ARE EXPRESSED SEQUENCE TAGS PATENTABLE UNDER THE EUROPEAN PATENT CONVENTION? A PRACTITIONER'S VIEW

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The Human Genome Project (HGP) has provided a large amount of sequence information about the human genome. One type of sequence information obtained relates to expressed sequence tags (ESTs), i.e. partial DNA sequences of expressed genes. These ESTs are usually between 300 and 500 nucleotides in length. In many cases the sequence is unique to a degree that allows the identification of the corresponding gene. The EST sequence in most cases does not provide definitive information about the biological function of the corresponding entire gene. The patentability of ESTs has become an important major object of discussion over the last years in patent literature[1]. The ongoing discussion lead in the US to the current practice of the USPTO to acknowledge, in principle, the patentability of ESTs[2]. The first EST patent in the US has issued.[3]

To the best of the author's knowledge, however, there is no decision of an Appeal Board of the European Patent Office (EPO) that addresses the Office's view of the patentability of EST's. The trilateral web site of the EPO cited in note one discuses several scenarios under which an EST might be patentable, however, that discussion is not binding on EPO examiners.

This article will examine whether any Article of the EPC or existing Case Law excludes the patenting of ESTs, even if the only known function of the EST is its use as a probe for screening libraries. Part II will discuss the probable impact of the new EU Biotechnology Directive, in force since July 30, 1998, on the patentability of ESTs before the EPO. Finally, the article will suggest a proper claim scope for EST patents.

1. Relevant Provisions of the EPC for the Patentability of ESTs

The question to be addressed in this Part 1 is whether a claim could be patentable reading

„Nucleic acid consisting of the sequence of SEQ ID No 1"

even if there is no information available about the biological function of the claimed EST (i.e. the sequence according to SEQ ID No 1). The following discussion assumes that the only known function that can be stated in the application claiming the EST is its use as a probe for screening libraries, mapping, or studies of variability of that sequence among different individuals or groups.

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1 *See e.g.* Jeffrey D. Isaacs. Gene Patenting, http://www.cs.dartmouth.edu/jisaacs/patent.html; Lynn Pasahow and Andrew Kumamoto, National Law Journal, October 20, 1997; http://www.ljx.com/patents/1020 genome.html; Joseph Strauss in IIC 06/1995, page 920; Martin Grund und Volker Vossius, BSLR 3 (1998), page 106; Andreas Oser in IIC 01/1999, page 1)

2 *See* Margaret Parr, Biotech Practice Specialist of the USPTO at a round table discussion of the Patent and Licensing Agency for the German Human Genome Project on June 23 and 24, 1998, Munich, Germany; and John Doll, Science 280, page 689 (1998).

3 U.S. Pat. No.5,817,479, October 6, 1998, Human kinase homologs.

1.1 Does Article 52 EPC exclude a patent for an EST?

Paragraph 1 of Article 52 states that European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step while paragraph 2 excludes several matters from patent protection.

Paragraph 2 reads as follows:

The following in particular shall not be regarded as inventions within the meaning of paragraph 1: a) Discoveries ...

ESTs are part of a naturally occurring product, such as a gene, and hence might be treated under patent law as any other naturally occurring product. Case law, such as the Relaxin Case,[4] as well as the Guidelines for Examination in the European Patent Office (in the following "Guidelines") clearly acknowledge the patentability of natural products under certain circumstances. The Guidelines explicitly state in Part C, Chapter IV, Item 2.3, in connection with **Discoveries**:

To find a substance freely-occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterized, either by structure, by the process by which it is obtained or by other parameters…. and it is „new" in the absolute sense of having no previously recognized existence, then the substance per se may be patentable.

Since an EST can be properly characterized by its structure, i.e. the nucleotide sequence, identification and provision of the EST is no longer merely „discovery" but an invention in the sense of Article 52(1) EPC. Therefore, Article 52(2) EPC excluding discoveries from patentability does not constitute a bar to the patentability of ESTs.

1.2 Does Article 53 EPC exclude a patent for an EST?

Article 53(a) EPC excludes from patent protection:

Inventions, the publication or exploitation of which would be contrary to „ordre public" or „morality" provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states.

A first bar to the patentability of ESTs could be seen in the exclusion of inventions being contrary to „ordre public."

The Guidelines (Part C, Chapter IV, item 3.1) state in connection with Article 53(a):

to exclude from protection inventions likely to induce riot or public disorders or to lead to criminal or other generally offensive behavior ... This provision is likely to be involved only in rare and extreme cases.

In Decision T 356/93 Plant Cells/PLANT GENETIC SYTEMS[5] an Appeal Board further stated:

The concept of „ordre public" covers the protection of public security and the physical integrity of individuals as part of society ... Accordingly, under Article 53(a) EPC inventions, said exploitation of which is likely to breach public peace or social order or to seriously prejudice the environment are to be excluded from patentability as being contrary to „order public."

The question as to whether any invention might contravene „ordre public" is to be considered in each particular case on its

4 Official Journal EPO, 1995, page 388

5 Official Journal EPO 1995, 545 (hereinafter PLANT GENETIC SYSTEMS)

merits.[6] It is hardly conceivable that an EST could fall into the category of inventions that are likely to breach public peace or seriously prejudice the environment and, therefore, be in conflict with the „ordre public“ according to Article 53(a) EPC.

The second aspect of Article 53(a) relates to the exclusion of inventions contravening morality. As stated above in connection with "ordre public", the question as to whether a claimed invention violates the concept of morality also has to be answered in each particular case on its merits.[7] The mere fact that an invention involves gene technology cannot render the invention „more contrary to morality“ than inventions involving other techniques. In PLANT GENETIC SYSTEMS the Board stated in connection with plant biotechnology:

Plant biotechnology per se cannot be regarded as being more contrary to morality than traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation…. Like any other tool, plant genetic engineering techniques can be used for constructive or destructive purposes. It would undoubtedly be against „ordre public“ or morality to propose a misuse or a destructive use of these techniques (item 17.1).

Therefore, the fact that an EST is obtained by applying “gene technology” does not render the EST per se as contravening morality. Thus, unless the specific circumstances of the case should give rise to an objection under Article 53(a) EPC, it is reasonable to assume that Article 53(a) EPC does not constitute a severe bar to obtaining a patent for an EST.

6 *Id.* PLANT GENETIC SYSTEMS at 13
7 *Id.*

1.3. Does Article 54 EPC exclude a patent for an EST?

According to Article 54 EPC, an invention is considered to be new if it does not form part of the state of the art, the state of the art comprising everything made available to the public by means of written or oral description, by use or any other way.

Novelty of the EST would, therefore, be given if the sequence is not found in the prior art such as a public database or a pre-published document. In this context it is worth noting that a single nucleotide difference between a prior art sequence and the EST would be sufficient to establish novelty of the EST. Moreover, the fact that the sequence of the EST in question was contained in a publicly available gene bank does not destroy the novelty of the EST.

In T 301/87 Alpha-Interferon/BIOGEN“[8] an Appeal Board decided that the public availability of a cDNA library (referred to in the decision as „Lawn’s gene bank“) did not render each clone of the c-DNA library to be state of the art. The Board explicitly states:

Accordingly, the mere existence of a DNA coding for a polypeptide of the IFN-alpha type within the multitude of clones of „Lawn's gene bank“ cannot automatically mean that the chemical compound (polynucleotide) concerned does become part of the state of the art. The latter would only then be the case if the existence of the compounds concerned had recognisably been made publicly available (item 5.8).

Therefore, if the sequence of the EST has not been made available to the public by any means, novelty is given. This could easily be examined. In this context, it is further to be noted that if the prior art discloses the existence of the full-length gene containing the EST sequence, it would not render the actual EST sequence

8 Official Journal EPO 1990, 335.

non-novel, as decided in T 886/91 (Hepatitis B Virus/BIOGEN, INC.“) (not published in the Official Journal EPO) where the Board stated under item 8.1.3:

Document (1) ... does not report any definite sequence data which can be said to affect the novelty of the claims at issue. In fact, although the nucleotide sequences referred to in the latter are likely to be contained in the said fragments, they are not identified and characterized in the exact primary structure, thus they are not made available in the sense of Article 54(2) EPC.

To summarize, so long as a reference does not disclose the EST as such, novelty of a claim using the “consisting of” wording and being directed to the EST should be acknowledged.

1.4. Does Article 56 EPC exclude a patent for an EST?

According to Article 56 EPC

[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

As for any chemical product the question as to whether the claimed product involves an inventive step has to be decided on a case by case basis. In the absence of any sequence in the prior art showing high homology to the EST in question there would be no information in the prior art which could make the claimed EST obvious. Consequently, the requirement of Article 56 EPC would be met.

According to Gugerell[9] an EST might not be patentable because the EST would not solve a technical problem. Gugerell stated:

If the technical problem underlying the alleged invention is to be considered as the provision of human genes probed by the ESTs but these genes have not yet been provided and have unknown functions, it could be argued that the invention as disclosed does not solve this problem.[10]

One might follow this argument if the technical problem is indeed formulated as proposed by Gugerell.

However, one could also see the technical problem underlying the invention as being the provision of a further probe being useful for identifying and isolating genes. The EST disclosed by the patent would solve this objective.

When objecting to the inventive step of the EST by arguing that the EST would not be useful for identifying and isolating genes (i.e. it would not solve the underlying object), the burden of proof is on the Patent Office’s side. Hence, the Patent Office would have to support the objection raised. Only if the specific circumstances of the case provide evidence that the claimed EST indeed might not be useful as a probe, would the burden of proof to demonstrate the usefulness of the claimed EST shift to the Applicant. The Patent Office therefore would have to rely on evidence to support their inventive step objection.

In a chemical case, T 939/92 „Triazole/ AGREVO“[11] the Board objected to a claim directed to a large number of triazole sulphonamides that, according to the specification, should be useful as herbicides. The specification provided a few examples of compounds falling under the claim and being useful as herbicides. Because the general formula of the claim comprised a large number of different compounds and the example only showed the herbicidal characteristics for a few compounds, the Board concluded that the

9 Patenting of Human Genes and Living Organisms, F. Vogel and R. Grunwald, Berlin, Heidelberg, New York,1994.

10 *Id.*

11 Official Journal EPO 1996, 309.

burden of proof had shifted to the Patentee to demonstrate that indeed all of the claimed compounds would show an herbicidal effect. The Board explicitly stated under item 2.6.1:

[I]f it is evident that the number of compounds claimed is such that it is **inherently unlikely** that all of them or at least substantially all of them will possess the promised activity, then the burden of proof of that fact, i.e. the possession of that activity can indeed only rest upon the shoulders of the person alleging it.

In the case of an EST that is of sufficient length to be useful as a probe and which does not contain sequence peculiarities, such as inverted repeats, that might render the sequence unsuitable as a probe, it is difficult to think of evidence to rely on by the Patent Office to support an inventive step objection. If the posed object underlying the EST application were to provide a further probe useful for screening libraries, the Patent Office would need good arguments to contest the usefulness of the EST as a probe. Mere allegation by the Patent Office that the EST could not solve the underlying object, is insufficient.

However, even if the Examining Division were to question whether the EST would indeed be useful as a probe, the applicant would still be in the position to provide further evidence - after the filing date - either by test results or by other means, that the claimed EST actually solves the underlying problem. In other words, the applicant could defend his invention by filing data demonstrating the successful isolation of a gene when using the claimed EST. This evidence could be filed, as mentioned above, after the filing date.[12]

An alternative for arguing against the inventive step of an EST - according to Gugerell at the round table discussion[13]- could be the line of argumentation used in the „Triazole/AGREVO“ decision.[14]. The starting point for denying the inventive step of the claimed compunds in T939/92 was that the Board cam to the conclusion that not all compounds claimed showed the alleged herbicidal activity. In such a case, not all compounds claimed would have the alleged characteristics and, hence, not all compounds would solve the problem underlying the invention. The Board argued therefore, that a more general object would have to be defined in order to fulfill the requirement that all compounds of an allowable claim must solve the underlying object. Since the application underlying T 939/92[15] did not disclose any other characteristic of the claimed compounds than the herbicidal activity, the Board stated that in such a case the underlying object could only be seen in the provision of further chemical compounds as such. The Board explicitly stated under item 2.5:

Using the above approach of the Boards [the Problem-Solution approach; note added by the author] and having regard to the cited state of the art, in this case the Board considers that if the claimed compounds were to be assumed not to have any technical useful property, then it could be postulated that the technical problem which is solved by the claimed compounds …would be the minimalist one in such a situation, namely the mere provision of further (or alternative) chemical compounds as such regardless of their likely useful properties.

The Board then came to the conclusion that the mere provision of further chemical compounds would not be patentable.

However, the Board’s reasoning in AGREVO, however, does not fit in the EST situation. The object underlying the EST application could be formulated as

12 *See* e.g. T 939/92 Triazole/AGREVO (hereinafter AGREVO), item 6.7; similarly the Guidelines, Part C, Chapter IV, Item 9.10.

13 In Vogel, *supra* note 9.
14 T 939/92 (AGREVO).
15 AGREVO, s*upra* note 12.

providing further probes useful for screening libraries. In other words, in the case of ESTs the object is not to provide compounds as a subject for screening, many of which in a screening process would show to be useless, as in AGREVO. Rather, each of the ESTs has value for use as a tool in the process of screening unknown mixtures, that is, with the technical effect of being useful for screening libraries.

Therefore, the facts in AGREVO are not comparable with the EST issue and could not form a proper basis for rejecting an EST claim on the basis of lacking an inventive step.

A claim directed to an hitherto unknown EST should, therefore, involve an inventive step in the absence of any further related prior art sequences which could make the claimed EST obvious. [16]

16 This discussion assumes that the protein encoded by the full length gene from which the EST derives is unknown and does not resolve the issue of what sort of prior art sequences would render a gene sequence obvious and lacking an inventive step, particularly where the prior sequence information is the amino acid sequence of the protein. In the United States, the Court of Appeals for the Federal Circuit, per Judge Lourie, has held that the existence of a prior amino acid sequence and the generally obvious means to proceed from the amino acid sequence to the gene sequence does NOT render the gene sequence obvious and unpatentable. Lourie's reasoning is essentially that since what is claimed is the sequence as a composition of matter, and not the method for obtaining the sequence, the resulting sequence could never be predicted in advance from among the huge number of potential nucleotide sequences all encoding the same protein, and therefore is nonobvious and patentable. *In Re Deuel*, 51 F.3d 1552 (CAFC 1995). Since the amino acid does suggest probes suitable for screening a c-DNA library (*Id.)*, the EST may in such a case lack an inventive step. The full consideration of this issue is beyond the scope of this article.

1.5. Does Article 57 EPC exclude a patent for an EST?

Generally, the relevance of Article 57 - the industrial application requirement - constitutes no bar to the patentability of a chemical compound. Article 57 states:

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

There is no doubt that an EST could be made, e.g. by chemical synthesis in a commercial institution and used in a pharmaceutical company, which would be one kind of industry, so that Article 57 EPC would be fulfilled. Therefore, the industrial application requirement under the EPC is of a much lower standard than the utility required under the US practice which requires somewhat more information about the invention to fulfill the US utility requirement.

Besides these basic requirements of novelty, inventive step and industrial application, to be patentable under Articles 52 to 57 EPC, a European patent application must also fulfill several additional requirements. The additional requirements which would be most relevant to EST patent applications are Articles 82 to 84 EPC. In the next sections of this paper ,Articles 83 and 84 concerning the substantive requirements of sufficiency of disclosure and support by the specification are first discussed before dealing with Article 82, the formal requirement of unity of the application.

1.6. Does Article 83 EPC exclude a patent for an EST?

Article 83 EPC requires:

[T]he European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a skilled person in the art.

An application directed to an EST should not meet with greater problems under Article 83 EPC than any other application directed to a gene or a protein. In any case, by mere indication of the sequence a skilled person should be in the position to prepare the EST, e.g. by chemical synthesis. Therefore, Article 83 does not create any severe bar to obtaining a patent for an EST.

1.7 Does Article 84 EPC exclude a patent for an EST?

Article 84 states:

The claims define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

A claim directed to an EST should also not be more problematic under Article 84 than any other claim directed to a protein or nucleic acid sequence.

Therefore, a claim with the wording:

„DNA consisting of a sequence according to SEQ ID NO. ...“

should not give rise to any problems under Article 84 EPC, neither with respect to the clarity of the claim wording nor to the support in the specification.

The question as to what extent derivatives of an EST could be incorporated into the claim wording depends on the circumstances of a specific case. If there is no sufficient information available to define the function of the derivatives, which will often be the case for ESTs, one might try to broaden the claim by defining the derivatives by their hybridization characteristics to the specific EST or by the definition of a degree of homology between the EST and the derivatives. In this context it should be noted that the EPC does not have a counterpart to the US "written description requirement". Therefore under the EPC one may obtain a "genus" claim even if only one specific sequence is disclosed. A prerequisite is that the genus claim must fulfill all patentability requirements according to Articles 52 to 57 EPC and the sufficiency of disclosure and clarity requirement of Articles 83 and Article 84 EPC. The question as to whether the application contains sufficient information to prepare all embodiments over the whole range claimed (Article 83 EPC) is a question which can only be answered on a case by case basis.

To summarize, as regards the substantive requirements for obtaining a patent for an EST under the EPC there is no stipulation or case law that *a priori* would prevent an applicant from obtaining a patent for the EST. However, from the practical or economic standpoint, a more severe bar for obtaining patent protection for a large number of unrelated ESTs could be seen in Article 82 EPC which is discussed in the next section.

1.8 Does Article 82 EPC practically exclude a patent for an EST?

Said Article states:

The European patent application shall relate to one invention only or to a group of inventions so-linked as to form a single general inventive concept.

As long as the claims of the European patent application are directed to one EST only Article 82 should not create any problems. However, as soon as two or more ESTs are claimed, Article 82 will become relevant. It is reasonable to assume that in most cases the ESTs contained within one application are structurally and functionally non-related. In such a case it will be difficult for an applicant to argue that the different ESTs are linked by a single general inventive concept, particularly if no function of the claimed ESTs is known except suitability for being used as probes. In such a case the Patent Office could ask the applicant to prosecute the application in question based on one of the several ESTs only.

The ESTs no longer prosecuted in the application could be made the subject of subsequent divisional applications that would, however, incur additional costs since for each separate EST application all fees for an application would fall due. The decision as to which ESTs should be further prosecuted has to be made at the latest when the parent application, directed to the first selected EST, fulfills all the EPC requirements and the applicant has to file his approval to the documents forming the basis for grant. This time frame, in the case of a PCT application using Chapter II, can be expected to be around 4 to 6 years after the priority date. It is to be noted that the first divisional application could be treated as the parent application for a further divisional application This means that a further second divisional application can be filed that is based on the first divisional application, the further second divisional application containing again those EST's that are patented neither in the parent application or the first divisional application.

To summarize, although the substantive requirements of the EPC do not exclude an EST from patenting, the formal requirements of Article 82 could make it expensive for an applicant to obtain patent protection for a large number of different ESTs.

2. Could the EU Biotechnology Directive increase the standards for obtaining a patent for ESTs?

The Biotechnology Directive of the European Union came into force on July 30, 1998 and has to be incorporated into the national laws of the Member States by July 30, 2000.

It is to be noted that the Directive is directed to the Member States of the EU but not to an international organization like the European Patent Organization. The non-binding character of the EU Directive for the European Patent Office was also questioned by an Appeal Board of the EPO in the referral decision T 1054/96 "Transgenic Plants/NOVARTIS."[17] However, the Patent Office, of course, would not be prevented from considering the regulations of the EU Directive for interpreting Articles of the EPC when deciding on the patentability of ESTs. Rather, it would be highly desirable if the EPO would consider the Directive and therefore apply the same criteria with regard to the patentability requirements as the national patent offices. The Appeal Board acknowledged this in NOVARTIS.[18]

Assuming that the standards of the EU Directive are applied by the Patent Office in future cases, the standard for obtaining an EST patent might be raised. The reason for this possibility is based on the following Articles of the Directive. Article 5, Paragraph 3 of the Directive requires:

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

The Articles of the Directive do not define what information is necessary to fulfill this disclosure requirement. In addition, Recital 23 of the Directive declares that a DNA sequence without indication of a function does not contain any technical information and is, therefore, not a patentable invention. Finally, Recital 24 of the Directive requires that where the claimed use of a sequence or partial sequence is to produce a protein or a part of a protein, the application must specify which protein or part of the protein is produced or what function it performs (Recital 24 of the Directive).

It is presently not clear whether the "function" of the EST "to be useful as a probe" might be sufficient to establish the industrial application requirement of Article 5(3) of the Directive. It should, however, be sufficient for the industrial application requirement if it is indicated that the EST is e.g. useful as a species or tissue

17 Official Journal EPO 1998, 511 at items 72 to 75 (hereinafter NOVARTIS).
18 *Id*. at 72.

specific probe, or for forensic purposes, or as genetic marker etc. The industrial application requirement should be satisfied if the EST fulfills at least **one** such function, and it should not be detrimental to the validity of the patent if some of the several functions indicated in an application should turn out not to be associated with the EST.

To summarize, if the principles of the EU Directive are applied by the EPO, it might provide the Patent Office with a basis for increasing the standards to obtain an EST patent. To what degree the standards might be raised is a still open question.

3. The proper scope of claims for an EST patent

When applying the present practice of the European patent office regarding the allowability of DNA claims, one may conclude that an EST claim containing the "comprising" language will be allowable. This in turn would mean that an allowed claim reading

"Nucleic acid comprising a sequence according to SEQ ID NO. 1"

would read on and be infringed by the full length DNA coding for the biologically active protein and including with it the previously claimed EST. This in turn would mean that a third party who identified the complete gene and the biological activity of the protein encoded thereby would literally infringe the EST claim when the full length sequence is used, for example, to express the protein.

At least in Germany the defendant in such a lawsuit could not raise as a defense in the infringement proceedings the fact that the EST patent does not contain an enabling disclosure for the entire gene. In Germany, the defendant would have to start a separate proceeding before the German Federal Patent Court to try to invalidate the EST patent, at least to the extent that it would no longer cover the complete gene.

One might well question whether such a result, which would be obtained by granting claims containing the "comprising" wording, is desired. In the author's opinion the answer is "No." This in turn raises the question of what should be the desirable form of an allowable EST claim. One answer would be to grant EST patents in a scope that is fair to the patentee and adequate under consideration of the patentee's contribution to the art. This concept is nothing new and has already been applied by an Appeal Board, for example in decision T 0694/92 „Modifying Plant Cells/MYCOGEN“,[19] where the Appeal Board stated:

A proper balance must be found between, on the one hand,

the **actual** technical contribution to the state of the

art that the invention disclosed in said patent or patent

application, if any and, on the other hand, the **manner of**

claiming so that, if patent protection is granted its scope

is fair and adequate (item 3).

Therefore it must be decided what is a fair and adequate claim scope for an EST, the only known "function" of which is its suitability for screening libraries. As stated above, the author is of the opinion that it would be too broad a claim scope if an EST patent would dominate the full-length gene and even could dominate the use of the full-length gene for preparing a protein having a desirable biological activity. In the author's opinion the contribution to the state of the art by an EST is not such that a claim scope would be justified which would cover the full-length gene.

On the other hand, it appears to be unfair to the applicant of an EST if the claim

19 Official Journal EPO 1997, 408.

would be limited to a nucleic acid consisting of the EST sequence. A compromise between said two extremes, the "comprising" language and the "consisting" language should be found by the Patent Office. One possibility could be to allow claims covering further embodiments besides the one specific EST, such as sequences that are homologous to a certain degree to the given EST. Such a claim could cover shorter fragments than the disclosed EST as well as derivatives derived therefrom including those containing some substitutions, as long as the degree of homology is within a certain range, e.g. 90% homology.[20]

There are further possibilities for broadening the claim in an application directed to a specific EST without necessarily resulting in a claim wording comprising the full length sequence, the latter not having been enabled or put into the public domain by the disclosure of the EST only. The extent to which a claim could be broadened, of course, depends on the facts of the case, in particular the breadth of applicant's own disclosure.

IV. Summary

1. There is currently no regulation under the EPC or any case law which *a priori* would prevent an applicant from obtaining a patent for an EST, the only known function of the EST being its usefulness as a probe for screening libraries.

2. The Appeal Boards of the EPO could raise the present standard of the EPC for obtaining EST patents by applying the requirements of the EU Biotechnology Directive to the practice of the EPO. The Biotechnology Directive requires to indicate the industrial application of an EST in a patent application. Said requirement is not laid down in the EPC.

3. The current practice of the EPO with regard to claims directed to nucleic acids is to allow the "comprising" wording in the claims. When applying this practice also in connection with an EST the resulting claim would dominate any embodiment that contains the EST as part of the sequence and the entire gene as well. There is already case law, however, that could form the basis for requesting a limitation of an EST claim to no longer comprise the full-length gene.

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20 Of course the problem of the narrow scope of the consisting of language would be handled in the United States by the doctrine of equivalents, see *Hilton-Davis Chemical Co. v. Warner-Jenkinson Co*. , 116 S. Ct. 1014 (1996).