QUESTION 150

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

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

Resolution

AIPPI notes

1. that development in biotechnology has led to new problems in relationship with the considerable inflow of information generated by genomic sequencing including ESTs, SNPs and entire genomes;

2. that the European Directive 98/44 on the legal protection of biotechnological inventions is a major step in harmonization of the Laws in European countries and in clarification of the rules of evaluation of inventions including DNA especially the sequences of genes (industrial applicability, indication of functions and dependency rules);

3. that actual policies of patent offices on patentability of these inventions are contradictory;

4. that the number of such patent applications is increasing rapidly together with the size of said applications;

5. that the scientific community together with national and international organizations have expressed great concern about the possible monopoly of human genomic information by a limited number of companies;

6. that Research and Development in biotechnology is essential.

AIPPI recognizes

7. that the financial investments in this field are very important, both from private companies and public organizations, and must be taken into consideration when

analysing the patent situation, but that public interest and ethical considerations are also important parameters to take into account especially to prevent unreasonable impediments to research and development in this field;

8. that ESTs, SNPs or entire genomes should be protected using the general principles of patent law.

AIPPI is of the opinion

9. that patenting ESTs, SNPs and entire genomes does not “per se” raise “ordre public” problems, and the patenting of DNA does not per se give rise to moral or ethical problems since the granting of a patent does not give the patentee the right to exploit the invention, it gives him the right to stop others from using his invention without his permission. There are many areas, for example pharmaceutical products, where the patentee has to obtain regulatory approval before he can market his product. The regulation of the use of such an invention, especially the question of whether the use of such an invention gives rise to moral or ethical problems should not be a matter to be decided by the patent office.

10. that ESTs, SNPs and entire genomes must be considered as patentable subject matter;

11. that one of the key issues is the problem of utility or industrial application and that the mere affirmation that an EST or SNP would be useful as a probe may be insufficient if no concrete (or enabling) information is given on the possibilities to use said probe or on the function of the corresponding sequence. It is not the intention of this resolution to address the question of when such information must be disclosed which is a matter of national law.

AIPPI recognizes

12. that a relationship may exist between utility or industrial application and inventive step (non-obviousness).

But AIPPI is of the opinion

13. that standard novelty, inventive step (non-obviousness) and sufficiency of disclosure criteria of national laws must be applied to this kind of invention;

14. that an analysis of the state of the art must be done in the same way as with other inventions even if the analysis of the situation may become very complicated in the case of several ESTs or SNPs of the gene;

15. that in granting such patents the patent offices must take care to ensure that the breadth of claims granted is commensurate with the contribution to the art.

AIPPI is not in favour of

16. special provisions for the written description or claims in this field, or special provisions for the use of said inventions such as
    - special provisions for experimental use or research tools or
    - special provisions for compulsory licenses.

But AIPPI considers

17. that a harmonized standard for all countries would be welcome, not only in practical terms, especially for the presentation of DNA sequences by abolishing the requirements for a printed sequence listing in favour of providing this information in an electronic form only, but also from the legal point of view in terms of unity of invention.

AIPPI is confident

18. that also in this sensitive area the Courts will be careful in evaluating the scope of the claims as granted and in particular that the scope of claims is commensurate with the contribution to the art.

AIPPI is also of the opinion

19. that further studies with respect to the specific requirements and scope of protection of DNA sequence data collections be carried out.

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