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The Role of Patents in Exploiting the Genome

The sequencing of the human genome is a great scientific accomplishment that opens the door to further scientific inquiry of a sort that would otherwise be impossible. In addition to being passionately interested in the patent issues this research presents, as a legal scholar I have a long-standing interest in the role of intellectual property in interactions between the public and private sectors and between universities and private firms in research science, with a focus on biomedical research. However, although the Human Genome Project has provided a rich terrain for exploring these issues, I am puzzled that intellectual property issues have become as prominent as they now are in public discourse regarding the genome project, particularly because patenting DNA sequences has been occurring for years and is certainly not a new practice.

DNA patenting began with little fanfare and controversy, in contrast to other expansions of the patent system, which have been extremely controversial during the same period. For example, a great deal of public controversy has occurred over the allowance of patents on microorganisms, animals, computer software, and, most recently, business methods. The issuance of patents in each of these areas promptly provoked opposition along with media commentary and congressional hearings. And in recent years, similar attention has been focused on the process of patenting genes, even though this did not occur when the first patent applications on genes were filed in the early days of the biotechnology industry about 20 years ago.

Thus, the practice of patenting genes was well established before it provoked any significant public controversy, which means that precedents had been set before the practice became questioned. The first public outcry over patenting DNA came in the early 1990s when the National Institutes of Health (NIH) filed patent applications on the first few thousand expressed sequence tags (ESTs, or gene fragments) to come out of the laboratory of Craig Venter when he was still at NIH. This provoked a great deal of controversy in the scientific community.

It also received a great deal of attention elsewhere, including antibiotechnology groups, and concern was signaled within the pharmaceutical industry from interests that generally favored the science but were uncomfortable with the patenting itself. More recently, stories about patenting genes have become almost a routine feature in media coverage of the Human Genome Project. Some stories are devoted entirely to intellectual property issues, while others focus on the so-called race between private- and public-sector initiatives to complete sequencing of the human genome.

Renewed Attention to DNA Patenting

So what has changed? For one thing the patent system generally is receiving more attention in public discourse than it did in the past, partly as a result of the boom in high technology and increased focus on the role of technology in the economy. Many questions

have been raised about whether patents are hurting or helping progress in certain areas, particularly in information technology. In addition, our society is experiencing a period of profound ambivalence about the role of the private sector in matters relating to human health, something that was most conspicuous in the rhetoric about drug prices and pharmaceutical profits during the last presidential election.

The changing character of discovery in genetics and genomics also accounts for the shifting interest in patents, particularly regarding DNA sequences. In the early days of genomics patenting, gene patenting seemed to be a variation on patenting drugs, while it now appears to be more like patenting scientific information. There is also a clear history regarding why it makes sense to issue patents on drugs, and although some might contest this history, it does provide a clear case for patent protection. It is significantly less clear whether it makes sense to issue patents on scientific information.

Early Claims

The first generation of DNA sequence patents was directed toward particular genes that encoded certain proteins of interest, and we could identify these genes before anyone set out to clone them. For example, we knew a great deal about the insulin gene before cloning was attempted. Thus, the patent applications that were filed typically claimed the isolated and purified DNA sequence encoding the protein of interest, a recombinant vector that includes the DNA sequence, and a transformed host cell that includes the vector. All of these claims were framed in a way that distinguished them from naturally occurring products and covered tangible materials that were used to make therapeutic proteins, which were basically like other pharmaceutical products. A patent on the recombinant DNA starting materials would give a company an effective commercial monopoly on the recombinant proteins encoded by the DNA sequences.

In other words, having a patent on DNA sequences was similar to having one on a drug, although the gene patent was directed to

the starting materials used in the production of the drug rather than to the drug itself. The Patent and Trademark Office, the agency that issues patents, and the courts treated patents on DNA sequences the same way they treated patents on new chemical compounds, or new drugs, looking to past cases that involved claims to new chemical compounds or newly isolated chemical compounds. The products-of-nature issue that seems to trouble many about gene patenting thus had been resolved before patenting occurred in cases involving isolated products, such as those that had been isolated from plasma or nature and that were made available in a form that served some human purpose. For example, there are old cases involving the patenting of aspirin, purified adrenaline, and vitamin B-12, all of which occur in nature. Therefore, the courts had no problem allowing the patenting of isolated and purified compositions that became available to meet a human purpose.

Motivations to Patent

The analogy to chemicals may never have been a perfect one, but it worked in the sense that it provided commercially effective patent protection that motivated investments in the development of new products. The biopharmaceutical industry is an area in which the patent system is important because it makes a difference in whether firms will invest in research. This is not the case in every industry.

Our patent system is a unitary one that purports to apply the same sets of rules across all fields of technology. But, in fact, those rules work very differently across different fields. In some industries, if you ask business managers or decisionmakers about the importance of patents to their motivation to invest in research and development, they will respond that it is not very important at all and that other factors are more significant in determining the profitability of their investments and innovations, such as being first to market or overcoming barriers to entry. In other words, the patents are just trading currency to get other patent holders to leave you alone. This is not so in the pharmaceutical industry, where there is empirical evidence to show that patents really do matter. This is

because, according to the pharmaceutical industry, it costs a fortune to develop new drugs, with many costly failures for each successful product. Moreover, large regulatory costs are imposed in bringing new products to market. If competitors could enter the market for successful products and drive down their prices without having to incur development costs, including the costs of all the failures (the “free rider effect”), it would drive existing drug companies out of business.

The early biotechnology firms saw themselves as smarter higher technology pharmaceutical firms focused on developing therapeutic protein products. And they too wanted patents that would prevent free riders from destroying their profits. Patents on genes promised to provide protection from competition from free riders and allowed these new firms to raise capital and seek collaborators in the pharmaceutical industry. Some biotechnology firms still follow this essential business model, looking to identify and bring to market new therapeutic proteins either on their own or with their partners in the pharmaceutical industry. But the biotechnology and genomics industries have become much more diverse in their research and business strategies.

Some of the DNA sequences that emerge from the sequencing of the human genome will undoubtedly encode therapeutic proteins, such as insulin, and some firms will focus on identifying those proteins and bringing them to market. However, the primary value of the genome will not be the encoded instructions for producing therapeutic proteins. Rather, the genome will be a source of information for future research, some of which will ultimately lead to the development of products that are far removed from the genomic information that helped researchers along the path to drug discovery. And it is not obvious how patents on genes or on other bits of DNA sequence information can be used to capture the value that genomic information contributes to these other discoveries. Different participants in the biopharmaceutical research effort have very different perspectives that lead to different outlooks on the role of patents.

The pharmaceutical industry generally supports the patent system, but it is concerned about some of the genomics patents, and in

recent years the pharmaceutical industry has invested in research to place genomic information in the public domain before the genomics firms can patent it. For example, the SNP Consortium, a group of major pharmaceutical firms, has been investing in identifying points of variance in the human genome and placing that information in the public domain. The Merck genome initiative is an effort by a private pharmaceutical firm to sponsor a university-based effort to create a catalog of fragments of genes and make that information freely available in the public domain. These private initiatives have provided an important reality check on the impact of the patent system, which motivates investment by allowing patent holders to charge monopoly prices. But, ultimately, it is the disaggregated consumers of end products who are paying those monopoly prices.

Trade-offs

The argument for patents in this situation is that without them consumers would not be able to benefit from a new product, and sometimes, but not always, this is true. In any event, consumers are not in a position to dispute this claim, although the prospect of Medicare drug coverage threatens to aggregate the interests of some of these consumers by consolidating them into a single powerful payer that would significantly alter the market for drugs.

Another way to view patents is that when they are issued for discoveries that are made on the road to drug development, they feed into future discoveries, or upstream innovations. The payoff that these patents promise to their owners will come from the pockets of future innovators. Most genomic discoveries are upstream inventions as opposed to downstream product developments, and they feed into a course of cumulative innovation. The trade-off presented by offering patent protection for these inventions is not simply how to balance the interests of consumers in low prices against the interests in creating incentives for further innovations but how to balance the interests of prior innovators against the interests of subsequent innovators. Another way to put it is that both the buyers and sellers

of these upstream innovations are involved in the process of biomedical innovation.

Thus, the trade-off is between creating incentives and promoting and rewarding early-stage innovation versus creating incentives and motivating end-product development. From the perspective of the end-product developers, those who hold patents on these research inputs look like so many tax collectors, diluting their profits on potential new products. End-product developers are well organized politically, and they have a clear business model that includes a grounded view about the role of patents. The earlier upstream innovators are organized to some extent, but they are very diverse and are less clear about their business models and the role of patents in those models. They use their patents to raise investment capital in order to conduct research, and they hope that some of those patents will someday help them make a profit, perhaps by capturing a share of the profits made by subsequent innovators in developing new drugs.

The lack of clarity in the nexus between patents and potential profits is a problem, which may explain the overreaction in the financial markets that occurred when President Clinton and Britain's Prime Minister Blair made a rather tame announcement that they approved of the policy of placing genomic information in the public domain.

Who Decides?

If patents on genes are good for some innovators but bad for others, how do we know whether, on balance, they are promoting progress? In some ways this is always a guess. The patent laws reflect certain presumptions that offer some guidance, but these presumptions plainly are not true across the range of innovations that the patent system covers. In addition, the law is often indeterminate, and the Patent and Trademark Office and the courts must make some choices within a system that usually resolves such issues very slowly.

In genomics, for example, the Patent and Trademark Office is currently working through patent applications on ESTs, or gene

fragments. These are relatively old discoveries, many of which were filed in the early 1990s. In determining what course to take, the Patent and Trademark Office looks to even older decisions based on older technologies for guidance. In many cases, however, the resolution of these issues is ultimately a policy decision. Although decisions can be appealed, this is a lengthy process that can take many more years. In addition, Patent and Trademark Office decisions are subject to review by the court of appeals for the federal circuit, and, more remotely, decisions of the federal circuit are subject to review in the U.S. Supreme Court. More remotely still, Congress can intervene at any time and change the rules.

Changing Views of What Can Be Patented

Although the patent statute includes a number of doctrinal levers for determining what can be patented and that constrain how the patent system responds to new technologies, genomics challenges some of the traditional tools for sorting through patent claims. Because we are 20 years into the biotechnology revolution, the landscape of discovery has shifted, and old cases offer limited guidance today.

A fundamental issue is one of how to patent DNA sequences. The statute says that a new process, machine, manufacture, or composition of matter can be patented. To date, DNA sequences have been patented as composition of matter, a characterization that emphasizes their material existence as tangible molecules. In this new high-throughput sequencing era, however, much of the value of newly identified sequences resides in the contribution they make to databases of information compared to their value as tangible molecules. Today, DNA sequences look more like information than molecules, as they are the tangible storage medium of cells, which use the information stored in their DNA to survive and reproduce. Newly sequenced DNA is stored in computer-readable form, and much of its value lies in making that information available to scientists.

Some patent applications are now pending that claim DNA sequences stored in machine-readable form. It is not clear what will happen to these patent applications and whether patents can be used

to protect data. A few years ago the answer would clearly have been *no*. Now, it is not so clear.

The patent system has been expanding in many different directions as the courts try to accommodate information technology. With computers it is difficult to distinguish between machines and information, and it is also difficult to distinguish between compositions of matter and information in genomics. Allowing patents on information represents a major shift for the patent system, one that is probably unwise because patent rights are not well adapted to protecting information, particularly information about the natural world where independent discovery is inevitable. It is also not clear that patents are needed to motivate investment in genomics. Overprotection of information during the early stages may slow subsequent research more than it promotes original data collection.

Our old model of patents on genes as tantamount to patents on drugs worked well for the first generation of recombinant DNA products. Now, however, with genes looking more like information and providing an information base for drug discovery, a different business model is emerging, and it is not clear what role the patent system will play.