WIPO

PCT/MIA/VI/9
ORIGINAL: English
DATE: February 3, 1997

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERNATIONAL PATENT COOPERATION UNION (PCT UNION)

MEETING OF INTERNATIONAL AUTHORITIES UNDER THE PCT

Sixth Session
Canberra, February 17 to 21, 1997

INTERNATIONAL SEARCH AND INTERNATIONAL PRELIMINARY EXAMINATION OF INTERNATIONAL APPLICATIONS CONTAINING LARGE NUMBERS OF SEQUENCE LISTINGS

Document prepared by the International Bureau

1. The recent growth of the biotechnology industry and, in particular, greater sophistication in genetic engineering have had a great impact on the nature of inventions being made in this field and the way in which they are disclosed and claimed in patent applications. Those changes have resulted in an increasing number of applications which disclose tens or even hundreds of nucleotide and amino acid sequences, presented in the form of sequence listings which, in written form, can run to hundreds or even thousands of pages. Such applications pose processing problems for International Searching Authorities (ISAs) and International Preliminary Examining Authorities (IPEAs) in carrying out international search and international preliminary examination, even with the aid of advanced computerized techniques. The practice of national and regional Offices as well as ISAs and IPEAs is necessarily evolving to deal with the challenge of processing applications in this area of technology (see, for example, the Notice "Examination of Patent Applications Containing Nucleotide Sequences," published in the *Official Gazette* of the United States Patent and Trademark Office, 1192 OG 68, on November 19, 1996, a copy of which is contained in the Annex to this document).

2. It is proposed that the Meeting discuss the problems connected with the international search and international preliminary examination of international applications which disclose large numbers of such sequences and consider whether, and along what lines, any amendments of the PCT Regulations and modifications of the PCT Administrative

Instructions, PCT Search Guidelines and PCT Preliminary Examination Guidelines would be desirable. The Meeting may wish to consider, in particular, the questions outlined in the following paragraphs.

3. *Unity of invention criteria.* Are there any special considerations which arise in the application of the PCT criteria relating to unity of invention in the case of international applications in which large numbers of sequences are claimed? For example, what significance should be placed on whether nucleotide sequences are encoded to produce the same protein or on whether the sequences derive from the same organism? Where there are claims to combinations of sequence fragments, is unity dependent upon whether different combinations of fragments contain a common fragment? Are additional guidelines needed to assist examiners in applying the criteria relating to unity of invention to international applications in this area of technology?

4. *Additional search fees and additional preliminary examination fees.* Where an international application in which a large number of sequences are claimed is found not to comply with the PCT requirements relating to unity of invention, are there special considerations which should be applied in relation to the number of additional search fees or additional preliminary examination fees which the applicant is invited to pay? For example, should distinctions be made depending on the size, complexity and/or the reasonableness of the number of sequences involved?

5. *"Scaled" search fees and preliminary examination fees.* Even for international applications which are found to comply with the PCT requirements relating to unity of invention, is there a case for introducing "scaled" fees for international search and international preliminary examination, that is, where the amount payable would depend on the number of sequences involved? If such scaled fees were to be introduced, what procedures should be followed to collect those fees and what consequences should flow from non-payment? In this connection, it should be noted that the search fee is collected by the receiving Office, but there would be difficulties for receiving Offices, if scaled fees were introduced, in deciding what search fees were payable in particular cases. There is, at present, no provision under the PCT Regulations for search fees to be paid direct to ISAs, except for additional search fees in cases where the international application is found to lack unity of invention.

6. *Additional questions*. While the Meeting's interests are particularly related to international search and international preliminary examination, it must be borne in mind that the approach adopted by ISAs and IPEAs for the handling of such international applications will also have consequences for receiving Offices and the International Bureau and, of course, for applicants.

7. The Meeting is invited to discuss the matters outlined above and to suggest any desirable changes to the PCT Regulations, PCT Administrative Instructions, PCT Search Guidelines and PCT Preliminary Examination Guidelines.

[Annex follows]

Examination of Patent Applications Containing Nucleotide Sequences

I. Introduction

Biotechnology is expected to be an important growth industry from now until well into the twenty-first century, particularly in the United States, one which will produce new therapeutics for the benefit of mankind. The Patent and Trademark Office (PTO) has taken a very active role in working together with its customers to simplify and standardize PTO policies and procedures and to encourage and promote the growth of this industry for the benefit of humanity.

For at least a decade, researchers in the biotechnology industry have been filing patent applications claiming isolated DNA or RNA sequences of nucleotides, referred to as nucleotide or nucleic acid sequences. Scientific and technological advances now permit researchers to identify large numbers of gene sequences rapidly. The ease of using automated techniques for sequencing large numbers of nucleotides in a nucleic acid has resulted in the filing of a growing number of patent applications, many of which recite thousands of individual nucleotide sequences with each sequence reciting at least several hundred nucleotides. The examination of these applications presents unprecedented search and examination challenges, even with the most modern, up-to-date equipment.

Faced with these challenges, the PTO held public hearings on issues relating to patent protection of nucleotide sequences on April 16, 1996, in San Diego, California and on April 23, 1996, in Arlington, Virginia. At those hearings, the PTO received several recommendations that restriction practice pursuant to 35 U.S.C. § 121 should be applied to patent applications claiming nucleotide sequences.

This Notice responds to comments received during the hearings. This Notice clarifies PTO's policy for examination of patent applications that claim large numbers of nucleotide sequences.

II. The PTO Will Permit Applicants to Claim Up to Ten Independent and Distinct Nucleotide Sequences In One National Application

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. § 121. Pursuant to this statute, the Rules of Practice in Patent Cases provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 *et seq.* Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

Accordingly, in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. The PTO believes that allowing applicants to claim up to ten (10) independent and distinct nucleotide sequences in a single application will promote efficient, cost-effective examination of these types of applications. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10). In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

III. Under the Unity of Invention Standard in an International Application or National Stage Application Filed Under 35 U.S.C. § 371, Up to Ten Nucleotide Sequences Will Be Searched and/or Examined Without Payment of An Additional Fee

International applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. § 371 will be treated in a similar manner. Under 37 CFR 1.475 and 1.499 *et seq.*, when claims do not comply with the requirement of unity of invention, i.e., when the claimed subject matter does not involve "one or more of the same or corresponding special technical features," 37 CFR 1.475(a), an additional fee is required to maintain the claims in the same application. 37 CFR 1.476(b).

The Commissioner has decided *sua sponte* to partially waive 37 CFR 1.475 and 1.499 *et seq.* to permit applicants to claim up to ten (10) nucleotide sequences which do not have the same or corresponding special technical feature, without the payment of an additional fee. The PCT permits inventions which lack unity of invention to be maintained in the same international application for the payment of additional fees. Thus, in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the PTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination. Further, claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences. Nucleotide sequences encoding the same protein are considered to satisfy the unity of invention standard and will continue to be examined together.

IV. Examples of Nucleotide Sequence Claims That Are the Subject of this Notice

Examples of typical nucleotide sequence claims impacted by this Notice include:

(1) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;

(2) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and

(3) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

Applications claiming more than ten (10) individual independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a restriction requirement. Only the ten (10) nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.

Applications claiming only a combination of nucleotide sequences, such as set forth in example 2, will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such

as set forth in example 3, will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example 2. More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

In applications containing all three claims set forth in examples 1-3, the PTO will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example 1, all combinations, such as in examples 2 and 3, containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed.

Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and non-selected and which are limited to the allowable sequence(s) will be rejoined and examined.

V. Other Possible Solutions

The PTO is pursuing other possible ways to efficiently examine applications that claim large numbers of nucleotide sequences, including the following:

A. *Software Development* - Using private contractors, the PTO will attempt to identify, modify or develop software tools to aid in searching and the analysis of search results.

B. *Feedback* - The PTO will pursue and evaluate suggestions from applicants, members of the bar, industry, scientists, government, and inventors.

C. *International Cooperation* - The PTO will encourage greater cooperation between the other patent offices of the world in the area of biotechnology. The PTO will work with these offices to share resources thereby minimizing duplication of search and examination.

D. *PTO Outside Search Center* - The PTO will explore the possibility of establishing an outside search center which would perform standard searches for all patent applicants submitting applications containing nucleotide sequences.

E. *Search Standards* - The PTO will explore the possibility of establishing quality and proficiency standards for prior art searches so that applicants can perform their own pre-examination searches. Applicants could then submit their searches with their applications, and the PTO could examine applications based on applicants' searches.

F. *Communication* - The PTO will communicate its procedures for searching the prior art and how the current hardware and software have been optimized for examination needs.

Any questions, comments or suggestions regarding this Notice should be directed to Esther M. Kepplinger, Supervisory Primary Examiner, Group Art Unit 1302: by mail to Box Comments-Patents, Assistant Commissioner for Patents, Washington, DC 20231; by FAX to (703) 305-3601; or by electronic mail addressed to ekepplin@uspto.gov.

October 17, 1996

BRUCE A. LEHMAN
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

[End of Annex and of document]