a protein or a partial protein*, one must designate which protein or partial protein is being produced and which mission it has.

Thus it seems that a concrete description of the function and the industrial applicability of the gene in terms of the encoded protein's properties is demanded only for genes that are to be used for producing the corresponding protein.

A bigger problem is caused by what the German legislator has outlined in section 3 of the substantiation of the draft GPA in its version of October 15, 2003.[35]

the patentability requirements need to be checked by the patent examiner in each individual case in detail. In this context § 1a subsection (3) is of great importance. The description of the *function* is the essential criteria based on which the examiner is to determine the gene portion for which protection is sought for. The legislator can be sure that an utmost narrow and precise functional description will occur. Based on the functional description the patent examiner must restrict the patent to that part of the gene for which patent protection was sought for and *which is essential for the described function and shall exclude parts of the gene which are not essential for the described function.*
(emphasis added)

35 Deutscher Bundestag, Druchsache (printed paper) 15/1709, p. 19

This concept deviates from the principle that the proceedings before the GPTO depend on the requests of the applicant. Examiners, thus, were only able so far to either except or reject a request. Furthermore, it is unlikely that the German patent examiners are going to be capable of performing this task which even the inventors could probably not perform with absolute precision in most cases, although they are ones who are most familiar with the technology concerned. Moreover – and most importantly – who would really care about which part of a claimed gene encodes the relevent part of a protein (domain?) when there is a gene that simply encodes a pharmaceutically useful protein? This may turn out to be of purely academic but no practical relevance. At least so far patents were rather granted for technically useful contributions. The legislator's comments on this issue alone may cause indefinite troubles in examination before the GPTO and in opposition proceedings and German litigation concerning any such patent. The hypothetical considerations fell short of the practical requirements and necessities.

Another open issue is, to what extent will experimental evidence for the disclosed "concrete function" be required. Will it be possible to disclose a concrete function based on an educated guess and submit experimental evidence later – as is the practice in the EPO meanwhile - or will the GPTO only consider experimental evidence as far as it was available at the filing or priority date and not allow applicants to rely on any further – later – evidence?

The requirement set forth in §1a (3) GPA that the "[biological] *function fulfilled by the sequence or partial sequence*" is to be disclosed in the patent application may have another albeit initially unintended implication on the assessment of the patentability of DNA sequences in the context of the concept of novelty.

In order to be patentable, an invention must be complete. It appears as if the disclosure of a DNA sequence without an allocated "[biological] *function fulfilled by the sequence or partial sequence*" does not amount to disclosing a complete invention in terms of a reproducible, enabling technical teaching under the new GPA. Therefore, pursuant to § 1a GPA such an invention would not be patentable. On the other hand, a prior art document can only be novelty destroying if it provides an enabling disclosure of the claimed invention, *i.e.* a technical teaching that is as complete as what is claimed and disclosed in the relevant patent application.

In consequence, when applying the same standards to the assessment of patentability of a given DNA sequence and to the assessment of whether a given disclosure in the prior art is novelty

destroying, it would be fair to conclude that the mere disclosure of a DNA sequence in the prior art without an allocated biological function will in future not be novelty destroying for a (purpose-limited) DNA claim in a patent application that discloses a complete invention, in particular the now identified proper biological function of the claimed DNA sequence. In this scenario, the applicant would for the first time be in possession of the complete technical teaching (complete invention).

C. Understanding § 1a (4) GPA and Defining the Term "Use" or "Purpose"

Before discussing what the term "use" or "purpose" could mean, there is another ambiguity that we have to deal with.

The wording of § 1a (4) GPA states that "If the subject matter of the invention is a sequence or partial sequence of a *gene* its use has to be included into the patent claim" thereby limiting the available compound protection for sequences or partial sequences of *genes*. Except for the situation in some viruses, genes are made of DNA. However, anybody who wanted to use the gene for making a protein would also have to make use of the mRNA encoded by the gene. Nevertheless, the mRNA encoded by the DNA of a gene is a different chemical entity, *i.e.* compound. Can we therefore obtain absolute compound protection for the mRNA encoded by a gene? Can such compound protection "circumvent" the limitation intended by the legislator? This appears to be another issue that was not taken into consideration when making the new law. It is therefore indicative that subsection (3) of the reasons provided together with the draft GPA only mentions DNA in its discussion of the purpose limitation. On the other hand, § 1a (4) GPA says that sequences "concordant to the structure of a natural sequence or partial sequence of a human gene" are to be excluded from absolute compound protection. Does concordant catch the RNA world? There is no hint in the law or in its accompanying reasons.

New section (4) of §1a GPA outlines that

> [the] *use*, for which the industrial *application* is concretely described in accordance with subsection 3, has to be included into the patent claim.[36]

36 Deutscher Bundestag, Drucksache (printed paper) 15/1709 p. 13; German wording: „Im Falle der Verwendung einer Sequenz oder Teilsequenz eines Gens zur Herstellung eines Proteins oder Teilproteins muss angeben werden, welches Protein oder Teilprotein hergestellt wird und welche Aufgabe es hat. Allgemeine Angaben zur gewerblichen Verwertbarkeit wie etwa „für medizinische Zwecke" reichen damit nicht aus, vielmehr ist eine konkrete Beschreibung der Funktion und der gewerblichen Anwendbarkeit des Gens gefordert."

However, what did the legislator actually mean by using the term "use" or rather "purpose"? Keep in mind that subsection (3) demands the designation of the "industrial application of the sequence (...) *by indicating the function fulfilled* (...)", which we now interpret to imply designating a "biological function" *and* an "industrial applicability" (see analysis above). Thus, it remains unclear how § 1a (3) GPA may help in executing the new requirement of § 1a (4) GPA.

How precisely will an applicant have to define the "use/purpose" in a claim? The legislator comments in the reasons for the amendment of the GPA on § 1a (3) stating that "general specifications of the industrial applicability such as for 'medical purposes' are not sufficient."[37] This statement of course does not help. To which extent would the medical use have to be defined in the claim? Would the mechanism by which the encoded protein acts in the pharmaceutical context aimed at also have to be put into the claim? This would be a possible interpretation of § 1a (4) GPA in view of the context with subsection (3).

For example one could define in a claim relating to a gene that its purpose is fulfilled in the context of "treating diseases associated with activated T-cells". Alternatively, the definition of the gene's purpose could be "for treating leukaemia". Obviously the two variants would result in a very different scope of protection. How will the examiner decide which of the two is legitimate in the absence of clear guidance in the GPA and its reasoning?

The limitation of the claim to the use concretely described in the application may have substantial implications. One of the essential advantages of absolute compound protection is its effectiveness when enforced against infringers. This is in particular true where the infringer benefits largely from off-label use. It is an established practice of the EPO to allow patent claims which are limited to the use of a substance for preparing a medicament for a specific new and inventive application (so called "Swiss-type" claims).[38] In infringement proceedings the patentee trying to enforce such claim must demonstrate that the alleged infringer has either prepared such medicament with the express instruction to use it for the indication specified in the patent claim (this might be proven by the instructions with which the medicament is sold)

37 Deutscher Bundestag, Drucksache (printed paper) 15/1709 p. 13. section E to Article 1 To No 2 lit. B);

38 EPO Enlarged Board of Appeal decision G1/83.

or (under the concept of contributory infringement) that he is aware of the fact that the receiver of the medicament will prepare it for such use. As has been held in a recent judgement rendered by the Regional Court of Düsseldorf,[39] the fact that even more than half of the patients treated with the medicament will fulfil the purpose as stated in the claim does not suffice for a direct infringement of such claim. Nor is it sufficient for a contributory infringement that the recipient administers the medicament directly for the patented use without that the medicament needs further preparation to be determined for such use. Hence, a Swiss type claim is more or less inefficient to encounter off-label use. It has to be expected that these principles will be applied accordingly to claims worded as § 1a (4) GPA requires.

D. Did the Legislator However Limit the New "Purpose-bound Compound Protection" to Naturally Occurring Human *DNA Sequences or Will This Apply to Other Species and/or Artificial DNA Sequences as Well?*

The question of whether or not a given DNA sequence is excluded from absolute compound protection furthermore depends on the actual meaning of "*concordant to the structure of a natural sequence or partial sequence of a human gene.*" [40]

This term could either exclude only sequences that are identical to naturally occurring human ones or it could exclude more than this, *e.g.* any sequence that corresponds to a certain extent or is structurally similar to a certain extent to a naturally occurring human sequence. In this context it is noteworthy that § 1a (2) GPA uses the term "identical" (in German "identisch") while § 1a (4) GPA uses the term "concordant". Was the use of different terms intentional?

The Reasons of the Legal Committee outline that

> The wording chosen takes into consideration that human genes according to present common knowledge are largely concordant with animal or plant genes and limiting effect of the regulation on the compound protection may be circumvented by, e.g. patenting a concurrent animal gene.[41]

39 LG Düsseldorf, InStGE 4, 97 ss- Ribavirin, (not final).

40 The German wording is "übereinstimmt" which is less than "identical" and could be translated as "concordant" or "congruent."

41 Deutscher Bundestag, Drucksache 15/4417.

This statement supports the broader interpretation of the exclusion from absolute compound protection.

If the legislator indeed wanted to have § 1a (4) GPA understood so as to exclude absolute compound protection for any DNA sequence that has *structural similarity* to a natural occurring human one, then how do we assess such structural similarity? Do we compare the relevant sequences to determine structural similarity? If we compare sequences, what is the threshold value of sequence identity to acknowledge concordance? Would we, instead or in addition, compare intron/exon structures of a given gene? Would structural similarity already be acknowledged when there is a human paralogue,[42] orthologue[43] or homologue[44] to the sequence that is to be patented, irrespective of the level of sequence identity? Would even a similar function of the sequence concerned be a sufficient basis to acknowledge sufficient structural similarity? There are numerous options but there is no guidance.

Another question is whether 'concordant' even excludes absolute compound protection for artificial variants of naturally occurring human DNA sequences. While the mere wording of § 1a (4) GPA would suggest that this is the case, there are hints that the legislator did actually not intend such a limitation. Accordingly, the fraction of the Freie Demokratische Partei (FDP) of the German Federal Parliament, which disagreed with the purpose-limited compound protection per se, stressed that the legislator had not meant to exclude genetically engineered human gene sequences from absolute compound protection.[45]

42 Paralogues are usually described as genes within the same genome that have evolved by duplication.

43 Orthologues are genes derived from a common ancestor through vertical descent. This is often stated as the same gene in different species. In contrast, paralogs are genes within the same genome that have evolved by duplication. The hemoglobin genes are a good example. Two separate genes (proteins) make up the molecule hemoglobin (alpha and beta). The alpha and beta DNA sequences are very similar and it is believed that they arose from duplication of a single gene, followed by separate evolution in each of the sequences. Alpha and beta are considered paralogs. Alpha hemoglobins in different species are considered orthologs (from: *www.ncbi.nlm.nih.gov* - education).

44 Homologue: Two biological entities (structures or molecule) are said to be homologues (or are homologous) if it is thought that they descend from a common ancestral structure or molecule. Corresponding body parts and genes in different or the same species can be homologous. The term has often been extended to include sequences as well. However it is incorrect to report a relative homology or percent homology as is sometimes said of sequences; genes or sequences are either homologous or they are not (from: *www.ncbi.nlm.nih.gov* - education).

45 Deutscher Bundestag, Drucksache (printed paper) 15/4417, page 8, Report III (FDP).

Still another question is, whether cDNA sequences are encompassed by the exclusion of DNA sequences from absolute compound protection. They are DNA, but they do never, as a matter of principle, occur in nature. On the other hand, they are solely composed of elements ("partial sequences") that occur in nature as such.

For the practitioner it is apparent that disputes about the issue about "concordant to" can and probably will cause substantial problems and uncertainties. This is because in nature both, an extensive intra- as well as inter-species variability exists. At the same time, numerous genomic regions have remained extremely conserved, even between distant species.

The following examples serve to illustrate that the examiners at the GPTO may have great difficulties implementing the intent of the legislator in substantive examination:[46]

(i) Applicant applies for a patent on a DNA sequence. The application discloses the function, and provides sufficient industrial applicability, but does not disclose the origin of the DNA sequence.
The examiner searches the databases available to him and determines that the sequence is *not identical* to that which may be found in the database. The difference is highly likely due to a small allelic variance in humans. The question is, provided it was novel and inventive, would it be patentable *with* or *without* purpose-bound restriction?
In the alternative, when the specification said that the sequence was isolated from a *human* individual,[47] it would clearly only be patentable with purpose bound restriction.
Such scenarios indicate that the purpose-limited compound protection may depend to a large extent on whether the applicant faithfully reveals the origin of the claimed DNA sequence in the patent specification.

(ii) (a): Applicant applies for a patent on a DNA sequence. Its origin is a non human *primate species*. It shares *80% sequence identity* at the DNA level with a human sequence. It is a *paralogue* to a known human DNA sequence.

46 The task is not really simplified by the fact that there is far less experience in this field of patent examination in the GPTO than in the EPO. In this respect, we also refer to the statistics set forth in section 7, infra.

47 The greatest human genetic variability may be observed in Africa.

(b): Applicant applies for a patent on a DNA sequence. It is of bovine origin. It shares *70% sequence identity* at the DNA level to the human homologue. It is an enzyme to be used in fermentation. There is *no orthologue in humans.*
(c): Applicant applies for a patent on a DNA sequence. It is of porcine origin. It shares *65% sequence identity* at the DNA level *to its human orthologue.*

(iii) A bovine DNA sequence was cloned. It encodes growth hormone. No human homologue or orthologue is known at the filing date. Two weeks after the grant of the patent – with absolute compound protection for the actually identified bovine DNA sequence and at least 80% identical DNA sequences – an 84% identical human orthologue is found. A competitor files an opposition. In this situation the set of facts known at the date of grant justified absolute compound protection since no human DNA sequence was concerned. Depending on the actually applicable interpretation of the term "concordant structure", after the discovery of the 84% identical human orthologue, absolute compound protection might have had to be denied in the first place. How is the Federal German Patent Court/GPTO going to deal with this in the opposition proceedings? Can there ever be legal certainty? How can patentees or investors ever reliably assess the value of such a patent?
The above discussion including the mentioned examples indicates that the only sensible way to proceed would be to apply "concordant" in § 1a (4) GPA so as to mean identical. Otherwise the legal uncertainty caused would be tremendous. Thus, absolute compound protection should indeed only be excluded for sequences that actually occur in the human genome. This interpretation should also allow absolute compound protection for human cDNA sequences.

IV. Impact Of The New GPA On Pending German Patent Applications And Granted German Patent Applications

A. Pending German Patent Applications and Granted German Patents

According to Art. 4 of the law for adopting the Directive, the amended GPA has come into force on February 28, 2005. Retroactivity of the new law, *i.e.* its application to (i) already pending German patent applications or (ii) previously granted German patents should be

excluded, for two reasons. First, the GPA does not provide for its retroactive application. Second, any retroactive limitation of the scope of patent protection which can be obtained for biotech inventions, would raise serious concerns as regards its conformity with the protection of property under Art. 14 of the German Constitution (*Grundgesetz, abbreviated "GG").*

According to German constitutional law a patentable invention constitutes a legal right which is protected under Art. 14 GG even before a patent is granted.[48] The protection of property is, however, subject to Art. 14 (1) GG stating that its content and limits are determined by the law. When determining the content and limits of the right of property, the legislator has to comply with the principle of due process of law (*"Rechtsstaatsprinzip")* and in particular with the principle of legal trust.[49] These principles which are also laid down in Art. 14 GG prohibt *"truly retroactive"* laws, *i.e.* those which expressly apply to acts committed before the law comes into force.[50] In a recent judgement, the German Constitutional Court has also clarified the limits of *"untrue retroactivity"* of laws.[51] These principles prohibit an application of the amended GPA to patent applications filed and patents granted before it came into force.

As a consequence, any applicant having filed a patent application at the GPTO prior to February 28, 2005 should obtain a patent on the basis of the GPA as it was in force when the application was filed. Hence, neither the requirement to disclose a function along with the concrete industrial applicability of the sequence nor the limitation of any compound claim to a certain use/purpose as demanded by the new § 1a (3) and (4) GPA should apply to such a patent application. However, it remains to be seen to what extent the new law will influence the interpretation of the industrial applicability requirement by the GPTO and the German Federal Patent Court also to "old" , *i.e.* already pending applications and granted patents.

As regards infringement proceedings, the civil courts are bound by the grant of the patent[52] and must construe the scope of protection

48 Judgement of the German Constitutional Court (Bundesverfassungsgericht), BverfGE 36, 281, 290 ss.; Maunz/Dürig/Herzog/Papier, Art. 14 GG Rz. 198.
49 BVerfGE 72.9, 23.
50 BVerfGE 76, 263, 345.
51 BVerfGE 97, 67, 70.
52 Rogge GRUR Int. 1996 386.

conferred by the patent on the basis of the patent claims in accordance with § 14 GPA. The infringement courts have no authority to limit the patent claims by the insertion of additional features.[53] Hence, the infringement court can not limit retroactively the scope of protection conferred by a German patent which is based on an application filed prior to February 28, 2005 to the use/purpose or function potentially described in the patent application.

V. Relationship Between The New GPA And The EPC

When the 1981 German Patent Act came into force, substance protection for chemical compounds and pharmaceutical compositions was long acknowledged. The principle judgement of the German Federal Supreme Court *"Imidazoline"* by which the substance protection for new chemical compounds without any limitation to a particular purpose was acknowledged already issued on March 14, 1972.[54] With regard to a patent protecting the amino acid sequence of interferon gamma as well as any allelic variants thereof, the Federal Supreme Court confirmed this principle in its judgement *"Polyferon."*[55] Thus, protection extends to all possible uses of a compound, independently of the question whether the patentee has recognized an individual use and has described it in the patent.

Prior to the amended GPA, the scope of protection conferred by a German patent was identical to that conferred by the German part of a European Patent.[56] In the past, the wording of the patentability criteria found in the GPA and in the EPC were identical because of a prior harmonization. It was the express purpose of the German Patent Act on International Patent Conventions of June 21, 1976 to ensure the conformity of the GPA, *inter alia*, with the provisions of the EPC.

As the German legislator has now decided - almost 30 years after - the harmonization of the requirements for patentability under the EPC and the GPA, to diverge from the EPC and its Implementing Regulations through the insertion of § 1a (4) into the GPA, the issue arises whether this divergence could have any impact on the German part of a European patent or patent application.

The following example may be considered: A European patent application filed after February 28, 2005, and designating the contracting

53 This has been confirmed by a recent judgement of the Federal Supreme Court of September 7, 2004- X ZR 255/01 "Bodenseitige Vereinzelungsvorrichtung."

54 BGH GRUR 1972, 541 = BGHZ 1958, S. 280 – „Imidazoline."

55 BGH GRUR 1996, 190, 193 – Polyferon.

56 However, Art. II § 8 IntPatÜG determines that a German patent has no effect insofar as a German part of a European patent has been granted on the same invention to the inventor or his successor in law.

state Germany, describes the industrial applicability of a claimed sequence of a human gene and therefore satisfies the requirement of Rule 23e (3) of the Implementing Regulations to the EPC. The applicant seeks protection for claims which do not comprise, as a limiting feature, the disclosed concrete function of the sequence.

Three different issues must be distinguished:

(i) Will the EPO only apply the EPC and its Implementing Regulations or will it have to grant claims for the contracting state Germany in which the use/purpose is inserted as a limiting feature?

(ii) With regard to the German part of a granted European patent, will the German Federal Patent Court apply § 1a (4) GPA when its validity is challenged in German nullity proceedings?

(iii) Again, with regard to the German part of a granted European patent, will the infringement courts grant injunctions on the basis of such a patent against other uses/purposes which have neither been inserted into the patent claims nor even disclosed in the patent?

A. Irrelevance of the GPA for European Patent Applications Designating the Contracting State Germany

The sole basis for the prosecution and grant of European patents is the EPC which constitutes an international treaty. All requirements of patentability for European patents must have their legal basis in the EPC and its Implementing Regulations.

Art. 167 EPC provides for the possibility that a contracting state at the time of signature or when depositing its instrument of ratification or accession, can make a reservation. The list of reservations which can be made for a transitional period comprises in Art. 167 (2) (a) EPC that no protection is conferred on chemical, pharmaceutical or food products as such. In fact several contracting states to the EPC have made such reservations in the past when joining the EPC.[57]

Germany did not make any reservation based on Art. 167 (2) (a) EPC when it signed and deposited its instrument of ratification of the EPC. Art. 167 EPC excludes the possibility of making such reservation at a later date.

57 Austria made the reservations provided for in Art. 167 para 2 lit. a and d, OJ EPO 1979, 289; these reservations ceased to have effect after October 7, 1987. Greece and Spain made the reservations provided for in Art. 167 para 2 a, OJ EPO 1986, 200. These reservations ceased to have effect after October 7, 1992 , OJ EPO 1992, 301. According to Art. 167 para 5 the reservations apply for the whole patent term to patents which have been filed when the reservation was in force.

Therefore, the EPO is — with regard to Germany — not entitled to deny the protection for even naturally occurring human DNA sequences as long as the molecule fulfils the requirements of the EPC, specifically of Rules 23b to 23e of the Implementing Regulations. In particular, there is no legal basis to require that a use/purpose of such a sequence be inserted into the claim as a limiting feature.

B. Irrelevance of the GPA for Granted German Parts of European Patents

1. Nullity Proceedings

Art. 167 EPC is also relevant for the question of whether the German Federal Patent Court could declare the German part of a European patent invalid for the reason that a claim covering a sequence being identical with the sequence of a human gene is not limited to a use/purpose. As such a reservation according to Art. 167 (2) (a) EPC has not been made by Germany, the Federal Patent Court is not entitled to declare such patent invalid for the reason that it covers the sequence as such and is not limited to a particular purpose.

Article II § 6 of the German Act on International Patent Conventions determines the grounds on which the German part of a European patent can be declared invalid. In accordance with Art. 138 EPC, all these grounds are based on the EPC and do not refer to the GPA. Art. 138 and 139 EPC contain an exhaustive list of grounds for the nullity of European patents.[58] Obviously, the objective of the EPC to offer one procedure for the grant of a European patent in all designated contracting states based on the same requirements of patentability would be thwarted if the national part of such patent would be subject to different requirements in national nullity proceedings.

2. Infringement Proceedings

According to Art. 69 EPC the extent of protection conferred by a European patent shall be determined by the terms of the claims. As stated above, the infringement courts are bound by the grant of the patent and have no authority to introduce limiting features into a claim.[59] The infringement courts also have no authority to deny for the German part of a European patent a part of the extent of protection provided by Art.

58 BGH GRUR 1996, 757, 759- Zahnkranzfräser. Official Statement of reasoning for the German Act on International Patent Conventions, BlPMZ 1976, 322, 327 to § 6.

59 See above, section 3.4, and footnote 35.

69 EPC for the reason that the patent would not have been granted with such a scope under the GPA. This would deprive the European patent of its effect in a Contracting State. Only if a reservation has been made by a contracting state under Art. 167 EPC and only for as long as such reservation is applicable it is entitled to deny to a patent its protection in the scope of such reservation.

Hence, there is no room to limit the scope of protection of the German part of a European patent to the concrete function of a sequence being identical with the sequence of a human gene as long as such limitation is not a feature of the claim as granted.

C. The German Legislator Was Well Aware of the Irrelevance of the New GPA for the German Part of European Patents

The German legislator was well aware of the fact that the new GPA would not have any impact on the German part of European patents. This was reconfirmed in the context of the deliberations in the German Federal Parliament on the amendments of the GPA. The following question was addressed to the Ministry of Justice:

> Are there legal means of limiting the scope of protection a granted European patent confers in Germany, in the manner § 1a (4) of the amended patent act, does?.[60]

Answer: "(...) In accordance with the EPC the EPO determines the scope of protection finally and bindingly when it grants the European Patents (see Art. 69 EPC). In view of such European Patents a limitation of the scope of compound protection may only be accomplished by a change of the EPC or its implementing regulations respectively."[61]

Further it was commented in the German Federal Parliament that:

> ... However, the suggestion to incorporate the limitation of the scope of protection also in § 9 of the Patent Act was rejected ... Thus, ... the limitation of the scope of protection only applies to the future grant of patents by the German Patent Office, not however to patents with German applicability granted by the EPO.[62]

60 Written question raised by Dr. Joachim Pfeiffer (CDU/CSU), member of the German Federal Parliament (from federal printed paper 15/4595).

61 Written answer given on December 17, 2004 by the German Federal Government through parliamentary undersecretary Alfred Hartenbach (from federal printed paper 15/4595).

62 Bundestag, 146th session comment by Dr. Wolfgang Wodarg (SPD), Member of the German Federal Parliament.

Based on the above, practitioners should not file a separate set of claims for the contracting state Germany in order to comply with the new GPA. The GPA is and should remain completely irrelevant for the German part of a European patent.

Depending on the route chosen, be it prosecution before the GPTO or the EPO, the patentee will obtain two different scopes of protection both of which would be legally binding in a German court. Specifically, it seems as if this legal "12 tone music" was deliberately taken into account by the legislator.

VI. Can The Amended Version Of The Eu Directive As Now Implemented In The Gpa Be Considered A Breach Of European Law?

Reading the new GPA it is worthwhile to have a look at the grounds given by the European Parliament and the European Council for the Directive:

Recital 8 of Directive 98/44/EC points out unambiguously that the general rules for assessing the patentability shall also apply to biotechnological inventions and that there is no need to introduce a specific law applying to such inventions. Moreover, Recital 3 of the Directive underlines that an effective and harmonized protection in all Member States constitutes an essential requirement for that investments in the field of biotechnology are pursued and supported. Recital 7 of the Directive warns that an ununified development of legal provisions on the protection of biotechnological inventions in the Community could have additional unfavourable effects on the trade and therefore lead to disadvantages in the industrial development of the concerned inventions and the smooth functioning of the European Market.

It is obvious that the German legislator has disregarded these objectives of the Directive. The decision to introduce specific law only applying to certain biotech inventions and to deviate from the Directive as well as from its implementation by the Implementing Regulations to the EPC clearly thwarts the objectives of the Directive.[63] Art. 15 of the

63 Germany has not only amended its patent act to discriminate biotech inventions it has also amended its Utility Model Act excluding biotech inventions from protection. The reason for this decision has to be seen in the fear that utility Models not being examined but only registered may be used to circumvent the limitations for patentability set by § 1a (4) GPA to patents.

Directive does not leave that liberty of divergences to the Member States when fulfilling their obligation to implement it into their national law.

The European Court of Justice decided in a judgement of October 28, 2004 that Germany was in breach of European law as it had not implemented the Directive even 4 years after the term for such implementation had expired.[64] It is not unlikely that the ECJ will one day for a second time determine that Germany has not complied with European law as the GPA diverges substantially from the Directive. Such case could be referred to the ECJ for instance by the German Federal Supreme Court if and when an applicant challenges the decision of the GPTO not to grant a patent on a sequence without limitation to the disclosed concrete function.

VII. Filing Strategies In View Of The Difference Between The German Implementation Act, European Patent Convention And The Applicable Law In Other Countries: The Drying Out Of The German Patent Office

One of the implications that is only apparent at second glance is the potential danger this new GPA poses for German applicants in terms of global competition. In order to exemplify this point we will make the following example.

Suppose a US company (US-C) as well as a German company (DE-C) are working on cloning the same gene, *i.e.* the therapeutic use of its encoded protein. Let us further assume, that US-C is advised by a US patent counsel and DE-C by a German patent counsel on the patentability requirements in their respective countries. Based thereon US-C would obtain a substantially earlier priority filing date as DE-C if indeed there is a difference between the US patentability requirements that demand concrete and credible utility whereas the German legislator apparently demands something more in terms of characterizing "biological function" not only based on practical considerations but also on academic requirements (whatever this may turn out to mean in practice). The latter would require additional experimentation and, thus, time, because it appears to go beyond the usual focus of pharmaceutical development. Applying such a filing strategy oriented towards fulfilling all theoretically possible patentability requirements in Germany would be detrimental to DE-C. DE-C would effectively loose the US market to its US competitor.

64 See also footnote 16.

On the other hand, ignoring the meanwhile apparently applicable German patentability attitude, DE-C would file its application in time to compete with US-C. In the broader context, such filing scenarios — which appear to make a lot more sense — could result in situations where German companies would get patents in foreign countries which residents from these countries could not get in Germany — a lack of reciprocity that will hardly be tremendously welcome by other countries' governments.

Finally, concerning our example, only patent applications filed subsequently to those effective for other countries might be able to comply with the disclosure requirements that the not very practically oriented GPA has in mind. But in what protection could such patent applications result in Germany? If the earlier applications have already been published, it is hardly conceivable that further experimental clarification of the actual "biological function" to suffice for the German standard can improve an already practically applicable invention to an extent that would make the subject matter of the purpose-limited claims inventive in the German application. As a consequence, there may be no reason whatsoever to consider such "improved" filings in Germany. This takes us to the view expressed by other authors, *i.e.* that the German "adoption" of the EU Biotech Directive will lead to a "drying out" [65] of the German Patent Office. Our analysis of the new GPA — including the above examples — gives good reasons for this prediction to become true. However, the following statistical survey indicates that any possible "drying out" would already start from a rather low level of application activity.

The survey we have carried out summarizes the number of biotech patent applications published between 1995 and 2004 at the GPTO in comparison to the EPO. We have chosen International Patent Classification (IPC) section C12N (micro-organisms or enzymes and compositions thereof) and IPC C12N15 (mutation or genetic engineering; DNA or RNA concerning genetic engineering vectors, e.g. plasmids, or their isolation, preparation or purification; use of hosts therefore) as representative classes for biotech and genetic engineering patent applications. As is evident from the following Table I and the following Figures 1 and 2, the number of biotech and genetic engineering patent applications per year in the GPTO can only be considered as a minor fraction of the number of such patent applications in the EPO.

65 Bernd Hansen, „Hände weg vom absoluten Stoffschutz – auch bei DNA Sequenzen"; Mitt. 2001, 477 ss.

Table 1

IPC C12N: Biotech										
	1995	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
EPO	1015	1101	1360	1619	1748	2472	2628	2598	2461	2136
GPTO	61	63	84	87	113	150	193	286	226	129
IPC C12N15: Genetic Engineering										
	1995	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
EPO	769	874	1058	1250	1382	1989	2064	1995	1857	1323
GPTO	28	37	55	57	59	80	89	154	113	53

Figure 1

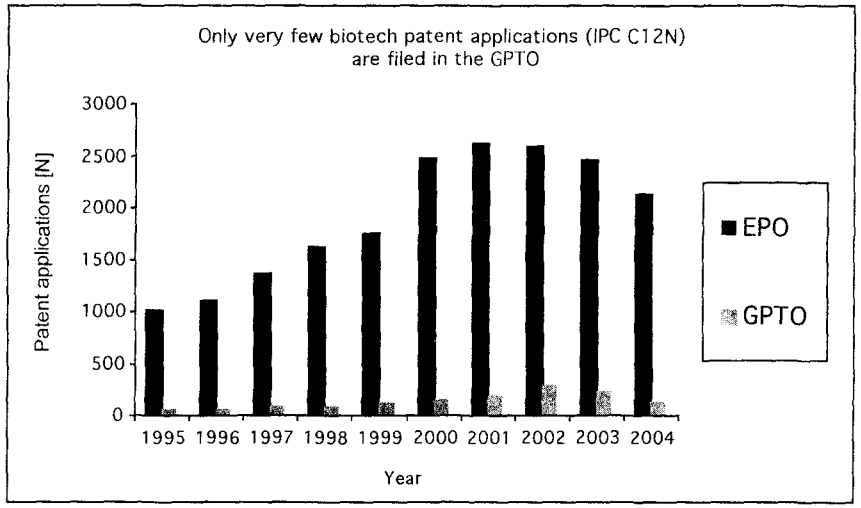


Figure 2

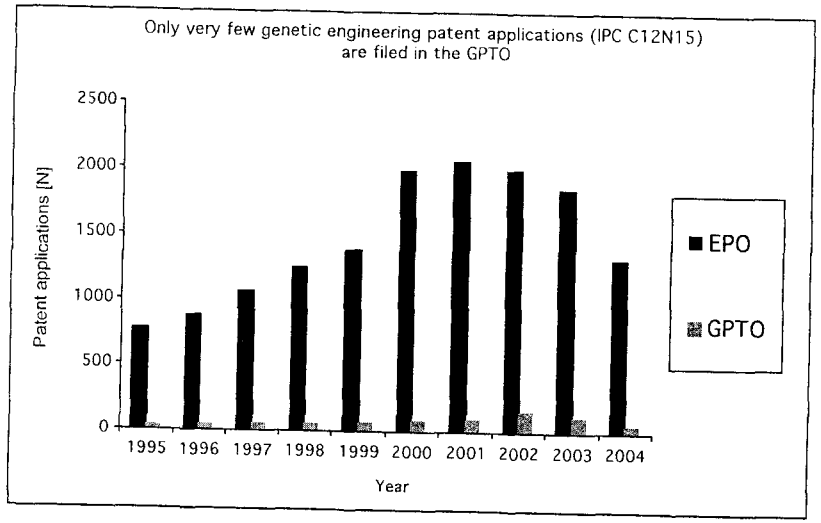


Figure 3

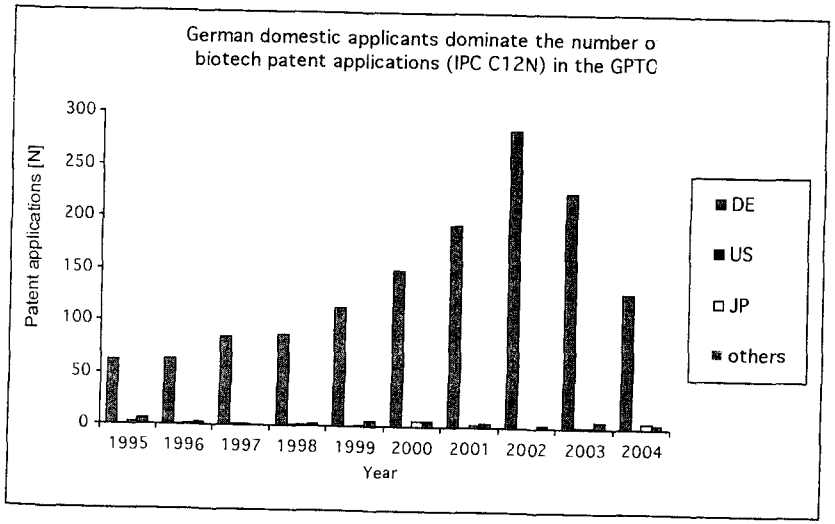
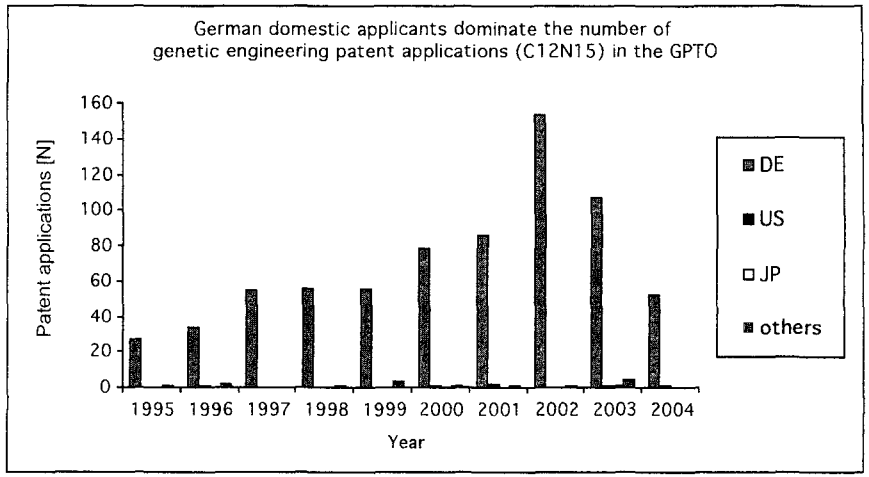


Figure 4



For further analyzing the situation, we have split up the number of published patent applications/year in the GPTO in the biotech patent application class IPC C12N and in the genetic engineering patent application class IPC C12N15 between German, Japanese and US applicants:

The following statistical data provide a rather clear picture: first, there are far less patent applications for biotech and genetic engineering inventions in the GPTO in comparison to the EPO and, second, those that are filed in the GPTO for such inventions are predominantly filed by German domestic applicants, in all likelihood most of them to establish a Paris Convention priority. If the new GPA would lead to a further reduction, hardly any patent application activity in that technical field would be left!

As the German Federal Patent Court recruits its technical judges from the GPTO, such "drying out" of practice and competence of the GPTO in the field of biotechnology could also in the long term have a negative impact on the technical competence of the judges at this Court in the field of biotechnology. As the German Federal Patent Court is also competent to hear nullity cases on the German part of European patents, such development should raise serious concerns.

Table 2

IPC C12N: Biotech										
	1995	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
DE	61	63	84	87	113	150	193	286	226	129
US	0	0	1	1	0	0	0	0	2	0
JP	3	2	2	1	1	5	3	0	2	5
others	5	3	0	3	5	5	4	3	7	4
IPC C12N15: Genetic Engineering										
	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
DE	27	34	55	56	56	78	86	153	107	52
US	0	1	0	0	0	1	2	0	1	1
JP	0	0	0	0	0	0	0	0	1	0
others	1	2	0	1	3	1	1	1	4	0

VIII. Writing Patent Applications And Drafting Claims

In view of the new situation in Germany and in view of the uncertainties created by the new GPA it appears recommendable to also take precautions in the prosecution of *European patent applications* in the EPO.

It seems advisable to carefully disclose all details known about the function of the gene concerned, especially also with respect to the encoded protein, when filing the application. In this context, all feasible levels should be considered, such as pharmaceutical usefulness, biological activity and how the biological activity causes the pharmaceutical effect. On the other hand disclosing too many different hypothetical functions bears the risk that some of them turn out to be incorrect. This could have really detrimental effects, especially if only

some of the functions provided as a "laundry list" are real ones. Picking and choosing from such a list might be considered as an inadmissible selection while it could very well also be considered as a deletion of items from the list that are actually given up. In summary, this precautionary measure probably is one that has been taken in the past in most patent applications in this area anyway.

For *German national patent applications* the same drafting strategy should be applied. Furthermore, any set of claims should start with a true compound claim for nucleic acids without any limitation. Subsequent claims could then provide fall back positions for certain use/purpose limitations of the nucleic acid claim. Separate claims could be drafted for any disclosed uses. To limit the requested scope of protection of any claimed nucleic acid to certain purposes/uses right away appears to prematurely give up territory that might turn out to be patentable after all if the German "adoption" is found to contradict European Community law.

In all these approaches it should be borne in mind that the *purpose limited compound protection* now established in Germany for certain DNAs *does not apply to any encoded proteins*. Thus, there should always be true compound claims for the encoded proteins.

Finally, here a claim that so far was a practical approach to protect a new and inventive human DNA/RNA:

1. A nucleic acid selected from the group consisting of
   (a) nucleic acids encoding the polypeptide having the amino acid sequence as shown in SEQ ID NO: 2;
   (b) the nucleic acid of SEQ ID NO: 1 [i.e., the one that is disclosed as the example encoding said polypeptide]; and
   (c) nucleic acids that are at least X% identical to the nucleic acids given in (a) or (b), above, and which encode a protein having the biological activity Y;
   or the complementary strand thereof.

2. The nucleic acid of claim 1 which is a DNA or an RNA.
   In the conventional sets of claims applied so far, proteins were frequently claimed by depending on the definition provided in the exemplified nucleic acid claim:

n. A protein encoded by a nucleic acid of claim 1 or 2.

IX. Conclusions

Germany has failed to truly adopt the EU Biotech Directive by introducing purpose-limited compound protection for certain nucleic acids. How to disclose a sufficient "concrete function" in the patent application is unclear. It is open whether only experimental evidence disclosed in the application as filed can be relied upon. It is also unclear how to practically sufficiently define the purpose to which the compound protection is to be limited in a claim. The purpose-limitation of compound protection might only apply to DNA, not to RNA. The purpose-limitation might not apply to cDNAs. There is a risk that the new German law will be interpreted so as to mean that not only DNA sequences actually occurring in the human genome but also structurally similar ones from other organisms or even engineered ones might be excluded from absolute compound protection in the future. There is no exclusion of absolute compound protection for the proteins encoded by the DNA sequences concerned.

Germany has given up the idea of reciprocity in the international patenting framework. German companies can now — or still — get absolute patent protection in other countries, in particular in the US and in Japan, while US or Japanese companies will not get such an absolute compound protection any more for certain "sequences" in Germany, unless they file at the EPO, designating the contracting state Germany.

The practical effect of Germany's "adoption" of the EU Biotech Directive may be very limited. Only patent applications filed as of February 28, 2005 at the GPTO will be concerned. Already in the last couple of years, however, there only was a rather low number of national German biotech patent applications.

Whereas the effect of the new GPA on German patents and patent applications in the field of biotechnology will be highly detrimental in the future, the new GPA should be irrelevant in all likelihood for the German part of European patents and patent applications. Neither the validity nor the scope of protection conferred by the German part of a European patent should be directly affected by the GPA. What can not be excluded is that the new GPA influences the jurisdiction of the German Courts on the disclosure requirements for industrial applicability both for national German patents and the German parts of European patents.

Christiaan Barnard crossed medical and ethical boundaries when he performed the first heart transplantation in Cape Town on December 3, 1976. In Germany politicians voiced that this act was to be condemned

as unethical and unfit for human beings. Humans were demoted to the rank of experimental animals and used "for spare part surgery". It was argued that the heart — the location of moral and emotions — should be left untouched.

One may ask what would have happened had these considerations led to laws limiting or forbidding heart transplantations in Germany. Specialists would have left Germany in even greater number. Patients would have forced to travel abroad for heart surgery. Germany would have become a "third world country" in the field of heart transplantation.

Similarly the field of biotechnology and biotech patent law rouses certain concerns and emotions and, thus, sadly also poses great opportunity for catching people's votes in the political arena.