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Bioinformatics Databases: Intellectual Property Protection Strategy*

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Intellectual property (IP) protection for bioinformatics databases plays a key role in accelerating development of biological sciences and biotechnological industry. This paper presents current and global position of IP protection in bioinformatics database. A protection method has been proposed after analysing characteristics of bioinformatics databases and considering different database protection methods. Further, the paper seeks to analyse the diffusion process of biological information and develops an argument that bioinformatics primary database should be put in public domain, though they may be given financial subsidies by the government or other public funds according to the diffusion phase of biological information. Suitable methods of IP protection in the bioinformatics secondary database have been suggested.

Keywords: Intellectual property, bioinformatics database, transmission model, copyright, contract, *sui generis*, trade secret, trademark

Bioinformatics is the science of information generation, transmission, receipt, and interpretation in biological systems.[1] It is one of the disciplines which consists of compiling, analysing, simulating, modeling and predicting using huge biological information by application of computing and information technologies.

In the current information technology era, bioinformatics is growing and developing rapidly due to the robust database systems available and the vast and increasing amount of the biological data published. For example, there were approximately 40 million known gene sequences in GenBank (NIH database) in 2004 compared to approximately 15,000 known genes in 1987, representing a 2,500-fold increase.[2] Bioinformatics database is a combined product of biotechnology and information technology and plays a vital role in accelerating modern life science research. Due to the perceived importance of bioinformatics databases, many countries including the United States, the European Union, Japan, India and China have been expending a lot of effort to study and construct bioinformatics databases, with the governments, as well as the private sector providing financial support. These efforts have already made great contribution to national or regional growth in science and technology.

At present, in most countries, bioinformatics databases are protected by the existing intellectual property laws.[3] However, the protection is often not adequate, due to lack of encouraging prospects for database providers which is a limiting factor in the development of bioinformatics databases. The strategy of IP protection for bioinformatics databases has become more and more important for experts in biological science and law.[4-6]

The Classification of Bioinformatics Databases

According to the contents and characteristics of bioinformatics databases, they can be classified as a primary or secondary database. Primary databases consist of gene related data including nucleic acid, proteins sequences, with information about features of the nucleic acid, amino acid sequences and biochemical reactions, metabolic pathway, etc. Secondary databases, on the other hand, are created based on primary databases and the information derived from the primary databases. The primary and secondary databases have some differences. Primary databases record mainly experimental results like the contents of DNA and protein sequence and protein structure obtained from genomic mapping, DNA and protein sequencing, X-ray diffractometry and Nuclear Magnetic Resonance measurements. Secondary databases are special in that their contents are completely derived from the primary databases. Primary databases contain extremely large amounts of data, which are updated very fast. They have a lot of

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*This paper is part of author's doctoral work and received financial support from the National Natural Science Foundation of China (No. 70633003) and the Institute of Intellectual Property Strategy users and require big hard disk space and database management systems with high efficiency. Secondary database have less information than the primary database and updating rates are slower.

At present, a majority of bioinformatics databases are sequence databases, including DNA, RNA and protein sequences. There are also a lot of databases on gene mapping, protein structure and literature citations (Table 1). These bioinformatics databases, special sequence and structure databases are the most useful types, for life science researchers.

Intellectual Property Protection for Bioinformatics Databases: Transnational Perspectives

Presently, in many countries, laws which protect bioinformatics databases are the same as those that protect other databases. The European Union (EU), takes the *sui generis* route to protect bioinformatics databases, whereas in most other countries the copyright law is used.[6, 16]

In July 1995, the EU Database Directive was passed which suggested a two-tier protection for databases. On one hand, there was the copyright to protect databases, whereas, on the other was the *sui generis* right which could be used to protect the makers' investment on some special but non-original databases which involved much manpower, material resources and money and can provide useful information to contribute to the users' creative work.[17] The aim of Database Directive was to protect the database investor and for the first time to protect databases by a special right. A balance was worked out as a result of which, copyright protection for databases was available to countries and parties under the Berne Convention or Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the *sui generis* right was made available only to makers who are nationals of EU member states (or have their habitual residence in the community, or companies formed in accordance with the law of a member state and having their registered office, central administration or principal place or business within the community).

Table 1—The type of bioinformatics database

Type	Available database
DNA sequence database (primary)	EMBL[7], GenBank[8], DDBJ[9]
Genomic database (primary)	GDB[10], ACeDB, SGD
Protein sequence database (primary)	SWISS－PROT[11]
Protein structure database (primary)	PDB[12], CarbBank
Genomic database (secondary)	EcoWeb, RansFac
Protein sequence database (secondary)	TrEMBL[13], PROSITE[14]
Protein structure database (secondary)	DSSP, FSSP, HSSP
Literature database	DBcat, MEDLINE, SCI, HUMAT
Miscellaneous database	BIOCAT, GENDIAG, LIMB, TaxonomyTAED
Comprehensive database	BioWarehouse[15]

In US, copyright law is used to protect databases. Before 1991, it was assessed whether databases can be protected by copyright, or the standards of 'industrious collection' or 'sweat of the brow' can be applied to them. Since, financial and professional investments are made in obtaining and collecting the contents of a database, it was concluded at that time that most databases can be protected by the copyright law in USA. After 1991, stringent originality standards were demanded in protecting databases through copyright law. As a result, many databases could not be protected since they did not meet the originality standards.

The fact that the laws in the EU and USA are so different, have a significant impact and the possibility of a collaborative effort between EU and the US seems remote. The EU may be affected by being excluded from collaborations with non-EU countries. Thus, the system of IP rights can result in unintentional consequences. Due to these contradictions, complex databases such as the bioinformatics databases are not well covered by the database law.[4]

The Strategy of Intellectual Property Protection in Bioinformatics Database

As bioinformatics databases are classified into primary and secondary databases, the problem of protecting these databases is very complex. Moreover, due to the selection and arrangement, the contents of primary and secondary databases are very different. It is therefore, necessary to take into account the characteristics of the database in strategizing a method for protecting these databases. There are some differences that need to be considered:

First of all, most primary databases are commonly financially supported by the governments and society funding bodies, while some secondary databases are financially supported by enterprises and individuals besides the government and society funding bodies. Secondly, in order to make the data comprehensive and authoritative, some important primary databases will exchange data every day through Internet, while secondary databases cannot exchange data in most cases. Thirdly, the amount of data in primary databases is very huge and updated quickly, whereas, the data in secondary databases is based on a primary database and often require software for exploitation. The updated rate of the secondary database data is far slower than that of primary database. Finally, many primary databases contents make use of prevalent or similar ways to the arrangement of data, while the arrangement of secondary database content has a more original design.

Bioinformatics Primary Databases

Primary Database in Public Domain

Primary databases play an important part in bioinformatics and form the cornerstone of bioinformatics research. The exploitation and creation of primary databases (for instance databases like Genbank, EMBL, DDBJ and PDB) are carried out by the government, the academia, etc. At present, many of them do not have IP protection and are in public domain. An analysis of this arrangement leads to the conclusion that primary databases should not be protected by IP. The reasons for this interpretation are:

(i) A significant number of primary databases are funded by the government and utilize taxpayer's money, and therefore, should be laid open to benefit the public.

(ii) IP protection for primary databases will shake the foundations of research in life sciences, since; these databases are the lifeline to scientists in the field of research gene engineering, molecular biology and proteomics. The use of free primary databases will promote communication among research groups and avoid tedious and expensive repetitions.

(iii) It is difficult to confirm the source of data in important primary databases because they are provided by not only the makers of the database but also active researchers in the field of life science. For example, the data of Genbank comes from many sources including publications and through researchers who register data. Many journals ask authors to provide the database registration number of the sequence before publication of their research results. Papers are often rejected for lack of registration of sequences in bioinformatics databases.[18] Further, when databases are governed by different countries, exchange of data is very frequent, again making it difficult to trace the source of data.

(iv) The arrangement of data in primary databases is not unique and often uses existing formats for the same. Besides, the content is an organism's discovered original sequence or structure data. Therefore, these databases do not satisfy the criteria of originality for the selection and arrangement of the databases' contents, which leads to the fact that many primary databases cannot be protected by copyright law, the traditional form of IP protection for databases.

Though the above arguments support including primary databases in public domain, since they are subsidized by government or public funds, the grant of public funds is a practice that needs to be re-evaluated in terms of maximizing availability of government funds.

Improve the Availability of the Government Subsidies for Primary Databases

The main aim of government action is to enhance the reach of biotechnology, thereby promoting the development and welfare of society in general. To achieve this objective, government should provide financial subsidies to the makers of bioinformatics databases. As a result of these financial subsidies, primary databases can be made freely available to users involved in active research. Furthermore, it can reduce the cost of secondary databases for researchers. However, financial resources of a government are limited and a method to improve the availability of these limited resources is analysed below:

Diffusion of Biological Information

The diffusion of the biological information plays a very important role in the proposed technique which includes invention, creation and diffusion. Invention is the creation of new knowledge, new principles, or new models, resulting out of scientific research. Creation is to develop the invention further, operationalize the new technology, new product and at times implement the first commercial application. Diffusion is a process during which the creation is diffused and applied. In this mechanism, diffusion is more important process than the creation itself.

Providing data or the biological information is the diffusion process in this technique. The purpose of creating a bioinformatics database is to give a platform for the researcher to further obtain newer biological information. However, there is a pattern observed in the diffusion and spread of biological information. The transmission model is the most appropriate to explain the diffusion process of biological information.

The transmission model is based on the epidemic model. During the spread of an epidemic, the number of carriers initially increases and so does the rate of spreading, until the number of healthy individuals is small when the rate of spreading starts declining. In case of transmission model for diffusion the information is the variable. In the beginning and midway during diffusion, the rate of information spread becomes faster and faster and most of the information is used, until the remaining potential users lack the ability to use new technology. Hereafter, the rate of diffusion becomes slower and slower and finally stops. The transmission in the diffusion process is expressed in Fig. 1.

Shown in the figure of the diffusion process is an 'S' shaped curve that is defined by the following equation:

$$\frac{dX(t)}{dt} = \beta X(t)(1 - X(t))$$

where $X(t)$ is the ratio of the technology diffusion and β is the diffusion coefficient.

The solution of the equation is

$$X(t) = \frac{1}{1 + e^{-\alpha - \beta t}}$$

When $\frac{d^2 X(t)}{d^2 t} = 0$, then $t = \frac{-\alpha}{\beta}$ and $X(t) = \frac{1}{2}$ $[\frac{-\alpha}{\beta}, \frac{1}{2}]$ is the inflexion point of the curve in Fig. 1.

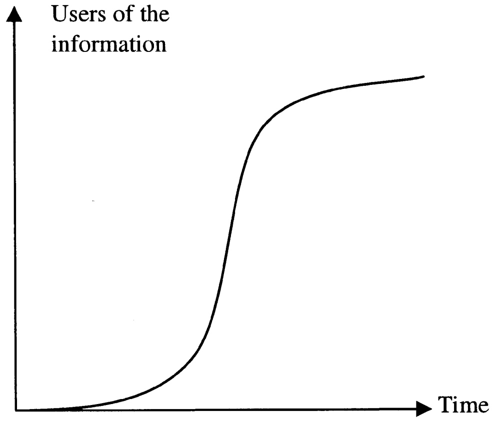

Fig. 1— Transmission model for diffusion process

This model has been verified by a number of researchers and the value of the coefficients (α and β) can be calculated based on actual data. The same transmission model can be applied to the diffusion of biological information, which in turn is defined by the diffusion characteristics of the biological information as follows.

In the first phase of the curve, researchers need to examine utilities for the diffusion of new biological information and explore ways of its possible applications. So the cost is high and users are less, which leads to the slow diffusion. But after a period of accumulation, the value of biological information can be assessed, the area of technology development determined and the expected returns can be predicted. In the second phase of diffusion of biological information, more users get involved and the diffusion rate of biological information becomes faster and faster where the information is mostly used. In the third phase, the biological information has been utilized sufficiently and most researchers have mastered them. Meanwhile, because of the high diffusion, the ways to obtain the biological information will also increase, while the research on the biological information will decrease. The rate of the diffusion at this phase will become stable and not change much.

The Government Strategy

Considering the above model, it will be appropriate for the government to give varying financial subsidies to bioinformatics databases depending on the diffusion phase of the biological information. Only when the funds are distributed reasonably can the financial subsidies of the government be utilized more efficiently.

For the first phase of biological information diffusion which is the first slow stage of 'S' curve (Fig. 1), there is a lot of research on application, which is a sensitive indicator of database cost. If cost of using the bioinformatics database is high, diffusion of the biological information will become slower and slower, which will hinder the progress of life science research. Therefore, for bioinformatics databases in the first phase, the government should provide adequate financial subsidies to make up for the high costs of application based research.

The second phase of diffusion is the accelerative period and there are still a lot of research applications. But because of earlier research breakthroughs, a number of commercial applications involved in the use of the biological information have already been formalized. Since the cost factor is now low, the government should reduce the financial subsidies grant and only provide partial support to the bioinformatics database. This is equivalent to not providing any subsidies to the users of the secondary databases but still supporting the users of the primary database.

During the third phase of diffusion, also the final stage, the diffusion and applications of the biological information are relatively mature and government subsidies are no longer required. Therefore, at this stage of biological information diffusion, the government may cancel subsidies fully and the operation of the bioinformatics database can be regulated by the market, which will reduce the government's financial burden.

Intellectual Property Protection in Bioinformatics Secondary Databases

Although secondary databases have a direct relationship with primary databases, they also have a lot of the differences. The data in a secondary database is not simply a collection, but is analysed and upgraded for a section of specific users. Secondary databases should be protected whether funded by government or private funds for the following reasons:

Primarily, the selection and arrangement of the content in a secondary database is original enough to satisfy the copyright criterion unlike a primary database. In secondary databases, the data from the primary database is reprocessed using bioinformatics software. Secondly, the content of a secondary database is what makes it significantly different from a primary database. Thirdly, secondary databases form the core of bioinformatics research. A large percentage of the investment in the bioinformatics sector is in creation of secondary databases, research in them and their exploitation. If attention is not paid to their protection, the makers of these databases are likely to be adversely affected. Finally, if all the government created bioinformatics databases are put in public domain; related research may have to be halted when funds are unavailable at any point of time. Therefore, the appropriate mechanism would be to protect secondary databases, earn the profits from it and in turn encourage development of bioinformatics databases which are funded by the government.

Copyright Law

One of the most popular methods of protecting databases is through the copyright law. Here, a database is usually considered as a compilation work. According to the TRIPS Agreement, 'compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.'[22] The Berne Convention, states that 'collections of literary or artistic works such as encyclopaedias and anthologies which, by reason of the selection and arrangement of their contents, constitute intellectual creations shall be protected as such, without prejudice to the copyright in each of the works forming part of such collections.'[23] In a secondary database, a large portion of the original data is reprocessed which involves creative labour, and further selection and arrangement of its contents are also original. They therefore, qualify for protection under the copyright law.

Nevertheless, the main limitation of copyright protection to databases is that the contents of a database may be copied and rearranged electronically without authorization of the maker to produce a database of identical content which does not infringe any copyright in the arrangement of the database.[4] In USA, the Supreme Court explored the restrictions of copyright protection for compilations in *Feist Publications Inc* v *Rural Telephone Service Co*. It was observed that 'Facts are not copyrightable, but compilations of facts generally are' and 'Originality is the *sine qua non* of copyright and copyright protection may extend only to those components of a work that are original to the author.'[24] Applying *Feist*'s principles, copyright protection would extend only to an original selection or arrangement in bioinformatics databases. A competitor who creates his own database using individual elements of the copyrighted database would not infringe the copyright as long as the competitor does not use the same selection or arrangement as the copyrighted database[18], which shall do away with any benefits the database maker may gain. This is a very big drawback and a significant deterrent to the cause of using copyright law to protect databases.

Sui generis Law

Having understood that copyright law cannot provide sufficient protection in the database, some countries have established the system of the *sui* *generis* law to protect databases. The s*ui generis* law is intended as a unique system of protection which can adapt to the development of the database industry. A *sui generis* law can protect the interests of the database maker as well as the content itself.

Although a *sui generis* law can protect the bioinformatics resource and benefit the investor, it has some disadvantages. For instance, in the case of *British Horseracing Board Limited and Others* v *William Hill Organization*[25], litigation arose over the use of information taken from the BHB database of British Horseracing Board Limited by William Hill Organization, for the purpose of organizing betting on horse racing. Britain's Magistrates′ Court of Justice and High Court of Justice gave similar judgments that the defendants had infringed the BHB database by unlicensed use of information. The European Court of Justice however, ruled that the defendants had not infringed the BHB database since the BHB database was not within the scope of *sui generis* protection. It therefore appears that the scope of *sui generis* protection is ambiguous and different courts interpreted the content of Directive 96/9/EC differently. Furthermore, the *sui generis* protection may grant monopoly to even 'non-original' databases, especially information in public domain. The same problems shall also be applicable when this law is employed for protection of bioinformatics databases.

Some other considerations include the fact that these rights can be enforced in a specific territory. In the above instance, s*ui generis* law is only applicable in the European Economic Area (EEA). As far as corporations or unincorporated bodies are concerned, they must be registered in an EEA state or have their principal place of business or a registered office within the EEA during the creation of the database. It follows that genomic databases created outside the EEA (e.g. the United States) do not qualify for *sui generis* protection.[26] Also, a bioinformatics database is a contributor to improving research in science. However, some of the existing *sui generis* laws contain regulations which allow prolongation of the protection period of renewable databases which may be detrimental in the long run since these databases shall not become available in the public domain. This will hinder communication of the biological information and disturb scientific development.

Trade Secret and Trademark Law

The trade secret is also an available means to protect secondary databases though the protection provided is weaker than the methods already discussed. The database can be protected by the trade secret because the maker takes all measures to prevent the content from being known to public. But in this era of information technology, it is very difficult to keep such vast biological data secret.

Secondary databases can also be protected by the trademark law. It will however, only protect the database trademark and not content of the database; protecting only famous secondary databases. This method is seldom used to protect the secondary databases.

Contract Law

The makers of a database can also gain protection from the copyright law. They can prevent third parties from copying or accessing contents using contract law. Using contract law to protect databases is very useful in a complementary manner. For non-original database, the contract law almost becomes the only mode of protection, especially in countries that have not set up a *sui generic* legal mechanism or an anti-unfair competition law. According to stipulations in the contract, the maker of the database can prevent breach of faith and infringement.

At present, Shrinkwrap licences and Clickwrap licences are two of the extensively used contracts to protect databases. Shrinkwrap licence is used for databases in CDs and is the licence, which is put down in writing during a products' packaging. When customers buy the products, they have the option of retaining or returning the product depending on whether they agree or disagree with the licence. Once the buyer uses the product, it means that he agrees to the contract. Clickwrap licence on the other hand is used for Internet databases. When the buyers want to access the content in the database, they should enter 'agree' online which means that they have agreed to the contract. Generally, the contract determines the kind of information that can be accessed or downloaded.

Bioinformatics databases are network databases and hence can use Clickwrap licences. The terms of the contract may include restrictions on the use of database, prohibit a third party from accessing the contents of the database or forbid downloading or transmitting the data. In addition, under the principle of freedom of contract, the database makers and users can implement more stringent terms than the applicable laws without violating them. However this will be valid only between the parties of the contract, not against any third party.

For instance, the GENSCAN service center[27], which provides access to its program Genscan for predicting locations and exon-intron structures of genes in genomic sequences from a variety of organisms, has an Academic Use Licence Agreement on its website.[28] The user's responsibilities and rights are prescribed in the terms of Clickwrap licence.

The contract law is a good method to protect bioinformatics databases, especially those which are not original and in countries where there are no *sui generis* laws. Most privately created databases use the contract route for protection. However, the terms of contract should not violate current law. The contract shall be considered invalid if the contract contains the clauses indicative of malicious collusion, infringes the state, or a third party, harms public interest or fraudulently projects illegal objectives as legal. In addition, the terms of contract for databases should be regulated so as to not limit or deprive legal rights of the user, prohibit unfair or unreasonable terms and prevent the imbalance of interests between the producer and user of the database. The best approach would be to design each contract according to the user needs.

Besides, the contract law also has some shortcomings, such as (i) just as it can solve the dispute between two parties of a contract, there is no provision to deal with third party disputes and (ii) the rules of contract law are rigid, and often conflict with public policy and the law.

The above arguments clearly spell out that secondary bioinformatics database should be protected; only the means need to be ascertained. The available means include use of copyright law, *sui generis* law, trade secret or contract law for protecting databases. In practice, it is up to the database maker to select the suitable law to protect his work according to the relevant situation. Comparing the various existing methods, although the contract law has some shortages, it has more advantages in terms of protecting financial returns of the database maker. The contract law can prevent breach of faith and infringement efficiently, and give the maker of the database more comprehensive rights. Furthermore, the contract law can be used freely in any country even where other means of protection may be absent and hence is an attractive option for database makers.[29]

Conclusion

Bioinformatics databases play a key role in promoting the development of life science. Due to the inherent nature of such databases, IP protection for them cannot follow traditional means. Since, bioinformatics databases are classified into primary and secondary databases and differ in creation, selection and arrangement, protection should take into account this classification. Primary databases should remain in public domain because they are very important for research in life science and also since they cannot be protected by conventional IP laws. However, they may be offered differing financial subsidies through government or public funds according to the diffusion phase of the biological information. Secondary databases, however, must be protected because of the nature of their content and presently, contract law seems the best option for its protection.

Although protecting bioinformatics databases will motivate the maker and promote development, an appropriate method should be selected to protect it. If the method is too strict, it may be opposed by researchers. Whatever the protection means, it should be reasonable enough to allow access for non-commercial uses like educational or research purposes. Admittedly, the goal would be to benefit the investor as well as promote science.

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