

Intellectual property management of biosequence information from a patent searching perspective

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Abstract

With recent advances in biotech research tools, the use of biosequence information has greatly facilitated the R&D process in the pharmaceutical and other life sciences industries. Concurrently, it has presented substantial challenges in the management of biosequence related intellectual property, due to the dramatic increase in the amount of sequence data, the nature of claims on sequences as well as limitations in available database resources for sequence analysis and searches. This paper discusses some of these challenges in-depth, and suggests ways to alleviate difficulties associated with conducting sequence-based patent information searches.

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1. Introduction

The sequencing of the human genome and genomes of other organisms offers an unprecedented opportunity for advances in the pharmaceutical, agricultural, medical and chemical industries. However, this opportunity is accompanied by significant challenges in the management of sequence related intellectual property, for example, in the patent information searching or in protecting inventions based on sequence information due to the following drawbacks:

- (1) Atypical and/or broad-scope detailed claims made on sequences in issued patents and published patent applications as described by Sheiness [1].

- (2) Limitations in the functionality of commonly used sequence analysis tools in the context of patent searches.
- (3) Inconsistent and incomplete indexing of sequence data in patent and non-patent sequence databases.

This review attempts to identify the problems that underlie overall sequence analysis process, such as the selection of answers from sequence analysis results for different legal contexts, and limitations of sequence analysis tools and databases. In addition, we describe approaches to alleviate such problems in conducting different types of legally significant searches related to sequence information.

2. Industrial utilization of sequence information

Biosequence or sequence, as the two terms have been interchangeably used, refers to biological sequence of

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Table 1
Industrial utilization of sequence information

Industry/Technology areas	Utility	Sequence to be analyzed	Sequence length (approx.)
Diagnosis	Probes	DNA	Commonly shorter than 100bp
	Biomarkers	DNA	Commonly shorter or greater than 100bp
Therapeutic biomolecules	Antisense	RNA/DNA	Commonly greater than 10bp and less than 50bp
	Gene therapy	DNA/protein	Varies
	Peptide products (e.g., antibodies)	Protein	Varies
Drug development	Drug targets	DNA/protein	Commonly greater than 300bp, used to generate recombinant cells for ligand screening
Agriculture	Modified foods, plants, seeds development	DNA, protein	Commonly greater than 300bp, genes may be integrated into host chromosomes
Chemical synthesis	Enzymes constituting synthetic pathways	DNA/protein	Commonly greater than 300bp, used to generate recombinant cells to produce chemicals

ordered nucleotide or amino acid structures constituting deoxyribonucleic acid (DNA), ribonucleic acid (RNA) or protein molecules which are essential building blocks of all living things. With the emergence of state-of-the-art biotech/bioinformatics tools, such as automated sequencing system, sequence analysis/assembly algorithms and sequence databases, sequence information of various organisms has become available as a critical part of R&D in all biotech areas. Typical examples of their industrial utilization are described in Table 1. However, these nucleotide and amino acid sequences of varying length should be analyzed in order to meet different needs of intellectual property management such as, to avoid infringing patents claiming sequences to be used in R&D operations, or to file patent applications of invention based on sequence, or when questioning the validity of the patent at issue, by performing freedom-to-operate, patentability or validity searches as described in the Sections 3 and 4 below.

3. Types of patent searches for the intellectual property management of sequence data

Intellectual property management of sequence data deals with three types of searches. The scope of each type of search differs according to the search objectives.

3.1. Freedom-to-operate

The primary goal of a freedom-to-operate (FTO) search is to determine whether any sequences that are to be utilized in either R&D, or in a manufacturing process, have been claimed in a granted patent or published patent application. The search typically focuses on sequences claimed in issued patents or published patent applications in the countries where the operations of interest are to be carried out and where any products that result from the operations may be used. Consequently, all relevant granted patents and/or patent

applications that may be granted within the timeframe of concern should be closely monitored. It is critical to examine all relevant claimed sequences from analysis results. As will be discussed more fully below, identifying all relevant claimed sequences is often difficult considering the fact that many of the claimed sequences do not explicitly appear within the publicly accessible sequence databases.

Another aspect to be considered in performing FTO searches is the Doctrine of Equivalents (DOE). While DOE is a very complex subject beyond the scope of this article, the basic idea is that the unauthorized practice of a composition/method may infringe a patent claim even though the composition/method does not literally fall within the scope of the patent claim. The rationale for the DOE is that, under certain circumstances, it would be inequitable not to extend the patent claim to encompass the composition/method not literally covered. More information on how the Doctrine of Equivalents may affect the scope and/or coverage of claims can be found in an article by Jones [2].

3.2. Validity

The purpose of a validity search is to identify sequences that were in the public domain prior to the effective priority date of the patent at issue that may materially affect the validity of the issued claims. Such sequences may form a basis to question the validity of the patent at issue. Searches are performed to find all sequences published anywhere in the world in issued patents and patent applications regardless of whether they are claimed or unclaimed. Sequence should be also searched in non-patent literature, such as journal articles also published anywhere in the world, or in publicly accessible sequence repositories/databases such as Genbank, EMBL, and DDBJ which were published prior to the effective priority date of subject patent. Selection of answers from sequence analysis results from all available sequence databases may depend on how claims are

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