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in the name of the Hungarian Group
by Zsuzsa LÁNG, Éva PARRAGH, Árpád PETHO, Erno SZARKA
and Ádám SZENTPÉTERI, Jr. (Head of the Working Committee)

Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ETSs), single Nucleotide Polymorphisms (SNPs) and Entire Genomes

The Hungarian Group thinks that the present subject is of high importance for the future of the development of biotechnology and, consequently, for the human life in general. A suitable resolution is highly desirable which should provide a fair balance between inventors' and applicants' rights on one hand and a support for further research in the public interest on the other. Expressed Sequence Tags (ESTs) and Single Nucleotide Polymorphisms (SNPs) may play a very important role in defined directions of research as well as in the clarification of the structure and possible use of entire genomes in future investigations and in searching for highly effective pharmaceutical compounds or in discovering still unknown possibilities of therapy of living organisms, including humans.

The Hungarian Group is of the opinion that the legal regulation of patentability of these objects is very important and future international guidelines to be elaborated should provide a definition of the scope of protection which is at least as precise than that applicable in other fields of technology, first of all in the nearest technological field of the chemistry offering also analogies. Our opinion is based on the belief that ESTs, SNPs and genomic DNA are specific objects the importance of use and utility of which cannot be at present properly anticipated. We think a detailed and strong regulation on the international level is necessary to avoid abuse of rights, e.g. the blocking of scientific use of the above objects.

The following answers of the Hungarian Group are based on the legislation and legal practice in Hungary, taking the Hungarian Patent Act (Act No. XXXIII of 1995) into consideration. Some of the answers also include a short summary of the possible difficulties which may arise in applying the rules of the above law.

3.1 Public policy

a) There seems to be no bar against patentability of inventions relating to ESTs and SNPs as far as "ordre public" or morality is concerned, the said DNA sequences not being highly specific to a single living organism. However, these problems might arise in connection with protection of genome inventions. In the view of the Hungarian Group no patents for genomes shall be granted. For the above reason in the course of the following discussion "genomes" or "genomic DNA" are only

mentioned for the sake of formality, i.e. only if the question raised by the Guidelines contains such terms (see 3.3 where this item is missing).

b) The Hungarian Group is not convinced that Patent Offices are the appropriate place to determine the question whether inventions under (a) are contrary to "ordre public" or morality. The main task of a Patent Office is the application of the law in force the passing of which by the Parliament is a political matter and the above question is also strongly disputed on a political level. However, considering that Article 6(2) of the Hungarian Patent Act excludes inventions against morality from the field of patentable inventions, the Hungarian Patent Office is bound to determine the scope of such exclusions. In deciding on these questions the Patent Office may consider other legal regulations not relating directly to the patent field (mainly the civil law as the background thereof) and/or make enquiries at other competent institutions.

3.2 Utility

Also according to the Hungarian Patent Act, a patentable invention shall be capable of industrial application which requirement may be considered as an equivalent to the notion of utility. In our opinion, the utility requirement may not be met by a simple statement by the applicant in the specification that ESTs, SNPs and genomic DNA are useful as probe or a tool for future research, but utility should be defined more precisely by disclosing at least one kind of a special field of use already found during the process of the creation of the invention.

In order not to exclude the possibility for several consecutive potential uses, in analogy one may refer to the practice of the European Patent Office concerning multiple medical indications wherein claims are allowed to the first use of a known compound in the manufacture of a medicament for medical treatment and to the second and further uses of such compound for the manufacture of a medicament for a new medical treatment. In this sense, recognition of a new utility of an EST, SNP and genomic DNA might also be regarded as a further patentable invention.

3.3 Invention

Provided that an application discloses merely the piece of information represented by an EST or SNP it seems not to relate to a patentable invention. However, satisfying all the criteria of patentability, among others providing a field of utility mentioned under 3.2, an information should be a patentable invention, likewise any information of using a discovery in a certain and defined technological process.

3.4 Novelty

To establish novelty, it should be examined if the EST, SNP or genome forms part of the state of the art. Accordingly, our answers to these questions are as follows.

c) EST and SNP may not form a part of the state of the art in relation to full length - significantly longer - gene sequences, while a genome, being a larger unit, may form part of the state of the art in relation to a full length, but shorter gene sequence.

d) In conformity with our answer to question (c), a later, longer gene sequence including an EST or SNP should be regarded as novel.

3.5 Obviousness

a) Simple sequencing of an EST, SNP or a genomic DNA may be obvious, however in accordance with our answer to question 3.2, it is the recognition of a precisely defined new utility of these objects which should overcome obviousness issues. In this case "use" claims might be allowed.

b) Examining authorities, including corresponding Courts may have difficulties in the field of obviousness especially in defining the person skilled in the art. Such a definition has always been very difficult as to the standard of skill and in the present area it might cause still more problems.

3.6 Sufficiency

The requirement of sufficiency should be taken even more seriously than in other, traditional patent applications. As already mentioned in the introductory part of this report and is evident from the answer to 3.4 the Hungarian Group suggests strict sufficiency rules as the presence of utility concerns the industrial applicability requirement which may provide for the patentability of the invention. As EST, SNP and genomic DNA are generally of high specificity, the specification needs to define the full sequence(s) and no deviation from these sequence(s) should be allowed. Neither is it advisable to define the field of utility broader than specified in the description and the examples.

3.7 Documenting DNA inventions

The rules we suggest for inventions relating to ESTs, SNPs and genomes may be derived from our previous opinion; i. e. a general disclosure regulation relating to the process of obtaining the said objects should not be more strict than in case of other biotechnological inventions, however, the sequences need to be specifically defined not only in the examples but also in the claims.

While unity requirement might be fulfilled by disclosing identical utility of more ESTs or SNPs in the same application, it is suggested that each claim shall relate to one and fully defined sequence only.

3.8 Scope of protection

Patent claims for ESTs and SNPs should provide the same protection as patent claims in other technological areas. As such patent claims need to be specific (see our answer to 3.7), we do not see any possibility of using any kind of equivalence applied frequently in case of chemical inventions when evaluating the scope of protection. We stress again that no claim for genomes shall be accepted.

Summary

The Hungarian Group believes that ESTs, SNPs and genomic DNA are of high importance the utility and use of which cannot even be anticipated at present. Therefore, a detailed and strong regulation on the international level is needed to avoid future abuse of rights, i.e. blocking of scientific development on one hand and free use of inventions based on enormous financial and mental efforts on the other. General requirements for patentability should partially be more restrictive as far as utility and obviousness issues are concerned. Novelty, sufficiency of disclosure and documenting requirements should be similar to those in other fields of inventions. The scope of protection, however, should extend to ESTs and SNPs specifically disclosed and defined by utility. The Hungarian Group thinks that no claims for genomes shall be accepted.

Résumé

Le Groupe Hongrois est d'avis que les EST, les SNP et l'ADN génomique sont des objects de grande importance dont l'utilité ne peut même pas être prévue actuellement. Par conséquence, on a besoin d'un règlement détaillé et fort sur le plan international pour éviter un abus futur de droit c'est-à-dire le dérangement du développement scientifique d'une part et l'utilisation libre des inventions fondées sur des efforts financiers et spirituels énormes d'autre part. Les termes de brevetabilité généraux doivent être en part plus restrictifs en relation avec les sujets de l'utilité et ainsi l'évidence. Les prescriptions sur les critères de nouveauté, la suffisance de divulgation et la documentation doivent être pareilles à celles employées sur les autres domaines des inventions. Cependant l'étendue de la protection ne doit porter que sur les EST et les SNP divulgés tels-quels et définis par leur utilité. Le Groupe Hongrois pense que nulle revendication peut porter sur les génomes.

Zusammenfassung

Der Meinung der Ungarischen Gruppe nach spielen EST, SNP und genomiale DNS, deren Anwendbarkeit und Verwendung zur Zeit gar nicht vorauszusehen ist, eine sehr bedeutende Rolle. Dementsprechend halten wir es für wichtig, eine strenge internationale Regulation einzuführen, um die eventuellen Rechtsverletzungen - einerseits Verhinderung bzw. Blockierung der wissenschaftlichen Forschung, andererseits die freie Benutzung von Erfindungen deren Ausarbeitung ausserordentliche finanzielle bzw. mentale Investitionen benötigte - zu vermeiden. Die allgemeinen Voraussetzungen der Patentfähigkeit hinsichtlich der Anwendbarkeit und der Offensichtlichkeit sollten teilweise höher limitiert werden. Die Neuheit, ausreichende Offenbarung bzw. Dokumentierungsvorschriften sollten in Einklang mit denen anderer Erfindungsgruppen festgestellt werden. Jedoch, der Schutzumfang sollte nur auf EST und SNP ausgedehnt, die eindeutig beschrieben und mittels Anwendbarkeit definiert sind. Der Meinung der Ungarischen Gruppe nach sollten Ansprüche für Genome nicht angenommen werden.