



HUGO INTELLECTUAL PROPERTY COMMITTEE STATEMENT ON THE SCOPE OF GENE PATENTS RESEARCH EXEMPTION, AND LICENSING OF PATENTED GENE SEQUENCES FOR DIAGNOSTICS

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1 Introduction

HUGO has taken the view that the granting of claims to DNA sequences in patents has the potential for a positive impact provided all the requirements for patentability are met¹. This position is consistent with international treaties governing the field, especially the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which ensures that product and process inventions in all areas of technology are eligible for patenting, and the European Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. HUGO does not consider that there are any grounds to deviate from its previous statements. However, recent scientific and commercial developments in genomics have highlighted the possible conflicts which may arise between the need to provide incentives for the inventor and the need to protect the public interest. The purpose of this statement is:

- to provide additional comment on the standards for patentability of DNA molecules and their sequences in the light of new knowledge;
- to draw attention to the need for a harmonised research exemption and
- to suggest a possible mechanism for enabling cost effective licensing of patented DNA molecules and their sequences.

2 Standards for patentability

As a result of the collaborative efforts of public institutions, databases comprising raw DNA sequences from human and other organisms are now publicly available. One effect of this development is that fewer patents are likely to be granted which claim such DNA sequences. In addition, growth in the annotation of raw sequence and the wide availability of sequence from model organisms is providing a sound basis for 'downstream' research, both broadening the basis for invention and potentially making increasingly difficult to meet the requirements for novelty and inventiveness in the isolation of DNA molecules and their sequences in general. In this regard HUGO has always emphasised the importance of the disclosure of function in respect of the criteria of patentability.

In many European countries, the acceptance of broad, product-based patents for DNA sequences is being questioned. This can partly be ascribed to the fact that a product patent traditionally covers all applications (uses) of the product, irrespective whether those uses were disclosed or claimed. HUGO notes that genes may be represented by many splice variants. Alternative splices in as many as 50% of our genes therefore complicate the definition of a gene. Moreover, biological functions in the human genome are not restricted to DNA sequences that encode proteins. From comparative genomics, it is increasingly clear that regulatory, structural and catalytic functions can be performed by DNA sequences that are transcribed but not translated (i.e. non-coding RNA) and genomic DNA directly (i.e. by sequences which are not transcribed).

HUGO takes the view that it should be generally understood that a claim on a DNA sequence does not extend to alternatively spliced transcripts if these have not been specified in the patent claim[s]. The issue raised by the question of alternative splicing is addressed by the guidance set out in HUGO's

¹ Previous HUGO Statements on patent-related issues were published in Genome Digest April 1995, 6-9, July 1997, 3, and October 2000, 10-11.

previous statement on the issue of the rights associated with claims to DNA sequences which overlap². In this statement, HUGO concurs with the Directive 98/44/EC (Recital 23) which states that determination of the DNA sequence as such without disclosure of its function does not constitute an invention, as well as with Recital 25, according to which, “when sequences overlap only in parts which are not essential to the invention, each sequences will be considered as an independent sequence in patent law terms. As HUGO pointed out in its statement of 2000, “the notion ‘are not essential to the invention’ is to be interpreted in the light of the function unambiguously disclosed by the respective applicant (patentee) and not on the basis of its objective (natural), not disclosed, importance as such. Regardless of how many forms of alternative splicing of a gene products exist, this guidance, developed to address the issue of overlapping sequences applies. Moreover, with reference to Article 9 of the Directive 98/44/EC, HUGO emphasizes that it should be interpreted along the same lines as Recital 25, i.e. the scope of a product patent on genetic information shall extend to all, but also only to material, in which the product (DNA molecules and their sequences) is incorporated and in which the genetic information is contained and performs its function. The performed function being that disclosed and claimed in the patent.

In summary, HUGO has adopted the view that patents which claim DNA sequences should be available under certain conditions, namely disclosure of function. In the case of those DNA sequences which are identical with those found in nature, the invention of the product as such has to meet all the criteria of patentability. The scope of patents is determined by the courts. HUGO takes the view that it is not appropriate to advocate the introduction of a specific rule in respect of scope because to do so would limit the freedom of the courts.

3 Research Exemption

HUGO considers that freedom to undertake research in genomics is fundamental to the acquisition of further knowledge and the development of applications to benefit human health. Researchers who wish to use patented technologies or products to further understanding in their work should not be unduly constrained by issues relating to licensing. In this respect, HUGO recognises the value of the exemption for research which is recognised in Europe. It is therefore of the opinion that a statutory research exemption should be introduced on a universal basis, irrespective of the final goal of research. HUGO recommends that the European statutory model of the exemption for research which covers all forms of research³ for the purpose of improving, or developing knowledge is used as a template.

4 Licensing of patented DNA molecules and their sequences for the development of diagnostics

HUGO considers that the concept of the research exemption could be usefully extended to address the problems of access to patented gene sequences in the development of clinical diagnostics. The identification of DNA molecules and their sequences that are significantly implicated in a disease can provide the basis for a diagnostic test. For example, the BRCA1 gene which is implicated in some forms of breast cancer, has been used to develop such a test. The test is protected by product patents which assert rights over the DNA sequences (molecules) and the proteins they encode, and by use patents which contain claims to the use of the DNA sequences for diagnosis.

There has been considerable opposition to the grant of these patents, primarily because they confer on the owners of the patents not only an exclusive right on their own diagnostic method but also the ability to prevent others from competing with them through the development of improvements in the diagnostic methods, using the same sequences. Thus there are currently no other methods of diagnosing the presence of the breast cancer susceptibility gene BRCA1 that can be used without

² HUGO Statement on Patenting of DNA sequences – In particular Response to the European Biotechnology Directive (2000) <http://www.hugo-international.org/hugo/statements.html>

³ Those inventions which are against *ordre publique* would be excluded from the provision.

infringing the patents. The resulting exclusive ownership, and the fact that the owner of the patents has not licensed others to use its patents widely, have enabled the company to establish an exclusive market for the tests.

To address the undue exclusivity that can be exercised in respect of diagnostics not only for patients with serious diseases but for a variety of other conditions, HUGO suggests the establishment of a clearing house to expedite the rapid and low cost licensing of patented DNA sequences which have potential applications in clinical diagnosis. This approach, initially suggested by the OECD⁴, would provide mutual benefit for the owners of such patents and the research community. At present, the patent owner has to consider the onerous possibility of prosecuting infringers worldwide. The existence of a clearing house could not only obviate such outcomes but could lead to increased levels of licensing. At the same time, researchers, not the private sector, would have the option of securing licenses to patented sequences at a reasonable cost which might encourage the pursuit of research in areas which might have deterred them in the past. This approach would be of particular benefit to companies who are developing high throughput technologies for the rapid diagnosis of multiple gene variants who may need to acquire licences for large numbers of patented DNA sequences. HUGO encourages the OECD to pursue this idea, but could also itself play an active role as organizer of a Bermuda-Type conference on this issue.

HUGO Intellectual Property Committee 2003

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⁴ OECD, Genetic Inventions, Intellectual Property Rights and Licensing Practises – Evidence and Policies, Paris 2002, p. 82.