1 Exclusive Rights in Life: Biotechnology, Genetic Manipulation, and Intellectual Property Rights

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1.1 Introduction

Attending any biotechnology conference will confirm it. Amid all the discoveries and developments in the applied sciences we loosely group under the heading of biotechnology, it is impossible to ignore the palpable and ubiquitous presence of commerce. While investors, managers, and financial markets may not share the same enthusiasm about the inner workings of living organisms as a bench scientist, they certainly share the excitement of uncovering novel ways to make money. The key is to turn inventions and developments into a commercial product.

It is at the junction of science and commerce that the system of laws we call property and intellectual property step in. Essentially, property and intellectual property rights – including patents, trade secrets, and copyright – bridge the gap between new scientific development and commercial exploitation by packaging these developments in a way that industry can use. Property and intellectual property rights create exclusive rights to control biological matter and biotechnological innovation. Industry uses these rights to attract financing, build alliances, and, not least of all, entice scientists to participate in the project of turning a bit of knowledge into something to sell.

The application of property and intellectual property rights to biotechnological innovation is anything but simple or straightforward. Arguments about these rights abound, touching on everything from the criteria used to determine when to award them (Barton 2000) to the social and ethical implications of these rights (Knoppers et al. 1999; Gold 2000). Put 20 patent experts in a room and disagreement is sure to arise on some, often seemingly esoteric, point of law. Put those same experts together with health professionals, farmers, or nongovernmental organizations and conflict is sure to erupt.

Despite the lack of complete agreement on all aspects of property and intellectual property rights in biological matter, most of the principal strands of how these rights apply to this matter are beyond controversy. Biological matter can be controlled and the rules about when we give out those rights of control are fairly straightforward. With time, patent offices, courts and, occasionally, legislatures fill in the remaining blanks.

This chapter provides an overview of the application of property and intellectual property law to biological materials. In Section 1.2 of this chapter, we

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divide innovation in the biotechnology field into two types: material and immaterial. We next, in Section 1.3, sketch out the principal property and intellectual property regimes that apply to these innovations, concentrating on those of particular relevance to industry. In the last section, Section 1.4, we review some of the challenges that property and intellectual property law faces in dealing with biological materials.

1.2 Biotechnological Innovation

From a legal point of view, biotechnological innovations have both a material and an immaterial aspect. Each molecule, cell, and organism has a physical existence. These materials can be used to produce things (e.g., silk, hormones, and spider webs), to transplant into humans (e.g., organs and stem cells), to accomplish various purposes (e.g., animals used in research), and to grow and consume (e.g., seeds, plants, and animals). In addition to this physical aspect, biotechnological innovations also have an immaterial aspect. Biological material contains, after all, information about how to make more of it or of something else. For example, a living cell or organism contains instructions and a mechanism to divide in order to produce daughter cells. DNA contains the instructions for making copies of proteins. Each of these uses of biological material is as important or more important that the actual use of the physical material itself.

The distinction between physical material and immaterial information is an important one for the law. Legal systems use different legal regimes to allocate control over and access to physical objects than they do over access to information. It is, therefore, always important to differentiate between the physical and immaterial aspects of biotechnological innovation. For example, the Sox-9 gene has both a physical existence – you can collect it in a test tube – and carries information – how to make the protein that can be used to promote bone and cartilage growth. We protect the physical embodiment of the gene through property law while we protect the information content of the gene through patents or trade secrets. In fact, US patent 6,143,878 has been issued on the use, reproduction, and sale of isolated DNA molecules containing the gene. The physical DNA molecules containing the gene are not, however, subject to the patent.

In addition to these two aspects of biotechnological innovation, there are processes that use biological material. For example, the process of making beer or wine from yeast is a process using these materials. These processes may also be subject to a property right. Returning to the Sox-9 gene, we could in theory create a process to insert that gene or cells containing that gene into someone suffering from cartilage or bone damage and seek rights to the process, either in patent or through trade secrecy protection.

1.2.1 Physical Innovations

Starting with the physical aspect of biotechnological innovation, we will survey the various kinds of biological matter that are of interest to modern biotechnology. We start with molecules, ranging from proteins to genetic sequences. We then move up to whole genomes, to cell lines, to tissues and organs and, finally, whole organisms.

1.2.1.1 DNA and Protein Molecules

DNA sequences (or corresponding RNA molecules) exist in their natural state within the cells of organisms. For most organisms, DNA contains the genetic information in that organism (the rest rely on RNA).

Apart from DNA sequences in their natural states, we can artificially create DNA molecules. For example, we can cut out a portion of DNA from the chromosome in which it usually resides corresponding to an entire gene. Alternatively, we can create numerous copies of smaller pieces of DNA, such as Expressed Sequence Tags (ESTs). If we are only interested in the DNA necessary to code for a particular protein, we can copy the edited RNA back into DNA to form complementary DNA (cDNA). This cDNA contains only the particular gene about which we are concerned.

Property rights of various sorts can exist in any of these molecules. Thus, one could own a particular piece of DNA, RNA, cDNA, or EST. We must remember, however, that property rights exist not only in the physical molecule, but in the information contained in that molecule. Usually, the value of the information contained in the DNA molecule is greater than the value of a physical copy of the molecule itself. More on this later.

The second set of molecules that are of particular interest is the set of proteins produced by an organism. Proteins are the molecules for which genes code, take on various forms and do the work of the organism. We can again separate physical proteins from the information that they contain. Unlike genetic material, the primary use of which is to carry information, proteins' primary use is to do and make things. We can thus use proteins to carry out work for us outside their normal environment. Therefore, the value of property rights in physical proteins molecules are at least as high as the value of the information they contain.

1.2.1.2 Cells

Almost every cell contains a full set of genetic information and a subset of the proteins and other ingredients to carry out life. While cells cannot usually live outside the organism in which they belong, we have developed techniques to

overcome this limitation and create cell lines. We have also developed methods to keep cells alive in tissues and organs for a period of time outside of the body. We may want to do this, for example, in order to transplant an organ.

Property rights can exist in physical cells, cell lines, including stem cells, and possibly tissues and organs. As stem cells promise everything from replacement brain or heart cells to new organs, the value of particular, tangible, stem cells may be high.

1.2.1.3 Whole Organisms

Property rights in complex higher life forms – plants and animals other than unicellular organisms – are common. After all, we are used to owning particular cows, pigs, and other farm and domestic animals as well as a variety of plants. Nevertheless, ownership of animals in particular gives rise to ethical concern over the treatment of animals both in agriculture and in research. With the advent of transgenic animals, concern has already been raised over the suffering of animals modified so as to suffer from some disability (European Patent Office Board of Appeal 1990).

1.2.2 Information and Other Intangibles

As discussed above, it is not only the physical aspect of biotechnological innovations that are interesting from a scientific and commercial point of view, but the immaterial aspects of these inventions. Biological matter such as DNA sequences contain information that is valuable both for developing new therapies for disease and for creating organisms with novel characteristics. Biological matter also contains information about the organism to which it is derived. For example, a blood sample can help identify an individual as having committed a crime or of being at a higher risk for developing a particular illness. In this section, we review the immaterial nature of biotechnological innovations.

1.2.2.1 DNA Sequences and Cells

Because DNA molecules contain genetic information, they are particularly important and valuable. As stated earlier, we are likely to be more interested in the information contained in a particular cDNA – the information about how to construct a particular protein – than in a single physical cDNA molecule. This means that the property rights in the information contained in these molecules – that is, the right to copy (reproduce), the right to use, and the right to sell access to this information – is often of greater value than rights in the molecules themselves.

Similarly, the right to reproduce cell lines can often be as valuable as holding the cell lines in your possession. Again, the information contained in the cells – for example, the instructions they contain on how to reproduce themselves – are subject to property rights.

1.2.2.2 Processes Using Biological Matter

In addition to biological matter, we can grant property rights to processes that make use of this matter. We already put biological matter to work making beer, wine, cheese and pharmaceuticals. While some of these processes are very old, some depend on modern biotechnology and the manipulation of genetic material within organisms to create them.

In addition to manufacturing things, we can use biological matter to perform certain functions. For example, we can use bacteria to bioremediate polluted soil. The process of using these bacteria, whether genetically modified or not, constitutes valuable information. Similarly, ways to conduct gene therapy using vectors and DNA sequences is information of value.

All of these processes can, at least in theory, be subject to property rights. While these property rights do not attach to the physical molecules or cells themselves, they relate to the use of these molecules and cells.

1.2.2.3 Bioinformatics

Both genomes and proteomes – being sets of information – are by their nature intangible. Yet, despite not having a dual physical material and immaterial aspect, genomes and proteomes can be looked upon as two different types of sets of information. The first is raw genomic or proteomic information: the sequence of the DNA as it exists in a representative organism of a species or a list of proteins that exist within that organism. The second type of information is the organization of this material into a database. This involves the creation of a database that supports the retrieval and manipulation of useful information about parts of the genome or proteome (such as identification of individual genes, the comparison of two sequences, models of the structure of the protein produced from a gene, etc.).

Both the raw genome and proteome on the one hand, and the organized genome and proteome on the other are valuable for different reasons. This value can be protected through different property rights. We can, for example, grant property rights over an entire genome or over the organization of that genome within a database. In the first case, we are interested in capturing the value implicit in the information that is the genome itself; in the second, in the value implicit in being able to compare and query that information.

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