R & D Tax Aspects of DNA Identification

By Charles R. Goulding, Eliana Goolcharan and Charles G. Goulding

Charles R. Goulding, Eliana Goolcharan and Charles G. Goulding provide an update on recent advancements in DNA identification technology and suggest that companies developing such technology may benefit from the R & D tax credit and other tax incentives.

Most Americans are familiar with some aspects of DNA identification as a result of nightly crime-solving shows. New lower cost DNA processing equipment and new favorable regulatory developments for human and packaging DNA identification support a wider range of DNA-related product and process developments. Many of these activities are eligible for R & D Tax Credits.

The Research & Development Tax Credit

Enacted in 1981, the Federal Research and Development (R & D) Tax Credit allows a credit of up to 13 percent of eligible spending for new and improved products and processes. Qualified research must meet the following four criteria:

- new or improved products, processes or software;
- technological in nature;
- elimination of uncertainty; and
- process of experimentation.

Eligible costs include employee wages, cost of supplies, cost of testing, contract research expenses and costs associated with developing a patent. On January 2, 2013, President Obama signed the bill extending the R & D Tax Credit for the 2012 and 2013 tax years.

Diagram 1 describes the first 60 years of cumulative DNA research and development. With that established technology foundation, four new major R & D legal and regulatory supported opportunities are discussed including:

1. integrating the Human Genome Data with Medical Record Data;
2. Supreme Court DNA Patenting Case;
3. Supreme Court DNA Arrest Testing Case; and
4. DNA Packaging Identification.

Integrating the Human Genome Data with Medical Record Data

After the world celebrated the faster-than-anticipated cloning of the Human Genome, reality set in when scientists then realized that, without comprehensive medical records data to compare the genome to, we

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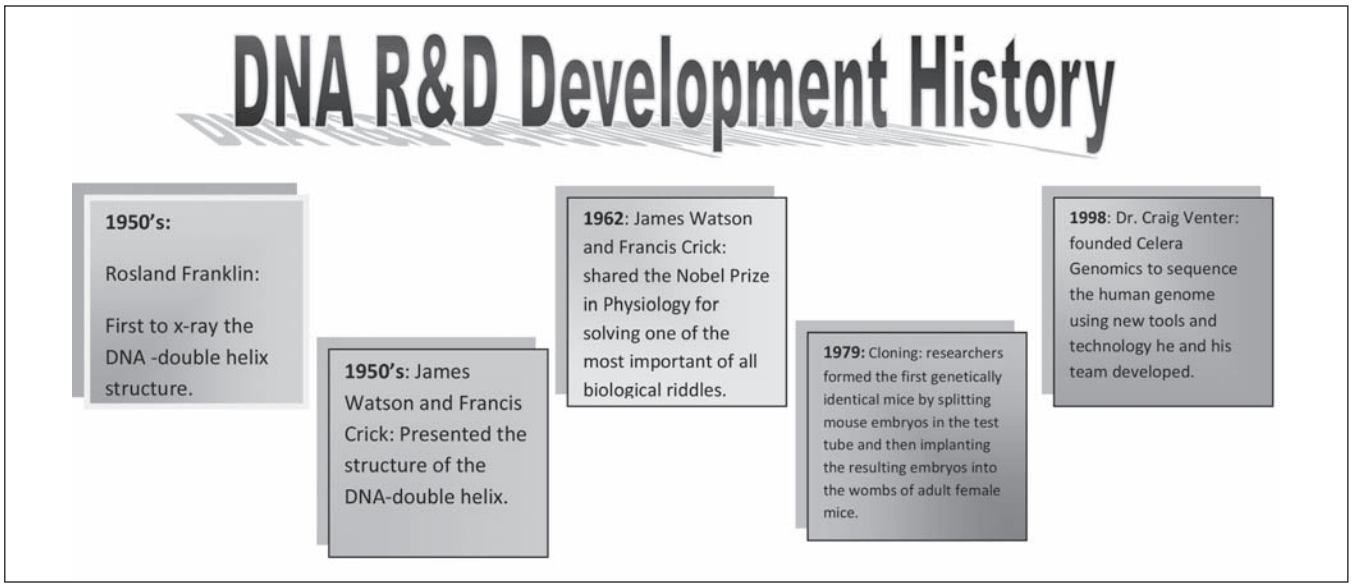
Diagram 1.



only had half the puzzle pieces needed to produce the real opportunities related to disease management. Now the rapid decrease in the cost of DNA sequencing combined with a large increase in United States electronic patient medical results are propelling a huge increase in integrated disease analysis.

Electronic Medical Record Integration

An electronic medical record is a database that represents all patients' medical history that would originally be found in a paper form, such as files, folders and charts. These databases contain any information ranging from pathology, radiology and clinical information that has transformed into a digital form. The system allows for the patients' medical record history to be viewed ensuring all data to be accurate, appropriate, legible and be seen at any point in time without having to physically track down the patient.

In the United States, the Center for Disease Control and Prevention (the "CDC") reported that, as of 2012, 60 percent of office physicians are using basic electronic medical records.[1] As of 2013, 70 percent of office physicians are using basic electronic medical records. By 2020, almost all office physicians and doctors are expected to be using an electronic medical system.

Medical Research Data

Many leading medical and research centers around the world are establishing a new project that will allow them to obtain and share immense amounts of data about patients' genetic and clinical information. According to the *DNA Data to be Shared Worldwide in Medical Research Project,* 60-plus institutions worldwide including North America have agreed to create the system to help "dramatically accelerate medical progress" through sharing of medical data. With this system, many should be able to unravel the biological bases of cancer and inherited and infectious diseases. These would shed light on variable effects that drugs have in different patients.[2]

Human Genome Integration

The Human Genome Project was first created in 1988 by a special committee of the U.S. National Academy of Sciences. The goals of the Human Genome Project included the configuration of physical and genetic maps of the human genome, which were accomplished in the mid-1990s, as well as the mapping and sequencing of a set of five model organisms, including the mouse. Genome-based research will eventually enable medical science to develop highly effective diagnostic tools, to better understand the health needs of people based on their individual genetic make-ups and to design new and highly effective treatments for disease. Individualized analysis based on each person's genome will lead to a very powerful form of preventive medicine.[3]

Innovation in Sequencing

DNA sequencing is the development of finding the precise order of nucleotides within a DNA molecule. It includes any method or technology that is used to distinguish the order of the four bases—

adenine, guanine, cytosine and thymine—in a strand of DNA. The initiation of rapid DNA sequencing methods has greatly accelerated biological and medical research. New and upcoming sequencing methods, which are currently being developed allow DNA sequence to be determined faster and more efficiently.

A Great Mind Now Attracted to Genome Health Record Data Analysis

On June 23, 2013, a NEW YORK TIMES article described the Wall Street-to-healthcare career conversion by a top mind. In 2005, Jeffrey Hammerbacher, a new graduate of Harvard University, began his quest on Wall Street. In 2012, Hammerbacher embarked on a very different path; he joined the Mount Sinai School of Medicine in New York City as an assistant professor. He is exploring and experimenting with genetic and other medical data in search of breakthroughs in disease modeling treatments. Hammerbacher said that the goal "is to turn medicine into the land of the quants." Hammerbacher was recruited by Eric Schadt, who is a professor and Chair of Genetics and Science and Director of the Institute for Genetics and Multiscale Biology at Mount Sinai.

Schadt's recruiting overture coincided with Mr. Hammerbacher's personal research into where next to best apply his skills. He discusses his career as a matter of "following the smartest people to find the best problem." Health care, in his view, is "the best problem by far," where his talents could do the most good. At Mount Sinai, Mr. Hammerbacher said he hoped to learn a lot and assemble a small group of computing and data experts to help speed up the genomic and medical research there.[4]

Supreme Court DNA Patenting Case

Molecular Pathology v. Myriad Genetics[5] is an important Supreme Court Case, which has been front page news. The Supreme Court decision is based on the substantive difference between natural DNA and synthetic DNA.

Natural DNA

Myriad Genetics claimed that they identified and had the right to patent the natural gene, BRCA1 and BRCA2, which is related to the risk for ovarian and breast cancer. They held patents on a pair of genes, which created an expensive test inhibiting other laboratories from offering low-cost testing. Other researchers and laboratories had to have permission from Myriad Genetics to conduct BRCA1 and BRCA2 tests and experiments. The testing costs over $3,000 per person, which most women cannot afford. Throughout its analysis, the Court emphasized that Myriad "did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes." Because of this decision, scientists can engage in research and can now provide genetic diagnostic testing on genes without fear of being sued. As a result of increased testing, more women can now be tested at a lower cost and can better obtain information and second opinions. The Court's decision can bring competition and innovation to the fast growing field of personalized medicine.

Synthetic DNA

In *Myriad,* the Supreme Court allowed patenting for Complementary DNA (cDNA). cDNA is also known as "synthetically created." It copies the parts of particular DNA strands that code for protein while excluding the bits of noncoding DNA. When scientists transfer a gene from one cell into another cell in order to express the new genetic material as protein in the recipient cell, the cDNA will be added to the recipient. The DNA for an entire gene may include DNA that does not code for the protein or that interferes with the coding sequence of the protein. Often times partial sequences of cDNA are seen as sequence tags. The creation of cDNA sequences comes from the mRNA. This process does not happen naturally, which is why the Court permitted cDNA patenting. "cDNA retains the naturally occurring exon of DNA, but it is distinct from the DNA from which it was derived.

Diagram 2. Biotech Research and Development Per Capita

Company	2012 R&D Spent	2012 Employees	2012 R&D/ Employee	2011 R&D Spent	2011 Employees	2011 R&D/ Employee	2010 R&D Spent	2010 Employees	2010 R&D/ Employee
Monsanto	$1,517,000,000	21,500	$70,558	$1,386,000,000	20,600	$67,282	$1,205,000,000	21,400	$56,308
Myraid Genetics	$42,645,000	1,169	$36,480	$27,751,000	1,057	$6,256	$21,873,000	870	$25,141
Amgen	$3,380,000,000	18,000	$187,778	$3,167,000,000	17,800	$177,921	$2,894,000,000	17,400	$166,322
Roche**	9,237,750,000	82,089	$112,533	$8,799,570,000	80,129	$80,129	$9,864,500,000	80,653	$122,308

** Used conversion factor of 1 Swiss Franc= 1.09 US Dollars for Roche expenditures
Note: Roche is a Switzerland based company, which acquired Genetech, a U.S. based company, in 2009.

As a result, cDNA is not a 'product of nature' and is patent eligible," said Justice Clarence Thomas.[6]

Diagram 2 projects the book per capita R & D expense of some of the leading companies involving genetics and DNA testing.

Supreme Court Approves DNA Arrest Testing

On June 3, 2013, the Supreme Court decision in *Maryland v. King* held that DNA samples can be obtained during an arrest by a certified police officer.[7] The Court decided that a DNA "buccal swab" (cheek swab) makes it possible to determine whether a biological tissue matches a suspect with near certainty. As of June 2013, 28 out of 50 states permit the collection of DNA samples during an arrest. Because of the high testing reliability and the Supreme Court's decision, it is anticipated that eventually all 50 states will approve of DNA sampling upon arrest. Justice Samuel Alito said that *Maryland v. King* is perhaps the most important criminal procedure case the Court has heard in decades.

New Technology Drives

In many jurisdictions, crime labs are unorganized and suboptimal. Because most prosecutors wait until their court date to analyze DNA samples, the result is a bottleneck in the entire DNA database system that delays case resolution. DNA certifiers and working professionals in the criminal justice system need better equipment to ensure the correct use of DNA evidence to effectively solve crimes and assist victims.

Forensic DNA analysis is quickly evolving. Research and development of tools that will allow crime laboratories to conduct DNA analysis quickly is crucial to the goal of improving the timely analysis of DNA samples. The development of "DNA chip technology" uses nanotechnology to improve both speed and resolution of DNA evidence analysis. This new technology can and will reduce the analysis time from several hours to several minutes and provide cost-effective miniaturized mechanisms. The development of more robust methods help more crime labs to have greater success in the analysis of degraded, old or compromised items of biological evidence.[8] With evidence being so old and untouched, forensic scientists still need to ensure sure they can get a clear reading of the DNA samples in a timely matter.

The RapidHIT 200 System is a self-sufficient human identification system for Rapid DNA. It is the process of producing standardized DNA profiles from mouth swabs and other human samples in less than 90 minutes. The traditional human identification (HID) process involved eight steps, with eight different machines that take 10 hours to process, with a turnaround time of typically 30 days. The RapidHIT 200 System requires minimal training and the ability to set up the bench-top machine virtually anywhere. As a result, DNA profiles can be founded with a touch of one button.[9]

This new DNA technology is already being tested by the West Johnson Police Department in Utah. With its mission to remove criminals from the street quicker and more efficiently, Rapid Hit DNA, as it is being called, is the future of DNA for law enforcement agencies.

Rapid Hit DNA is also being used to fight property crime. According to the FBI, in 2011 there were an estimated 9,063,173 property crime offenses in the nation.[10] In June of 2008, the National Institute of Justice studied the effectiveness of performing DNA analysis on biological evidence collected from property crime scenes. They found that compared to a traditional crime investigation, when DNA evidence was collected suspect identifications, arrests and cases accepted for prosecutions all doubled. The suspects that were arrested through DNA identifications were also more dangerous. Rapid DNA approaches help expand the use of DNA analysis to high-volume property crimes. Increasing the identification and prosecution of career criminals using DNA analysis has proven effective while simultaneously reducing police investigation costs. The use of a technology such as Rapid Hit DNA brings significant benefits and will eventually be used nationwide.

The Swedish Example

Sweden has announced it will begin introducing Applied DNA's smartDNA technology in every police force within that Scandinavian country in June 2013, following a successful pilot program by the Stockholm County Police. SmartDNA is a unique and patented security system based on botanical DNA, which can help to prevent crime. It can be used for the protection of valuables in highly covert sting operations and be incorporated within existing security, anti-theft systems. "A lot of times the robber is wearing a helmet or other clothing that they discard," said Anders Buren, detective

superintendent of the Stockholm County Police. "When we find that clothing we can link it to the robbery and extract any human DNA left on it." The system involves spraying criminals' belongings left behind with an almost invisible mist containing unique plant DNA. The DNA can then be used to trace criminals to the scene of the crime. Stockholm County has been using smartDNA for the past year. Over 40 locations have installed smartDNA spray systems. Those institutions using the system advertise it, and crime has dropped off significantly. Locally, several banks and pharmacies on Long Island, New York, have also installed the smartDNA system.[11]

Protecting DNA for Natural Disaster

Pre-Hurricane Sandy, the Erie Basin, Brooklyn, New York, auto pound and evidence warehouses seemed like a safe and logical place to store 9,846 barrels of evidence containing important and sensitive DNA material, along with roughly 5,000 "narcotic items" and 3,250 firearms. As Hurricane Sandy hit the city, it wrecked hundreds, perhaps thousands of barrels that fell into the wet muck destroying all the evidence needed to prosecute criminals. In addition to the nearly 10,000 barrels of DNA evidence kept at Erie Basin, there were an additional 1,177 barrels of DNA evidence at the Kingsland Avenue Greenpoint, Brooklyn location, which was eventually destroyed because of water damage.[12] Installing HID equipment in individual police departments provides a more effective and logical way to protect crucial DNA samples from natural disasters.

Packaging

Drug counterfeiting is a national problem estimated to cost the United States $75 billion dollars per year. In recent years, the increase in packaging forgery has negatively affected consumers and brand owners, causing health, safety and financial concerns. This is particularly sensitive for the pharmaceutical industry, which has experienced significant market erosion due to counterfeiting. The Federal Drug Administration (FDA) has enacted some new rules and regulations to try and prevent counterfeiting drugs.

DNA Authentication

DNA "taggants" are an innovative tool to prevent counterfeit packaging. Scientists have determined that DNA taggants is a new and improved technology that can help identify what a product is, exactly where it is going and where it came from. By incorporating unique DNA sequences that cannot be reproduced, this technique offers an unprecedented level of security and constitutes an effective forensic means to verify a product's authenticity. Custom DNA sequences containing information (manufacturer's name, facility location, *etc.*) are embedded into a host carrier, such as ink, which is then printed onto the packaging or label.[13]

Conclusion

The innovation of DNA identification has vastly developed within the past decade. Integrating sequencing of the Human Genome DNA with the country's new electronic medical system is one of the recent, innovative DNA-related developments. Additional innovative developments include the Supreme Court cases in patenting DNA and criminal DNA and the utilization of DNA for identifying packaging to combat counterfeiting. These developments described above are designed to drive a wave of DNA-related technology innovation which can be supported with federal and state R & D tax credits.

Endnotes

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