
Bioinformatics - New Legal Issues Raised in the Intersection of Computer Science, Biology and the Internet

2001-11-05

The post-genomic era is upon us. The recently-completed genome map and the vast amounts of scientific data being collected, through means such as high-throughput screening, call for immense databases of scientific information to be accessed, analyzed and exploited. Combining computer science and biology, the discipline of bioinformatics provides the means to manipulate this information. Through the Internet, this information can then be made accessible to researchers around the world. Not surprisingly, bioinformatics presents new issues under intellectual property laws, fresh concerns over legal risk allocation and additional privacy challenges.

Bioinformatics employs sophisticated computer systems to store and analyze vast amounts of scientific data, permitting information to be processed more quickly and accurately than could have been done using traditional laboratory methods. Biotechnology is now focusing on enabling the analysis of both the structure and the function of genes and the complex proteins which genes express, in an effort to speed drug design and drug development.

Participants in the bioinformatics field include developers of software modeling and analysis tools, manufacturers of computer hardware, creators of scientific content and companies that generate products and services based on the results of genetic data analysis. Joining the specialized start-ups

in the field, mature biotechnology and pharmaceutical companies have developed vast computer systems to support their drug discovery and development efforts. Just as computer-aided design tools allow manufacturers to design, simulate and test electronic devices in software before incurring the expense of building them in factories, computer-aided drug design may enable companies to design and test drugs in software before incurring the expense of clinical trials. Ultimately, these efforts may result in databases of protein models which may be used to determine how a drug can best interact with certain proteins to cure a particular disease. Regardless of whether a company has entered the bioinformatics field from information technology or life sciences, or whether it is a mature company or a start-up, it will face issues regarding computational power, data standards, intellectual property rights, risk allocation and privacy, among others. In order to share data with their strategic allies more efficiently, bioinformatics companies have begun to work together to define industry-standard database descriptions without violating antitrust laws. Companies must also seek to protect their developments -- whether software, biological models or drugs -- through U.S. and international intellectual property laws and then license these developments to their strategic allies. The intersection of information technology and life sciences also requires a bioinformatics company to think carefully about the allocation of new legal risks. For example, to what extent will health care licensees require different warranties than those expected by traditional software users? To what extent might a bioinformatics product or service subject the company to liability for effects on individuals' health? Are there contractual means by which this liability should be allocated to a more suitable party? Bioinformatics efforts must be undertaken with the intent of protecting patient donor privacy. As discussed in our [May 31, 2001 Internet Alert](#), federal and an increasing number of state legislatures are imposing or are considering requirements to minimize the risk of disclosure of medical

histories or susceptibility to diseases under study. These requirements are being developed in conjunction with minimum national health data privacy standards, as discussed in our [November 2, 1999 Internet Alert](#). While these privacy issues are significant, the prospects of major improvements in health care offered through bioinformatics leads one to believe that these considerations can be successfully reconciled.

Careful thought must be given to determining how to respond to each of the numerous legal issues raised by bioinformatics products and services. In addition, as legislation and case law evolve to reflect society's understanding of and response to these issues, bioinformatics companies will need to consider the impact of those legal developments on their relationships and agreements with vendors and customers.

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