Article Summary

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DNA Patenting

In 1982, the United States Patent and Trademark Office (USPTO) issued the first gene patent to Regents of the University of California for work carried out in a bacterium**.** Since then, genome research, gene isolation and purification, and genetic engineering have exploded. Concomitantly attempts to obtain patents on the results of these new scientific endeavors have also skyrocketed. The applications on genes have been filed in the United States, Canada, Japan, and the European Patent Office. The number of patents granted on these applications number in the tens of thousands. As with other patents, the decision whether or not permit patenting of a certain category of inventions generally rests with the national patent authorities and is based on consideration of public policy and the answer to the question of whether patents on genetic materials are beneficial or detrimental to the advance of science and human knowledge. The debate on this topic raged on the pages of academic journals, in legislative committees, national patent offices, and the courts. This is not surprising for several reasons.

First, unlike other chemical entities, genetic materials are carriers of information and that information is the same regardless of whether the relevant molecule is created by nature or by human effort. Second, this information is conserved not only as between "naturally-occurring" molecules and artificially engineered ones, but it is also conserved across essentially all biological entities. In other words, a genetic sequence carries the same information whether the sequence appears in a human or in a bacterium. Thus, allowing patents on any given genetic sequence potentially precludes the use of that sequence not just in humans, but in all future research. Third, there is something generally disconcerting about allowing an individual to

obtain exclusive rights to what could be described as pieces of our own bodies. With the grant of such rights a number of difficult questions arise: Do individuals who carry a patented gene (whether naturally or as a result of a treatment) infringe someone's patents rights, and if so what are the remedies?

At the same time, it cannot be gainsaid that laboratory-created genes are chemically and physically different from those that occur in nature even if both sets have the same informational content. Focusing purely on the chemical structure then, these molecules should easily be eligible for patent protection as chemical entities. The problem though is that these molecules' chemical structure and their informational content are inseparable and, therefore, granting a patent to the innovators in this field may confer exclusive rights not just over the chemical structure, but over the informational content – all to the detriment of future research in genetics and genetic diseases.

Of course patent seekers in this area do not seek to patent random genetic sequences. Instead, patent protection is sought on genes that are either known to produce certain proteins or the expression of which is found to be associated with a certain medical condition. Thus, for instance, a patent on genes known as BRCA1/BRCA2 was sought because these particular genetic sequences are associated with a higher incidence of breast cancer. The exclusive rights granted by the patent allow the patent-holder to limit the use and manufacture of these genes in testing or treating the disease, and for that matter in future genetic research about breast cancer or other disease. What is important to re-emphasize is that the value of a patent on genes such as BRCA1/BRCA2 is derived not just from decoding a portion of human genome as such, but from the fact that these genes are associated with a particular medical condition that is of importance to patients and one that patients want to know get tested so that they can get it treated if

necessary. The problem for the patentees is that these associations between certain genetic sequences and corresponding conditions are products of nature and are not anyone's invention. These associations are no more patent eligible than an association between locations of oil and natural gas in the earth soil. Though the search for these associations is laborious, expensive, painstaking, and ultimately of significant importance to science and medicine, the fruits of the search cannot be made exclusive to anyone. Nor can the genetic code in and of itself, once found, be eligible, for a patent for that code is also a product of nature.

On the other hand, once the association between certain genetic code and a condition is discovered, smaller laboratory-created versions of genetic material bearing the same informational content as the naturally occurring code can be created. These molecules, because they are the creation of human ingenuity, have been held by various patent offices around the globe (and recently by the courts) to be patent eligible. Nevertheless, these molecules are subject to another problem. Given the advances in and the current state of the art of molecular engineering, it does not take much (if any) creativity to create these molecules once the association and the native code is known. Once that information is available, the derivation of the lab-created molecules is fairly straight-forward, if occasionally laborious and expensive. Patent laws, on the other hand, require that a patent seeker not only the establish that the subject matter of his application is eligible for patents as a general matter, but is also sufficiently innovative ("non-obvious" in patent terminology) to qualify for a patent once general eligibility has been established.

Explorers in this field are thus placed in a lose-lose situation. The true discoveries (of native code and its association with medical conditions) are not patent eligible, and those which are patent eligible are not truly innovative and therefore though they clear the eligibility

threshold, fail to qualify for patent issuance. This inability to obtain patents because of either the subject matter eligibility bar or the obviousness bar means that the incentive to innovate that is inherent in the patent system would be absent in the field of genetics. And given the fact that the search for the genes and their associations with specific diseases is very costly and unpredictable, inability to recoup investments through exclusivity presents a real problem and discourages investments in this area. On the other hand, even if in some specific instances patents were to be available, they present a problem for the public. Since patents grant exclusive rights to *make* or *use* the patented invention, one who holds a patent on a lab-created genetic sequence could prevent other scientists from making the same sequence in their laboratories for the purposes of further experiments. This would be true even if no immediate economic benefit would accrue to those scientists and even if they were not selling (and competing) with the patentee. If patents foreclose not just competitors' economic gains but further scientific exploration

This Article proposes a solution to the quandary. Innovation and research in genetics can be incentivized by providing innovators in this field with alternate and more limited form of exclusivity than that bestowed by patents. The model for the system can be based on the exclusivity provisions of the Food & Drug Act that are applicable to some new drugs and the exclusivity provisions of the new Biologics Price Competition and Innovation Act. Under these FDA administered exclusivity regimes, no generic manufacturer can gain approval to market a drug or biologic product similar to the protected one, *whether or not* the protected product is covered by a valid U.S. Patent. Unlike a patent, which grants exclusive rights to *make*, *use* or sell, these types of statutory exclusivity provisions are limited to restrictions on competitors' marketing. On the other hand, in order to take advantage of the statutory exclusivity provisions one need not satisfy the strict novelty requirements of the Patent Act. It is these distinctions

between patent protection and the marketing exclusivity regime that make the latter ideally suited to promoting research and innovation in genetics.

Under the proposed regime, individuals who spend time, money, and energy looking for correlations between certain genetic sequences and medical conditions would be able to apply for market exclusivity for the tests and treatments designed after the proper association has been found. By being the sole providers of either tests or treatments (or both) they would be able to recoup their investment and make a profit, and they would be able to do so even if these very same tests and treatments would not qualify for patent protection. On the other hand, by limiting exclusive rights to the sale of tests or treatments, other researchers would not be constrained in creating their own copies of molecules containing the newly discovered relevant genetic code so long as the purpose is future research rather than sale to the public. In this way, the information-carrying function of the gene would be preserved in the public domain, whereas the chemical structure of the laboratory-created molecules would be available for exclusive commercial exploitation (for a limited time) to one who first discovered the correct genetic code and created said molecule.