

## How to Protect Bioinformatics Tools?

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### LEGAL VIEW

#### How to Protect Bioinformatics Tools?

Bioinformatics is beset with its own set of opportunities and challenges. Intellectual protection for developments occurring in this field is important too.

Take a simple case of identification and discovery of a protein. To determine the structure of the protein, which tells a few stories about its activity and mechanism of action, bioinformatics tools come handy. These tools offer specific algorithms, which are derived from basic knowledge of chemistry, physics and analysis of other proteins, and assist in predicting the structure of the newly discovered protein in a matter of minutes shaving off several years of research. Bioinformatics also assists in placing the protein in the phylogenetic tree, which throws light on the evolutionary history of the protein.

Similarly, when genomic data of various individuals is collected, a "reference library" of various genes in humans may be used to analyze the differences (polymorphism) between individuals. It is useful in predicting why someone is predisposed to a disease while another is not or even diagnose whether a person is susceptible to a specific disease.

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The above examples may be some very grossly simplified ones. Clearly, bioinformatics tools are designed to assist and complement research in molecular biology. Such tools require years of research and substantial investment of time and money: hence, protection is not just desirable, but necessary.

### **IP protection**

Take the case of a micro-array analysis. This involves more than 1,000 wells and provides a snapshot of genes expressed at anytime. Analysis of this information by individual well-trained scientists usually takes few days. This chore is now performed by computer software. It picks up the digital photographs of each of the wells and analyzes the same and the output of several hundreds of such micro-array experiments is available in matter of minutes.

The core of this micro-array technology is driven by few algorithms, some proprietary and public domain databases. It generates its own database, which gets regularly updated after each analysis cycle. The technology is licensed to users who pay a licence fee for use of the tool and are not authorized to modify the software.

The subject matter for protection in this example boils down to software: specifically the database used by the software, the database generated by the software, algorithms used by the software and the manuals and other allied material.

Is patent a good protection? Although not a wholesome solution, it may be an option worth exploring. A patent, we know, is granted for an invention that is novel, non-obvious and is capable of industrial application. Further, a patent is territorial in nature and therefore dependent heavily on the patent laws of each country.

USA: After the US Federal Circuit clarified in the State Street Bank case that a software invention is patentable, if it produces a new, useful and a tangible result, the road for patenting software inventions became smoother. The decision also opened the floodgates for several other similar types of inventions employing software. The example described above would be patentable in the US. Similarly, software that can identify the precursor of a peptide by identifying a specific nucleotide sequence and then determining the peptide formed by the sequence may also be protected.

Algorithms used for comparing sequences, finding genes, determining their functions etc. are also capable of protection. The US Federal Circuit in the AT &T case held that algorithms are patentable, if it is applied in a practical manner to produce a useful result.

Given the above precedents, patentability of bioinformatics tools, essentially the software, has now become common, paving the way for grant of patents for software that enable diagnosis or testing for susceptibility based on presence of particular proteins or that which assist in determining the homology between various nucleotide sequences.

Europe: According to the European Patent Office, an invention in respect of a software is patentable, if it makes a "technical contribution" over the known art. Technical contribution may be solving of a long existing problem, a means to solve the problem or technical issues to arrive at a solution for the problem. Therefore, the example stated above may be protected in Europe.

India: The Indian Patents Act, 1970 (as amended) specifically provides that mathematical formulae, business methods and computer software are not patentable. However, a machine embedded software or a firmware is patentable. Therefore, the example technology may not be eligible for patent protection in India.

### **Copyright**

Copyright protects an original work fixed in a tangible medium. There are several categories of works that are eligible for copyright protection, one being a "literary work". A software, whether the source code or an object code or a flow chart are all included within the category called "literary work" and thus eligible for protection under this law. Registration under copyright law is highly recommended, especially for purposes of enforcement.

### **Copyright protection has its own advantages.**

- It is created automatically when software is fixed in a tangible medium.
- Affords universal protection unlike patent law that requires registration in every country
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It is less expensive and the procedure for registration is simple

- Term of protection is life of author plus 60 years in India and could vary in each country.
- Legal remedies are available in many countries for violation of copyright, which may not be available for a patent infringement.

### **Patent or copyright?**

Patent law protects the ideas behind software, while copyright law protects an idea as expressed. In other words, copyright extends to the software as written by the programmer and not its variations.

Copyright protection does not prevent another from reverse engineering or implementing the same idea in a different manner. A patent protects the underlying idea of the software so that the path is blocked for the next entrant.

### **Database rights**

Proprietary databases are integral parts of the bioinformatics tool kits. Development of such tool kits requires substantial investment in terms of time and money. In most countries including India, databases are considered as compilations and therefore eligible for protection under copyright law. The only caveat for such protection is that the database must be original in the selection or arrangement of data. A typical example of such a database is that maintained by GenBank, European Molecular Biology Laboratory, Cambridge (EMBL), SWISS-PROT (protein sequences), BLOCKS (protein motifs).

Many countries are sensitive to the needs of this industry and have provided for special database rights whereby any proprietary database wherein the maker has made substantial investment in making, presenting or verifying the contents is eligible for a 15-year protection from the date of creation or date of substantial modification. In effect, these databases may enjoy perpetual protection.

### **Trade secrets**

A trade secret may consist of any formula, process, device or compilation of information which is used in one's business and which gives an advantage over a competitor who does not know of it. Also known as confidential information, the essence lies in maintaining and keeping the subject matter as a secret. The owner of the secret information must take adequate steps to make sure that the information is maintained as a secret by extracting non-disclosure covenants from employees and those who use the information.

The virtually unlimited monopoly that trade secret protection provides to the owner includes certain inherent risks and problems. If the proprietary software is accidentally or illegally disclosed, all protection is lost. Protection is also lost if the information enters public domain. It may run into problems if obtained illegally by industrial espionage.

Despite these problems, it is a useful tool for protection of algorithms and databases.

### **Overall strategy**

It is noteworthy that all the above aspects of intellectual property are not mutually exclusive in that one tool may be protected by all forms of intellectual property. Any company serious in this sector must use a combination of intellectual property rights for protection of its tools. The tool that is most appropriate depends on the position of the company and the business goals that it seeks to achieve.

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### **K & S Partners**

K&S Partners is a full-fledged intellectual property law firm with offices in New Delhi and Bangalore. It specializes in the entire gamut of intellectual property laws, protection and enforcement.