

Bioinformatics and Legal Challenges

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The legal system does have and will continue to have an impact on bioinformatics.

Bioinformatics is the use of computers to store, retrieve, analyze or predict the sequence or structure of biological information. It combines aspects of mathematics, statistics, computer science, and biology within a given set of partly discovered biological rules and IT solutions.

The global bioinformatics market was valued at around \$697 million in 2001 and is expected to increase to around \$1.7 billion by 2006.

There are three areas of opportunities in bioinformatics for India.

- At the highest level is the integrated research application service providers.
- Then there are the providers of data base services and discovery software.
- The software requirements of the biotech industry includes micro array analysis, database software, sequence analysis, visualization software, array management and testing in silico.

Legal issues

As opportunities increase, more and more businesses will find themselves contemplating transactions relating to bioinformatics. Fully protecting your company requires not only an understanding of the technology involved but the special legal issues involved with bioinformatics-related transactions.

When negotiating a software transaction, companies should typically focus on such provisions as acceptance testing, service level agreements, upgrades and enhancements, confidentiality, ownership and licensing rights between the parties. Because of the newness and complexity of the hardware and software geared specifically to the bioinformatics field, these transactions may also include a collaboration between the vendor of the hardware or software and the purchaser or licensee. In these cases, it is critical that intellectual property ownership be addressed upfront during the negotiations.

Legal issues relating to bioinformatics transactions, especially in the realm of data, however, go beyond what has been described.

In the case of representing a lab or drug company, companies should conduct due diligence by investigating a software vendor's use and ownership rights in the software applications it intends to license. The company should also keep in mind other contractual protections such as representations, warranties, indemnifications, and limitation on liabilities when it pertains to any software at issues.

Bioinformatics & Intellectual Property

In India, the intellectual property rights of computer software is covered under the Copyright Law as software is not yet permitted to be patented.

It is important for bioinformatics companies to ensure that their IP is protected. There are basically two aspects to the bioinformatics industry:

- services component and;
- software used by such companies

With respect to the IP issues for bioinformatics companies, there is a need to protect all information being provided to the company by the sponsor. There is also a need for all bioinformatics companies to have an IP game plan. This will largely consist of deciding to protect your intellectual property through statutory means (copyright and trademark) or through contractual means. In an ideal situation, it should be a combination of both.

While this relatively new field offers compelling opportunities, companies need to consider the many issues in bioinformatics transactions beyond the usual hardware and software concerns, including issues involving privacy and restrictions on related intellectual property.

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