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

The subject under discussion is so complex, new and is developing so fast that it is difficult to state if Romanian legislation would be adequate to give a final decision. However, the Romanian group analyzed the data indicated in the Yearbook 1999/1 and, in the followings, will answer to the specific questions taking into account the provisions of the Romanian Patent Law no. 64/1991.

3.1(a) Are ESTs, SNPs and genomes inventions the patenting of which is contrary to "ordre public" or morality (TRIPS art.27.2)?

In our opinion, all the three subject matters, namely the ESTs, the SNPs and the Entire Genomes, are patentable, they being considered products, due to the fact they can fulfill the three criteria generally valid: novelty, inventive step and industrial applicability, with the specific condition that these criteria to result clearly from the invention description. According to the Law no. 64/1991, in force in Romania "biological material" is patentable. Thus, ESTs, SNPs and Genomes can be patented because they do not fall under the incidence of the provisions of art. 12 of the Law no. 64/1991 (the inventions which are contrary to public policy or morality). Indeed, they are new elements including the sequence or partial sequence of a gene, characterized by the new their structures and specific properties.

Nevertheless, if during the substantive examination of the patent application having as subject matter such a product, the examiner finds out from the description or from the applicant's answers to his notifications, in which details for the complete understanding of invention were requested, that the claimed product is contrary to the public order, that it could be dangerous in any way to the society or to the environment, then the patent application is rejected based on the provisions of art. 12 mentioned above.

For genes and for the corresponding proteins, patents are granting in many countries, the patenting of these inventions being considered not contrary to order public or morality. ESTs, SNPs and genomes inventions are in the similar situation.
3.1(b) Are patent offices the correct place to determine these questions and do they have sufficient resources to make such decisions?

The patent offices represent one of the institutions that can decide in this matter, because they are able to give the most correct and official interpretation of the law in their countries. However, in this case, their opinion is never sufficient, because it is possible that the inventor(s) did not have described correct or complete the effects of the claimed product use.

Therefore, it could be useful to ask to a specialized authority a notice concerning the inexistence of any undesirable/unwanted effect or even of dangerous effect for the society, for human beings. Such an authority has the necessary resources and specialists to decide in this matter, but the issuing of such a notice will spend time and thus, the taking of the decision on the patent application could be prolonged.

In our opinion, the provision concerning compulsory filing of such a notice should exist in the laws of all countries where these products could be patented.

3.2 What level of utility should be required of patents for ESTs, SNPs and genomic DNA?

According to Art. 10 of the Law no. 64/1991, in Romania the utility, the applicability of a claimed product must clearly and explicitly result from the invention description. The scientific utility of ESTs, SNPs, and genomic DNA cannot be deemed as an industrial applicability.

In our opinion, especially for this kind of inventions, the national patent legislations should contain a provision concerning the concrete practical utility requirement. For instance, after creating an EST, the inventor must perform at least one test and indicate its final result. Also, in cases where a sequence or partial sequence is used to produce a protein or part of a protein, it is necessary to specify which protein or part of a protein is produced and what function it performs.

3.3 Is an EST or SNP an "invention" at all?

An EST or a SNP is an "invention", because it is a product in itself, having its own utility. It cannot be found in nature as such, so that it is not a discovery. ESTs and SNPs are, undoubtedly, merely pieces of information, but at the same time, they are chemical compounds not even found in nature but made by man at the end of technical process, and that have always technical application. Therefore, the status of invention cannot be denied for them, as it cannot be denied for any other chemical compounds in a similar situation. The Romanian Patent Law contains no specific provision regarding the patenting of ESTs or SNPs so that; its Implementing Rules should be amended.

3.4(c) Do ESTs, SNPs or genomes form part of the state of the art in relation to full-length gene sequences?

In our opinion the ESTs, the SNPs and the genomes are part in the state of the art in relation to full-length gene sequences, but they are not opposable, meaning that they cannot destroy the novelty of full-length genes, because these ones have their specific structures and utilities, distinct from the genes to which they correspond.
3.4(d) If it is possible to patent an EST, SM, should a later, longer gene sequence including that EST or SNP nevertheless be regarded as novel?

A longer gene sequence including a patented EST or SNP is new in relation to the previous patent as the later represent another chemical/biological structure, with different properties and different uses. However, a license might be required.

3.5(a) What standard of obviousness should apply to inventions concerning ESTs, SNPs and genomes?

The standard of obviousness for these inventions must be equally severe to that for all other patent inventions. One could say that a new EST patent, for instance, has an inventive step represented by the activity of the inventor in processing a biological material in such a way that a new product useful in a predetermined practical purpose to be obtained.

3.5(b) What particular difficulties do courts and patent examiners face in assessing inventive step?

No particular difficulty in assessing inventive step can be revealed due to lack of experience of our courts and patent examiners in the field of patentability of ESTs, SNPs and genomes.

3.6 What should be the sufficiency requirements or patents for ESTs, SNPs and genomic DNA?

According to the Romanian Patent Law requirements, the invention description must disclose:
- the structure of the nucleotide sequences (the nucleotide chain) which must be claimed exactly in the form indicated in the description;
- it must be described clear and complete the way of the sequence obtaining;
- it must be described clear and complete at least a test proving its utility, with detailed description of this utility.

3.7 Are there, and should there be special provisions for written description or claims (e.g. considering unity of invention) of ESTs, SNPs and genomes?

In our opinion special provisions for written description and claims of ESTs, SNPs and genomes are not necessary (excepting those on point 3.6.), because these subject matters of inventions could be assimilated with new, patentable chemical compounds or microbiological products, for which there are legal provisions concerning draft of description and claims in national legislations. However, a guideline to assist both, patent examiners and patent practitioners in their activity, is necessary to be drafted by each country, due to the novelty and specificity of this field. Referring to the unity criterion, we believe that in a single application may be claimed a reasonable number of such independent and distinct sequences with the condition to have a common source or similar function, without the unity of invention to be affected. So, allowing applicants to claim more independent and distinct sequences in a single application, efficient costs of these types of applications will be promoted and consequently the patentability will be encouraged.
3.8(a) **Should patent claims for ESTs, SNPs and genomic DNA afford the same protection as other patent claims?**

The answer is yes. Claims for ESTs, SNPs and Genomes must be considered equal to all product claims. All inventions must be subjected to the same criteria for granting, so that all inventions must give the same protection to their owners. However, a patented biological material can be used as research tools without being necessary to obtain a license from the owner of the patent.

**Summary**

EST, SNP and entire genomes are patentable subject matter, which are not contrary to public order or morality.

The Patent Offices are institutions that can decide in this matter, based on a notice issued by a National Authority in each country concerned the effects of the claimed biological material.

The utility of EST, SNP and genomes patents presented in detail in the description must be a practical one, not only for research uses.

Their novelty consist in the specific structures of the EST, SNP and genomes, respectively so that they can be cited as prior art without affecting the novelty of a later, longer gene sequence.

The standard of obviousness and the sufficiency requirements should be the same as that for all other new product inventions.

The description must indicate the structure of the EST, SNP or genome claimed, a way of its obtaining and at least a test proving its utility, the claims afford the same protection as other products patent claims.