



# Protecting Bioinformatics as Intellectual Property

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**Although trade secrets and copyright provide some protection to bioinformatics tools, a carefully drafted patent can provide the broadest available protection in an increasingly competitive market.**

**S**cientists and software developers often identify patent law as the area of intellectual property with which they have at least some familiarity. Sometimes their experience has been positive; for example, a patent holder has been able to use a patent to stop a competitor from misusing, or copying, a product or a process that he has expended significant amounts of time and money developing. For others, the experience has persuaded them that monopoly rights stifle innovation and protect established market participants at the expense of emerging businesses.

However, with regard to protecting bioinformatics as intellectual property—using the laws of trade secrets, copyright, and patents, for example—the debate sometimes expands to include certain ethical considerations that arise because of the potential therapeutic benefits of this technology.

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## WHAT IS BIOINFORMATICS?

Broadly speaking, the term *bioinformatics* refers to the use of information technology in the analysis and organization of data relating to biology. Researchers have pursued the development of such technology for decades, and its necessity for accessing the rapidly expanding data made available in the postgenomic era is evidenced by information from the Human Genome Project (HGP) itself.

Launched in 1990, the HGP set out to sequence the entire human genome by 2005, at an estimated cost of US\$3 billion. It did so more quickly than projected, and under budget, and a working draft of the genome was announced in 2001; the finished sequence—more than 330 times longer than the working draft—was made available in 2003.

With approximately 30,000 genes in the sequence, and around 18,000 megabases (1 million genetic base pairs), the data scale is remarkable.

Without a computer, a researcher could never review even a single complete sequence, much less analyze it for patterns or anomalies, compare one person's genome to that of another, or compare it to genomes of other organisms. The cost of sequencing has also fallen more quickly than Moore's law alone would suggest: whereas the cost of sequencing a megabase was just over \$5,000 in September 2001, by January 2012, the cost had fallen to just 9 cents. By combining in vitro and in silico research, researchers have accessed databases of previously sequenced genomes and other biological data to analyze and compare that data, and they have done this quickly, accurately, and cost-effectively.

Using bioinformatics has several key consequences for medical research and disease control. For



example, researchers can use an algorithm to identify a similarity between one gene sequence for which the function is known and another gene sequence for which the function is being investigated. Using this information, researchers can infer that the second sequence might have a function similar to the first. In the study of protein and channel structures, the understanding of which is fundamental to the targeting of drugs, homology dictates that it's possible to predict a protein's structure, and therefore the effect of a particular drug on it, using a combination of experimental data and a homologous protein's known structure.

### AVAILABLE PROTECTION

Bioinformatics represents a significant force in education, personalized medicine (or biological warfare), and commerce. As bioinformaticians avail themselves of the ability to tap into unused CPU capacity from anywhere in the world through online processor exchanges, bioinformatics will do more at a lower cost, and will become increasingly competitive as a business model. Yet the availability of bioinformatics protection is complex.

### Databases

Databases such as the US National Institutes of Health's GenBank, which contains electronic records of the sequence data that the HGP generated, can be protected in their own right. In the US, they can be protected under copyright law as compilations. In Europe, they can be protected by copyright or by a separate database right that prevents the unauthorized extraction or reutilization of the whole or a substantial part of the database. The stored data format can be more of a practical issue than a legal one: recent decisions from

courts in the US and Europe indicate that data formats can't get their own protection under copyright law.

As with other intellectual property rights, rights in databases and the information they contain grant their owners the ability—although not the obligation—to exclude others from using their works without permission. An HGP operating principle is that the data and resources the project generates should be made available to researchers. Nonetheless, the right to exclude people from performing particular acts arises automatically, irrespective of whether the owner intends to exercise it.

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### Software tools

The bioinformatics tools themselves can typically be protected like software—by using trade secrets, copyright, and patents. Trade secrets are not well-suited to business models that distribute to users any product that embodies or incorporates the secret, rather than licensing that product's use as a service through the cloud.

Copyright law also has limitations when it comes to software. Subject to very limited exceptions, copyright doesn't protect a program's functionality or design; because it covers only original expression, only the GUI and the source code can be protected. This means that if code has been rewritten such that it's no longer substantially similar to the original code, a copyright claim will likely fail. Similarly, anyone seeking

to enforce a copyright must also demonstrate copying of the work: if the defendant can show that he created his work independently, then the copyright claim will fail.

Of these three rights, patents offer the broadest protection since they are the only true monopoly over the patented work and don't need to be copied to be infringed. As such, they're attractive to those seeking the right to prevent others from using an invention without permission. Software patents, however, are the most difficult to obtain.

The US and the European Union, as well as individual EU members such as the UK, France, and Germany, are all signatories to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which aims to harmonize the fundamentals of various IP rights, including patent rights. TRIPS provides that patent protection of about 20 years shall be available for any inventions, whether products or processes, that are new, involve an inventive step (that is, are not obvious), and have industrial applications. These same criteria are to apply "in all fields of technology."

Notwithstanding this, Europe treats software inventions differently than the US. In Europe, inventions that are computer programs "as such" are excluded from patentability. An applicant must instead claim more than just a program for a computer: at the European Patent Office, it's likely sufficient that the invention be tied to hardware; but in the UK, an application must describe to a person skilled in the art how the computer-implemented invention achieves a "technical effect" before it can proceed to be examined for novelty, inventive step, and industrial application.

Where bioinformatics programs are concerned, a particularly efficient method of identifying

patterns in a sequence might be patentable, but the mere use of a computer to perform a mental calculation is clearly not.

In the US, the Supreme Court's 2010 decision in *Bilski v. Kappos* didn't recast software such as bioinformatics as subject matter that's unpatentable ([www.supremecourt.gov/opinions/09pdf/08-964.pdf](http://www.supremecourt.gov/opinions/09pdf/08-964.pdf)). Indeed, the Supreme Court broadened the test for what's patentable subject matter by stepping back from the so-called machine or transformation test, which could have limited the patentability of bioinformatics in the US. The Supreme Court stressed that additional criteria would be used to test for patentability and, at this point, those criteria have not presented any significant roadblocks to patenting bioinformatics.

Assuming that an invention is not excluded from patent protection, a practical challenge for the bioinformatics industry is that the examiner must review the application from the point of view of a person skilled in the art. It's unlikely that large numbers of patent examiners are themselves skilled in the art of bioinformatics. Therefore, applicants in both the US and Europe would do well to make their applications as clear as possible, with both jurisdictions guarding against patents for abstract ideas by requiring applicants to disclose "specific, substantial, and credible" uses for the claimed invention.

## ETHICAL ISSUES UNDER TRIPS

One issue concerns the ethical objection to governments granting entities the right to prohibit other entities from using inventions that have the potential to save lives and alleviate suffering.

Leaving to one side the issue of whether compulsory licensing can meet this objection, it's interesting

to note that TRIPS only provides for signatories to exclude patent protection for inventions for which commercial exploitation would run counter to public policy or morality. There's no public policy or moral objection to patentability where a patent-holder refuses to allow an invention to be commercially exploited.

**A**lthough trade secrets and copyright provide some protection to bioinformatics tools, a carefully drafted patent can provide the broadest available protection in an increasingly competitive market. Many research institutes, however, have no desire to exclude others from using tools that are essential in furthering their shared aims of improving health and well-being.

Many, such as those involved in the HGP, have made it a priority to ensure that the ethical, legal, and social implications of their work are not ignored. The challenge, however, is to ensure that those who invest time and money in developing these tools can continue to do so, without hindering the essential work they and their competitors do. Securing

intellectual property protection enables these institutes to protect their products and processes, but it doesn't oblige them to do so. **■**

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